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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

**JOINT BRIEF REGARDING CROSS
MOTIONS FOR SUMMARY
JUDGMENT**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

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UNITED’S INTRODUCTION

The DOJ alleges that United improperly kept money it was paid to provide healthcare to Medicare Advantage (“MA”) members. But after years of litigation, DOJ has not reviewed a single medical record of United’s MA members—the *only* evidence that could establish whether United may have been overpaid. That failure dooms all of DOJ’s claims.

The Centers for Medicare and Medicaid Services (“CMS”) pays insurers like United and other MA plans to cover their members’ healthcare costs. These payments are based in part on the members’ medical conditions, with the basic goal of paying MA plans more for taking care of sicker patients. Most of the diagnoses United submits to CMS for payment come directly from doctors, who certify that the patients they have seen have the health conditions, represented by alphanumeric diagnosis codes, listed on insurance claims forms. But doctors often fail to identify all the medical conditions their patients have on claims forms because they are typically paid based on the services they perform, not their patients’ diagnoses. MA plans like United thus obtain some of their patients’ underlying medical records (or “charts”) and hire medical coders to review the charts to capture additional diagnoses doctors may have missed in submitting claims forms.

DOJ’s theory in this case is novel. Unlike a traditional case of alleged “upcoding,” DOJ does not contend that United’s coders falsely documented *any* medical conditions. Nor does DOJ allege that United failed to convey accurately the diagnoses doctors submitted to it. DOJ also does not contend that there is anything inherently wrong with MA plans reviewing medical charts to submit more complete diagnostic information (which is an industry-standard practice). And DOJ likewise does not contend that United has an obligation to conduct audits of all the codes it receives from doctors, since MA plans should be allowed to rely on doctors’ certified codes—and no one expects perfect coding accuracy in this payment system.

DOJ’s sole contention is instead that if United coders who reviewed a chart did not identify a diagnosis code, then that necessarily means that a doctor who previously

1 certified and submitted the same code on a claim form did so in error. For example, in
2 DOJ's view, if a doctor's office submitted a "diabetes" code on a claim form after seeing
3 a patient, but United coders did not code "diabetes" in reviewing the medical chart for the
4 date of that claim, then the diabetes code *must* be invalid. DOJ believes that, in this
5 situation, the United coders were *always* right, and the doctor's office—where the patient
6 was seen and where the doctor certified the code—was *always* wrong.

7 The problem with DOJ's categorical theory is that it is not supported by any
8 evidence. For one, United's coders are unaware of what codes doctors have previously
9 submitted in claims forms and thus make no effort to validate those codes in performing
10 chart review. For another, DOJ's own coding expert concedes that there are multiple
11 reasons a United coder reviewing a chart might fail to identify a diagnosis code that is
12 actually present there. United's coders could be unfamiliar with the doctor's handwriting
13 or area of specialization, could be missing pages of the medical record, might have lacked
14 sufficient time to complete the review, or might simply have missed a diagnosis certified
15 by a doctor because a record was lengthy or complex. And, of course, as both sides' experts
16 agree, coders are human and make mistakes. The mere fact that United's coders may
17 identify different codes than those a doctor submits is not *evidence* sufficient to allow a
18 jury to conclude the doctor's office was necessarily wrong in submitting the code.

19 Accordingly, to meet its burden in opposing summary judgment, DOJ needed to
20 offer *something* other than mere coding differences to show that some or all of the 28
21 million doctor-certified codes at issue are unsupported. One obvious approach would have
22 been to review some or all of the medical charts at issue. DOJ could have hired an expert
23 to review charts and offer an opinion about the portion of the doctor-certified diagnosis
24 codes that are in fact not supported. Yet, after more than a decade of litigation in a case in
25 which DOJ seeks to punish United for billions of dollars, DOJ has chosen instead not to
26 review a *single* chart—not even a sample—perhaps because it was afraid of what that
27 review would show. DOJ must now accept the consequences of that decision, which is
28

1 that its experts are left hopelessly unable to say which (if any) of the diagnosis codes at
2 issue are unsupported.

3 Indeed, the only record evidence conclusively disproves the categorical assumption
4 on which DOJ's case rests. Outside this litigation, the government conducts routine audits
5 of MA plans. Through such audits, CMS reviewed medical records relating to roughly
6 6,500 of the 28 million diagnosis codes DOJ claims in this case are invalid. Crucially,
7 CMS coders found that an overwhelming percentage of the health conditions associated
8 with those codes—approximately 89%—*were* supported in the patients' medical records.
9 Put another way, 89% of the health conditions DOJ says United *knew* were false were in
10 fact supported by the patient's medical records. Faced with this undisputed fact, DOJ's
11 statistical expert bluntly conceded that DOJ's theory is wrong "to a certainty," and that the
12 record evidence provides "no reliable way" to estimate what doctor-submitted codes were
13 in fact unsupported in medical charts. This would leave a jury unable to do anything but
14 guess that some number of codes (ranging from 0 to 28 million) *might* have been invalid
15 and *might* have affected payment. That is far short of the evidence needed to survive
16 summary judgment.

17 There are also other insurmountable problems with DOJ's case. Although DOJ
18 argues that United should have second-guessed the codes doctors submitted in claims
19 forms that United's own reviewers did not capture, there is no rule, regulation, or other
20 source of law that imposes that obligation. CMS considered adopting exactly that rule in
21 2014 but abandoned it. That abandonment was unsurprising at the time, as commentators
22 noted that the proposed rule would have required a complex process of attempting to match
23 diagnosis codes submitted by doctors to particular medical charts and then reviewing those
24 charts to second-guess the doctors who certified the diagnoses as accurate. At any rate,
25 DOJ cannot plausibly assert that United committed fraud by failing to follow a rule that
26 CMS considered a decade ago but declined to adopt.

27 United has also been transparent with CMS about its conduct. When CMS proposed
28 the rule just described, United sought guidance from its regulator about its obligations.

1 When CMS later declined to finalize the rule, United informed CMS that it would no
2 longer second-guess doctor-submitted codes. United has repeated those facts every year
3 since in bid submissions and annual attestation transmittals, yet CMS has continued to pay
4 United's claims and has not taken remedial action of any kind against United. For these
5 reasons, as a matter of law, United's challenged acts involved no deception and were
6 immaterial to CMS's decision to pay United—both of which are required elements under
7 the False Claims Act ("FCA").

8 DOJ's common-law claims for payment by mistake and unjust enrichment fail for
9 many of the same reasons. They also fail because the parties' express contracts preclude
10 such quasi-contract causes of action. DOJ could have brought a contract claim but, perhaps
11 knowing that the law is settled that a "garden variety" breach of contract does not amount
12 to fraud under the FCA, chose not to do so.

13 The fact that this is a large and lengthy case does not change the fact that it is also
14 a textbook case for summary judgment. DOJ is seeking enormous damages and penalties
15 under a punitive fraud statute, and it must be held to its burden of opposing summary
16 judgment with evidence, not speculation. The Court should enter summary judgment.

17 UNITED STATES' INTRODUCTION

18 If a Medicare Advantage Organization (MAO) such as United receives a diagnosis
19 code from a provider, submits the diagnosis to CMS for risk adjustment payment, and then
20 later reviews the medical record from that provider, and finds that code to be unsupported,
21 the organization surely cannot hold onto the payment it received for that code without
22 further inquiry. Yet that is the core of United's argument. There is considerable evidence¹
23 from which a jury can reasonably conclude that the diagnosis codes at issue were
24 unsupported and resulted in overpayments, including United's own Chart Review coders'
25 review of the medical records, United's own data, and the United States' expert's
26

27 ¹ While the United States does not object to United's use of deposition testimony in support
28 of its motion for summary judgment, pursuant to FED. R. CIV. P. 56(c), it does not waive
any objection to the admissibility of such testimony at trial, pursuant to FED. R. CIV. P. 32
or Federal Rules of Evidence.

1 calculation of the financial impact of United’s failure to delete those codes. There is
2 binding precedent from the Ninth Circuit in *United States ex rel. Swoben v. United*
3 *Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016) that MAOs such as United have
4 longstanding duties prohibiting them from turning a blind eye to unsupported codes
5 submitted for payment. United’s remaining arguments likewise cannot support summary
6 judgment. Materiality is not an element of the reverse false claims provision at issue here,
7 but, regardless, United’s motion ignores material factual disputes concerning the April
8 2014 videoconference on which it relies. Finally, the plain text of the False Claims Act
9 (FCA) demonstrates that the reverse false claims provision at issue here does not require
10 an “act of deception” to prove liability.

11 A foundational principle of the MA program – unwavering since the program’s
12 inception – is that MAOs are paid only for diagnosis codes that are supported by the
13 beneficiary’s medical records (supported codes). MAOs are not required to audit every
14 single diagnosis code they submit, but they have contractual and regulatory duties –
15 incorporated into every MA contract – to undertake due diligence and make good faith
16 efforts to ensure that the diagnosis codes they submit to CMS are supported. CMS adopted
17 the FCA knowledge standard into those duties, meaning that an MAO must exercise due
18 diligence and conduct in good faith any audit of provider-submitted data it chooses to
19 conduct, and correct unsupported diagnosis codes that have been submitted for payment
20 revealed by those audits. In this case, United obtained information from its own internal
21 auditing program (Chart Review) that diagnosis codes that it had already submitted to
22 CMS for payment were unsupported. Rather than making a good faith effort to inquire as
23 to the accuracy of those codes and correct them as required by both regulation and contract,
24 it simply buried its head in the sand and did nothing but keep the money.

25 As opposed to a “novel theory,” the FCA allegation in this case is straightforward
26 – United violated the second prong of the reverse false claims provision, which imposes
27 liability on a person who “knowingly and improperly avoids. . . an obligation to pay. . .
28 the Government.” 31 U.S.C. § 3729(a)(1)(G). To prevail, the government must show only

1 that United: (1) improperly avoided its obligation to pay CMS; and (2) did so knowingly.
2 *See United States ex rel. Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010, 1055-56 (N.D.
3 Cal. 2020). United’s obligation to pay arises from independent, yet legally and factually
4 aligned, sources: (1) its regulatory and contractual duties, and (2) its retention of an
5 overpayment. And there is ample evidence that by deliberately ignoring or recklessly
6 disregarding the negative results of its Chart Review, United knowingly and improperly
7 avoided its obligation and improperly retained billions of dollars.

8 Yet, United wants the Court to impose elements of proof beyond those of the reverse
9 false claims provision, and seeks to confuse the issues with reference to parts of the MA
10 program wholly unrelated to the allegations at issue. Since United cannot meet the real
11 issues and facts head-on, it instead uses its motion to set up and knock down strawmen
12 arguments. For example, United wholly ignores the express statement in the FCA that an
13 established duty does not have to be fixed at the time it gives rise to the obligation to pay. 31 U.S.C.
14 § 3729(b)(3). Indeed, United goes so far as to omit those four key words – “whether or not
15 fixed” – when quoting the statute, and instead argues that the government cannot prevail
16 unless it proves an overpayment fixed in time and amount. That simply is not the law.
17 Similarly, United invents a narrative in support of its contentions regarding materiality.
18 However, as the United States shows in its motion for partial summary judgment,
19 materiality is not a required element under the provision of the FCA at issue – and, in any
20 event, the facts show that the United States can establish materiality.

21 United also spends an inordinate amount of time on CMS’s RADV audits. But this
22 case has nothing to do with RADV audits. It is not an action to enforce RADV audits, and
23 it does not involve the same processes or standards applied in RADV audits – which take
24 place well after the deadline for MAOs to submit risk adjustment data. United also makes
25 much of a purported 89% RADV validation rate, but *even if* RADV audits had anything
26 to do with the issues in this case (they do not), the import of that analysis from United’s
27 expert is hotly disputed as a factual matter – e.g., the United States’ expert points out that
28

1 this calculation is utterly meaningless statistically – and therefore, cannot carry the day for
2 United at summary judgment.

3 United employs another red herring by vociferously complaining that *the*
4 *government* did not review the medical records underlying the diagnoses at issue in this
5 litigation. The key point, however, is that *United* reviewed the medical records in its Chart
6 Review audits. Indeed, United’s own certified coders reviewed each medical record –
7 many times twice – and did not find any support for the diagnosis codes at issue in this
8 case. United relied on those reviews to submit additional diagnosis codes generating over
9 \$7 billion in revenue for United, and those same reviews are equally sufficient to
10 demonstrate the absence of support for the codes at issue here. As a result of its coders’
11 work, United had knowledge of a potential overpayment, and the United States will
12 present evidence that United failed to meet its duties to undertake good faith measures to
13 ensure the accuracy of its diagnosis codes. Additionally, United’s complaint that the
14 government did not review any medical records is particularly disingenuous because
15 United steadfastly refused to produce any medical records in discovery, despite repeated
16 requests from the government and even a motion to compel.

17 In a similar vein, United mischaracterizes the government’s contention as United’s
18 “obligation to second-guess doctors’ certifications that their diagnoses accurately reflect
19 the patients’ health conditions.” Joint Brief, 32. That is not remotely the government’s
20 allegation. Rather, the United States contends that *when* United undertook a review of
21 medical records to second-guess its provider diagnoses, and collected \$7 billion as a result,
22 it obtained knowledge that its certified coders did not find support for some of the
23 diagnosis codes that it had already submitted for payment. Rather than act on that
24 information, United buried its head in the sand and ignored that information from its Chart
25 Reviews. United, as the largest MAO, simply cannot be excused from its obligation to
26 return to the Medicare Trust Funds billions of dollars to which it is not entitled.

27 The Court should reject United’s distortion of the governing legal standards and its
28 mischaracterization of the facts and deny United’s Motion for Summary Judgment. In

1 addition, the United States respectfully requests that this Court grant the United States’
2 motion for partial summary judgment that as a matter of law proving liability under the
3 second prong of the reverse false claim provision does not require a showing of
4 materiality.

5 UNITED’S BACKGROUND

6 A. Medicare and Payments to MA Plans

7 The Medicare Act establishes a federal health insurance program for seniors and
8 individuals with disabilities. Joint Statement of Uncontroverted Facts (“JS”) at D2; Exhibit
9 (“Ex.”) D-3 at 161. Parts A and B of the Act create the Traditional Medicare (“Medicare”)
10 program. 42 U.S.C. § 1395c *et seq.*; *id.* § 1395j *et seq.*; JS at D3-D5; Ex. D-3 at 161-62.
11 In Medicare, CMS pays doctors directly for the care they provide members. JS at D5; Ex.
12 D-3 at 162.

13 This case concerns Part C, the MA program in which CMS pays private insurers to
14 cover members’ medical care. 42 U.S.C. § 1395w-21 *et seq.*; *id.* §§ 1395w-23, 1395w-
15 24(a)(6)(A); 42 C.F.R. § 422.254(b)(1); JS at D6-D7, D9; Exs. D-1 at 9, 11-14, D-3 at
16 161-62, D-57 at 1448-9. The MA program has seen tremendous growth in recent years, as
17 MA plans are often able to provide superior benefits, like vision care and dental care,
18 without requiring additional premiums or other member payments. JS at D11-D14; Exs.
19 D-3 at 161, D-56 at 1340-41, 1343-1347, 1365, D-99 at 2671:21-75:23 .

20 Under MA, CMS pays MA plans a fixed amount per member to compensate plans
21 for insuring that member. JS at D9; Exs. D-57 at 1449, D-52 at 1230. MA plans are paid
22 more for enrolling members who are sicker than average for taking on the risk that those
23 members will be more costly to insure. JS at D15; Exs. D-86 at 2377, D-127 at 3245:20-
24 23. The process by which CMS pays MA plans based on the health status of their
25 beneficiaries is commonly referred to as “risk adjustment.” See JS at D10; Ex. D-149 at
26 3743. CMS determines which members are sicker by looking at the health conditions those
27 members have, as represented by diagnosis codes doctors submit through claims forms
28 (*see, e.g.*, Ex. D-40 at 944-45). JS at D16-D18, D21; Exs. D-18 at 658, D-54 at 1285, D-

1 132 at 3376:21-77:5. After a patient visits a doctor, the doctor records the patient's
2 diagnoses in a medical chart, then the doctor or the doctor's coder assigns one or more
3 corresponding diagnosis codes on a claim form (*see, e.g.*, Ex. D-150 at 3775-860). JS at
4 D19-D20; Ex. D-54 at 1285. The doctor then submits that claim form to CMS (if the
5 patient is in Medicare) or an MA plan (if in the MA program), certifying that the patient
6 has the medical conditions represented by the diagnosis codes submitted. *See* JS at D21,
7 D267; Exs. D-54 at 1285, D-44 at 1010-11, D-48 at 1204-05.

8 There are thousands of diagnosis codes coders can select when coding medical
9 charts. *See* JS at D23-D24; Exs. D-18 at 658, D-43 at 980. But for payment to MA plans
10 for the costs of insuring individuals, CMS groups diagnosis codes into Hierarchical
11 Conditions Categories ("HCCs"). *See* 42 C.F.R. § 422.2; JS at D16, D18; Ex. D-18 at 658.
12 Many different diagnoses are grouped to the same "HCC" or health condition. JS at D23-
13 D24; Exs. D-18 at 658, D-64 at 1851, n.145. For example, both a diagnosis code for "type
14 2 diabetes mellitus without complications" and the diagnosis code for "other specified
15 diabetes mellitus without complications" (as well as others) map to the same HCC of
16 "diabetes without complications" (HCC19). JS at D25-27; Ex. D-64 at 1860-61. CMS will
17 pay an MA plan the same amount regardless of which of the two diagnosis codes is
18 submitted. *Id.*; JS at D29-D31; Ex. D-57 at 1454. Similarly, diagnosis codes for numerous
19 different forms of malignant cancer (bone, lung, liver) would all establish that a patient
20 has the health condition of "metastatic cancer and acute leukemia" (HCC7), and any of
21 those numerous diagnosis codes would lead to the same payment for any given MA
22 member. JS at D28, D29-D31; Ex. D-64 at 1856-61, D-57 at 1454.

23 In addition, the payment for a condition—such as HCC19—is proper as long as a
24 single diagnosis code mapping to that HCC is supported by a single medical chart for the
25 member during the year. *See* JS at D29-D31; Ex. D-15 at 633 ("[A]ll that is required is
26 medical record documentation from one visit to a physician or a hospital, over the course
27
28

1 of the data collection year, to validate the audited HCC.”)² So, if three different doctors
2 submit seven different diagnoses that correspond to “diabetes without complication,” the
3 payment for that condition is valid as long as *one* of those doctors adequately documents
4 one of those diagnoses in one medical chart for the year. *Id.* The other six diagnoses from
5 an MA plan’s data, even if they are unsupported, do not affect the payment to the MA
6 plan. *Id.*

7 **B. Diagnosis Coding Discrepancies and Chart Review**

8 It is well known that, when filing claims forms, doctors often fail to identify all the
9 medical conditions with which they have diagnosed their patients and which they have
10 documented in the medical records. JS at D34-D35; Exs. D-117 at 2997:4-98:4, D-120 at
11 3050:12-23, D-54 at 1288. The principal reason is that doctors do not have the incentive
12 to list all supported diagnosis codes. JS at D36-D40; Exs. D-152 at 3872, D-48 at 1203,
13 D-87 at 2393:8-15, D-54 at 1288, D-42 at 965, D-99 at 2677:20-78:18. Doctors are
14 generally paid based on procedures (e.g., an office visit, an injection, etc.), not the
15 particular diagnosis codes included on a claim. See JS at D36; Exs. D-152 at 3872, D-87
16 at 2393:8-15. Doctors typically need only include one certified diagnosis code on a claims
17 form to justify the services the doctor provided. See JS at D37; Ex. D-107 at 2799:12-20.

18 Doctors also sometimes submit diagnosis codes on claims forms that are not
19 supported by the patients’ medical records. JS at D32; Ex. D-44 at 1010-11. This is
20 unsurprising. Diagnosis coding is a complex process, medical charts can be difficult to
21 read and understand, and coders have different levels of experience. JS at D56-63; Exs.
22 D-54 at 1291-96, 1307, D-108 at 2824:15-25:4, 2829:17-30:8, 2837:3-7, D-122A at

23 ² See also Ex. D-145 at 3676:23-77:7 (“Q. Right. The plan might go delete the code, but
24 just knowing that there was a single code that was unsupported, that alone wouldn’t tell
25 you you’ve been overpaid if you’re the plan, right? You would need to know, for
26 example, if another record supported the code, correct? A. Yes. Yes.”); Ex. D-60 at 1588,
27 1594 (“Reporting a diagnosis once during a year was deemed sufficient for the diagnosis
28 to be considered to be included in an enrollee profile. . . . It does not matter how many
times a condition is coded through the year or whether more than one ICD-10 code in an
HCC is reported.”); Ex. D-141 at 3546:2-6 (incorporating April 17 errata) (“I understand
that payments are based on the member demographics and the HCCs that the diagnoses
for that member map to for the year and that only a single instance of each HCC matters.
Multiple instances don’t change anything.”); Ex. D-57 at 1454.

1 3121:5-24:17, 3125:2-28:6, D-87 at 2403:21-05:2, 2409:1-10:5. CMS has long known that
2 some percentage of doctor-submitted diagnosis codes are unsupported by medical charts.³
3 Yet, CMS has acknowledged that MA plans have no general obligation to audit their data
4 to ensure the accuracy of provider-submitted diagnosis codes.⁴ MA plans are generally
5 entitled to rely on doctors' coding decisions despite CMS's awareness that doctors make
6 mistakes. *See* United MSJ, *supra* at 10-11.

7 Because doctors often fail to submit documented diagnoses through claims, MA
8 plans like United commonly obtain and review some patients' medical records (or
9 "charts") to capture additional diagnoses doctors may have missed in submitting claims
10 forms. JS at D41, D44; Exs. D-119 at 3027:17-28:11, D-99 at 2686:9-25, D-145 at 3669:3-
11 17. United hires medical coders as part of its chart review program for such reviews. JS at
12 D45, D48; Exs. D-88 at 2425:21-26:3, D-91 at 2512:23-13:10, D-95 at 2584:21-85:5.
13 United's chart review coders, typically based offshore, perform what are known as "blind"
14 reviews because they do not know what diagnosis codes that doctor has already submitted
15 in claims forms. JS at D49, D51-D53; Exs. D-1 at 28-29, D-89 at 2456:6-19, 2489:18-22,
16 2494:17-95:14, D-57 at 1464. United's chart review program does not try to undertake the
17 challenge of matching particular codes to particular charts from a particular doctor on a
18

19 ³ JS at D66-D67; Ex. D-97 at 2609:12-23, 2624:9-25:8 (Sean Cavanaugh—former director
20 of CMS's Center for Medicare—testifying: "Q. Setting aside your belief about the extent
21 to which it occurred, you agree that both fee for service and Medicare Advantage, you
22 know, submitted data included codes that were not supported by the medical records, and
23 omitted diagnostic codes that would be supported by the medical records? Right?
24 THE WITNESS: Yes, it was my understanding that that was true."); *see also*, Ex. D-117
25 at 2992:14-93:1 (Anne Hornsby—CMS corporate representative—testifying: "Q. So you
agree with this testimony that CMS was aware that the diagnosis codes that were coming
from providers to MA plans and then coming to CMS included some unmeasured error
rate; right? A. . . . yes, from the RADV audit process, CMS understood that there was
some error rate because that would be a typical result of the audit process."), D-66 at 2039,
D-155 at 3913:11-22.

26 ⁴ JS at D69-D70; Exs. D-137 at 3435:2-39:17, 3441:10-15, (C. Rice—CMS's Deputy
27 Director of the Center for Medicare—testifying: "Q. So your -- let me ask it this way:
Does a -- does a Medicare Advantage plan have to confirm, through record review, that
28 there is specific support for every single code that it submits for risk adjustment? A. No.");
D-46 at 1099 ("We recognize as well that, as Cigna said, there is no CMS requirement that
MA organizations verify every diagnosis submitted by providers."); D-116 at 2968:6-8
("CMS doesn't have a requirement that tells MAOs they must audit medical records").

1 particular date of service. JS at D50; Exs. D-57 at 1462-64, D-92 at 2547:22-48:4. This
2 means that United's coders are not looking at the chart with an eye toward the diagnoses
3 that doctor had previously submitted and are not making any judgment about whether
4 those codes are supported.⁵ JS at D53; Exs. D-89 at 2456:6-12, D-104 at 2761:2-8, D-57
5 at 1464 .

6 DOJ's own coding expert concedes that there are multiple reasons United coders
7 performing blind chart review might fail to identify a diagnosis code that is actually
8 documented in the medical record. JS at D56; Ex. D-87 at 2396:13-2400:16. United's
9 coders could be unfamiliar with the doctor's handwriting or area of specialization, could
10 be missing pages of the medical record, might have lacked sufficient time to complete the
11 review, or might simply have missed a diagnosis certified by a doctor because a record
12 was lengthy or complex. *See, e.g.*, JS at D58-D61; Exs. D-87 at 2404:4-05:2, D-54 at
13 1291-92; D-87 at 2402:6-04:3; D-93 at 2558:10-59:3; D-108 at 2836:17-37:7. For these
14 reasons, the mere fact that coders reach different outcomes in reviewing a medical record
15 as compared to the codes a doctor's office identified does not necessarily mean the United
16 coders were right and the doctors were wrong. JS at D55-D56, D246, D62; Exs. D-87 at
17 2396:13-400:16, 2404:12-16:, D-54 at 1307-10, D-96A at 2603:10-04:9.

18 **C. Risk Adjustment Data Validation ("RADV") Audits**

19 CMS conducts periodic audits of MA plans—called RADV audits—to determine
20 whether those plans received "overpayments." JS at D71; Exs. D-15 at 623, D-122A at
21 3104:24-05:2, D-117 at 2979:23-80:12. CMS targets particular MA contracts CMS
22 believes are more likely to result in overpayment to the plan. JS at D72-D73; Exs. D-18,
23 at 665-66, D-122A at 3108:2-10:9. To conduct RADV audits, CMS selects a sample of an
24 MA plan's members. *See* JS at D74; Exs. D-122A at 3113:7-14, D-18 at 661. MA plans
25 then submit medical charts for those sampled members, which CMS reviews. *See* JS at
26 _____

27 ⁵ As a practical matter, MA plans must conduct chart review, because Congress enacted
28 legislation that imposes a substantial downward adjustment to MA payment based on
differences in coding patterns between MA plans and traditional Medicare. *See* 42 U.S.C.
§ 1395w-23(a)(1)(C)(ii).

1 D75-D76; Exs. D-122A at 3113:5-14:10, D-15 at 632-33, D-18 at 661. If CMS finds at
2 least one diagnosis from a single chart that corresponds with the health condition for that
3 member for the year, then the condition is upheld and that payment to the MA plan is
4 appropriate. JS at D77-D78; Exs. D-122A at 3119:2-20:19, D-36 at 886-87, D-141 at
5 3523:14-21, D-117 at 2976:13-77:20.

6 CMS conducted RADV audits on certain United contracts for 5 of the 9 years in
7 question here and overwhelmingly validated United's data. JS at D81, D83, D88; Ex. D-
8 82 at 2365-67, D-84 at 2371, D-85 at 2373, D-64 at 1887-88, fig. 15. The audits validated
9 roughly 90% of the conditions for which United was paid. See JS at D83, D88-D89; Exs.
10 D-64 at 1887-88, fig. 15, D-141 at 3520:13-21:22. That level of accuracy was dramatically
11 higher than the data of other large MA plans. See JS at D84-D85; Exs. D-75 at 2256, D-
12 82 at 2365-67, D-122A at 3157:10-64:22. Indeed, after reviewing United's contracts and
13 correcting any discrepancies in the data, CMS found that United had been net *underpaid*
14 for 13 of the 15 contracts reviewed. JS at D91; Exs. D-122A at 3174:13-77:19, D-81 at
15 2342-44, D-83 at 2369 (showing that United was net underpaid by over \$261 million for
16 the contracts audited for 2011–13).

17 **D. United's Complex Auditing Program and the Proposed Medical Record**
18 **Review Rule ("MRRR")**

19 In 2009, the first year covered by this case, there was no rule that required MA plans
20 to design their chart review programs to second-guess diagnosis codes already submitted
21 by doctors. JS at D105-D107; Exs. D-116 at 2954:18-56:22, D-137 at 3473:3-16, D-97 at
22 2628:15-21, 2631:12-17. Admittedly, there was a rule requiring MA plans to attest
23 annually that their data is "accurate, complete, and truthful" based on the plans' "best
24 knowledge, information, and belief." 42 C.F.R. § 422.504(l); JS at D104; Ex. D-1 at 8.
25 Even so, it was true then (and remains true today) that MA plans do *not* have a general
26 obligation to audit their doctor-submitted diagnosis codes before signing the annual
27 attestation. See United MSJ, *supra* at 10-11, n.4; see also, e.g., JS at D69-D70; Ex. D-46
28 at 1099 ("[T]here is no CMS requirement that MA organizations verify every diagnosis

submitted by providers.”). There was also no CMS rule specifying how MA plans should conduct chart reviews. *See* JS at D106, D116; Ex. D-115 at 2955:22-56:22 (Q. “so that’s true to this day, right . . . [never] has CMS, you know, prescribed any requirements for [MA plans] as to how a medical record review must be conducted? A: that is correct.”).⁶

Nevertheless, United tried to develop a process to investigate certain doctor-submitted codes that had not been independently identified by a chart reviewer. JS at D108, D111; Exs. D-95 at 2589:11-18, D-91 at 2516:15-17:21. United implemented the program, which it named “Claims Verification,” in phases from 2010 to 2013. JS at D108-D111; Exs. D-57 at 1466, D-91 at 2516:15-17:21, D-95 at 2589:2-18. The process was time-consuming, complex, and created the possibility of introducing significant errors. JS at D112-D115; Exs. D-92 at 2528:10-29:9, 2535:13-36:15, D-147 at 3717:5-20.

In January 2014, CMS proposed a rule, the MRRR, that would have required MA plans conducting chart review to build the complex auditing program United was already running. *See* JS at D117; Ex. D-16 at 638. The MRRR would have “*strengthen[ed]* existing regulations” by requiring chart review programs to “be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.” *Id.* (emphasis added). Commentators like United opposed the rule, noting among other things that the process described in the MRRR was vague and would have been complex and burdensome to implement. *See* JS at D118-D119, D135; Exs. D-17 at 651-52, D-114 at 2928:23-29:18, D-124 at 3211:5-16, D-137 at 3455:20-56:12. In May 2014, CMS declined to finalize the MRRR. JS at D136; Ex. D-17 at 651-52.

⁶ *See also* Ex. D-97 at 2628:15-21 (“Q. When you took over as the director for the Center for Medicare, [in March or April 2014] was there any rule or regulation in place that affirmatively required Medicare Advantage plans to proactively review medical records, to audit them, and determine which, if any, codes were not supported? A. Not that I’m aware of.”); *see also* JS at D105; Ex. D-114 at 2925:10-15 (“Q. CMS never specified in regulation prior to this proposal that MA plans were required to design their medical record review rules to look for or identify overpayments? . . . A. Over and under, correct. Q. Otherwise, why would you be proposing the new regulation; right? A. Right.”).

1 For United, the proposed MRRR was especially perplexing because United had
2 *already* built the same kind of complex auditing program before January 2014. JS at D120-
3 D121; Exs. D-154 at 3891:8-21, D-144 at 3639:8-40:16, D-131 at 3352:17-53:24. The
4 MRRR was new, and it was prospective, both of which strongly implied there was no
5 (unwritten) preexisting rule already requiring MA plans to do the same thing. *See* JS at
6 D117-D119, D121; Exs. D-16 at 638, D-114 at 2928:23-29:18, D-144 at 3640:9-16, D-
7 154 at 3891:8-21. In the months that followed, United contacted CMS to clarify whether
8 United’s complex auditing program was already required. JS at D122-D127; Exs. D-9 at
9 421, 427, 445-46, 449, D-10 at 475-76, D-22 at 674-75, D-142 at 3600:3-20. After a
10 number of conversations, on April 29, 2014, United sent key executives to meet with top
11 officials from CMS. JS at D123-D126; Exs. D-9 at 445-46, D-10 at 475-76, D-22 at 674.
12 United’s witnesses testified (and their contemporaneous notes reflect) that during the
13 meeting, CMS told United that unless the proposed MRRR rule became final, MA plans
14 did not have an obligation to confirm whether diagnosis codes submitted by doctors are
15 supported in the medical records. *See* JS at D127, D130-D133; Exs. D-131 at 3352:17-
16 53:24, D-138 at 3487:24-88:10.⁷ CMS witnesses by contrast generally did not recall what
17 was said at the meeting. *See* JS at D128-D129; *see, e.g.*, Exs. D-137 at 3459:7-60:18, D-
18 145 at 3661:25-62:2. Regardless, it is undisputed that, in a follow-up letter, United
19 confirmed its understanding to CMS that “MA plans are [] not currently required to design
20 their medical record reviews to determine the accuracy of risk adjustment diagnoses [and
21 submit appropriate deletes].” JS at D133, D137; Ex. D-71 at 2208.

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26 ⁷ *See* JS at D126; Ex. D-22 at 674-75 (T. Johnson notes from April 29, 2014 meeting,
27 noting that “CMS representatives reiterated that, under CMS regulations, MA plans were
28 not required to design their chart review programs for overall accuracy until the proposed
rule is finalized” and that Cheri Rice of CMS stated that “until the proposed rule relating
to medical records review was finalized, MA plans do not have a proactive responsibility
to confirm whether diagnoses submitted by physicians are correct”).

1 Shortly after CMS declined to finalize the MRRR, United told CMS that it was
2 ceasing its complex auditing program.⁸ United reiterated its understandings and disclosed
3 its practices repeatedly in subsequent bids and data attestations.⁹ CMS took no remedial
4 action against United. JS at D227-D231; Exs. D-8 at 384-89, D-131 at 3356:8-12.

5 **E. The Diagnosis Codes at Issue**

6 This case is different from cases involving alleged “upcoding”; DOJ does not
7 contend United’s coders falsely documented *any* medical conditions or that there is
8 anything fundamentally wrong with chart review. JS at D41; Exs. D-119 at 3027:17-28:11,
9 D-99 at 2686:13-25 . DOJ also does not contend that United failed to convey accurately
10 the diagnostic data doctors submitted to it. JS at D162; Exs. D-147 at 3707:22-09:14, D-
11 134 at 3395:7-21. And DOJ does not contend that United has an obligation to conduct
12 audits of all the codes it receives from doctors, since no one expects perfect coding
13 accuracy in this payment system. *See* United MSJ, *supra* at 10-11; *see also* D141; Ex. D-
14 35 at 759. Rather, DOJ’s case rests on the assumption that if United coders who reviewed
15 a chart did not identify a diagnosis code, then that necessarily means that a doctor who
16 previously submitted the same code on a claim form did so in error.

17 In order to understand DOJ’s theory, in 2016, United’s very first interrogatory asked
18 DOJ to identify every diagnosis code DOJ alleged United should have “deleted or
19 otherwise returned as an overpayment.” JS at D155; Ex. D-7 at 354. In response, DOJ
20 listed 28 million diagnosis codes (the “FIR” list). JS at D156; Exs. D-11B at 574-75, D-
21 141 at 3569:15-70:1. DOJ asserted that the list contained “every diagnosis code . . .
22 _____

23 ⁸ *See, e.g.*, JS at D137, D154; Exs. D-71 at 2207-08 (April 30, 2014 email from S. Nelson
24 to C. Rice (CMS) regarding 2012 DOS risk adjustment data attestation, noting that CMS
25 confirmed “that MA plans are [] not currently required to design their medical record
26 reviews to determine the accuracy of risk adjustment diagnoses”); D-25 at 689 (providing:
27 “We . . . adjusted projected risk scores to account for changes in our medical record review
28 processes. Specifically, based on multiple conversations with CMS and CMS’s treatment
29 of medical record review in its recent rulemaking process, the health plan has decided to
30 cease one of its prior processes that identified and deleted certain diagnoses codes through
31 the medical record review process.”).

32 ⁹ *See, e.g.*, JS at D150-D154; Exs. D-21 at 671 (email qualifying attestation for 2013
33 DOS); D-23 at 677-78 (attestation for 2014 DOS), D-33 at 729-30.

1 UnitedHealth . . . improperly failed to delete when UnitedHealth’s own reviewers found
2 no support for the diagnosis code in the member’s medical records.” JS at D157; Ex. D-5
3 at 289. As DOJ explained, “[f]or each diagnosis code on the United States’ list: (1) the
4 diagnosis code was submitted by UnitedHealth to CMS . . . ; (2) that medical record went
5 through UnitedHealth’s medical record review program; and (3) UnitedHealth’s own
6 reviewers did not find the diagnosis code to be supported by medical records.” JS at D158;
7 Ex. D-5 at 289. In another response, DOJ accused United of “failing to delete . . . diagnosis
8 codes . . . that its Chart Review program revealed were not supported by medical record
9 documentation.” JS at D159; Ex. D-12 at 597.

10 DOJ’s central allegation, memorialized in these responses, is that whenever a
11 doctor-certified diagnosis code was not identified in a chart review, that “revealed” the
12 diagnosis did not exist and any payment based on that diagnosis was invalid. For example,
13 in DOJ’s view, if a doctor submitted a “diabetes” code in a claim form after seeing a
14 patient, but United coders did not code “diabetes” in reviewing the medical chart, then the
15 diabetes code *must* be invalid because United’s coders reviewed the chart for the same
16 visit for which the doctor’s office submitted a code for diabetes. DOJ did not review *any*
17 medical records to test that allegation. JS at D165-D166; Exs. D-57 at 1547, D-110 at
18 2864:21-65:3.

19 Consistent with its categorical theory that every time United coders do not identify
20 a diagnosis that necessarily “revealed” the doctor was wrong, DOJ produced an expert,
21 Dr. Craig Garthwaite, to identify the set of diagnosis codes that were unsupported and led
22 to overpayments. *See* JS at D163-D164; Ex. D-57 at 1446-47. Dr. Garthwaite did not
23 review *any* medical charts and did not opine as to whether a single diagnosis code was in
24 fact unsupported. JS at D165-D166; Exs. D-57 at 1547, D-110 at 2864:21-65:3. Dr.
25 Garthwaite also disclaimed that he had, or would express at trial, any opinion as to the rate
26 at which the diagnosis codes at issue were unsupported. JS at D167-D168; Ex. D-110 at
27 2868:12-69:11. Instead, the Garthwaite report is *entirely* based on an assumption that
28

1 parallels DOJ's hypothesis that *every* diagnosis previously certified by a doctor but not
2 separately identified by a United chart reviewer is invalid. JS at D169; Ex. D-57 at 1547.

3 The report proceeds in two conceptual steps. *First*, Dr. Garthwaite identifies a set
4 of what he calls "potential deletes," which is the set of diagnosis codes submitted by
5 doctors in claims but not identified by United's chart reviewers: "To identify Potential
6 Deletes, I identify all diagnosis codes that are Submitted Diagnosis Codes but not
7 Supported Diagnosis Codes (i.e., all diagnosis codes from Reviewed Encounters that were
8 submitted to CMS but were not found to be supported in the Chart Review Program)." JS
9 at D170-D176; Ex. D-57 at 1484. *Second*, Dr. Garthwaite tried to determine the subset of
10 these "potential deletes" that impacted United's *payment* from CMS. Dr. Garthwaite called
11 this subset of codes "deletes." JS at D177-D178; Ex. D-57 at 1489-90. He identifies 1.97
12 million diagnosis codes as "deletes," or roughly 7% of the 28 million codes DOJ claims
13 in the First Interrogatory Response United was required to delete. JS at D179; Ex. D-65 at
14 1917-18, D-110 at 2875:18-21. The remaining 93% of the "potential deletes" concededly
15 had no payment impact. JS at D183; Ex. D-65 at 1916-19.

16 UNITED STATES' BACKGROUND

17 United's Contracts with CMS. Each year, United entered into contracts with CMS and
18 agreed to comply with "the requirements of this contract and applicable Federal statutes,
19 regulations, and policies." Pursuant to these contracts, United received a monthly payment
20 for each beneficiary enrolled in its health plans. See D-3, Dkt. 250-1, at 162-63 ¶¶ 6, 8-9
21 (undisputed by both parties). And as a condition for receiving those monthly payments,
22 United agreed that it would attest to the "accuracy, completeness, and truthfulness" of the
23 data it submitted to CMS "based on best knowledge, information and belief." See, e.g., P-
24 1A, at 3984 Art. II(A), 3986 Art. IV(D) (2017 PY Contract); see also P-1, at 3977 ¶ 7
25 (Joint Stipulation).

26 During the relevant time period, Optum, a member of United's corporate family and
27 a defendant in this case, performed risk adjustment services for United, including, among
28 other things, Chart Review and Coding, Claims Verification, and submitted beneficiary

1 data to CMS on behalf of the MAO Defendants. D-69, at 2116-2203; P-1, at 3977 ¶ 6; P-
2 1B, 3994-99 (Optum EDI Agreement); P-2, United 30(b)(6) (Cannon) (Jun. 6, 2023) Tr.
3 4021 at 31:11-18. Before submitting any data, both the MAO Defendants and Optum
4 signed EDI Agreements, P-1, at 3977 ¶ 2, which included the following terms: “Based on
5 best knowledge, information, and belief, that it will submit risk adjustment data that are
6 accurate, complete, and truthful” and “that it will research and correct risk adjustment data
7 discrepancies.” P-1C, at 4022 §§ A(5) and A(11) (Defendant MAO EDI Agreement); P-
8 1B, at 3994 §§ A(5) and A(11) (Optum EDI Agreement).

9 Risk Adjustment Payment Process. The monthly payments from CMS to MA Plans
10 are determined based on the health status of a beneficiary. *See* D-3, Dkt. 250-1, at 162-63
11 ¶¶ 6, 8-9 (undisputed by both parties). Diagnosis codes represent a specific health
12 condition (for example, diabetes) and are used to determine the health status of a
13 beneficiary. P-3, 2008 RAPS Participant Guide (Participant Guide) at 4039-40 § 6.2.
14 MAOs like United receive claims and encounter data, including diagnosis codes, from
15 healthcare providers who treat their beneficiaries. P-3, Participant Guide at 4034 § 2.2.2.
16 These diagnosis codes may have been coded by the healthcare providers themselves or by
17 office personnel or professional coders. *See* D-53, Acevedo (US Expert) Rebuttal Rep.
18 1272 ¶ 72. MAOs submit that diagnosis data to CMS. P-5, United 30(b)(6) (Sedor) Tr.
19 4074:19-4075:7. Separately, an MAO may conduct Chart Reviews (i.e., employ
20 professional coders to review a provider’s medical record for supportable diagnosis codes)
21 and submit additional diagnosis data emanating from that review. *Id.* Regardless of the
22 source of the data, MAOs bear the ultimate responsibility for the accuracy of the data they
23 submit to CMS. P-8, Medicare Managed Care Manual, Rev. 118 (Sept. 19, 2014), at 4200-
24 01 Ch.7 § 120.2.1.

25 Every diagnosis code submitted to CMS must be supported by documentation in the
26 medical record based on a face-to-face encounter with a provider (e.g., a doctor visit on
27 May 1, 2014 where it is documented in the patient’s medical record that he had COPD).
28 *See* P-60, 42 C.F.R. § 422.310(d)(1), at 4848; P-77, 45 C.F.R. § 162.1002(c)(2)-(3), at

4953-54; P-9, Managed Care Manual, at 4204-06 Ch. 7, Exhibit 30 (Aug. 13, 2004); P-8, Managed Care Manual, Rev. 118 (Sept. 19, 2014) at 4197-99 § 40; P-3, Participant Guide at 4036 § 3.2.4; P-5, United 30(b)(6) (Sedor) Tr. 4076:4-22. MAOs are required to delete incorrect diagnosis data (including unsupported codes). P-8, Managed Care Manual, Rev. 118 (Sept. 19, 2014), at 4197-99 Ch.7, § 40; P-3, Participant Guide at 4037-38 §§ 4.13-4.14, 4.16; P-5, United 30(b)(6) (Sedor) Tr. 4080:22-4081:21.

When determining payment to MAOs, CMS groups multiple diagnosis codes for similar or related conditions together under broader categories known as Hierarchical Condition Categories (HCCs). P-5, United 30(b)(6) (Sedor) Tr. 4062:25-4066:20. For example, both simple chronic bronchitis (diagnosis 4910) and interstitial emphysema (5181) map to Chronic Obstructive Pulmonary Disease (HCC 108). P-43 at 4472-4527 (2012 Risk Model Diagnoses); P-80, at 4983 (2013 Call Letter). CMS uses the HCCs associated with a particular beneficiary, together with certain demographic information, to calculate the beneficiary's "risk score." P-5, United 30(b)(6) (Sedor) Tr. 4063:14-4064:2. Because many of the HCCs are in hierarchies, only the highest HCC in the hierarchy will increase the risk score. *Id.* at 4064:12-4065:13. The risk score determines the monthly payment the MAO will receive for that beneficiary. *Id.* at 4067:25-4068:7, 4078:23-4079:6. Therefore, diagnosis codes that "map" to an HCC (i.e., diagnosis codes that feed into, or map, to the higher-level broader category, or HCC) directly increase the MAO's payment for that beneficiary. *Id.* at 4072:23-4073:5.

If an MAO submits multiple diagnosis codes for the same beneficiary that map to the same HCC, the CMS payment system only counts each HCC once per year in calculating the beneficiary's risk score (and thus payment). *Id.* at 4064:12-4065:13. This process for calculating risk scores is done automatically within the CMS system. P-3, Participant Guide at 4033, 4035, 4045-46 §§ 2.1, 2.2.4, 8.1 at Table 8A. Since the payment system automatically "maps" each diagnosis code to the appropriate HCC and only counts once each HCC impacting the risk score, MAOs do not need to determine whether multiple

1 diagnosis codes mapping to the same HCC have been submitted for a beneficiary before
2 submitting or deleting diagnosis codes. P-10, Rice Tr. 4216:13-4217:1, 4225:14-4226:3.

3 CMS recalculates all risk scores three times per year and makes interim payments
4 to MAOs monthly. P-5, United 30(b)(6) (Sedor) Tr. 4057:19-4058:4, 4067:16-4068:23,
5 4084:25-4085:6. Each time the risk scores are calculated, CMS uses whatever diagnosis
6 data the MAO has submitted up to that time, including additions and deletions, and adjusts
7 the per member/per month payment amount for each beneficiary. *Id.* at 4067:16-4068:23.
8 In other words, the final reconciliation automatically “trues up” the payments to the MAO
9 based on the data that is in the system at the time of the final reconciliation, and either
10 increases payments resulting from the submission of additional codes or recovers
11 overpayments resulting from the deletion of invalid codes (by reducing future payments).
12 *See id.* at 4067:16-4069:23. CMS sets deadlines for the submission of additional supported
13 codes before it conducts a final reconciliation. P-60, 42 C.F.R. § 422.310(g)(2), at 4850;
14 P-3, Participant Guide at 4032 § 1.4. While MAOs can correct (i.e., delete) previously
15 submitted data after the final submission deadline, MAO’s are not permitted to add
16 diagnosis codes to increase payments after final reconciliation. P-60, 42 C.F.R.
17 § 422.310(g)(2)(ii), at 4850; P-5, United 30(b)(6) (Sedor) Tr. 4067:16-4069:23. CMS
18 periodically reruns the risk scores and recalculates the MAO payments to account for
19 deletions made after the final submission deadline. *Id.* If an MAO deletes a code after the
20 final submission deadline, during a rerun the system again automatically calculates the
21 amount of any overpayment and recovers the overpayment by reducing future payments.
22 P-5, United 30(b)(6) (Sedor) Tr. 4072:4-22.

23 RADV Audits: CMS’s RADV audit process is completely distinct from the ordinary
24 MA payment process; this case is not about RADV Audits. *See* P-3, Participant Guide at
25 4042 § 7.1.1. RADV is a process that CMS uses to address mistaken payments, not an
26 assessment of damages for knowing conduct. P-56, CMS 30(b)(6) (Kapustij) Tr. 4796:5-
27 18 (“CMS is not conducting RADV Audits to determine if there is fraud.”). And the
28 RADV process differs from the payment process in important ways. In RADV Audits,

1 long after the final submission deadline, CMS allows MAOs to search for and submit up
2 to five medical records (from any source) in an attempt to show support for an HCC
3 selected for audit. D99, D100. This means that a RADV Audit could find support in a
4 medical record for a diagnosis code (that maps to the relevant HCC) that was never
5 submitted to CMS, or even one that was never submitted to the MAO by the provider. P-
6 6, Renjilian Tr. 4151:7-4152:14 (United Expert testifying that MAOs “can submit any
7 medical records in support of the HCC and they don’t necessarily need to relate to a
8 specific diagnosis that was submitted” and that RADV auditors may “consider[] a record
9 that is not associated with a submitted diagnosis code and find[] that record to support the
10 HCC”). In contrast, in the routine payment process, plans receive payment only for
11 diagnosis codes they actually submit to CMS in advance of the final submission deadline,
12 which must be supported by a medical record associated with a specific provider-
13 encounter for a specific date of service. P-6, Renjilian (United Expert) Tr. 4120:13-4123:7,
14 4155:23-4156:21; P-5, United 30(b)(6) (Sedor) Tr. 4069:9-14. United’s own expert agrees
15 that validation of an HCC in a RADV Audit does not mean that the provider-submitted
16 diagnosis codes are supported by the specific medical record reviewed in Chart Review.
17 P-6, Renjilian Tr. 4143:18-4144:5 (United Expert testifying that it is unknown “which
18 specific diagnosis was found by the RADV auditors to be supported, but it’s just that the
19 HCC was supported.”).

20 United’s Chart Review Program. United’s Chart Review program is an audit
21 process to “second-guess providers” to generate additional revenue from CMS by
22 identifying diagnosis codes supported by medical charts that its providers had not
23 submitted. Although the Chart Review program is central to this case, United provides
24 scant – and sometimes misleading – information about the program. United’s Chart
25 Review program was a highly sophisticated operation designed to “submit a more
26 complete health status from medical records collected on a member for appropriate
27 payment from CMS.” P-7, United 30(b)(6) (Baker) Tr. 4167:10–20. Chart Review was a
28 highly lucrative program for United; in fact, United estimated that for date of service years

2009–2016, CMS paid it more than \$7.2 billion in **additional** risk-adjustment payments for codes United added during Chart Review that were not previously submitted by providers. P-11 at 4245-47, United’s Responses and Objections to US Interrogatory Set Six, at Response to Interrogatory 18. In its Chart Review program, United collected charts from providers who had reported to United encounters with beneficiaries, and for which United had submitted diagnosis codes to CMS. *See* D47.

United’s policy was to use only certified medical coders for its Chart Reviews. P-12 at 4254-58, Chart Review Policy; P-7, United 30(b)(6) (Baker) Tr. 4180:1–4. United also trained its coding staff, both before they began coding charts and thereafter. *Id.* at 4180:5-4181:9. United measured its coders based on their coding accuracy. Coders had to achieve an accuracy score of 95% or higher on several sets of practice charts in order to successfully complete training and move into production (i.e., start reviewing charts for diagnosis codes that would be submitted to CMS). P-13, Coding Guide at 4261; P-7, United 30(b)(6) (Baker) Tr. 4179:11-15. Even after a coder moved into production, United employed quality assurance processes to ensure that the coder was meeting or exceeding a 95% accuracy standard. *Id.* at 4168:3-9, 4177:21-4178:4 (“[O]ur program was designed to have what they were coding to be at 95 percent or above accuracy.”).

United’s Chart Review was generally done in a “blind” fashion, meaning that the coder reviewing a particular chart did not know what diagnosis codes the provider had submitted. D51; P-7, United 30(b)(6) (Baker) Tr. 4184:18-22, 4186:17-4187:14. United instructed its coders to identify **all** risk-adjusting diagnosis codes supported by the charts for each date of service reviewed. P-14 at 4264, Coding Policy (“All ICD-9s that map to medical and/or Rx HCC will be coded for every date of service for that patient. . . . OptumInsight coding practice instructs those coding on its behalf to code all medical and Rx HCCs for every date of service of each patient.”); P-15, United 30(b)(6) (Baker) Tr. 4267:12-22. In fact, United evaluated coders based on their ability to identify diagnosis codes supported by the medical records, and assigned “completeness” scores based on whether a quality assurance coder identified additional diagnosis codes that had not been

1 identified by the initial coder. P-7, United 30(b)(6) (Baker) Tr. 4192:1-13. For dates of
2 service years 2014-2016, United also introduced a process called “second-level review,”
3 in which certain charts that had already gone through an initial blind chart review were
4 assigned to a second coder to conduct yet another blind review in an attempt to capture
5 even more diagnosis codes. D243; P-7, United 30(b)(6) (Baker) Tr. 4188:4-12 (second-
6 level review instituted because not every coder would get to “100 percent completeness”).

7 From the beginning of its Chart Review program, United was aware that providers
8 sometimes submit diagnosis codes to MAOs that were not supported in the underlying
9 medical records. *See* D32; P-73, at 4918-19 (2004 Presentation showing unsupported
10 provider-submitted diagnosis codes identified in a chart review performed by United’s
11 acquisition, Pacificare). Critically, United’s database contained all the provider reported
12 diagnosis codes that United submitted to CMS for payment, so United could readily
13 compare the codes identified from its Chart Review program with what had previously
14 been submitted. D-57, Garthwaite (US Expert) Report, at 1472-75 ¶¶ 69-75. In fact, United
15 **did** compare its Chart Review results to diagnosis codes it previously submitted to CMS
16 to identify codes found supported in Chart Review that were new (i.e., not previously
17 submitted for that beneficiary). P-76, Martin Tr. 4949:13-24 (United’s “x19 process”
18 compared diagnosis codes identified in Chart Review with diagnosis codes submitted from
19 providers for the same date of service before submitting the diagnosis codes identified in
20 Chart Review); P-72, United 30(b)(6) (Cannon) Tr. 4910:8-14 (same); P-5, United
21 30(b)(6) (Sedor) Tr. 4094:24-4095:22 (describing United’s process to “identify which of
22 those codes from a chart review were new and unique for submission” by comparing the
23 diagnosis codes that had been submitted by a provider with what had been found in the
24 chart review). Conversely, United **did not** run a comparison to identify diagnosis codes
25 previously submitted to CMS that were **not found supported** in United’s Chart Review of
26 the medical record associated with that submission. *See* D50, P-71 Bird Tr. 4905:22-
27 4906:8. In fact, other than in the limited “Claims Verification” program discussed below,
28 United took no steps to follow up on any such discrepancies for diagnoses submitted for

1 Service Years 2008-2016 and did not delete those codes. P-5, United 30(b)(6) (Sedor) Tr.
2 4108:24-4109:6. Those are the **only** codes at issue in this case.

3 United's Claims Verification Program. From 2010 to April 2014, United conducted
4 a limited audit program called Claims Verification. In Claims Verification, United
5 investigated some (though not nearly all) of the codes that United had submitted for
6 payment but were not found supported by its Chart Review coders. *See* P-16, United
7 30(b)(6) (Bird) Tr. 4271:11-4273:20; D-57, Garthwaite (US Expert) Report, at 1466-69
8 ¶¶ 55-60. Optum described its Claims Verification program as a Risk Adjustment
9 Compliance Service with the sole purpose of complying with CMS's expectation that
10 when plans conduct chart review, they "should be correcting/removing codes that were
11 submitted on claims and not supported in the corresponding charts." P-17, at 4293
12 ("Recently, CMS announced a settlement with SCAN health plan¹⁰ which outlined the
13 expectation that when plans conduct chart review, they should be correcting/removing
14 codes that were submitted on claims and not supported in the corresponding charts, *which*
15 *is the sole purpose of our Claims Verification offering.*") (emphasis added); *see also* P-16,
16 United 30(b)(6) (Bird) Tr. 4283:7-25 (noting the purpose of Claims Verification was to
17 submit "delete transactions" to CMS where "HCCs that were supposed to be evidenced in
18 a chart were either not evidenced in the chart, or not appropriately evidenced in the
19 chart.").

20 In Claims Verification, United compared the codes that United's coders identified
21 as supported in the medical records in the Chart Review program to the codes that United
22 had already submitted for payment in connection with the same medical record in order to
23 identify discrepancies to be investigated or deleted. *Id.* at Tr. 4282:1-12. United used
24 "matching logic" to compare: (a) the HCCs associated with the diagnosis codes that
25 providers had submitted to United in claims for services to its beneficiaries; and (b) the
26 HCCs associated with the diagnosis codes that United's own coders found supported based
27

28 ¹⁰ The SCAN settlement was an August 2012 FCA settlement, as United was aware. P-18,
at 4297 (March 7, 2013 CV Presentation).

1 on their review of those same beneficiaries' charts in Chart Review. *Id.* at 4286:21-24.
2 When HCCs associated with diagnosis codes that originated from providers were *not*
3 identified as supported in Chart Review, the corresponding medical records were placed
4 in the "CV inventory" for additional medical record review. *Id.* at 4284:20-4285:10.
5 Rather than simply deleting all such discrepancies, United further reviewed the charts to
6 determine if it could find support for those codes. *Id.* If United could not validate the
7 discrepant diagnosis codes by finding support in medical records through this review, it
8 deleted those diagnosis codes. *Id.* at 4277:24-4278:6. United designed Claims Verification
9 with a limited scope, such that only a small subset (less than 25%) of the charts that went
10 through Chart Review were deemed "eligible" for the Claims Verification. *See id.* at
11 4287:19-4289:21. United terminated Claims Verification entirely in 2014. *Id.* at 4272:22-
12 7274:11. Thus, in Claims Verification, United identified some of the diagnosis codes it
13 had submitted, but were not found supported in Chart Review, and deleted those diagnosis
14 codes. Pursuant to those deletes from Claims Verification program, CMS recouped more
15 than \$200 million from United. P-11 at 4249-50, Response to Interrogatory 20.

16 The Resulting Overpayments. United's own data shows that codes not found
17 supported in Chart Review had been submitted for payment and resulted in overpayments.
18 The government's expert witness, Dr. Craig Garthwaite, analyzed United's Chart Review
19 and risk adjustment data and identified diagnosis codes that were: (1) submitted for
20 payment by United; (2) not found to be supported by United's Chart Review Coders'
21 review of the medical record linked to that submission; and (3) not deleted. Dr. Garthwaite
22 also calculated how much United's payments would have decreased had United deleted
23 those codes. *See* D-57, Garthwaite Report, at 1446-47 ¶ 13. Dr. Garthwaite identified
24 approximately 2 million diagnosis codes, listed on Attachment 1 to his expert report, that
25 resulted in overpayments to United, and for which the government seeks damages. *Id.*; P-
26 74, Garthwaite Tr. 4938:10-11 ("There are millions of diagnosis codes, 1.9 million
27 diagnosis codes on Attachment 1"). According to Dr. Garthwaite's analysis, every
28 diagnosis code on Attachment 1 was submitted by United to CMS for risk adjustment

1 payment, linked to a Chart Review in United’s databases, and was not found supported by
2 United coders in that Chart Review when the coder was looking at the medical record
3 underlying the original provider-submitted diagnosis code for an encounter on given date
4 of service. D-57, Garthwaite Report, at ¶ 1446-47, 1479 ¶13, 85.

5 Dr. Garthwaite calculated that United’s risk adjustment payments for the relevant
6 time period would have decreased by approximately \$2.1 billion if United had deleted the
7 approximately 2 million diagnosis codes. *Id.* at 1446-47, 1480 ¶¶ 13-14, ¶ 86. Importantly,
8 Dr. Garthwaite essentially simulated CMS’s payment system process by searching data
9 that was submitted to CMS for any other diagnosis code that mapped to the same HCC as
10 the unsupported code and thus would have, pursuant to the CMS payment system rules,
11 resulted in a payment to the MAO for the HCC, before concluding that the unsupported
12 code had a financial impact (i.e., resulted in an overpayment). Dr. Garthwaite also took
13 his analysis one step further, as he removed diagnosis codes from his list of deletes if
14 United’s risk adjustment data contained another instance of a diagnosis code mapping to
15 the same HCC that was not impacted by the results of United’s Chart Review program,
16 even if that other instance was never submitted to CMS (essentially giving United “credit”
17 for diagnosis codes it could *not* have received from CMS in routine processing). D-57,
18 Garthwaite Report, at 1489 ¶ 116; P-74, Garthwaite Tr. 4935:5-13.

19 First Interrogatory Response. During discovery in this matter, Defendants requested
20 that the United States identify “every Diagnosis Code You allege UnitedHealth
21 ‘knowingly and improperly failed to delete . . . or otherwise return to the Medicare
22 Program [as an] overpayment.’” D-11B, US Responses and Objections to UnitedHealth’s
23 First Interrogatory (First Supplemental), at 573. The United States identified
24 approximately 28 million diagnosis codes responsive to this interrogatory. *Id.* While those
25 codes should have been deleted because they were unsupported, not all of those deletions
26 would have impacted payment, which is the question addressed by Dr. Garthwaite. P-10,
27 Rice Tr. 4216:13-4217:1, 4225:14-4226:3; P-74, Garthwaite Tr. 4937:16-22; *see also id.*
28 at 4930:13-4934:18 (explaining how his analysis is conceptually different from what he

understands is included in the US First Interrogatory Response). Additionally, Dr. Garthwaite conservatively did not include on his “deletes list” every diagnosis code that United’s Chart Review program showed was unsupported, but rather only included diagnosis codes that would impact a beneficiary’s risk score if deleted, and only included diagnosis codes where United’s risk adjustment databases contained no other instance of any diagnosis mapping to the same HCC, even those United never submitted to CMS. D-57, Garthwaite Report, at 1489 ¶ 116; P-74, Garthwaite Tr. 4935:5-13. Because Dr. Garthwaite is addressing a question fundamentally different from the question in United’s First Interrogatory, the resulting numbers are starkly different. To be clear, the United States is only seeking damages in this matter with respect to the approximately 2 million deletes identified by Dr. Garthwaite. United’s constant reference to the 28 million codes listed on the discovery response is nothing more than further attempt to muddy the facts.

Medical Record Review Rule. The Medical Record Review Rule (MRRR) was one part of a much broader rule that CMS proposed in January 2014 to address a wide range of MA topics. D-16 at 636-40, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. 1918 (Jan. 10, 2014). The proposed rule provided that “medical record review methodology must be designed to identify errors in diagnoses submitted to CMS. . . regardless of whether the data errors would result in positive or negative payment adjustments.” *Id.* at 638. Because of stakeholder concerns with the broader rule, CMS ultimately did not finalize this provision in the final rule published in May 2014. P-92, at 5044, 5047, Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. 29,844, 29,926 (May 23, 2014) (to be codified at 42 C.F.R. pts. 417, 422-24); P-21, CMS 30(b)(6) (Hornsby) Tr. 4334:7-11; P-10, Rice Tr. 4227:23-4228:12. However, CMS advised MAOs that not finalizing the proposed MRRR did “not change CMS’s existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS” and did “not change the long-standing risk adjustment data requirement that a diagnosis

submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.” P-92, at 5047. Before and after the MRRR was proposed, CMS’s longstanding regulatory and contractual requirements for MA plans remained the same. MA plans always had a duty to submit accurate, complete, and truthful data, and to delete unsupported diagnosis codes. P-10, Rice Tr. 4241:18-25; P-22, CMS 30(b)(6) (Hornsby) Tr. 4338:20-4339:21; P-20, Cavanaugh Tr. 4314:9-15; P-23, Blum Tr. 4344:16-19. CMS communicated this message directly to United at the time. *See, e.g.*, P-20, Cavanaugh Tr. 4315:15-20; P-24 at 4347-48, 2014 CMS/United correspondence.

April 29, 2014 Videoconference. United asserts that during a 45-minute videoconference on April 29, 2014, CMS advised United that it had no obligation to confirm the validity of codes not found supported in its Chart Review program until the proposed MRRR was finalized. Joint Brief, 15. United misstates the facts about this highly disputed videoconference between several CMS employees and several United employees. While United’s Chart Review program is at the heart of this case, United’s Claims Verification program was the focus of discussion at this brief videoconference. P-25, Nelson Tr. 4351:7-23 (United objectives of meeting were to get clarification on timing of proposed rule and get info to make decision on CV program), 4352:24-4353:5 (purpose of meeting was to discuss status and timing of proposed rule and “requirement or not” to have a CV program).

There is no evidence that United explained or that CMS understood that United was proposing to ignore the negative results of its Chart Review program, and ample evidence to dispute United’s contention that CMS consented to United’s decision to ignore those negative results. Further, there is abundant evidence that United did not even provide CMS with enough information about its Claims Verification program to allow CMS to provide specific guidance about United’s practices. P-10, Rice Tr. 4238:12-4239:2 (CMS did not know the details of United’s program or what review of potential unsupported codes had been done); 4236:20-4237:7 (CMS would have needed a lot more information about the scope of what United was doing, what information they had, and how much due diligence

1 they had done); P-26, CMS 30(b)(6) (Hornsby) Tr. 4364:4-19 (information provided was
2 vague); P-28 at 4376 (contemporaneous notes of Daniel Schumacher (UHC CFO) quoting
3 Cheri Rice as saying she did not know enough about United's process to make
4 "judgments").

5 Rather, CMS warned United that there are legal requirements in place, including
6 the False Claims Act, that govern the accuracy of data submitted to CMS. P-20,
7 Cavanaugh Tr. 4318:14-4319:2; P-10, Rice Tr. 4232:4-12 (Rice reminded United about
8 potential FCA exposure). Contemporaneous notes taken by United's Dan Schumacher
9 explicitly include these statements he attributed to CMS's Cheri Rice: "Not acceptable to
10 not delete what we know;" "If you have knowledge of deletes, you should delete;"
11 "Statutory obligations to report and repay;" "FCA implications;" "Haven't known enough
12 process to give feedback on our judgments." P-28 at 4376, Schumacher Notes. Relatedly,
13 Thad Johnson, United's in-house counsel who participated in the videocall, recalls that in
14 response to United raising the issue of "deletes" being submitted or in process, Rice raised
15 the topic of the FCA. P-29, Johnson Tr. 4379:21-4380:16.

16 CMS reiterated this message in writing following the meeting: "I would note that
17 regardless of the effective date of the proposed requirement related to medical record
18 reviews, there are other laws that do impose standards, requirements and responsibilities
19 on MA plans in connection with the federal payments they receive from CMS. We cannot
20 provide advice to United about the scope of those other laws. Nor can we provide advice
21 on whether United's plan course of action and/or purported limits on the scope of its
22 attestation are compliant with such other laws." P-24, at 4347 (2014 CMS/United
23 correspondence); P-10, Rice Tr. 4234:13-4235:1, 4236:13-17 (Rice's intent in sending this
24 email to United was "making clear that they should not take away from that meeting that
25 we had said that it was okay to stop the claims verification program, or that it was okay
26 not to continue to review and determine whether those questionable diagnoses were
27 accurate or not"). CMS has continued to reiterate that message to United since then. P-1D
28

1 at 4008-09; P-1E at 4011-12; P-1F at 4015-16 (CMS's responses to United's
2 correspondence sent with its 2014/2015/2016 Payment Year attestations).

3 Tellingly, United fails to mention that at the time it requested this meeting with
4 CMS, it knew that the DOJ had already been investigating this matter for approximately
5 two years. United likewise fails to mention that at the time it arranged to meet with CMS,
6 it was grappling with a projected \$500 million budget deficit and that high-ranking United
7 executives, including some of those that attended this videoconference, were considering
8 cancelling its Claims Verification program as part of a solution to bridge that budget gap.
9 P-81, MAPL009701356, at 4986, 4988 (UHC M&R Draft Business Plan 2015). These are
10 facts the jury should be able to consider in determining United's motivation for and
11 conduct related to – including its retelling of anything it “took away” from – that meeting.
12 Following the meeting, and upon receiving correspondence from United's outside counsel
13 with its “interpretation” of the events of the meeting, *see* P-40 at 4462-63 (Letter from
14 Latham & Watkins to DOJ), DOJ counsel responded, specifically referring to Ms. Rice's
15 correspondence, and further informing United that, “Thus, CMS did not agree that
16 UnitedHealth Group's planned actions and its purported limited attestation are compliant
17 with the laws that apply to Medicare Advantage plans. As you know, such laws include
18 the federal False Claims Act.” P-75 at 4942-43 (Letter from DOJ to Latham & Watkins).

19 Finally, a short videocall with one individual MAO (out of hundreds) is simply not
20 a forum in which CMS would dispense advice on how MAOs must comply with its
21 regulatory duties. *See* P-26, CMS 30(b)(6) (Hornsby) Tr. 4363:1-24 (CMS did not have
22 enough information, but even if it did, CMS does not provide advice in meetings like that);
23 P-27, Tudor Tr. 4373:3-11, 20-24 (CMS can provide information on what requirements
24 are, but does not opine on whether specific activity is compliant with a regulation).

LEGAL ARGUMENT REGARDING UNITED’S MOTION FOR SUMMARY JUDGMENT

I. UNITED’S LEGAL ARGUMENT ON ISSUE NO. 1: WHETHER THE COURT SHOULD GRANT SUMMARY JUDGMENT AS TO THE REVERSE FCA CLAIM

As relevant here, the FCA penalizes “[a]ny person who . . . knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G). The Supreme Court has explained that “[w]hat matters is not the label the government attaches to a requirement [for payment], but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.” *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 181 (2016) (*Escobar*). To prevail, DOJ must prove that United (1) was overpaid, (2) knowingly violated an “obligation” to return money to the government, (3) engaged in conduct that was material to CMS’s decision to pay, and (4) engaged in some form of deceit to meet the “rigorous” definition of “fraud.” *Id.* at 187, 192.

DOJ’s case falters on each element. DOJ has no proof that the diagnoses at issue were incorrect or led to overpayments. DOJ also cannot show that United had any obligation to second-guess doctors’ certifications that their diagnoses accurately reflect the patients’ health conditions. DOJ also cannot show that United’s chart review practices were material to CMS’s payments, or that United took any steps to deceive CMS. For these four independent reasons, the Court should grant United’s motion for summary judgment.

US RESPONSE TO ISSUE NO. 1: THE COURT SHOULD DENY SUMMARY JUDGMENT AS TO THE REVERSE FCA CLAIM

The United States alleges that United violated the second prong of the reverse false claims provision. 31 U.S.C. § 3729(a)(1)(G). Under that provision, United is liable if it: (1) improperly avoided an obligation to pay; and (2) did so “knowingly.” *Sutter*, 444 F.

1 Supp. 3d at 1055-56. Congress first added the reverse FCA provision in 1986, to cover
2 Government money. . . that is knowingly retained by a person even though they have no
3 right to it.” *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 676 (9th Cir. 2018)
4 (citations omitted). Congress intended “to provide that an individual who makes a material
5 misrepresentation to avoid paying money owed the Government would be equally liable
6 under the Act as if he had submitted a false claim to receive money.” See S. Rep. No. 99-
7 345, at 18, *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5283.

8 In 2009, Congress amended the FCA through the Fraud Enforcement and Recovery
9 Act of 2009 (FERA), “broaden[ing] the scope to which reverse false claims liability would
10 attach.” *United States ex rel. Customs Fraud Investigations, LLC. V. Victaulic Co.*, 839
11 F.3d 242, 253, 255 (3d Cir. 2016). Congress added a second prong to the reverse FCA
12 provision, which eliminated the need for a false statement and imposed liability on anyone
13 who “knowingly conceals **or knowingly and improperly avoids or decreases an**
14 **obligation to pay or transmit money or property to the Government.**” 31 U.S.C.
15 § 3729(a)(1)(G) (emphasis added). Under the reverse FCA provision, “avoiding” an
16 obligation to pay is when an individual is put on notice of a potential issue, is legally
17 obligated to address it, and does nothing. See *Kane ex rel. United States v. Healthfirst,*
18 *Inc.*, 120 F. Supp. 3d 370, 394 (S.D.N.Y. 2015).

19 Through FERA, Congress added the following definition of the term “obligation:”
20 “an established duty, **whether or not fixed**, arising from an express or implied contractual,
21 grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship,
22 from statute or regulation, or from the retention of any overpayment.” 31 U.S.C.
23 § 3729(b)(3) (emphasis added). In doing so, Congress rejected prior court interpretations
24 of the reverse FCA provision that required an obligation to be a sum certain, and instead
25 adopted the Ninth Circuit standard that an obligation arises “where there is a relationship
26 between the Government and a person that ‘results in a duty to pay the Government money,
27 whether or not the amount owed is yet fixed.’” S. Rep. No. 111-10, at 14 (2009) (quoting
28 Brief for the Appellee at 24, *United States v. Bourseau*, 531 F.3d 1159, 1170 (9th Cir. 2008)).

1 Upon a finding of liability, a defendant must pay for “3 times the amount of damages
2 which the Government sustains because of the act.” 31 U.S.C. § 3729(a)(1); *Bourseau*,
3 531 F.3d at 1172. Damages are appropriately determined by simulating how CMS would
4 have calculated the amount of the improperly inflated interim payments – the overpayment
5 – if the unsupported diagnoses were withdrawn from CMS’s payment system. See
6 *Bourseau*, 531 F.3d at 1173 (affirming the government’s damages calculation which
7 simulated CMS’s reconciliation process).

8 In addressing the elements that must be proved in this case, United ignores the plain
9 language of the reverse FCA provision. Indeed, when quoting the statutory definition of
10 “obligation,” United misleadingly omits the key phrase “whether or not fixed” from
11 “established duty.” Joint Brief, 48. And United fails to cite a single case involving that
12 provision. Joint Brief, 32. Instead, United resorts to the Supreme Court’s decision in
13 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), which
14 involved a direct false claim – not a reverse false claim – which has different statutory
15 language and substantially different elements of proof. *Escobar*, 579 U.S. at 187. United’s
16 reliance on *Escobar* is therefore misplaced.

17 **A. United’s Legal Argument: DOJ Cannot Show That United Was**
18 **Overpaid**

19 The threshold element for a reverse FCA case is that the defendant has money that
20 should have been returned to the government, i.e., that it was overpaid. To satisfy that
21 element here, DOJ must show that the diagnosis codes at issue were in fact unsupported
22 by the patient’s medical charts. In addition, not all invalid diagnosis codes lead to
23 overpayments, because other supported diagnoses could justify payment for the same
24 HCC. See United MSJ, *supra* at 9-10. DOJ must thus also show that any unsupported
25 diagnosis codes resulted in CMS overpaying United. DOJ has no evidence of either.

1 **1. DOJ Cannot Show the Diagnosis Codes Were Unsupported**

2 DOJ must show that the doctor-certified diagnoses were in fact not supported by the
3 patient's medical records. But DOJ has steadfastly refused to look at the only evidence
4 that could substantiate its allegations—the underlying medical charts. JS at D165-D168;
5 Ex. D-110 at 2864:21-65:3.

6 The relevant facts are undisputed. DOJ does not dispute that doctors certified that
7 every diagnosis code at issue here correctly reflected their patients' health conditions. JS
8 at D22, D161, D181-D182; Exs. D-40 at 944-45, D-126 at 3233:21-15. DOJ also does not
9 dispute that United accurately conveyed to CMS those same doctor-certified codes. JS at
10 D162; Exs. D-147 at 3707:22-09:3, D-134 at 3395:4-22. DOJ does not allege that it is
11 unlawful to conduct chart review programs, or challenge the accuracy of the codes
12 United's coders identified during chart review. *See* United MSJ, *supra* at 11-14. And DOJ
13 concedes that MA plans do *not* have any general obligation to second-guess doctor-
14 submitted diagnosis codes before submitting them to CMS for payment. *Id.* at 11, 13-14;
15 *see also, e.g.*, JS at D70; Ex. D-46 at 1099 ("We recognize as well that . . . there is no
16 CMS requirement that MA organizations verify every diagnosis submitted by providers.").

17 DOJ's sole contention is that anytime "UnitedHealth's own reviewers found no
18 support for [a] diagnosis code in the member's medical records," the diagnosis was
19 necessarily invalid, even if a doctor certified that diagnosis in claims forms. JS at D155-
20 D158; Ex. D-5 at 289. DOJ alleges that the 28 million doctor-submitted diagnosis codes
21 that United's chart reviewers did not identify during chart review were all "invalid." *See*
22 United MSJ, *supra* at 16-17. DOJ argues that United coders' failure to identify particular
23 diagnosis codes during chart review "revealed" that the diagnosis codes at issue "were not
24 supported by medical record documentation." JS at D159; Ex. D-12 at 593.

25 This is a sleight of hand. In truth, United's chart review program did not "reveal"
26 that any (let alone all) of these 28 million codes were unsupported. *See* United MSJ, *supra*
27 at 11-12. At most, the program revealed an unresolved discrepancy between United's
28 coders and a doctor (or doctor's coder). *See id.* As the party with the burden of proof, DOJ

1 needed to marshal sufficient evidence on which a jury could reasonably conclude which
2 (if any) of those codes are actually unsupported. And DOJ has *none*. Lacking any
3 evidence, DOJ cannot simply pretend all 28 million are unsupported and call it a day for
4 trial. *See In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010) (“the non-
5 moving party must come forth with evidence from which a jury could reasonably render
6 a verdict”). After all, “a jury is permitted to draw only those inferences of which the
7 evidence is reasonably susceptible; it may not resort to speculation.” *Brit. Airways Bd. v.*
8 *Boeing Co.*, 585 F.2d 946, 952 (9th Cir. 1978); *see Neely v. St. Paul Fire & Marine Ins.*
9 *Co.*, 584 F.2d 341, 345 (9th Cir. 1978). Here, DOJ’s theory is so wildly speculative and
10 unsound that *none* of its experts will opine which of the 28 million diagnosis codes were
11 in fact unsupported.

12 The core reason DOJ’s theory fails is that it does not account for the nature of
13 coding. DOJ’s own coding expert agreed that there are multiple reasons coders conducting
14 “blind” chart review—review without knowing what diagnosis codes a doctor
15 submitted—might at times miss valid diagnosis codes. JS at D54-D60, D246; Ex. D-53 at
16 1266, D-87 at 2403:21-05:2, 2396:13-400:16, 2409:1-10:5. United coders may not have a
17 complete collection of the medical charts, may have had insufficient time to review the
18 charts, may have had different degrees of experience in coding, and may have lacked
19 familiarity with the doctor’s medical specialty or handwriting. *See United MSJ, supra* at
20 11-12.¹¹ In addition, diagnosis coding is an inherently complex enterprise where human
21 errors occur, as multiple DOJ experts agreed. JS at D246; Exs. D-141 at 3515:25-16:14,

23 ¹¹ *See, e.g.*, JS at D54-D61, D98, D246; Exs. D-65 at 1919 (“[B]ased on my many years
24 of professional experience supervising coding reviews in a variety of circumstances, there
25 are many practical, real-world factors that can make it difficult to identify diagnosis codes
26 from a medical record comprehensively and with complete accuracy. These can include,
27 among other things, the time available for the review; the completeness, legibility and
28 clarity of the medical record documentation; and the skill and experience of the
reviewer.”); D-93 at 2557:10-58:1, D-87 at 2409:1-10:5, D-54 at 1292-93 (incomplete
record); D-87 at 2403:21-04:3, D-93 at 2558:10-59:3, D-54 at 1294, D-108 at 2829:17-
30:8 (legibility); D-108 at 2833:15-34:5, D-54 at 1301-02 (human error); Ex. D-53 at 1266
 (“human error is inevitable”); Ex. D-67 at 1209 (agreeing that two coders may reach
different results for a variety of reasons, including judgment, experience, provider
handwriting, and human error).

1 D-110 at 2861:6-7, D-87 at 2404:12-18. Even CMS coders miss supported codes when
2 reviewing charts in RADV.¹² In short, it is undisputed that (for whatever reason) two
3 coders reviewing the same medical record will at times reach different results. JS at D62-
4 D63; Exs. D-94, D-96A at 2603:10-04:9, D-108 at 2824:15-25:4, D-118 at 3009:2-11:16.
5 It is thus undisputed that at least sometimes the doctor—who diagnosed the patient and
6 certified the submitted diagnosis code as accurate—was correct, and United’s coders
7 simply missed the code. JS at D204; Ex. D-141 at 3515:9-17. For these reasons, no
8 reasonable jury could possibly find, as DOJ hypothesizes, that every single time an
9 offshore United coder reviewing a medical record failed to spot a diagnosis a doctor had
10 previously submitted and certified, that diagnosis was wrong.

11 Indeed, outside of this litigation, CMS’s own coders audited a portion of the health
12 conditions here at issue, and the results of those reviews eviscerate DOJ’s categorical
13 theory. In determining the validity of a diagnosis code, the ultimate standard is whether
14 CMS would have validated the diagnosis during a RADV audit. See JS at D31, D71; Ex.
15 D-117 at 2976:14-77:20 (confirming that when CMS validates a health condition (HCC)
16 in RADV “there is no change in payment. So there would be no overpayment”). Here,
17 there is an overlap of roughly 6,500 health conditions that correspond to the diagnoses at
18 issue in this case *and* that CMS’s coders also reviewed in RADV audits. JS at D184; Ex.
19 D-64 at 1887-89, fig. 15. Remarkably, *CMS validated 89% of those codes*. See JS at 185;
20 Exs. D-64 at 1887-89, fig. 15, D-141 at 3520:13-21:2, D-63 at 1763. This means that 89%
21 of the CMS-reviewed codes DOJ insists were “revealed” to be invalid in this litigation,
22 and that United allegedly knew were false, correspond to health conditions that were in
23 fact validated by CMS during RADV audits. It is hardly an exaggeration for United to
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27 ¹² See, e.g., JS at D98; Exs. D-94 at 2567:17-69:16 (addressing when senior coder
28 overrides junior coder on whether a code is supported by medical record); D-112 at
2902:23-04:17 (“You have some tests that give you false positives and some tests that give
you false negatives. That’s why you repeat it. You have more than one person looking at
it.”).

1 assert that DOJ's made-for-litigation theory that *all* of those codes were false is without
2 any factual basis.¹³

3 DOJ's statistical expert, Dr. Stark, agrees. Like United's expert, Dr. Stark confirmed
4 that CMS auditors validated 89% of the health conditions corresponding to the overlapping
5 codes DOJ claims are fraudulent.¹⁴ He then testified that the conclusions reached by those
6 auditors prove "to a certainty" that DOJ's hypothesis is just plain wrong:

7 Q. The hypothesis is every time a United chart review coder fails to find a
8 diagnosis code submitted by a provider, the [health condition] associated with
9 that diagnosis code is not supported [in that year], that hypothesis is false,
correct?

10 A. I agree.

11 Q. Okay. And you agree that that's false to a certainty, right?

12 A. Yes, sir. Well, yes, my—if by "supported," we mean RADV found
support, yes.

13 JS at D204; Ex. D-141 at 3535:9-18.

14 The undisputed facts on this issue end the case. DOJ had options over the course of
15 more than a decade pursuing this case to try to create a jury question on this issue. It could
16 have reviewed all of the medical records to show *which ones* are in fact unsupported.
17 DOJ's coding expert testified that she would have been qualified to perform that review
18 but was not asked. JS at D205; Ex. D-87 at 2389:1-10. Alternatively, DOJ might also have
19 reviewed a statistically valid random sample (as it has in other cases) and sought to
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24 ¹³ The RADV validation rate likely *understates* the real validation rate, since in RADV
25 CMS targets contracts and codes it believes are most likely to contain errors, and because
26 these validation rates are from before any United challenge to the conditions that CMS
found unsupported. JS at D72-D73; Exs. D-18 at 665-66, D-122A at 3108:2-10:9.

27 ¹⁴ See JS at D185; Ex. D-141 3520:21-21:2 ("Q. So the independent analysis that you
performed matched the same results as Mr. Renjilian on Figure 15 of his report, right? A.
The left panel? Q. Yes. A. For 2013 -- from 2011 through 2013, yes, sir."); see also JS
28 at D89; Ex. D-141 at 3560:7-65:23 (Dr. Stark calculating an 88.8% validation rate for
United HCCs audited in RADV for contract years 2011-2015).

1 extrapolate those results.¹⁵ DOJ did not do that either, disavowing any effort to sample.¹⁶
2 But having chosen neither the labor-intensive path nor the statistical one, DOJ is left with
3 no evidence at all. It would be particularly inappropriate in this fraud case seeking billions
4 of dollars in punishment to relieve DOJ of its burden of opposing summary judgment with
5 actual *evidence* on which a jury could reasonably rely.

6 **2. DOJ Cannot Show the Diagnosis Codes Resulted in Overpayments**

7 DOJ has also failed to show that any unsupported diagnosis codes actually resulted
8 in *overpayments* to United. The reverse FCA claim requires DOJ to show that the
9 diagnosis codes at issue caused United to be *overpaid*. 31 U.S.C. § 3729(a)(1)(G). For a
10 diagnosis code to result in an overpayment, that specific diagnosis code must not only be
11 unsupported by the medical chart, the health condition associated with that diagnosis code
12 must also be unsupported by any other diagnosis documented in any chart for the member
13 for that year. *See* United MSJ, *supra* at 9-10. As just explained, DOJ has no evidence on
14 the first point. DOJ likewise has no evidence on the second point.

15 The only DOJ expert to try to identify a set of allegedly unsupported diagnosis codes
16 that resulted in incremental payment to United is Dr. Garthwaite. JS at D163-D164; Ex.
17 D-57 at 1446-47. As noted, Dr. Garthwaite created a list of 1.97 million “deletes” by (1)
18 declaring all diagnoses missed in chart review to be unsupported because United’s chart
19 reviewers did not independently identify them and (2) filtering (through a complex
20 process) those allegedly unsupported diagnosis codes he calculates increased United’s
21 payment from CMS. JS at D179, D208-D209; Exs. D-65 at 1905, 1917-18, 1928-29. Dr.

23 ¹⁵ *See, e.g.*, JS at D206; Exs. D-18 at 657 (“[A]s part of the RADV audit methodology,
24 CMS will extrapolate RADV audit findings.”); D-47 at 1181-83 (using extrapolation to
25 calculate overpayments); D-38 at 904-05 (discussing use of extrapolation by DOJ in tax
cases).

26 ¹⁶ *See, e.g.*, JS at D207; Ex. D-4 at 240 (“United States and Relator’s Position: At this
27 time, Plaintiffs’ damages calculations for both its Chart Review and RACCR damages
28 analyses do not involve sampling or extrapolation. Rather, at this time, Plaintiffs intend to
identify the specific diagnoses that Defendants failed to delete.”); Dkt. 317 at 12-13 (“In
addition, as stated, the damages here are not based on sampling, extrapolation, or contract-
level payment error rates.”); D-6 at 344-45 (noting that the government refused to review
every medical record that United reviewed in chart review).

1 Garthwaite agrees that the remainder of the approximately 28 million diagnosis codes at
2 issue—roughly 26 million diagnosis codes—did not result in increased payment to United
3 because United’s data contained other support for the health condition. JS at D210; Exs.
4 D-57 at 1485-90, D-65 at 1917. What this means is that, as United’s expert calculated, and
5 no DOJ expert has challenged, *more than 93%* of the diagnosis codes DOJ alleged are *all*
6 unsupported in its First Interrogatory Response did not affect the payment United received
7 from CMS and thus could not have possibly led to an overpayment. JS at D183; Exs. D-
8 65 at 1916-19. And for the remaining 7% of codes, DOJ still must establish that the
9 diagnoses were not supported in the medical records in order for them to result in
10 overpayments. But DOJ has no evidence of that for the reasons discussed above, even as
11 to this smaller subset, since it has not reviewed a single medical record as part of this
12 litigation.

13 There is also another fundamental shortcoming. Dr. Garthwaite does not show that
14 even the 1.97 million codes he calls “deletes” actually represent overpayments. That is
15 because of the critical differences between (1) a diagnostic code and a *health condition* or
16 HCC, and (2) a single medical encounter and a payment year. *See* United MSJ, *supra* at
17 9-10. MA plans are paid a specific amount if a member has an HCC, such as “diabetes
18 without complications” (HCC19), and the payment would be the same whether the
19 member had type 2 diabetes without complications or some other type of diabetes that
20 maps to the same HCC. As Dr. Garthwaite himself put it, if an MA plan “submits multiple
21 diagnosis codes mapping to the same HCC for a beneficiary, the beneficiary’s risk score
22 does not depend on which specific diagnosis code was reported” or “how many times a
23 particular diagnosis code is reported within a service year.” JS at D232; Ex. D-57 at 1454.
24 In addition, so long as one doctor in that year documented in a single chart one of the many
25 possible diagnoses that corresponds to HCC19, the plan would be entitled to that same
26 payment. JS at D29, D213; Exs. D-15 at 632-33, D-60 at 1594, D-141 at 3545:20-46:10,
27 D-145 at 3680:15-82:7. What matters when determining whether a plan was overpaid is
28 thus not whether one particular *diagnosis* submitted by a particular doctor for a particular

1 visit is supported, but whether the medical records for the member *for the year* support the
2 *health condition (HCC)*. See JS at D29-D31; Ex. D-145 at 3676:23-77:7 (“Q. [J]ust
3 knowing that there was a single code that was unsupported, that alone wouldn’t tell you
4 you’ve been overpaid if you’re the plan, right? . . . You would need to know, for example,
5 if another record supported the code, correct? A. Yes.”).

6 For these reasons, Dr. Garthwaite cannot simply point to evidence that a diagnosis
7 code submitted by one doctor on a given day was unsupported. DOJ would further need
8 evidence that none of the member’s charts from any doctor documented the existence of
9 any diagnosis mapping to the same HCC during the year. For example, if an MA plan
10 received an incremental payment for a member for “diabetes without complications,” DOJ
11 would need evidence that none of the member’s charts for the year documented support
12 for any of the multiple diagnosis codes that map to that same HCC. DOJ has not even tried
13 to develop that evidence. DOJ has done nothing whatsoever to determine whether *other*
14 medical charts from other doctors on other dates during a year support the conditions
15 corresponding to the diagnosis codes at issue. Again, DOJ could have reviewed the set of
16 medical records for a sample of members and extrapolated from those findings, just as
17 CMS does during RADV, but chose not to do so, leaving it with nothing but speculation
18 about the portion of the Garthwaite deletes that are actual overpayments.¹⁷ See United
19 MSJ, *supra* at 35-39, n.15-16. Again, Dr. Stark thus concedes DOJ’s case is fundamentally
20 flawed:

21 Q. Based on the data that you have available and that you reviewed in your
22 work on this case, there is not a way to reliably estimate the fraction of
23 diagnosis instances in the final deletes—the Garthwaite final deletes list that
24 map to [a health condition of a member in a given year] that would be
25 supported by RADV auditors, right?

A. I agree with that.

26 ¹⁷ DOJ cannot fill this evidentiary hole with the RADV audits. Both parties’ experts agree
27 that the RADV audits are not a representative random sample of the diagnosis codes at
28 issue—which means they provide no basis on which DOJ could extrapolate the actual rate
of unsupported codes or reliably estimate how many of the diagnosis codes are
unsupported. JS at D186-D187, D190-D195; Exs. D-63 at 1769-70, 1776-77, D-135 at
3406:9-17, D-141 at 3573:7-78:11.

1 Q. And similarly, there is not a way to estimate the fraction that would not
2 be supported, correct?

3 A. I agree with that, too.

4 JS at D211-D212, D214; Ex. D-141 at 3581:11-22. A party with the burden of proof at
5 trial cannot overcome summary judgment by speculating that some number of codes may
6 have been unsupported and may have caused overpayments. It must present evidence from
7 which a jury could make that estimate. DOJ has no such evidence.

8 **US Response to Issue 1.A.: There is Abundant Evidence that Codes**
9 **United Submitted for Payment Were Unsupported and that those**
10 **Unsupported Codes Resulted in Overpayments**

11 United contends it is entitled to summary judgment because there is no evidence
12 from which a jury could reasonably conclude that codes United submitted for payment
13 were unsupported or that those unsupported codes resulted in overpayments. Joint Brief,
14 34-42. But there is abundant evidence in this case from which a jury could reasonably
15 reach both conclusions. As such, United is not entitled to summary judgment.

16 Codes United Submitted for Payment Were Unsupported. There is ample evidence
17 for a jury to find that the diagnosis codes at issue were unsupported. The coders that United
18 retained to review medical records in Chart Review were certified, trained, and quality
19 tested. P-12 at 4254-58, Chart Review Policy; P-7, United 30(b)(6) (Baker) Tr. 4168:3-9,
20 4177:21-4178:4, 4180:1-4. According to their instructions, these Chart Review coders
21 identified all the codes they found to be supported in the medical records they reviewed.
22 P-14, Coding Policy, at 4264; P-15, United 30(b)(6) (Baker) Tr. 4267:12-22. From 2014-
23 2016, United's coders reviewed many medical records twice. P-7, United 30(b)(6) (Baker)
24 Tr. 4190:17-4191:3; D-57, Garthwaite Report, at 1464 ¶ 51. United relied *exclusively* on
25 these coders' findings to submit to CMS *new* codes found through its Chart Review
26 process which United had not previously submitted to CMS – and received an additional
27 \$7.2 billion for these efforts. P-11 at 4245-47, Response to Interrogatory 18 (United
28 confirming through Interrogatory response). The United States' expert used United's own
data to identify the codes that had previously been submitted for payment, but were not

1 identified as supported by United’s Chart Review coders, D-57, Garthwaite Report, at
2 1446-47 ¶ 13, and United’s own expert does not challenge this analysis, P-6, Renjilian Tr.
3 4124:4-25 (United Expert testifying that he does not have an expert opinion whether Dr.
4 Garthwaite correctly identified Reviewed Encounters); *id.* at 4126:1-4129:2 (United
5 Expert testifying that he does not have an expert opinion as to whether Dr. Garthwaite
6 incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr.
7 Garthwaite incorrectly compared codes identified in Chart Review to those submitted by
8 providers.). A jury can conclude from this evidence that codes submitted for payment by
9 United were unsupported.

10 United, however, contends that the only avenue for a jury to find that the diagnosis
11 codes at issue were unsupported is for the United States to have conducted its own review
12 of these medical records. Joint Brief, 34-35, 37-38. This contention, however, wholly
13 misses the point. United’s own coders – who were certified, trained, and quality-tested –
14 already conducted a thorough review of these medical records. Those expert coders did
15 not find support for codes that United submitted for payment, which provided United with
16 information it had a regulatory and contractual duty not to ignore.

17 The Ninth Circuit has already rejected a similar argument made by United in
18 *Swoben*. The Court held that if an MAO’s “reviewer finds a previously reported diagnosis
19 code is not supported by the very medical record used to document the diagnosis code in
20 the first place, then the diagnosis code was reported in error, even if it is possible that some
21 other, unidentified record might support the same diagnosis.” 848 F.3d at 1176-77.
22 Nothing in *Swoben* or any other jurisprudence makes the duty to withdraw these codes
23 contingent upon a government record review.

24 Nor does liability based on United’s duties arising from the retention of an
25 overpayment require a government review of medical records. If “a [MA] insurer has
26 received a payment increment for a beneficiary’s diagnosis and discovers that there is no
27 basis for that payment in the underlying medical records, that is an overpayment that the
28 insurer must correct by reporting it to CMS within sixty days for refund.”

1 *UnitedHealthcare Ins. Co. v. Becerra*, 16 F. 4th 867, 870 (D.C. Cir. 2021). MAOs “are
2 required to refund payments based on unsupported diagnoses that they themselves
3 discover through the course of their business.” *Id.* at 877-78; *see also Sutter*, 444 F. Supp.
4 3d at 1068 (payments received by an MA participant predicated on unsupported diagnosis
5 codes are “‘overpayments’ subject to the reporting-and-return requirements of” the ACA).

6 United also asserts that the factual nature of coding, such as the complexity of
7 coding and reasons coders might miss a valid code, establish that no reasonable juror could
8 possibly find that the codes not found supported by United’s own coders were in fact not
9 supported. Joint Brief, 36-38. But that intensely factual argument goes to the weight and
10 credibility of the evidence, which only a jury can evaluate. And there are powerful reasons
11 for juries not to credit this evidence. Coding complexity and second-guessing doctors did
12 not prevent United from relying on its coders to find “additional” supported codes, and
13 United had no trouble relying on its coders’ judgment to submit those additional codes to
14 CMS and pocket the resulting \$7.2 billion. P-11 at 4245-47, Response to Interrogatory 18.
15 Furthermore, United could have taken additional steps to resolve ambiguities and confirm
16 whether such codes were in fact supported. *See* P-30, Acevedo (US Expert) Tr. 4397:6-13
17 (discussing physician queries); P-6, Renjilian (United’s Expert) Tr. 4157:7-4158:4
18 (discussing coders conferring to resolve disagreements); P-31, Blair (United’s Coding
19 Expert) Tr. 4404:24-4405:2 (discussing successfully resolving coder disagreement).

20 United also argues that initial results of medical record reviews in preliminary
21 RADV audit findings establish that the codes at issue were in fact supported. Joint Brief,
22 3, 37-38. Those preliminary findings are not final and are subject to change. P-32,
23 Declaration of Steven Ferraina (Jul. 12, 2024), at 4412-13 ¶ 8. Furthermore, United
24 implies the audits validated 89% of the codes listed in the United States’ First Interrogatory
25 Response. But the overlap between the tiny RADV sample (8,215 relevant RADV results)
26 and the 27.9 million codes in the Interrogatory Response is **less than 0.03%**. D-64
27 Renjilian Report, at 1885-86 ¶¶ 161-62. Nor does United acknowledge that Dr. Garthwaite
28 did not base any aspect of his damages analysis on the 28 million “Interrogatory codes,”

1 but instead concluded that only approximately 2 million codes were unsupported and
2 resulted in damage to the United States. As United’s own expert admits, it is statistically
3 improper to extrapolate from the tiny handful of codes from RADV audits to the entirety
4 of the United States’s damages analysis. P-6, Renjilian Tr. 4139:9-11 (“Well, as I’ve said,
5 I don’t think the RADV overlap can statistically or mathematically be extrapolated to any
6 population.”). The United States’ statistical expert agrees that any such extrapolation
7 would be “nonsense from a statistical perspective.” D-63, Stark Report, at 1768-69 § IV,
8 ¶ 41 (“the uncertainty in estimated support rates for individual HCCs is so large that the
9 estimates are not helpful”).

10 Importantly, “[w]hile RADV audits are intended to identify improper risk
11 adjustment payments, they are not specifically designed to detect fraud, nor are they
12 intended to identify all improper diagnosis submissions made by MAOs for risk
13 adjustment payment.” D-18 at 659, Policy and Technical Changes to the Medicare
14 Advantage Program for Years 2020 and 2021, 88 Fed. Reg. 6643, 6645 (Feb. 1, 2023) (to
15 be codified at 42 C.F.R. pt. 422). This, however, is not a RADV audit but an FCA case, in
16 which damages flow from knowing misconduct. United uses smoke and mirrors to confuse
17 the two, as a deceptive basis to argue that there is no evidence of liability. Unlike in a
18 RADV audit, the factual question here in determining the validity of a diagnosis code is
19 whether there is documentation in the medical record for that diagnosis code based on the
20 face-to-face encounter pursuant to which the code was identified (i.e., every submitted
21 diagnosis code matters in the payment process because diagnosis codes submitted to CMS
22 are a claim for payment. D-66 at 2039, Medicare+Choice Program, 65 Fed. Reg. 40,170,
23 40,268 (June 29, 2000). In a RADV audit, on the other hand, the question is whether an
24 HCC has been validated for the entire year and whether the MAO can identify some
25 medical record – even for a code that was never submitted to the MAO or to CMS – to
26 support the HCC. P-6, Renjilian (United Expert) Tr. 4143:12-17 (“It’s really saying that
27 the HCC is validated.”).

1 In a RADV audit, plans may submit up to five medical records for a given
2 beneficiary in an attempt to validate an HCC. Joint Brief, 12-13. So long as one diagnosis
3 code – from any of those medical records – that maps to the HCC is supported by any
4 medical record submitted by the MAO for RADV, payment for that HCC is not retracted.
5 Thus, in the RADV audit context, CMS gives the MAO “credit” for HCCs mapping to
6 diagnosis codes regardless of whether those codes had ever been submitted. As part of the
7 CMS payment process, however, “[e]ach diagnosis code submitted must be supported by
8 a properly documented medical record.” *Swoben*, 848 F.3d at 1168; *Silingo*, 904 F.3d at
9 673. An unsupported code must be deleted, P-10, Rice Tr. 4216:13-4217:1, 4225:14-
10 4226:3; P-8, Medicare Managed Care Manual, Rev. 118 (Sept. 19, 2014), Ch.7, at 4197-
11 99 § 40; P-3, Participant Guide at 4037-38 §§ 4.13-4.14, 4.16, and CMS’s payment system
12 internally accounts for other codes that are in the system at the time that may map to the
13 same HCC, reducing payment only when no other code in the system maps to the same
14 HCC. P-10, Rice Tr. 4216:13-4217:1, 4225:14-4226:3. Here, there is evidence (from
15 United’s own data and the government expert’s analysis thereof) that submitted diagnosis
16 codes reviewed by United’s Chart Reviewers were not found supported, and, thus, should
17 have been deleted.

18 Unsupported Codes Resulted in Overpayments. The United States’ expert
19 calculated the payment adjustments the CMS payment system would have made had
20 United deleted the unsupported codes, and the jury can reasonably conclude from this
21 evidence that the unsupported codes resulted in overpayments. D-57, Garthwaite Report,
22 at 1447 ¶ 14. Rather than concluding that each of those unsupported diagnosis codes
23 necessarily resulted in an overpayment, Dr. Garthwaite essentially simulated CMS’s
24 payment process, recalculating beneficiary risk scores after searching the data for any
25 other diagnosis code that mapped to the same HCC as the unsupported code. Pursuant to
26 the CMS payment rules, Dr. Garthwaite included that HCC in the calculation of that
27 beneficiary’s risk score, before concluding that the unsupported code had a financial
28 impact (i.e., an overpayment).

1 Furthermore, the testimony United relies on from one of the United States’ experts
2 (Dr. Stark) does not say what United asserts it does. Joint Brief, 38. Dr. Stark’s testimony
3 does not address, let alone contradict, that the diagnosis codes not found supported by
4 United’s coders were in fact unsupported. Nor does his testimony support United’s
5 argument that there is undisputed evidence as to this issue. Whether the HCC associated
6 with those unsupported codes was supported by another diagnosis code is a separate
7 question, and one that Dr. Stark does not address. He simply affirms that a diagnosis code
8 not found supported by United’s coder does not necessarily mean the associated HCC
9 would not be found supported in a RADV Audit – audits with different rules than the
10 regular payment process. But the United States is not seeking to conduct a RADV Audit.
11 P-57, Stark Tr. 4804:23-4805:21.

12 United also contends that for the United States to show the unsupported codes at
13 issue resulted in overpayments it must first hunt for other theoretical medical records that
14 may exist somewhere that support other codes that may map to the same HCC. Joint Brief,
15 40-41. No such extra step is part of the process CMS uses to calculate risk adjustment
16 payments to MAOs, and therefore none is required here. *See Bourseau*, 531 F.3d at 1173
17 (affirming the government’s damages calculation which simulated CMS’s reconciliation
18 process). As explained above, to the extent that United’s data submitted to CMS contains
19 other diagnosis codes that map to the same HCC as that of the code not found supported
20 in United’s Chart Review, the CMS payment system automatically accounts for the “other
21 code” when it processes the deletion of the unsupported code. The CMS system
22 recalculates payment based on all the data submitted by the plan that is in the system. CMS
23 does not hunt to see if there are other medical records somewhere supporting codes that
24 have not been submitted by the MAO before it recalculates payment. The government’s
25 expert simply undertook an analysis akin to CMS’s process. D-57, Garthwaite Report, at
26 1446-47 ¶ 13. The reasoning behind United’s “theoretical medical record support”
27 argument would prevent CMS from ever recalculating payments when an MAO deletes a
28 code and thus prevent CMS from recouping overpayments and is inconsistent with

1 United’s obligation to delete unsupported codes “even if it is possible that some other,
2 unidentified record might support the same diagnosis.” *Swoben*, 848 F.3d at 1177.

3 **B. United’s Legal Argument: DOJ Cannot Show That United Violated Any**
4 **Duty to Second-Guess Doctor-Certified Codes**

5 DOJ’s reverse FCA claim fails for the additional reason that it cannot show United
6 violated an “obligation” to return money. 31 U.S.C. § 3729(a)(1)(G). The FCA does not
7 create obligations; it instead defines an obligation as an “established duty” from “an
8 express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a
9 fee-based or similar relationship, from statute or regulation, or from the retention of any
10 overpayment.” 31 U.S.C. § 3729(b)(3). DOJ must thus identify an independent source of
11 the obligation, yet it is unable to do so.

12 **1. DOJ Cannot Identify Any Independent Obligation**

13 No rule or guidance required MA plans to second-guess doctor-submitted diagnosis
14 codes whenever a chart reviewer did not identify that same code. DOJ’s corporate
15 representative, Dr. Hornsby, testified repeatedly that “CMS never tells MAOs how to
16 conduct medical record reviews.” JS at D105-D107; Ex. D-116 at 2956:8-10; *id.* at
17 2956:20-22 (“CMS never set out any guidance telling MAOs how to design medical record
18 reviews.”). Dr. Hornsby further testified that CMS was aware of MA-industry-chart-
19 review practice, which was to identify diagnoses supported in medical records without
20 using those reviews to second-guess diagnoses doctors had submitted. *See* JS at D65; Exs.
21 D-116 at 2959:8-60:20 (explaining CMS officials “talked a lot about” how the “search for
22 additional[] [supported diagnosis codes] was becoming more common”), D-140 at
23 3502:11-03:2, D-39 at 918. Despite this knowledge, CMS never adopted a rule detailing
24 how MA plans must conduct chart review. *See* United MSJ, *supra* at 13-15, n.6.

25 In 2014, CMS proposed to “strengthen existing regulations” by imposing this
26 obligation in the MRRR but declined to do so. *See id.* CMS staff recognized that this new
27 rule would have created new obligations, asserting in a memorandum that “[u]nder
28 existing regulation, there is no requirement for plans to audit medical records for

1 overpayments. If a plan is conducting medical record reviews to identify underpayments,
2 we recommend that they be required to audit as well for overpayments.” JS at D221
3 (emphasis added); Exs. D-79 at 2315, D-116 at 2963:19-66:13. CMS’s decision to propose
4 the MRRR reflected its understanding that the rule would “establish[] or change[] a
5 substantive legal standard,” thereby requiring formal rulemaking, including notice and
6 comment. 42 U.S.C. § 1395hh(a)(2). Yet, at the end of the day, CMS abandoned the
7 proposed rule.

8 That regulatory history bars DOJ’s claims. DOJ cannot impose through the punitive
9 FCA the very obligation CMS considered and rejected a decade ago. The Supreme Court
10 recently rejected a similar government attempt to achieve through backdoor means a
11 policy change that was considered and withdrawn during a formal rulemaking proceeding.
12 *See Azar v. Allina Health Servs.*, 587 U.S. 566, 584 (2019). DOJ’s position here is far
13 weaker than it was in *Allina*, given the fact that it is a punitive litigation position untethered
14 to *any* regulatory action. Indeed, the record evidence shows that CMS was fully aware that
15 its rules were unclear and decided, rather than adopt a rule, simply to follow the wave of
16 whistleblower litigation against MA plans. JS at D146; Ex. D-72 at 2210.

17 The two actual rules DOJ has at times invoked in this litigation do not support its
18 position. *First*, DOJ errs in relying on the rule requiring MA plans to attest “based on best
19 knowledge, information and belief” that their data is “accurate.” 42 C.F.R. § 422.504(l).
20 That rule does not require that all of an MA plan’s codes be accurate, which would impose
21 a sweeping auditing obligation CMS has long admitted does not exist (in a payment system
22 where coding errors are known to be common). JS at D66-D70; Exs. D-66 at 2039, D-46
23 at 1099, D-100 at 2716:10-19:5, D-116 at 2968:6-10, D-136 at 3423:7-24:6, D-137 at
24 3441:10-15. Nor does it require MA plans to represent anything about how they have
25 structured their chart review programs. Even if it did, United *told* CMS *in its attestations*
26 how it performed chart review, but CMS continued to pay United and took no remedial
27 action. *See* United MSJ, *supra* at 16. And DOJ does not dispute that United both accurately
28 transmitted the data it received from doctors to CMS and that the codes United’s reviewers

1 “added” during chart review were accurate. JS at D162; Exs. D-134 at 3394:7-21, D-147
2 at 3707:22-09:14. The attestation rule adds nothing.

3 Second, DOJ attempts to rely on the requirement that MA plans maintain an
4 “effective compliance program” to “prevent, detect, and correct non-compliance.” 42
5 C.F.R. § 422.503(b)(4)(vi). But unless *other* specific rules already obligated United to
6 investigate and delete diagnosis codes not independently identified by chart review, then
7 there was no relevant obligation for United to carry out through its compliance program.
8 DOJ’s position is thus entirely circular.

9 The best evidence that neither source of authority imposed the specific obligation
10 DOJ alleges here is that, long after the attestation and compliance requirements were in
11 effect, CMS proposed a new rule—the MRRR—which would have “strengthened existing
12 regulations” by creating an express obligation *for the first time*. See United MSJ, *supra* at
13 13-14. But CMS ultimately declined to finalize the MRRR. JS at D136; Ex. D-17 at 651-
14 52. In short, CMS proposed a rule it acknowledged would impose a new and prospective
15 obligation to investigate doctor-submitted codes; it then rejected that rule; and yet DOJ
16 now seeks to subject United to treble damages and penalties for noncompliance with the
17 very same obligation CMS proposed and rejected. The Court cannot allow such a claim to
18 proceed.

19 Given the withdrawal of the MRRR and the lack of clarity concerning the scope of
20 the two other rules on which DOJ relies, DOJ’s theory would also raise serious due process
21 concerns. “A fundamental principle in our legal system is that laws which regulate persons
22 or entities must give fair notice of conduct that is forbidden or required.” *FCC v. Fox*
23 *Television Stations, Inc.*, 567 U.S. 239, 253 (2012); *see also id.* at 257 (rejecting FCC
24 sanction where rules in effect at the time gave no notice that challenged conduct was
25 prohibited). This principle applies to the FCA, whose treble damages and civil money
26 penalties “are essentially punitive in nature.” *Vt. Agency of Nat. Res. v. United States ex*
27 *rel. Stevens*, 529 U.S. 765, 784 (2000). The Supreme Court reiterated these “concerns
28 about fair notice and open-ended liability” under the FCA. See *Escobar*, 579 U.S. at 192.

1 The obligation DOJ seeks to impose on United was not clearly established during the
2 relevant time, and the Court should avoid an interpretation of the supposed “obligation”
3 that raises due process concerns. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg.*
4 *& Const. Trades Council*, 485 U.S. 568, 575 (1988) (collecting constitutional avoidance
5 cases).

6 **2. DOJ’s Red-Flag Theory Cannot Establish an Obligation**

7 DOJ has at times shifted to a different approach, asserting that United had an
8 “obligation” to delete codes that it “knew” were unsupported. JS at D156; Exs. D-11A at
9 563-65, D-11B at 574-75. As already noted, there is no straight-faced argument that United
10 had *actual knowledge* that specific diagnosis codes were unsupported whenever its coders
11 did not identify them in chart review. Instead, DOJ appears to claim that MA plans have
12 an “obligation” to investigate those codes further because they have such a high risk of
13 error that it would be reckless or deliberately ignorant not to do so. For three independent
14 reasons, this “red flag” theory does not advance the ball.

15 *First*, it fails to avoid the problems described above. Even if a particular code
16 warranted further investigation, United was not overpaid unless the code was in fact
17 unsupported and resulted in overpayment (neither of which DOJ can prove). *See United*
18 *MSJ, supra* at 34-42. Any obligation to “investigate” suspicious codes cannot substitute
19 for the required showing of an overpayment, no matter how much DOJ tries to conflate
20 those distinct elements of an FCA claim.

21 *Second*, DOJ’s “red flag” theory must depend on the existence of some feature of
22 the 28 million diagnosis codes at issue that renders them more likely to be invalid than any
23 random code in an MA plan’s data. Otherwise, this alleged obligation would require MA
24 plans to audit all doctor-submitted codes, which CMS has conceded is not the law. JS at
25 D69-D70; Exs. D-116 at 2968:6-10, D-137 at 3441:10-15, D-100 at 2716:10-19:5, D-97
26 at 2628:15-21, D-46 at 1099. When asked whether there was any rule “that affirmatively
27 required Medicare Advantage plans to proactively review medical records, to audit them,
28 and determine which, if any, codes were not supported,” the former director of CMS’s

Center for Medicare, Sean Cavanaugh, testified “[n]ot that I am aware of.” JS at D69; Ex. D-97 at 2628:15-21.

On the critical comparison between the rate of error of the codes at issue here and *any other codes* submitted for payment, DOJ has *no* evidence. DOJ cannot identify anything about this particular set of diagnosis codes showing that they had a particularly high risk of error such that it would be reckless not to investigate them. And, again, the only record evidence shows the opposite. RADV auditors validated approximately 89% of the health conditions associated with diagnosis codes in DOJ’s FIR list—which is *higher* than the rate of validation of all the remaining HCCs in United’s data (87.6%). See JS at D185, D224-D225; Exs. D-63 at 1763, D-64 at 1887-89, D-141 at 3520:13-21:2, 3527:21-28:4.¹⁸ DOJ’s expert Dr. Stark independently confirmed these validation rates in his report and confirmed at his deposition that this differential higher rate of validation was statistically significant. See JS at D196, D226; Exs. D-63 at 1763, D-64 at 1887-89, D-141 at 3520:13-21:2, 3527:21-28:4. In other words, the RADV results showed that a code that was not identified by United in chart review was *more likely* to be valid than the broader universe of codes submitted by United.

Third, it is not “reckless” or “deliberately ignorant” to fail to act on a small probability that a diagnosis code might be unsupported and might constitute an overpayment. The term “reckless disregard” requires “a *substantial and unjustifiable risk* that . . . claims are false.” *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 751 (2023) (emphasis added). To constitute recklessness, there must thus be an *objectively* high risk of error. See Restatement (Second) of Torts § 500(a) (1977) (explaining “[a]n objective standard is applied” to cover those who do not subjectively “appreciate the high degree of risk”). There must *in fact* be a high risk of error for a defendant to be reckless. Likewise, “deliberate ignorance” requires showing knowledge of a “substantial risk,” *Schutte*, 598 U.S. at 751, or a “high probability” that a fact exists and then taking deliberate

¹⁸ Dr. Stark validated Mr. Renjilian’s calculations with only one irrelevant “small discrepancy” for 2014–2015. See Ex. D-63 at 1765-66.

1 action to avoid learning the truth, *Siebert v. Gene Sec. Network, Inc.*, 75 F. Supp. 3d 1108,
2 1116–17 (N.D. Cal. 2014).

3 Here, there was indisputably not a high probability of overpayment. As shown by
4 the Garthwaite report, 93% of the diagnosis codes in question did not affect United’s
5 payment from CMS. *See* United MSJ, *supra* at 17-18, 39-40. That means if every one of
6 the codes Dr. Garthwaite calls “deletes” was unsupported, there was still only a 7%
7 probability that a diagnosis code submitted by a doctor and not identified in chart review
8 would be, if investigated, an overpayment. And as Dr. Stark confirmed through his
9 analysis, the RADV results prove “to a certainty” that codes in this 7% universe (the
10 Garthwaite “deletes”) are not all unsupported. *See* United MSJ, *supra* at 37-38. If even
11 half of that universe were supported, the odds that any one code on the FIR list would be
12 an overpayment after investigation would be only 3.5%. Regardless whether the risk of a
13 diagnosis code being an overpayment is 7% or 3.5%, such small chances of error are not
14 an “objectively” high risk of overpayment, particularly in a system that recognizes coding
15 errors are inevitable. Thus, failing to undertake the intense work to chase down potential
16 errors was not reckless as a matter of law.

17 In another context, the government agrees. In a recent guidance document from the
18 HHS’s Office of Inspector General (OIG), the government identified certain diagnoses as
19 being “at high risk of being miscoded” based on estimated error rates of 70% to 90%. JS
20 at D222-D223; Ex. D-45 at 1022. Such probabilities of error are orders of magnitude
21 higher than the risk that any of the diagnosis codes on DOJ’s “deletes” list were
22 overpayments. United is not aware of any case where a court held that failing to investigate
23 something like a 3.5%–7% risk of error was reckless.

24 For these reasons, DOJ cannot show that United violated any independent
25 obligation to return money to the government.
26
27
28

US Response to Issue 1.B.: United Had an Obligation to Return Money it Received for Unsupported Diagnosis Codes, Arising out of its Regulatory and Contractual Duties, as well as its Retention of an Overpayment

United's obligation to pay arises from its (1) existing contractual and regulatory duties, and independently (but relatedly) from (2) retention of an overpayment. Those duties require United to conduct its Chart Review in good faith and to exercise due diligence in taking steps to correct the submission of unsupported diagnosis codes, and prohibit United from turning a blind eye to unsupported codes submitted for payment. United's obligation to pay arises from these duties even if the amount owed is not yet fixed, and even before United has actual knowledge that codes are unsupported.

United's Regulatory Duties. United's argument that no rule requires it to take any steps after its Chart Review coders did not find support for certain codes, Joint Brief, 51-52, is the same argument it made in *Swoben*, 848 F.3d at 1174 (United argued it had no duty to do anything to address the codes not found supported by its reviewers, contending that "there was no 'authority [to] indicate that a [MA] plan was obliged to undertake affirmative steps to unearth potentially unsupported codes before it could certify the third-party risk adjustment data based on its 'best knowledge, information, and belief . . .'").

The Ninth Circuit flatly rejected United's argument, extensively analyzing United's regulatory due diligence, good faith and compliance duties, concluding that those longstanding duties obligated MAOs that conduct chart reviews to do so in good faith and to take steps to address errors, and prohibits turning a blind eye to unsupported codes submitted for payment. 848 F.3d at 1174-76. This Court too should reject that argument.

From the start of the MA program, CMS has always been clear that because diagnostic data is "used as a factor in calculating payments" and the data submission "represents a 'claim' for payment," accurate and complete data submissions are essential to ensure accurate risk adjustment payments. D-66 at 2039, Medicare+Choice Program, 65 Fed. Reg. at 40,268; *Silingo*, 904 F.3d at 673. "Each diagnosis code submitted must be supported by a properly documented medical record." *Swoben*, 848 F.3d at 1168; *see also*

1 *Silingo*, 904 F.3d at 673. MAOs “have an obligation to take steps to ensure the accuracy,
2 completeness, and truthfulness of” data submitted for payment. D-66 at 2039,
3 Medicare+Choice Program, 65 Fed. Reg. at 40,268; *Swoben*, 848 F.3d at 1174.

4 In 2000, CMS recognized that codes come to MAOs in great volume and from many
5 sources. D-66 at 2039, Medicare+Choice Program, 65 Fed. Reg. at 40,268. While MAOs
6 “cannot be reasonably expected to know that every piece of data is correct,” they are
7 obligated to undertake “due diligence” to ensure the accuracy and truthfulness of the codes
8 they submit for payment. *Id.*; *Swoben*, 848 F.3d at 1174. CMS holds MAOs to a “best
9 knowledge, information, and belief” standard and requires them to make “good faith
10 efforts to certify” the accuracy and truthfulness of codes they submit. D-66 at 2039,
11 Medicare+Choice Program, 65 Fed. Reg. at 40,268; *Swoben*, 848 F.3d at 1174. When an
12 MAO takes steps to verify risk adjustment data by conducting retrospective chart reviews,
13 it must conduct those reviews in good faith. *Swoben*, 848 F.3d at 1179. When it adopted
14 the “best knowledge, information, and belief” standard, CMS made clear that it was the
15 same standard as FCA knowledge, encompassing “not only actual knowledge of falsity
16 but also reckless disregard and deliberate ignorance.” D-66 at 2039, Medicare+Choice
17 Program, 65 Fed. Reg. at 40,268; *Swoben*, 848 F.3d at 1174.

18 The Ninth Circuit also held that United’s contention “that they were under no
19 obligation to take affirmative steps to address errors also ignores [42 C.F.R.] § 422.503,
20 which since 2005 has required [MAOs] to have effective compliance programs in place,
21 including ‘[p]rocedures for internal monitoring and auditing’ and for ‘ensuring prompt
22 response to detected offenses.’” *Swoben*, 848 F.3d at 1174 (citation omitted). The Ninth
23 Circuit held that conducting chart reviews “deliberately to avoid identifying erroneously
24 submitted diagnosis codes that might otherwise have been identified with reasonable
25 diligence” violates these regulatory duties. *Swoben*, 848 F.3d at 1175. Where an MAO
26 conducts blind chart reviews but “runs a unidirectional comparison with previously
27 submitted codes to reveal only under-reporting errors . . .,” it “turns a blind eye to the over-
28 reporting errors . . . [exhibiting] reckless disregard and deliberate ignorance toward the

1 truth or falsity of the data submitted to CMS” showing “a lack of diligence and an absence
2 of good faith.” *Swoben*, 848 F.3d at 1175-76. Using blind chart reviews “cannot excuse
3 failing to ‘check whether diagnosis codes previously submitted to CMS were included on
4 the list of diagnoses found by the reviewers to be supported by the medical records.’”
5 *Swoben*, 848 F.3d at 1175. If an MAO’s retrospective reviewer concludes that the medical
6 record that was used to document a submitted code does not support the code, “then the
7 code should be withdrawn.” *Swoben*, 848 F.3d at 1177 n.8; *Silingo*, 904 F.3d at 673 (“The
8 importance of accurate data certifications and effective compliance programs is obvious:
9 if enrollee diagnoses are overstated, then the capitation payments to [MAOs] will be
10 improperly inflated.”).

11 United contends that, because *Swoben* involved false certifications as direct false
12 claims and this case involves reverse false claims, its interpretation of United’s regulatory
13 duties is inapposite. United is wrong. These regulatory duties exist whether the United
14 States seeks to enforce them through a direct FCA action based on false certifications or
15 based on knowingly avoiding the obligation to pay as reverse false claims. There is no
16 requirement that the United States must only pursue a direct false claims action to enforce
17 these duties. Congress intended that a person who improperly avoids paying money owed
18 to the government should be equally liable as one who acts to obtain money. If United
19 received a diagnosis from a provider and hired an expert to review the chart who concluded
20 that the chart did not support the diagnosis, it would be absurd to conclude that United
21 could press ahead and submit that code for payment without further inquiry. No different
22 result is required here simply because United had already received payment by the time
23 its trained coders did their work.

24 Moreover, the Ninth Circuit did not limit its analysis only to duties arising from the
25 certification regulation. Instead, it also based its ruling on duties arising out of the
26 compliance regulation. In *Sutter*, the court applied *Swoben* to a reverse FCA action and
27 held that “[t]he *Swoben* court did not limit its holding – that MA Participants must submit
28 accurate diagnosis codes and withdraw unsupported codes – to false certifications and

1 compels the conclusion that MA Participants cannot bill CMS for false diagnosis codes
2 (and keep and not report the resulting overpayment).” 444 F. Supp. 3d at 1071 n.447
3 (citations omitted). Similarly, in *Graves v. Humana*, 281 F. Supp. 3d 1260, 1275 (S.D.
4 Fla. 2017), relator alleged that Humana (an MAO like United) deliberately ignored
5 overpayments it received for invalid diagnoses in violation of the reverse FCA. Relator
6 alleged that red flags “should have alerted Humana to investigate whether it had submitted
7 unsupported codes and received corresponding overpayments as a result.” *Id.* at 1276. The
8 court followed *Swoben*’s reasoning and ruled that liability under the reverse FCA arises
9 when an MAO conducts retrospective reviews similar to United’s Chart Review that
10 “either avoid or conceal over-reporting errors” because the MAO fails to act with diligence
11 and good faith. *Id.* at 1276. The court concluded it was a fact question for the jury to decide
12 whether Humana recklessly disregarded or deliberately ignored overpayments. *Id.* at
13 1275-76. Here too, whether United knowingly violated its duties and ignored
14 overpayments is a disputed issue for the jury to evaluate.

15 United’s Contractual Duties. United’s obligation to pay also arises out of its annual
16 contracts and EDI Agreements with CMS. Each year in its contracts with CMS, United
17 agreed to operate its plans in compliance with “applicable Federal statutes, regulations,
18 and policies (e.g., policies as described in the Call Letter, Medicare Managed Care
19 Manual, etc.).” *See, e.g.*, P-1A, at 3984 Art. II(A) (2017 PY Contract); P-1, at 3977 ¶ 2
20 (Joint Stipulation). United also agreed to sign and submit an attestation prior to the Final
21 Reconciliation, in which it must certify (based on best knowledge, information, and belief)
22 that the risk adjustment data it submits to CMS is “accurate, complete, and truthful.” *Id.*;
23 *see, e.g.*, P-1G at 4018 (2017 Attestation). These annual attestations reflect that MAOs are
24 required to undertake due diligence in good faith to ensure the accuracy and completeness
25 of their risk adjustment data and not to act in deliberate ignorance or reckless disregard of
26 the truth or falsity of its risk adjustment data. D-66 at 2039, Medicare+Choice Program,
27 65 Fed. Reg. at 40,268 (“However, we believe that [MAOs] have an obligation to
28 undertake ‘due diligence’ to ensure the accuracy, completeness, and truthfulness of

1 encounter data submitted to [CMS].”). At a minimum, “due diligence” requires United to
2 do *something* when it reviews a beneficiary’s medical record and does not find support for
3 a previously submitted diagnosis code. P-10, Rice Tr. 4224:16-24.

4 In addition, in order to submit diagnostic data to CMS’s data processing systems,
5 United was required to sign an EDI Agreement. P-8, Medicare Managed Care Manual,
6 Rev. 118 (Sept. 19, 2014), at 4200-01 Ch.7, §120.2.1. “The EDI Agreement is a contract
7 between the MAO and CMS attesting to the accuracy of the data submitted.” *Id.* Under
8 the EDI Agreement, United agreed that it was responsible for all risk adjustment data
9 submitted by “themselves, their employees, and agents,” that it would “submit risk
10 adjustment data that are accurate, complete, and truthful . . . [b]ased on best knowledge,
11 information, and belief,” and to “research and correct risk adjustment data discrepancies.”
12 P-1C, at 4002 §§ A.1, A.5 and A.11 (Defendant MAO EDI Agreement); P-1B at 3994
13 (same) (Optum EDI Agreement); *see also* P-1, at 3977 ¶¶ 2, 5, 6 (all EDI Agreements
14 signed by the MAO Defendants and Optum included the same terms).

15 Duty Arising from Retention of an Overpayment. Under the reverse FCA provision,
16 United’s obligation to pay the government also arises from its retention of an overpayment.
17 31 U.S.C. § 3729(b)(3). The governing statute, regulations, and caselaw establish that a
18 risk adjustment payment made to an MAO based upon an unsupported diagnosis code is
19 an overpayment. “Neither Congress nor CMS has ever treated an unsupported diagnosis
20 for a beneficiary as valid grounds for payment to a [MA] insurer.” *Becerra*, 16 F.4th at
21 869. MAOs have a duty to refund CMS for, and not retain, such overpayments. The FCA
22 imposes liability on a person who deliberately ignores or recklessly disregards information
23 of potential overpayments. United does not even mention these duties in its brief.

24 As noted above, a risk adjustment payment for an unsupported code is an
25 overpayment. *See supra*, at 42-48; *Silingo*, 904 F.3d at 673; *Becerra*, 16 F.4th at 870, 890;
26 *Sutter*, 444 F. Supp. 3d. at 1026, 1062 n.424, 1077. No court has ever held that an MAO
27 “can keep and not report or return payments based on unsupported codes.” *Id.* at 1072; *see*
28 *also id.* at 1060, 1068 n.441, 1071. If an MAO’s retrospective reviewer determines that

1 the underlying medical record does not support the code submitted, then the MAO should
2 delete the code. *Swoben*, 848 F.3d at 1177 n.8; *Sutter*, 444 F. Supp. 3d at 1067. CMS's
3 processing system then recalculates the respective payment amount and recoups the
4 payment associated with the deleted code. *Sutter*, 444 F. Supp. 3d at 1026.

5 Under the reverse false claims provision, health care providers may not avoid
6 liability simply by ignoring audits or terminating investigations that would have revealed
7 overpayments received from the government. See *United States ex rel. Keltner v.*
8 *Lakeshore Med. Clinic, Ltd.*, 2013 WL 1307013, at *3-4 (E.D. Wis. Mar. 28, 2013) (relator
9 stated a reverse false claim where defendant found high rates of upcoding by physicians
10 in audits but failed to follow up on non-audited claims). Here too there is evidence for the
11 jury to find that United deliberately ignored or recklessly disregarded the results of its
12 Chart Review audits in violation of the FCA.

13 In 2010, Congress codified this already existing obligation in the Patient Protection
14 and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010). The ACA
15 was enacted a year after the FERA amendment to the FCA and is instructive as to what
16 Congress intended by defining obligation to include a duty arising "from the retention of
17 an overpayment." See *Graves v. Plaza Med. Ctrs., Corp.*, 281 F. Supp. 3d 1260, 1275
18 (S.D. Fla. 2017). The ACA mandated that an overpayment must be returned within 60
19 days after it is identified, 42 U.S.C. § 1320a-7k(d)(2), and defined overpayment as, "any
20 funds that a person receives or retains under [the Medicare or Medicaid programs] to
21 which the person, after applicable reconciliation, is not entitled." 42 U.S.C. § 1320a-
22 7k(d)(4)(B). Congress made explicit that continued retention of an overpayment beyond
23 the 60-day deadline is an "obligation" under the FCA. 42 U.S.C. § 1320a-7k(d)(3). Under
24 the ACA, therefore, an MAO must return to CMS an overpayment (payment for an
25 unsupported code) within 60 days of when the MAO identifies an overpayment, or it
26 otherwise becomes an obligation to pay under the FCA. *Id.* The statutory overpayment-
27 refund obligation "corrects particular mistaken payments to [MA] insurers that exceed
28 what the relevant medical records support." *Becerra*, 16 F.4th at 886.

1 If “a [MA] insurer has received a payment increment for a beneficiary’s diagnosis
2 and discovers that there is no basis for that payment in the underlying medical records,
3 that is an overpayment that the insurer must correct by reporting it to CMS within sixty
4 days for refund.” *Becerra*, 16 F.4th at 870. “Insurers are required to refund payments based
5 on unsupported diagnoses that they themselves discover through the course of their
6 business.” *Id.* at 877-78. *See also Sutter*, 444 F. Supp. 3d at 1068.

7 In accordance with the FCA’s deliberate ignorance and reckless disregard standard,
8 an overpayment is “identified” under the overpayment-refund statute when an MAO ““is
9 put on notice of a potential overpayment, rather than the moment when an overpayment is
10 conclusively ascertained.”” *Sutter*, 444 F. Supp. 3d at 1080 (citing *Kane*, 120 F. Supp. 3d
11 at 387-88). In *Sutter*, the court rejected the defendant’s argument that “identified” in the
12 overpayment-refund statute required showing that defendants “had actual knowledge of
13 specific unsupported diagnosis codes and payments based on those codes. . .,” holding that
14 an overpayment is identified when the defendant was put on notice of a potential
15 overpayment. *Id.* at 1078-80 (agreeing with the reasoning of *Kane*).

16 The court in *Kane* conducted an extensive analysis of the term “identified” in the
17 ACA, including the plain meaning of the text,¹⁹ legislative history, and legislative purpose
18 of the provision, concluding that put on notice was the correct interpretation, rejecting
19 defendants’ argument that identified means “classified with certainty.” *Kane*, 120 F. Supp.
20 3d at 384-91. Both the *Sutter* and *Kane* courts recognized that interpreting “identified” to
21 mean “classified with certainty” would lead to absurd results. *Sutter*, 444 F. Supp. 3d at
22 1079; *Kane*, 120 F. Supp. 3d at 388-90. The *Kane* court reasoned that “[u]nder the
23 Defendants’ framework, their obligation to pay would not be triggered until *after* they
24 have done the work necessary to determine conclusively the precise amount owed to the
25 Government, thus creating a perverse incentive to delay learning the amount due and
26 relegating the sixty-day period to merely the time within which they would have to cut the

27
28 ¹⁹ The court found that the plain meaning of “identified” was susceptible to two or more
reasonable meanings and consequently resort to canons of statutory construction was
warranted. *Kane*, 120 F. Supp. 3d at 385 (citation omitted).

1 check. This is likely not what Congress intended.” *Kane*, 120 F. Supp. 3d at 390. The court
2 held that “[i]t would be an *absurd result* to construe this robust anti-fraud scheme as
3 permitting willful ignorance to delay the formation of an obligation to repay the
4 government money that is due.” *Id.* at 390 (emphasis added); *see also Swoben*, 848 F.3d
5 at 1169 (“[i]f the requirement to return and report overpayments applied only to situations
6 where the [MAO]. . . has actual knowledge of the existence of an overpayment, then these
7 entities could easily avoid returning improperly received payments”).

8 Both the *Sutter* and *Kane* courts found that the put-on-notice standard was in line
9 with Congress’s purpose in passing the FCA and FERA, and incorporating, in the ACA, a
10 mandate to report and return Medicare and Medicaid overpayments. *Kane*, 120 F. Supp.
11 3d at 390-91; *Sutter*, 444 F. Supp. 3d at 1079. Both courts recognized that limiting
12 “identified” to when the overpayment has been conclusively ascertained “would frustrate
13 Congress’s intention to subject willful ignorance of Medicaid [and Medicare]
14 overpayments to the FCA’s stringent penalty scheme.” *Kane*, 120 F. Supp. 3d at 391;
15 *Sutter*, 444 F. Supp. 3d at 1079.

16 Further, both courts rejected defendants’ arguments that Congress’ choice of
17 “identified” instead of “known” overpayments reflects “an intent to impose a higher
18 standard than the FCA’s ‘knowing’ standard.” *Sutter*, 444 F. Supp. 3d at 1080; *Kane*, 120
19 F. Supp. 3d at 386-88. Both courts found that the legislative history was silent on why
20 Congress made this choice, and that to interpret “identified” to mean “when a provider is
21 put on notice of a potential overpayment, rather than the moment when an overpayment is
22 conclusively ascertained, is compatible with the legislative history of the FCA and the
23 FERA.” *Kane*, 120 F. Supp. 3d at 388; *Sutter*, 444 F. Supp. 3d at 1080.

24 Other courts have held that the “put on notice” standard is consistent with the
25 deliberate ignorance and reckless disregard standard in the FCA. *See, e.g., Graves*, 276 F.
26 Supp. 3d at 1348 (holding that a reasonable jury could find that an MAO knowingly
27 retained overpayments for unsupported codes where the MAO ignored red flags and failed
28 to investigate whether it had submitted unsupported codes); *see also Lakeshore Med.*

1 *Clinic*, 2013 WL 1307013, at *3-4. And the Ninth Circuit recognizes that being put on
2 notice of a potential error supports a finding of deliberate ignorance or reckless disregard.
3 *Silingo*, 904 F.3d at 681 (“Silingo simply claims that all of the defendant organizations
4 were equally *put on notice* by the warning signs that allegedly infected MedXM’s health
5 assessment reports. These allegations, if true, give rise to the reasonable inference that the
6 defendant organizations knowingly submitted false claims and used false records, or else
7 acted with reckless disregard or deliberate indifference of the falsity of the claims and
8 records”) (emphasis added).

9 Establishing United’s Obligation to Pay does not require showing an Objectively
10 High Risk of Overpayment. United contends that the United States cannot establish an
11 obligation to repay unless the government establishes that the codes at issue resulted in
12 such an “objectively” high risk of overpayment that United would be reckless or
13 deliberately ignorant not to investigate them further. Joint Brief, 52-53. United essentially
14 contends that unless the United States shows that there was an “objectively” high risk of
15 overpayment, United can turn a blind eye to evidence from its own Chart Review program.
16 *Id.* But United is not moving for summary judgment on the element of knowledge, which,
17 of course, is a highly fact intensive analysis for a jury to determine.

18 Moreover, United distorts the Supreme Court’s ruling in *United States ex rel.*
19 *Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023). *SuperValu* does not require the
20 government to establish the existence of an “objectively” high risk of overpayment to
21 prove scienter. In fact, *SuperValu rejected* the contention that there was a “purely objective
22 safe harbor” with respect to scienter. *Id.* at 755. Instead, it held that the “FCA’s scienter
23 element refers to respondents’ knowledge and subjective beliefs – not to what an
24 objectively reasonable person may have known or believed.” *Id.* at 749.²⁰

25
26
27 ²⁰ The Court did not decide how or whether reckless disregard also includes an “objective
28 form of ‘recklessness’ . . . [since] it is enough to say that the FCA’s standards can be
satisfied by a defendant’s subjective awareness of the claim’s falsity or an unjustifiable
risk of such falsity.” *Id.* at 751 n.5.

1 The Supreme Court recognized that deliberate ignorance captures “defendants who
2 are aware of a substantial risk that their statements are false, but intentionally avoid taking
3 steps to confirm the statements’ truth or falsity,” and where “a person making a false
4 statement had shut his eyes to the facts, or purposely abstained from inquiring into them .
5 . . . ,” while reckless disregard “similarly captures defendants who are conscious of a
6 substantial and unjustifiable risk that their claims are false, but submit the claims anyway.”
7 *SuperValu*, 598 U.S. at 751.²¹

8 Importantly, the Supreme Court held that scienter turns on “what the defendant
9 thought when submitting the false claim – not what the defendant may have thought *after*
10 submitting it,” *id.* at 752 , and “[n]othing in *Safeco* suggests that we should look to facts
11 that the defendant neither knew nor had reason to know at the time he acted.” *Id.* at 755.
12 United bases its contention that there was no “objectively” high risk of overpayment on
13 (an incorrect perspective of) the work done by the United States’ expert in this litigation
14 to identify unsupported codes, and to calculate the impact on payments to United had it
15 deleted those codes. Joint Brief, 53 (referring to Dr. Garthwaite’s 2023 expert report). This
16 work, of course, was done many years after United decided to ignore the codes not found
17 supported by its Chart Review coders. United took no steps to address those errors when
18 it received its Chart Review results. P-5, United 30(b)(6) (Sedor) Tr. 4108:24-4109:6.
19 United neither knew nor had reason to know the after-the-fact risk of overpayment it relies
20 on here when it acted in deliberate ignorance or reckless disregard of its coders’ results.
21 As such, under *SuperValu*, the after-the-fact risk of overpayment alleged by United has no
22 bearing on its scienter or obligation to pay.²²

23 ²¹ The Court used the phrase “intentionally avoid taking steps to” learn the truth in
24 describing deliberate ignorance, *SuperValu*, 598 U.S. at 751, not “taking deliberate action
25 to avoid learning the truth” as United contends. *Supra* at 52-53 (citing *Siebert v. Gene Sec.*
26 *Network, Inc.*, 75 F. Supp. 3d 1108, 1116-17 (N.D. Cal. 2014)). In any event, the Ninth
Circuit made clear in *Swoben* that failing to make simple inquiries into the truth or falsity
of a claim constitutes deliberate ignorance. 848 F.3d at 1174.

27 ²² The same is true for after-the-fact RADV audit feedback. United obtained the
28 preliminary RADV audit data it relies on here many years after it took no steps to address
the errors found by its coders. P-32, Declaration of Steven Ferraina (Jul. 12, 2024) 4412
¶¶ 3, 6, 7 (initial feedback made available starting in April 2019); *see also* P-5, United

1 Additionally, United's argument conflates two different concepts – the *rate* at which
2 individual unsupported codes impact payment, and the overall *risk* of overpayment when
3 United knew of large numbers of unsupported diagnosis codes. Even if United were
4 correct that there was only a 7% probability that an individual unsupported diagnosis code
5 resulted in an overpayment, Joint Brief, 53, that *rate* would not establish anything about
6 the *risk* that millions of unsupported codes in the aggregate resulted in overpayments to
7 United. And United had every reason to know that risk was high. See P-11 at 4249-50,
8 Response to Interrogatory 20 (CMS recouped more than \$200 million from United for the
9 deletes submitted under Claims Verification).

10 Finally, United's argument again leads to absurd results. If United's duty to conduct
11 its Chart Review in good faith and to take steps to address errors only arises if it knows
12 there is an "objectively" high risk of overpayment, then United could easily avoid its duty
13 by doing nothing after receiving Chart Review results and never learning what the risk of
14 overpayment is. But doing nothing violates United's duties to conduct its Chart Review in
15 good faith and take steps to address errors as required by regulation and contract, as held
16 by the Ninth Circuit in *Swoben*. 848 F.3d at 1174-76.

17 Here, there is, at a minimum, a genuine dispute of material fact as to whether United
18 acted with deliberate ignorance or reckless disregard when it failed to make any inquiry
19 into the validity of previously submitted codes that were not found to be supported by
20 United's Chart Reviewers. The jury can find that when United's coders failed to find
21 support for diagnosis codes that United had previously submitted to CMS, United was
22 aware of a substantial risk that the diagnosis codes were unsupported, but intentionally
23 avoided taking any steps to inquire further into their validity. United's reliance on
24 information generated years after it performed Chart Review fails to establish that it is
25 entitled to summary judgment.

26 30(b)(6) (Sedor) Tr. 4059:13-4061:1 (MAOs had to submit all diagnosis data by the final
27 submission deadline, which was generally January 31st of the year following the payment
28 year). Consequently, United neither knew nor had reason to know of the after-the-fact
initial results of RADV medical record reviews at the time it ignored its negative Chart
Review results.

1 United’s Other Meritless Arguments Regarding its Regulatory and Contractual
2 Duties. United makes several other meritless arguments in an attempt to avoid its
3 longstanding contractual and regulatory duties. It contends that CMS’s decision in 2014
4 not to finalize a proposed rule relating to medical record reviews gives it a free pass to
5 ignore the negative results of its Chart Reviews. Joint Brief, 48-49. The proposed MRRR
6 provided that “medical record review methodology must be designed to identify errors in
7 diagnoses submitted to CMS . . . regardless of whether the data errors would result in
8 positive or negative payment adjustments.” D-16 at 638, Contract Year 2015 Policy and
9 Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. at 2000.

10 But United ignores that on May 23, 2014, when CMS announced it was not adopting
11 the proposed MRRR, it expressly stated that this decision did not change the “long-
12 standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA[O]
13 for payment purposes must be supported by medical record documentation,” nor the
14 “existing contractual requirement that MA[Os] must certify (based on best knowledge,
15 information, and belief) the accuracy, completeness, and truthfulness of the risk
16 adjustment data they submit to CMS.” P-92 at 5044, 5047, Contract Year 2015 Policy and
17 Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. at 29,921-22,
18 29,926. And the “best knowledge, information, and belief” duty is the very one that the
19 Ninth Circuit concluded United violated when it ignored the results of its Chart Reviews.
20 *Swoben*, 848 F.3d at 1175-76. In so ruling, the Ninth Circuit expressly concluded that
21 CMS’s decision to not finalize the MRRR did not negate United’s longstanding
22 obligations nor give United a free pass to ignore the negative results of its Chart Reviews.
23 *Id.* at 1169. CMS’s decision not to finalize a rule requiring MAOs to design all their chart
24 reviews to identify over-reporting errors does not excuse an MAO from turning a blind
25 eye to over-reporting errors found in chart reviews it chooses to conduct.

26 Referring to the MRRR, United further contends that the United States cannot
27 impose a duty which “CMS considered and rejected a decade ago,” citing *Azar v. Allina*
28 *Health Servs.*, 587 U.S. 566, 584 (2019). Joint Brief, 49. But the duties at issue in this case

1 were not “considered and rejected a decade ago” because they were established long
2 before CMS proposed the MRRR and explicitly remained unchanged after CMS did not
3 finalize the MRRR. *Allina* is also inapposite because it held that where the government
4 establishes or changes a policy, it must do so through notice-and-comment rulemaking.
5 587 U.S. at 583-84. Here, United’s obligation to pay arises from regulation, contract, and
6 statute, not from a policy that did not go through notice-and-comment rulemaking.

7 Employing yet another red herring, United feebly asserts that the regulation
8 reflecting the good faith and due diligence standard does not require all codes submitted
9 by an MAO to be accurate, nor requires MA plans to represent something about how they
10 structured their chart reviews. Joint Brief, 49. But, of course, the United States is not
11 making these assertions, but instead contends that United’s turning a blind eye to over-
12 reporting errors found by its own coders shows “a lack of diligence and an absence of
13 good faith,” as *Swoben* concluded. 848 F.3d at 1175-76. In its similarly frail argument
14 disputing its compliance duties, Joint Brief, 50, United ignores completely the fact that the
15 Ninth Circuit held that the compliance regulations impose a duty on MA plans to take
16 affirmative steps to address errors. *Swoben*, 848 F.3d at 1174.

17 Additionally, United, with no relevant support, speciously contends that CMS’s
18 decision not to finalize the MRRR and the “lack of clarity” in the due diligence, good faith
19 and compliance regulations raise due process concerns. Joint Brief, 50-51. But United,
20 ignoring that the Ninth Circuit held that CMS has been clear since 2000 that plans are
21 required to undertake good faith efforts and to take steps to address errors by correcting
22 the submission of unsupported codes, *Swoben*, 848 F.3d at 1178-79, fails to address
23 evidence that it was aware that CMS applied the FCA’s knowledge standard to MAOs’
24 “best knowledge, information, and belief” requirement and expected MAOs to correct
25 submitted codes not found supported in their chart reviews. P-33, United 30(b)(6)
26 (Theisen) Tr. 4416:1-4419:17; *see also* P-17, at 4293 (referencing SCAN settlement).
27 Where rules have been clear for more than twenty years and a defendant was aware of
28 them, no due process concerns arise in applying them to the defendant.

1 **C. United’s Legal Argument: DOJ Cannot Show That United’s Conduct**
2 **Was Material to CMS’s Decision to Pay United**

3 DOJ also cannot show that the alleged fraud was “material” to CMS’s decision to
4 pay United. It is undisputed that CMS was aware of United’s chart review practices. See
5 United MSJ, *supra* at 10-11, 15-16. If CMS considered that practice to be material to its
6 payment decision, it would have refused to accept United’s bids, refused to pay United, or
7 taken *some* remedial action. It did *none* of those things. See United MSJ, *supra* at 16.

8 The starting point is the Supreme Court’s recent decision in *Escobar*. There, the
9 Court explained the FCA is “not a vehicle for punishing garden-variety breaches of
10 contract or regulatory violations,” but rather “material” misrepresentations that amount to
11 fraud. 579 U.S. at 193. This requirement is “rigorous.” *Id.* at 192. As the Court explained,
12 “if the Government pays a particular claim in full despite its actual knowledge that certain
13 requirements were violated, that is very strong evidence that those requirements are not
14 material.” *Id.* at 195. Since *Escobar*, the Ninth Circuit has confirmed that courts may
15 “properly dismiss an FCA claim on summary judgment based on a claimant’s failure to
16 meet the rigorous standard for materiality under the FCA,” including for “reverse false
17 claims.” *Kelly v. Serco, Inc.*, 846 F.3d 325, 333–36 (9th Cir. 2017).

18 This Court already followed *Escobar* in dismissing the three “attestation-based”
19 FCA claims at the pleading stage for failing to allege materiality. Those claims were based
20 on allegations that United’s attestations of accuracy were false because United knew that
21 diagnosis codes previously submitted by doctors were unsupported when its coders
22 conducting chart review did not independently identify them. As to those claims, the Court
23 held that DOJ failed to allege that the attestations were material to CMS’s payment
24 decision. See Dkt. 212 (quoting *Escobar*, 579 U.S. 176, 190–93 (2016)). The Court gave
25 DOJ the option to amend its complaint to address that deficiency, but DOJ declined to do
26 so.

27 Now, at summary judgment, DOJ’s remaining reverse FCA claim founders on the
28 same basic (and now undisputed) facts. Applying *Escobar*, there is “very strong evidence

1 that those requirements are not material,” because CMS knew about United’s chart review
2 practices, continued accepting United’s bids, and continued paying United’s claims “in
3 full despite its actual knowledge.” 579 U.S. at 195. CMS knew about the practices DOJ
4 now claims are fraudulent but did not alter its decision to contract with or pay United. *See*
5 United MSJ, *supra* at 10-11, 15-16; *see also* JS at D150-D154, D227-D228, D231; *see*,
6 *e.g.*, Exs. D-68 at 2113-14, D-21 at 671, D-8 at 384-89, D-140 at 3505:19-06:8. Nor did
7 CMS take remedial action at all. JS at D229-D230; Exs. D-8 at 0384-89, D-131 at 3356:8-
8 12.

9 This should not be a debatable point. In 2014, when CMS proposed adopting the
10 MRRR, United contacted CMS to clarify the rules. *See* United MSJ, *supra* at 15. In April
11 2014, United representatives met with CMS officials to discuss whether MA plans had an
12 affirmative obligation to confirm the validity of diagnosis codes submitted by doctors but
13 not identified by MA plan coders during chart review. *See id.* United witnesses recall that
14 CMS confirmed MA plans do not have such an obligation unless the proposed MRRR
15 became final (which it never did). JS at D127; Exs. D-131 at 3352:17-53:24, D-138 at
16 3487:24-88:10, D-22 at 674-75, D-24 at 680. CMS officials did not recall what was said
17 during the meeting, with only one attendee claiming a limited recollection at best. JS at
18 D128-D129; Exs. D-137 at 3460:11-18, D-145 at 3661:25-62:2, 3664:25-66:16, D-146 at
19 3701:8-03:25, D-105 at 2775:2-76:3, D-97 at 2637:22-38:3, 2640:2-18. What is
20 undisputed is that after the meeting, United disclosed year after year to CMS in subsequent
21 bids and attestations that it was ceasing (and later, had ceased) its complex auditing
22 program and thus no longer affirmatively sought to confirm such codes in its chart review
23 program. *See, e.g.*, JS at D150-D154; Exs. D-25 at 689, D-33 at 729-30, D-26 at 709-10,
24 D-31 at 725.

25 For these reasons, DOJ cannot satisfy *Escobar*’s “rigorous” materiality element,
26 which is an independent basis for granting summary judgment for United.
27
28

US Response to Issue 1.C.: Materiality is Not an Element of the Claim at Issue, But Even if it Were, the United States Can Establish Materiality

United’s materiality argument fails for four distinct reasons: (1) as discussed in the United States’ Motion for Partial Summary Judgment (MPSJ), *see infra* at 84-86, materiality is not an element of a claim under the second prong of 31 U.S.C. § 3729(a)(1)(G); and even if materiality were a requirement; (2) CMS did not have knowledge of United’s chart review practices; (3) the relevant question is whether specific unsupported codes are material, not United’s chart review practices generally; and (4) materiality can be established absent CMS terminating United’s MA contract or stopping payment.

First, United cites no case from any jurisdiction that discusses materiality within the context of the second prong of the reverse false claims provision. Rather, United attempts to contort *Escobar* to its unfounded theories, but *Escobar* only addresses materiality under the affirmative False Claim Act provision, 31 U.S.C. § 3729(a)(1)(A); 579 U.S. at 181; United States’ MPSJ, Joint Brief, 84-86. The only other case cited by United, *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 333-36 (9th Cir. 2017), also discusses materiality in the context of § 3729(a)(1)(A). Therefore, the Court can end the inquiry here and reject United’s materiality argument.

While the Court need not consider any of the factual information presented regarding materiality, United grossly distorts the record. United alleges that “it is undisputed that CMS was aware of United’s chart review practices.” Joint Brief, 67. It is, however, very much disputed what and when CMS knew about any of United’s internal practices. United admits that its Chart Review and Claims Verification program are not the same thing. D47; D109. United has set forth no evidence that it provided CMS with information about the details of its Chart Review program or its relationship to Claims

1 Verification. Instead, United relies on cursory high-level explanations of its Claims
2 Verification Program that it alleges it provided CMS in 2014²³ to support its argument.

3 United incredulously asserts that in a 45-minute videoconference, CMS officials
4 revised the bedrock deliberative ignorance/reckless disregard standard of the “best
5 knowledge, information, and belief” requirement and the FCA by allegedly confirming
6 that United could deliberately ignore information obtained in its Chart Review program
7 showing it had previously submitted unsupported codes. Joint Brief, 68. There is evidence,
8 however, that nothing of the sort occurred at the April 29 videoconference. United’s own
9 witnesses acknowledge that the videoconference focused on United’s Claims Verification
10 process (as opposed to Chart Review). P-34, Erickson Tr. 4425:17-4426:8; P-25, Nelson
11 Tr. 4352:24-4353:5; 4354:10-17. United could have asked CMS a simple, straightforward
12 question that cut to the heart of this case: If we review a medical record and do not find
13 support for a diagnosis code that we’ve already submitted, can we ignore that information
14 and neither delete those unsupported diagnoses, nor investigate further to determine their
15 accuracy? Rather than ask that straightforward question, United provided incomplete
16 information to CMS and focused on obtaining a statement to justify terminating its Claims
17 Verification program.

18 Both CMS and United witnesses recall CMS reminding United that the FCA applied
19 to United’s conduct under discussion. P-10, Rice Tr. 4232:4-12; P-29, Johnson Tr.
20 4379:25-4380:16; P-35, Schumacher Tr. 4432:18-4433:3; D-22, at 675 (Johnson
21 contemporaneous notes). And, importantly, Sean Cavanaugh, then Deputy Administrator
22 of CMS and Director of the Center for Medicare, categorically denies United’s
23 characterization that CMS endorsed United’s position that they could both cease the
24 Claims Verification process and not delete known unsupported codes. P-20, Cavanaugh
25 Tr. 4321:14-25; 4322:14-4323:23; P-36 at 4436-37 (2015 Cavanaugh email disputing
26 same). Rather, he recalls CMS making entirely different statements than those United has
27

28 ²³ United thus concedes that even any limited knowledge CMS had only occurred as of
2014 - well into the relevant period of this litigation.

1 set forth, namely that: aside from the proposed MRRR, United “should be aware there are
2 other statutes, regulations, requirements that apply to your obligation to submit complete
3 and accurate data. You should make sure you’re aware of them, and if you’re asking us
4 questions about how to specifically comply with the law, that’s more appropriately posed
5 to your own counsel.” P-20, Cavanaugh Tr. 4318:14-4319:2.

6 Based on notes taken at the meeting by United’s own executives, a jury may find
7 that CMS officials said they did not know enough about United’s processes to give
8 feedback on United’s proposed course of action, that it was unacceptable to not delete
9 what United knew were unsupported codes, and that there was an FCA requirement that
10 plans not knowingly keep overpayments. Dan Schumacher, then CFO of United
11 HealthCare, included in his notes these statements attributed to CMS’s Cheri Rice: “Not
12 acceptable to not delete what we know;” “If you have knowledge of deletes, you [should]
13 delete;” “Statutory obligation to report & repay;” “false claims act implications;” “Haven’t
14 known enough process to give feedback on our judgments.” P-28 at 4376 (Schumacher
15 Notes).

16 Following the April 29, 2014 videoconference, there is evidence that CMS was left
17 with very little understanding regarding United’s Claims Verification program and no
18 understanding of United’s Chart Review program. P-26, CMS 30(b)(6) (Hornsby) Tr.
19 4363:1-24; P-10, Rice Tr. 4236:20-4237:7; 4238:12-4239:2.

20 United’s follow-up email on April 30, 2014 provided no specific details to CMS
21 about United’s Claims Verification Program and included no details about Chart Review
22 whatsoever. P-24 at 4347-48 (2014 CMS/United correspondence). Importantly, United
23 fails to acknowledge that CMS responded by email on May 2, 2014 that, “[r]egardless of
24 the effective date of the proposed requirement related to medical record reviews, there are
25 other laws that do impose standards, requirements and responsibilities on MA plans in
26 connection with the federal payments they receive from CMS. We cannot provide advice
27 to United about the scope of those other laws. Nor can we provide advice on whether
28 United’s plan [sic] course of action and/or purported limits on the scope of its attestation

1 are compliant with such other laws.” *Id.* Ms. Rice testified that, with this email, she sought
2 to make clear “that [United] should not take away from that meeting that we had said that
3 it was okay to stop the claims verification program, or that it was okay not to continue to
4 review and determine whether those questionable diagnoses were accurate or not.” P-10,
5 Rice Tr. 4234:13-4235:1. United continued to email CMS yearly during the relevant
6 period reiterating that it had ceased its Claims Verification program and CMS responded
7 with that same message that it could not endorse United’s practices. *See* P-1D at 4008-09,
8 P-1E at 4011-12; P-1F at 4015-16.

9 United also claims that a short blurb it included with its MA bids after 2014 likewise
10 provided CMS with sufficient knowledge about United’s “Chart Review practices.”
11 Specifically, United points to the sentence, “[t]he health plan has decided to cease *one of*
12 its prior processes that identified and deleted certain diagnosis codes through the medical
13 record review process.” D-25 at 689 (emphasis added). But this statement did not, and
14 could not, give any meaningful information to CMS actuaries unfamiliar with United’s
15 processes and procedures. P-79, Spitalnic (US Expert, CMS Chief Actuary) Tr. 4978:16-
16 4979:4; P-38, CMS 30(b)(6) (Limmer) Tr. 4450:25-4451:20. Further, on its face it
17 suggests that the data review process that had been terminated was only “*one of*” United’s
18 programs identifying and deleting diagnosis codes in the medical review process.
19 Moreover, United has offered no evidence in this case that CMS’s actuaries actually
20 reviewed or considered this sentence when evaluating United’s bids. P-38, CMS 30(b)(6)
21 (Limmer) Tr. 4452:10-4453:19.

22 Therefore, contrary to United’s assertions, the evidence very much disputes that
23 CMS had “actual knowledge” of United’s Chart Review practices. *See, e.g., Escobar*, 579
24 U.S. at 195 (discussing actual knowledge of Government); *United States ex rel. Campie*
25 *v. Gilead Sci., Inc.*, 862 F.3d 890, 906-7 (9th Cir. 2017) (“[T]he parties dispute exactly
26 what the government knew and when, calling into question its ‘actual knowledge.’”).

27 Further, United obfuscates the question of what information or conduct would be
28 material to the government in a case brought under the second prong of the reverse false

1 claims provision, should such a requirement exist. United argues that “CMS knew about
2 the practices DOJ now claims are fraudulent but did not alter its decision to contract with
3 or pay United.” Joint Brief, 68. However, as United concedes, the United States does not
4 contend that chart review practices generally are “fraudulent.” Instead, the claim in this
5 case is that United knowingly ignored information that it received payment from CMS for
6 unsupported diagnosis codes. *See* Joint Brief, 16 (acknowledging that the Government
7 “does not contend . . . that there is anything fundamentally wrong with chart review”).
8 Even if CMS had generalized knowledge about United’s Chart Review program (which it
9 did not), such knowledge does not mean CMS knew of invalid codes. Without such
10 specific knowledge, CMS would not have known that payment adjustments were
11 necessary. Therefore, it is the diagnosis codes themselves that impact accurate MA
12 payments by CMS. *See Sutter*, 444 F. Supp. 3d at 1025. If a showing of materiality is
13 required here, it is whether the specific unsupported diagnosis codes are material to CMS
14 because, as described above, CMS adjusts payment when it has information that a specific
15 diagnosis code is unsupported – it does not pay MA Plans for codes that plans delete.
16 There is certainly evidence for the jury to conclude these unsupported codes are material.

17 Finally, even if the caselaw United relies on regarding materiality in the context of
18 affirmative false claims applied to the second prong of the reverse false claims provision,
19 United presents the law in a misleading manner. The FCA defines “material” as “having
20 a natural tendency to influence, or be capable of influencing, the payment or receipt of
21 money . . .” 31 U.S.C. § 3729(b)(4). The plain meaning of “tendency to influence” and
22 “capable of influencing” covers conduct beyond the exclusive question of whether CMS
23 would have refused to pay United if it had known of its chart review practices. United
24 omits reference to the FCA definition because it defeats United’s argument.

25 Likewise, United opportunistically ignores the relevant caselaw regarding
26 materiality by suggesting CMS’s continued contracting with and continued payments to
27 United are dispositive. However, *Escobar* makes clear that materiality is a holistic, fact-
28 intensive inquiry that “cannot rest on ‘a single fact or occurrence as always

determinative.’” *Escobar*, 579 U.S. at 191 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)). *Escobar* lists several non-dispositive factors for courts to consider in examining materiality. 579 U.S. at 194-95; *United States ex rel. Mei Ling v. City of Los Angeles*, Case No. CV 11-974 PSG (JCx), 2018 WL 3814498, at *13 (C.D. Cal. July 25, 2018) (“In sum, *Escobar* suggests that the following factors are relevant to the materiality inquiry: whether the violated requirement was expressly identified as a condition of payment, which, though ‘relevant, [is] not automatically dispositive’; whether the violation went to the essence of the bargain; whether the violation was minor or insubstantial; and the actions that the Government took in response to these or similar violations.”). The jury should be able to consider that many of the factors weigh in favor of a finding of materiality here, including that accurate diagnosis codes are a condition of payment, and that the violation was substantial.

United disregards the *Escobar* factors that weigh against its argument and improperly makes stopping payment and terminating contracts the *sine qua non* of materiality. See, e.g., *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110-12 (1st Cir. 2016) (finding on remand from the Supreme Court that materiality was sufficiently alleged despite continued payment by the Government). United wholly ignores the reality that CMS is charged with providing health coverage to more than 160 million people, including through the Medicare program. See P-39 at 4457, CMS website, <https://www.cms.gov/about-cms> (last visited July 15, 2024). CMS takes very seriously the critical importance of ensuring the continuity of coverage and care for this vulnerable population. P-26, CMS 30(b)(6) (Hornsby) Tr. 4360:14-22 (CMS “want[s] beneficiaries to have continuity of coverage and to be protected. . .”); 4361:4-14 (“beneficiary harm is the overarching reason for termination”). CMS could not simply stop making payments to United broadly or terminate its contract with United, as doing so would have had significant, deleterious consequences for *millions* of American seniors, including potential continuity of care concerns. P-26, CMS 30(b)(6) (Hornsby) Tr. 4362:7-17. Courts have recognized that there are circumstances where public interest concerns

1 may fairly weigh on an agency’s determination to continue payment. *See, e.g., Mei Ling*,
2 2018 WL 3814498 at *19.

3 **D. United’s Legal Argument: DOJ Cannot Show United “Conceal[ed]” or**
4 **“Improperly Avoid[ed]” an Obligation to Return Money**

5 DOJ’s reverse FCA claim fails for a final reason: There is no evidence United
6 committed any acts of deception. DOJ must show United not only knowingly retained
7 overpayments but also took affirmative deceptive steps to retain them. That requirement
8 is central to the definition of “fraud.” Yet, there is no evidence United engaged in any
9 fraudulent act. Instead, DOJ contends United’s mere knowing retention of an overpayment
10 is sufficient under the reverse FCA. That view directly contradicts the Supreme Court’s
11 command that the FCA is not “a vehicle for punishing garden-variety breaches of contract
12 or regulatory violations.” *Escobar*, 579 U.S. at 194. This Court should enforce the FCA’s
13 core fraud requirement.

14 **1. The FCA Requires a Fraudulent Act of Concealment**

15 The FCA is a fraud statute, and the key defining feature of fraud is deceptive acts.
16 The FCA does *not* cover non-fraudulent conduct. It “would be unreasonable to assume
17 [that the FCA] covers both fraudulent and nonfraudulent conduct Without fraud,
18 punitive damages—a mandatory penalty of up to \$10,000 for each claim and treble
19 damages—would seem an unreasonable levy against individuals guilty only of
20 ‘knowingly’ receiving an overpayment from the government fisc.” *Olson v. Fairview*
21 *Health Servs. of Minn.*, 831 F.3d 1063, 1074 (8th Cir. 2016). Like the common law of
22 fraud, the reverse FCA requires an affirmative act of deception. The statute penalizes
23 “[a]ny person who . . . knowingly *conceals* or knowingly and *improperly avoids* or
24 *decreases* an obligation to pay or transmit money or property to the government.” 31
25 U.S.C. § 3729(a)(1)(G) (emphasis added). Thus, it is insufficient for DOJ to show that a
26 defendant knowingly violated an obligation to pay or transmit money to the government.
27 The defendant must also take steps to “conceal” or “improperly avoid” or “decrease” that
28 obligation.

1 The common law confirms the plain meaning of the FCA. The Supreme Court has
2 made clear the “FCA is largely a fraud statute.” *United States ex rel. Schutte v. SuperValu*
3 *Inc.*, 598 U.S. 739, 750–51 (2023). Thus, “[i]n the absence of statutory text to the
4 contrary,” courts must interpret the FCA as incorporating “the well-settled meaning of
5 such a common-law term.” *Id.* at 751. At common law, fraud always required deception.
6 See 1 Joseph Story, *Commentaries on Equity Jurisprudence* §§ 205–79 (1846). The
7 common law distinguishes between fraudulent acts, like concealment, and non-fraudulent
8 acts, like non-disclosure. “[F]raudulent concealment—without any misrepresentation or
9 duty to disclose—can constitute common-law fraud. This does not mean, however, that
10 simple nondisclosure similarly constitutes a basis for fraud.” *United States v. Colton*, 231
11 F.3d 890, 899 (4th Cir. 2000). Instead, “concealment” “is characterized by deceptive acts
12 or contrivances intended to hide information, mislead, avoid suspicion, or prevent further
13 inquiry,” whereas “nondisclosure” is “characterized by mere silence.” *Id.*

14 In addition, acts such as breach of contract are not in and of themselves fraudulent.
15 See Restatement (Third) of Torts: Liability for Economic Harm § 10 (2018)
16 (distinguishing breach of contract from fraud and explaining that “[i]n short, the law of
17 fraud is concerned with various sorts of lies, not with . . . broken promises”); *id.* (“A party
18 who promises an act but then decides not to carry it out may be liable for breach of contract
19 or on a theory of promissory estoppel, but is not liable for fraud unless the statement of
20 intention was false when made.”). Courts have steadfastly held that “failing to disclose a
21 breach of promise does not transform a contract action into one for fraud.” *Compania Sud-*
22 *Americana de Vapores, S.A. v. IBJ Schroder Bank & Trust Co.*, 785 F. Supp. 411, 423
23 (S.D.N.Y. 1992); *cf. Myklatun v. Flotek Indus., Inc.*, 734 F.3d 1230, 1235–36 (10th Cir.
24 2013).

25 DOJ’s contrary position would have absurd results. The reverse FCA applies to all
26 “obligations” to transmit money to the government. This extends beyond “overpayments”
27 and includes payment obligations arising from contractual obligations. 31 U.S.C.
28 § 3729(b)(3); *see also, e.g., Kennard v. Comstock Res.*, 363 F.3d 1039, 1048 (10th Cir.

2004) (applying the reverse FCA to alleged underpayment of mineral royalties to the government). If there were no requirement for an affirmative deceptive act, then any deliberate failure to pay royalties or other payments or debts due under a contract would constitute fraud under the FCA. But “the common law does not permit a fraud claim based solely on contractual breach.” *United States ex rel. O’Donnell v. Countrywide Home Loans, Inc.*, 822 F.3d 650, 658 (2d Cir. 2016).

None of this means that DOJ cannot bring suit to recover overpayments. DOJ could sue for breach of contract. But DOJ did not bring a breach of contract claim here. Having failed to do so, DOJ cannot leverage the *in terrorem* effect of the FCA with its civil penalties and treble damages when the defendant has not taken the critical act of deception.

2. United Did Not Undertake Any Deceptive Acts

DOJ alleges that United knew that diagnosis codes were unsupported and thus violated its obligation to repay money to the government. Its theory is that United’s mere failure to return money owed to CMS is sufficient to satisfy the reverse FCA’s requirement to show fraud in the form of “knowingly conceal[ing]” or “knowingly and improperly avoid[ing] or decreas[ing]” an obligation to repay money. 31 U.S.C. § 3729(a)(1)(G). But DOJ offers no evidence United concealed its actions in any way, such as by destroying evidence or otherwise engaging in deceptive, fraudulent conduct to hide or avoid the obligation. And CMS has acknowledged that, without more, the mere existence of unsupported diagnosis codes or payment discrepancies does not equate to fraud. See JS at D233; Ex. D-122A at 3151:5-8 (“Q. But you understand that CMS has said in the RADV context that neither payment errors nor coding differences are fraud; right? A. Correct. In and of themselves, no.”).

Far from concealing its conduct, United *told* CMS that it was not validating the diagnoses submitted by doctors that were not independently identified by chart reviewers. See United MSJ, *supra* at 15-16, n.8. That is the opposite of fraud. In fact, it is exactly the type of conduct DOJ has recommended for regulated entities like United when facing uncertainty. Just last year, DOJ argued to the Supreme Court that “companies that seek

1 funds from the government . . . often have ready avenues for resolving ambiguity about
2 payment rules—for example, by consulting their contacts.” JS at D235, Ex. D-148 at 3733,
3 3738, Brief for United States at *25 n.4, *United States ex rel. Schutte v. SuperValu Inc.*,
4 598 U.S. 739 (2023); *id.* at 32 (“The government therefore relies on its contracting partners
5 to approach the inevitable ambiguities in good faith, following what they understand to be
6 the best interpretation and seeking clarification when necessary.”). Having disclosed its
7 chart-review practices and sought the sort of clarification DOJ told the Supreme Court
8 should be sought, United cannot now be held liable for defrauding the government under
9 the FCA.

10 **US Response to Issue 1.D.: The Reverse False Claims Provision of the**
11 **FCA Does Not Require Proof of Deceptive Acts to Establish Knowing**
12 **and Improper Avoidance of an Obligation**

13 United’s argument that the government cannot show that it improperly avoided an
14 obligation to return money because it purportedly did not commit any “acts of deception”
15 is based on two false premises. First, United contends that this is a fraud case, and “at
16 common law, fraud always required deception.” Joint Brief, 75-76. But this is not a
17 common law fraud case; it is an FCA case, and there is an entire body of caselaw analyzing
18 the statute, including the language of the reverse false claims provision. Second, United
19 contends that the reverse FCA provision requires showing an act of deception. But, the
20 second prong of the reverse FCA provision imposes liability on a person who “knowingly
21 and improperly avoids . . . an obligation to pay.” 31 U.S.C. § 3729(a)(1)(G).²⁴ This
22 provision does not require proof that United took affirmative deceptive steps. As discussed
23 above, the 2009 FERA amendments broadened the scope of the reverse FCA provision
24 and eliminated the need to show an affirmative use of a false statement. “[T]he post-FERA
25 FCA specifies that mere knowledge and avoidance of an obligation is sufficient, without
26 the submission of a false record, to give rise to liability.” *Victaulic Co.*, 839 F.3d at 255.

27
28 ²⁴ The FCA explicitly does not require “proof of specific intent to defraud.” 31 U.S.C. § 3729(b)(1)(A)-(B).

1 In similar situations, courts have held that the reverse FCA provision imposes
2 liability on defendants who do nothing after being put on notice of a potential
3 overpayment, thereby avoiding an obligation to pay money. For example, in *Kane*, the
4 defendants argued that the government needed to plead that they took “‘active and
5 conscious’ action to establish avoidance.” *Kane*, 120 F. Supp. 3d. at 393. In rejecting that
6 argument, the court surveyed various definitions of “avoid,” and ultimately found that
7 these definitions “support the conclusion that the plain meaning of ‘avoid’ includes
8 behavior where ***an individual is put on notice of a potential issue, is legally obligated to***
9 ***address it, and does nothing.***” *Id.* at 394 (emphasis added); *see also Lakeshore Med.*
10 *Clinic*, 2013 WL 1307013, at *4 (“If the *government* overpaid defendant for [evaluation
11 and management] services and defendant ***intentionally refused to investigate the***
12 ***possibility that it was overpaid***, it may have unlawfully avoided an obligation to pay
13 money to the government” (emphasis added)).

14 *Sutter* relied on *Kane* to find that plaintiffs had sufficiently pleaded that defendants
15 had violated the reverse FCA provision when they failed to take action after being put on
16 notice of thousands of false claims to the MA program. *Sutter*, 444 F. Supp. 3d at 1080-
17 81. The *Sutter* court, considering allegations that defendant healthcare providers who
18 submitted diagnosis codes to MAOs, including United, where various audits conducted by
19 the MAOs (including one by United) showed that submitted diagnosis codes were
20 unsupported, found that “[p]ayments based on false diagnosis codes are overpayments,”
21 and “internal and external reviews of diagnosis codes put the defendants on notice of the
22 potential overpayments.” *Id.* at 1077-78. The government alleged that the defendants
23 failed to report and return the overpayments within 60 days of their being identified, and
24 the overpayments therefore became “obligations” within the meaning of the reverse FCA
25 provision. *Id.* at 1080-81. The court found that in light of the allegations that the defendants
26 were on notice of the potential overpayments and did nothing, the government had
27 sufficiently pleaded that the defendants had “concealed or avoided obligations to pay the
28 government.” *Id.* at 1081. The same is true here – the government does not have to prove

1 that United committed an affirmative act of deception; rather, it only has to prove that
2 United was put on notice of potential overpayments, was legally obligated to address them,
3 and did nothing, which the evidence clearly shows.

4 United does not cite any cases applying its “affirmative deceptive act” requirement
5 to the second prong of the reverse FCA provision. Rather, it ignores the text of the statute
6 in favor of relying on common law fraud.²⁵ For example, United cites cases for the
7 proposition that common law fraud claims cannot be based solely on breach of contract.
8 Joint Brief, 76 (citing *Compania Sud-Americana de Vapores, S.A. v. IBJ Schroder Bank*
9 *& Tr. Co.*, 785 F. Supp. 411, 423 (S.D.N.Y. 1992); *Myklatun v. Flotek Indus., Inc.*, 734
10 F.3d 1230, 1235–36 (10th Cir. 2013), *United States ex rel. O’Donnell v. Countrywide*
11 *Home Loans, Inc.*, 822 F.3d 650, 662 (2d Cir. 2016). The Supreme Court has recognized
12 that certain elements of common law fraud are retained in the FCA to the extent they are
13 “**consistent with the statutory text**,” but of course “[t]he [FCA] abrogates the common law
14 in certain respects.” *Escobar*, 579 U.S. at 176 n.2 (emphasis added). United’s attempt to
15 shoehorn in a “deceptive acts” requirement is inconsistent with the statutory text of the
16 second prong of the reverse FCA provision and should be rejected.

17 United claims that the government’s position would lead to “absurd results,” Joint
18 Brief, 76-77, but there is nothing absurd about following the plain language of the FCA.
19 And there is certainly nothing absurd about employing the FCA to recoup billions of
20 dollars for the Medicare Trust Funds that United is not entitled to retain but refuses to
21 return. This Court should adhere to the statutory language of the FCA and reject United’s
22 self-serving attempt to insert into it an “affirmative deceptive act.”
23
24

25 ²⁵ The limited number of FCA cases cited by United are inapposite. United cites *Olson v.*
26 *Fairview Health Servs. of Minn.*, which held that the heightened pleading requirements of
27 FED. R. OF CIV. P. 9(b) applied to claims under the reverse FCA provision but did not
28 address what conduct constituted knowing and improper avoidance of an obligation to pay
under that provision. 831 F.3d 1063, 1072-74 (8th Cir. 2016). United also cites *Kennard*
v. Comstock Res., Inc., 363 F.3d 1039 (10th Cir. 2004), a case that predated the FERA
amendments to the FCA and does not address at all what sort of conduct violates the post-
FERA version of the FCA. *See id.* at 1047.

II. UNITED’S LEGAL ARGUMENT ON ISSUE NO. 2: WHETHER THE COURT SHOULD GRANT SUMMARY JUDGMENT AS TO THE COMMON-LAW CLAIMS

DOJ’s common-law claims for unjust enrichment and payment by mistake are equally unavailing and should be dismissed for at least two reasons.

First, both common-law claims are unavailable because of the existence of express contracts between the parties. “As a general rule, the existence of a valid contract precludes a plaintiff from asserting unjust enrichment and payment by mistake claims, which are based on quasi-contract theories.” *United States v. Symantec Corp.*, 471 F. Supp. 3d 257, 297–98 (D.D.C. 2020) (citing *United States v. First Choice Armor & Equip.*, 808 F. Supp. 2d 68, 77–78 (D.D.C. 2011)). This is a “foundational principle of contract law,” *United States v. Kellogg Brown & Root*, 800 F. Supp. 2d 143, 160 (D.D.C. 2011) (citation omitted), and courts regularly apply it to dismiss quasi-contract claims, including where the government is the plaintiff, *see, e.g., Lee v. Canada Goose US*, 2021 WL 2665955, at *9 (S.D.N.Y. June 29, 2021) (“[T]he court dismisses Plaintiff’s unjust-enrichment claim because such a claim is unavailable when there is an express agreement governing the dispute.” (citation omitted)).

There is no question that a contract exists between the parties here—DOJ attached the contracts to its Complaint. *See* JS at D234; Ex. D-1 at 36-56.²⁶ Courts in FCA cases regularly reject quasi-contract claims on this basis, and this Court should too. *See United States v. Sci. Applications Int’l Corp.*, 555 F. Supp. 2d 40, 60 (D.D.C. 2008) (holding in FCA case that “because the express contracts existing between the parties here preclude quasi-contractual claims, [defendant’s] motion for summary judgment on the

²⁶ Although plaintiffs may generally plead quasi-contract claims in the alternative, “these alternative claims ‘must be supported by, at the very least, an allegation that there is no valid contract.’” *Symantec Corp.*, 471 F. Supp. 3d at 298 (quoting *Kellogg Brown*, 800 F. Supp. 2d at 160). DOJ makes no such allegation here.

1 government's quasi-contractual claims [of unjust enrichment and payment by mistake]
2 will be granted").²⁷

3 Second, both common-law claims are based on DOJ's flawed FCA theory and fail
4 for many of the reasons discussed above. DOJ alleges that United received money from
5 CMS to which it was "not entitled, which unjustly enriched Defendants," because United
6 "received such money by claiming and retaining Medicare risk adjustment payments based
7 on invalid risk adjustment data." JS at D268; Ex. D-1 at 31. DOJ also alleges that it "paid
8 money to Defendants as a result of a mistaken understanding," specifically by paying
9 United's "claims for risk adjustment payments under the mistaken understanding that such
10 claims were based on valid risk adjustment data." JS at D269; Ex. D-1 at 32. But as
11 discussed above, DOJ has no evidence that the risk adjustment data at issue—the diagnosis
12 codes—were invalid. Nor does DOJ have evidence that the codes caused United to be
13 overpaid, let alone that CMS, which was aware of United's chart review process, paid by
14 mistake. And DOJ cannot show United had any obligation to return these funds. DOJ thus
15 cannot establish unjust enrichment or payment by mistake. *See, e.g., United States v. Aegis*
16 *Therapies, Inc.*, 2015 WL 1541491, at *14 (S.D. Ga. Mar. 31, 2015) (dismissing the
17 government's "claims for unjust enrichment (Count III) and payment by mistake (Count
18 IV)" because those "claims are purely derivative of the FCA claims," which the court
19 dismissed).

20 **US RESPONSE TO ISSUE NO. 2: THE COURT SHOULD DENY SUMMARY**
21 **JUDGMENT AS TO THE COMMON LAW CLAIMS**

22 This Court should also reject United's motion for summary judgment with respect
23 to the common law claims of unjust enrichment and payment by mistake. First, United
24 argues that the common law claims are defective because of the existence of a contract.

25 ²⁷ *See also, e.g., United States ex rel. Reeves v. Mercer Transp.*, 253 F. Supp. 3d 1242,
26 1255–56 (M.D. Ga. 2017) (dismissing "the Government's claims for unjust enrichment
27 and payment by mistake" in FCA case because of the parties' "underlying contract");
28 *United States v. First Choice Armor & Equip.*, 808 F. Supp. 2d 68, 77–78 (D.D.C. 2011)
(granting motion to dismiss "the payment by mistake count and the unjust enrichment
count" in FCA case because "the government acknowledges that its complaint alleges the
existence of an express contract between [defendant] and the United States").

1 Joint Brief, 81-82. United cites three out-of-circuit district court opinions with starkly
2 different facts, only one of which actually dismissed the United States’ quasi-contractual
3 claims. However, United’s exact argument was rejected by a district court in this Circuit,
4 and with almost identical facts. *See United States ex rel. Osinek v. Permanente Med. Grp.,*
5 *Inc.*, 640 F. Supp. 3d 885, 914-15 (N.D. Cal. 2022) (rejecting argument that payment by
6 mistake and unjust enrichment should be dismissed due to existence of a contract because
7 “the government has not simply alleged the violation of the CMS/Kaiser contract but also
8 the violation of federal regulations.”). In *Osinek*, as here, the government alleged that the
9 defendant MAOs violated the MA contracts *and* federal regulations with respect to the
10 risk adjustment data they submitted to CMS. *Id.* There, the defendant MAO made the same
11 argument that United advances here – namely that the quasi-contractual claims of unjust
12 enrichment and payment by mistake were unavailable to the government due to the
13 existence of MA contracts between the government and the defendants. *Id.* The *Osinek*
14 court squarely rejected this, reasoning that the trier of fact may “find that Kaiser’s failure
15 to comply with the ICD Guidelines was not a violation of the CMS/Kaiser contract” but
16 nevertheless was a violation of federal regulations, allowing the government to proceed
17 with a quasi-contractual theory at that point. *Id.* Even if quasi-contract claims cannot be
18 brought to enforce contractual obligations, they remain viable to recover erroneous
19 payments premised on regulatory violations.

20 Additionally, as the *Osinek* court held, “even if a quasi-contract claim might
21 ordinarily be barred where an express contract exists,” that rule does not apply where the
22 government is the plaintiff because the government’s “[well]-established right to sue for
23 money wrongfully or erroneously paid from the public treasury, [is] *a right arising*
24 *separate and apart from statute, regulation, or contract.*” *Id.* (second quoting *Agility Pub.*
25 *Warehousing Co. K.S.C.P. v. United States*, 969 F.3d 1355, 1365 (Fed. Cir. 2020)). As the
26 Supreme Court has held, “The Government by appropriate action can recover funds which
27 its agents have wrongfully, erroneously, or illegally paid.” *United States v. Wurts*, 303
28

U.S. 414, 415 (1938). The same rationale applies here and is sufficient to defeat United’s motion for summary judgment on the common law claims.

Second, United relies on another out-of-circuit district court case to argue that the claims for unjust enrichment are “purely derivative” of the FCA claims, and (according to United) are “based on DOJ’s flawed FCA theory and fail for many of the reasons discussed above.” Joint Brief, 82. This argument holds no more merit than United’s flawed arguments related to the FCA allegations. But this argument fails for another reason – United’s assertion that the common law claims are “purely derivative” of the FCA and therefore the two claims rise and fall together is wrong. The Ninth Circuit recognizes that such common law claims may be viable even where the United States is unable to prove every element of an FCA violation – for example, knowledge. *United States v. Mead*, 426 F.2d 118, 124, 125 n.6 (9th Cir. 1970). Because the jury can find United liable for the common law claims even if it does not find FCA liability, and United advances no independent reason why it is entitled to judgment as a matter of law on the common law claims, its motion should be denied.

LEGAL ARGUMENT REGARDING UNITED STATES MOTION FOR PARTIAL SUMMARY JUDGMENT

I. UNITED STATES’ ARGUMENT

A. Materiality is Not an Element Under the Second Prong of the Reverse False Claims Provision of the False Claims Act.

The United States brings this action under 31 U.S.C. § 3729(a)(1)(G), commonly known as the False Claims Act’s “reverse false claim” provision. The reverse false claim provision includes two parts, imposing liability on anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, *or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government*”. 31 U.S.C. § 3729(a)(1)(G) (emphasis added). The United States is pursuing this case only under the second prong of this provision. At trial, the United States

1 will show that UnitedHealth violated the second prong of the reverse false claim provision
2 by knowingly and improperly avoiding its obligation to repay the Medicare Program for
3 Medicare Advantage Risk Adjustment payments it received for unsupported diagnosis
4 codes. To clarify the issues for trial, the United States now seeks partial summary
5 judgment that, as a matter of law, materiality is not a required element of establishing
6 liability under the second prong of the reverse false claim provision.

7 The fact that materiality is not an element of the second prong of the reverse false
8 claim provision is clear from the structure of the statutory text. As discussed below, Courts
9 have recognized that the text itself draws a meaningful distinction between the first prong
10 – which requires a “false record or statement *material* to an obligation” – and the absence
11 of that same requirement within the second prong.

12 In its 2018 ruling on Defendants’ Motion to Dismiss (MTD), the Court addressed
13 issues related to materiality, including in the broader context of the United States’ original
14 claims, which included claims under 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B), and the first
15 prong of (a)(1)(G). *United States ex rel. Poehling v. UnitedHealth Group, Inc. et al.*, Case
16 No. CV 16-08697-MWF (SSx), 2018 WL 1363487 (C.D. Cal. Feb. 12, 2018). Yet, the
17 Court has not squarely addressed the threshold question of whether materiality is a
18 *required element* under the second prong of the reverse false claim provision. However,
19 since the 2018 MTD order, courts, including in the Ninth Circuit, have explicitly
20 recognized that materiality is not a required element of the second prong of the reverse
21 false claim provision.

22 The seminal case on materiality under the False Claims act, *Universal Health*
23 *Services v. United States ex rel. Escobar*, did not address materiality under the reverse
24 false claim provision, but rather focused on materiality with respect to affirmative false
25 claims under 31 U.S.C. § 3729(a)(1)(A). 579 U.S. 176, 181 (2016). Since *Escobar*,
26 several Courts have expressly held that materiality is not an element under the second
27 prong of the reverse false claim provision. For example, in *United States ex rel. Ormsby*
28 *v. Sutter Health*, an analogous case involving allegations that defendants knowingly

1 concealed or improperly avoided their obligation to return overpayments to the Medicare
2 Advantage program by failing to delete unsupported diagnosis codes, the Court held that
3 there was no materiality element under the second prong of the reverse false claim
4 provision. 444 F. Supp. 3d 1010, 1056 (N.D. Cal. 2020) (“The elements of a violation
5 under the second prong of the reverse-FCA provision are that the defendant (1) concealed
6 or improperly avoided or decreased an obligation to pay the government and (2) did so
7 knowingly. There is no requirement under the second prong to show that the defendant
8 used a false record or statement or that a record or statement was material.” (internal
9 citations omitted)). *See also United States ex rel. Jacobs v. Pac. Dermatology Inst., Inc.*,
10 Case No. EDCV 20-1906 JGB (SHKx), 2022 WL 17401522, at *13 (C.D. Cal. Aug. 16,
11 2022) (discussing the elements of a claim under the second prong of 31 U.S.C. §
12 3729(a)(1)(G)); *United States ex rel. Frey v. Health Mgmt. Sys., Inc.*, Civil Action No.
13 3:19-CV-0920-B, 2021 WL 4502275, at *7 (N.D. Tex. Oct. 1, 2021) (“Under 31 U.S.C. §
14 3729(a)(1)(G), the relator must prove either five or three elements. Both methods requires
15 [sic] relator to establish the “obligation” and “knowledge” elements. But only the first
16 method requires proving the materiality element.” (internal citations omitted)); *United*
17 *States ex rel. Little v. Shell Expl. & Prod. Co.*, No. CV H-07-871, 2017 WL 4742917, at
18 *29 n.260 (S.D. Tex. Aug. 18, 2017) (noting that Congress amended the reverse false
19 claim provision in 2009 “by articulating the materiality requirement *in the false record or*
20 *statement portion and adding an alternative in the absence of a false record or statement*
21 *that stated ‘knowingly conceals or knowingly and improperly avoids or decreases an*
22 *obligation’” (emphasis added)). Therefore, the United States respectfully requests that*
23 *this Court grant partial summary judgment that as a matter of law*²⁸ *proving liability under*
24 *the second prong of the reverse false claim provision does not require a showing of*
25 *materiality.*

26
27
28 ²⁸ Because the United States’ Motion for Partial Summary Judgment under FED. R. CIV. P.
56 is related to a pure issue of law, the United States is not submitting a Statement of
Undisputed Facts with its Motion.

1 **UNITED’S ARGUMENT**

2 DOJ’s sole basis for seeking partial summary judgment is its extreme argument that
3 the reverse FCA provision at issue here does not require the allegedly fraudulent conduct
4 to be *material*. In making that argument, DOJ asks this Court to ignore the Supreme
5 Court’s clear holding in another FCA case that “the common law could not have *conceived*
6 of ‘fraud’ without proof of materiality.” *Universal Health Servs., Inc. v. United States ex*
7 *rel. Escobar*, 579 U.S. 176, 193 (2016) (emphasis added) (citation omitted). DOJ’s
8 inconceivable motion should be denied.

9 The reverse FCA provides two bases for liability. See 31 U.S.C. § 3729(a)(1)(G).
10 The first prong imposes liability on one who “knowingly makes, uses, or causes to be
11 made or used, a false record or statement material to an obligation to pay or transmit money
12 or property to the Government.” *Id.* The second prong, which DOJ alleges United violated
13 in this case, imposes liability on one who “knowingly conceals or knowingly and
14 improperly avoids or decreases an obligation to pay or transmit money or property to the
15 Government.” *Id.* DOJ asserts that “materiality is not a required element of establishing
16 liability under the second prong of the reverse false claim provision.” DOJ Mot., *supra* at
17 85. That argument is baseless. Not only is materiality a cornerstone element of fraud, but
18 the text, structure, and history of the reverse FCA all require its “rigorous materiality
19 requirement” to be enforced. *Escobar*, 579 U.S. at 181. Precedent and common sense
20 require the same.

21 **A. The Reverse FCA Requires Proving That The Alleged Fraud Was**
22 **Material**

23 DOJ asserts that “the structure of the statutory text” shows that the second prong of
24 the reverse FCA does not include a materiality element. Yet DOJ fails to address the
25 Supreme Court’s unanimous decision in *Escobar* addressing a mirror-image structure in
26 the same statute. DOJ Mot., *supra* at 85-86. While noting that *Escobar* is “[t]he seminal
27 case on materiality under the False Claims [A]ct,” DOJ cannot reconcile its position with
28 that decision—and does not even try to do so. *Id.*

1 **1. *The FCA’s Text and Structure Impose a Materiality Element***

2 In *Escobar*, the Supreme Court addressed the materiality requirement in a provision
3 of the affirmative FCA, 31 U.S.C. § 3729(a)(1)(A), which imposes liability on one who
4 “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or
5 approval.” That provision does not expressly include a materiality element. But the second
6 affirmative FCA provision that follows *does*: Section 3729(a)(1)(B) imposes liability on
7 one who “knowingly makes, uses, or causes to be made or used, a false record or statement
8 *material* to a false or fraudulent claim.” (emphasis added). Faced with this statutory
9 structure, the Supreme Court had no hesitation holding that *both* provisions require a
10 showing of materiality. *See* 579 U.S. at 190, 192-95.

11 Starting “with the language of the statute,” the Court recited the longstanding
12 principle of statutory interpretation that, “absent other indication, Congress intends to
13 incorporate the well-settled meaning of the common-law terms it uses.” *Id.* at 187
14 (citations omitted). The Court then explained that the common-law meaning of “fraud”
15 necessarily includes a “rigorous” materiality requirement. *Id.* at 192. As the Court held,
16 “the common law could not have *conceived of* ‘fraud’ without proof of materiality.” *Id.* at
17 193 (emphasis added) (citation omitted). What is more, that materiality standard is
18 “demanding”—the FCA “is not ‘an all-purpose antifraud statute,’ or a vehicle for
19 punishing garden-variety breaches of contract or regulatory violations.” *Id.* at 194 (citation
20 omitted). A rules violation cannot be material if the government would merely “have the
21 option to decline to pay if it knew of the defendant’s noncompliance.” *Id.* The Court
22 explained further, “if the Government pays a particular claim in full despite its actual
23 knowledge that certain requirements were violated, that is very strong evidence that those
24 requirements are not material.” *Id.* at 195. The Court thus unanimously enforced the
25 materiality requirement as to the first provision of the affirmative FCA,
26 Section 3729(a)(1)(A), even though it did not contain an express materiality requirement
27 like the second provision, Section 3729(a)(1)(B).

1 Indeed, the argument for including a materiality requirement in the first affirmative
2 FCA provision was so strong that DOJ conceded the point. Before the Supreme Court,
3 DOJ acknowledged the Court must adopt an interpretation “consistent with the FCA’s
4 common-law antecedents, and with this Court’s recognition that ‘the common law could
5 not have conceived of fraud without proof of materiality.’” Brief for the United States,
6 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 2016 WL 1554735, at *30
7 n.7 (Mar. 3, 2016) (conceding that both affirmative FCA provisions include a materiality
8 element but arguing for a weaker version of materiality than the Supreme Court adopted).
9 In doing so, DOJ recognized that even though the first affirmative FCA provision “does
10 not” have an express materiality requirement, the first provision must still be interpreted
11 as including a materiality requirement because “historically” such fraud terms were
12 understood “as limited to claims that are false or misleading in some *material* respect.” *Id.*

13 The reverse FCA provisions at issue here directly parallel the structure of the
14 affirmative FCA provisions in *Escobar*. The first reverse FCA prong, just like one of the
15 affirmative FCA provisions, includes an express materiality requirement tied to a false
16 statement—requiring a “false record or statement material to an obligation.” 31 U.S.C.
17 § 3729(a)(1)(G). But the second reverse FCA prong, like the other affirmative FCA
18 provision, does not. *See id.* The reasoning in *Escobar* applies just as clearly to this parallel
19 situation; even absent the express inclusion of the word “material,” the second prong of
20 the reverse FCA necessarily includes a materiality requirement because of its “common-
21 law antecedents” and the inconceivability of common-law fraud without a materiality
22 requirement. 579 U.S. at 193 (citation omitted). DOJ has no answer for *Escobar*, let alone
23 for its concession to the Supreme Court in that case.

24 **2. Legislative History Confirms the Statutory Text and Structure**

25 The legislative history likewise confirms that the second prong of the reverse FCA
26 includes a materiality element. In 2009, in the Fraud Enforcement and Recovery Act, Pub.
27 L. No. 111-21, 123 Stat. 1617 (“FERA”), Congress amended the FCA to add the second
28 prong of the reverse FCA at issue here. Before FERA, the reverse FCA contained only

1 one basis for liability, which required a “false record or statement to conceal, avoid, or
2 decrease an obligation to pay or transmit money or property to the Government.” 31 U.S.C.
3 § 3729(a)(7) (2008). This stood in contrast to the affirmative FCA provisions, which
4 contained two ways of establishing liability—one that required a false record or statement
5 and another that did not have that requirement. *See id.* § 3729(a)(1)–(2) (2008).

6 In FERA, Congress amended the reverse FCA with the goal of removing a
7 perceived loophole that resulted from the requirement of a “false record or statement,”
8 thereby making it parallel with the affirmative FCA. Both the Senate Judiciary report and
9 the Department of Justice acknowledged this targeted legislative objective. *See* Fraud
10 Enforcement and Recovery Act of 2009, S. Rep. No. 111-10 at 13-14 (Mar. 23, 2009).
11 The Senate Judiciary report explained that the reverse FCA as written at that time “does
12 not capture conduct described in [the affirmative FCA],” which extends beyond false
13 records or statements and includes “liability for actions to conceal, avoid, or decrease an
14 obligation directly to the Government.” *Id.* at 14. The report explained that FERA was
15 intended to “close[] this loophole.” *Id.*; *see also* Letter from M. Faith Burton, Acting
16 Assistant Attorney General, U.S. Dep’t of Justice, to Sen. Patrick Leahy, Chairman, Senate
17 Comm. On the Judiciary, at 2 (Feb. 24, 2009) (similar).

18 When FERA added a second basis for liability in the reverse FCA that did not
19 require a “false record or statement,” aligning it with the affirmative FCA, no one
20 suggested that the amendment would remove the longstanding common-law requirement
21 of materiality. Any such change would have been actively debated—or at least
22 *mentioned*—given the upheaval it would cause to the settled understanding that fraud must
23 be material. Yet there was no such debate or mention of eliminating the materiality
24 element. Congress “does not alter the fundamental details of a regulatory scheme in vague
25 terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.”
26 *Whitman v. Am. Trucking Assns.*, 531 U.S. 457, 468 (2001). If Congress had intended to
27 fundamentally redefine the FCA to omit the materiality requirement—thereby punishing
28 *immaterial* violations—it would have said so clearly, there would have been legislative

1 debate over that change, and it certainly would not have gone completely unnoticed until
2 this case over a decade later.

3 **3. DOJ's Contrary Position Is Not Supported by the Case Law and**
4 **Would Lead to Absurd Results**

5 DOJ's position on materiality is not only contrary to the text, structure, and history
6 of the FCA, it is also unsupported by the case law it invokes and would lead to untenable
7 outcomes.

8 *First*, DOJ incorrectly claims that "several Courts have expressly held that
9 materiality is not an element under the second prong of the reverse false claim provision."
10 DOJ Mot., *supra* at 85. None of the cases cited by DOJ hold any such thing. And counsel
11 is aware of no other case that does.

12 To the contrary, courts of appeal have applied *Escobar*'s materiality requirement
13 broadly to *all* FCA claims. *See, e.g., United States ex rel. Doe v. Heart Sol., PC*, 923 F.3d
14 308, 317 (3d Cir. 2019) (stating that *Escobar* "held that materiality is an element of *all*
15 *FCA claims*, regardless of whether the specific statutory provision lists materiality as an
16 element") (emphasis added); *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 105
17 (2d Cir. 2021) ("Although *Escobar* involved an implied false certification claim, nothing
18 in the opinion suggests that its materiality requirement was intended to be limited to that
19 specific theory of liability."). Similarly, in *Kelly v. Serco, Inc.*, 846 F.3d 325, 333–36 (9th
20 Cir. 2017), the Ninth Circuit confirmed that courts may "properly dismiss an FCA claim
21 on summary judgment based on a claimant's failure to meet the rigorous standard for
22 materiality under the FCA," including for "reverse false claims."

23 None of DOJ's cases conclude otherwise. DOJ first cites *United States ex rel.*
24 *Ormsby v. Sutter Health*, 444 F. Supp. 3d 1010 (N.D. Cal. 2020), claiming that it "held
25 that there was no materiality element under the second prong of the reverse false claim
26 provision." DOJ Mot., *supra* at 85-86. *Ormsby* contains no such holding. As DOJ's own
27 citation to *Ormsby* shows, that case merely held that the second prong of the reverse FCA
28 does not require showing "*a false record or statement* or that *a record or statement* was

1 material.” 444 F. Supp. 3d at 1056 (emphasis added). That quotation simply acknowledges
2 that the second prong of the reverse FCA no longer requires a false statement, which was
3 the legislative goal of FERA. *See supra*, at 89-90. *Ormsby* makes this point expressly in a
4 footnote, explaining that FERA was designed to eliminate the false statement requirement.
5 *See* 444 F. Supp. 3d at 1056 & n.408. In fact, no party in *Ormsby*—including DOJ—even
6 made the extreme no-materiality argument DOJ advances here. *See* United States’ Opp. to
7 Defs.’ Mot. to Dismiss, *United States ex rel. Ormsby v. Sutter Health, et al.*, No. 3:15-cv-
8 01062, Dkt. 82 (Aug. 27, 2019); Relator’s Opp. to Defs.’ Mot. to Dismiss, Dkt. 80 (Aug.
9 27, 2019). The court in *Ormsby* merely restated the impact of FERA—it did not *sua sponte*
10 issue a sweeping ruling that eliminated the reverse FCA’s materiality requirement.

11 DOJ’s three other citations also miss the mark. In *United States ex rel. Jacobs v.*
12 *Pac. Dermatology Inst., Inc.*, 2022 WL 17401522, at *13 (C.D. Cal. Aug. 16, 2022), the
13 court merely recited the elements for the reverse FCA’s second prong, noting that a relator
14 “need not show a false record or statement.” In *United States ex rel. Frey v. Health*
15 *Management Systems, Inc.*, 2021 WL 4502275, at *7 (N.D. Tex. Oct. 1, 2021), the court
16 issued no holding on whether materiality was a required element under the second prong
17 of the reverse FCA because it had already found that the relator had adequately pleaded
18 materiality under the first prong. And in *United States ex rel. Little v. Shell Exploration &*
19 *Production Co.*, 2017 WL 4742917, at *29 n.260 (S.D. Tex. Aug. 18, 2017), the FERA
20 amendments did not even apply to the case: “The parties and the United States agree that
21 the *pre-FERA* version of the FCA is applicable to the claims in this case.” (emphasis
22 added). *None* of these cases support DOJ’s position.

23 *Second*, DOJ’s attempt to eliminate the materiality requirement would result in
24 absurd outcomes never intended by Congress—not to mention outcomes the Supreme
25 Court already rejected in *Escobar*. There, the Supreme Court employed a vivid
26 hypothetical involving staplers to underscore the necessity of a rigorous materiality
27 requirement under the FCA. 579 U.S. at 195-96. The Court posited a scenario where the
28 government contracts for health services and includes a stipulation that contractors must

1 use “American-made staplers.” *Id.* at 195. At oral argument, DOJ argued that if the
2 contract made using American-made staplers a condition of payment, then a contractor
3 who otherwise fully performed the contracted health services but used “foreign staplers”
4 would be liable under the FCA regardless of whether its stapler use had any actual impact
5 on the government’s payment decision. *Id.* at 195-96. The Court swiftly rejected that
6 untenable position, explaining that the FCA “does not adopt such an extraordinarily
7 expansive view of liability.” *Id.* at 196. *Escobar* thus makes clear that, notwithstanding a
8 rule being contractually required or labeled a condition of payment, FCA liability does not
9 attach when violating such a rule would be immaterial because the government would not
10 have denied payment on that basis.

11 DOJ’s position here would allow exactly that untenable result. Under its view, a
12 defendant would incur liability under the reverse FCA in this very same stapler example
13 if the government simply added the allegation that the contractor *retained* the allegedly
14 noncompliant payments received under the contract—regardless of whether use of foreign
15 staplers would have had any impact on the government’s payment decision. DOJ thus asks
16 this Court to adopt the same “extraordinarily expansive view of liability” under the FCA
17 the Supreme Court unanimously rejected. *Id.* That would eviscerate *Escobar*. Just as the
18 affirmative FCA provisions necessitate a materiality requirement to prevent the statute
19 from becoming a tool for punishing minor infractions, the reverse FCA provisions must
20 also include a materiality requirement to maintain the integrity and purpose of the statute.
21 Without this safeguard, the reverse FCA would be susceptible to the same overreach and
22 misuse, transforming every minor regulatory misstep into actionable fraud, which the
23 Supreme Court explicitly directed courts to avoid. The Court should reject that radical
24 approach and enforce the FCA’s materiality requirement.

1 **4. This Case Illustrates the Critical Role Played by the Materiality**
2 **Element**

3 DOJ's argument is so extreme that, to counsel's knowledge, it is the first time that
4 DOJ has pressed this argument before any court. As already explained, DOJ conceded in
5 *Escobar* itself that a fraud statute like the FCA must be interpreted to include a materiality
6 requirement. *See supra*, at 88-89. And DOJ did not make this argument in *any* of the four
7 post-*Escobar* cases that DOJ incorrectly claims support its position. *See* DOJ Mot., *supra*
8 at 85-86; United States' Opp. to Defs.' Mot. to Dismiss, *United States ex rel. Ormsby v.*
9 *Sutter Health, et al.*, No. 3:15-cv-01062, Dkt. 82 (Aug. 27, 2019); United States'
10 Statement of Interest, *United States ex rel. Jacobs v. Pac. Dermatology Inst., Inc.*, No.
11 EDCV 20-1906 JGB (SHKx), Dkt. 38 (Mar. 25, 2022); United States' Statement of
12 Interest, *United States ex rel. Frey v. Health Mgmt. Sys., Inc.*, No. 3:19-CV-0920-B, Dkt.
13 32 (June 9, 2021); United States' Statement of Interest, *United States ex rel. Little v. Shell*
14 *Expl. & Prod. Co.*, No. CV H-07-871, Dkt. 251 (Dec. 23, 2016).

15 To be clear, there is no mystery as to why DOJ is resorting to this extreme argument
16 here: It is because the summary judgment record makes clear that CMS undisputedly knew
17 of United's conduct and did not consider it material to CMS's payment decision.
18 Accordingly, if the reverse FCA incorporates a materiality element—as it surely does—
19 then DOJ knows that its case cannot survive summary judgment.

20 As detailed above, DOJ cannot show that the alleged violation was material to
21 CMS's decision to pay United. *See* United MSJ, *supra* at 67-68 (citing evidence). CMS
22 was indisputably aware of United's chart review practices. *Id.* at 15-16. Notably, in 2014,
23 United met with CMS to discuss whether MA plans were required to confirm the validity
24 of diagnosis codes certified and submitted by doctors but not independently identified by
25 MA plan coders during chart review. JS at D123, D127; Exs. D-9 at 445-46, D-138 at
26 3487:24-88:10. And it is undisputed that United has repeatedly disclosed to CMS that it
27 did *not* affirmatively seek to confirm such codes in its chart review program. JS at D150-
28 D154; Exs. D-21 at 671, D-23 at 677, D-27 at 714, D-33 at 729-30, D-25 at 682. If CMS

1 considered those practices to be fraudulent, it would have refused to continue paying
2 United—or at least imposed some intermediate form of sanctions. *See* 42 C.F.R.
3 § 422.752. But it never did. JS at D227-231; Exs. D-9 at 384-88, D-131 at 3356:8-12. That
4 record—CMS’s “actual knowledge” of United’s conduct and its continued payment—is
5 “very strong evidence” that the purported fraudulent conduct was “not material.” *Escobar*,
6 579 U.S. at 195. DOJ comes nowhere close to satisfying the FCA’s “rigorous” materiality
7 requirement. *Id.* at 192.

8 Nor can DOJ reframe the materiality analysis by contending that CMS would have
9 taken action if it knew the specific diagnosis codes that were unsupported by medical
10 charts. Any such reframing cannot cure the materiality problem because it is inconsistent
11 with DOJ’s theory of fraud. In this case, DOJ has repeatedly argued that United’s conduct
12 was fraudulent because its chart-review process did not delete or investigate diagnosis
13 codes that doctors had certified and submitted to United, but which United’s coders did
14 not independently identify during their blind chart review. *See* United MSJ, *supra* at 16-
15 17. But CMS *knew* about this very process that DOJ now claims is fraudulent and
16 continued to pay United anyway. *Id.* at 13-16, 67-68, 77-78.

17 In addition, regardless of whether CMS knew *which* specific diagnosis codes
18 United’s coders did not independently identify, it knew that United was submitting
19 substantial volumes of such codes for reimbursement. *Id.* Nor can DOJ quibble over
20 whether CMS knew every minute detail of how United conducted chart review. CMS
21 knew all of the facts necessary for it to know that United was engaged in the very conduct
22 that DOJ now claims is fraudulent. *Id.* Yet CMS did not treat this conduct as fraudulent in
23 any way, neither declining payment, refusing to renew United’s contracts, nor imposing
24 any other form of lesser punishment whatsoever. JS at D229; Exs. D-8 at 384, 388-89, D-
25 131 at 3356:8-12.

26 DOJ also cannot solve its materiality problem by claiming that if United had
27 submitted requests to delete the diagnosis codes in question, CMS would have
28

1 automatically reduced United’s payments, thus rendering all of United’s action “material”
2 to payment. Such a sweeping theory fails in numerous respects.

3 *First*, that argument focuses on the wrong category for purposes of CMS’s payment
4 decision. While MA plans submit diagnosis codes to CMS, MA payment is ultimately
5 determined based on whether there is support for the beneficiary’s *health condition*. JS at
6 D31, D77; Exs. D-117 at 2976:13-77:20, D-145 at 3676:23-77:7. CMS validates a
7 beneficiary’s health condition provided that any medical chart or diagnosis code from a
8 doctor during the service year supports the condition—even if some other charts and
9 diagnosis codes do not. JS D39-D31; Ex. D-145 at 3676:23-77:7, D-141 at 3546:2-6. As
10 DOJ’s expert put it, if an MA plan “submits multiple diagnosis codes mapping to the same
11 HCC for a beneficiary, the beneficiary’s risk score does not depend on which specific
12 diagnosis code was reported” or “how many times a particular diagnosis code is reported
13 within a service year.” JS at D30; Ex. D-57 at 1454. An invalid diagnosis code is simply
14 immaterial when the same health condition is otherwise supported by valid data.

15 *Second*, the summary judgment record contains no evidence establishing that these
16 diagnosis codes were in fact unsupported and thus material to CMS’s payment decision.
17 To the contrary, the only direct evidence (the results of RADV audits of the overlapping
18 codes) shows that the health conditions for United’s beneficiaries—the relevant category
19 for payment—overwhelmingly *were* supported. JS D184-D185; Exs. D-64 at 1887-89, fig.
20 15. D-141 at 3520:13-21:2, D-63 at 1763.

21 *Third*, such a theory would gut the materiality requirement and leave *Escobar* an
22 empty shell. It is always true that CMS (or any other party) would accept a purported
23 repayment of an overpayment. If that were all that was required, DOJ could duplicate any
24 affirmative FCA claim with a reverse FCA claim, alleging that the government would have
25 accepted repayment of the funds obtained as a result of the false claims or statements if
26 offered. That would render the materiality element meaningless. It is well established that
27 the government cannot generate “redundant” reverse FCA claims this way. *See, e.g.,*
28 *United States v. Kinetic Concepts, Inc.*, 2017 WL 2713730, at *13-14 (C.D. Cal. 2017);

1 *Pencheng Si v. Laogai Rsch. Found.*, 71 F. Supp. 3d 73, 96-97 (D.D.C. 2014). Nor can it
2 defy *Escobar*'s clear admonition to "rigorous[ly]" enforce the FCA's materiality
3 requirement. 579 U.S. at 192.

4 **UNITED'S CONCLUSION**

5 For these reasons, this Court should grant United's motion for summary judgment,
6 and should deny DOJ's partial motion for summary judgment.

7 **UNITED STATES' CONCLUSION**

8 For the reasons above, United's motion for summary judgment should be denied
9 and the United States' motion for summary judgment should be granted.

10
11 Dated: August 6, 2024

Respectfully submitted,

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ATTESTATION

I hereby attest that the other signatories listed, on whose behalf this filing is submitted, concur in its content and have authorized its filing.

Dated: August 6, 2024

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

**STATEMENT OF
UNCONTROVERTED FACTS**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

1 Pursuant to Local Rule 56-1 and the Order re Summary Judgment Motions (ECF
2 No. 365), UnitedHealth Group Incorporated and its affiliated entities named as Defendants
3 in this action (“United” and “Defendants”) and Plaintiff United States of America
4 (“Plaintiff”) hereby submit the following Joint Statement of Uncontroverted Facts in
5 connection with the Joint Brief regarding the Cross Motions for Summary Judgment.

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
D1	For purposes of this litigation, the Defendants are collectively referred to as "United" or "UnitedHealth."	<i>See, e.g.</i> , Ex. D-1, Am. Compl. at 2-3	Undisputed.	
D2	Medicare is a federal health insurance program established under the Medicare and Medicaid Act for the elderly and disabled administered by the Centers for Medicare and Medicaid Services ("CMS").	42 U.S.C. § 1395c <i>et seq.</i> (federal statute noting the Medicare Part A program provides protection for those over the age of 65 and individuals under 65 who are disabled); <i>id.</i> § 1395j <i>et seq.</i> (federal statute providing that Medicare Part B is an insurance program is established "for aged and disabled individuals"); Ex. D-3, Dkt. No. 250-1 (Statement of Genuine Disputes and Additional Uncontroverted Facts ("Original SUF")) at A.1 (asserting that all parties to this litigation agree that "Medicare is a federal health insurance program for the elderly and disabled . . . administered by . . . CMS")	Undisputed.	
D3	Medicare Part A covers medical services furnished	<i>See</i> 42 U.S.C. § 1395c <i>et seq.</i> (federal statute describing	Undisputed that Medicare Part A covers	<i>See, e.g.</i> , Ex. P-41, 42 U.S. Code § 1395d(d) (describing hospice

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	by hospitals and other institutional doctors.	Medicare part A that states it provides protections for costs of “hospital, related post-hospital, home health services, and hospice care”); Ex. D-3, Original SUF at A.2 (noting that all parties to this litigation agree that Medicare Part A “covers medical services furnished by hospitals and other institutional care providers”)	medical services furnished by hospitals and other institutional providers. Otherwise disputed, mischaracterizes cited evidence.	coverage under Medicare Part A), Ex. P-42, 42 U.S. Code § 1395x(dd)(1) and (3)(B) (an attending physician for a hospice program may be a Physician, Nurse Practitioner, or a Physician’s Assistant)
D4	Medicare Part B is an optional supplemental insurance program that pays for items and services not covered by Part A, including outpatient physician services, clinical laboratory tests, and durable medical equipment, among other things.	42 U.S.C. § 1395l <i>et seq.</i> (federal statute describing coverage for Medicare Part B benefits); Ex. D-3, Original SUF at A.3 (noting that all parties to this litigation agree that Medicare Part B “is an optional supplemental insurance program that pays for items and services not covered by part A, including outpatient physician services, . . . clinical laboratory tests, and durable medical equipment, among other things” (internal quotations omitted))	Undisputed.	
D5	As a general matter, Medicare Parts A and B	Ex. D-143, Tee Dep. 19:11-44:11 (CMS employee	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	("Traditional Medicare") compensate providers on a fee-for-service ("FFS") basis.	describing his role as CMS Director of the Division of Practitioner Services (2018-present) and former roles as the Director of the Division of Encounter Data and Risk Adjustment Operations (2014-2018) and Deputy Director of the Division of Encounter Data and Risk Adjustment Operations (2013-2014)), 49:16-50:1 (defining Traditional Medicare); Ex. D-103, Duggan Dep. 223:8-9 (United expert explaining that "Traditional Medicare is fee for service and reimbursement is based on services"); Ex. D-3, Original SUF at A.7 (asserting that CMS pays providers directly for medical services under Parts A and B)		
D6	This matter concerns Part C and Part D of the Medicare Act.	Ex. D-1, Am. Compl. ¶¶ 54-65 (describing Medicare Parts C and D Risk Adjustment Payments)	Undisputed.	
D7	Medicare Part C, now known as Medicare Advantage (or the "Medicare	See 42 U.S.C. § 1395w-21 <i>et seq.</i> (federal statute outlining that Medicare+Choice	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	Advantage program”), allows people to opt out of Parts A and B and instead enroll in health insurance plans offered by private insurers (“Medicare Advantage plans”).	individuals can enroll either in Medicare fee-for-service or a Medicare+Choice plan); Ex. D-143, Tee Dep. 26:23-27:4 (CMS employee describing that Medicare Advantage is an alternative to traditional Medicare); Ex. D-1, Am. Compl. ¶ 45 (same); Ex. D-3, Original SUF at A.4 (asserting that Medicare Part C is known as Medicare Advantage)		
D8	Medicare Part D allows people to obtain prescription drug coverage through Medicare Advantage plans.	Ex. D-1, Am. Compl. ¶ 46	Undisputed.	
D9	CMS pays the Medicare Advantage plans a fixed amount per month for each member that they insure, based in part on the relative health of the individual members.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 21 (government expert describing the per member, per month payments CMS makes to Medicare Advantage plans); Ex. D-52, Amended Acevedo Rep. (4/5/2024) ¶¶ 24-25 (government expert describing monthly premiums paid to Medicare Advantage plans); Ex. D-56, Duggan Rep. (9/29/2023)	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		¶ 16 (United expert explaining how CMS compensates Medicare Advantage plans)		
D10	Paying Medicare Advantage plans based on the relative health of their members is called "risk adjustment."	Ex. D-149, 2004 Advanced Notice Attachment 2 ("The Balanced Budget Act of 1997 (BBA) mandated that a risk adjustment payment methodology, incorporating information on beneficiaries' health status, be implemented in the Medicare+Choice (M+C) program no later than January 2000")	Undisputed.	
D11	Medicare Advantage plans may provide supplemental benefits to their members consisting of benefits that Traditional Medicare does not provide to its beneficiaries.	42 U.S.C. § 1395w-22(a)(3) (federal statute noting that Medicare+Choice plans may provide supplemental benefits to enrollees); <i>Matthews v. Leavitt</i> , 452 F.3d 145, 146 n.1 (2d Cir. 2006) (noting that Part C plans must provide the same benefits under Parts A and B and may also provide supplemental benefits); Ex. D-3, Original SUF at A.5 (same); Ex. D-56, Duggan Rep. (9/29/2023) ¶¶ 45, 53-54, 58, 91 (United expert	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		describing supplemental benefits Medicare Advantage plans may offer); Ex. D-127, Limmer 30(b)(6) Dep. 149:9-150:2 (CMS corporate representative agreeing that Medicare Advantage plans are required to use their rebate to provide supplemental benefits)		
D12	The supplemental benefits that Medicare Advantage plans can provide to their members include vision care.	Ex. D-56, Duggan Rep. (9/29/2023) ¶¶ 45, 58, 91 (United expert providing examples of supplemental benefits like vision care); Ex. D-99, Creighton Dep. (3/23/2022) 33:7-34:6 (former CMS employee Sean Creighton describing his prior role as the CMS Director for the Division of Payment Policy from 2007-2012), 41:21-45:23 (describing the additional benefits Medicare Advantage plans offer their beneficiaries, including vision care)	Undisputed.	
D13	The supplemental benefits that Medicare Advantage plans can provide to their	Ex. D-56, Duggan Rep. (9/29/2023) ¶¶ 53, 58, 91 (United expert providing	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	members include dental care benefits.	examples of supplemental benefits like dental care); Ex. D-99, Creighton Dep. (3/23/2022) 41:21-45:23 (former CMS employee describing the additional benefits Medicare Advantage plans offer their beneficiaries, including dental care)		
D14	Medicare Advantage plans can provide these supplemental benefits to their members at no additional cost to those members.	Ex. D-56, Duggan Rep. (9/29/2023) ¶¶ 33,45, 54, 58 (United expert describing reduced costs in Medicare Part C); Ex. D-99, Creighton Dep. (3/23/2022) 23:12–26:11 (describing role as former CMS Deputy Administrator and Director of the Center for Medicare), 41:21-45:23 (describing reduced costs in Medicare Part C)	Undisputed.	
D15	The Medicare Advantage program is intended to pay Medicare Advantage plans more per month for the risk of insuring sicker beneficiaries and less per month for the risk of	Ex. D-86, Kronick Dep. Ex. 1535 at 3 (noting CMS pays MA plans more for older and sicker enrollees); Ex. D-127, Limmer 30(b)(6) Dep. 75:20-23 (CMS corporate representative describing that risk scores are	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	insuring healthier beneficiaries.	calculated based demographic variables and health conditions)		
D16	CMS uses hierarchical condition categories ("HCCs") to determine the payment that is received by the Medicare Advantage plan for the plan's beneficiaries.	Ex. D-97, Cavanaugh Dep. 49:22-50:17 (former CMS employee describing how HCCs are used to calculate costs for beneficiaries); Ex. D-18, 88 Fed. Reg. 6643, 6644 (Feb. 1, 2023) (describing HCCs and how those are used to calculate risk scores); Ex. D-73, Lara Dep. Ex. 1133-2 at 803-04 (same)	Undisputed.	
D17	Diagnosis codes are alphanumerical codes that represent a patient's health conditions.	Ex. D-132, Paul Dep. 16:1-29:1 (CMS employee Rebecca Paul describing her role as CMS Director for the Division of Plan Policy in the Medicare Plan Payment Group (2012-Present) and Senior Health Policy Analyst (2005-2012)), 31:21-32:5 (describing diagnosis codes and their use); Ex. D-67, Acevedo Dep. Ex. 1582 (government expert describing medical codes)	Disputed as to the description of Ex. D-67 in the citation parenthetical, mischaracterizes cited evidence. Otherwise, undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
D18	HCCs are made up of groups of diagnosis codes that are related clinically and have similar cost implications.	Ex. D-18, 88 Fed. Reg. 6643, 6644 (Feb. 1, 2023) (describing HCCs); 42 C.F.R. § 422.2 (federal regulation noting that HCCs are groups of disease codes)	Undisputed.	
D19	After a patient visits a doctor, the doctor is expected to document the encounter, including the patient's diagnoses, in a medical chart.	Ex. D-54, Blair Rep. (9/29/2023) ¶ 7 (United expert describing what CMS uses to calculate payments to plans, including diagnosis codes reported by providers after patient visits); <i>see, e.g.</i> , Ex. D-150, MAPL006426592 (example of a medical chart)	Disputed to the extent the fact implies a doctor documents a diagnosis code in the medical record, conflicting evidence presented. Disputed to the extent that the fact states a doctor documents a diagnosis in the medical record, mischaracterizes cited evidence and conflicting evidence presented. Otherwise, undisputed.	Ex. D-54, Blair (United Expert) Rep. (Sept. 29, 2023), ¶ 7 ("After a patient visit, a provider submits the claim to the patient's MA Plan, which contains information about the patient visit, such as the services provided and relevant diagnosis codes. A provider may identify the diagnosis code(s) to submit on the claim or the provider may rely on coders to review the information documented in a patient's medical record and translate this information into diagnosis codes. The MA Plan then, in turn, submits the diagnosis codes for all its beneficiaries to CMS, and CMS uses this information (along with other characteristics of the beneficiary, including demographic information) to determine payment to the MA Plan for providing health coverage to this beneficiary."); Ex. D-150,

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
				MAPL006426592 at MAPL006426612-6614 (medical record does not include a diagnosis code); Ex. P-4, Dickey Tr. 49:22-50:24 (Optum Coding Director testifying that a diagnosis is documented in a medical record and a coder translates the diagnosis into an ICD-9 and 10 diagnosis code); Ex. P-5, United 30(b)(6) (Sedor) Tr. 120:21-122:21 (Corporate representative confirming that, to submit a diagnosis code for payment, the diagnosis must be a confirmed and current diagnosis that is documented in the medical record); Ex. P-82, Ferron Tr. 190:25-193:22 (United's coding consultant agreeing Physician queries are necessary "when clinical indications are noted in the medical record that raise the possibility that a condition may be present, but is not stated as a diagnosis.")
D20	After a doctor documents an encounter with a patient in a medical chart, the doctor or the doctor's coder then identifies one or more diagnosis codes that they	Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 7-9 (describing provider coding and chart review of codes reported by providers); Ex. D-106, Ferron Dep. 219:15-220:19 (iCodify	Disputed to the extent fact implies that only a doctor or a certified medical coder assigns diagnosis codes, mischaracterizes	Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: "In all but the largest physician practices and academic

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	determine match the conditions documented in the medical chart.	employee noting that the physician, medical provider, or coder could provide the diagnostic coding)	evidence. Otherwise, undisputed.	medical centers, provider coders may not hold coding certifications.”)
D21	After a patient visits a doctor and the doctor or the doctor’s coder identifies one or more diagnosis codes that they determine match the conditions documented in the medical chart, the doctor then submits that information on a claim form to a Medicare Advantage plan (if the beneficiary is in the Medicare Advantage program).	Ex. D-54, Blair Rep. (9/29/2023) ¶ 7 (United expert noting that providers submit claims to MA Plans after patient visits); Ex. D-40, Claim Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf) (example claim form)	Disputed to the extent that fact implies that only a doctor or a certified medical coder assigns diagnosis codes, mischaracterizes evidence. Otherwise, undisputed.	Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: “In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications.”)
D22	When submitting the claim form, doctors certify that the information on the claim form, including diagnosis codes, is correct.	Ex. D-126, Leonard 30(b)(6) Dep. 204:21-205:15 (CMS corporate representative noting providers agree to submit accurate claims); Ex. D-113, Higgins Dep. 132:2-133:2 (former United employee stating that providers were required to attest that the information they	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		provided was accurate, complete, and truthful)		
D23	There are thousands of possible diagnosis codes that map to HCCs.	Ex. D-18, 88 Fed. Reg. 6643, 6647 (Feb. 1, 2023) (federal regulation noting “[t]here are approximately 9,875 diagnoses mapped to 86 HCCs in the CMS-HCC Risk Adjustment Model for 2022”); <i>see</i> Ex. D-43, Kimberly O’Malley <i>et al.</i> , Measuring Diagnoses: ICD Code Accuracy, 40 Health Servs. Res. 1620, 1621, 1629 (2005) (noting ICD-10-CM has 120,000 total codes)	Undisputed.	
D24	Many different diagnosis codes map to the same HCC.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 106 & n.145 (United expert stating that “[m]ore than 9,500 unique ICD-10-CM diagnosis codes mapped to just 79 unique HCC codes”); Ex. D-18, 88 Fed. Reg. 6643, 6647 (Feb. 1, 2023) (federal regulation noting that there may be multiple diagnoses that substantiate the same HCC)	Disputed to the extent the fact implies that every HCC has many diagnosis codes mapping to it, conflicting evidence presented. Otherwise, undisputed.	<i>See, e.g.</i> , Ex. P-43, Risk Model Diagnoses for FY 2012, available at https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/risk2012 (last visited July 2, 2024) (showing that only one diagnosis code, ICD-9-CM 7991 Respiratory Arrest, mapped to HCC 78 for FY 2012)

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
D25	For dates of service in 2016, the diagnosis code for “type 2 diabetes mellitus without complications” maps to HCC 19.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 115	Undisputed.	
D26	For dates of service in 2016, the diagnosis code “other diabetes mellitus without complications” maps to HCC 19.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 115	Undisputed.	
D27	For dates of service in 2016, other diagnosis codes map to HCC 19.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 115	Disputed. Incomplete fact, not supported by cited evidence.	
D28	For dates of service in 2012, many diagnosis codes for many different forms of malignant cancer would each map to HCC 7.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 113-115	Undisputed.	
D29	If at least one diagnosis code corresponding to a particular HCC is supported by at least one medical chart for the beneficiary for the year,	<i>See, e.g.</i> , Ex. D-15, CMS-4085-F – 75 Fed. Reg. 19678, 19748 (describing the one best medical record policy for RADV audits); <i>see also, e.g.</i> , Ex. D-145, Tudor Dep. 18:5-31:4 (former CMS	Disputed. Conflicting evidence presented.	Ex. P-6, Renjilian (United Expert) Tr. 32:8-36:8 (UnitedHealth’s expert witness agreeing that in the regular payment process, every diagnosis submitted to CMS for payment must be supported by medical record

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	payments associated with that HCC are appropriate.	employee Cynthia Tudor describing her former roles as the CMS Deputy Director (2014-2017) and Director of the Medicare Drug Benefit and C & D Group (2004-2013), and employee in the office of Research and Demonstrations (1994-2005), 212:23-213:7 (agreeing that there could be multiple medical records to support one diagnosis code); 221:15-223:7 (agreeing that a plan would not be overpaid if a diagnosis code was deleted that had no impact on risk adjustment); Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 113-115 (United expert describing instances where deletion of diagnosis codes would not change the HCC, and therefore no impact on payment); Ex. D-60, Ingber Rep. at 19 (government expert explaining that it “does not matter how many times a condition is coded through the year or whether more than one ICD-10 code in an HCC is reported”); Ex. D-141, Stark Dep. 67:20-68:10 (government expert describing		associated with a face-to-face encounter on a specific date of service); Id at 68:17-70:7 (United expert testifying that the CMS payment process will not account for diagnosis codes that have not been submitted to CMS and diagnosis code must be submitted to CMS in order to be considered in the risk score calculation for a given beneficiary); Ex. D-64, Renjilian (United Expert) Updated Rep. (Dec. 3, 2023), p. 11 at ¶ 31 and p. 12 at ¶ 34 (same); Ex. P-6, Renjilian (United Expert) Tr. 50:19-51:7 (United expert testifying that he would advise clients to delete diagnosis codes that were not supported by the medical record even if the client did not know if the deletion of the diagnosis codes would have a financial impact); Ex. P-10, Rice Tr. 84:13-85:1 (CMS Deputy Director of Medicare testifying that plans need to correct inaccurate date regardless of whether the diagnosis code has a payment impact if deleted); <i>id.</i> at 147:14-148:3 (same); Ex. P-5, United 30(b)(6) (Sedor) Tr. 85:8-86:22 (UnitedHealth Corporate Representative confirming “The expectation is that every diagnosis

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		that “only a single instance of each HCC matters”); Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 31 (government expert describing that a beneficiary’s risk score doesn’t depend on which diagnosis code was reported that maps to the same HCC)		code we submit is supported by a medical record, so we would expect to only get paid on a diagnosis supported by a medical record.”); Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (CMS stating that submission of a diagnosis code is considered a claim for payment without distinguishing whether the diagnosis code is the only one submitted for the year that maps to a given HCC); Ex. P-9, Medicare Managed Care Manual, Ch. 7, Exhibit 30 (Aug. 13, 2004) (“... a medical record must substantiate all diagnostic information provided to CMS.”); Ex. P-8, Medicare Managed Care Manual, Rev. 118 (September 19, 2014), Ch.7 § 40 (requiring every diagnosis code submitted to CMS to be derived from face-to-face encounters and supported by documentation in the medical record underlying the encounter)
D30	Dr. Garthwaite explained that if a Medicare Advantage plan “submits multiple	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 31	Undisputed.	

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	diagnosis codes mapping to the same HCC for a beneficiary, the beneficiary's risk score does not depend on which specific diagnosis code was reported. Nor does the risk score depend on how many times a particular diagnosis code is reported during a service year."			
D31	A health plan is not overpaid for a particular health condition (HCC) when that HCC is supported by documentation in the medical record for the beneficiary for the year.	Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 55:14-56:20 (CMS corporate representative stating that if CMS confirms a diagnosis code submitted during RADV, then the MA plan is not overpaid); Ex. D-145, Tudor Dep. 212:23-213:7 (former CMS employee agreeing that a plan is not overpaid if a code that is deleted was supported by another medical record)	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. P-6, Renjilian (United Expert) Tr. 68:17-70:7 (testifying that the CMS payment process will not account for diagnosis codes that have not been submitted to CMS); Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (CMS stating that submission of a diagnosis code is considered a claim for payment without distinguishing whether the diagnosis code is the only one submitted for the year that maps to a given HCC); Ex. P-9, Medicare Managed Care Manual, Ch. 7, Exhibit 30 (Aug. 13, 2004) ("... a medical record must substantiate all diagnostic information provided to CMS."); Ex. P-8, Medicare

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				Managed Care Manual, Rev. 118 (September 19, 2014), Ch.7 § 40 (requiring every diagnosis code submitted to CMS to be derived from face-to-face encounters and supported by documentation in the medical record underlying the encounter); Ex. P-5, United 30(b)(6) (Sedor) Tr. 85:8-86:22 (UnitedHealth Corporate Representative confirming "The expectation is that every diagnosis code we submit is supported by a medical record, so we would expect to only get paid on a diagnosis supported by a medical record."); <i>id.</i> at 94:14-95:4 (United corporate representative testifying that diagnosis codes is one of the data elements an MAO must submit to CMS in order to receive payment); Ex. P-6, Renjilian (United Expert) Tr. 32:8-36:8 (UnitedHealth's expert witness agreeing that in the regular payment process, every diagnosis submitted to CMS for payment must be supported by medical record associated with a face-to-face encounter on a specific date of service); Ex. D-64, Renjilian (United Expert) Updated Rep. (Dec. 3, 2023), p. 11 at ¶ 31 and p. 12 at ¶ 34 (same); Ex. P-10, Rice Tr. 84:13-85:1 (CMS

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				Deputy Director of Medicare testifying that plans need to correct inaccurate date regardless of whether the diagnosis code has a payment impact if deleted); <i>id.</i> at 147:14-148:3 (same); Ex. P-6, Renjilian (United Expert) Tr. 50:19-51:7 (United expert testifying that he would advise clients to delete diagnosis codes that were not supported by the medical record even if the client did not know if the deletion of the diagnosis codes would have a financial impact)
D32	Diagnosis codes that are not supported in the beneficiary's medical charts are sometimes submitted on the claim form when treating doctors are submitting claims to Medicare Advantage plans.	Ex. D-44, Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare Advantage at 103-04, in Report to Congress: Medicare and Health Care Delivery System (Chapter 4), Washington, DC (June 2012) (describing that coding for various HCCs between 2007 and 2008 were not consistently coded by MA plans in those years)	Undisputed.	

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D33	Diagnosis codes that are not supported in the beneficiary's medical charts are sometimes submitted on the claim form when treating doctors are submitting claims to CMS directly.	Ex. D-122, Kapustij Dep. (8/25/2022) 15:21-20:22 (former CMS employee Carolyn Kapustij describing her role in the CMS Division of Payment Validation from 2009-2012), 39:22-40:4 (stating there was coding error in FFS claims data); Ex. D-44, Medicare Payment Advisory Commission, <i>Issues for Risk Adjustment in Medicare Advantage</i> at 103-04, in Report to Congress: Medicare and Health Care Delivery System (Chapter 4), Washington, DC (June 2012) (describing that coding for various HCCs between 2007 and 2008 were not consistently coded by MA plans in those years); Ex. D-48, Richard Kronick & W. Pete Welch, <i>Measuring Coding Intensity in the Medicare Advantage Program</i> , Medicare & Medicaid Research Review, 4(2), at E5 (2014) (stating FFS coding is "often incomplete"); Ex. D-119, Hutchinson Dep. 18:12-22 (testifying about his role as Director of the Medicare Plan	Undisputed to the extent this fact is referring to providers in the Medicare Part A and Part B programs, who submit claims to CMS directly. Otherwise disputed, not supported by cited evidence.	

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		Payment Group from September 2006 to June 2010), 32:21-33:4 (former government employee stating there was coding error in FFS claims data); Ex. D-120, Ingber Dep. (6/14/2022) 21:19-23:14 (former CMS employee Melvin Ingber describing his former role as Director of Division of Payment Research within CMS), 32:12-21 (stating that FFS data had "all kinds" of errors)		
D34	Diagnosis codes that are supported in the beneficiary's medical charts are sometimes left off the claim forms when the treating doctors are submitting claims to Medicare Advantage plans.	Ex. D-117, Hornsby 30(b)(6) Dep. 144:4-145:4 (11/21/2023) (CMS corporate representative noting that MA plans discovered that providers were not coding completely); Ex. D-54, Blair Rep. (9/29/2023) ¶ 18 (United expert stating that coders conducting chart review for MA plans may find diagnosis codes that are submitted by the medical record but were not submitted on the claim); Ex. D-111, Grower Dep. 113:17-114:3 (former United employee noting that there was	Undisputed.	

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		some encounter data that was not fully reported)		
D35	Diagnosis codes that are supported in the beneficiary's medical charts are sometimes left off the claim forms when the treating doctors are submitting claims to CMS directly.	Ex. D-120, Ingber Dep. (6/14/2022) 32:12-21	Disputed to the extent fact is not supported by cited evidence and disputed to the extent that providers do not submit directly to CMS in Medicare Advantage, conflicting evidence presented. Otherwise, undisputed.	Ex. P-5, United 30(b)(6) (Sedor) Tr. 59:19-63:1 (Corporate representative describing the timing of the Part C and D data submission process and testifying that all UnitedHealth had to submit all additional data for a beneficiary by the final submission deadline); Ex. P-1, Joint Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations and Related Entities, ¶¶ 3, 5, 6 (Optum and the Defendant MAOs were authorized pursuant to an EDI agreement to submit data to CMS on behalf of the UnitedHealth MAOs and "Each of the diagnosis codes listed on Attachment 1 to Dr. Garthwaite's expert report is associated with a UnitedHealth MAO that executed an applicable MA Contract, MA-PD Addendum, EDI Agreement and an Attestation, and for which Optum executed an EDI Agreement.")

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D36	Doctors are generally paid based on procedures, not based on diagnosis codes.	Ex. D-54, Blair Rep. (9/29/2023) ¶ 18 (United expert stating that provider reimbursement is more commonly derived from procedures, rather than documentation of diagnoses); Ex. D-48, Richard Kronick & W. Pete Welch, <i>Measuring Coding Intensity in the Medicare Advantage Program</i> , Medicare & Medicaid Research Review, 4(2), at E3 (2014) (noting physicians billing under FFS are paid based on procedures); Ex. D-87, Acevedo Dep. 118:8-15 (government expert noting that providers are paid on procedures, and therefore they often fail to submit a complete set of diagnosis codes); Ex. D-42, Gregory C. Pope et al., <i>Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model</i> , Health Care Finance Review 25, at 129 (Summer 2004) ("Concern about the quality of diagnostic reporting is the greatest in physician offices, where	Disputed. Conflicting evidence presented.	Ex. P-44, CMS 30(b)(6) (Leonard) Tr. 241:4-242:9 (describing the impact a diagnosis code that is not supported by medical record documentation has on payments to providers in traditional Medicare); Ex. P-46, Ingber (US Expert) Tr. 74:15-75:14 (US Expert describing how certain providers in traditional Medicare can also receive payments based on principal diagnosis identified with the service); Ex. P-33, United 30(b)(6) (Theisen) Tr. 93:15-94:18 (Corporate representative describing how Medicare Advantage capitated provider groups are paid on a "on a capitated percentage of revenue basis for the members they served."); Ex. P-45, Redmond Tr. 80:22-81:22 (defining capitated providers as providers paid on a per member per month basis to care for beneficiaries and fee-for-service providers as providers paid based on every encounter with the provider has with a beneficiary); Ex. P-5, United 30(b)(6) (Sedor) Tr. 133:9-134:17 (Corporate representative describing provider types with an

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		diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals.”).		incentive to oversubmit diagnosis codes)
D37	To be paid, doctors only need to submit on a claim form one diagnosis code that they attest is true and accurate.	Ex. D-107, Foster Dep. 21:9-19 (former CMS employee Richard Foster testifying he was CMS Chief Actuary for 18 years from 1995 through January 2013), 62:12-20 (noting that providers are not supposed to submit every diagnosis that a patient has); Ex. D-99, Creighton Dep. (3/23/2022) 95:7-18 (former CMS employee stating that physicians can submit amended claim forms if their first claim was missing a diagnosis but there is no incentive to do so); Ex. D-98, Chaudhuri Dep. 30:5–18 (describing prior role as Deputy Director of CMS Division of Payment Policy from 2012 to 2015), 168:5-169:15 (agreeing that a claim may not indicate the diagnosis code but the costs are still accurately captured); Ex. D-40, Claim Form 1500 (available at: https://www.cms.gov/Medicare/	Undisputed to the extent this fact applies to non-audited Medicare Part A and B claims. Otherwise disputed for Medicare Part A and B claims that are later audited and Part C and D submissions, conflicting evidence presented.	Ex. P-44, CMS 30(b)(6) (Leonard) Tr. at 241:4-242:9 (describing the impact a diagnosis code that is not supported by medical record documentation has on payments to providers in traditional Medicare, including a statement that an auditor may downgrade the code to one that has not been submitted but is supported by the medical record); Ex. P-33, United 30(b)(6) (Theisen) Tr. 93:15-94:18 (Corporate representative describing how Medicare Advantage capitated provider groups are paid on a “on a capitated percentage of revenue basis for the members they served.”); Ex. P-45, Redmond Tr. 80:22-81:22 (defining capitated providers as providers paid on a per member per month basis to care for beneficiaries and fee-for-service providers as providers paid based on every encounter with the provider has with a beneficiary); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17

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		CMS-Forms/CMS-Forms/downloads/cms1500.pdf (example claim form including an attestation)		(Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement)
D38	Doctors do not generally have an incentive to list all supported diagnosis codes on the claim form submitted to CMS.	Ex. D-152, AAPC, <i>Risk Adjustment—Predictive Modeling, Documentation & Capture of Diagnosis Code</i> at 19-20 (2014) (noting that “[i]f one were to ask any coder, biller, or provider how a diagnosis code is chosen for a particular visit, the answer will likely be the diagnosis code that will get the procedure code paid”); Ex. D-48, Richard Kronick & W. Pete Welch, <i>Measuring Coding Intensity in the Medicare Advantage Program</i> , Medicare & Medicaid Research Review, 4(2), at E3 (2014) (describing that physicians billing FFS are paid based on procedures, not on the number of diagnoses, and therefore will not submit all diagnoses on the claim to CMS)	Undisputed to the extent this fact is limited to Medicare Parts A and B but disputed to the extent it applies to Medicare Parts C and D, conflicting evidence provided.	Ex. P-33, United 30(b)(6) (Theisen) Tr. 93:15-94:18 (Corporate representative describing how capitated provider groups are paid on a “on a capitated percentage of revenue basis for the members they served.”); Ex. P-45, Redmond Tr. 80:22-81:22 (defining capitated providers as providers paid on a per member per month basis to care for beneficiaries and fee-for-service providers as providers paid based on every encounter with the provider has with a beneficiary); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); <i>id.</i> at 133:9-134:17 (describing providers with an incentive to oversubmit diagnosis codes)

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D39	Doctors do not generally have an incentive to list all supported diagnosis codes on the claim form submitted to the Medicare Advantage plan.	Ex. D-87, Acevedo Dep. 118:8-15 (government expert noting that providers are paid on procedures, and therefore they often fail to submit a complete set of diagnosis codes); Ex. D-54, Blair Rep. (9/29/2023) ¶ 18 (United expert stating that provider reimbursement is more commonly derived from procedures, rather than documentation of diagnoses)	Disputed. Conflicted evidence presented.	Ex. P-33, United 30(b)(6) (Theisen) Tr. 93:15-94:18 (Corporate representative describing how capitated provider groups are paid on a "on a capitated percentage of revenue basis for the members they served."); Ex. P-45, Redmond Tr. 80:22-81:22 (defining capitated providers as providers paid on a per member per month basis to care for beneficiaries and fee-for-service providers as providers paid based on every encounter with the provider has with a beneficiary); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); <i>id.</i> at 133:9-134:17 (Corporate representative describing providers with an incentive to oversubmit diagnosis codes)
D40	One reason that not all diagnosis codes that correspond to a patient's medical chart are submitted on the claim forms is	Ex. D-87, Acevedo Dep. 118:515 (government expert noting that providers are paid on procedures, and therefore they often fail to submit a complete	Disputed. Conflicting evidence presented.	Ex. P-46, Ingber (US expert) Tr. 74:15-85:13 (US Expert describing Medicare Advantage provider incentives to submit diagnosis codes to increase payments from CMS or

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	because the doctors do not have an incentive to list them all.	set of diagnosis codes); Ex. D-133, Poehling Dep. 218:24-220:9 (former United employee noting one reason doctors do not have an incentive to code completely is that only one code is required to justify a procedure in a Medicare claim)		increase bonus payments from an MAO); Ex. P-33, United 30(b)(6) (Theisen) Tr. 93:15-94:18 (Corporate representative describing how Medicare Advantage capitated provider groups are paid on a "on a capitated percentage of revenue basis for the members they served."); Ex. P-45, Redmond Tr. 80:22-81:22 (defining Medicare Advantage capitated providers as providers paid on a per member per month basis to care for beneficiaries and fee-for-service providers as providers paid based on every encounter with the provider has with a beneficiary); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that Medicare Advantage capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); <i>id.</i> at 133:9-134:17 (describing provider types with an incentive to oversubmit diagnosis codes)
D41	It is common practice for Medicare Advantage plans to conduct reviews of patient medical charts to improve	Ex. D-119, Hutchinson Dep. 78:17-79:11 (former CMS employee noting that CMS knew about MA plans	Disputed to the extent fact claims chart reviews are a "common practice", not supported	

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	the completeness of diagnoses submitted to CMS.	conducting chart reviews and therefore having more codes); Ex. D-99, Creighton Dep. (3/23/2022) 127:13-25 (former CMS employee noting CMS understood MA plans conducted reviews of medical records to look for additional codes); Ex. D-54, Blair Rep. (9/29/2023) ¶ 17 (United expert stating MA plans often conduct chart reviews to determine whether additional diagnoses are documented in medical records); Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 34:13-16 (United corporate representative stating that chart review was trying to provide a more complete health status); Ex. D-125, Lambert Dep. 189:6-15 (United expert stating that adding unsubmitted codes in their expert analysis would result in more complete coding, similar to MA coding)	by cited evidence. Otherwise, undisputed.	
D42	The practice of reviewing medical charts to identify diagnosis codes that are supported by documentation	Ex. D-54, Blair Rep. (9/29/2023) ¶ 17 (United expert stating MA plans often conduct chart reviews to determine	Undisputed.	

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	in those charts is sometimes called "chart review."	whether additional diagnoses are documented in medical records); Ex. D-138, Schumacher Dep. 38:1-22 (United employee describing chart review); Ex. D-92, Bird Dep. (8/10/2022) 229:11-22 (same)		
D43	Medicare Advantage plans conduct these chart reviews because doctors do not always submit all the applicable diagnosis codes for a patient on the claim form even though those diagnosis codes are supported by documentation in the patient's medical chart.	Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 16-18 (United expert describing that providers do not have incentives to report all applicable diagnoses); Ex. D-123, Kessler Dep. 69:5-14 (United expert noting plans conduct chart reviews to have diagnoses that better reflect a patient's true medical records); Ex. D-111, Grower Dep. 113:17-114:3 (Optum employee noting that there was encounter data that was not fully reported, so chart review could be used to validate other diagnoses that could be submitted to CMS)	Disputed to the extent fact fails to present other reasons why MA plan performs chart reviews, mischaracterizes evidence. Otherwise, undisputed.	Ex. P-11, Dep. Ex. 381, United response to US Interrogatory (Set Six, Jul. 19, 2022), at Response to Interrogatory 18 (United estimated that for Date of Service Years 2009-2016, CMS paid it more than \$7.2 billion in additional risk adjustment payments or codes United added during chart review that were not previously submitted by providers)
D44	Medicare Advantage plans often use medical coders to review patients' medical	Ex. D-145, Tudor Dep. 110:3-17 (former CMS employee describing chart review and	Disputed as to whether Medicare Advantage plans "often" use	

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	charts to identify diagnosis codes that are supported by documentation in those charts.	noting a reason for chart review is to look for diagnoses that a provider failed to include); Ex. D-54, Blair Rep. (9/29/2023) ¶ 16 (United expert noting that MA plans may conduct chart reviews using medical coders to determine diagnoses codes that are supported by documentation)	medical coders to review patients' medical charts, not supported by cited evidence. Otherwise, undisputed.	
D45	United conducted chart reviews.	Ex. D-147, Meyer Dep. 145:24-146:14 (United employee describing chart review); Ex. D-95, Brennan Dep. 131:21-133:13 (former United employee describing chart review and noting Optum performed chart review for UnitedHealthcare Medicare & Retirement); Ex. D-91, Bird 30(b)(6) Dep. (6/22/2023) 50:23-51:10 (United employee stating Optum performed chart review for UnitedHealthcare)	Undisputed.	
D46	As part of its chart review program, United retrieved available patient medical	Ex. D-111, Grower Dep. 120:17-24 (former United employee agreeing that part of chart review included collecting	Disputed. Mischaracterizes evidence.	Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 221:19-222:2 (Corporate representative testifying that a medical record collected by

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	records from doctors for a given date of service.	medical records from providers); Ex. D-95, Brennan Dep. 131:21-132:5 (former Optum employee agreeing that part of chart review included collecting medical records from providers)		United for review in Chart Review could contain multiple dates of service, reflecting multiple encounters a beneficiary had with a provider)
D47	United's "Chart Review Program" "identified and collected Charts from certain providers who had reported encounters with beneficiaries to Defendants, and for which Defendants had submitted diagnosis codes to CMS."	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 47	Undisputed.	
D48	United hired medical coders to review the available medical charts retrieved from the doctors to identify diagnosis codes that were supported by documentation in those charts.	Ex. D-88, Baker Dep. 93:21-94:3 (Optum employee noting that Optum employed medical coders); Ex. D-109, Gardner Dep. 98:17-24 (United employee noting that PacifiCare collected medical records from providers and used vendors to review those records); Ex. D-111, Grower Dep. 113:17-114:3 (former Optum employee noting that a benefit of chart review was to validate that there were	Undisputed.	

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		diagnosis codes that could be submitted to CMS)		
D49	The medical coders that United hired to conduct its chart review were typically based in India or the Philippines.	Ex. D-1, Am. Compl. ¶¶ 167, 170 (stating United employed coders in India and the Philippines); Ex. D-2, Answer ¶¶ 167, 170 (agreeing that United employed coders in India and the Philippines); Ex. D-88, Baker Dep. 37:4-18 (Optum employee noting Optum had offshore coders in India and the Philippines)	Disputed. Mischaracterizes evidence.	Ex. P-47, Am. Compl. (Dkt. 171), ¶ 170 (alleging that United and its vendors utilized coders in Tennessee as well as in India and the Philippines without indicating where coders were “typically” located); Ex. D-2, Answer (Dkt. 223), ¶ 170 (admitting that United and its vendors utilized coders in Tennessee as well as in India and the Philippines); <i>see also</i> Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 93:18-95:9 (Corporate representative noting that there were “onshore/offshore restrictions” and “not all charts could be sent offshore for coding”)
D50	As part of its Chart Review Program, United generally did not compare the diagnosis codes identified through its chart reviews to those diagnosis codes submitted by doctors on the	Ex. D-92, Bird Dep. 230:22-231:15 (Optum employee noting that for chart review, there was no comparison between diagnosis codes found through chart review and those submitted by providers); Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 47, 50 (government expert	Undisputed.	

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	claim form for that same date of service.	describing chart review and noting reviews were generally done in a "blind" fashion)		
D51	United's medical coders generally reviewed medical charts in a "blind" manner, meaning the coder did not know what diagnosis codes the doctor had submitted.	Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 260:18-260:22, 298:17-299:14 (United corporate representative agreeing that Optum coded charts using blind coding and that a coder would not be informed about diagnoses previously submitted by a provider); Ex. D-102, Dickey Dep. 76:18-77:17 (Optum employee describing blind review and noting the coder has no information about diagnoses a provider has submitted)	Undisputed.	
D52	United's Chart Review Program "generally conducted reviews in a 'blind' fashion, meaning that the Coder did not know which diagnosis codes the provider had initially reported."	Ex. D-57, Garthwaite (9/29/2023) Rep. ¶ 40	Undisputed.	

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D53	During the "blind" reviews, medical coders were not reviewing charts for the purpose of determining whether doctor-submitted diagnosis codes were supported by documentation in the medical charts.	Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 48:6-19 (United corporate representative stating that chart review was not designed to see what the provider may have coded in the medical record); Ex. D-104, Erickson Dep. 107:2-8 (United employee stating that for blind review, coders did not know what was previously submitted by providers); Ex. D-92, Bird Dep. 230:8-231:15 (Optum employee noting that for chart review, there was no comparison between diagnosis codes found through chart review and those submitted by providers); Ex. D-54, Blair Rep. (9/29/2023) ¶ 16 (United expert noting that for blind reviews, coders review medical records without knowledge of codes submitted by providers)	Disputed to the extent the fact implies "blind" reviews would not reveal whether doctor-submitted diagnosis codes were supported by documentation in the medical charts, mischaracterizes evidence. Otherwise, undisputed.	Ex. P-14, Dep. Ex. 34B, MARA1546907, at 14 ("All ICD-9s that map to medical and/or Rx HCC will be coded for every date of service for that patient. . . . OptumInsight coding practice instructs those coding on its behalf to code all medical and Rx HCCs for every date of service of each patient."); P-15, United 30(b)(6) (Baker) Tr. 422:12– 22 (Corporate representative confirming United's coders were instructed to identify all diagnosis codes supported by documentation in the medical record); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum's coders had to achieve quality standards in order to successfully complete training)
D54	There are a number of reasons why two different medical coders may reach different coding results when	Ex. D-87, Acevedo Dep. 153:21-155:2 (government expert describing reasons that coders reach different conclusions on coding); Ex. D-	Disputed to the extent the fact implies initial disagreements among coders are not resolved in coding projects,	Ex. P-30, Acevedo (US expert) Tr. 173:6-178:14 (US Expert describing process used at Acevedo Consulting to resolve rare disagreements among medical coders in chart reviews,

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	reviewing the same medical chart.	65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 34 (United expert providing reasons a coder may fail to independently identify a diagnosis on a medical record); Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 26-29, 34, 36, 42-44, 48-55 (same); Ex. D-53, Acevedo Rebuttal Rep. (1/29/2024) ¶ 54 (government expert describing that mistakes in coding may occur); Ex. D-88, Baker Dep. 257:18-262:6 (Optum employee describing various reasons a coder may not identify diagnoses documented in a medical record)	conflicting evidence presented. Otherwise undisputed that there may be initial disagreements between two coders before they resolve the disagreement.	including through dialogue, consulting resources such as a more senior medical coder or the Coding Clinic, or querying the provider); <i>see also</i> Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (1/29/2024), ¶ 27-28 (US Expert: "For any content in the medical record that is unclear, ambiguous, or subject to interpretation and disagreement, the coder must ignore that portion of the medical record, unless the coder obtains definitive clarity (for instance, through a physician query). . . That coders may disagree on the proper code assignment also does not mean coding itself lacks objectively correct or incorrect answers."); Ex. P-31, Blair (United expert) Tr. 169:24-170:2 (testifying that she could not think of any instance in which a coder disagreement was not able to be resolved); Ex. P-6, Renjilian (United Expert) Tr. 219:7-220:4 (describing process he uses in government audits to convene coders to resolve any initial disagreements in the coding of a medical record); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum's coders had to achieve

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				quality standards in order to successfully complete training)
D55	There are a number of reasons why a medical coder may not identify a diagnosis code submitted on a claim form by a doctor.	Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 56-62 (United expert describing reasons a coder may not identify a diagnosis code submitted by a provider); Ex. D-89, Baker 30(b)(6) Dep. (Day 1) 36:10-37:20 (United corporate representative describing why Optum may not be able to submit complete diagnosis data for MA members to CMS)	Disputed. Conflicting evidence presented and mischaracterizes evidence.	Ex., P-4, Dickey Tr. 145:10–12 (Optum Coding Director stating that the “golden rule of coding [is] that if it’s not documented, then you don’t code it.”); Ex. P-31, Blair (United expert) Tr. 108-5-7 (coders can only assign diagnosis codes supported in the medical records); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶¶ 70-85 (US Expert rebutting United’s expert’s reasons a coder may not identify a diagnosis code, describing why MA chart review medical coders tend to be more reliable and accurate than provider coders, and explaining that provider-submitted codes without support in medical record are improper and MA chart review coders are correct not to code them); Ex. P-12, Dep. Ex. 265-1, MAPL000814082 (United’s chart review policy mandated use of certified coders and initial and ongoing coding training as well as accuracy reviews of coding staff); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 41:3–9 (Corporate

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				representative: "As part of the retrospective chart review program we have quality assurance[] programs that look at what our coders code and ensure – to ensure or work towards a 95 percent industry standard, which is what we all do."); Ex. P-30, Acevedo (US Expert) Tr. 234:19-235:10 (US Expert rejecting United counsel's proposition that a coder can "infer" documentation exists for a code and noting a code is "not supported until you provide me with the documentation"); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶¶ 34-36 (US Expert stating that notwithstanding issues of incomplete or unavailable provider documentation "coding rules require that a coder rely on the medical record before it. The coder cannot assume that a 'theoretical' medical record or portion of a medical record not yet retrieved or accessible exists to support the code."); Ex. P-31, Blair (United expert) Tr. 108:5-7 ("As I said before, to assign a diagnosis code, it must be in the medical record that you've received") (emphasis added); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 27-28 (US

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				Expert: "For any content in the medical record that is unclear, ambiguous, or subject to interpretation and disagreement, the coder must ignore that portion of the medical record, unless the coder obtains definitive clarity (for instance, through a physician query). . . That coders may disagree on the proper code assignment also does not mean coding itself lacks objectively correct or incorrect answers."); <i>id.</i> at ¶¶ 37-38 (disputing United expert's claim that a code is "in fact, properly supported by documentation in the medical record" when that record is not legible except to those uniquely familiar with a provider's handwriting.); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 6.5 at Table 6C (Table 6C requiring that acceptable documentation supporting code assignment is documentation that is: "legible."); Ex. P-48, ICD-10-CM Official Guidelines for Coding and Reporting, at p. 1 ("consistent, complete documentation" is required and "[w]ithout such documentation

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				accurate coding cannot be achieved."); Ex. P-49, Dep. Ex. 815, at p. 2, AAPC Article entitled "Medical Record Entries What Is Timely and Reasonable" (AAPC Knowledge Center: "The medical record must be legible to an individual who is not familiar with the provider's handwriting."); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 54 (US Expert: "Blair provides no evidence or explanation why human error is more likely to cause undercoding rather than overcoding."); P-69, Higgins Tr. 116:18-19 ("Our basic mantra was, if it wasn't in the medical record, it didn't happen."); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum's coders had to achieve quality standards in order to successfully complete training)
D56	There are a number of reasons why a medical coder reviewing a patient's medical chart may not identify a diagnosis code that is in fact supported by	Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 56-58 (United expert describing reasons a coder may not identify a diagnosis code submitted by a provider); Ex. D-87, Acevedo Dep. 132:13-136:16	Disputed. Conflicting evidence presented.	Ex. P-30, Acevedo (US Expert) Tr. 234:19-235:10 (US Expert rejecting United counsel's proposition that a coder can "infer" documentation exists for a code and noting a code is "not supported until you provide me with the documentation"); Ex. D-53,

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	documentation in the medical chart.	(government expert describing reasons certified coders may come to different conclusions on the appropriate diagnosis code)		Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶¶ 34-36 (US Expert stating that notwithstanding issues of incomplete or unavailable provider documentation “coding rules require that a coder rely on the medical record before it. The coder cannot assume that a ‘theoretical’ medical record or portion of a medical record not yet retrieved or accessible exists to support the code.”); Ex. P-31, Blair (United expert) Tr. 108:5-7 (“As I said before, to assign a diagnosis code, it must be in the medical record that you’ve received”) (emphasis added); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 27-28 (US Expert: “For any content in the medical record that is unclear, ambiguous, or subject to interpretation and disagreement, the coder must ignore that portion of the medical record, unless the coder obtains definitive clarity (for instance, through a physician query). . . That coders may disagree on the proper code assignment also does not mean coding itself lacks objectively correct or incorrect answers.”); <i>id.</i> at ¶¶ 37-38 (disputing United expert’s claim that a code is “in fact, properly

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				supported by documentation in the medical record” when that record is not legible except to those uniquely familiar with a provider’s handwriting.); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 6.5 at Table 6C (Table 6C requiring that acceptable documentation supporting code assignment is documentation that is: “legible.”); Ex. P-48, ICD-10-CM Official Guidelines for Coding and Reporting, at p. 1 (“consistent, complete documentation” is required and “[w]ithout such documentation accurate coding cannot be achieved.”); Ex. P-49, Dep. Ex. 815, at p. 2, AAPC Article entitled “Medical Record Entries What Is Timely and Reasonable” (AAPC Knowledge Center: “The medical record must be legible to an individual who is not familiar with the provider’s handwriting.”); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 54 (US Expert: “Blair provides no evidence or explanation why human error is more likely to cause undercoding

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				rather than overcoding.”); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum’s coders had to achieve quality standards in order to successfully complete training)
D57	One reason a medical coder may not identify a diagnosis that is in fact supported by documentation in the medical chart is because of human error.	Ex. D-87, Acevedo Dep. 153:21-155:2 (government expert agreeing that ability to read handwriting may be a reason coders might reach different conclusions on a medical record); Ex. D-108, Fry Dep. 23:20-27:3 (testifying about her role as a former CMS sub-contractor and contractor providing training and guidance on coding), 98:15-99:5 (describing various reasons a coder may miss diagnosis codes supported in a medical record); Ex. D-54, Blair Rep. (9/29/2023) ¶ 29 (United expert describing that legibility of documentation may affect a coders ability to identify diagnosis codes)	Disputed. Mischaracterizes evidence.	Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 54 (US Expert: “Blair provides no evidence or explanation why human error is more likely to cause undercoding rather than overcoding.”); Ex. P-31, Blair (United expert) Tr. 214:2-19 (unable to provide any evidence regarding the prevalence of human error in medical record coding); <i>id.</i> at 215:21-216:12 (agreeing that human error can lead to reporting diagnosis codes not supported in the medical record); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum’s coders had to achieve quality standards in order to successfully complete training)

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D58	One reason a medical coder may not identify a diagnosis that is in fact supported by documentation in the medical chart is because of differences in medical coder experience levels.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 34 (United expert describing factors that “make it difficult to identify diagnosis codes from a medical record”); Ex. D-87, Acevedo Dep. 154:4-155:2 (government expert explaining that different levels of experience affect whether a coder identifies a diagnosis code in a medical record); Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 23, 25 (explaining that differences in levels of coding experience affects whether a coder identifies a diagnosis code in a medical record)	Disputed. Mischaracterizes evidence.	Ex. P-50, Acevedo (US expert) Amended Rep. (Apr. 5, 2024), ¶¶ 50-51 (US Expert: explaining that coder experience can impact coding, but there are objectively correct results); <i>see also</i> Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024), ¶¶ 30-33 (same), ¶¶ 73 (explaining well-established Medicare Advantage industry best practices for achieving complete and accurate coding); Ex. P-12, Dep. Ex. 265-1, MAPL000814082 (United’s chart review policy mandated use of certified coders and initial and ongoing coding training as well as accuracy reviews of coding staff); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 41:3–9 (Corporate representative: “As part of the retrospective chart review program we have quality assurance[] programs that look at what our coders code and ensure – to ensure or work towards a 95 percent industry standard, which is what we all do.”); Ex. P-13, Dep. Ex. 33B, MARA1262848, Coding Guide at 7 (Optum’s coders had to achieve

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				quality standards in order to successfully complete training)
D59	One reason a medical coder may not identify a diagnosis that is in fact supported by documentation in the medical chart is because the record being reviewed by the medical coder is incomplete.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 34 (United expert describing factors that “make it difficult to identify diagnosis codes from a medical record”); Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 26-28 (United expert describing how the availability of medical records affects whether a coder identifies a diagnosis code in a medical record); Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 119:13-121:6 (United corporate representative describing an example where a coder may not have the complete medical charts for a beneficiary); Ex. D-93, Blair Dep. 181:10-182:1 (United expert stating that getting a complete medical record is one of the most challenging aspects of chart review); Ex. D-87, Acevedo Dep. 188:1-189:5 (government expert testifying that it “could happen” that providers might not have the	Disputed. Conflicting evidence presented.	Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024), ¶¶ 34-36 (US Expert stating that, notwithstanding issues of incomplete or unavailable provider documentation “coding rules require that a coder rely on the medical record before it. The coder cannot assume that a ‘theoretical’ medical record or portion of a medical record not yet retrieved or accessible exists to support the code.”); Ex. P-30, Acevedo (US Expert) Tr. 234:19-235:10 (US Expert rejecting United counsel’s proposition that a coder can “infer” documentation exists for a code and noting a code is “not supported until you provide me with the documentation”); Ex. P-31, Blair (United expert) Tr. 108:5-7 (“As I said before, to assign a diagnosis code, it must be in the medical record that you’ve received”) (emphasis added)

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		full medical record and agreeing that a coder would not be able to draw conclusions about diagnosis codes supported in medical records they were not provided)		
D60	One reason a medical coder may not identify a diagnosis that is in fact supported by documentation in the medical chart is because of the legibility of handwritten entries in the medical charts.	Ex. D-87, Acevedo Dep. 153:21-154:3 (government expert testifying that two coders might reach different conclusions from the same medical record due to legibility of handwriting); Ex. D-108, Fry Dep. 89:17-90:8 (government coding contractor testifying that legibility would impact a coder's ability to identify a diagnosis code); Ex. D-54, Blair Rep. (9/29/2023) ¶ 29 (United expert stating that clarity and legibility of documentation impacts a coder's ability to identify diagnosis codes); Ex. D-93, Blair Dep. 182:10-183:3 (United expert testifying to the same)	Disputed. Conflicting evidence presented.	Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024), ¶¶ 37-38 (US Expert disputing United expert's claim that a code is "in fact, properly supported by documentation in the medical record" when that record is not legible except to those uniquely familiar with a provider's handwriting.); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 6.5 at Table 6C (requiring that acceptable documentation supporting code assignment is documentation that is: "legible."); Ex. P-48, Dep. Ex. 1581 ICD-10-CM Official Guidelines for Coding and Reporting, at p. 1 ("consistent, complete documentation" is required and "[w]ithout such documentation accurate coding cannot be achieved."); Ex. P-49, Dep. Ex. 815,

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				at p. 2, AAPC Article entitled "Medical Record Entries What Is Timely and Reasonable" ("The medical record must be legible to an individual who is not familiar with the provider's handwriting.")
D61	One reason a medical coder may not identify a diagnosis that is in fact supported by documentation in the medical chart is because of insufficient time to review the medical chart.	Ex. D-108, Fry Dep. 128:3-7	Disputed. Mischaracterizes evidence.	Ex. P-51, Fry Tr. 128:3-7 (discussing program review steps to avoid "potential" coder error due to "productivity standards"); Ex. P-50, Acevedo (US expert) Amended Rep. (Apr. 5, 2024) ¶154 (US Expert opining that any coding accuracy and completeness issues are more likely to be avoided when an organization's policies and procedures encompass elements described in report); Ex. P-12, Dep. Ex. 265-1, MAPL000814082 (United's chart review policy mandated use of certified coders and initial and ongoing coding training as well as accuracy reviews of coding staff); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 41:3-9 (Corporate representative: "As part of the retrospective chart review program we have quality assurance[] programs that look at what our coders code and ensure – to ensure or

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				work towards a 95 percent industry standard, which is what we all do.”)
D62	Even in government-conducted audits, there are instances when two government-hired coders disagree.	Ex. D-96A, Bresette (OIG) 30(b)(6) Dep. (8/9/2023) 31:10-32:9 (OIG corporate representative testifying that in OIG contract-level audits a second coder could find support for a specific diagnosis code that a first coder did not find support for); Ex. D-108, Fry Dep. 84:15-85:4 (government coding contractor testifying that in RADV audits a senior coder may disagree with a junior coder’s determination about support for a diagnosis code); Ex. D-94, Bonner Dep. 19:18-20:8 (describing current role as CMS Communications Specialist previously involved in RADV), 84:20-25 (stating that in RADV audits disagreements occurred between certified coders); Ex. D-118, Hughes Dep. 25:4-16 (former CMS employee testifying about her role as Team Leader for Risk Adjustment Data Validation from 2006 to 2012),	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-94, HHS-OIG 30(b)(6) (Bresette, Aug. 9, 2023) Tr. 30:19-32:9 (responding “I’m not going to say that it did or did not happen” in response to question about whether there were instances when first senior coder determined that an HCC was not validated but OIG ultimately determined it was validated; testifying also that there were instances when coders requested assistance from a physician reviewer); Ex. P-51, Fry Tr. 86:21-25 (testifying that in discussions between herself and other professional coders on the quality assurance panel “we could typically come up with a good decision as far as what the medical record documented”); Ex. D-94, Bonner Tr. 84:20-25 (testifying “I don’t remember specific instances [of disagreements between two certified coders], but I do know that, yes, there could be disagreements about coding.”); Ex. P-6, Renjilian (United Expert) Tr. 219:7-220:4 (describing process he uses in government audits

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		39:2-41:16 (noting that in RADV audits there were “levels of coders disagreement” as coding was a “subjective activity”)		to convene coders to resolve any initial disagreements in the coding of a medical record)
D63	The government uses an independent medical reviewer to conduct a second level review of instances in which two coders disagree.	Ex. D-96A, Bresette (OIG) 30(b)(6) Dep. (8/9/2023) 31:10-32:9 (OIG corporate representative testifying that in OIG contract-level audits a second coder could find support for a specific diagnosis code that a first coder did not find support for); Ex. D-108, Fry Dep. 84:15-85:4 (testifying that in RADV audits a senior coder may disagree with a junior coder’s determination about support for a diagnosis code); Ex. D-118, Hughes Dep. 39:2-41:16 (noting that in RADV audits there were “levels of coders disagreement” as coding was a “subjective activity”); see Ex. D-94, Bonner Dep. 90:3-91:25 (describing accuracy standards for coders)	Disputed. Not supported by cited evidence.	Ex. P-52, HHS-OIG 30(b)(6) (Bresette, Aug. 9, 2023) Tr. 31:10-32:9 (noting that there were instances when a physician reviewer consulted with coder to make a determination); Ex. P-51, Fry Tr. 84:15-85:4 (cited testimony does not discuss independent medical reviewer at all); Ex. D-118, Lateefah Hughes Tr. 39:2-41:16 (cited testimony does not discuss independent medical reviewer at all); see Ex. D-94, Bonner Tr. 90:3-91:25 (cited testimony does not discuss independent medical reviewer at all)

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D64	Determining whether the health condition submitted by the doctor on the claim form is supported by documentation in the medical chart requires a review of the medical record.	Ex. D-132, Paul Dep. 42:10-43:4 (CMS employee distinguishing coding from diagnosing); Ex. D-106, Ferron Dep. 227:4-19 (United coding consultant describing process of coding charts); Ex. D-96, Bresette (OIG) 30(b)(6) Dep. (5/31/2023) 168:15-24 (OIG corporate representative describing need "to review the medical records supporting them to determine whether they are accurate or not")	Undisputed except to the extent fact implies a medical record review has not already occurred with respect to the deletes identified by Dr. Garthwaite, in which case, disputed, conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: "According to my analysis, Defendants reviewed the medical records that were the source of these diagnosis codes as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories"); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D65	During the time period covered by this case, CMS knew that Medicare Advantage plans conducted	Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) at 175:11-16 (CMS corporate representative testifying "[i]n general, CMS understood, through informal	Disputed. Not supported by cited evidence in Ex. D-39, conflicting evidence presented, and	Ex. P-26, CMS 30(b)(6) (Hornsby, May 19, 2023) Tr. 104:3-8 ("What I said is there wasn't a general awareness in -- among CM leadership -- and Cynthia Tutor [sic]

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	chart reviews that sought to add diagnosis codes.	networks, that looking just for additional in medical records was going on.”); Ex. D-140, Spitalnic Dep. 17:4-14 (CMS employee Paul Spitalnic describing his current role as Chief Actuary (2017-present) and his prior role as Former Director of Parts C and D Actuarial Group), 89:11-90:2 (government expert acknowledging awareness of United’s Chart Review Program); Ex. D-39, 2009 Advance Notice at 12 (“CMS understands that MA plans have made efforts to identify enrollees’ conditions and may be coding more completely than FFS.”)	mischaracterizes the evidence.	also said this in her deposition. There wasn’t a general awareness that plans were -- were going to medical records and only looking for additional.”); Ex. P-91, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 131:22-134:1 (testifying CMS did not have knowledge in 2014 that MA plans were conducting chart reviews to add diagnoses but had “informal network information but nothing that would rise to the level of knowledge because CMS cannot see what’s inside an MAO in terms of its data and due diligence activities.”); Ex. P-79, Spitalnic (US Expert) Tr. 89:11-90:15 (“Q. by the way, do you know what “chart reviews” are? A. I’m familiar with the term. Q. You understand that United had a chart review program in place during the period relevant to this case? A. I understand United takes a number of actions with respect to supporting or developing or -- related to the diagnoses they submit for plan payment. Q. And would those actions include a chart review program? A. That is my understanding. Q. When did you first become aware that United had a chart review program? A. I don’t think I was ever aware that

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				there was a specific program. I know that United and other MAOs, Medicare Advantage organizations, do various -- have various initiatives in support of their diagnosis submission. Q. So you have no specific information about how United may have conducted its chart review program during the period relevant to this case? A. I do not) (Outside Counsel Only); Ex. P-23, Blum Tr. 95:6-12 ("Q. Right. And one of those behaviors was one-way chart review, correct? MS. LIKOFF: Objection to form. Asked and answered. Vague. A. I cannot speak to the operations that a plan had. I can speak to the policy that CMS set.")
D66	Current CMS officials have confirmed that CMS knew not all diagnosis codes submitted by doctors to Medicare Advantage plans were supported by medical records.	Ex. D-155, Blum Dep. 154:11-22 (former CMS employee acknowledging that by 2010, he was aware of "diagnosis codes that were submitted that weren't documented by medical record"); Ex. D-46, OIG, Medicare Advantage Compliance Audit of Cigna at 23 (Mar. 2023) ("We recognize as well that . . . there is no CMS	Disputed. Not supported by cited evidence.	

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		requirement that MA organizations verify every diagnosis submitted by providers.”); Ex. D-66, Higgins Dep. Ex. 164 (Medicare Program; Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (noting that “M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce”)		
D67	Former CMS officials who worked at CMS during the time period covered by this case confirmed that CMS knew during those officials’ times of service that not all diagnosis codes submitted by doctors to Medicare Advantage plans were supported by medical records.	Ex. D-119, Hutchinson Dep. 32:21-33:4 (former CMS employee describing unsupported codes in FFS data); Ex. D-97, Cavanaugh Dep. 64:9-65:8 (former CMS Director describing awareness of unsupported codes in both MA and FFS Medicare); Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 130:14-131:7 (CMS corporate representative	Disputed. Conflicting evidence presented.	Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 105:15-22 (clarifying CMS’s understanding of provider submitted codes in RADV: “Q. Is RADV, the RADV process that CMS is performing, is it designed to separate inaccurate codes that originate with providers as opposed to inaccurate codes that were potentially added by the plans themselves? A. That is not CMS’s intention. And as I’ve explained, CMS cannot make that distinction in

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		stating CMS was aware of unsupported codes in MA data)		any systematic way.”); <i>id.</i> at 106:20-107:2 (“Q. And CMS is making no distinction in that process between codes that originated with the providers themselves versus codes that were added downstream by the plans through chart review; correct? A. CMS doesn’t have that information so it would not be possible to incorporate it in the sampling frame.”); Ex. D-119, Hutchinson Tr. 32:21-33:10 (limiting testimony cited in D67 to 2009 and to FFS providers); Ex. P-20, Cavanaugh Tr. 64:9-65:8 (testifying that he was aware during time as director that there was overcoding and undercoding in both traditional FFS data and MA data; no testimony regarding CMS’s knowledge of source of inaccuracies in MA plan data)
D68	The Department of Health and Human Services, Office of the Inspector General has also confirmed that they knew not all diagnosis codes submitted by doctors to Medicare Advantage plans	Ex. D-46, OIG, Medicare Advantage Compliance Audit at 23 (Mar. 2023)	Disputed as to HHS-OIG's knowledge within relevant timeframe for this matter, not supported by the cited evidence.	

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	were supported by medical records.			
D69	CMS has acknowledged that Medicare Advantage plans have no obligation to audit all of their data to ensure the accuracy of diagnosis codes.	Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) 236:6-10 (CMS corporate representative stating that "CMS doesn't have a requirement that tells MAOs they must audit medical records."); Ex. D-137, Rice Dep. 16:2-20:17 (CMS employee Cheri Rice describing her current role as CMS's Deputy Director of the Center for Medicare, Medicare Advantage and Part D (2017-present), and her prior roles as CMS Director of Medicare Plan Payment Group (2010-2017) and Deputy Director Medicare Plan Payment Group (2004-2010), 69:10-15 (confirming no obligation to audit all diagnoses); Ex. D-46, 2023 OIG, Medicare Advantage Compliance Audit of Cigna (Mar. 2023) at 23 ("We recognize as well that . . . there is no CMS requirement that MA organizations verify every diagnosis submitted by	Disputed. Conflicting evidence presented.	Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (CMS stating that "encounter data will be used as a factor in calculating payments to [MAOs]. Therefore, encounter data submissions, like enrollment data and ACR information, represent a "claim" for payment. As such, [MAOs] have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data. We acknowledge that encounter data come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake "due diligence" to ensure the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a "best knowledge, information, and belief" standard. Therefore, M+C

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		providers"); Ex. D-100, Creighton Dep. (10/4/2022) 63:10-65:5 (former CMS employee stating no rule requiring chart reviews also validate provider-submitted diagnoses); Ex. D-97, Cavanaugh Dep. 74:15-21 (former CMS Director testifying no obligation to proactively audit diagnoses codes), 153:12-17 (similar), 155:9-23 (similar)		organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."); Ex. P-10, Rice Tr. 76:19-79:1 (CMS Deputy Director for the Center for Medicare discussing MAOs' responsibilities relating to data submitted to CMS, stating "that their plan has to do -- has some proactive responsibilities to take a good faith effort to make sure that -- that the data that they're submitting are correct."); Ex. P-1B, MAPL007637301, Optum EDI Agreement, at § A5 (Optum agreeing that "[b]ased on best knowledge, information, and belief that it will submit encounter data that is accurate, complete, and truthful"); Ex. P-1C, MAPL008081457, Defendant MAO EDI Agreement, at § A5 (Defendant MAOs agreeing to the same); Ex. P-1A, USBP009418488, 2017 PY Contract, at Art. IV(D) (Contract requiring MAOs to annually attest that the data they submit is accurate, complete, and truthful based on best knowledge, information, and belief); e.g., Ex. P-1G, USBP009417433,

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				2017 PY Attestation (United attestation stating that “Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.”)
D70	Medicare Advantage plans do not have a general obligation to audit doctor-submitted diagnosis codes.	Ex. D-100, Creighton Dep. (10/4/2022) 63:10-65:5 (former CMS employee stating no rule requiring chart reviews also validate provider-submitted diagnoses); Ex. D-136, Renshaw Dep. 98:13-99:6 (OIG employee testifying “I don’t think that it would be reasonable to expect a Medicare Advantage organization to determine whether every single diagnosis submitted to CMS is supported to have a good -- I mean, I don’t think a good compliance program would require that level of review.”); Ex. D-137, Rice Dep. 69:10-15 (CMS employee confirming no obligation to audit all diagnoses); Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) 236:6-10 (CMS corporate	Disputed. Conflicting evidence presented.	Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (to be codified at 42 C.F.R. pt. 422) (CMS stating that “encounter data will be used as a factor in calculating payments to [MAOs]. Therefore, encounter data submissions, like enrollment data and ACR information, represent a “claim” for payment. As such, [MAOs] have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data. We acknowledge that encounter data come into [MAOs] in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that [MAOs] have an obligation to undertake “due diligence” to ensure

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		representative stating that “CMS doesn’t have a requirement that tells MAOs they must audit medical records”); Ex. D-46, 2023 OIG, Medicare Advantage Compliance Audit of Cigna (Mar. 2023) at 23 (“We recognize as well that . . . there is no CMS requirement that MA organizations verify every diagnosis submitted by providers”);		the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a “best knowledge, information, and belief” standard. Therefore, [MAOs] will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.”); Ex. P-10, Rice Tr. 76:19-79:1 (CMS Deputy Director for the Center for Medicare discussing MAOs’ responsibilities relating to data submitted to CMS, stating “that their plan has to do -- has some proactive responsibilities to take a good faith effort to make sure that -- that the data that they’re submitting are correct.”); <i>id.</i> at 55:11-56:5 (describing requirements for MAOs to have a compliance program in place and exercise good faith efforts to verify the accuracy of data submissions)
D71	CMS conducts periodic Risk Adjustment Validation (“RADV”) Audits to determine whether the Medicare Advantage plans	Ex. D-15, 75 Fed. Reg. 19,678, 19742 (April 15, 2010) (“Under the RADV audit process we plan to recover the overpayments identified during	Undisputed.	

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	selected for audits received "overpayments."	the RADV audit."); Ex. D-98, Chaudhuri Dep. 24:16-25:9 (CMS employee discussing RADV audit process); Ex. D-122A, Kapustij 30(b)(6) Dep. 41:24-42:2 (CMS corporate representative discussing same); Ex. D-80, Kapustij 30(b)(6) Dep. (8/25/2023) Ex. 1497-10 at 1 (describing purpose of RADV audits as "recovery of overpayments"); Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 58:23-59:13 (CMS corporate representative discussing same)		
D72	CMS developed its RADV sampling and extrapolation methodology to target Medicare Advantage plans and enrollees' HCCs that are more likely to result in payment error.	Ex. D-18, 88 Fed. Reg. 6643, 6651-52 (Feb. 1, 2023) (noting that RADV audits would be focused on MA plans and beneficiaries' HCCs "identified as being at high risk for improper payments"); Ex. D-122A, Kapustij 30(b)(6) Dep. 53:1-7 (CMS corporate representative testifying that MA plans with increase in coding were selected for RADV audits because CMS viewed them as being indicative of	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-18, 88 Fed. Reg. 6643, 6651-52 (Feb. 1, 2023) (noting that sampling and extrapolation methodologies adopted by CMS "will be" focused on contracts and HCCs that are at highest risk for improper payments in a modification to CMS's prior approach); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 53:1-54:9 (testifying that there was a "hypothesis that an increase in coding might be indicative of larger probability for error" but that plans were selected

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		“probability for an error”), 53:23-54:22 (testifying that CMS hypothesized that MA plans with increase in coding were more likely to have higher rates of payment errors)		from the high, medium, and low coding intensity groups, and responding “I’m not sure, and none of the documentation supported that” in response to question whether CMS’s goal in selecting MA plans for the CY 2011-2013 RADV audits was to identify plans that were more likely to have payment errors)
D73	In contract-level RADV audits, CMS targets contracts that it believes are most likely to contain errors.	Ex. D-122A, Kapustij 30(b)(6) Dep. 52:2-54:9 (CMS corporate representative describing how CMS identified which MA plans to audit for payment years 2011-2013); <i>id.</i> at 205:17-206:3 (identifying plans selected due to their “coding intensity”)	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-18, 88 Fed. Reg. 6643, 6651-52 (Feb. 1, 2023) (noting that sampling and extrapolation methodologies adopted by CMS “will be” focused on contracts and HCCs that are at highest risk for improper payments in a modification to CMS’s prior approach); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 53:1-54:9 (testifying that there was a “hypothesis that an increase in coding might be indicative of larger probability for error” but that plans were selected from the high, medium, and low coding intensity groups, and responding “I’m not sure, and none of the documentation supported that” in response to question whether CMS’s goal in selecting MA plans for the CY 2011-2013 RADV audits

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				was to identify plans that were more likely to have payment errors)
D74	To conduct a RADV audit, CMS selects a sample of Medicare Advantage plans and beneficiaries within those Medicare Advantage plans for review.	Ex. D-18, 88 Fed. Reg. 6643, 6647 (Feb. 1, 2023) (describing selection of Medicare Advantage plans and beneficiaries); Ex. D-122A, Kapustij 30(b)(6) Dep. 84:15-19 (CMS corporate representative testifying that in a RADV audit, CMS audits every HCC for the sampled beneficiaries selected from a MA plan); Ex. D-74, Bonfante Dep. Ex. 1143-1 (AEO) at 4 (“sample beneficiaries enrolled in MA plans” listed as a step in RADV audit methodology)	Undisputed.	
D75	After the beneficiaries for the RADV audit are selected, Medicare Advantage plans submit medical records for those beneficiaries to CMS.	Ex. D-18, 88 Fed. Reg. 6643, 6647 (Feb. 1, 2023) (citing 42 C.F.R. 442.310(e)) (noting that MA plans submit sample of medical records for RADV audits); Ex. D-122A, Kapustij 30(b)(6) Dep. 84:15-19 (CMS corporate representative acknowledging that after a sample of beneficiaries is	Undisputed.	

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		selected, the next step is request and submission of medical records), <i>id.</i> at 89:22-90:7 (testifying similarly as to the submission of medical records by MA plans); Ex. D-74, Bonfante Dep. Ex. 1143-1 (AEO) at 4 (noting that CMS requests medical records from MA plans)		
D76	In conducting RADV audits, CMS reviews the medical records that the Medicare Advantage plans submitted for purposes of identifying whether the documentation in the medical charts supports the HCCs for that beneficiary for that year.	Ex. D-122A, Kapustij 30(b)(6) Dep. 84:20-85:10 (CMS corporate representative testifying that after MA plans submit medical records, CMS oversees review of those records); Ex. D-15, 75 Fed. Reg. 19678, 19742 (Apr. 14, 2010) (noting that medical records are reviewed “to determine whether they support diagnosis codes (known as Hierarchical Condition Codes, or HCCs)” submitted to CMS)	Undisputed.	
D77	In conducting RADV audits, if CMS finds support in at least one of the medical charts for at least one	Ex. D-122A, Kapustij 30(b)(6) Dep. 90:2-91:19 (CMS corporate representative describing how an HCC can be	Undisputed.	

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	diagnosis code that corresponds to the HCC for that member for that year, the HCC is found to be supported.	supported by more than one record); Ex. D-153, 83 Fed. Reg. 54982, 55040 at FN 30 (Nov. 1, 2018) (acknowledging that only one instance of medical record support was necessary to make the diagnosis valid for that year); Ex. D-36, 2007 Risk Adjustment Data Training Participant Guide (acknowledging the difference between a data discrepancy that does not affect payment and a risk adjustment discrepancy that does affect payment); Ex. D-141, Stark Dep. 39:14-21, 48:13-23 (government expert testifying that in RADV, MA plans are to provide documentation to support specific HCCs, and that if at least one chart that year supported the HCC, then the HCC is validated)		
D78	If the HCC is found to be supported, CMS has determined that the Medicare Advantage plan	Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 55:14-56:20 (CMS corporate representative testifying that if CMS confirmed that a code was supported there was no	Disputed to the extent this fact is not limited to the RADV context. Otherwise, undisputed.	

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	was not overpaid based on that HCC.	overpayment to the plan); Ex. D-145, Tudor Dep. 221:14-223:7 (former CMS employee acknowledging that there is no overpayment where a diagnosis code eligible for risk adjustment and mapping to an HCC is supported by at least one provider record)		
D79	During a contract-level RADV audit, CMS coders also identify diagnosis codes that are supported by documentation in the medical chart, but were not submitted to CMS for payment.	Ex. D-15, 75 Fed. Reg. 19678, 19746 (Apr. 15, 2010) (noting that the RADV process “addresses under-coding” by identifying diagnoses not submitted for payment); Ex. D-122A, Kapustij 30(b)(6) Dep. 148:24-149:5 (CMS corporate representative testifying that during the RADV process, CMS coders also reported additional HCCs a plan did not submit for payment); Ex. D-130, Morse Dep. 17:9-39:25 (former CMS official Jonathan Morse describing his role as Acting Deputy Administrator and Center Director for the CMS (2016-2018) and Deputy Center Director for the Center for Program Integrity), 122:2-13	Undisputed.	

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		(testifying that during RADV medical records were also reviewed for “adds” that were supported in the medical records but not submitted to CMS)		
D80	Based on the results of its medical record review, CMS determines the corrected net payment for each of the sampled beneficiaries, considering both additions and deletions of HCCs.	Ex. D-77, Kapustij Dep. Ex. 1306 at 23-27 (describing the calculation of the corrected risk score and payment); Ex. D-130, Morse Dep. 122:14-19 (former CMS employee describing how net payment error determination is made); Ex. D-122A, Kapustij 30(b)(6) Dep. 142:3-12 (CMS corporate representative describing how corrected risk score and payment are calculated)	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. D-77, Kapustij Dep. Ex. 1306 at 23-27 (description of process for extrapolating error rate to contract; does not say CMS will calculate “corrected net payment for each of the sampled beneficiaries, considering both additions and deletions of HCCs”); Ex. D-130, Morse Dep. 122:14-123:7 (former CMS employee testifying about his understanding of calculations in the context of an extrapolated RADV Audit); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 147:18-150:6, 153:3 (testifying that, under the 2012 RADV audit methodology, accounting for additional codes identified in the course of a RADV audit was constrained to zero in the RADV Audit process and that CMS did not make additional payments to a plan based on the results of a RADV Audit that, when extrapolated, made it appear as if there was a net underpayment due to

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				the plan.); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final.”)
D81	CMS initiated contract-level RADV audits on United contracts for contract years 2011, 2012, 2013, 2014 and 2015.	Ex. D-82, Kapustij 30(b)(6) Dep. Ex. 1498 (OCO) at 19 (reflecting United contracts audited for contract year 2011), 20 (same for 2012), 21 (same for 2013); Exs. D-84 & D-85, Hornsby 30(b)(6) Dep. 11/21/2023) Exs. 1521 (same for 2014), 1522 (same for 2015)	Undisputed.	
D82	For contract years 2011-2013, CMS initiated contract-level RADV audits on 15 United contracts.	Ex. D-122A, Kapustij 30(b)(6) Dep. 203:3-203:11 (CMS corporate representative agreeing that 4 United plans were audited for contract year 2011), 241:10-241:13 (agreeing that 5 United plans were audited for contract year 2012), 242:3-242:7 (agreeing that 6 United plans were audited for contract year 2013); Ex. D-82, Kapustij 30(b)(6) Dep. Ex. 1498 (OCO) at 19 (reflecting 4 United contracts audited for contract year 2011), at 20 (reflecting 5	Undisputed.	

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		United contracts audited for contract year 2012), at 21 (reflecting 6 United contracts audited for contract year 2013); Ex. D-81, Kapustij 30(b)(6) Dep. Ex. 1497-18 at 19-21 (listing summary of plans); Ex. D-83, Kapustij 30(b)(6) Dep. Ex. 1501 (listing United contracts)		
D83	In the contract-level RADV audits for contract years 2011-2013, CMS contractors preliminarily determined that nearly 87% of the HCCs that were audited in the United contracts were supported ("validated") by documentation in the medical records that the CMS contractors reviewed.	Ex. D-64, Updated Renjilian Rep. (12/3/2023) ¶ 166, Figure 15 (reflecting that 86.6% of the HCCs submitted by United and reviewed during RADV were supported); Ex. D-141, Stark Dep. 36:13-37:22 (government expert agreeing with Renjilian calculation of HCC validation rate for RADV audits in contracts years 2011-2013); Ex. D-63, Stark Rep. (3/28/2024) ¶ 30 (government expert testifying to same)	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")
D84	The preliminary RADV medical record review	Ex. D-122A, Kapustij 30(b)(6) Dep. 230:15-22 (CMS corporate	Disputed. Mischaracterizes evidence and	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The

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	results showed that the rate of validation for United HCCs was higher than other plans that went through RADV audits in contract year 2011.	representative testifying that United had the lowest discrepancy rate among the other major MA plans audited for payment year 2011); Ex. D-75, Paul Dep. Ex. 1187-1 at 10 (showing a 12.3% discrepancy rate for United for contract year 2011 audit)	conflicting evidence presented.	RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D85	Preliminary RADV audit results that CMS calculated showed that United had among the lowest recovery amount (i.e. amount CMS expected to recover from an MA plan) of all major MA organizations for contract years 2011-2013.	Ex. D-122A, Kapustij 30(b)(6) Dep. 223:10-225:2 (CMS corporate representative testifying that, of the major Medicare Advantage plans audited for contract year 2011, United had the lowest payment error); <i>id.</i> at 226:12-229:3 (same); 238:8-239:10 (identifying payment error rates for United plans for payment years 2012 and 2013); Ex. D-82, Kapustij 30(b)(6) Dep. Ex. 1498 at slide 4 (reflecting preliminary RADV recovery amounts for contract years 2011-2013 and	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul.

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		reflecting that United had a lower error rate than Aetna, Humana, and Cigna for 2011, than Cigna and Humana for 2012, and than Humana and Cigna for 2013)		12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); D-82, Dep. Ex. 1498 at slide 4 (cited slide provides that “[r]ecoverly amount is the extrapolated payment error amount based on the lower bound of the 99% confidence interval for the total”); D-18, 88 Fed. Reg. 6643, 6654 (Feb. 1, 2023) (CMS announcing that RADV payment recoveries for payment years 2011-2017 would be limited to “enrollee-level adjustments” rather than extrapolated recoveries)
D86	For contract years 2014 and 2015, CMS initiated RADV audits pertaining to members	Ex. D-64, Renjilian Updated Rep. (12/3/2023)¶ 154	Undisputed.	

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	enrolled in 97 United Medicare Advantage plans.			
D87	For contract years 2014 and 2015, CMS made United's preliminary RADV medical record review results available to United via the CMS RADV Report Portal.	Ex. D-64, Renjilian Updated Rep. (12/3/2023)¶153, n.220	Disputed to the extent the fact characterizes the medical record review feedback for RADV Contract Years 2014-2015 as "preliminary . . . results", conflicting evidence presented. Otherwise undisputed that initial feedback of medical record reviews was made available to MAOs through a portal.	Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")

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D88	In the RADV audits for contract years 2014-2015, CMS contractors validated approximately 88% of the HCCs pertaining to members in United's Medicare Advantage plans.	Ex. D-64, Renjilian Updated Rep. (12/3/2023) ¶ 166, Figure 15.	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")
D89	In the RADV audits CMS initiated for contract years 2011-2015, CMS contractors validated approximately 88% of the member-HCCs pertaining to members in United's Medicare Advantage plans.	Ex. D-64, Renjilian Updated Rep. (12/3/2023) ¶ 166, Figure 15 (reflecting that 87.8% of United HCCs audited in RADV for contract years 2011-2015 were supported); Ex. D-141, Stark Dep. 82:7-87:23 (government expert calculating an 88.8% validation rate for United HCCs audited in RADV for contract years 2011-2015)	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by

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				medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D90	Medicare Advantage plans have the opportunity to appeal the results of CMS’s review of the medical charts in RADV audits.	Ex. D-122A, Kapustij 30(b)(6) Dep. 85:22-86:3 (CMS corporate representative testifying that once the RADV report was provided to MA plans, they had the opportunity to seek reconsideration of HCCs that CMS did not validate), 180:4-13 (describing the reconsideration process in RADV audits); Ex. D-101, Davis Dep. 37:7-41:10 (former CMS employee describing role as CMS Health Insurance Specialist for Medicare Plan Payment Group from October 2013 to January 2017), 47:3-8 (testifying that MA plans can seek reconsideration of the RADV audit findings)	Undisputed that Medicare Advantage plans will have the opportunity to appeal the results of CMS’s review of the medical charts in RADV audits.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D91	Preliminary results of CMS-initiated RADV audits for	Ex. D-122A, Kapustij 30(b)(6) Dep. 243:13-22 (CMS corporate	Disputed. Mischaracterizes evidence and	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The

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	contract years 2011-2013 revealed net underpayments to at least 13 of those 15 United contracts.	representative testifying that of the 15 United plans audited for contract years 2011, 2012, and 2013, 13 of them had net underpayments); Ex. D-81, Kapustij 30(b)(6) Dep. Ex. 1497-18 at 19-21 (showing recovery amounts for each plan for contract years 2011, 2012, and 2013); Ex. D-83, Kapustij 30(b)(6) Dep. Ex. 1501 (showing recovery amounts for United contracts for contract years 2011, 2012, and 2013)	conflicting evidence presented.	RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 147:18-150:6, 150:23-153:3 (testifying that, under the 2012 RADV audit methodology, accounting for additional codes identified in the course of a RADV audit was constrained to zero in the RADV Audit process and that CMS did not make additional payments to a plan based on the results of a RADV Audit that, when extrapolated, made it appear as if there was a net underpayment due to the plan. Further testifying that CMS’s application of a 99 percent confidence interval taken at the lower bound in the extrapolation process could explain why some initial

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				extrapolated results appeared to go below zero)
D92	"Preliminary" RADV audit results are recovery amounts that have not yet been appealed.	Ex. D-122A, Kapustij 30(b)(6) Dep. 85:6-86:3 (CMS corporate representative describing preliminary result calculations subject to medical record review reconsideration), 181:4-16 (agreeing that preliminary audit results do not account for appeals), 214:9-215:5 (same); Ex. D-75, Paul Dep. Ex. 1187-1 ("Preliminary recovery amounts are subject to change based on the FFSA and appeals, which are triggered by regulation upon release of the audit reports.")	Undisputed that "Preliminary" RADV audit results will be recovery amounts that have not yet been appealed. Otherwise disputed, mischaracterizes evidence.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative.")
D93	"Preliminary" RADV medical record review results are HCC validation determinations that have not yet been appealed.	Ex. D-122A, Kapustij 30(b)(6) Dep. 85:6-86:3 (CMS corporate representative describing preliminary result calculations subject to medical record review reconsideration), 179:15-180:13 (describing appeal of the preliminary RADV medical record review results)	Disputed. Conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The

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				portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”)
D94	Preliminary RADV audit recovery amounts cannot increase and will only decrease (if they change at all) when they become final, after appeals.	Ex. D-122A, Kapustij 30(b)(6) Dep. 85:6-86:3 (CMS corporate representative describing preliminary result calculations), 181:4-16 (agreeing that preliminary audit results do not account for appeals), 214:9-215:5 (same); Ex. D-75, Paul Dep. Ex. 1187-1 (“Preliminary recovery amounts are subject to change based on the FFSA and appeals, which are triggered by regulation upon release of the audit reports.”)	Disputed. Conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); Ex. P-56, CMS 30(b)(6) (Kapustij,

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				Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative.")
D95	Preliminary rates of HCC validation calculated from RADV audit medical record reviews cannot decrease and will only increase (if they change at all) when they become final, after appeals.	Ex. D-122A, Kapustij 30(b)(6) Dep. 179:15-184:5 (CMS corporate representative describing plan's ability to argue that an HCC is in fact supported)	Disputed. Conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized."); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not

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				been issued, so I'm being kind of speculative.")
D96	Preliminary rates of validation calculated on HCCs submitted by United cannot decrease and will only decrease (if they change at all) when they become final after United has the opportunity to appeal.	Ex. D-122A, Kapustij 30(b)(6) Dep. 179:15-184:5 (CMS corporate representative describing plan's ability to argue that an HCC is in fact supported)	Disputed. Conflicting evidence presented.	Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized."); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative.")

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D97	“[T]here is a strong, statistically significant association between a [Diagnosis] instance having financial impact if deleted . . . and that instance not being supported by the RADV audit.”	Ex. D-63, Stark Rep. (3/28/2024) ¶ 33	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. D-63, Stark (US Expert) Updated Rep. (Mar. 28, 2024) (ellipsis excludes “according to Renjilian’s Opinion 3” thereby changing the meaning of the quote), ¶ 33; Ex. P-57, Stark (US Expert) Tr. 34:5-35:6 (US Expert explaining that his analyses were relying on United expert’s results that he does not know to be independently correct)
D98	CMS coders sometimes miss codes supported by documentation in the medical charts when reviewing charts in contract-level RADV audits.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 34 (United expert stating “[I]t would not be surprising for a Chart Review coder to fail to identify a diagnosis code that was actually supported by the member’s record.”); Ex. D-54, Blair Rep. (9/29/2023) ¶¶ 26-28, 29, 34, 36, 42-44, 48-55 (United expert describing reasons coders may miss supported codes); Ex. D-53, Acevedo Rebuttal Rep. (1/29/2024) ¶ 54 (government expert stating in report that “[h]uman error is inevitable”); Ex. D-87, Acevedo Dep. 153:21-155:2 (government expert agreeing to reasons why	Disputed to the extent fact implies that coders are conducting medical record reviews to identify all diagnosis codes supported by the medical record in the RADV audit context and further disputed to the extent fact fails to acknowledge that plans are given credit for HCCs as long as one coder finds support for that HCC in the medical record review, not supported by cited	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr.118:8-19 (testifying “I would not necessarily say that the coder misses it. . . . there are certain circumstances where one coder would find evidence for it and the other coder would feel no, that that was not sufficient.”); <i>id.</i> at 98:5-12 (“Q. And isn’t it also true that the individuals doing the focused review were blind as to which HCCs the MA plan had submitted for payment for a given sampled enrollee? A. Based on my conversations, it was my understanding that the coders did have knowledge to see what is called the cover sheet which indicated what HCCs were submitted for payment.”); <i>id.</i> at 121:17-122:1

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		coders may miss diagnosis codes); see Ex. D-94, Bonner Dep. 75:17-77:16 (former CMS employee describing accuracy thresholds for RADV coders); Ex. D-112, Guy Dep. 29:5-30:17 (CMS employee testifying that she worked from 2006 to the present in the Medicare Plan Payment Group, Division of Risk Adjustment Operations), 75:23-77:14 (CMS employee testifying “[y]ou have some tests that give you false positives and some tests that give you false negatives. That’s why you repeat it. You have more than one person looking at it.”); Ex. D-122A, Kapustij 30(b)(6) Dep. 119:4-11, 120:2-8 (CMS corporate representative stating that CMS employed two levels of coders in case the first missed a supported code)	evidence and conflicting evidence presented.	(testifying that “the HCC was considered validated if either of the coders abstracted it.”); Ex. P-31, Blair (United Expert) Tr. 87:19-21 (testifying she has never done work for CMS)
D99	In RADV audits, CMS reviews up to five medical charts for each beneficiary before making the determination that an HCC is not supported by	Ex. D-122A, Kapustij 30(b)(6) Dep. 90:2-91:14 (CMS corporate representative describing policy for submission of up to five medical records); Ex. D-41, CMS, <i>Notice of Final</i>	Undisputed to the extent that the RADV process for Contract Years 2011-2015 included a review of all medical records submitted by a Medicare	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 91:9-14, 97:7-14 (testifying that starting in payment year 2011, CMS allowed plans to submit up to five medical records to support a particular HCC for a

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	documentation in the medical charts.	<i>Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits</i> , Feb. 24, 2012, at 3 (describing submission of multiple records); Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 44 (“CMS has allowed audited MA contracts to submit up to five records for each HCC being validated.”)	Advantage Organization, which could include up to five medical records for a particular HCC for a particular enrollee. Otherwise disputed, mischaracterizes evidence.	particular sampled enrollee, and further that “the focused review process resulted in a review of all the medical records submitted”)
D100	In RADV audits, CMS reviews up to five medical charts for each HCC before making the determination that an overpayment exists.	Ex. D-41, CMS, <i>Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits</i> , Feb. 24, 2012, at 3 (describing submission of multiple records); Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 44 (“CMS has allowed audited MA contracts to submit up to five records for each HCC being validated.”)	Undisputed to the extent that the RADV process for Contract Years 2011-2015 included a review of all medical records submitted by a Medicare Advantage Organization, which could include up to five medical records for a particular HCC for a particular enrollee. Otherwise disputed, mischaracterizes evidence.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 91:9-14, 97:7-14 (testifying that starting in payment year 2011, CMS allowed plans to submit up to five medical records to support a particular HCC for a particular sampled enrollee, and further that “the focused review process resulted in a review of all the medical records submitted”)

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D101	In RADV audits, CMS reviews a selection of medical charts that the Medicare Advantage plan identifies.	Ex. D-122A, Kapustij 30(b)(6) Dep. 97:7-14 (CMS corporate representative stating that “the focused review process resulted in a review of all the medical records submitted”); <i>see, e.g.</i> , Ex. D-36, 2007 Risk Adjustment Data Training Participant Guide at 7-8—7-9 (7.2.2.2 Medical Record Request, Example 1) (describing selection process)	Undisputed to the extent that the RADV process for Contract Years 2011-2015 included a review of all medical records submitted by a Medicare Advantage Organization, which could include up to five medical records for a particular HCC for a particular enrollee. Otherwise disputed, mischaracterizes evidence.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 91:9-14, 97:7-14 (testifying that starting in payment year 2011, CMS allowed plans to submit up to five medical records to support a particular HCC for a particular sampled enrollee, and further that “the focused review process resulted in a review of all the medical records submitted”)
D102	The selection of medical charts that the Medicare Advantage plan identifies are selected because the Medicare Advantage plan believes they contain documentation that would support the sampled health condition.	Ex. D-122A, Kapustij 30(b)(6) Dep. 91:9-19 (CMS corporate representative describing medical record submission process); Ex. D-135, Renjilian Dep. 77:4-20 (United expert stating “That’s my understanding is that they submit what they think are the -- you know, five best records to support that HCC.”); Ex. D-141, Stark Dep. 39:22-40:10 (government expert stating that RADV involves “asking the	Undisputed.	

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		MAO for support for the HCCs that were assigned to that beneficiary that year, that the MAO is allowed to provide up to five pieces of information -- I think their chart specifically, but five pieces of information to support each HCC, and that support might or might not be from the diagnosis instance that was originally submitted")		
D103	The Medicare Advantage plan identifies those medical charts from the full set of medical charts for the beneficiary for that year.	Ex. D-141, Stark Dep. 39:22-40:10 (government expert stating that RADV involves "asking the MAO for support for the HCCs that were assigned to that beneficiary that year, that the MAO is allowed to provide up to five pieces of information -- I think their chart specifically, but five pieces of information to support each HCC, and that support might or might not be from the diagnosis instance that was originally submitted"); Ex. D-135, Renjilian Dep. 77:4-20 (United expert stating "That's my understanding is that they submit what they think are the --	Undisputed.	

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		you know, five best records to support that HCC")		
D104	Medicare Advantage plans are required to annually attest to the accuracy, completeness, and truthfulness of the diagnosis data submitted for risk adjustment payments based on their best knowledge, information, and belief.	42 C.F.R. § 422.504(l) ("As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests."); Ex. D-1, Am. Compl. ¶ 5 ("[T]he Government requires that each MA Organization expressly certify that the diagnosis codes it has submitted for risk adjustment payments are accurate and truthful based on best	Undisputed.	

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		knowledge, information, and belief.”)		
D105	CMS has not promulgated any rules specifying how Medicare Advantage plans should perform chart reviews.	Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) at 169:18-170:8 (CMS corporate representative stating that “CMS never told MAOs how to design their medical record reviews. They -- the MAOs are responsible for developing their own protocols.”); Ex. D-114, Hornsby Dep. 73:10-15 (former CMS employee agreeing that, prior to the proposed medical record review rule, CMS did not specify in any regulation that MA plans were required to design their chart reviews to identify overpayments)	Disputed. Mischaracterizes evidence.	Ex. P-10, Rice Tr. 134:2-137:24 (CMS Deputy Director for the Center for Medicare describing data accuracy requirements that apply should an MAO opt to perform a Chart Review, stating that “you can’t just do nothing. You have to do something.”); Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (MAOs are responsible for ensuring data submitted to CMS is accurate, complete, and truthful based on best knowledge, information and belief and the submission of a diagnosis code to CMS is considered a claim for payment); D-17, 79 Fed. Reg. 29844, 29926 (May 23, 2014) (when CMS decided not to finalize a rule that would dictate the precise format a Chart Review must take, CMS emphasized that MAOs’ still had a contractual requirement to certify based on best knowledge, information and belief the accuracy, completeness, and truthfulness of the

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				risk adjustment data they submit to CMS and further reiterated the requirement that a diagnosis submitted to CMS must be supported by medical record documentation); Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 74:14-75:11 (“[CMS is] not providing a detailed series of steps or a recipe for how to conduct and organize and design a chart review program. CMS requires that diagnoses be accurate, complete, and truthful. It’s the MAO’s responsibility to figure out how to make that truth which allows them to certify every year.”)
D106	CMS has not issued any subregulatory guidance specifying how Medicare Advantage plans should perform chart reviews.	Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) at 170:22-171:22 (CMS corporate representative stating “That is correct. CMS never set out any guidance telling MAOs how to design medical record reviews.”); Ex. D-137, Rice Dep. 206:3-206:16 (CMS employee stating “[I]n terms of a specific procedure that plans were to follow to -- to meet their obligations to submit correct data, no, we did not have	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-100, Creighton (Oct. 4, 2022) Tr. 66:19-67:5 (former CMS employee discussing the Affordable Care Act, not Medicare Advantage chart review programs); Ex. P-10, Rice Tr. 134:2-137:24 (CMS Deputy Director for the Center for Medicare describing certain subregulatory data accuracy requirements that apply should an MAO opt to perform a Chart Review); Ex. P-9, Medicare Managed Care Manual, Ch. 7, Exhibit 30 (Aug. 13, 2004) (“... a medical record must substantiate all

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		specific procedures that we were telling plans to follow.”); Ex. D-100, Creighton Dep. (10/04/2023) at 66:19-67:5 (former CMS employee confirming no subregulatory guidance requiring plans to design their chart review programs in a fashion that validates previously-submitted diagnosis codes)		diagnostic information provided to CMS.”); Ex. P-8, Medicare Managed Care Manual, Rev. 118 (Sept. 19, 2014), Ch.7, § 40 (diagnosis codes must be supported by medical record documentation and unsupported diagnosis codes must be deleted); <i>id.</i> at § 120.2.1 (MAOs and anyone submitting data on behalf of an MAO must first sign an EDI agreement); Ex. P-59, MAPL001126483 (UnitedHealth employee, Patty Brennan, noting chart review guidance included in the 2012 Encounter Data Participant Guide, which she attached to the email); Ex. P-59A, MAPL001126484, 2012 Encounter Data Participant Guide, § 2.4.3 (“Chart reviews may be performed by MAOs and other entities for the purpose of diagnosis code validation. Because diagnoses drive risk adjustment, all chart review encounters must be supported by the medical record.”) and § 2.5.4 (“MAOs and other entities are responsible for the accuracy of all encounter data submitted and must ensure that every submission can be supported by an original source document (i.e., a medical record). MAOs and other entities must also

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				attest that the data submitted is based on best knowledge, information, and belief and be accurate and truthful."); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 4.16 (stating that MAOs must delete erroneous diagnosis clusters and further that "if the MA organization submits corrected data, the MA organization must submit the appropriate deletion record. That is, if the correct diagnosis cluster is submitted, the erroneous diagnosis cluster cannot be ignored."), § 3.2.4 (diagnosis codes must be supported by medical record documentation), § 6.5 at Table 6C (same); Ex. P-5, United 30(b)(6) (Sedor) Tr. 98:1-99:3 (Corporate representative confirming that UnitedHealth understood that if it corrected a diagnosis cluster representing a given encounter, UnitedHealth knew they also had to delete a cluster that was previously submitted erroneously); see Ex. P-1, Joint Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations and Related Entities, ¶ 5, <i>see also</i> ,

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				Ex. P-1C, MAPL008081457, §§ A5 and A11 (UnitedHealth agreed “Based on best knowledge, information, and belief, that it will submit risk adjustment data that are accurate, complete, and truthful[]” and further agreed to “research and correct risk adjustment data discrepancies”), Ex. P-1B, MAPL007637301, Optum EDI Agreement (Optum agreeing to the same); Ex. P-1G, USBP009417433, 2017 PY Attestation (United attestation stating that “Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.”); Ex. P-93, Tudor Tr. 25:4-6 (Former Deputy Director for the Center for Medicare stating: “A. In general -- in general, I would say that you have to design medical record review to look for both adds and deletes.”)
D107	In 2009, CMS had not proposed any rule that required Medicare Advantage plans to design their chart review programs	Ex. D-97, Cavanaugh Dep. 74:15-21, 153:12-17, 155:9-23 (former CMS employee stating no known requirement that plans design their chart review	Disputed. Conflicting evidence presented.	Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (MAOs are responsible for

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	to assess whether doctor-submitted diagnosis codes were supported in the medical charts.	programs to assess whether doctor-submitted diagnosis codes were supported in the medical charts); Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) at 170:22-171:22 (CMS corporate representative stating "That is correct. CMS never set out any guidance telling MAOs how to design medical record reviews.")		ensuring data submitted to CMS is accurate, complete, and truthful based on best knowledge, information and belief and the submission of a diagnosis code to CMS is considered a claim for payment. Also, stating that MAOs must act in good faith and exercise due diligence in the submission of diagnosis data to CMS); Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 74:14-75:11 ("[CMS is] not providing a detailed series of steps or a recipe for how to conduct and organize and design a chart review program. CMS requires that diagnoses be accurate, complete, and truthful. It's the MAO's responsibility to figure out how to make that truth which allows them to certify every year.")
D108	United attempted to implement a program to investigate whether certain doctor-submitted diagnosis codes not identified in chart reviews were supported by documentation in the	Ex. D-95, Brennan Dep. 148:10-18 (former United employee describing Claims Verification Program); Ex. D-128, Martinez Dep. 28:23-29:21 (same)	Disputed to the extent fact says United "attempted" to implement a Claims Verification program, conflicting evidence presented. Otherwise, undisputed	Ex. P-11, Dep. Ex. 381, United response to US Interrogatory (Set Six, Jul. 19, 2022), Response to Interrogatories 19 and 20 (describing the volume of deletes empirically made through the claims verification program); Ex. P-16, United 30(b)(6) (Bird, Jun. 22, 2023) Tr.102:11-14 (Corporate representative: "Q. Mr.

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	patients' medical charts ("Claims Verification").			Bird, another risk adjustment program that Optum performed for UnitedHealthcare was called claims verification; right? A. Correct."); <i>id.</i> at 109:1-110:6 (Corporate representative explaining that the program examined HCCs)
D109	"Claims Verification" is a program Defendants conducted between 2010 and 2014 in which they reviewed "some [medical c]harts from some of the [c]hart [r]eview [p]rogram for service years 2009-2012" to determine "if there were any provider-reported diagnosis codes that had been submitted to CMS, but were not supported by the [medical c]hart."	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 55-56 (government expert describing Claims Verification Program); Ex. D-91, Bird 30(b)(6) Dep. 102:15-103:21 (United corporate representative stating that Claims Verification "was a program that we operated during a certain time frame that identified and reviewed exclusive HCCs that were submitted by providers that were part of the chart review program.").	Undisputed.	
D110	United's Claims Verification Program "applied only to a subset of Charts that had been reviewed in the Chart Review Program. For example, a Chart was only	Ex. D-57, Garthwaite (9/29/2023) Rep. ¶ 56	Undisputed.	

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	eligible for inclusion in the” Claims Verification Program “if it was associated with” an ““exclusive HCC.’ ... [A]n exclusive HCC is one that was included in a beneficiary’s record solely on the basis of a diagnosis code (or diagnosis codes) reported by one provider in the service year” but United’s coders “in the Chart Review Program identified no diagnosis codes mapping to that HCC in the review of that provider’s Chart.”			
D111	United attempted to implement the Claims Verification program in phases between 2010 to 2013.	Ex. D-91, Bird 30(b)(6) Dep. 102:25-103:21	Disputed to the extent fact says United "attempted" to implement a Claims Verification program, conflicting evidence presented. Also, disputed as to timeframe for Claims Verification, conflicting evidence presented. Otherwise, undisputed.	Ex. P-11, Dep. Ex. 381, United response to US Interrogatory (Set Six, Jul. 19, 2022), Response to Interrogatories 19 and 20 (describing the volume of deletes empirically made through the claims verification program); Ex. P-16, United 30(b)(6) (Bird, Jun. 22, 2023) Tr. 102:11-14 (Corporate representative: “Q. Mr. Bird, another risk adjustment program that Optum performed for UnitedHealthcare was called claims verification; right? A. Correct.”); <i>id.</i> at 109:1-110:6 (Corporate

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				representative explaining that the program examined HCCs); Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶¶ 55-56 (US Expert stating that United conducted CV through April 2014)
D112	United witnesses testified that the Claims Verification program was a complex process in terms of “whether you got the right medical record, whether you got the entire medical record” and to “overturn[] what a provider has actually submitted for their patient.”	Ex. D-92, Bird Dep. 47:10-48:9	Disputed to the extent that the fact claims multiple witnesses made this statement, but Defendants only cite to the testimony of one witness, mischaracterizes cited evidence. Otherwise, undisputed.	
D113	United witnesses testified that the Claims Verification program was time consuming and could take “a year . . . to process.”	Ex. D-92, Bird Dep. 47:10-48:9	Disputed to the extent that the fact claims multiple witnesses made this statement, but Defendants only cite to the testimony of one witness, mischaracterizes cited evidence. Otherwise, undisputed.	

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D114	United witnesses testified that the Claims Verification program was an attempt to perform “a very complex process to try and link provider information” with “data that existed within the various claims systems.”	Ex. D-92, Bird Dep. 84:25-85:11	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. P-61, Dumcum Tr. 205:15-207:17 (describing the comparison of diagnosis codes on claims with data from chart review as “easy enough.”); Ex. P-62, Martinez Tr. 67:19-70:13 (United witness describing the process of matching claims to chart review results.)
D115	United “receiv[ed] complaints from providers” that diagnoses “were being deleted inappropriately” when United attempted to review doctor-submitted codes.	Ex. D-147, Meyer Dep. 160:5-16	Disputed. Not supported by cited evidence.	Ex. P-90, Meyer Tr. 160:15-16 (Describing a program other than CV: “We received those complaints through the RACCR program specifically”)
D116	CMS “does not prescribe” to MA plans how to conduct chart review programs, because “[t]here’s no one-size-fits-all for a review program.”	Ex. D-115, Hornsby 30(b)(6) Dep. (5/19/2023) at 222:7-15 (CMS corporate representative describing CMS requirements); <i>see also</i> Ex. D-97, Cavanaugh Dep. 74:15-21, 153:12-17, 155:9-23 (former CMS director failing to identify any rule or regulation prior to the proposed medical record review rule describing how MA plans should conduct chart review);	Undisputed.	

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		Ex. D-145, Tudor Dep. 173:12-174:13 (former CMS employee stating that CMS was “thinking about proposing” a rule requiring MA plans to conduct chart review to identify both over- and under-payments in 2013); Ex. D-119, Hutchinson Dep. 150:9-16 (former CMS employee testifying that he did not have knowledge of CMS telling MA plans that they would also have to examine whether diagnosis codes submitted by providers were supported during chart review)		
D117	On January 10, 2014, CMS solicited public comment on a proposed rule that would have established that “medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.”	Ex. D-16, 79 Fed. Reg. 1918, 2000 (Jan. 10, 2014) (proposing rule that would require MA plans to design their chart review to verify accuracy of diagnosis codes submitted by providers); Ex. D-119, Hutchinson Dep. 150:9-16 (former CMS employee testifying that he did not have knowledge of CMS telling MA plans that they would also have to examine whether diagnosis codes submitted by providers	Undisputed.	

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No.	Statement of Fact	Citation	Response	Citation
		were supported during chart review)		
D118	In response to the January 10, 2014 proposed Medical Record Review Rule, CMS received comments from the Medicare Advantage industry expressing concerns about the clarity of the proposed rule.	Ex. D-17, 79 Fed. Reg. 29844, 29848 (May 23, 2014) (noting comments from the industry about vagueness and potential for operational instability); <i>id.</i> at 29925-26 (noting comments received from the industry regarding the “overly broad” nature of the proposed medical review rule); Ex. D-114, Hornsby Dep. 77:23-78:18 (former CMS employee testifying that there was an “uproar” in the industry after the proposed medical record review rule); Ex. D-137, Rice Dep. 159:20-160:12 (CMS employee stating that the proposed medical record review rule was not finalized because of “stakeholder concern and pushback”)	Disputed to the extent not supported by cited evidence in Ex. D-114 and Ex. D-137. Otherwise, undisputed.	
D119	In response to the January 10, 2014 proposed Medical Record Review Rule, CMS received comments from the	Ex. D-17, 79 Fed. Reg. 29844, 29848 (May 23, 2014) (noting comments from the industry about vagueness and potential	Disputed to the extent not supported by cited evidence in Ex. D-17	

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No.	Statement of Fact	Citation	Response	Citation
	Medicare Advantage industry expressing concerns about how burdensome it would be to implement it.	for operational instability); <i>id.</i> at 29925-26 (noting comments received from the industry regarding the “vagueness” of the proposed medical review rule); Ex. D-114, Hornsby Dep. 77:23-78:18 (former CMS employee testifying that there was an “uproar” in the industry after the proposed medical record review rule); Ex. D-137, Rice Dep. 159:20-160:12 (CMS employee stating that the proposed medical record review rule was not finalized because of “stakeholder concern and pushback”)	and Ex. D-137. Otherwise, undisputed.	
D120	United witnesses testified that the proposed Medical Record Review Rule “led to a lot of confusion on our part inside UnitedHealthcare” because “we had a claims verification process in place at the time.”	Ex. D-154, Thompson Dep. 151:8-21 (United employee testifying that it seemed “contradictory” to introduce a proposed rule containing a requirement similar to that fulfilled by the claims verification process); <i>see also</i> Ex. D-144, Theisen 30(b)(6) Dep. 130:8-132:18 (United corporate representative testifying that United stopped claims verification after	Undisputed.	

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No.	Statement of Fact	Citation	Response	Citation
		discussions with CMS regarding the proposed medical record review rule)		
D121	United witnesses testified that before the April 29, 2014 meeting, United was confused about whether it was required to construct its medical record reviews to validate doctor-submitted HCCs.	Ex. D-131, Nelson Dep. 284:17-285:24 (former United employee testifying that one of the reasons United wanted the April 29, 2014 meeting with CMS was clarity regarding whether its claims verification was required); Ex. D-144, Theisen 30(b)(6) Dep. 130:8-132:18 (United corporate representative testifying that one of the reasons United wanted the April 29, 2014 meeting with CMS was clarity regarding whether its claims verification was required)	Disputed to the extent cited evidence relates to Claims Verification rather than Chart Review, mischaracterizes cited evidence and conflicting evidence presented. Otherwise, undisputed.	Ex. P-35, Schumacher Tr. 200:23-201:1 ("And we were clear to say that, you know, "Chart program is one thing. It has its own QA process. We're not asking about that right now. We're asking you about our claims verification process."); Ex. P-64, Gardner Tr. 149:14-22 ("Q. Okay. Did you believe, during the period that you worked at United, that if data was incorrectly submitted, you had an obligation to notify CMS? A. My understanding was that if we were aware that a -- a condition was not -- incorrectly submitted, as in not supported by the medical record documentation, then that we should proceed with deleting it."); Ex. P-5, United 30(b)(6) (Sedor) Tr. 92:11-15 (Corporate representative: "If as an organization we had knowledge that we submitted a risk -- I'm sorry, a diagnosis code that was in error, if we had knowledge that the diagnosis code was in error and unsupported, we would submit a delete."); Ex. P-65,

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				Halva Tr. 309:8-25 ("Q. All right. If M&R opened a given medical record to look for all diagnosis codes that were supported by documentation in that record, but did not find documentation to support a diagnosis that had been previously submitted - A. Okay. Q. -- do you believe that M&R had an obligation to delete that code? MR. SCHINDLER: Same objection. Vague and ambiguous as framed. Calls for a legal conclusion as well. A. My general thought is if the circumstances were correct, yes. I mean, as we discussed before, there's potentially some one-offs that wouldn't require the deletion of that code. But, in general, yes, I believe it should be deleted.")
D122	United sought clarification from CMS about whether its Claims Verification program was already required.	Ex. D-9, United States' Responses and Objections to Request for Admission No. 36 (admitting it was possible that United raised the topic of claims verification on a phone call between Larry Renfro and Jonathan Blum); Ex. D-9, United States' Responses and Objections to Request for Admission No. 48; Ex. D-142,	Disputed. Not supported by cited evidence.	

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		Tavener Dep. 27:7-33:14 (former CMS employee Marilyn Tavener describing her role as Administrator (2013-2015) and CMS Chief Deputy Administrator (2010-2013)), 110:3-13 (testifying that she recalled being approached by Larry Renfro to discuss concern about the process for reviewing charts)		
D123	On April 29, 2014, there was a meeting between United and CMS officials.	Ex. D-9, United States' Responses and Objections to Request for Admission No. 79	Undisputed.	
D124	The stated purpose of the April 29, 2014 meeting was to discuss the proposed Medical Record Review Rule.	Ex. D-9, United States' Responses and Objections to Request for Admission No. 81	Undisputed.	
D125	The April 29, 2014 meeting was attended by Sean Cavanaugh, Cynthia Tudor, Cheri Rice, Dan Farmer, and Julia Uebersax (née Grover) from CMS.	Ex. D-22, MARA2157039 (United's Thad Johnson's notes from April 29, 2014 meeting listing CMS attendees); Ex. D-10, United States' Responses and Objections to Request for Admission No. 117 (admitting	Undisputed that the April 29, 2014 meeting was attended by Sean Cavanaugh, Cynthia Tudor, Cheri Rice, Dan Farmer, and Julie	

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		that Sean Cavanaugh, Cheri Rice, Cynthia Tudor, Dan Farmer, and Julia Uebersax were the only attendees from CMS at the April 29, 2014 meeting)	Uebersax (née Grover) from CMS.	
D126	The April 29, 2014 meeting was attended by Dan Schumacher, Steve Nelson, Karen Erickson, and Thad Johnson from United.	Ex. D-22, MARA2157039 (United's Thad Johnson's notes from April 29, 2014 meeting listing United attendees); Ex. D-9, United States' Responses and Objections to Request for Admission No. 90 (admitting that Karen Erickson, Thad Johnson, Steve Nelson, and Dan Schumacher from United attended the April 29, 2014 meeting)	Undisputed.	
D127	United's witnesses testified that during the meeting, CMS told United that unless the proposed Medical Record Review Rule became final, Medicare Advantage plans did not have an affirmative obligation to confirm whether doctor-submitted diagnosis codes	Ex. D-131, Nelson Dep. 284:17-285:24 (former United employee testifying that United "got a very clear answer" from CMS at the April 29, 2014 meeting that there was no need to continue claims verification); Ex. D-138, Schumacher Dep. 194:24-195:10 (United employee testifying that CMS	Disputed to the extent that fact is not supported by Ex. D-22 and Ex. D-24, not supported by cited evidence. Also, disputed to the extent the testimony in Ex. D-131 and Ex. D-138 relates to Claims Verification rather than Chart	

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	are supported by documentation in the medical records.	told United at the April 29, 2014 meeting that United did not have an obligation to perform claims verification until the proposed medical record review rule was finalized); Ex. D-22, MARA2157039 (United's notes from the April 29, 2014 meeting noting that CMS confirmed that until the proposed medical record review rule was finalized, MA plans did not have an obligation to confirm that diagnoses submitted by doctors were accurate); Ex. D-24, USBP000548071 (CMS notes from April 29, 2014 meeting stating "no proactive resp. to confirm accuracy of dx")	Review, mischaracterizes cited evidence. Otherwise, undisputed.	
D128	Four of the five CMS personnel who attended the April 29, 2014 meeting between United and CMS did not recall what was said at the meeting.	Ex. D-137, Rice Dep. 189:11-189:18 (CMS employee stating she did not remember what was discussed at the April 29, 2014 meeting), 190:18-191:5 (testifying she did not remember what she or others said at the April 29, 2014 meeting and that nothing she reviewed refreshed her recollection); Ex. D-145,	Disputed. Conflicting evidence presented.	Ex. P-10, Rice Tr. 200:21-201:12 (CMS Deputy Director for the Center for Medicare recalls "reminding United about the False Claims Act" during the April 29, 2014 videoconference); <i>id.</i> at 201:21-202:8 (same)

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		Tudor Dep. 89:25-90:2 (former CMS employee stating she did not recall meeting with United on April 29, 2014), 92:25-94:16 (testifying she did not recall what was said at the April 29, 2014 meeting); Ex. D-105, Farmer Dep. 31:20-37:8 (describing role as special assistant to Sean Cavanaugh, Deputy Administrator of CMS and Director of the Center for Medicare), 68:2-69:3 (testifying he did not recall any statements made or topics discussed at the April 29, 2014 meeting); Ex. D-146, Uebersax Dep. 16:13-28:11 (CMS employee describing her current role as a Senior Advisor/Health Insurance Specialist to Deputy Director (2019-present) and former roles as a CMS Health Insurance Specialist (2015-2019), Special Assistant to Group Director for the Medicare Plan Payment Group (2012-2015), and CMS Health Insurance Specialist (2010-2012), 92:8-94:25 (testifying she did not remember specific		

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		discussions at the April 29, 2014 meeting).		
D129	One CMS attendee of the April 29, 2014 meeting between United and CMS, Sean Cavanaugh, had a limited recollection.	Ex. D-97, Cavanaugh Dep. 180:22-181:3 (testifying that he recalled United describing its Claims Verification program), 183:2-183:18 (former CMS employee testifying he did not recall anyone stating that MA plans did not have a proactive obligation to confirm whether diagnosis codes submitted by providers were accurate)	Disputed. Conflicting evidence presented.	Ex. P-20, Cavanaugh Tr. 177:14-178:2 (recalling CMS saying at the videoconference something along the lines of "yes, there's a proposed regulation. It may or may not be finalized. We can't tell you one way or the other. However, if you're solely focused on that, you should be aware there are other statutes, regulations, requirements that apply to your obligation to submit complete and accurate data. You should make sure you're aware of them, and if you're asking us questions about how to specifically comply with the law, that's more appropriately posed to your own counsel."); <i>id.</i> at 176:8-24 (same); <i>id.</i> at 182:5-25 (referencing his recollection of repeating the same response given in previous testimony over and over and denying "saying anything else about what their obligations were under either the probes reg or existing requirements."); <i>id.</i> at 191:14-25 ("Q. And do you see the sentence that reads, near the end of that paragraph, 'Sean Cavanaugh stated

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				that, under current rules, if UHG doesn't know codes are inaccurate the company would not have to delete them. He went on to state that if UHC does not know until the end of its claims verification process that a code is incorrect then there is no requirement to delete the code until the effective date of CMS's final rule.' Do you see that? A. I see that. Q. You -- you deny saying that? A. I deny it, absolutely."); <i>id.</i> at 202:13-22 ("Q. All right. Mr. Nelson writes that 'CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that Medicare Advantage plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses.' Do you see that? A. I see that. Q. And you deny saying that anybody from CMS said that at the meeting, right? A. Absolutely.")
D130	Certain attendees of the April 29, 2014 Meeting, including from United and from CMS, memorialized the meeting in notes.	Ex. D-22, MARA2157039 (United's Thad Johnson's notes from the April 29, 2014 meeting); Ex. D-24, USBP000548071 (CMS's	Disputed as to D-24, conflicting evidence presented. Otherwise, undisputed.	Ex. P-27, Tudor Tr. 91:22-92:8 (calling the words written in her daytimer at the time of the meeting a "vague" piece of paper); <i>id.</i> at 100:15-101:11 (questioning whether the words written in her daytimer are

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		Cynthia Tudor's notes from the April 29, 2014 meeting)		"accurate" or "even close to being right")
D131	Cynthia Tudor memorialized her recollection of the April 29, 2014 meeting in notes.	Ex. D-24, USBP000548071 (CMS's Cynthia Tudor's notes from the April 29, 2014 meeting)	Disputed. Conflicting evidence presented.	Ex. P-27, Tudor Tr. 91:22-92:8 (calling the words written in her daytimer at the time of the meeting a "vague" piece of paper); <i>id.</i> at 100:15-101:11 (questioning whether the words written in her daytimer are "accurate" or "even close to being right")
D132	Thad Johnson memorialized his recollection of the April 29, 2014 meeting in notes.	Ex. D-22, MARA2157039 (United's Thad Johnson's notes from the April 29, 2014 meeting)	Disputed. Conflicting evidence presented.	Ex. P-20, Cavanaugh Tr. 202:13-203:7 (disputing United's understanding of the April 29, 2014 videoconference: "Q. All right. Mr. Nelson writes that 'CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that Medicare Advantage plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses.' Do you see that? A. I see that. Q. And you deny saying that anybody from CMS said that at the meeting, right? A. Absolutely. Q. All right. So let's -- let's look at -- because you had agreed to deliver the mantra, and

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				that's all you did, as you recall it? A. But also, as phrased here, the reason why my memory is so crystal clear, none of us would say, if you're doing a medical record review, you shouldn't -- you wouldn't be held to a standard of trying to be accurate. Like that -- that's just not a posture CMS would take."); Ex. P-66, USBP0061943 (June 26, 2015 Cavanaugh e-mail to Rice in response to Nelson email to Rice disagreeing that CMS stated that "M[edicare] A[dvantage] plans are [] not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses.")
D133	United memorialized its understanding of the April 29, 2014 meeting in an email to CMS stating "M[edicare] A[dvantage] plans are [] not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes."	Ex. D-71, Cavanaugh Dep. Ex. 1063 (USBP000197069, 70) (April 30, 2014 email from United to CMS stating that CMS had confirmed to United that MA plans were not required to design their chart review to verify the accuracy of provider-submitted diagnosis codes)	Disputed. Conflicting evidence presented.	Ex. P-20, Cavanaugh Tr. 202:13-203:7 (disputing United's understanding of the April 29, 2014 videoconference: "Q. All right. Mr. Nelson writes that 'CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that Medicare Advantage plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses.' Do you

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				see that? A. I see that. Q. And you deny saying that anybody from CMS said that at the meeting, right? A. Absolutely. Q. All right. So let's -- let's look at -- because you had agreed to deliver the mantra, and that's all you did, as you recall it? A. But also, as phrased here, the reason why my memory is so crystal clear, none of us would say, if you're doing a medical record review, you shouldn't -- you wouldn't be held to a standard of trying to be accurate. Like that -- that's just not a posture CMS would take."); Ex. P-66, USBP0061943 (June 26, 2015 Cavanaugh e-mail to Rice in response to Nelson email to Rice disagreeing that CMS stated that "M[edicare] A[dvantage] plans are [] not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses.")
D134	There was internal support at CMS for the proposed Medical Record Review Rule.	Ex. D-137, Rice Dep. 156:1-10 (CMS employee testifying that CMS supported the proposed Medical Record Review rule because "it would be helpful to be more specific"), 159:20-	Disputed. Not supported by cited evidence.	

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		161:23 (discussing why the rule was not finalized); see Ex. D-17, 79 Fed. Reg. 29,844, 29,925-26 (May 23, 2014) (describing CMS's proposed Medical Record Review Rule)		
D135	The Medicare Advantage plan industry expressed concerns with the proposed Medical Record Review Rule.	Ex. D-114, Hornsby Dep. 77:23-78:18 (former CMS employee testifying that there was an "uproar" in the industry after the proposed medical record review rule); Ex. D-124, Kornfield Dep. 20:21-22:4, 25:17-32:21 (former CMS official Thomas Kornfield describing his prior roles as a Health Insurance Specialist in the Division of Payment Systems (2014-2015), Director of the Division of Payment Systems (2012-2014), and Health Insurance Specialist in the Centers for Medicare and Medicaid Innovation (2014-2015)), 183:5-183:16 (stating that CMS had received "significant pushback" from the MA industry regarding the proposed medical record review rule); Ex. D-137, Rice Dep.	Undisputed.	

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		159:20-160:12 (CMS employee stating that the proposed medical record review rule was not finalized because of “stakeholder concern and pushback”); Ex. D-17, 79 Fed. Reg. 29844, 29848 (May 23, 2014) (noting comments from the industry about vagueness and potential for operational instability); <i>id.</i> at 29925-26 (noting comments received from the industry regarding the “vagueness” and “overly broad” nature of the proposed medical review rule)		
D136	CMS decided to not finalize the proposed Medical Record Review Rule.	Ex. D-17, 79 Fed. Reg. 29844, 29925–26 (May 23, 2014) (noting CMS decision to finalize the proposed medical record review rule)	Undisputed.	
D137	Shortly after CMS declined to finalize the Medical Record Review Rule, United told CMS that it had ceased its Claims Verification program.	Ex. D-71, Cavanaugh Dep. Ex. 1063 (USBP000197069, 70) (April 30, 2014 email from United to CMS stating that CMS had confirmed to United that MA plans were not required to design their chart review to	Disputed to the extent that parenthetical for Ex. D-71 mischaracterizes evidence. Otherwise, undisputed.	Ex. P-20, Cavanaugh Tr. 202:13-23 (denying CMS told United that MA plans are not required to design their medical review to verify the accuracy of risk adjustment diagnosis); Ex. P-66, USBP0061943 (June 26, 2015)

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		verify the accuracy of provider-submitted diagnosis codes and therefore United was suspending its claims verification program); Ex. D-137, Rice Dep. 197:14-198:7 (CMS employee testifying United sent an email on April 30, 2014 informing CMS that it had suspended its claims verification program)		(Cavanaugh email to Rice, denying the same)
D138	On September 27, 2013, several CMS employees exchanged emails about whether to define "reasonable diligence" in connection with its regulations."	Ex. D-35, USBP066819447	Disputed to the extent that Ex. D-35 discusses a single regulation (not "regulations"), mischaracterizes cited evidence. Otherwise, undisputed.	Ex. D-17, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (discussing in final rule what is required under "reasonable diligence")
D139	On September 27, 2013, CMS employee John Scott sent an email to Jennifer Harlow and other CMS employees suggesting that their division of CMS "deliberately cho[o]se not to define" reasonable diligence in its proposed regulations.	Ex. D-35, USBP066819447	Disputed to the extent that Ex. D-35 discusses a single regulation (not "regulations"), mischaracterizes cited evidence. Also, disputed to the extent the fact implies cited material reflects CMS policy, mischaracterizes	Ex. D-17, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (discussing in final rule what is required under "reasonable diligence"); Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 199:21-200:5 (staff opinions "not particularly meaningful" to CMS point of view")

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			evidence. Otherwise, undisputed.	
D140	On September 27, 2013, CMS employee Ilina Chaudhuri sent an email to Jennifer Harlow and other CMS employees that she “like[d]” the approach of “deliberately choosing not to define the term” reasonable diligence.	Ex. D-35, USBP066819447	Disputed. Mischaracterizes evidence. Otherwise, undisputed that CMS employee sent this email on September 27, 2013.	Ex. D-17, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (discussing in final rule what is required under “reasonable diligence”); Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 199:21-200:5 (staff opinions “not particularly meaningful” to CMS point of view”)
D141	On September 27, 2013 CMS employee Maricruz Bonfante sent an email to Jennifer Harlow and other CMS employees that she “agree[d]” with the approach to “hold on trying to create a standard” for reasonable diligence, “especially if [CMS] want[s] to lessen plan burden and also not create an affirmative obligation to ‘identify’” unsupported HCCs.	Ex. D-35, USBP066819447	Disputed. Mischaracterizes evidence. Otherwise, undisputed that CMS employee sent this email on September 27, 2013.	Ex. D-17, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (discussing in final rule what is required under “reasonable diligence”); Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 199:21-200:5 (staff opinions “not particularly meaningful” to CMS point of view”)

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D142	After 2007, Jennifer Harlow became the Deputy Director of the Medicare Plan Payment Group within CMS.	Ex. D-76, Harlow Dep. Ex. 1253 (listing Jennifer Harlow as Deputy Director of CM/MPPG from July 2012); Ex. D-156, Harlow Dep. 18:1-11 (CMS employee testifying she became Deputy Director "at some point" after 2007)	Disputed. Mischaracterizes cited evidence.	Ex. D-76, Dep. Ex. 1253, Feb. 11, 2022 United States' Custodians Employment Chart (listing Jennifer Harlow as Deputy Director of CM/MPPG from July 2012 and showing that she held a Division Director position from 2007-2012); Ex. D-156, Harlow Tr. 18:1-11 (CMS employee testifying the Division Director position she held starting in February of 2007 was the Director of the Division of Payment Validation and confirming that she held her role as Deputy Director of MPPG "subsequently")
D143	Between approximately 2010 and 2016, Maricruz Bonfante was a health insurance specialist within the Medicare Plan Payment Group within CMS's Center for Medicare.	Ex. D-157, Bonfante Dep. 19:7-16	Undisputed.	
D144	Between 2012 and 2015, Ilina Chaudhuri was the Deputy Director for the Division of Payment Policy,	Ex. D-98, Chaudhuri Dep. 30:5-12	Undisputed.	

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	within the Medicare Plan Payment Group of CMS.			
D145	John Scott was a special assistant to the group director in the Medicare Plan Payment Group within CMS.	Ex. D-157, Bonfante Dep. 137:10-20	Disputed. Mischaracterizes evidence. Otherwise, undisputed that John Scott was a special assistant to the group director in the Medicare Plan Payment Group for a limited period of time.	Ex. P-68, Medicare Advantage & Prescription Drug Plan Fall Conference & Webcast, Conference Guide (Sept. 7, 2017), at p. 11, https://www.cms.gov/outreach-and-education/training/cteo/downloads/2017-fall-conference/cms-ma-pdpconffall2017guidefinalpdf.pdf (last visited July 9, 2024) (description of John Scott's various roles at CMS, which only included a role as special assistant to the group director in the Medicare Plan Payment Group within CMS for a certain time period)
D146	On October 26, 2015, Cheri Rice wrote in an email to Sean Cavanaugh, Jennifer Harlow, and Cynthia Tudor that CMS "regs say that plans must use reasonable diligence to identify overpayments" but that CMS "ha[s] not yet defined what that means. [CMS] could, through regulation define	Ex. D-72, Cavanaugh Dep. Ex. 1067 (USBP001891973)	Undisputed that Cheri Rice sent the October 26, 2015 email. Disputed to the extent fact excludes Rice testimony regarding the same email, mischaracterizes evidence.	Ex. D-17, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (discussing in final rule what is required under "reasonable diligence"); Ex. P-10, Rice Tr. 54:22-56:5 (clarifying that October 26, 2015 email referred to defining "specific steps" that CMS would "prescribe" for plans to meet reasonable diligence obligation.)

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	specific steps a plan must take, at a minimum, to meet that requirement. For example, [CMS] could require them to self-audit (i.e., their own RADV audits). [CMS] could also revive the NPRM proposal we had that if a plan is checking a medical record for underpayments, they must also look for overpayments. . . . Another thought is getting more help supporting DOJ whistleblower activity. The volume of these cases is increasing and they often need technical assistance from [CMS] to evaluate whether to intervene and to support cases they choose to prosecute. We think the whistleblower activity could be as effective – or even more effective – than CMS audits in getting plans to do more to prevent and identify risk adjustment overpayments.”			

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D147	Between 2010 and 2017, Cheri Rice was the Director of the Medicare Plan Payment Group within CMS.	Ex. D-137, Rice Dep. 16:22-17:4	Undisputed.	
D148	Between March or April 2014 and January 2017, Sean Cavanaugh was the Deputy Administrator and Director for the Center for Medicare within CMS.	Ex. D-97, Cavanaugh Dep. 23:12-26:16, <i>id.</i> at 30:5-22	Undisputed.	
D149	Between approximately 2014 and July 2017, Cynthia Tudor was the Deputy Director of the Center for Medicare within CMS.	Ex. D-145, Tudor Dep. 26:4-11	Undisputed.	
D150	CMS knew that United did not seek to validate doctor-submitted codes through its Chart Review Program.	Ex. D-32, USBP009417619 (external attestation for 2013 DOS submitted June 26, 2015); Ex. D-21, MARA2152278 (June 26, 2015 email from United to CMS communicating that United "did not use [its] previous process to determine whether diagnosis codes submitted through claims are	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 266:11-15 ("So when an MAO is doing chart reviews or medical record reviews, they have a protocol, presumably. CMS knows nothing about the MAO chart review protocols, but they have a protocol presumably which gives them results."); Ex. P-20, Cavanaugh Tr. 163:14-18 (Q: . . . Did you know that

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		unsupported in the medical record” and qualifying attestation for 2013 DOS); Ex. D-31, USBP009417534 (external attestation for 2014 DOS, submitted June 7, 2016); Ex. D-23, USBP000498420 (June 7, 2016 email from United to CMS communicating that United “did not use [its] previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record” and qualifying attestation for 2014 DOS); Ex. D-30, USBP009417526 (external attestation for 2015 DOS, submitted October 12, 2018); Ex. D-29, USBP009417442 (external attestation for 2016 DOS submitted October 12, 2018); Ex. D-33, USBP058101090 (October 12, 2018 email from United to CMS qualifying attestation for DOS 2015 and 2016); Ex. D-137, Rice Dep. 239:21-240:14 (CMS employee testifying that she understood United’s June 26, 2015 email to be informing her that it was not		in 2014? That medical -- Medicare Advantage plans were conducting medical record reviews, and for the most part, not looking for deletes? A. I did not know that.); Ex. P-27, Tudor Tr. 112:1-11 (“I understood they were doing chart reviews. To the extent to which [MAO] were only adding and not -- not validating, if you will, to what they had already submitted, I was not aware.”); Ex. P-24, Dep. Ex. 324, MAPL000497870 (email from Steve Nelson, UHC M&R CEO, to Cheri Rice regarding Claims Verification); P-10, Rice Tr. at 197:1-198:7 (CMS Deputy Director for the Center for Medicare testifying that she read the 2014 Nelson email as referring to Claims Verification); <i>id.</i> at 239:2-12 (recognizes June 26, 2015 email as the same language as was in the 2014 Nelson email),

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		performing the same type of medical record review for DOS 2013 as it had for DOS 2012); Ex. D-10, United States' R&Os to United's RFA No. 147 (admitting that CMS received United's June 26, 2015 email)		
D151	In 2015, United emailed CMS and stated that United had decided to discontinue its process of reviewing certain medical records to determine the accuracy of doctor-submitted diagnoses and submit appropriate deletes based on United's 2014 conversations with CMS, CMS's withdrawal of the proposed Medical Record Review Rule, and CMS's ongoing consideration of an adjustment to account for unsupported codes in the FFS data used to calibrate the CMS-HCC risk adjustment model ("FFS Adjuster").	Ex. D-32, USBP009417619 (external attestation for DOS 2013 submitted June 26, 2015); Ex. D-27, USBP001354165, 66 (June 26, 2015 email from United to CMS communicating that United "did not use [its] previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record" and qualifying attestation for DOS 2013); Ex. D-137, Rice Dep. 239:21-240:14 (CMS employee testifying that she understood United's June 26, 2015 email to be informing her that it was not performing the same type of medical record review for DOS 2013 as it had for DOS 2012); Ex. D-10, United States' R&Os to United's RFA No. 147	Disputed to the extent the fact suggests cited portion of email is about a program other than Claims Verification, mischaracterizes evidence. Otherwise, undisputed.	Ex. P-1D, USBP001354165, at USBP001354166 (July 30, 2015 Rice email to Nelson stating "there are laws and contractual provisions that impose standards, requirements and responsibilities on MA organizations in connection with federal payments . . . MA organizations are required to implement effective compliance programs that prevent, detect and correct non-compliance with CMS program requirements, to exercise reasonable diligence in identifying overpayments, and to report and return such overpayments to the Medicare Program within 60 days."); Ex. P-10, Rice Tr. 239:2-12 (CMS Deputy Director for the Center for Medicare recognizes June 26, 2015 email as the same language as was in the 2014 Nelson email); <i>id.</i> at 197:1-198:7 (testifying that she read the 2014 Nelson email as referring to

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		(admitting that CMS received United's June 26, 2015 email).		Claims Verification); Ex. P-26, CMS 30(b)(6) (Hornsby, May 19, 2023) Tr. 219:1-24 ("A. My understanding is that CMS' entire discussion with United, with Steve Nelson in particular, started with that April 2014 meeting and is still continuing here, and CMS still doesn't know exactly what United was doing. You know, were they targeting a population? Were they doing blind coding or not, you know? Who knows what that claims verification program was? Who knows if there are other parts of United, other MAOs that are still doing some kind of review? So CMS doesn't give specific recommendations to MAOs in meetings like that. CMS will restate CMS' position, and -- and that's it")
D152	In 2016, United emailed CMS and stated United had decided to discontinue its process of reviewing certain medical records to determine the accuracy of doctor-submitted diagnoses and submit appropriate deletes based on United's 2014	Ex. D-26, USBP001354107 (June 7, 2016 email from United to CMS communicating that United "did not use [its] previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record" and qualifying	Disputed to the extent the fact suggests cited portion of email is about a program other than Claims Verification, mischaracterizes evidence. Otherwise, undisputed.	Ex. P-1F, USBP009866579 (May 28, 2020 Shapiro Letter to Thompson regarding all of United's risk adjustment correspondence to date and stating "the decision in 2014 by CMS not to finalize the proposed amendment to 42 CFR § 422.310(e) did "not change CMS' existing contractual requirement that MA

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	conversations with CMS, CMS's withdrawal of the proposed Medical Record Review Rule, and CMS's ongoing consideration of a FFS Adjuster.	attestation for DOS 2014); Ex. D-31, USBP009417534 (external attestation for DOS 2014, submitted June 7, 2016)		organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS." 79 Fed. Reg. 29,844, 29,926 (May 23, 2014). Nor did it change the requirement that all diagnosis codes submitted for risk adjustment payments must be documented in the beneficiaries' medical records pursuant to the ICD-9 and -10 Guidelines for Coding and Reporting with which HHS and Medicare regulations require compliance. CMS has not stated otherwise to United.")
D153	In 2018, United emailed CMS and stated United had decided to discontinue its process of reviewing certain medical records to determine the accuracy of doctor-submitted diagnoses and submit appropriate deletes based on United's 2014 conversations with CMS, CMS's withdrawal of the proposed Medical Record Review Rule, and CMS's	Ex. D-30, USBP009417526 (external attestation for DOS 2015, submitted October 12, 2018); Ex. D-29, USBP009417442 (external attestation for DOS 2016 submitted October 12, 2018); Ex. D-33, USBP058101090 (October 12, 2018 email from United to CMS qualifying attestation for DOS 2015 and 2016)	Disputed to the extent the fact suggests cited portion of email is about a program other than Claims Verification, mischaracterizes evidence. Otherwise, undisputed.	Ex. P-1F, USBP009866579 (May 28, 2020 Shapiro Letter to Thompson regarding all of United's risk adjustment correspondence to date and stating "the decision in 2014 by CMS not to finalize the proposed amendment to 42 CFR § 422.310(e) did "not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to

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	ongoing consideration of a FFS Adjuster.			CMS.” 79 Fed. Reg. 29,844, 29,926 (May 23, 2014). Nor did it change the requirement that all diagnosis codes submitted for risk adjustment payments must be documented in the beneficiaries’ medical records pursuant to the ICD-9 and -10 Guidelines for Coding and Reporting with which HHS and Medicare regulations require compliance. CMS has not stated otherwise to United.”)
D154	In its bid documentation for Contract Years 2015 and 2016, United stated that, based on conversations with CMS and CMS’s treatment of medical record review in its 2014 rulemaking process, United had ceased one of its processes of reviewing certain medical records to determine the accuracy of doctor-submitted diagnoses and submit deletes.	Ex. D-25, USBP000674257, 64 (June 2, 2014 MA Supporting Documentation for CY 2015 bid stating that United had decided to “cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process”); Ex. D-34, USBP062135635, 42 (similar language in August 4, 2015 MA Supporting Documentation for CY 2016 bid); Ex. D-127, Limmer 30(b)(6) Dep. 217:11-19 (CMS corporate representative agreeing that the bid documentation language stated that United had decided to end its process that identified	Disputed. Mischaracterizes evidence.	See Ex. D-25, USBP000674257, 64 (June 2, 2014 MA Supporting Documentation for CY 2015 bid stated that “based on multiple conversations with CMS and CMS’s treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process[]” without mentioning that the prior process was focused on the review of doctor submitted diagnosis codes for accuracy); Ex. D-34, USBP062135635, 42 (August 4, 2015 MA Supporting Documentation for CY 2016 bid stated that “based on multiple conversations with CMS

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		and deleted certain diagnoses codes)		and CMS's treatment of medical record review in its 2014 rulemaking process, beginning in 2014, the health plan ceased one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process" without mentioning that the prior process was focused on the review of doctor-submitted diagnosis codes for accuracy); Ex. P-79, Spitalnic (US Expert) Tr. 214:10-215:18 (US Expert and CMS Chief Actuary explaining that CMS bid review does not involve reading "every word" of a bid submission); <i>id.</i> at 217:12-219:14 (Chief actuary of CMS noting that neither he nor anyone on his staff were aware of the specific language in United's bid supporting documentation.); Ex. P-38, Limmer 30(b)(6) Dep. 217:11-19 (CMS 30(b)(6) only acknowledging that the statement "says they've decided to cease one of its prior processes that identified and deleted certain diagnoses codes[]" but does not testify that the statement referenced the review and deletion of doctor-submitted diagnosis codes.); <i>id.</i> at Tr. 218:4-20, 222:19-224:13 (stating that the statement included in United's

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				bid documentation has “very little information in here in terms -- to make an assessment on what -- you know, the -- the entirety of what’s happening here[]” and further testifying that, despite efforts to confirm, CMS was not able to identify anyone who read the statement United included in the documentation supporting its bid.)
D155	In 2020, United’s First Interrogatory asked the government to identify each diagnosis code the government alleged United “knowingly and improperly failed to delete . . . or otherwise return to the Medicare Program [as an] overpayment.”	Ex. D-7, Defendant UHC Of California’s First Interrogatory to the Government (Jan. 3, 2020)	Undisputed.	
D156	In its First Interrogatory Response, the government identified 27,937,651 “invalid diagnoses” that it claimed United knew were “unsupported by medical records” and that United allegedly either “‘knowingly	Ex. D-11A, United States’ Responses and Objections to UHC of California’s First Interrogatory (Feb. 3, 2020) (explaining basis for determining the “invalid diagnoses”); Ex. D-11B, United States’ First Supplemental	Undisputed.	

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	and improperly failed to delete in the RAPS system' or 'knowingly and improperly failed to otherwise return to the Medicare Program.'"	Responses and Objections to UHC of California's First Interrogatory (Aug. 17, 2020) (same and identifying approximately 28 million codes); Ex. D-141, Stark Dep. 104:15-105:1 (government expert confirming the number of diagnostic instances in the First Interrogatory Response)		
D157	The government explained to the court that its list of approximately 28 million diagnosis codes in its First Interrogatory Response contained "every diagnosis code . . . UnitedHealth submitted to CMS to increase its risk adjustment payments, and then improperly failed to delete when UnitedHealth's own reviewers found no support for the diagnosis code in the member's medical records."	Ex. D-5, Joint Stipulation Re United States' Motion to Compel Discovery at 2 (Apr. 16, 2021)	Undisputed.	
D158	The government explained to the Court that, "[f]or each diagnosis code on the United	Ex. D-5, Joint Stipulation Re United States' Motion to	Undisputed.	

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	States' [First Interrogatory Response] list: (1) the diagnosis code was submitted by UnitedHealth to CMS . . . ; (2) that medical record went through UnitedHealth's medical record review program; and (3) UnitedHealth's own reviewers did not find the diagnosis code to be supported by medical records."	Compel Discovery at 2 (Apr. 16, 2021)		
D159	The government's response to United's Interrogatory No. 12 accused United of "failing to delete or otherwise retract diagnosis codes" in the First Interrogatory Response that were (in the government's words) "previously submitted by UnitedHealth to CMS that its Chart Review program revealed were not supported by medical record documentation."	Ex. D-12, United States' Responses and Objections to Defendant UHC of California's Interrogatory No. 12 (June 23, 2022)	Disputed as to the use of "accused," mischaracterizes cited evidence. Otherwise, undisputed.	

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D160	Doctors submitted every diagnosis code listed in the Government's First Interrogatory Response on a claim form.	Ex. D-113, Higgins Dep. 132:2-133:2 (former United employee testifying that he relied on providers signing an attestation that the diagnoses codes were true, complete, and accurate); Ex. D-40, Claims Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf)	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. P-69, Higgins Tr. 282:20-25 (Higgins stopped working for UnitedHealth in August, 2007, before the date of service years at issue); Ex. D-11B, US Responses and Objections to UnitedHealth's First Interrogatory (First Supplemental), p. 2 (Interrogatory seeking diagnosis codes from Date of Service Years 2008-2016, post-dating Mr. Higgins' time at UnitedHealth); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 2.2.2 (identifying formats "MA organizations may choose to collect data from providers," only one of which is the Claim Form 1500); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 76:13-20 (Corporate representative confirming face-to-face encounters could include encounters with nurse practitioners);

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				P-4, Dickey Tr. 32:10-18 (Optum Coding Director testifying that she had experience as a medical coder in a provider office before she worked for Optum); <i>id.</i> at 165:3-19 (Optum Coding Director describing work performed by providers' in-office coders); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: "In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications.")
D161	The claims forms on which the doctors submitted the diagnosis codes listed in the First Interrogatory Response stated that the doctor was certifying that the diagnosis codes were truthful and accurate.	Ex. D-113, Higgins Dep. 132:2-133:2 (former United employee testifying that he relied on providers signing an attestation that the diagnoses codes were true, complete, and accurate); Ex. D-40, Claims Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf)	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. P-69, Higgins Tr. 282:20-25 (Higgins stopped working for UnitedHealth in August, 2007, before the date of service years at issue); Ex. D-11B, US Responses and Objections to UnitedHealth's First Interrogatory (First Supplemental), p. 2 (Interrogatory seeking diagnosis codes from Date of Service Years 2008-2016, post-dating Mr. Higgins' time at UnitedHealth); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to

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				United because they are paid under a different arrangement); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, § 2.2.2 (identifying formats “MA organizations may choose to collect data from providers,” only one of which is the Claim Form 1500); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 76:13-20 (Corporate representative confirming face-to-face encounters could include encounters with nurse practitioners); P-4, Dickey Tr. 32:10-18 (Optum Coding Director testifying that she had experience as a medical coder in a provider office before she worked for Optum); <i>id.</i> at 165:3-19 (Optum Coding Director describing work performed by providers’ in-office coders); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: “In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications.”)

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D162	United accurately submitted to CMS the diagnosis codes that United had received from doctors on claims forms.	Ex. D-147, Meyer Dep. 26:22-27:8, 27:11-28:8 (former United employee testifying that United was responsible to submit codes as they were received from the providers); Ex. D-134, Polich Dep. 124:7-21 (former United employee testifying that United would accurately submit codes received from providers)	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 76:13-20 (Corporate representative testifying that face-to-face encounters could include "Physician encounters, in-office encounters or provider encounters, let's say, like if it's a nurse practitioner, and then, like, hospital reviews like you were just describing. Those are some of the examples."); Ex. P-4, Dickey Tr. 32:10-18 (Optum Coding Director testifying that she had experience as a medical coder in a provider office before she started working for Optum); <i>id.</i> at 165:3-19 (describing work performed by providers' in-office coders); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, 2.2.2 (identifying formats "MA organizations may choose to collect data from providers," only one of which is the Claim Form 1500); Ex. P-55, Rasmussen Tr. 44:12-45:14 (testifying that, at times, UnitedHealth modified or otherwise corrected data received from

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				providers when submitting that data to CMS)
D163	The government has produced only one expert report—that of Dr. Craig Garthwaite—that attempts to identify the set of diagnosis codes that the government alleges are allegedly unsupported.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 13	Disputed as to the use of the word "attempted" in the fact, mischaracterizes cited evidence. Otherwise, undisputed.	
D164	The government has produced only one expert report—that of Dr. Craig Garthwaite—that attempts to identify the set of diagnosis codes that the government alleges were allegedly overpayments.	Ex. D-57, Garthwaite (9/29/2023) Rep. ¶ 13	Disputed as to the use of the word "attempted" in the fact, mischaracterizes cited evidence. Otherwise, undisputed.	
D165	Dr. Garthwaite did not review any medical charts.	Ex. D-110, Garthwaite Dep. 133:21-134:3	Undisputed.	
D166	Dr. Garthwaite did not opine as to whether a single diagnosis code was in fact unsupported.	Ex. D-110, Garthwaite Dep. 133:21-134:3 (government expert stating that Dr. Garthwaite did not look at any medical records to determine	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: "According to my analysis, Defendants reviewed the medical records that were the source of the[]

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		whether the diagnoses were unsupported); Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 44-45 (“I consider an instance of a given diagnosis code from a provider-reported encounter to be supported if, and only if, the same diagnosis code is included in the chart review record of that encounter . . . Otherwise, I consider that particular diagnosis code instance to be unsupported.”)		diagnosis codes [on Attachment 1 - approximately 1.97 million codes] as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories.”); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United’s expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D167	In his deposition, Dr. Garthwaite disclaimed that he had any opinion about the percentage of codes that would be found supported in the relevant medical record after a medical record review.	Ex. D-110, Garthwaite Dep. 165:12-23	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: “According to my analysis, Defendants reviewed the medical records that were the source of the[] diagnosis codes [on Attachment 1 - approximately 1.97 million codes] as part of their Chart Review Program and their review found no support for

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				these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories.”); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United’s expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D168	In his deposition, Dr. Garthwaite disclaimed that he would express at trial any opinion about the rate at which the diagnosis codes at issue were in fact unsupported.	Ex. D-110, Garthwaite Dep. 165:12-166:11	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: “According to my analysis, Defendants reviewed the medical records that were the source of the[] diagnosis codes [on Attachment 1 - approximately 1.97 million codes] as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories.”); Ex. P-6,

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				Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (Mr. Renjilian does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D169	Dr. Garthwaite in his expert report "considers" a diagnosis code to be unsupported if a diagnosis code submitted by a doctor is not identified by a United chart reviewer during their blind review as part of the Chart Review Program.	Ex. D-57, Garthwaite Rep. (9/29/2023) Appendix D ¶ 44	Undisputed, except to the extent Dr. Garthwaite refers to a "provider" instead of a "doctor," mischaracterizes cited evidence, in which case, disputed, conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023), Appendix D ¶ 44 (US Expert refers to "provider-reported encounter"); <i>id.</i> at ¶ 13 ("According to my analysis, Defendants reviewed the medical records that were the source of the[] diagnosis codes [on Attachment 1 - approximately 1.97 million codes] as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories."); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does

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				not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D170	Dr. Garthwaite identifies a set of what he calls "Potential Deletes," which are "all diagnosis codes that are Submitted Diagnosis Codes but not Supported Diagnosis Codes (<i>i.e.</i> , all diagnosis codes from Reviewed Encounters that were submitted to CMS but were not found to be	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 104	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-74, Garthwaite (US expert) Tr. 51:1-16 (US Expert: "There was no actual list of potential deletes, but it's a way we describe it in the report conceptually."); Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023), ¶ 85, fn. 123 ("The method summarized herein provides an overview of the analytical steps I have undertaken. Further technical detail is provided in Appendix D, which along with the programs I

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	supported in the Chart Review Program)."			have provided can be used to replicate my results.");
D171	Dr. Garthwaite's "Reviewed Encounters" do not include any "encounters for which the data from the Chart Review Program is potentially incomplete because the Coder was 'informed.'"	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 100	Undisputed.	
D172	All of Dr. Garthwaite's Potential Deletes are diagnosis codes that United coders did not identify during a blind chart review.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 100, 104	Undisputed except to the extent fact indicates there was only one blind chart review of the medical records associated with Dr. Garthwaite's Deletes, in which case, disputed, mischaracterizes evidence.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 51 (US Expert stating that two blind chart reviews were performed for medical records that went through the Second Level Review process); <i>id.</i> at ¶ 92, fn. 124 ("Of the \$997,051,302 total financial impact for Part C and Part D in service years 2014-2016 shown in Exhibit 10, \$799,407,848 is associated with diagnosis codes submitted by Defendants to CMS associated with Charts that were reviewed in Defendants' Second Level Review program.")

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D173	All of Dr. Garthwaite's Deletes are codes that were not identified by United coders during a blind chart review.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 100, 104	Undisputed except to the extent fact indicates there was only one blind chart review of the medical records associated with Dr. Garthwaite's Deletes, in which case, disputed, mischaracterizes evidence.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 51, 92 (US Expert describing a process called "second level review")
D174	Dr. Garthwaite's list of "Potential Deletes" is conceptually the same codes included in the government's First Interrogatory Response.	Ex. D-57, Garthwaite Rep. (9/29/2023) Appendix D ¶ 44 (government expert explaining methodology used to identify Potential Deletes); Ex. D-11A, United States' Responses and Objections to UHC of California's First Interrogatory (Feb. 3, 2020) (explaining basis for determining the "invalid diagnoses"); Ex. D-11B, United States' First Supplemental Responses and Objections to UHC of California's First Interrogatory (Aug. 17, 2020) (same and identifying approximately 28 million codes)	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-74, Garthwaite (US expert) Tr. 54:13-58:18 (US Expert explaining how his analysis is conceptually different from what he understands is included in the United States' First Interrogatory Response)

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D175	To identify Potential Deletes, Dr. Garthwaite identifies "all diagnosis codes from Reviewed Encounters that were submitted to CMS but were not found to be supported in the Chart Review Program."	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 104	Undisputed.	
D176	Dr. Garthwaite's report treats every doctor-submitted diagnosis code not found by a United chart reviewer in a blind review as unsupported.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 104	Disputed, mischaracterizes evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 94 (US Expert explaining that he only identifies codes as potential deletes if he first matches the Chart Review encounter to the provider-reported encounter); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)

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D177	From the Potential Deletes, Dr. Garthwaite identified “those diagnosis codes on the Potential Deletes list that do not share an HCC with any other submitted diagnosis code, do not share an HCC with any other risk adjustment-eligible but unsubmitted diagnosis code, <i>and</i> do not map to an HCC recorded in the Claims Verification program.”	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 116	Undisputed.	
D178	In other words, to identify the “Deletes” Dr. Garthwaite attempted to determine the subset of the “Potential Deletes” that impacted United’s payment from CMS, which Dr. Garthwaite called the “Deletes.”	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 116-118	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶¶ 13, 110-114 (US Expert listing steps he applied to identify Deletes)
D179	The Garthwaite Deletes number approximately 1.97 million codes, or roughly 7% of the 28 million codes the	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶¶ 30, 32 & Figures 4, 5 (United expert explaining the Garthwaite Deletes number); Ex. D-110, Garthwaite Dep. 321:18-23	Undisputed.	

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	government included in the First Interrogatory Response.	(government expert stating that he identified the Garthwaite Deletes)		
D180	The Garthwaite Deletes correspond to approximately 0.5% of the total diagnosis codes submitted by United during the period relevant to this case for the members with medical records that underwent Chart Review.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 59, Figure 9	Undisputed.	
D181	Doctors submitted every diagnosis code in the Garthwaite Deletes on a claims form.	Ex. D-113, Higgins Dep. 132:2-133:2 (former United employee testifying that he relied on providers signing an attestation that the diagnoses codes were true, complete, and accurate); Ex. D-40, Claims Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf)	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. P-69, Higgins Tr. 282:20-25 (Testifying that he stopped working for UnitedHealth in August, 2007); see Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) at ¶ 137, Exhibit 10 (showing US Expert, Dr. Garthwaite's, analysis was limited to diagnosis codes from Date of Service Years 2008-2016, post-dating Mr. Higgins' time at UnitedHealth); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); Ex. P-3, Dep.

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				Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, 2.2.2 (identifying formats "MA organizations may choose to collect data from providers," only one of which is the Claim Form 1500); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 76:13-20 (Corporate representative confirming face-to-face encounters could include encounters with nurse practitioners); P-4, Dickey Tr. at 32:10-18 (Optum Coding Director testifying that she had experience as a medical coder in a provider office before she started working for Optum); <i>id.</i> at 165:3-19 (describing work performed by providers' in-office coders); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: "In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications.")
D182	The claims form on which doctors submitted the diagnosis codes in the Garthwaite's Deletes stated	Ex. D-113, Higgins Dep. 132:2-133:2 (former United employee testifying that he relied on providers signing an attestation	Disputed. Not supported by cited evidence, mischaracterizes	Ex. P-69, Higgins Tr. 282:20-25 (Testifying that he stopped working for UnitedHealth in August, 2007); <i>see</i> Ex. D-57, Garthwaite (US

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	that the doctor was certifying that the diagnosis codes were truthful and accurate.	that the diagnoses codes were true, complete, and accurate); Ex. D-40, Claims Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf)	evidence, and conflicting evidence presented.	Expert) Rep. (Sept. 29, 2023) at ¶ 137, Exhibit 10 (showing US Expert, Dr. Garthwaite's, analysis was limited to diagnosis codes from Date of Service Years 2008-2016, post-dating Mr. Higgins' time at UnitedHealth); Ex. P-5, United 30(b)(6) (Sedor) Tr. 127:9-17 (Corporate representative explaining that capitated providers do not submit claims or diagnosis codes to United because they are paid under a different arrangement); Ex. P-3, Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, 2.2.2 (identifying formats "MA organizations may choose to collect data from providers," only one of which is the Claim Form 1500); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 76:13-20 (Corporate representative confirming face-to-face encounters could include encounters with nurse practitioners); P-4, Dickey Tr. at 32:10-18 (Optum Coding Director testifying that she had experience as a medical coder in a provider office before she started working for Optum); <i>id.</i> at 165:3-19 (Optum Coding Director describing

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				work performed by providers' in-office coders); Ex. D-53, Acevedo (US Expert) Rebuttal Rep. (Jan. 29, 2024) ¶ 72 (US Expert: "In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications.")
D183	Based on Garthwaite's analysis, more than 93% of the codes in the government's First Interrogatory Response did not affect the payment United received from CMS and did not lead to an overpayment.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶¶ 29-33, Figure 5	Disputed. Mischaracterizes cited evidence.	Ex. P-74, Garthwaite (US expert) Tr. 54:13-55:3 (US Expert testifying that he was not involved in the First Interrogatory Response and is only aware of it, meaning that he could not have done analysis with respect to the First Interrogatory Response)
D184	During RADV audits, CMS coders reviewed approximately 6,500 health conditions that correspond to diagnoses included in the government's First Interrogatory Response.	See Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 164-167 & Figure 15	Undisputed.	

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D185	CMS validated approximately 89% of the approximately 6,500 health conditions corresponding to the diagnosis codes included in the United States' Response to Interrogatory No. 1.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 164-167 & Figure 15 (United expert describing analysis of Interrogatory 1 diagnosis codes); Ex. D-63, Stark Rep. (3/28/2024) ¶ 30 (government expert agreeing with the left side of Figure 15 in the Renjilian Report); Ex. D-141, Stark Dep. at 36:13-37:2 (same)	Disputed. Conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may

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				increase or decrease before the RADV Audits are finalized.”);
D186	Extrapolating RADV audit results to any portion of diagnosis codes identified in the First Interrogatory Response may have considerable statistical bias.	Ex. D-141, Stark Dep. 141:7-144:13 (government expert discussing statistical bias); Ex. D-135, Renjilian Dep. 132:9-132:17 (United expert discussing how the RADV audit results cannot be statistically extrapolated to any population); <i>id.</i> at 190:16-190:24 (United expert discussing how the RADV audit results cannot be statistically extrapolated to any population); Ex. D-63, Stark Rep. (3/28/2024) ¶ 53 (government expert stating that RADV validation rates should not be extrapolated)	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. P-57, Stark (US Expert) Tr. 142:13-16, 144:8-13 (US Expert describing “unknown bias” and “bias of unknown magnitude”); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final

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				and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D187	Extrapolating RADV audit results to any portion of diagnosis codes identified in the Garthwaite Deletes may have considerable statistical bias.	Ex. D-141, Stark Dep. 141:7-144:13 (government expert discussing statistical bias); Ex. D-135, Renjilian Dep. 132:9-132:17 (United expert discussing how the RADV audit results cannot be statistically extrapolated to any population); <i>id.</i> at 190:16-190:24 (United expert discussing how the RADV audit results cannot be statistically extrapolated to any population); Ex. D-63, Stark Rep. (3/28/2024) ¶ 53 (government expert stating that RADV validation rates should not be extrapolated)	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. P-57, Stark (US Expert) Tr. 142:13-16, 144:8-13 (US Expert describing “unknown bias” and “bias of unknown magnitude”); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the

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				audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D188	The RADV medical record review results, including the medical record review results of the codes reviewed that are also on the First Interrogatory Response list, are the results as determined prior to United’s appeals.	Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 65:22-66:3 (CMS corporate witness noting that CMS has not released final CON11-13 results); <i>id.</i> at 81:2-9 (no preliminary findings as to CON 14 or CON 15); Ex. D-64, Renjilian Updated Initial Rep. (12/3/2023) ¶ 154 n.221 (United expert explaining the disclaimer associated with the coding results that state they are not final); Ex. D-135, Renjilian Dep. 238:17-239:15 (United expert stating that the results were not final)	Disputed. Conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (discussion of the preliminary RADV results for contract years 2011-2013); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and

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				estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D189	The RADV medical record review results, including the medical record review results of the codes reviewed that are also on the Garthwaite Deletes, are the results as determined prior to United’s appeals.	Ex. D-117, Hornsby 30(b)(6) Dep. (11/21/2023) 65:22-66:3 (CMS corporate witness noting that CMS has not released final CON11-13 results); <i>id.</i> at 81:2-9 (no preliminary findings as to CON 14 or CON 15); Ex. D-64, Renjilian Updated Initial Rep. (12/3/2023) ¶ 154 n.221 (United expert explaining the associated with the coding results that state they are not final); Ex. D-135, Renjilian Dep. 238:17-239:15 (United expert stating that the results were not final)	Disputed. Conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (discussion of the preliminary RADV results for contract years 2011-2013); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results

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				of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D190	The RADV audits were not conducted based on a random sample of member-HCCs that are at issue in this case.	Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 52-53 (government expert explaining RADV audits sample frame); Ex. D-64, Renjilian Updated Initial Rep. (12/3/2023) ¶ 161 n.233 (United expert explaining RADV audit sample frame)	Undisputed.	
D191	The RADV audits were not conducted based on a random sample of diagnosis codes that are at issue in this case.	Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 52-53 (government expert explaining RADV audits sample frame); Ex. D-141, Stark Dep. 142:9-16 (government expert explaining RADV audits sample frame)	Undisputed.	

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D192	The RADV audits were not conducted based on a representative sample of member-HCCs that are at issue in this case.	Ex. D-141, Stark Dep. 142:17-143:12 (government expert explaining RADV audit sampling); Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 42-45 (explaining that RADV audits are not conducted based on a "simple random sample of member-HCC-years"), ¶¶ 52-53 (government expert explaining RADV audit sampling methodology)	Undisputed.	
D193	The RADV audits were not conducted based on a representative sample of diagnosis codes that are at issue in this case.	Ex. D-141, Stark Dep. 142:17-143:12 (government expert explaining RADV audit sampling); Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 42-45 (government expert describing RADV audits as not having been conducted on the member-HCC-years at issue in this case), ¶¶ 52-53 (government expert explaining RADV audit sampling methodology)	Undisputed.	
D194	The RADV audit results cannot be extrapolated to identify the payment	Ex. D-141, Stark Dep. 145:13-146:11 (government expert explaining that RADV audits	Undisputed to the extent that the 2011-2015 CY RADV audit results	

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	associated with any allegedly mis-coded HCCs at issue in this case.	cannot be extrapolated "to any larger group"); Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 53 (government expert explaining RADV audits sample frame)	cannot be extrapolated to identify the payment associated with any diagnosis codes at issue in this case. Otherwise disputed, not supported by cited evidence.	
D195	The RADV audit results cannot be extrapolated to identify the actual rate of unsupported diagnosis codes at issue in this case.	Ex. D-141, Stark Dep. 145:5-9 (government expert explaining that it not be appropriate to extrapolate RADV findings to codes at issue in this case because of how the sample was drawn); Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 53 (government expert explaining RADV audits sample frame)	Undisputed.	
D196	The government's statistical expert, Dr. Philip Stark independently confirmed that CMS auditors validated approximately 89% of the health conditions corresponding to the diagnosis codes included in the United States' Response to Interrogatory No. 1.	Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 30, 36 (government expert confirming his results match United's experts' results); Ex. D-64, Renjilian Rep. (12/3/2023) Figure 15 (United expert figure showing that CMS audits validated 89% of the health conditions corresponding to diagnosis codes on the First	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been

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		Interrogatory Response); Ex. D-141, Stark Dep. 36:13-25 (government expert confirming results of Renjilian analysis)		released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); Ex. P-57, Stark (US Expert) Tr. 36:13-37:20 US Expert explaining that his work only involved checking Mr. Renjilian’s arithmetic, not verifying his assumptions); Ex. D-63, Stark (US Expert) Updated Rep. (Mar. 28, 2024), ¶¶ 25-30; Ex. P-57, Stark (US Expert) Tr. 35:7-22 (US Expert describing his starting point for the relevant opinion was using Mr. Renjilian’s determination”); Ex. P-6, Renjilian (United Expert) Tr. 123:3-

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				13 (testifying that the United States' First Interrogatory Response included approximately 28 million diagnosis code instances); <i>id.</i> at 126:4-130:12 (UnitedHealth's expert testifying about the meaning of "overlap" between the HCCs audited by CMS auditors and the United States' First Interrogatory Response); <i>see</i> Ex. D-64, Renjilian (United Expert) Updated Rep. (Dec. 3, 2023), ¶¶ 159 and 160 (UnitedHealth's expert determined that 8,215 diagnosis codes identified on the United States' First Interrogatory Response mapped to HCCs that were reviewed in a CMS RADV Audit)
D197	Not all of the diagnosis codes identified by the government in their First Interrogatory Response are in fact unsupported.	Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 152-161 (United expert analyzing the diagnosis codes on the government's First Interrogatory Response), Figure 13 (identifying supported diagnosis codes); Ex. D-63, Stark Rep. (3/28/2024) ¶ 30 (government expert confirming his results match United's experts' results); Ex. D-141, Stark Dep. 38:23-39:8 (government expert explaining	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-57, Stark (US Expert) Tr. 39:5-8 (Q. And out of those 1,119 instances, the RADV auditors found 980 of them to be supported, right? A. Not of the diagnosis instances, but of the resulting HCC for that beneficiary for that year."); <i>id.</i> at 63:22-64:10 ("Q. So just because a United chart review coder did not find a provider-submitted code, that does not mean that the associated member-HCC-year is unsupported, assuming RADV is correct? You 1

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		that all not diagnoses codes identified by the government in the First Interrogatory Response were found to be supported by RADV auditors)		agree with that, right? A. Yes, the -- just because chart review did not find support for a diagnosis code submitted for a particular diagnosis instance, there might be somewhere - - there still might be somewhere support for the HCC that that diagnosis code maps to or an HCC higher in the hierarchy, possibly in the chart that was reviewed by the United chart reviewers and possibly in some other chart for that member for that year"); Ex. P-6, Renjilian (United Expert) Tr. 136:18-137:5 (testifying that it is unknown "which specific diagnosis was found by the RADV auditors to be supported, but it's just that the HCC was supported."); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other.")
D198	Not all of the 1.97 million diagnosis codes in the Dr. Garthwaite Deletes are in fact unsupported.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 60	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-6, Renjilian (United Expert) Tr. 129:4-15 (explaining RADV audits were done at the HCC level); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific

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				diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other."); Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: "According to my analysis, Defendants reviewed the medical records that were the source of these diagnosis codes as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories"); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr. Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D199	Not all of the diagnosis codes identified by the	Ex. D-64, Renjilian Rep. (12/3/2023) ¶161, Figure 13	Disputed. Not supported by cited evidence and	Ex. P-6, Renjilian (United Expert) Tr. 129:4-15 (explaining RADV

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	government in their First Interrogatory Response would be unsupported if the beneficiary's corresponding medical charts were reviewed.	(United expert showing validation rates for diagnosis codes reviewed in RADV that were also identified by the government in their First Interrogatory Response)	conflicting evidence provided.	audits were done at the HCC level); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other.")
D200	Not all of the 1.97 million diagnosis codes Dr. Garthwaite called "Deletes" would be unsupported if the beneficiary's medical charts were reviewed.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 32 (United expert describing Garthwaite Deletes), ¶ 60 (United expert analyzing if possible to determine how many of the Garthwaite Deletes would be unsupported)	Disputed. Not supported by cited evidence and conflicting evidence provided.	Ex. P-6, Renjilian (United Expert) Tr. 129:4-15 (explaining RADV audits were done at the HCC level); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other."); Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 13 (US Expert: "According to my analysis, Defendants reviewed the medical records that were the source of these diagnosis codes as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated Hierarchical Condition Categories or Rx Hierarchical Condition Categories"); Ex. P-6, Renjilian (United Expert) Tr. 94:4-25 (Mr.

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				Renjilian testifying that he does not have an expert opinion as to whether Dr. Garthwaite correctly identified Reviewed Encounters); <i>id.</i> at 96:1-99:2 (United's expert does not opine whether Dr. Garthwaite incorrectly identified diagnosis codes that were recorded in Chart Review nor that Dr. Garthwaite incorrectly compared codes identified in Chart Review to those submitted by providers.)
D201	The government had the ability to review a statistically valid sample of United's medical records corresponding to the First Interrogatory Response list to estimate the portion of them that are unsupported.	Ex. D-18, 88 Fed. Reg. 6643, 6648 (Feb. 1, 2023) (indicating that CMS will review a sample for RADV audits); Ex. D-38, 71 DOJ J. Fed. L. & Prac. 4, 196-97 (2023) (describing examples of extrapolation in cases and providing an example from 1999)	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-78, Order Denying Without Prejudice Plaintiff's Motion to Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt. 419), May 28, 2021 (Special Master denying United States' Motion to Compel production of underlying medical records); Ex. P-54, Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021 (Order denying United States' Motion for Review of Dkt. 419)
D202	The government had the ability to review a statistically valid sample of United's medical records corresponding to	Ex. D-18, 88 Fed. Reg. 6643, 6648 (Feb. 1, 2023) (stating that sampling and extrapolation have been used in Medicare Parts A and B for decades); Ex. D-38,	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-78, Order Denying Without Prejudice Plaintiff's Motion to Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt. 419), May 28, 2021 (Special Master

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	Garthwaite's Deletes to estimate the portion of them that are unsupported.	71 DOJ J. Fed. L. & Prac. 4, 196-97 (2023) (describing examples of government use of extrapolation in cases and providing an example from 1999)		denying United States' Motion to Compel production of underlying medical records); Ex. P-54, Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021 (Order denying United States' Motion for Review of Dkt. 419)
D203	Dr. Stark's would have been qualified and able to design a statistically valid sample of either the diagnoses on the First Interrogatory Response list or the Garthwaite Deletes.	Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 41-53	Undisputed that Dr. Stark is a qualified statistician. Disputed to the extent that Dr. Stark testified that there is no such thing as a "statistically valid sample" as a term of art in Statistics, conflicting evidence presented. Disputed to the extent that drawing a statistically valid sample of either the diagnoses on the First Interrogatory Response list or the Garthwaite Deletes, mischaracterizes evidence and is not relevant.	Ex. D-63, Stark (US Expert) Updated Rep. (Mar. 28, 2024), ¶ 78 (US Expert stating, "For instance, paragraph 3 of the Salve Report states, '[m]y study began with drawing a statistically valid sample of HCC markers found in the 2013 HCC Dataset referenced above.' There is no such thing as 'statistically valid sample' as a term of art in Statistics."); <i>see, id.</i> at ¶¶ 12-16 (assignment does not include drawing a statistically valid sample); Ex. P-78, Order Denying Without Prejudice Plaintiff's Motion to Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt. 419), May 28, 2021 (Special Master denying United States' Motion to Compel production of underlying medical records); Ex. P-54, Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021

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				(Order denying United States' Motion for Review of Dkt. 419)
D204	Dr. Stark admitted that the hypothesis that "every time a United chart review coder fail[ed] to find a diagnosis code submitted by a" doctor the HCC associated with that code for that member for the year is not supported, is a false hypothesis.	Ex. D-141, Stark Dep. at 57:9-14 (government expert agreeing with the fact that the hypothesis "every time a United chart review coder fail[ed] to find a diagnosis code submitted by a" doctor the HCC associated with that code for that member for the year is not supported, is a false hypothesis); <i>see also id.</i> 61:15-62:25 (government expert explaining that it is possible that there is support for a HCC even if a RADV reviewer did not find support for a code); <i>see also id.</i> at 75:18-79:6 (government expert explaining whether or not a chart review coder found support for a diagnosis code in a particular chart does not mean that there may be support for the particular HCC)	Disputed. Not supported by cited evidence and mischaracterizes evidence.	Ex. P-57, Stark (US Expert) Tr. 57:24-58:3 (US Expert limiting his testimony to HCCs found supported in the RADV Audit context); <i>id.</i> at 39:22-40:10, 42:2-18, 57:17-64:10 (Dr. Stark testifying that his understanding is that UnitedHealth could submit additional medical records to support an HCC in the context of a RADV Audit and that the review in the RADV Audit may not be of the encounter associated with the medical record reviewed in UnitedHealth's Chart Review Program and may not be for a diagnosis code that was ever submitted to CMS)
D205	The government's coding expert, Jean Acevedo, testified that she would have been qualified to perform a	Ex. D-87, Acevedo Dep. 97:1-10	Disputed. Mischaracterizes evidence.	Ex. P-78, Order Denying Without Prejudice Plaintiff's Motion to Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt.

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	medical record review of a sample of relevant diagnosis codes and associated medical records at issue in this case but was not asked to do so.			419), May 28, 2021 (Special Master denying United States' Motion to Compel production of underlying medical records); Ex. P-54, Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021 (Order denying United States' Motion for Review of Dkt. 419)
D206	The government uses statistical methods to extrapolate from a random sample of reviewed records on a regular basis.	Ex. D-18, 88 Fed. Reg. 6643 (Feb. 1, 2023) (stating that sampling and extrapolation have been used in Medicare Parts A and B for decades); Ex. D-47, OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS (Jan. 2022) (noting the sampling used for this audit); Ex. D-38, 71 DOJ J. Fed. L. & Prac. 4, 196-97 (2023) (describing examples of government use of extrapolation in cases and providing an example from 1999)	Undisputed.	
D207	The government chose not to estimate the portion of the	Ex. D-4, Amended Joint Rule 26(f) Report at 18 (Apr. 2,	Disputed, mischaracterizes	Ex. P-78, Order Denying Without Prejudice Plaintiff's Motion to

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	diagnosis codes at issue in this case that are unsupported by reviewing a random sample of diagnoses and relevant medical records.	2018) (noting plaintiff's damages calculation does not include sampling or extrapolation); Dkt. No. 317, United States' Supplemental Memorandum in Opposition to United's Motion to Compel Production of Documents, at 3 (Nov. 30, 2018) (same); <i>id.</i> at 12-13 (alleging that documents related to RADV are irrelevant because damages "are not based on sampling, extrapolation, or contract-level payment error rates"); Ex. D-6, Order Denying Motion to Compel responses to Interrogatory No. 14 and Request for Production No. 147 (5/28/2021), at 9-10 (noting that the government refused to review every medical record that United reviewed in chart review)	evidence. Otherwise, undisputed.	Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt. 419), May 28, 2021 (Special Master denying United States' Motion to Compel production of underlying medical records); Ex. P-54, Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021 (Order denying United States' Motion for Review of Dkt. 419)
D208	It is a complex exercise to identify provider submitted diagnosis codes that are associated with charts that went through Chart Review	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 81 (government expert explaining process to identify provider submitted codes which went through chart review); Ex. D-92, Bird Dep. 47:10-48:4; 84:25-85:15	Disputed. Conflicting evidence presented.	Ex. P-61, Dumcum Tr. 205:15-207:17 (United witness describing the comparison of diagnosis codes on claims with data from chart review as "easy enough."); Ex. P-62, Martinez Tr. 67:19-70:13 (United witness

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	and were not identified during Chart Review.	(8/10/2022) (United witness explaining the matching process to link provider information from chart review data and claims data); Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶¶ 53-54 (United expert explaining difficulty of identifying codes that were submitted for risk adjustment, associated with the charts that went through chart review, and not independently verified in chart review)		describing the process of matching claims to chart review results.)
D209	It took Dr. Garthwaite and his support team months and multiple attempts to try to match doctor-submitted diagnosis codes found in claims to particular medical records reviewed by United's chart reviewers.	Ex. D-59, Errata to Garthwaite Rep. (3/11/2024) ¶ 1 (government expert explaining that he submitted multiple iterations of his report); Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 10 (United expert explaining process by which Dr. Garthwaite to identify the diagnosis codes that were not supported in the Chart Review program); Ex. D-110, Garthwaite Dep. 45:10–46:5 (government expert explaining process for creating report)	Disputed. Not supported by cited evidence.	

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D210	Dr. Garthwaite agrees that the diagnosis codes on the government's approximately 28 million long First Interrogatory Response list that are not on his list of approximately 1.97 million deletes—roughly 26 million diagnosis codes—did not result in overpayment to United because United's data contained other support for the health condition.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 106-118 (government expert describing classification of Potential Deletes), Exs. D-11A & D-11B, United States' Response to UHG First Interrogatory & First Supplemental Response to UHC of California's First Interrogatory (identifying diagnosis codes); Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 30 (identifying the 1.97 diagnosis codes)	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. P-74, Garthwaite (US expert) Tr. 54:13-55:3 (US Expert describing lack of familiarity with the United States' Response to UnitedHealth's First Interrogatory)
D211	Dr. Stark agreed that on the basis of the data he had available and reviewed, there is no basis on which to reliably estimate what portion of the Garthwaite final deletes universe correspond to health conditions that are unsupported in any of the members' charts for the year.	Ex. D-141, Stark Dep. 166:11-22	Disputed. Not supported by cited evidence and mischaracterizes evidence.	Ex. P-57, Stark (US Expert) Tr. 166:11-22 (US Expert limiting his comments to whether the HCC would be found supported in a RADV Audit); <i>id.</i> at 39:22-40:10, 42:2-18, 57:17-64:10 (Dr. Stark testifying that his understanding is that UnitedHealth could submit additional medical records to support an HCC in the context of a RADV Audit and that the review in the RADV Audit may not be of the encounter associated with the medical record reviewed in UnitedHealth's Chart Review

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				Program and may not be for a diagnosis code that was ever submitted to CMS)
D212	Dr. Stark testified that he was “not aware of any data” that “would allow one to estimate what fraction of the diagnosis ... events in the final deletes list map to an HCC-member-year that RADV would have found support for...”	Ex. D-141, Stark Dep. 165:24-166:22	Undisputed.	
D213	Dr. Stark testified that “payments are based on the . . . HCCs that the diagnosis for that member map to for the year and that only a single instance of each HCC matters” for purposes of analyzing whether a Medicare Advantage plan has been overpaid.	Ex. D-141, Stark Dep. 67:20-68:10	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-57, Stark (US Expert) Tr. 64:24-68:15 (US Expert testifying in response to the question “Do you understand that if a member-HCC-year is unsupported, that would be considered an overpayment?” that he does not know how the term “overpayment” is used and if it is a legal term of art. Counsel for UnitedHealth responds that “That’s fair. I am not trying to play gotcha or suggest a term or trick you with a term of art” and counsel for UnitedHealth further represents: “I understand you’re not an expert in RADV, and I am not trying to

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				suggest that anything you say would bind the government on its interpretation of RADV.” Dr. Stark also testifying that there may be distinctions between the RADV Audit process, and the regular payment process agreed to under the MAO’s contract with CMS.)
D214	Dr. Stark agrees that there is “no way to reliably estimate” what portion of the Garthwaite final deletes in fact represent overpayments.	Ex. D-141, Stark Dep. 166:11-18	Disputed. Not supported by cited evidence and mischaracterizes evidence.	Ex. P-57, Stark (US Expert) Tr. 166:11-22 (US Expert specifically testifying about what portion of the Garthwaite deletes would be found supported by RADV Auditors and not testifying about the portion of the Garthwaite deletes that result in overpayments); <i>id.</i> at 57:17-64:10 (Dr. Stark testifying that his understanding is that UnitedHealth could submit additional medical records to support an HCC in the context of a RADV Audit and that the review in the RADV Audit may not be of the encounter associated with the medical record reviewed in UnitedHealth’s Chart Review Program)
D215	United’s Chart Review Program reviewed medical	Ex. D-88, Baker Dep. 252:11-254:17 (Optum employee noting	Undisputed.	

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	records retrieved from certain doctors encompassing specific visits to doctors on specific dates of service.	chart retrieval vendors did not obtain all charts); Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 68:10-71:11 (United corporate representative explaining chart review process), 93:18-95:9 (explaining chart targeting process); Ex. D-69, Baker 30(b)(6) Dep. Ex. 608 at 19-20 (presentation explaining the chart review process)		
D216	United's Chart Review Program did not encompass all medical charts for a beneficiary during the date of service year.	Ex. D-88, Baker Dep. 252:11-254:17 (Optum employee explaining chart retrieval); Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 68:10-71:11 (United corporate representative explaining chart review process), 93:18-95:9 (explaining chart targeting process); Ex. D-69, Baker 30(b)(6) Dep. Ex. 608 at 19-20 (presentation explaining the chart review process)	Disputed. Not supported by cited evidence.	Ex. P-88, Baker (Jul. 12, 2022) Tr. 252:11-254:17 (cited testimony does not establish that United never reviewed all of the charts for any beneficiary in any date of service year in chart review); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 68:10-71:11 (same); <i>id.</i> at 93:18-95:9 (same); Ex. D-69, Dep. Ex. 608 at 19-20 (cited document does not establish that United never reviewed all of the charts for any beneficiary in any date of service year in chart review)

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D217	As part of its Chart Review Program, United did not collect all medical charts for all doctors' visits that a beneficiary had during the date of service year.	Ex. D-88, Baker Dep. 252:11-254:17 (Optum employee explaining chart retrieval); Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) at 68:10-71:11 (United corporate representative explaining chart review process), 93:18-95:9 (explaining chart targeting process); Ex. D-69, Baker 30(b)(6) Dep. Ex. 608, at 19-20 (presentation explaining the chart review process)	Disputed. Not supported by cited evidence.	Ex. P-88, Baker (Jul. 12, 2022) Tr. 252:11-254:17 (cited testimony does not establish that United never reviewed all of the charts for any beneficiary in any date of service year in chart review); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 68:10-71:11 (same); <i>id.</i> at 93:18-95:9 (same); Ex. D-69, Dep. Ex. 608 at 19-20 (cited document does not establish that United never reviewed all of the charts for any beneficiary in any date of service year in chart review)
D218	United's Chart Review Program did not encompass a complete set of charts for a beneficiary during the date of service year because the provider may not provide a complete medical record.	Ex. D-54, Blair Rep. (9/29/2023) ¶ 26 (United expert explaining provider documentation provided to coders during chart review); Ex. D-87, Acevedo Dep. 188:8-14 (government expert explaining how it can be difficult to get a full set of paper records)	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. P-30, Acevedo (US Expert) Tr. 189:6-12 ("Q. Do you have any experience with what -- or do you track what percentage of time in the chart retrieval process you're able to obtain a complete set of the patient's medical records? A. I don't track it, but I will tell you that it's the overwhelming majority of the time with electronic medical records."); <i>id.</i> at 95:14-18; 96-5-8 (testifying she has no opinion on and is not familiar with United's chart review program); Ex. P-31, Blair (United expert) Tr. 41: 10-22 (acknowledging she has no

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				familiarity with United's chart review program)
D219	A provider may not provide a complete medical record because they may struggle to obtain offsite records.	Ex. D-54, Blair Rep. (9/29/2023) ¶ 26 (United expert stating that a provider may have difficulty pricing offsite records); Ex. D-90, Baker 30(b)(6) Dep. (5/31/2023) 552:15-553:18 ("And when we go to retrieve that chart, not all dates of services or encounters for that provider or provider group are able to be picked up. When the -- some other items could also include if the provider themselves sent us the chart, they could have not included all of the dates of services. And a member has multiple different charts across different locations and we may not have all that information.")	Disputed. Conflicting evidence presented.	Ex. P-30, Acevedo (US Expert) Tr. 193:20-194:11 ("Q. Is it the case that providers always respond to every request for medical records that you make? MS. KRIEG: Object to form. A. The overwhelming majority of the time, yes. Most definitely, yes. BY MR. BAAK: Q. But not always? Not all providers respond to all requests for medical records, right? A. No, but it's probably about 99 percent. I mean, it's really rare that we don't have a provider that provides to us what we need, even if what we need, they say let me get you access to the EMR and we find it ourselves. So yeah.")
D220	United chart review medical coders only reviewed the available medical records retrieved from a doctor that	Ex. D-88, Baker Dep. 252:11-255:10 (Optum employee describing difficulty accessing all medical records); Ex. D-90, Baker 30(b)(6) Dep. (5/31/2023) 552:15-553:18	Disputed to the extent this fact implies that United attempted to collect all available charts from providers who had a face-to-face	Ex. D-69, Dep. Ex. 608, pp. 19-23 (internal Optum presentation discussing chart targeting and retrieval, including prioritizing charts based on chart score groups and excluding approximately 1.3 million

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	saw the beneficiary during the date of service year.	("And when we go to retrieve that chart, not all dates of services or encounters for that provider or provider group are able to be picked up. When the -- some other items could also include if the provider themselves sent us the chart, they could have not included all of the dates of services. And a member has multiple different charts across different locations and we may not have all that information.")	encounter with a beneficiary during the date of service year. Conflicting evidence presented. Otherwise, undisputed.	charts from the list of targeted charts to pursue); Ex. P-7, United 30(b)(6) (Baker, May 30, 2023) Tr. 69:7-71:11 (Corporate representative testifying about Optum's "suspecting" and "targeting" processes to identify "member-provider combinations [to look for] based upon health statuses, based upon their -- their health risk status"); Ex. P-30, Acevedo (US expert) Tr. 189:6-12 (US Expert testifying that she is able to obtain a complete set of a patient's medical records "the overwhelming majority of the time with electronic medical records")
D221	CMS staff wrote in a memorandum advocating for the adoption of the Medical Record Review Rule that: "Under existing regulation, there is no requirement for plans to audit medical records for overpayments. If a plan is conducting medical record reviews to identify underpayments, we recommend that they be	Ex. D-79, Hornsby 30(b)(6) Dep. Ex. 1460 (CMS memorandum); Ex. D-116, Hornsby 30(b)(6) Dep. (5/25/2023) 218:19-221:13 (CMS corporate representative testifying about memorandum)	Disputed as to the use of "advocated" to characterize the memo, mischaracterizes evidence.	Ex. P-19, CMS 30(b)(6) (Hornsby, May 25, 2023) Tr. 199:21-200:5 ("This is just my memo done with Jennifer that just reflects two people of the many people within MPPG to present some approaches to heri, the di- -- the group director. So this memo is really not particularly meaningful from CMS's point of view. It's -- you know, it's just a little staff memo.")

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	required to audit as well for overpayments.”			
D222	The government’s OIG toolkit identifies particular HCCs that are at “high risk of being miscoded.”	Ex. D-45, OIG Toolkit at 1	Disputed as to HHS-OIG's knowledge within relevant timeframe for this matter, not supported by the cited evidence.	
D223	All HCCs listed in the toolkit have estimated error rates of 70% to 90%.	Ex. D-45, OIG Toolkit at 1	Disputed as to HHS-OIG's knowledge within relevant timeframe for this matter, not supported by the cited evidence.	
D224	The approximately 89% validation rate in RADV of the healthcare conditions (HCCs) associated with the diagnosis codes on the government’s First Interrogatory Response list is higher than the rate of validation of all the remaining healthcare conditions (HCCs) in	Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 164-167 & Figure 15 (United expert noting validation rate of 89% for RADV-audited health conditions not associated with codes on the First Interrogatory Response list); Ex. D-141, Stark Dep. 43:21-44:4 (government expert confirming same)	Disputed. Mischaracterizes evidence and conflicting evidence presented.	Ex. P-57, Stark (US Expert) Tr. 36:13-37:20 (US Expert explaining that his work only involved checking Mr. Renjilian’s arithmetic, not verifying his assumptions); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”);

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	United's data that were reviewed in RADV.			Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")
D225	The validation rate for the healthcare conditions in United's data that were reviewed in RADV for contract years 2011-2015 that are not associated with diagnosis codes on the	Ex. D-64, Renjilian Rep. (12/3/2023) ¶¶ 164-167 & Figure 15 (United expert noting validation rate of 87.6% for RADV-audited health conditions not associated with codes on First Interrogatory	Disputed. Conflicting evidence provided.	Ex. P-57, Stark (US Expert) Tr. 36:13-37:20 (US Expert explaining that his work only involved checking Mr. Renjilian's arithmetic, not verifying his assumptions); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying

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	government's First Interrogatory Response list is 87.6%.	Response list); Ex. D-141, Stark Dep. 43:21-44:4 (government expert confirming same)		that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")
D226	The government's expert, Dr. Stark, performed a	Ex. D-141, Stark Dep. 36:13-37:22 (government expert	Disputed. Not supported by cited evidence and	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7

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	calculation at his deposition confirming that the higher rate of validation of the healthcare conditions associated with the diagnosis codes on the government's First Interrogatory Response list that overlap with the healthcare conditions reviewed in RADV for contract years 2011-2015 as compared to the validation rate of the health conditions that were reviewed in RADV is statistically significant but were not on the government's First Interrogatory Response list.	confirming independent calculations matched those of Renjilian); Ex. D-63, Stark Rep. (3/28/2024) ¶¶ 30, 36 (same)	conflicting evidence presented.	(testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized."); Ex. P-57, Stark (US Expert) Tr. 36:13-37:20 (US Expert explaining that his work only involved checking Mr.

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				Renjilian's arithmetic, not verifying his assumptions)
D227	CMS performs a thorough review of Medicare Advantage plans' bid submissions prior to execution of the final contract.	Ex. D-140, Spitalnic Dep. 214:19-215:8 (government expert who "certainly believe[s] that it's reasonable for a plan to expect that CMS is going to do a thorough review of their bid submission. And [who] think[s] many of the actuaries that go through the bid review procedure would agree that there is a thorough review of the bid submission -- of their bid submissions."); Ex. D-62, Lambert Rep. (9/29/2024) at 5 (United expert describing CMS review and approval of bids)	Disputed to the extent that the fact includes an implication that a thorough review necessarily includes a review of the language that United included in some of its bid submissions that "[t]he health plan has decided to cease one of its prior processes that identified and deleted certain diagnosis codes through the medical record review process," mischaracterizes evidence. Otherwise, undisputed.	Ex. P-79, Spitalnic (US Expert) Tr. 214:19-216:12 (US Expert and CMS Chief Actuary, Paul Spitalnic, clarifies that the Office of the Actuary ("OACT") does "as thorough and comprehensive a job in reviewing those bids that have been submitted as possible, given the various time and other constraints placed upon us." Mr. Spitalnic further states that he "would also expect that actuaries [submitting the bids] would not be surprised that every word of their submission is not reviewed or necessarily relied upon in drawing ultimate conclusions" but that OACT does specifically rely on "the actuary to -- that that's -- that CMS places on the actuary to ensure that there is compliance with the laws, regulations and instructions and the various Actuarial Standards of Practice."); <i>id.</i> at 217:12-219:14 (Chief actuary of CMS noting that neither he nor anyone on his staff were aware of the specific language in United's bid supporting documentation.); Ex. P-38, Limmer

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				30(b)(6) Dep. Tr. at 218:4-20, 222:19-224:13 (stating that, despite efforts to confirm, CMS was not able to identify anyone who read the statement United included in the documentation supporting its <i>bid</i> .)
D228	CMS continued to accept bids for contract years 2015, 2016, and 2017 after United disclosed that it had discontinued its Claims Verification program.	Ex. D-8, United States' Responses and Objections to United's Second Set of Interrogatories, No. 5 (stating that the government had not identified any CMS individual who believed or expressed in writing that CMS would have stopped payment to United or would have terminated contracts with United and stopped entering into new contracts with United); Ex. D-131, Nelson Dep. 311:812 (former United employee stating that CMS did not tell United to reinstate Claims Verification or risk a lawsuit)	Disputed. Not supported by cited evidence, mischaracterizes evidence, and conflicting evidence presented.	Ex. D-8, United States' Responses and Objections to United's Second Set of Interrogatories, No. 5 (does not confirm fact); Ex. P-25, Nelson Tr. 311:8-12 (does not confirm fact); Ex. P-79, Spitalnic (US Expert) Tr. 214:19-216:12 (US Expert and CMS Chief Actuary, Paul Spitalnic, clarifies that the Office of the Actuary ("OACT") does "as thorough and comprehensive a job in reviewing those bids that have been submitted as possible, given the various time and other constraints placed upon us." Mr. Spitalnic further states that he "would also expect that actuaries [submitting the bids] would not be surprised that every word of their submission is not reviewed or necessarily relied upon in drawing ultimate conclusions" but that OACT does specifically rely on "the actuary to -- that that's -- that CMS places on the actuary to ensure

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				that there is compliance with the laws, regulations and instructions and the various Actuarial Standards of Practice.”); <i>see</i> , Ex. P-26, CMS 30(b)(6) (Hornsby, May 19, 2023) Tr. 219:1-24 (testifying that there was a lot of information CMS did not know about United’s process during and following the April 29, 2014 video teleconference CMS had with United.); Ex. P-10, Rice Tr. 236:12-237:2 12 (CMS Deputy Director for the Center for Medicare: “And so we didn’t know all the details of their program, and all the details of the work that they had done in terms of the review of the diagnoses that they had -- at least initially -- identified as not being supported in the medical record, so we didn’t have enough information to say, at that point, it definitively is or is not in compliance with these other laws and regulations.”); <i>id.</i> at 232:20-233:7 (same); Ex. P-28, Dep. Ex. 317, MARA2156615 (April 29, 2014 handwritten notes of Daniel Schumacher taken during video teleconference with CMS employees where he notes that Cheri Rice said she did not know enough about

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				United's process to make "judgments")
D229	CMS did not take any remedial action against United following United's disclosure that it had ceased its Claims Verification program.	Ex. D-8, United States' Responses and Objections to United's Second Set of Interrogatories, No. 5 (stating that the government had not identified any CMS individual who believed or expressed in writing that CMS would have stopped payment to United or would have terminated contracts with United and stopped entering into new contracts with United); Ex. D-131, Nelson Dep. 311:8-12 (former United employee stating that CMS did not tell United to reinstate Claims Verification or risk a lawsuit)	Disputed. Conflicting evidence presented.	Ex. P-75, Dep. Ex. 328, Letter from DOJ to Latham & Watkins (Oct. 22, 2014) (attorney representing CMS in investigation of UnitedHealth sending letter to UnitedHealth about UnitedHealth's decision to end its Claims Verification program, reminding UnitedHealth of the False Claims Act); Ex. P-47, Am. Compl. (Dkt. 171), ¶¶ 196-238 (Nov. 17, 2017) (Dkt. 171) (CMS filing a lawsuit against UnitedHealth, alleging over \$1 Billion in damages, based in part on UnitedHealth's decision to terminate its Claims Verification program); Ex. P-37, Spitalnic (US Expert) Tr. 214:19-216:12 (US Expert and CMS Chief Actuary, Paul Spitalnic, clarifies that the Office of the Actuary ("OACT") does "as thorough and comprehensive a job in reviewing those bids that have been submitted as possible, given the various time and other constraints placed upon us." Mr. Spitalnic further states that he "would also expect that actuaries [submitting the bids] would not be

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				surprised that every word of their submission is not reviewed or necessarily relied upon in drawing ultimate conclusions” but that OACT does specifically rely on “the actuary to -- that that’s -- that CMS places on the actuary to ensure that there is compliance with the laws, regulations and instructions and the various Actuarial Standards of Practice.”); Ex. P-26, CMS 30(b)(6) (Hornsby, May 19, 2023) Tr. 219:1-24 (testifying that there was a lot of information CMS did not know about United’s process during and following the April 29, 2014 video teleconference CMS had with United.); Ex. P-10, Rice Tr. 236:12-237:2 12 (CMS Deputy Director for the Center for Medicare: “And so we didn’t know all the details of their program, and all the details of the work that they had done in terms of the review of the diagnoses that they had -- at least initially -- identified as not being supported in the medical record, so we didn’t have enough information to say, at that point, it definitively is or is not in compliance with these other laws and regulations.”); <i>id.</i> at 232:20-233:7 (same); Ex. P-28, Dep. Ex. 317,

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				MARA2156615 (April 29, 2014 handwritten notes of Daniel Schumacher taken during video teleconference with CMS employees where he notes that Cheri Rice said she did not know enough about United's process to make "judgments")
D230	CMS did not impose any sanctions against United following United's disclosure that it had ceased its Claims Verification program.	Ex. D-8, United States' Responses and Objections to United's Second Set of Interrogatories, No. 5 (stating that the government had not identified any CMS individual who believed or expressed in writing that CMS would have stopped payment to United or would have terminated contracts with United and stopped entering into new contracts with United); Ex. D-131, Nelson Dep. 311:8-311:12 (former United employee stating that CMS did not tell United to reinstate Claims Verification or risk a lawsuit)	Disputed. Conflicting evidence presented.	Ex. P-47, Am. Compl. (Dkt. 171) (CMS filing a lawsuit against UnitedHealth, alleging over \$1 Billion in damages, based in part on UnitedHealth's decision to terminate its Claims Verification program); Ex. P-79, Spitalnic (US Expert) Tr. 214:19-216:12 (US Expert and CMS Chief Actuary, Paul Spitalnic, clarifies that the Office of the Actuary ("OACT") does "as thorough and comprehensive a job in reviewing those bids that have been submitted as possible, given the various time and other constraints placed upon us." Mr. Spitalnic further states that he "would also expect that actuaries [submitting the bids] would not be surprised that every word of their submission is not reviewed or necessarily relied upon in drawing ultimate conclusions" but

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				that OACT does specifically rely on "the actuary to -- that that's -- that CMS places on the actuary to ensure that there is compliance with the laws, regulations and instructions and the various Actuarial Standards of Practice."); Ex. P-26, CMS 30(b)(6) (Hornsby, May 19, 2023) Tr. 219:1-24 (testifying that there was a lot of information CMS did not know about United's process during and following the April 29, 2014 video teleconference CMS had with United.); Ex. P-10, Rice Tr. 236:12-237:2 12 (CMS Deputy Director for the Center for Medicare: "And so we didn't know all the details of their program, and all the details of the work that they had done in terms of the review of the diagnoses that they had -- at least initially -- identified as not being supported in the medical record, so we didn't have enough information to say, at that point, it definitively is or is not in compliance with these other laws and regulations."); <i>id.</i> at 232:20-233:7 (same); Ex. P-28, Dep. Ex. 317, MARA2156615 (April 29, 2014 handwritten notes of Daniel Schumacher taken during video teleconference with CMS employees

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				where he notes that Cheri Rice said she did not know enough about United's process to make "judgments")
D231	CMS continued to pay United in full under its contracts.	Ex. D-8, United States' Responses and Objections to United's Second Set of Interrogatories, No. 5 (stating that the government had not identified any CMS individual who believed or expressed in writing that CMS would have stopped payment to United or would have terminated contracts with United and stopped entering into new contracts with United); Ex. D-131, Nelson Dep. 311:8-311:12 (former United employee stating that CMS did not tell United to reinstate Claims Verification or risk a lawsuit)	Undisputed.	
D232	The government's expert, Dr. Garthwaite, stated in his expert report that if a Medicare Advantage plan "submits multiple diagnosis codes mapping to the same	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 31	Undisputed.	

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	HCC for a beneficiary, the beneficiary's risk score does not depend on which specific diagnosis code was reported" or "how many times a particular diagnosis code is reported within a year."			
D233	CMS has acknowledged that, without more, the mere existence of unsupported diagnosis codes or payment discrepancies does not equate to fraud.	Ex. D-122A, Kapustij 30(b)(6) Dep. 208:5-8	Disputed. Not supported by cited evidence and mischaracterizes evidence.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 208:5-18 (statements are limited to RADV and witness clarifies that "CMS is not conducting RADV Audits to determine if there is fraud."); Ex. P-10, Rice Tr. at 77:4-79:1 (CMS Deputy Director for the Center for Medicare testifying that if a plan has information that a diagnosis code that was previously submitted to CMS is not supported by the medical record when reviewing that record, they need to look into it and delete the code if they cannot find support for it); see, Ex. P-47, Am. Compl. (Dkt. 171) (CMS filing a lawsuit against UnitedHealth for failing to delete diagnosis codes that UnitedHealth's coders did not find as having sufficient support in the medical record associated with the instance of

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				the diagnosis code); Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422) (adopting the knowledge standard from the False Claims Act and stating "We acknowledge that encounter data come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake "due diligence" to ensure the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a "best knowledge, information, and belief" standard. Therefore, M+C organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.")
D234	United and the government entered into contracts related	Ex. D-1, Am. Compl. ¶¶ 66-86, Ex. 1	Undisputed.	

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	to the Medicare Advantage program.			
D235	The government argued to the United States Supreme Court last year that “companies that seek funds from the government (particularly on a recurring basis) often have ready avenues for resolving ambiguity about payment rules—for example, by consulting their contacts in state Medicaid agencies, or contractual intermediaries like pharmacy benefit managers.”	Ex. D-148, Brief for United States at *24 n.4, <i>United States ex rel. Schutte v. SuperValu Inc.</i> , 598 U.S. 739, 751 (2023); <i>id.</i> at *31-32	Undisputed.	
D236	When United representatives met with CMS on April 29, 2014, there were a number of DOS 2011 and 2012 diagnosis codes associated with encounters for which the multi-stage Claims Verification program had begun but was not completed (“In Process Codes”).	Ex. D-64, Renjilian Rep. (12/3/2023) ¶ 67 (United expert discussing encounters that were in-process when Claims Verification was discontinued); Ex. D-70, Cavanaugh Dep. Ex. 1062 (former CMS employee notifying CMS of decision to suspend Claims Verification and discussing in-process	Undisputed.	

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		encounters); Ex. D-131, Nelson Dep. 198:14-199:9 (same)		
D237	After the April 29, 2014 meeting and CMS's decision not to implement the proposed Medical Record Review Rule, United submitted for deletion only those diagnosis codes associated with encounters that had already completed the multi-stage Claims Verification program and had been identified as not supported by documentation in the medical record.	Ex. D-68, Nelson Dep. Ex. 324 (former United employee describing submission of codes that completed Claims Verification and were found to be unsupported); Ex. D-154, Thompson Dep. 294:12-23 (United employee recalling stopping "mid-process" on in-review codes)	Disputed to the extent that fact implies United deleted all diagnosis codes that completed the multistage CV process, conflicting evidence presented. Otherwise, undisputed.	Ex. P-16, United 30(b)(6) (Bird, Jun. 22, 2023) Tr. 102:15-105:11 (Corporate representative explaining that the CV program was in operation until April 2014, when the deletes process was suspended, and the program was terminated in May 2014); Ex. P-5, United 30(b)(6) (Sedor) Tr. 187:17-198:11 (Corporate representative discussing accruals and reserves made in anticipation of CV deletes prior to April 2014); Ex. P-85, Brennan Tr. 267:9-269:16 (United witness discussing CV deletes being placed on hold); <i>id.</i> 186:9-24 (Discussion of the CV analyst step of the CV program); Ex. P-62, Martinez Tr. 83:21-84:10 (same); Ex. P-89, Dep. Ex. 348, ICODIFY-0170934 (Email chain between ICodify, the company performing the final step in United's CV process, and United indicating which HCCs ICodify identified as "unlikely to validate in our second level review" including, <i>e.g.</i> , diagnosis code 3369); Ex. P-82, Ferron Tr. 134:15-135:15 (United's

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				coding consulting confirming that for the diagnoses identified in Ex. P-89, Dep. Ex. 348, ICODIFY-0170934, “one level of review was sufficient to determine that these codes should be deleted.”); <i>see also</i> Ex. P-86, Dep. Ex. 726, Mar. 27, 2016 Letter from Latham & Watkins to DOJ (Identifying MARA2160501 as a complete list of CV cancelled deletes for DOS 2012); Ex. P-87, Dep. Ex. 727, MARA2160501 (excerpt of a spreadsheet of DOS 2012 cancelled deletes, which include, <i>e.g.</i> , an instance of Diagnosis Code 3369)
D238	64.2% of the In Process Codes that correspond to health conditions (HCCs) that were reviewed by CMS during RADV audits were validated by CMS auditors.	Ex. D-64, Renjilian Rep. (12/3/3023) ¶ 163, Figure 14 (United expert showing 64.2% validation rate for In-Process Codes); Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 58 (same)	Disputed. Conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not been issued, so I’m being kind of speculative.”); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32,

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				Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 (“The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”); Ex. D-64, Renjilian (United Expert) Updated Rep. (Dec. 3, 2023), ¶ 154 n.221 (explaining the disclaimer associated with the coding results that state they are not final); Ex. P-6, Renjilian (United Expert) Tr. 238:17-239:15 (stating that the results were not final)
D239	58.8% of the In Process Codes that are listed on the government’s First Interrogatory Response that correspond to health conditions (HCCs) that were	Ex. D-64, Renjilian Rep. (12/3/3023) ¶ 163, Figure 14	Disputed. Conflicting evidence presented.	Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying “That was the process as designed,” but “these results have not

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	reviewed by CMS during RADV audits were validated by CMS auditors.			been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized."); Ex. D-64, Renjilian (United Expert) Updated Rep. (Dec. 3, 2023) ¶ 154 n.221 (explaining the disclaimer associated with the coding results that state they are not final); Ex. P-6, Renjilian (United Expert) Tr. 238:17-

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				239:15 (stating that the results were not final)
D240	Dr. Garthwaite separately calculated the alleged financial impact on Medicare Part C and Part D payments from a set of “diagnosis codes included on two spreadsheets produced by Defendants, which contain diagnosis codes that [United] identified as having been included in their Claims Verification program but not having completed all the steps of the program” (“CV Pipeline List”).	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 8	Undisputed that Dr. Garthwaite separately calculated the financial impact on Medicare Part C and Part D payments from a set of “diagnosis codes included on two spreadsheets produced by Defendants, which contain diagnosis codes that [United] identified as having been included in their Claims Verification program but not having completed all the steps of the program” (“CV Pipeline List”).	
D241	Only 85.8% of the total CV Pipeline List diagnosis codes are in the First Interrogatory Response.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 58	Undisputed.	

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D242	Only 54.4% of the total CV Pipeline List diagnosis codes are in the Garthwaite Deletes.	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 58	Undisputed.	
D243	As part of United's Chart Review Program, United conducted Second Level Reviews for certain charts in date of service years 2014-2016.	Ex. D-57, Garthwaite Rep. (9/29/2023) ¶ 51 (government expert noting second blind review of certain charts in service years 2014-2016); Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶¶ 22-24 (United expert confirming same)	Undisputed.	
D244	During RADV audits, CMS auditors validated 89.5% of health conditions associated with codes on the government's First Interrogatory Response list whose charts underwent review by two United coders (so-called "Second Level Review").	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 26	Disputed. Conflicting evidence presented.	Ex. P-6, Renjilian (United Expert) Tr. 129:4-15 (explaining RADV audits were done at the HCC level); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other."); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these

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				results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.")
D245	During RADV audits, CMS auditors validated 92.2% of health conditions associated with codes on the government's First	Ex. D-65, Renjilian Rebuttal Rep. (3/18/2024) ¶ 26	Disputed. Conflicting evidence presented.	Ex. P-6, Renjilian (United Expert) Tr. 129:4-15 (explaining RADV audits were done at the HCC level); <i>id.</i> at 148:5-149:7 ("We can't know or don't know which specific

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	Interrogatory Response list whose charts underwent chart review by only one coder (so-called one level of review).			diagnoses the RADV auditors reviewed to get to their conclusion that a given HCC was supported; so we don't know, one way or the other."); Ex. P-56, CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr. 182:20-184:7 (testifying that no preliminary audit reports have been issued; further testifying "That was the process as designed," but "these results have not been issued, so I'm being kind of speculative."); Ex. P-21, CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr. 22:12-23:7 (Preliminary results of RADV audits have not been released); <i>id.</i> 34:14-20 (testifying that there were no preliminary RADV results for contract years 2014 and 2015); Ex. P-32, Declaration of Steven Ferraina (Jul. 12, 2024), ¶ 8 ("The RADV Audits for CY 2011 through CY 2015 are not final. The initial results of medical record reviews and estimates of the portion of the audited HCCs that were found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by

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				medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.”)
D246	Three of the government experts—Dr. Stark, Dr. Acevedo, and Dr. Garthwaite—agreed that medical coders almost certainly miss some codes that are supported by documentation in the medical chart due to human error.	Ex. D-141, Stark Dep. 31:25-33:2 (government expert stating “[w]ell, I understand that coders don’t always find the same answer. So it seems that there’s some variation and, therefore, some uncertainty.”), 41:6-41:16 (stating with respect to RADV coders: “I mean, any process involving humans reading printed materials, some error rate. I just don’t know -- I haven’t seen attempts to quantify it. I don’t have an independent basis for knowing what the accuracy would be.”); Ex. D-110, Garthwaite Dep. 120:6-7 (government expert stating “I would imagine that like all processes in life, there are error rates.”); Ex. D-87, Acevedo Dep. 154:12-18 (government expert agreeing that human error is a reason coders will miss supported codes)	Disputed. Not supported by cited evidence.	See Ex. D-141, Stark Dep. 31:25-33:2, <i>id.</i> at 41:6-41:16; Ex. D-110, Garthwaite Dep. 120:6-7; Ex. D-87, Acevedo Dep. 154:12-18 (cited material does not discuss errors resulting in missed codes)

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D247	In Part C and Part D of Medicare, changes in risk score for one member do not affect risk scores for other members.	Ex. D-110, Garthwaite Dep. 181:24-182:6	Undisputed.	
D248	When conducting Claims Verification, United's coders reviewed only the same charts as those reviewed for that member in chart review.	Ex. D-91, Bird 30(b)(6) Dep. (6/22/2023) 102:21-103:21 (United corporate representative describing review of exclusive HCCs), 109:1-18 (same); Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 55-56 (government expert noting "CV utilized Charts previously reviewed in the Chart Review Program to determine if there were any provider-reported diagnosis codes that had been submitted to CMS, but were not supported by the Chart."); Ex. D-139, Sedor 30(b)(6) Dep. 115:9-18 (United corporate representative noting "[w]hat [Claims Verification] did was to, when a medical record was looked at for chart review purposes to identify diagnosis codes that were not on the claim, it would also utilize those medical records to	Undisputed to the extent that, when conducting Claims Verification, United's coders reviewed the same charts as those reviewed for that member in chart review. Otherwise disputed to the extent the fact says "only," conflicting evidence presented.	Ex. P-16, United 30(b)(6) (Bird, Jun. 22, 2023) Tr. 179:19-181:4 (Corporate representative testifying that Ex. P-84, Exhibit 712-4, MARA161485 was accurate at the time it was written); Ex. P-84, Exhibit 712-4, MARA161485, at P. 13 (CV process document showing that part of the CV process included querying other medical records already collected by United to attempt to identify support for an HCC)

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		compare against the claim submitted by the provider to see if there were any codes submitted on the claim that were not supported by the medical records.”)		
D249	When conducting Claims Verification, United’s coders did not review all medical charts for each beneficiary for each year.	Ex. D-91, Bird 30(b)(6) Dep. (6/22/2023) 102:15-103:21(United corporate representative stating that Claims Verification “was a program that we operated during a certain time frame that identified and reviewed exclusive HCCs that were submitted by providers that were part of the chart review program.”), 109:1-18 (describing exclusive HCCs in-scope for Claims Verification as an “HCC or diagnoses that mapped to an HCC and that HCC is submitted by one and only one provider”); Ex. D-57, Garthwaite Rep. (9/29/2023) ¶¶ 55-56 (government expert noting “[t]he CV program applied only to a subset of Charts that had been reviewed in the Chart Review Program.”);	Disputed. Not supported by cited evidence.	

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		Ex. D-139, Sedor 30(b)(6) Dep. 115:9-18 (United corporate representative describing HCCs eligible for Claims Verification)		
D250	The existence of an unsupported diagnosis code, alone, does not necessarily mean that a Medicare Advantage plan has been overpaid.	Ex. D-125, Lambert Dep. 198:22-199:6 (United expert testifying that “unsupported diagnoses do not necessarily result in overpayments”); Ex. D-62, Lambert Rep. (9/29/2023) at 1, 14 (existence of unsupported code cannot necessarily be an overpayment under actuarial principle of Data Consistency); Ex. D-123, Kessler Dep. 114:10-115:16 (United expert noting that the fact that “there are unsupported -- so the fact that there are unsupported codes in Medicare Advantage doesn’t tell you whether Medicare Advantage plans in general are overpaid or underpaid”); Ex. D-61, Kessler Rep. (9/29/2023) ¶ 50 (“the presence of unsupported codes in any particular plan’s data is insufficient to establish that CMS has ‘overpaid’ or ‘underpaid’ it.”); Ex. D-116,	Disputed. Mischaracterizes evidence.	Ex. P-10, Rice Tr. 84:4-85:1 and 147:6-148:3 (CMS Deputy Director for the Center for Medicare testifying that MAOs are required to correct previously submitted diagnosis data and they do not need to make an overpayment determination before deleting a diagnosis code that is not supported by a medical record since the payment system automatically makes that determination.); Ex. P-6, Renjilian (United Expert) Tr. 50:19-51:7 (testifying that he would advise clients to delete diagnosis codes that were not supported by the medical record even if the client did not know if the deletion of the diagnosis codes would have a financial impact); <i>id.</i> at 68:17-70:7 (testifying that his understanding is that the CMS payment process will not account for diagnosis codes that have not been submitted to CMS); Ex. D-66, Dep. Ex. 164, Medicare+Choice Program, 65 Fed. Reg 40,170, 40,268 (proposed June 29, 2000) (to be

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		Hornsby 30(b)(6) Dep. (5/25/2023) 281:2-18 (CMS corporate representative agreeing that existence of an unsupported code does not necessarily mean plan is overpaid); Ex. D-145, Tudor Dep. 212:23-213:7 (former CMS employee agreeing to the same); Ex. D-137, Rice Tr. 80:24-84:7 (CMS employee admitting deletion of certain codes would not affect payment)		codified at 42 C.F.R. pt. 422) (CMS stating that submission of a diagnosis code is considered a claim for payment)
D251	Between at least 2010 and 2018, CMS considered how to adjust RADV-audit results to account for unsupported codes present in the FFS data used to calibrate the CMS-HCC risk adjustment model using a FFS Adjuster.	Ex. D-129, Mills 30(b)(6) Dep. 59:5-70:10 (CMS corporate representative describing CMS consideration of the FFS Adjuster between January 2010 through 2018), Ex. D-41, CMS, <i>Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits</i> , Feb. 24, 2012, at 4-5 (same)	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
D252	During this time, individuals within CMS believed that the existence of unsupported codes in FFS data used to calibrate the model affected whether payments to Medicare Advantage plans were accurate.	Ex. D-129, Mills 30(b)(6) Dep. 78:1-80:2 (CMS corporate representative describing CMS recommendation to implement FFS Adjuster), <i>id.</i> at 157:6-19 (same); <i>id.</i> at 150:18-152:8 (describing Notice of Final Payment Error Calculation Methodology that proposed FFS Adjuster); Ex. D-41, CMS, <i>Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits</i> , Feb. 24, 2012, at 4-5 (same)	Disputed. Mischaracterizes cited evidence, not supported by cited evidence, and conflicting evidence presented.	Ex. D-129, Mills 30(b)(6) Dep. 78:1-80:2 (discussion is limited to application of an FFS Adjuster in the context of an extrapolated RADV Audit and witness does not confirm that "individuals within CMS believed that the existence of unsupported codes in FFS data used to calibrate the model affected whether payments to Medicare Advantage plans were accurate"); <i>id.</i> at 157:6-19 (same); <i>id.</i> at 150:18-152:8 (same); D-41, CMS, <i>Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits</i> , Feb. 24, 2012, at 4-5 (same)
D253	According to one of CMS's 30(b)(6) witnesses, during this time, some officials within CMS believed that some type of accounting for the errors in the data used to calibrate the CMS-HCC risk adjustment model, akin to the FFS Adjuster, needed to be applied outside of RADV in determining plan-	Ex. D-129, Mills 30(b)(6) Dep. 181:19-187:7	Disputed. Mischaracterizes cited evidence and conflicting evidence presented.	Ex. D-129, CMS 30(b)(6) (Mills) Tr. 184:2-7; 186:17-187:20 (clarifies that the discussion was in the context of RADV Audits and referring to an Notice of Proposed Rulemaking where CMS decided not to apply a FFS Adjuster in the context of an extrapolated RADV Audit); Ex. P-70, Rebecca Paul Tr. 181:23-182:13, 250:3-15, (the FFS Adjuster concept was linked to RADV Audits); Ex. P-

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	identified overpayments on the grounds that overpayments in RADV are “very similar” to self-identified overpayments.			10, Rice Tr. 109:8-111:4 (CMS Deputy Director for the Center for Medicare testifying that the FFS Adjuster was only considered within the context of extrapolated RADV Audits); Ex. P-83, Kapustij (Aug. 25, 2022) Tr. 16:6-19 (witness testifying she worked at CMS from 2009-2021, which included work on the FFS Adjuster, stating: “So the fee-for-service adjuster was a concept that was put forward by the MA industry and taken up by CMS as a means to offset recoveries for risk adjustment data validation audits.”); Ex. P-53, Kornfield Tr. 106:13-109:1 (testifying that an FFS Adjuster only makes sense in the context of an extrapolated RADV Audit)
D254	A government expert—Dr. Ingber—admitted that the relative factors estimated by the CMS-HCC risk adjustment model would increase if you remove unsupported HCCs from the data used to develop the CMS-HCC risk adjustment model and hold everything	Ex. D-121, Ingber Dep. (3/14/2024) 59:13-61:17 (government expert describing knowledge of unsupported codes in the FFS data used to develop the CMS-HCC risk adjustment model), 160:5-162:6 (calculating what would happen to the weighted average of the relative factors in an exemplar CMS-HCC risk adjustment	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-60, Ingber (US Expert) Rebuttal Report (Jan. 26, 2024), at p. 27 (US Expert: “In the estimation for relative risk factors, because all the beneficiary costs used in the model estimation are accounted for, irrespective of the presence of the unsupported codes, the unsupported codes have only small effects on the average estimated risk factors. Some go up and some go down, and the net

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	else, including costs, constant.	model when unsupported codes are removed), 166:7-172:2 (agreeing that the weighted average of the relative factors goes up when you take out the unsupported codes from the exemplar CMS-HCC risk adjustment model)		effect on large group risk scores is much smaller than the effect on risk scores in the payment phase. If the result of an unsupported code for a beneficiary is to reduce a relative factor, the value for everyone in the same demographic group or some related HCC would be slightly increased.”)
D255	A government expert—Dr. Ingber—admitted that the relative factors estimated by the CMS-HCC risk adjustment model are lower than they otherwise would have been as a result of the inclusion of unsupported HCCs in the data used to develop the CMS-HCC risk adjustment model.	Ex. D-121, Ingber Dep. (3/14/2024) 59:13-61:17 (government expert describing knowledge of unsupported codes in the FFS data used to develop the CMS-HCC risk adjustment model), 160:5-162:6 (calculating what would happen to the weighted average of the relative factors in an exemplar CMS-HCC risk adjustment model when unsupported codes are removed), 166:7-172:2 (agreeing that the weighted average of the relative factors goes up when you take out the unsupported codes from the exemplar CMS-HCC risk adjustment model)2	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-60, Ingber (US Expert) Rebuttal Report (Jan. 26, 2024), p. 24 (US Expert describing the impact of accounting for both unsubmitted and unsupported diagnosis codes on relative factors and concluding the result may be to “minimize or cancel out impacts on the relative risk factors.” Dr. Ingber also criticizes Ms. Julia Lambert, for failing to consider the impact of unsubmitted codes in her analysis.); Ex. P-67, Lambert (United Expert) Tr. 181:14-182:22 (confirming that if CMS accounts for both unsubmitted diagnosis codes and unsupported codes when re-calibrating the CMS HCC Risk Adjustment model, as a matter of math, the average of the risk factors “can go up, the average can go down, or the average can stay

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
				the same.”); Ex. P-37, Spitalnic (US Expert) Rebuttal Report (Jan. 25, 2024), ¶ 5 (US Expert and CMS Chief Actuary stating that “even if there were data inconsistencies resulting from the reliance on unaudited diagnosis data used in the development of the risk adjustment model, this potential inconsistency would not result in an underpayment to Medicare Advantage plans” and opining that an audit of the FFS data would review for both unsubmitted codes and unsupported codes and that “it is uncertain if this would lead to a net increase or decrease in cumulative diagnoses codes as the audit would result in some codes being added and others being deleted.”.)
D256	CMS’s deadline for risk adjustment data submissions for 2008 dates of service was January 31, 2010.	See Ex. D-14, Medicare Program, 73 Fed. Reg. 48434, 48651 (Aug. 19, 2008) (noting that the deadline for risk adjustment submissions was being moved from December 31 to January 31); Ex. D-158, 2010 Call Letter at 100 (March 30, 2009) (listing submission	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		deadline for DOS 2008 as January 31, 2010)		
D257	For Payment Year 2009, Justin Roth signed an attestation on March 19, 2009 on behalf of specified UnitedHealth entities certifying that based on UnitedHealth's best knowledge, information, and belief as of the date the attestation was signed, all risk adjustment information submitted to CMS for 2008 dates of service as of December 31, 2008 and not subsequently deleted prior to the date of signature was accurate, complete, and truthful.	Ex. D-159, USBP060624234 at -24253	Undisputed.	
D258	Justin Roth's March 19, 2009 attestation included a footnote explaining that the certification was based on "based on facts reasonably available or made available to the MA Organization as of the date of this	Ex. D-159, USBP060624234 at -24253	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	Certification,” and that “best knowledge, information, and belief means based on normal business practices.”			
D259	All attestations signed by United for Payment Year 2009 contained identical terms to the attestation signed by Justin Roth on March 19, 2009 and were signed in or around March 2009.	Ex. D-160, Joint Stipulation on Contracts and Related Entities	Disputed to the extent that D-160 does not include a stipulation as to the timing of all attestation signatures for 2009, not supported by cited evidence. Otherwise, undisputed.	
D260	CMS’s deadline for risk adjustment data submissions for 2009 dates of service was January 31, 2011.	See Ex. D-158, 2010 Call Letter at 101 (March 30, 2009) (listing submission deadline for DOS 2009 as January 31, 2011)	Undisputed.	
D261	For Payment Year 2010, John Larsen signed an attestation on March 26, 2010 on behalf of specified UnitedHealth entities certifying that based on UnitedHealth’s best knowledge, information, and belief as of the date the attestation was signed, all	Ex. D-28, USBP008083511	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	risk adjustment information submitted to CMS for 2009 dates of service as of December 31, 2009 and not subsequently deleted prior to the date of signature was accurate, complete, and truthful.			
D262	John Larsen's March 26, 2010 attestation included a footnote explaining that the certification was based on "based on facts reasonably available or made available to the MA Organization as of the date of this Certification," and that "best knowledge, information, and belief means based on normal business practices."	Ex. D-28, USBP008083511	Undisputed.	
D263	All attestations signed by United for Payment Year 2010 contained identical terms to the attestation signed by John Larsen on March 26, 2010 and were	Ex. D-160, Joint Stipulation on Contracts and Related Entities	Disputed to the extent that D-160 does not include a stipulation as to the timing of all attestation signatures for 2010, not supported by	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	signed in or around March 2010.		cited evidence. Otherwise, undisputed.	
D264	Dr. Garthwaite has not and is not offering an opinion about what would happen in a but-for world in which United had performed the analysis that Dr. Garthwaite performed in his report and had changed its submission of codes accordingly.	Ex. D-110, Garthwaite Dep. 77:10-79:3	Disputed. Not supported by cited evidence and conflicting evidence presented.	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 86(iii) (US Expert explaining that he calculated a “change in payment, which reflects the amount by which Defendants’ risk adjustment payments would have been reduced had they submitted the Deletes to CMS.”); Ex. P-74, Garthwaite (US expert) Tr. 78:16-22 (US Expert: “the question we are trying to answer is how would the flow of funds have changed if as of the time period we’re asking the question, the code that lacks support in United’s chart review and risk adjustment data were removed from the system.”); Ex. P-6, Renjilian (United Expert) Tr. 253:7-10 (“So, in other words, modeling -- I think in Dr. Garthwaite’s work he’s modeled what he believes reimbursement might have looked like had these things been deleted.”)
D265	Dr. Garthwaite has not and is not offering an opinion about	Ex. D-110, Garthwaite Dep. 77:10-79:3	Disputed. Not supported by cited evidence and	Ex. D-57, Garthwaite (US Expert) Rep. (Sept. 29, 2023) ¶ 86(iii) (US Expert explaining that he calculated a

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	but for damages.		conflicting evidence presented.	“change in payment, which reflects the amount by which Defendants’ risk adjustment payments would have been reduced had they submitted the Deletes to CMS.”); Ex. P-74, Garthwaite (US expert) Tr. 78:16-22 (US Expert: “the question we are trying to answer is how would the flow of funds have changed if as of the time period we’re asking the question, the code that lacks support in United’s chart review and risk adjustment data were removed from the system.”); Ex. P-6, Renjilian (United Expert) Tr. 253:7-10 (“So, in other words, modeling -- I think in Dr. Garthwaite’s work he’s modeled what he believes reimbursement might have looked like had these things been deleted.”)
D266	Dr. Garthwaite has not and is not offering an opinion about how United would have contemporaneously changed their other behaviors if United had deleted the codes on the Garthwaite deletes list.	Ex. D-110, Garthwaite Dep. 77:10-79:3	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS

No.	Statement of Fact	Citation	Response	Citation
D267	After a patient visits a doctor and the doctor or the doctor's coder identifies one or more diagnosis codes that they determine match the conditions documented in the medical chart, the doctor then submits that information on a claim form to CMS (if the beneficiary is in FFS).	Ex. D-122, Kapustij Dep. (8/25/2022) 39:22-40:4 (government employee stating there was coding error in FFS claims data); Ex. D-44, Medicare Payment Advisory Commission, <i>Issues for Risk Adjustment in Medicare Advantage</i> at 103-04, in Report to Congress: Medicare and Health Care Delivery System (Chapter 4), Washington, DC (June 2012) (describing that coding for various HCCs between 2007 and 2008 were not consistently coded by MA plans in those years); Ex. D-48, Richard Kronick & W. Pete Welch, <i>Measuring Coding Intensity in the Medicare Advantage Program</i> , Medicare & Medicaid Research Review, 4(2), at E5 (2014) (stating FFS coding is "often incomplete"); Ex. D-119, Hutchinson Dep. 32:21-33:4 (former CMS employee stating there was coding error in FFS claims data); Ex. D-120, Ingber Dep. (6/14/2022) 32:12-21 (government employee stating	Disputed. Not supported by cited evidence.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		that FFS data had “all kinds” of errors)		
D268	DOJ alleges that United received money from CMS to which it was “not entitled, which unjustly enriched Defendants,” because United “received such money by claiming and retaining Medicare risk adjustment payments based on invalid risk adjustment data.”	Ex. D-1, Am. Compl. ¶ 357	Undisputed.	
D269	DOJ alleges that CMS “paid money to Defendants as a result of a mistaken understanding” because it paid United’s “claims for risk adjustment payments under the mistaken understanding that such claims were based on valid risk adjustment data.”	Ex. D-1, Am. Compl. ¶ 360	Undisputed.	
D270	For 2008-2016 DOS years, Optum targeted charts to review in part based on suspect logic intended to	See Ex. D-89, Baker 30(b)(6) Dep. (5/30/2023) 68:14-71:11, 93:18-101:19	Undisputed.	

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
	identify patients with medical conditions for which corresponding diagnosis codes were not already reflected in the claims data submitted by the patients' providers for the relevant year.			
D271	In 2009, as part of the official OIG RADV audit process, United informed HHS-OIG officials that its chart review program did not seek to determine whether codes previously reported to CMS were documented in the medical record.	Ex. D-151, Lara Dep. Ex. 1124-2 (PacifiCare Response to OIG Questions), at USBP064584717 ("[A] chart review involved review of the diagnoses reflected in a selected provider's patient charts to determine if any documented diagnoses had not been reported to CMS. Following a chart review, we submitted to CMS any new codes documented in the medical chart but did not determine whether the codes previously reported to CMS were documented in the medical record..."); Ex. D-136, Renshaw (Assistant Regional Inspector General of Audit Services at the Office of Audit Services in HHS's OIG) Dep. 103:23-104:6 ("Q. So is it fair to	Disputed. Conflicting evidence presented.	Ex. D-151, Dep. Ex. 1124-2, USBP064584712 at USBP064584717 (the same 2009 PacifiCare Response to Questions communicated that United's "chart validation" process "involved the review of a provider's patient charts to determine whether they supported certain codes that the provider had reported" and that "[c]odes found to be inaccurate or incomplete through chart validations were deleted"); Ex. P-58, Lara Tr. 60:14-61:11 (agreeing that PacifiCare stated that in addition to Chart Review, United had a Chart Validation program that "involved the review of a provider's patient charts to determine whether they supported certain codes that the provider had reported" and where "[c]odes found to be inaccurate or

DEFENDANTS' UNCONTROVERTED FACTS				
No.	Statement of Fact	Citation	Response	Citation
		say that PacifiCare explained to OIG here that as part of its chart review, it was not also determining whether codes previously reported to CMS were documented in the medical record? MS. GLOVER: Objection to form. THE WITNESS: That's clear—yeah, that's clear. That's sort of— that's been my understanding of this all along.”).		incomplete through chart validations were deleted.”)

1 Dated: August 6, 2024

Respectfully submitted,

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ATTESTATION

I hereby attest that the other signatories listed, on whose behalf this filing is submitted, concur in its content and have authorized its filing.

Dated: August 6, 2024

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 1 OF 14
INDEX OF EXHIBITS**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

UnitedHealth Group Incorporated and its affiliated entities named as Defendants in this action (collectively, “United” and “Defendants”) and Plaintiff United States of America hereby submit the following Joint Evidentiary Appendix in connection with the Joint Brief regarding the Cross Motions for Summary Judgment consisting of the following:

Exhibit No.	Description
DEFENDANTS’ EXHIBITS	
D-1	Excerpts from Amended Complaint (Nov. 17, 2017) (ECF 171)
D-2	Answer to Amended Complaint (Mar. 23, 2018) (ECF 223)
D-3	Statement of Genuine Disputes of Material Fact (July 23, 2018) (ECF 250-1)
D-4	Amended Joint Rule 26(f) Report (Apr. 2, 2018)
D-5	Joint Stipulation re United States’ Motion to Compel Discovery (Apr. 16, 2021)
D-6	Order Denying Motion to Compel re Rog 14 and RFP 147 (May 28, 2021)
D-7	Defendant UHC Of California’s First Interrogatory to the Government (Jan. 3, 2020)
D-8	United States’ Responses and Objections to Defendant UHC Of California’s Second Set of Interrogatories, No. 5 (Apr. 21, 2021)
D-9	United States’ Responses and Objections to Defendant UHC Of California’s Request for Admission Nos. 26, 36, 48, 79, 81, 90 (Nov. 4, 2019)
D-10	United States’ Responses and Objections to Defendant UHC Of California’s Request for Admission No. 117, 147 (Feb. 12, 2020)
D-11A	United States’ Responses and Objections to Defendant UHC Of California’s First Interrogatory (Feb. 3, 2020)
D-11B	United States’ First Supplemental Responses and Objections to Defendant UHC Of California’s First Set of Interrogatories (Aug. 17, 2020)
D-12	United States’ Responses and Objections to Defendant UHC of California’s Interrogatory No. 12 (June 23, 2022)
D-13	Intentionally Blank
D-14	Excerpts from 73 Fed. Reg. 48434 Aug. 19, 2008)
D-15	Excerpts from 75 Fed. Reg. 19678 (Apr. 15, 2010)
D-16	Excerpts from 79 Fed. Reg. 1918 (Jan. 10, 2014)
D-17	Excerpts from 79 Fed. Reg. 29844 (May 23, 2014)

Exhibit No.	Description
D-18	Excerpts from 88 Fed. Reg. 6643 (Feb. 1, 2023)
D-19	Intentionally Blank
D-20	Intentionally Blank
D-21	MARA2152278
D-22	MARA2157039
D-23	USBP000498420
D-24	USBP000548071
D-25	USBP000674257
D-26	USBP001354107
D-27	USBP001354165
D-28	USBP008083511
D-29	USBP009417442
D-30	USBP009417526
D-31	USBP009417534
D-32	USBP009417619
D-33	USBP058101090
D-34	USBP062135635
D-35	USBP066819447
D-36	2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide
D-37	Intentionally Blank
D-38	Excerpts from 71 DOJ J. FED. L. & PRAC. 4 (Dec. 2023)
D-39	Advance Notice of Methodological Changes for Calendar Year (CY) 2009 (Feb. 22, 2008)
D-40	Claim Form 1500 (available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf)
D-41	CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits (Feb. 24, 2012)
D-42	Gregory C. Pope <i>et al.</i> , Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model, Health Care Financing Review (Summer 2004)
D-43	Kimberly O'Malley <i>et al.</i> , Measuring Diagnoses: ICD Code Accuracy, 40 Health Services Research 1620 (Oct. 2005)
D-44	Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare Advantage, in Report to Congress: Medicare and Health Care Delivery System (Chapter 4), Washington, DC (June 2012)

Exhibit No.	Description
D-45	OIG Toolkit (Dec. 2023)
D-46	OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring Insurance Life & Health Insurance Contract first Health Plan, Inc., (Contract H4513) (Mar. 2023)
D-47	OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS (Jan. 2022)
D-48	Richard Kronick & W. Pete Welch, Measuring Coding Intensity in the Medicare Advantage Program, Medicare & Medicaid Research Review (2014)
D-49	Intentionally Blank
D-50	Intentionally Blank
D-51	Intentionally Blank
D-52	Amended Expert Report of Jean Acevedo (Apr. 5, 2024)
D-53	Expert Rebuttal Report of Jean Acevedo (Jan. 29, 2024)
D-54	Expert Report of Barbara Blair (Sept. 29, 2023)
D-55	Intentionally Blank
D-56	Expert Report of Mark Duggan, PhD (Sept. 29, 2023)
D-57	Expert Report of Craig Garthwaite (Sept. 29, 2023)
D-58	Intentionally Blank
D-59	Errata to Expert Report of Craig Garthwaite (Mar. 11, 2024)
D-60	Expert Report of Melvin J. Ingber, PhD (Jan. 29, 2024)
D-61	Expert Report of Daniel Kessler, PhD (Sept. 29, 2023)
D-62	Expert Report of Julia Lambert (Sept. 29, 2023)
D-63	Updated Expert Report of Philip B. Stark (Mar. 28, 2024)
D-64	Updated Expert Report of M. Timothy Renjilian (Dec. 3, 2023)
D-65	Updated Rebuttal Report of M. Timothy Renjilian (Mar. 18, 2024)
D-66	Exhibit 164 to the May 3, 2022 deposition of Jimmy Higgins
D-67	Exhibit 1582 to the March 22, 2024 deposition of Jean Acevedo
D-68	Exhibit 324 to the July 26, 2022 deposition of Steven Nelson
D-69	Exhibit 608 to the May 30, 2023 deposition of 30(b)(6) Designee 3 Katie Baker
D-70	Exhibit 1062 to the February 17, 2022 deposition of Sean Cavanaugh
D-71	Exhibit 1063 to the February 17, 2022 deposition of Sean Cavanaugh

Exhibit No.	Description
D-72	Exhibit 1067 to the February 17, 2022 deposition of Sean Cavanaugh
D-73	Exhibit 1133-2 to the April 22, 2022 deposition of Lisa Lara
D-74	Exhibit 1143-1 to the March 21, 2022 deposition of Maricruz Bonfante
D-75	Exhibit 1187-1 to the April 13, 2022 deposition of Rebecca Paul
D-76	Exhibit 1253 to the August 5, 2022 deposition of Jennifer Harlow
D-77	Exhibit 1306 to the August 25, 2022 deposition of Carolyn Kapustij
D-78	Intentionally Blank
D-79	Exhibit 1460 to the May 25, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby
D-80	Exhibit 1497-10 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij
D-81	Exhibit 1497-18 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij
D-82	Exhibit 1498 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij (This exhibit marked Outside Counsel Only)
D-83	Exhibit 1501 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij
D-84	Exhibit 1521 to the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Exhibit is Excel native file)
D-85	Exhibit 1522 to the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Exhibit is Excel native file)
D-86	Exhibit 1535 to the March 5, 2024 deposition of Richard Kronick
D-87	Excerpts from the March 22, 2024 deposition of Jean Acevedo
D-88	Excerpts from the July 12, 2022 deposition of Katie Baker
D-89	Excerpts from the May 30, 2023 deposition of 30(b)(6) Designee 3 Katie Baker
D-90	Excerpts from the May 31, 2023 deposition of 30(b)(6) Designee 3 Katie Baker
D-91	Excerpts from the June 22, 2023 deposition of 30(b)(6) Designee 2 Jon Bird
D-92	Excerpts from the August 10, 2022 deposition of Jon Bird
D-93	Excerpts from the April 3, 2024 deposition of Barbara Blair
D-94	Excerpts from the May 13, 2022 deposition of Mary Bonner
D-95	Excerpts from the September 12, 2023 deposition of Patricia Brennan

Exhibit No.	Description
D-96	Excerpts from the May 31, 2023 deposition of 30(b)(6) Designee 5 Christopher Bresette
D-96A	Excerpts from the August 9, 2023 deposition of 30(b)(6) Designee 5 Christopher Bresette
D-97	Excerpts from the February 17, 2022 deposition of Sean Cavanaugh
D-98	Excerpts from the August 10, 2022 deposition of Ilina Chaudhuri
D-99	Excerpts from the March 23, 2022 deposition of Sean Creighton
D-100	Excerpts from the Oct. 4, 2022 deposition of Sean Creighton
D-101	Excerpts from the September 8, 2022 deposition of Joanne Davis
D-102	Excerpts from the May 24, 2022 deposition of Tammy Dickey
D-103	Excerpts from the March 29, 2024 deposition of Mark Duggan
D-104	Excerpts from the August 2, 2022 deposition of Karen Erickson
D-105	Excerpts from the March 18, 2022 deposition of Daniel Farmer
D-106	Excerpts from the July 27, 2022 deposition of Melissa Ferron
D-107	Excerpts from the March 31, 2022 deposition of Richard Foster
D-108	Excerpts from the June 2, 2022 deposition of Janet Fry
D-109	Excerpts from the June 30, 2021 deposition of Stephanie Gardner
D-110	Excerpts from the April 2, 2024 deposition of Craig Garthwaite
D-111	Excerpts from the March 10, 2022 deposition of Ronnie Grower
D-112	Excerpts from the March 30, 2022 deposition of Mary Guy
D-113	Excerpts from the May 3, 2022 deposition of Jimmy Higgins
D-114	Excerpts from the May 18, 2022 deposition of Anne Hornsby
D-115	Excerpts from the May 19, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby
D-116	Excerpts from the May 25, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Attorneys Eyes Only)
D-117	Excerpts from the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby
D-118	Excerpts from the February 4, 2022 deposition of Lateefah Hughes
D-119	Excerpts from the January 26, 2022 deposition of Thomas Hutchinson
D-120	Excerpts from the June 14, 2022 deposition of Melvin Ingber
D-121	Excerpts from the March 14, 2024 deposition of deposition of Melvin Ingber
D-122	Excerpts from the August 25, 2022 deposition of Carolyn Kapustij

Exhibit No.	Description
D-122A	Excerpts from the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij
D-123	Excerpts from the March 25, 2024 deposition of Daniel Kessler
D-124	Excerpts from the March 10, 2022 deposition of Thomas Kornfield
D-125	Excerpts from the April 5, 2024 deposition of Julia Lambert
D-126	Excerpts from the May 26, 2023 deposition of 30(b)(6) Designee 4 Connie Leonard
D-127	Excerpts from the June 21, 2023 deposition of 30(b)(6) Designee 2 Kirk Limmer
D-128	Excerpts from the August 30, 2022 deposition of John Martinez
D-129	Excerpts from the September 7, 2023 deposition of 30(b)(6) Designee 3 George Mills
D-130	Excerpts from the August 17, 2022 deposition of Jonathan Morse
D-131	Excerpts from the July 26, 2022 deposition of Steven Nelson
D-132	Excerpts from the April 13, 2022 deposition of Rebecca Paul
D-133	Excerpts from the October 18, 2022 deposition of Benjamin Poehling
D-134	Excerpts from the September 28, 2022 deposition of Cynthia Polich
D-135	Excerpts from the March 21, 2024 deposition of M. Timothy Renjilian
D-136	Excerpts from the August 24, 2022 deposition of Jeff Renshaw
D-137	Excerpts from the August 3, 2022 deposition of Cheri Rice
D-138	Excerpts from the September 20, 2022 deposition of Daniel Schumacher
D-139	Excerpts from the June 29, 2023 deposition of 30(b)(6) Designee 1 Melissa Sedor
D-140	Excerpts from the March 20, 2024 deposition of Paul Spitalnic
D-141	Excerpts from the March 12, 2024 deposition of Philip Stark
D-142	Excerpts from the February 28, 2018 deposition of Marilyn Tavenner
D-143	Excerpts from the November 30, 2022 deposition of Gift Tee
D-144	Excerpts from the June 6, 2023 deposition of 30(b)(6) Designee 4 Scott Theisen
D-145	Excerpts from the August 23, 2022 deposition of Cynthia Tudor
D-146	Excerpts from the June 29, 2022 deposition of Julie Uebersax
D-147	Excerpts from the June 7, 2022 deposition of Marybeth Meyer

Exhibit No.	Description
D-148	Brief for United States, <i>United States ex rel. Schutte v. SuperValu Inc.</i> , 598 U.S. 739 (2023)
D-149	Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rules (Mar. 28, 2003)
D-150	MAPL006426592
D-151	Ex 1124-2 to the March 18, 2022 deposition of Lisa Lara
D-152	AAPC, Risk Adjustment—Predictive Modeling, Documentation & Capture of Diagnosis Code at 19-20 (2014)
D-153	Excerpts from 83 Fed. Reg. 54982 (Nov. 1, 2018)
D-154	Excerpts from the March 1, 2022 deposition of Brian Thompson
D-155	Excerpts from the March 4, 2022 deposition of Jonathan Blum
D-156	Excerpts from the August 5, 2022 deposition of Jennifer Harlow
D-157	Excerpts from the March 21, 2022 deposition of Maricruz Bonfante
D-158	Excerpts from 2010 Call Letter (Mar. 30, 2009)
D-159	USBP060624234
D-160	Joint Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations and Related Entities
PLAINTIFF'S EXHIBITS	
Exhibit No.	Description
P-1	Joint Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations and Related Entities (May 28, 2024)
P-1A	USBP009418488, 2017 PY Contract
P-1B	MAPL007637301, Optum EDI Agreement
P-1C	MAPL008081457, Defendant MAO EDI Agreement
P-1D	USBP001354165, 2015 Rice and Nelson Email
P-1E	USBP001354107
P-1F	USBP009866579
P-1G	USBP009417433, 2017 PY Attestation
P-2	United 30(b)(6) (Cannon, Jun. 6, 2023) Tr.
P-3	Dep. Ex. 30B, MARA1576299, 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide
P-4	Dickey Tr. (May 24, 2022)
P-5	United 30(b)(6) (Sedor, Jun. 29, 2023) Tr.
P-6	Renjilian (United Expert) Tr. (Mar. 21, 2024)

Exhibit No.	Description
P-7	United 30(b)(6) (Baker, May 30, 2023) Tr.
P-8	Medicare Managed Care Manual, Rev. 118 (Sept. 19, 2014), Ch.7
P-9	Medicare Managed Care Manual, Ch. 7 (Aug. 13, 2004)
P-10	Rice Tr. (Aug. 3, 2022)
P-11	Dep. Ex. 381, United response to US Interrogatory (Set Six, Jul. 19, 2022)
P-12	Dep. Ex. 265-1, MAPL000814082, Chart Review Policy Document
P-13	Dep. Ex. 33B, MARA1262848, Coding Guide
P-14	Dep. Ex. 34B, MARA1546907, Coding Policy
P-15	United 30(b)(6) (Baker, May 31, 2023) Tr.
P-16	United 30(b)(6) (Bird, Jun. 22, 2023) Tr.
P-17	Dep. Ex. 508A, MAPL005123236, Product Scorecard
P-18	Dep. Ex. 201, MARA2036153, CV Presentation (Mar. 7, 2013)
P-19	CMS 30(b)(6) (Hornsby, May 25, 2023) Tr.
P-20	Cavanaugh Tr. (Feb. 17, 2022)
P-21	CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr.
P-22	Hornsby Tr. (May 18, 2022)
P-23	Blum Tr. (Mar. 4, 2022)
P-24	Dep. Ex. 324, MAPL000497870, 2014 Rice and Nelson Email
P-25	Nelson Tr. (Jul. 26, 2022)
P-26	CMS 30(b)(6) (Hornsby, May 19, 2023) Tr.
P-27	Tudor Tr. (Aug. 23, 2022)
P-28	Dep. 317, MARA2156615, Handwritten notes of Daniel Schumacher (Apr. 29, 2024)
P-29	Johnson Tr. (Nov. 17, 2022)
P-30	Acevedo (US expert) Tr. (Mar. 22, 2024)
P-31	Blair (United expert) Tr. (Apr. 3, 2024)
P-32	Declaration of Steven Ferraina (Jul. 12, 2024)
P-33	United 30(b)(6) (Theisen, Jun 6, 2023) Tr.
P-34	Erickson Tr. (Aug. 2, 2022)
P-35	Schumacher Tr. (Sep. 20, 2022)
P-36	Dep. Ex. 331, USBP000619443, 2015 Cavanaugh Email
P-37	Spitalnic (US Expert) Rebuttal Report (Jan. 25, 2024)
P-38	CMS 30(b)(6) (Limmer, Jun. 21, 2023) Tr.

Exhibit No.	Description
P-39	About CMS, https://www.cms.gov/about-cms (last visited July 15, 2024)
P-40	Dep. Ex. 327, July 1, 2014 Letter from Latham & Watkins to DOJ re UHG Updates
P-41	42 U.S. Code § 1395d(d)
P-42	42 U.S. Code § 1395x(dd)(1) and (3)(B)
P-43	Risk Model Diagnoses for FY 2012, available at https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/risk2012 (last visited July 2, 2024)
P-44	CMS 30(b)(6) (Leonard, May 26, 2023) Tr.
P-45	Redmond Tr. (Jul. 29, 2022)
P-46	Ingber (US expert) Tr. (Mar. 14, 2024)
P-47	Am. Compl. (Dkt. 171)
P-48	Dep. Ex. 1581 ICD-10-CM Official Guidelines for Coding and Reporting
P-49	Dep. Ex. 815, AAPC Article entitled "Medical Record Entries What Is Timely and Reasonable"
P-50	Acevedo (US expert) Amended Rep. (Apr. 5, 2024)
P-51	Fry Tr. (Jun. 2, 2022)
P-52	HHS-OIG 30(b)(6) (Bresette, Aug. 9, 2023) Tr.
P-53	Kornfield Tr. (Mar. 10, 2022)
P-54	Order Re: Objections to Special Master's Order (Dkt. 437), Sept. 10, 2021
P-55	Rasmussen Tr. (Jul. 22, 2022)
P-56	CMS 30(b)(6) (Kapustij, Aug. 25, 2023) Tr.
P-57	Stark (US Expert) Tr. (Mar. 12, 2024)
P-58	Lara Tr. (Mar. 18, 2022)
P-59	MAPL001126483
P-59A	MAPL001126484 (attachment to MAPL001126483), 2012 Encounter Data Participant Guide
P-60	42 CFR 422.310
P-61	Dumcum Tr. (Jul. 28, 2021)
P-62	Martinez Tr. (Aug. 30, 2022)
P-63	MAPL000814082

Exhibit No.	Description
P-64	Gardner Tr. (Jun. 30, 2021)
P-65	Halva Tr. (Feb. 24, 2022)
P-66	USBP0061943
P-67	Lambert (United Expert) Tr. (Apr. 5, 2024)
P-68	Medicare Advantage & Prescription Drug Plan Fall Conference & Webcast, Conference Guide (September 7, 2017), https://www.cms.gov/outreach-and-education/training/cteo/downloads/2017-fall-conference/cms-mapdpconffall2017guidefinalpdf.pdf (last visited July 9, 2024)
P-69	Higgins Tr. (May 3, 2022)
P-70	Paul Tr. (Apr. 13, 2022)
P-71	Bird Tr. (Aug. 10, 2022)
P-72	United 30(b)(6) (Cannon, Jun. 7, 2023) Tr.
P-73	Dep. Ex. 167-1, MAPL008247236 (2004 Presentation)
P-74	Garthwaite (US expert) Tr. (Apr. 2, 2024)
P-75	Dep. Ex. 328, Oct. 22, 2014 Letter from DOJ to Latham & Watkins
P-76	Martin Tr. (Aug. 5, 2022)
P-77	45 CFR 162.1002(c)(2) and (c)(3)
P-78	Order Denying Without Prejudice Plaintiff's Motion to Compel Re Interrogatories No. 14 and Request for Production 147 (Dkt. 419), May 28, 2021
P-79	Spitalnic (US Expert) Tr. (Mar. 20, 2024)
P-80	2013 Call Letter
P-81	Dep. Ex. 309, MAPL009701356
P-82	Ferron Tr. (Jul. 27, 2022)
P-83	Kapustij Tr. (Aug. 25, 2022)
P-84	Dep. Ex. 712-4, MARA161485
P-85	Brennan Tr. (Sep. 12, 2023)
P-86	Dep. Ex. 726, Mar. 27, 2016 Letter from Latham & Watkins to DOJ
P-87	Dep. Ex. 727, MARA2160501
P-88	Baker Tr. (Jul. 12, 2022)
P-89	Dep. Ex. 348, ICODIFY-0170934
P-90	Meyer Tr. (June 7, 2022)

Exhibit No.	Description
P-91	CMS 30(b)(6) (Hornsby, Nov. 21, 2023) Tr.
P-92	Contract Year 2015 Policy and Technical Changes to the Medicare Advantage Program, 79 Fed. Reg. 29,844 (May 23, 2014) (to be codified at 42 C.F.R. pts. 417, 422-24)
P-93	Tudor Tr. (Aug. 23, 2022)
P-94	HHS-OIG 30(b)(6) (Bresette, Aug. 9, 2023) Tr
ATTORNEY DECLARATIONS	
DA-1	Declaration of David Schindler
PA-1	Declaration of Martha Glover

1 Dated: August 06, 2024

Respectfully submitted,

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ATTESTATION

I hereby attest that the other signatories listed, on whose behalf this filing is submitted, concur in its content and have authorized its filing.

Dated: August 06, 2024

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 2 OF 14
EXHIBITS D-1 THROUGH D-15
PAGES 0001 THROUGH 0634**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024
Hearing Time: 10:00 a.m.
Courtroom: 6D

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EXHIBIT D-1

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,
v.

UNITEDHEALTH GROUP, INC., a
Delaware corporation; UNITED
HEALTHCARE SERVICES, INC., a
Minnesota corporation; UNITED
HEALTHCARE, INC., a Delaware
corporation; OVATIONS, INC., a
Delaware corporation; OPTUM, INC., a
Delaware corporation;
OPTUMINSIGHT, INC., a Delaware
corporation; AMERICHOICE OF NEW

No. CV 16-08697 MWF (SSx)

UNITED STATES' AMENDED
COMPLAINT-IN-PARTIAL-
INTERVENTION AND DEMAND FOR
JURY TRIAL

1 JERSEY, INC., a New Jersey
2 corporation; ARIZONA PHYSICIANS
3 IPA, INC., an Arizona corporation;
4 CARE IMPROVEMENT PLUS OF
5 MARYLAND, INC., a Maryland
6 corporation; CARE IMPROVEMENT
7 PLUS OF TEXAS INSURANCE
8 COMPANY, a Texas insurance
9 company; CARE IMPROVEMENT
10 PLUS SOUTH CENTRAL
11 INSURANCE CO., an Arkansas
12 insurance company; CARE
13 IMPROVEMENT PLUS WISCONSIN
14 INSURANCE COMPANY, a Wisconsin
15 insurance company; OPTUM
16 INSURANCE CO., an Ohio corporation;
17 CITRUS HEALTH CARE, INC., a
18 Florida corporation; HEALTH PLAN OF
19 NEVADA, INC., a Nevada corporation;
20 MEDICA HEALTHCARE PLANS,
21 INC., a Florida corporation; OXFORD
22 HEALTH PLANS (CT), INC., a
23 Connecticut corporation; OXFORD
24 HEALTH PLANS (NJ), INC., a New
25 Jersey corporation also known as Oxford
26 Health Plans of New Jersey, Inc.;
27 OXFORD HEALTH PLANS (NY),
28 INC., a New York corporation;
PACIFICARE LIFE AND HEALTH
INSURANCE COMPANY, an Indiana
insurance company; PACIFICARE OF
ARIZONA, INC., an Arizona
corporation; PACIFICARE OF
COLORADO, INC., a Colorado
corporation; PACIFICARE OF
NEVADA, INC., a Nevada corporation
also known as PacifiCare/UHC of
Nevada; PHYSICIANS HEALTH
CHOICE OF TEXAS, LLC, a Texas
limited liability company; PREFERRED
CARE PARTNERS, INC., a Florida
corporation; ROCKY MOUNTAIN
HEALTH MAINTENANCE
ORGANIZATION, INC., a Colorado
company; SIERRA HEALTH AND
LIFE INSURANCE COMPANY, INC.,
a Nevada corporation; SYMPHONIX
HEALTH INSURANCE, INC., an
Illinois insurance company;
UNITEDHEALTHCARE OF
CALIFORNIA, INC., a California
corporation also known as UHC of
California, Inc. and formerly known as
PacifiCare of California, Inc. and
PacifiCare of California/Secure
Horizons; UNISON HEALTH PLAN OF

1 TENNESSEE, INC., a Tennessee
2 corporation; UNITED HEALTH CARE
3 INS. CO. AND UNITED NEW YORK, a
4 New York insurance company;
5 UNITEDHEALTHCARE BENEFITS
6 OF TEXAS, INC., a Texas corporation
7 formerly known as PacifiCare of Texas,
8 Inc.; UNITEDHEALTHCARE
9 COMMUNITY PLAN OF OHIO, INC.,
10 an Ohio corporation formerly known as
11 Unison Health Plan of Ohio, Inc.;
12 UNITEDHEALTHCARE
13 COMMUNITY PLAN OF TEXAS,
14 L.L.C., a Texas limited liability company
15 formerly known as Evercare of Texas,
16 LLC; UNITEDHEALTHCARE
17 COMMUNITY PLAN, INC., a Michigan
18 corporation also known as Great Lakes
19 Health Plan, Inc. and UnitedHealthcare
20 of the Great Lakes Health Plan, Inc.;
21 UNITEDHEALTHCARE INSURANCE
22 COMPANY, a Connecticut insurance
23 company also known as United
24 Healthcare Insurance Company;
25 UNITEDHEALTHCARE INSURANCE
26 COMPANY OF NEW YORK, a New
27 York insurance company also known as
28 United Healthcare Insurance Company of
New York; UNITEDHEALTHCARE OF
ALABAMA, INC., an Alabama
corporation also known as United
HealthCare of Alabama, Inc.;
UNITEDHEALTHCARE OF
ARIZONA, INC., an Arizona
corporation also known as United
HealthCare of Arizona, Inc.;
UNITEDHEALTHCARE OF
ARKANSAS, INC., an Arkansas
corporation also known as United
Healthcare of Arkansas, Inc.;
UNITEDHEALTHCARE OF
FLORIDA, INC., a Florida corporation
also known as United Healthcare of
Florida, Inc.; UNITEDHEALTHCARE
OF GEORGIA, INC., a Georgia
corporation also known as United
Healthcare of Georgia, Inc.;
UNITEDHEALTHCARE OF NEW
ENGLAND, INC., a Rhode Island
corporation also known as United
HealthCare of New England, Inc. and
United Health Plans of New England,
Inc.; UNITEDHEALTHCARE OF NEW
YORK, INC., a New York corporation
also known as AmeriChoice of New
York, Inc. and United Healthcare of New

York, Inc.; UNITEDHEALTHCARE OF NORTH CAROLINA, INC., a North Carolina corporation also known as United Healthcare of North Carolina, Inc.; UNITEDHEALTHCARE OF OHIO, INC., an Ohio corporation also known as United Healthcare of Ohio, Inc.; UNITEDHEALTHCARE OF OKLAHOMA, INC., an Oklahoma corporation formerly known as PacifiCare of Oklahoma, Inc.; UNITEDHEALTHCARE OF OREGON, INC., an Oregon corporation formerly known as PacifiCare of Oregon, Inc.; UNITEDHEALTHCARE OF PENNSYLVANIA, INC., a Pennsylvania corporation formerly known as Unison Health Plan of Pennsylvania, Inc.; UNITEDHEALTHCARE OF TENNESSEE, INC., a Tennessee corporation also known as United Healthcare of Tennessee, Inc.; UNITEDHEALTHCARE OF THE MIDLANDS, INC., a Nebraska corporation also known as United Healthcare of the Midlands, Inc.; UNITEDHEALTHCARE OF THE MIDWEST, INC., a Missouri corporation also known as United Healthcare of the Midwest, Inc.; UNITEDHEALTHCARE OF UTAH, INC., a Utah corporation also known as United Healthcare of Utah, Inc.; UNITEDHEALTHCARE OF WASHINGTON, INC., a Washington corporation formerly known as PacifiCare of Washington, Inc.; UNITEDHEALTHCARE OF WISCONSIN, INC., a Wisconsin corporation also known as United Healthcare of Wisconsin, Inc.; UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC., an Illinois corporation also known as United Healthcare Plan of the River Valley, Inc., UnitedHealth Care Plan of the River Valley, Inc., and United HealthCare of the River Valley, Inc.,

Defendants.

1 This is a civil fraud action brought by the United States of America (“United
2 States” or “Government”) to recover treble damages and civil penalties under the False
3 Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, as well as for restitution and common
4 law damages, for monies unlawfully obtained and retained by Defendant UnitedHealth
5 Group Inc. and various of its direct and indirect subsidiaries (“Defendants”) involved in
6 Parts C and D of the Medicare Program. Defendants knowingly submitted false claims
7 and made false statements to the Medicare Program. Moreover, Defendants have
8 knowingly and improperly avoided their obligations to repay significant sums of money
9 to the Medicare Program.

10 Having filed a notice of intervention pursuant to 31 U.S.C. § 3730(b)(4), the
11 United States alleges for its amended complaint-in-partial-intervention (the “Amended
12 Complaint”) as follows:

13 **INTRODUCTION**

14 1. Millions of elderly and disabled individuals throughout the United States receive
15 their Medicare benefits through Parts C and D of the Medicare Program, hereinafter
16 referred to as the Medicare Advantage (MA) Program, which is administered by the
17 Government agency called the Centers for Medicare and Medicaid Services (“CMS”). A
18 central, distinguishing feature of the MA Program is the provision of Medicare benefits
19 by private healthcare insurance organizations, which are called Medicare Advantage
20 Organizations (“MA Organizations”). Medicare beneficiaries enroll in managed
21 healthcare insurance plans called Medicare Advantage Plans (“MA Plans”) and
22 prescription drug plans (“PD Plans”) that are offered by these MA Organizations. The
23 MA Plans are packages of healthcare insurance benefits and the PD Plans are packages
24 of prescription drug benefits. Hereinafter MA Plans and PD Plans are collectively
25 referred to as “Plans.”

26 2. The Government pays each MA Organization a fixed monthly payment for each
27 Medicare beneficiary enrolled in its Plans. The Government adjusts these payments for
28 various risk factors that affect expected healthcare expenditures, including the age,

gender, and health status of each beneficiary. The adjustments are intended to ensure that MA Organizations are paid more for beneficiaries whose healthcare expenses are *expected* to be more and less for beneficiaries whose health care expenses are *expected* to be less. However, these adjustments to the fixed monthly payments are made regardless of the actual services provided to the beneficiaries and, thus, regardless of whether those beneficiaries expected to need more or more costly services actually obtain more or more costly services, and whether those beneficiaries expected to need less or less costly services actually obtain less or less costly services.

3. To obtain payments based on adjustments for health status, MA Organizations submit diagnosis codes to the Government for the beneficiaries in their Plans. These diagnosis codes are from the beneficiaries' medical encounters with healthcare providers (*e.g.*, physician office visits and hospital stays) during the year prior to the actual payment year (often referred to as the "data collection" year or the "date of service" year). Payments are based on diagnoses from the prior year because they are used to predict the *expected* needs of a beneficiary for more or less costly healthcare services during the payment year. Using these diagnosis codes submitted by or on behalf of MA Organizations, the Government calculates a risk score for each beneficiary. The beneficiary's risk score is then used to calculate monthly payments to the MA Organization for that beneficiary for the payment year. In general, the more numerous and severe the conditions identified by the diagnosis codes, the higher the risk score for a beneficiary and, thus, the greater the risk adjustment payments made to the MA Organization for that beneficiary for the payment year.

4. This payment model creates powerful incentives for MA Organizations and their owners and operators to exaggerate the expected healthcare costs for the beneficiaries in their Plans by submitting invalid diagnosis codes and failing to comply with their obligation to retract invalid diagnoses. In order to combat these incentives and protect the Government from overpaying MA Organizations, the Government requires that submitted diagnoses be unambiguously supported and, thus, validated by the

beneficiaries' medical records for medical encounters during the data collection year. Medical records are the "source of truth" for the purpose of receiving and retaining risk adjustment payments.

5. The medical records that must support the diagnosis codes are not provided to the Government as part of the payment process. Instead, the Government requires that each MA Organization expressly certify that the diagnosis codes it has submitted for risk adjustment payments are accurate and truthful based on best knowledge, information, and belief. 42 C.F.R. § 422.504(l)(2). Each MA Organization must exercise due diligence in order to make this express certification. Each MA Organization must also "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with [the Government's] program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 422.503(b)(4)(vi).

6. As explained by the United States Court of Appeals for the Ninth Circuit, CMS, in 2000, made clear that

Medicare Advantage organizations have always had "an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the [medical] encounter data" [i.e., diagnoses] and "an obligation to undertake 'due diligence' to ensure the accuracy, completeness, and truthfulness of encounter data submitted to [CMS]." . . . CMS made perfectly clear that Medicare Advantage organizations would be "held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."

United States ex rel. Swoben v. UnitedHealthcare Ins. Co., 848 F.3d 1161, 1174 (9th Cir. 2016) (quoting 65 Fed. Reg. 40,170, 40,268 (June 29, 2000)). The Ninth Circuit further explained that the requirement that MA Organizations take affirmative steps to address errors in their data is further demonstrated by "§ 422.503, which since 2005 has required Medicare Advantage organizations to have effective compliance programs in place,

THE MEDICARE PROGRAM

I. The Medicare Statute

43. Medicare is a federally-operated health insurance program administered by CMS. Medicare benefits individuals age 65 and older and the disabled. 42 U.S.C. § 1395c *et seq.* Parts A and B of the Medicare Program are known as “traditional” Medicare.

Medicare Part A covers inpatient and institutional care. Medicare Part B covers physician, hospital outpatient, and ancillary services and durable medical equipment.

44. Under Medicare Parts A and B, CMS reimburses healthcare providers (*e.g.*, hospitals and physicians) using what is known as a “fee-for-service” (“FFS”) payment system. Under an FFS payment system, healthcare providers submit claims to CMS for reimbursement for each service actually rendered, such as a physician office visit or a hospital stay. CMS then pays the providers directly for each service based on payment rates pre-determined by the Government.

45. Under Medicare Part C, Medicare beneficiaries can opt out of the traditional Medicare Program (Parts A and B) and instead enroll in MA Plans and receive health care services managed by those MA Plans. MA Plans must provide Medicare beneficiaries all the services that they are entitled to receive from the traditional Medicare Program.

46. Under Medicare Part D, Medicare beneficiaries can elect to enroll in either a Prescription Drug plan (known as a PD Plan) or an MA Plan that provides prescription drug coverage in addition to the physician office visit and hospital outpatient and inpatient coverage provided under Part C (known as an MAPD Plan). For simplicity, in this Amended Complaint, the Government refers to Parts C and D collectively as the MA Program and refers collectively to MA, PD, and MAPD Plans as Plans.

47. MA Organizations are “risk-bearing” entities that must be licensed by the State in which they are located. 42 C.F.R. §§ 422.2 & 422.503(b)(2). Each MA Organization agrees to bear the risk that the amount that it pays providers for the health services for a

1 particular beneficiary in one of its Plans may exceed the amount that it was paid to
2 insure the beneficiary.

3 48. Medicare beneficiaries who enroll in an MA, PD or MAPD Plan are considered
4 members of and enrollees in that Plan. In this Amended Complaint, the terms
5 beneficiaries, members, enrollees, and patients are used interchangeably, but mean the
6 same thing, that is, individuals enrolled in Plans.

7 49. MA Organizations' obligations to the MA Program and the requirements for them
8 to participate in the Program are set forth in federal regulations and, each year, the MA
9 Organizations must agree in writing to comply with those regulations and to other terms
10 and conditions in order to participate in the MA Program. 42 C.F.R. §§ 422.504 &
11 422.505 (Part C); 42 C.F.R. §§ 423.504 & 423.505 (Part D). In addition, MA
12 Organizations must comply with requirements set forth in statutes, such as the FCA, and
13 guidance documents, such as the Medicare Managed Care Manual, the Medicare
14 Prescription Drug Benefit Manual, the Risk Adjustment Participant Guides, and
15 Medicare Advantage operating instructions.

16 50. Related Entities include those entities that are related to an MA Organization by
17 common ownership or control and perform at least some of the MA Organization's
18 management functions. 42 C.F.R. §§ 422.2 & 422.500. As previously explained, the
19 UHG Managing Defendants are or were Related Entities.

20 51. First Tier Entities include those providers or provider groups that enter into a
21 written arrangement with an MA Organization to provide healthcare services to the
22 beneficiaries in the organization's Plan(s). 42 C.F.R. §§ 422.2 & 422.500. The capitated
23 providers in the RACCR Program were First Tier Entities.

24 52. The obligations of Related Entities and First Tier Entities to the MA Program are
25 also set forth in the MA Program regulations. Related Entities and First Tier Entities
26 must, among other things, (i) perform their services in a manner that complies with the
27 MA Organization's contractual obligations to the Government, *id.* at 422.504(i)(3)(iii);
28 agree to "comply with all applicable Medicare laws, regulations, and CMS instructions,"

1 *id.* at 422.504(i)(4)(v); and receive effective compliance training and education relating
2 to preventing fraud, waste, and abuse. *Id.* at § 422.503(b)(4)(vi)(C)(1). Furthermore, if
3 a Related Entity or First Tier Entity generates data relating to an MA Organization’s
4 claims for payments from the MA Program, it (as well as the MA Organization) must
5 certify the accuracy and truthfulness of the data. *Id.* at § 422.504(l)(3).

6 53. An MA Organization, however, cannot evade its legal and contractual obligations
7 to the Government by using Related Entities to manage it or by contracting with First
8 Tier Entities to provide services to its beneficiaries. An MA Organization “maintains
9 ultimate responsibility for adhering to and otherwise fully complying with all terms and
10 conditions of its contract with CMS.” 42 C.F.R. § 422.504(i)(1). Thus, an MA
11 Organization cannot delegate away its ultimate responsibility for its obligations to the
12 Government.

13 **II. Medicare Parts C and D Risk Adjustment Payments**

14 54. Under Part C, the Government pays each MA Organization a predetermined base
15 monthly amount for each Medicare beneficiary in its MA Plans. This monthly payment
16 is known as a “per-member, per-month” payment. This predetermined base payment
17 varies for each MA Plan depending on various factors, including amounts set forth in the
18 MA Plan’s bid submitted to the Government, the scope of medical services covered by
19 the Plan’s benefit package (all packages must cover at least those services offered by
20 Parts A and B of the Medicare Program), and the amount of premiums, deductibles, and
21 co-pays for which an enrollee in the Plan is responsible (Plans have different premiums,
22 deductibles and co-pays such that Plans with higher deductibles and co-pays may have
23 lower premiums).

24 55. Since 2000, Congress has also required that the payments be risk adjusted for each
25 beneficiary based on “such risk factors as age, disability status, gender, institutional
26 status, and *such other factors as [the Secretary of the United States Department of*
27 *Health and Human Services] determines to be appropriate, including adjustment for*
28 *health status . . . to ensure actuarial equivalence.”* 42 U.S.C. § 1395w-23(a)(1)(C)

1 (emphasis added). By risk adjusting for health status, the Government pays MA
2 Organizations more for beneficiaries with certain serious chronic medical conditions
3 and, thus, higher risk scores than for beneficiaries who do not have those conditions and,
4 thus, have lower risk scores.

5 56. Pursuant to 42 U.S.C. § 1395w-23(a)(1)(C), the Secretary has the authority to
6 determine how to adjust for health status. For example, the Secretary has the authority to
7 decide to risk adjust only for serious chronic medical conditions and to risk adjust by
8 requiring the submission of diagnoses from medical encounters that occurred the year
9 preceding each payment year and projecting the possibility of additional costs for each
10 payment year. The Secretary also has authority to decide what historical cost and/or
11 utilization data it should consider in projecting how much more it may cost an MA
12 Organization to provide services to a beneficiary who has been assigned a diagnosis
13 relating to a serious chronic medical condition.

14 57. From 2000 to 2004, the Secretary employed a Principal Inpatient Diagnostic Cost
15 Group (“PIP-DCG”) model that took into account diagnoses from inpatient hospital
16 stays to determine the risk scores of beneficiaries in MA Plans. The PIP-DCG model
17 was prospective. Diagnoses for one year were used to determine each beneficiary’s risk
18 score for the following payment year. During the 2000 to 2004 time period, MA
19 Organizations (which were then called Medicare + Choice Organizations) had many of
20 the same obligations that they have had since 2004. For instance, they had the obligation
21 to design and implement effective systems to monitor and review the accuracy and
22 truthfulness of the diagnoses they submitted for risk adjustment payments in order to
23 certify the accuracy and truthfulness of that data. See Medicare Managed Care Manual,
24 Chapter 7, Section 110.2 (entitled “Certification of Data Accuracy, Completeness, and
25 Truthfulness”) (Rev. 2, 10-01-01).

26 58. Since 2004, the Secretary has employed the Hierarchical Conditions Category
27 (“HCC”) model, which takes into account both demographic factors (such as age and
28 gender) and health status to determine the risk scores for beneficiaries in MA Plans.

1 With respect to health status, the model takes into account diagnoses from physician
2 office visits and hospital outpatient encounters as well as hospital inpatient stays. Like
3 the PIP-DCG model, the HCC model is prospective, meaning that it relies on diagnoses
4 assigned to a beneficiary in one year (referred to by CMS as the “data collection” year
5 but also generally known as the “date of service” or “DOS” year) to determine the risk
6 score for the beneficiary for the following year (often referred to as the “payment year”
7 or “PY”). The medical conditions included in the model are grouped into HCCs, which
8 are categories of clinically-related medical diagnoses. *See* 42 C.F.R. § 422.2. The
9 diagnoses grouped into HCCs include major, severe, and/or chronic illnesses. Related
10 groups of diagnoses are ranked on the basis of disease severity and the cost associated
11 with their treatment. Between 2004 and 2013, the CMS-HCC model included 70 HCCs.
12 Starting in 2014, the CMS-HCC model included 79 HCCs.

13 59. Under Medicare Part D, payments to PD or MAPD Plans for prescription drug
14 benefits are also risk-adjusted based on health status. As with Part C, Part D employs a
15 health-based risk adjustment model known as the Rx Hierarchical Condition Categories
16 (“RxHCC”) model. Like HCCs, RxHCCs are also groups of clinically-related medical
17 diagnoses that are ranked by disease severity and the cost associated with the
18 pharmaceutical drugs used to treat them.

19 60. The Government assigns a relative numerical value (also known as a relative
20 factor, multiplier, or coefficient) to each HCC and RxHCC group that correlates to the
21 predicted incremental costs of care associated with treating the medical conditions in
22 each category. It currently determines the relative values based on an analysis of the
23 additional amounts that it paid on average for the treatment of these major, severe, and
24 chronic medical conditions under Parts A and B of the Medicare Program. Higher
25 relative values are assigned to HCCs and RxHCCs that include diagnoses with greater
26 disease severity and greater costs associated with their treatment.

27 61. As previously stated, the HCC and RxHCC risk adjustment models are
28 prospective and a beneficiary’s risk score for a particular payment year is determined by

1 his or her medical conditions during the previous year (*i.e.*, the date of service year). For
2 risk adjustment payment purposes, these medical conditions must be documented by a
3 qualified healthcare provider (*e.g.*, a doctor) in the beneficiary's medical record during
4 the previous year. Accordingly, for risk adjustment payment purposes, the diagnosis
5 codes that the healthcare provider, his or her administrative or billing support staff, or
6 anyone else (such as the MA Organization or a Related Entity) assigns to a beneficiary
7 must be supported by the beneficiary's medical record.

8 62. Each beneficiary's risk score is calculated anew for each payment year. For
9 example, a beneficiary's risk score for payment year 2012 is determined by the
10 diagnoses that his or her qualified healthcare providers documented in his or her medical
11 records during medical encounters during date of service year 2011.

12 63. MA Organizations obtain diagnosis data from the healthcare providers that treat
13 the beneficiaries in their plans (as well as through other means and sources such as the
14 MA Organizations' own medical record reviews). Healthcare providers can transmit
15 diagnosis codes to MA Organizations with claims for payment for services rendered, in
16 encounter records reporting the services rendered, or by alternative means. In this
17 Amended Complaint, the United States refers to diagnosis codes reported by providers
18 through any means as "provider-reported diagnoses."

19 64. MA Organizations submit risk adjustment data, including diagnoses, to CMS
20 using CMS' Risk Adjustment Processing System ("RAPS"). Each RAPS submission
21 must include the following information: the Medicare beneficiary's identification
22 number (called a "HIC number" or "HICN"); the date(s) of the medical encounter (the
23 physician office visit, hospital outpatient visit, or hospital inpatient stay); the type of
24 provider (physician or hospital); and the diagnosis code(s) reported by the provider for
25 the encounter. Each RAPS submission is a claim for payment. If the data submitted is
26 invalid, the claim is false.

27 65. RAPS also has a field that is called a "Delete Indicator" and allows MA
28 Organizations and Related Entities to comply with their obligation to delete invalid

1 diagnoses that they previously submitted in order to withdraw or retract the invalid
2 diagnoses. That is, the RAPS system enables MA Organizations and Related Entities to
3 withdraw or retract their false claims for risk adjustment payments.

4 **DEFENDANTS' AGREEMENTS**

5 **I. The Annual Parts C and D Agreements**

6 66. As previously explained, in order to participate in the MA Program, the Defendant
7 MA Organizations were required to agree in writing to comply with the Part C and D
8 regulations and any other terms and conditions CMS deemed appropriate. 42 C.F.R.
9 §§ 422.504 & 422.505 (Part C); 42 C.F.R. §§ 423.504 & 423.505 (Part D). Each year
10 during the relevant time period, one or more executives of one or more of the UHG
11 Managing Defendants or their predecessors executed these written agreements or
12 renewals of these written agreements between the Defendant MA Organizations and
13 CMS.

14 67. The regulations specifying the terms and conditions of the contractual relationship
15 between MA Organizations and CMS have remained the same for many years.
16 Accordingly, from year to year, the terms and conditions of these written agreements
17 between the Defendant MA Organizations and CMS remained very similar, if not
18 identical.

19 68. The terms and conditions of the Part C agreements are exemplified by the attached
20 contract that Defendant UnitedHealthcare Plan of River Valley, Inc. entered into with
21 CMS relating to its participation in Medicare Part C in 2010. *See* Exhibit 1, attached
22 hereto. The terms and conditions of these Part C contracts include, among many other
23 things, that each of the MA Organizations agrees to (i) operate its Plans “in compliance
24 with the requirements of [the] contract and applicable Federal statutes, regulations, and
25 policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual,
26 etc.)” (Article II, Section A); (ii) “implement a compliance plan in accordance with the
27 requirements of § 422.503(b)(4)(vi)” (Article III, Section F); (iii) “[a]s a condition of
28 receiving a monthly payment under” the contract, “request payment under the contract

1 on the forms attached” to the contract, including “Attachment B (risk adjustment data)
2 which attest[s] to *(based on best knowledge, information and belief, as of the date*
3 *specified on the attestation form)* the accuracy, completeness, and truthfulness of the
4 data identified on” Attachment B (Article IV, Section C) (emphasis in the original); (iv)
5 ensure that related entities, contractors, and subcontractors that generated risk adjustment
6 data also attest to the accuracy and truthfulness of the data (Article IV, Section C.2); (v)
7 ensure that all agreements with related entities, contractors, and subcontractors specify
8 that the related entities, contractors, and subcontractors “must comply with all applicable
9 Medicare laws, regulations, and CMS instructions” (Article V, Section D(5)); and (vi)
10 comply with “Federal laws and regulations designed to prevent or ameliorate fraud,
11 waste, and abuse, including, but not limited to, applicable provisions of the Federal
12 criminal law [and] the False Claims Act (31 USC 3729 et seq.)” (Article IX, Section
13 A.1). In accordance with 42 C.F.R. § 422.510, the agreements also provided that CMS
14 may terminate the MA Organization’s participation in the MA Program if it determines
15 that the organization has submitted false data to it or “fail[ed] to provide CMS with valid
16 risk adjustment data.” Article VIII, Section B.1(a)(iv) & (vii).

17 69. The agreements for other years were very similar, if not identical. For example, in
18 September 2010, Tom Paul, the Chief Executive Office of UnitedHealthcare Medicare &
19 Retirement, executed a new agreement between Defendant UnitedHealthcare of
20 California (the successor to PacifiCare of California) and CMS relating to this MA
21 Organization’s participation in Medicare Part C in 2011. *See* Exhibit 2, attached hereto.
22 By executing this contract, UnitedHealthcare of California agreed to, among many other
23 things, (i) operate its Plans “in compliance with the requirements of [the] contract and
24 applicable Federal statutes, regulations, and policies (e.g., policies as described in the
25 Call Letter, Medicare Managed Care Manual, etc.)” (Article II, Section A); (ii)
26 “implement a compliance plan in accordance with the requirements of §
27 422.503(b)(4)(vi)” (Article III, Section F); (iii) “[a]s a condition of receiving a monthly
28 payment under” the contract, “request payment under the contract on the forms attached”

1 to the contract, including “Attachment B (risk adjustment data) which attest[s] to *(based*
2 *on best knowledge, information and belief, as of the date specified on the attestation*
3 *form)* the accuracy, completeness, and truthfulness of the data identified on” Attachment
4 B (Article IV, Section D); (iv) ensure that related entities, contractors, and
5 subcontractors that generated risk adjustment data also attest to the accuracy and
6 truthfulness of the data (Article IV, Section D.2); (v) ensure that all agreements with
7 related entities, contractors, and subcontractors specify that the related entities,
8 contractors, and subcontractors “must comply with all applicable Medicare laws,
9 regulations, and CMS instructions” (Article V, Section D.5); and (vi) comply with
10 “Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse,
11 including, but not limited to, applicable provisions of the Federal criminal law [and] the
12 False Claims Act (31 USC 3729 et seq.)” (Article IX, Section A.1). The agreement also
13 provided that CMS had the right to terminate the agreement with the MA Organization if
14 it determined that the organization had submitted false data to it or “fail[ed] to provide
15 CMS with valid risk adjustment data.” Article VIII, Section B.1(a)(iv) & (vii). In
16 September 2010, Paul also executed an agreement with CMS relating to
17 UnitedHealthcare of California’s offering of prescription drug benefits under Medicare
18 Part D. This Part D agreement was, in all respects relevant to this Amended Complaint,
19 very similar to the one described above for the offering of healthcare insurance benefit
20 packages under Part C. Furthermore, in September 2010, Tom Paul executed the same
21 Part C and D agreements on behalf of other of the Defendant MA Organizations. All
22 these agreements were very similar, if not identical, to the ones he executed for
23 UnitedHealthcare of California.

24 70. In September 2011, August 2012, and August 2013, Scott Theisen, the Chief
25 Financial Officer of UnitedHealthcare Medicare & Retirement, executed agreements for
26 many of the Defendant MA Organizations relating to their participation in Medicare
27 Parts C and D for 2012, 2013, and 2014, respectively. *See, e.g.*, Exhibits 3, 4, & 5,
28 attached hereto (Defendant UnitedHealthcare of California’s Parts C agreements for

1 these years). In August 2014 and 2015, Brian Thompson, the Chief Financial Officer of
2 UnitedHealthcare Medicare & Retirement, executed agreements for many of the
3 Defendant MA Organizations relating to their participation in Medicare Parts C and D
4 for 2015 and 2016. See, e.g., Exhibits 6 & 7, attached hereto (Defendant
5 UnitedHealthcare of California’s Part C agreements for these years). These agreements
6 were, in all respects relevant to this Amended Complaint, very similar, if not identical, to
7 the agreements described in the preceding paragraphs relating to the agreements for 2010
8 and 2011 and imposed the same contractual obligations on the Defendant MA
9 Organizations as the earlier agreements.

10 71. The annual Attestations executed in order to renew existing contracts were also
11 very similar as shown by the following: In the fall of 2006, Jerry Knutson, the Chief
12 Financial Officer of Ovations and Jeff Putnam, the Chief Financial Officer of Secure
13 Horizons, executed Attestations renewing (for calendar year 2007) the existing contract
14 between PacifiCare of California (the predecessor of Defendant UnitedHealthcare of
15 California) and CMS. Knutson and Putnam attested that PacifiCare of California would
16 “comply with all applicable program guidance that CMS has issued to date and will issue
17 during the remainder of 2006 and 2007 pursuant to Medicare program authorizing
18 statutes and regulations, including but not limited to, . . . the CMS memoranda issued
19 through the Health Plan Management System (HPMS).” (HPMS is one of the web-
20 based systems used by CMS to provide program information to MA Organizations and is
21 used to communicate program requirements.) In September 2007, Joseph Haferman, the
22 Chief Financial Officer of Secure Horizons, executed another Attestation renewing the
23 existing contract for PacifiCare of California (this time for calendar year 2008).
24 Haferman thereby attested that PacifiCare of California would comply “with all
25 applicable program authorizing statutes and regulations and program guidance that CMS
26 has issued to date and will issue during the remainder of 2007 and 2008, including but
27 not limited to, . . . the Medicare Managed Care Manual, and CMS memoranda issued
28 through the Health Plan Management System (HPMS).” In September 2008, Kenneth

1 Burdick, the Chief Executive Officer of Secure Horizons at the time, executed another
2 Attestation renewing the existing contract for PacifiCare of California (this time for
3 calendar year 2009). Burdick thereby attested that PacifiCare of California would
4 comply “with all applicable Medicare program authorizing statutes and regulations and
5 program guidance that CMS has issued to date and will issue during the remainder of
6 2008 and 2009, including but not limited to, . . . the Medicare Managed Care Manual,
7 and the CMS memoranda issued through the Health Plan Management System
8 (HPMS).” In September 2009, both Tom Paul, the Chief Executive Officer of Ovations,
9 and John Way, the Chief Financial Officer of Secure Horizons, executed an Attestation
10 renewing the existing contract for PacifiCare of California (this time for calendar year
11 2010). They thereby attested that PacifiCare of California would comply “with all
12 applicable Medicare program authorizing statutes and regulations and program guidance
13 that CMS has issued to date or will issue during the remainder of 2009 and 2010,
14 including but not limited to, . . . the Medicare Managed Care Manual, and the CMS
15 memoranda issued through the Health Plan Management System (HPMS).”

16 72. The United States hereby incorporates by reference as if they were recited herein
17 and attached hereto all of the agreements that all of the Defendant MA Organizations
18 entered into with CMS relating to their participation in Medicare Parts C and D for 2007
19 to present date. All of these agreements were, in all respects relevant to this Amended
20 Complaint, very similar, if not identical, to the agreements described in the preceding
21 paragraphs.

22 **II. The Electronic Data Interchange Agreements**

23 73. In addition, since at least 2003, MA Organizations and entities that submit risk
24 adjustment data on their behalf have been required to execute Electronic Data
25 Interchange (“EDI”) agreements prior to submitting risk adjustment data. These EDI
26 agreements are considered contracts by which the MA Organizations attest to the
27 accuracy of the data submitted. Even if another entity submits the data, the MA
28 Organizations are still responsible for the content of the submissions. See 2003 Regional

1 Risk Adjustment Training for Medicare+Choice Organizations Participant Guide, §
2 6.1; 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations
3 Participant Guide, § 4.1; 2005 Risk Adjustment Data Basic Training for Medicare
4 Advantage Organizations Participant Guide § 4.1; 2006 Risk Adjustment Data Basic
5 Training for Medicare Advantage Organizations Participant Guide § 4.1; 2007 Risk
6 Adjustment Data Training for Medicare Advantage Organizations Participant Guide §
7 4.1; 2008 Risk Adjustment Technical Assistance for Medicare Advantage Organizations
8 Participant Guide § 4.1; Risk Adjustment 101 Participant Guide § 2.1 (2013). See also
9 Medicare Managed Care Manual, Chapter 7, § 111.6.1 (Rev. 57, 08-13-04); *id.* § 120.2.1
10 (Rev. 114, 06-07-13). By executing these EDI forms, the MA Organizations agree that
11 (i) they will be responsible for all risk adjustment data submitted to CMS by themselves,
12 their employees, and their agents; (ii) they will submit risk adjustment data that is
13 accurate, complete, and truthful based on best knowledge, information, and belief; (iii)
14 *they will research and correct risk adjustment data discrepancies*; and (iv) CMS has the
15 right to audit and confirm the risk adjustment data, including diagnoses, submitted by the
16 MA Organization and the right of access to the beneficiaries' medical records to conduct
17 such audits.

18 74. Each of the Defendant MA Organizations and Defendants Optum (and its
19 predecessor, Ingenix) and Ovations executed these EDI agreements and submitted them
20 to the MA Program in order to submit risk adjustment data to and receive risk adjustment
21 payments from the MA Program. Pursuant to the express terms of these EDI
22 agreements, these Defendants promised to submit valid risk adjustment data to the MA
23 Program and *to research and correct any data discrepancies*.

24 75. For instance, in 2005, Joseph Haferman, the Chief Financial Officer of Defendant
25 Ovations, executed and submitted to CMS an EDI agreement in order to obtain a
26 "submitter ID" permitting Ovations to submit risk adjustment data on behalf of various
27 of the Defendant MA Organizations. See Exhibit 8, attached hereto. By executing this
28 agreement and submitting it to CMS on behalf of the "eligible organization," which was

1 identified as “United Health Group – Ovations” on the form, Defendants UHG and
2 Ovations and the Defendant MA Organizations each agreed that they would (i) be
3 responsible for all risk adjustment data submitted to CMS by themselves, their
4 employees, or their agents; (ii) submit accurate and truthful risk adjustment data; and
5 (iii) *research and correct discrepancies with its risk adjustment data*. In addition, each
6 of them agreed that CMS could audit the data and have access to medical records to
7 conduct such audits.

8 76. Additional examples include the EDI agreements that James Higgins, the Finance
9 Director of PacifiCare Health Systems, executed on behalf of the following Defendant
10 MA Organizations or their predecessors: On September 14, 2006, Higgins signed EDI
11 agreements for UnitedHealthcare Insurance Company of New York (contract numbers
12 H5515 and R5342); UnitedHealthcare Insurance Company (the name for a number of
13 different MA Organizations with contract numbers R3175, R5287, H1717, H2803,
14 H2001, H2003, H2111, H2408, H0624, H0620, H1303, H1509, H3921, H0319, H5500,
15 H2406, H4106, H3812, H3209, H5918, H5697, H5754, H0315, H2228, H1108, H4522,
16 H5532, H5516, H5507, H5440, H5417, H5424, H5008, H5527, H2226 and H5518);
17 PacifiCare of Nevada, Inc. (contract number H2949); PacifiCare of Arizona, Inc.
18 (contract number H0303); UnitedHealthcare of Alabama, Inc. (contract number H0151);
19 UnitedHealthcare of the Midwest, Inc. (contract number H2654); Oxford Health Plans
20 (CT), Inc. (contract number H0752); Oxford Health Plans (NJ), Inc. (contract numbers
21 H3113 and H3107); UnitedHealthcare of Ohio, Inc. (contract numbers H3659 and
22 H5678); UHC of California, then known as PacifiCare of California (contract number
23 H0543); UnitedHealthcare of Florida, Inc. (contract number H1080 and H9011);
24 UnitedHealthcare Benefits of Texas, Inc. (contract number H4590); UnitedHealthcare of
25 Utah, Inc. (contract number H4604); UnitedHealthcare of Arizona, Inc. (contract number
26 H0316); UnitedHealthcare of Arkansas, Inc. (contract number H0401); UnitedHealthcare
27 of Georgia, Inc. (contract number H1111); UnitedHealthcare of Tennessee, Inc. (contract
28 number H4406); UnitedHealthcare of New England, Inc. (contract number H4102);

1 UnitedHealthcare of Oregon, Inc. (contract number H3805); UnitedHealthcare of
2 Oklahoma, Inc. (contract number H3749); UnitedHealthcare of New York, Inc. (contract
3 number H3379); Oxford Health Plans (NY), Inc. (contract number H3307);
4 UnitedHealthcare of the Midlands, Inc. (contract number H2802); UnitedHealthcare of
5 North Carolina, Inc. (contract number H3456); PacifiCare of Colorado, Inc. (contract
6 number H0609); Sierra Health and Life Insurance Company, Inc. (contract number
7 H5652); UnitedHealthcare of Washington, Inc. (contract number H5005);
8 UnitedHealthcare of Wisconsin, Inc. (contract number H5253); and UnitedHealthcare
9 Community Plan of Texas, L.L.C. (contract number H4514). On November 2, 2006,
10 Higgins signed EDI agreements for UnitedHealthcare of the Midwest, Inc. (contract
11 number H3887), UnitedHealthcare Insurance Company of New York (contract number
12 H4720), and UnitedHealthcare Insurance Company (contract numbers H9418, H8000,
13 and H4779). On December 13, 2006, Higgins signed EDI agreements for
14 UnitedHealthcare Insurance Company (the name for a number of MA Organizations
15 with contract numbers H0408, H1286, H3435, H7274, H7254, H0410, and H6717) and
16 UnitedHealthcare of Wisconsin, Inc. (contract number H7187). On January 1, 2007,
17 Higgins signed an EDI agreement for UnitedHealthcare Insurance Company (contract
18 number H5435). On January 14, 2008, Higgins signed an EDI agreement for
19 UnitedHealthcare Insurance Company (contract numbers H3912 and H0710). *See, e.g.,*
20 Exhibit 9, attached hereto (September 14, 2006 EDI for PacifiCare of California).
21 Pursuant to these EDI agreements, each of these MA Organizations agreed that it would
22 (i) be responsible for all risk adjustment data submitted to CMS by itself, its employees,
23 or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii) *research and*
24 *correct discrepancies with its risk adjustment data*. In addition, each of them agreed that
25 CMS could audit the data and have access to medical records to conduct such audits.
26 77. In addition, on January 14, 2008, Patricia Rasmussen, who worked as a manager
27 for Ingenix, signed EDI agreements for UnitedHealthcare Insurance Company (contract
28 numbers H4971, H0710, H3912, H7698, H4971, H0710, H6793, H5749, and H6228),

1 UnitedHealthcare of New England, Inc. (contract number H1944), and UnitedHealthcare
2 Insurance Company of New York (contract number H4720). On June 18, 2008,
3 Rasmussen signed an EDI agreement for PacifiCare of Nevada, Inc. (contract number
4 H7949). In January 2009, Rasmussen signed additional EDI agreements for
5 UnitedHealthcare Insurance Company (contract numbers H7444, H8748, H2182, and
6 H1949). Pursuant to these EDI agreements, each of these MA Organizations agreed that
7 it would (i) be responsible for all risk adjustment data submitted to CMS by itself, its
8 employees, or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii)
9 *research and correct discrepancies with its risk adjustment data*. In addition, each of
10 them agreed that CMS could audit the data and have access to medical records to
11 conduct such audits.

12 78. On December 15, 2010, Timothy Noel, who was Vice President of Finance for
13 UnitedHealthcare Medicare & Retirement, signed an EDI agreement for Oxford Health
14 Plans (CT), Inc. (contract number H0755). On September 22, 2011, Noel signed an EDI
15 agreement for UnitedHealthcare Insurance Company of New York (contract number
16 H1537). Pursuant to these EDI agreements, each of these MA Organizations agreed that
17 it would (i) be responsible for all risk adjustment data submitted to CMS by itself, its
18 employees, or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii)
19 *research and correct discrepancies with its risk adjustment data*. In addition, each of
20 them agreed that CMS could audit the data and have access to medical records to
21 conduct such audits.

22 79. On April 27, 2011, Scott Theisen, the Chief Financial Officer of UnitedHealthcare
23 Medicare & Retirement, submitted an EDI agreement for PacifiCare of California, which
24 included all the same promises. On October 21, 2013, Theisen also signed EDI
25 agreements for Care Improvement Plus Wisconsin Insurance Company (contract number
26 H3794) and Care Improvement Plus South Central Insurance Co. (contract number
27 H5322). Accordingly, each of these Defendant MA Organizations also agreed that it
28 would (i) be responsible for all risk adjustment data (which includes encounter data)

1 submitted to CMS by itself, its employees, or its agents; (ii) submit accurate and truthful
2 risk adjustment data; and (iii) *research and correct discrepancies with its risk adjustment*
3 *data*. In addition, each of them agreed that CMS could audit the data and have access to
4 medical records to conduct such audits.

5 80. Patricia Rasmussen also executed and submitted an EDI agreement so that Ingenix
6 could submit risk adjustment data on behalf of the Defendant MA Organizations. *See*
7 Exhibit 10, attached hereto. By doing this, Ingenix also agreed that it would (i) be
8 responsible for all risk adjustment data submitted to CMS by itself, its employees, or its
9 agents; (ii) submit accurate and truthful risk adjustment data; and (iii) *research and*
10 *correct discrepancies with its risk adjustment data*. In addition, it agreed that CMS
11 could audit the data and have access to medical records to conduct such audits. When
12 Ingenix became OptumInsight, Rasmussen also notified CMS (that is, CMS' contractor
13 Palmetto, which helped operate RAPS) that its records should be updated to reflect that
14 OptumInsight was making the risk adjustment submissions for the Defendant MA
15 Organizations. Rasmussen identified OptumInsight as "part of Optum." *See* Exhibit 11,
16 attached hereto.

17 81. Jeffrey Dumcum, a Senior Vice President at Optum, also executed an EDI
18 agreement in May 2011 in order to submit risk adjustment data (also known as encounter
19 data) to the MA Program on behalf of many of the Defendant MA Organizations,
20 including those MA Organizations listed in a letter sent by Theisen to CMS' contractor
21 in April 2011. By doing this, Dumcum agreed that Optum would be responsible for the
22 data it submitted, submit valid data, and *research and correct data discrepancies*. *See*
23 Exhibit 12, attached hereto.

24 82. All EDI agreements executed by the UHG Managing Defendants on their own
25 behalf and on behalf of the Defendant MA Organizations are incorporated by reference
26 in this Amended Complaint as if they were recited in full and attached hereto.

III. The Ingenix/Optum Service Agreements

83. Depending on the time period, Ingenix or Optum entered into internal agreements with Ovation or UnitedHealthcare regarding the risk adjustment-related services that Ingenix or Optum would provide to the Defendant MA Organizations. These services included, among other things, the submission of risk adjustment data to CMS and the management of the Chart Review, Claims Verification, and RACCR Programs. These internal agreements further confirm the parties' joint and several obligations to the MA Program to submit accurate and truthful risk adjustment data and to investigate and correct any data discrepancies. These agreements also exemplify the UHG Managing Defendants' understanding of their joint and several obligations to the MA Program. All of these agreements are incorporated herein by reference.

84. By way of example, the Memorandum of Understanding ("MOU") entered into between Optum and UnitedHealthcare for risk adjustment-related services rendered by Optum in 2011 exemplifies the obligations undertaken by Optum not only to UnitedHealthcare but to the MA Program. That MOU was executed by Jerry Knutson, Chief Financial Officer of Optum, and Scott Theisen, Chief Financial Officer of UnitedHealthcare Medicare & Retirement. Paul Bihm at Optum, Relator Poehling at UnitedHealthcare Medicare & Retirement, and Jason Bainbridge at UnitedHealthcare Community & State were copied on the MOU. (The MOU referred to UnitedHealthcare Medicare & Retirement and UnitedHealthcare Community & State collectively as "UnitedHealth Group's Public and Senior Markets Group ("PSMG")." This is but one of many examples of the confusion that Defendants have created by the way they used names of groups and entities interchangeably.) Pursuant to the MOU, Optum was compensated for its services through an "intercompany allocation of fees paid pursuant to [a separate] Management Agreement."

85. Pursuant to this 2011 MOU, Optum provided many risk adjustment-related services to the Defendant MA Organizations, including, but not limited to the submission of risk adjustment data to CMS "pursuant to CMS risk adjustment rules and

requirements” and conducting the Chart Review, Claims Verification, and RACCR Programs. Importantly, Optum also agreed to (i) conduct “[p]rovider engagement and education regarding accurate and complete diagnostic coding and documentation”; (ii) “[c]ontribute (along with PSMG) to the level of accuracy and completeness of diagnostic coding for a respective population by identifying opportunities to improve documentation and coding for accuracy, facilitating improvement in accuracy by working directly with providers to improve documentation and coding practices, and executing the timely and accurate submission of claim coding information to CMS, thereby ensuring appropriate revenues are being paid by CMS for the underlying risk inherent within the member population;” (iii) “[m]onitor[] the appropriateness and accuracy of provider coding;” and (iv) conduct “[i]nternal validation testing of outlier providers, internal validation testing of other sample populations and support CMS validation requirements.”

86. The 2011 MOU also included a “Medicare Advantage Regulatory Requirements Appendix.” This Appendix included Optum’s agreement to (i) “comply with all applicable federal and Medicare laws, regulations, and CMS instructions, including but not limited to . . . federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including but not limited to, applicable provisions of federal criminal law [and] the False Claims Act (31 U.S.C. § 3729 et seq.);” (ii) “perform services and provide the products set forth in the MOU in a manner consistent with and in compliance with [the Defendant MA Organizations’] obligations under the CMS Contact[s]; “ and (iii) certify in writing that the risk adjustment data it submitted to CMS was “accurate, complete, and truthful, based on [its] best knowledge, information and belief.” The Appendix further specified that UnitedHealthcare and the Defendant MA Organizations were accountable to CMS for fulfilling their regulatory and contractual obligations under the MA Program, including those that they had delegated to Optum under the MOU and, thus, that they were responsible for overseeing and monitoring Optum’s performance under the MOU.

DEFENDANTS' DATA INTEGRITY OBLIGATIONS

I. Obligation to Submit Valid Diagnoses

87. MA Organizations are entitled to risk adjustment payments based on the diagnosis codes that they submit to CMS *only* if the codes are from face-to-face medical encounters between the Medicare beneficiary and provider, the encounter occurred during the relevant date of service year, the provider was of a type and specialty acceptable for risk adjustment purposes, and at the time of the encounter, the provider documented the medical conditions identified by the diagnosis codes in the medical record based on acceptable documentation. In addition, codes should be based on documented conditions that require or affect patient care treatment or management. *See* Medicare Managed Care Manual, Chapter 7, Exhibit 30 (August 13, 2004) (stating that diagnosis codes submitted for risk adjustment payments should be for documented conditions that “require or affect patient care treatment or management”). *See also* 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide (“2008 RA Participation Guide”) at § 6.4.1.

88. Risk adjustment claims are valid, and the resulting risk adjustment payments are therefore proper and justified, only to the extent that the diagnosis codes submitted by the MA Organizations are valid. The diagnoses must be coded according to the *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting* (“ICD-9-CM” & “ICD-10-CM”) and documented with sufficient clinical specificity. *See* Medicare Managed Care Manual, Chapter 7, Exhibit 30 (August 13, 2004). In addition, codes cannot be submitted for diagnoses that are only probable or suspected, for diagnoses that are questionable, or for a condition that the provider is trying to rule out. *Id.*

89. Moreover, all diagnosis codes submitted by MA Organizations must be supported by medical record documentation. The 2004 Medicare Managed Care Manual stated that “M+C organizations [now known as MA Organizations] must submit risk adjustment data that are substantiated by the physician or provider’s full medical record.” Medicare

1 codes identifying those conditions, and give all of those codes to the UHG Managing
2 Defendants. But, the UHG Managing Defendants selectively utilized results of these
3 chart reviews – that is, the coders’ list of diagnosis codes – for the sole purpose of
4 identifying diagnosis codes that the providers had not reported and submitting ADDS for
5 additional risk adjustment payments. They did not utilize the coders’ lists of diagnosis
6 codes to determine if the providers had reported codes that were not supported by their
7 own medical records. If the UHG Managing Defendants had looked both ways and
8 deleted these unsupported and, thus, invalid provider-reported codes, their national Chart
9 Review Program would have been far less lucrative.

10 165. The UHG Managing Defendants’ national Chart Review Program was their largest
11 risk adjustment revenue-generating program. This program was started in 2005 as an
12 outgrowth of the chart review program that PacifiCare was already conducting.
13 Dumcum, Will, and other former PacifiCare employees became key participants in
14 designing, implementing, and managing the United Managing Defendants’ revenue-
15 generating national Chart Review Program. Will was the Program Manager for the
16 program.

17 166. During the first few years of the program, hundreds of thousands of charts were
18 reviewed each year in order to mine them for additional diagnosis codes. In 2008, The
19 Coding Source (“TCS”), a chart review/diagnosis coding vendor retained by Ingenix,
20 reported to Carol Thompson at Ingenix that “[s]ince 2005, TCS has partnered with
21 PacifiCare-United and Ingenix to support your HHC initiatives. TCS has successfully
22 completed 460,000 chart reviews for multiple United regions.”

23 167. In 2009, the UHG Managing Defendants significantly expanded the size of the
24 national Chart Review Program by providing Ingenix with the funds to acquire a coding
25 vendor called AIM Healthcare Services, Inc. and integrating Ingenix’s operations in
26 Santa Ana, California, and the AIM coding operations in Tennessee, and by providing
27 Ingenix with the funds to develop an in-house chart review computer database system
28 called ChartSync so that Ingenix’s in-house coders and third-party coding vendors could

1 electronically review medical records and electronically record the coding results of their
2 reviews. At or about the same time, the UHG Managing Defendants also expanded the
3 size of the Chart Review Program by providing Ingenix with the funds to open offices in
4 foreign countries (the Philippines and India) where it could hire foreign workers to
5 review beneficiaries' medical records in order to try to find additional diagnosis codes.

6 168. Due to the increased resources devoted to the Chart Review Program, the number
7 of medical records reviewed in the hunt for additional codes significantly increased over
8 time. For the first few years of the Chart Review Program, between 500,000 and
9 600,000 charts were reviewed each year. According to a presentation by Dumcum,
10 600,000 charts were reviewed in 2006 and, as of September 21, 2007, 400,000 charts had
11 been reviewed so far that year with 200,000 charts remaining for review during the
12 fourth quarter of 2007.

13 169. By 2010, the number of chart reviews had increased substantially to
14 approximately 850,000 charts for that year. For 2011 to 2014, approximately 1.5 million
15 charts were reviewed each year. The Government believes that, after 2014, the national
16 Chart Review Program was most likely similar in size.

17 170. As part of this national Chart Review Program, the UHG Managing Defendants
18 focused primarily on the review of charts from providers paid on a fee-for-service basis.
19 Ingenix and then Optum or their vendors obtained medical records from thousands of
20 these providers throughout the United States. They or their vendors sent these medical
21 records to coders that they employed in Tennessee, India, and the Philippines. They also
22 hired coding vendors to review these medical records. Those vendors were located in
23 various locations within and outside of the United States.

24 171. Physician groups owned by one or more of the UHG Managing Defendants also
25 had chart review programs. WellMed had a group called DataRaps that conducted
26 reviews of its physicians' medical records for patients in one or more Defendant MA
27 Organizations' MA plans. Southwest Medical Associates conducted some of its own
28

347. By virtue of the said false or fraudulent claim, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

THIRD CLAIM FOR RELIEF

False Claims Act: Making or Using False Records or Statements

31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2))

348. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

349. Defendants violated 31 U.S.C. § 3729(a)(1)(B) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation material to a false or fraudulent claim for risk adjustment payments from the Medicare Program.

350. Defendants violated former 31 U.S.C. § 3729(a)(2) as follows: Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation to get a false or fraudulent claim for risk adjustment payments paid or approved by the Medicare Program.

351. By virtue of the said false record or statement, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

FOURTH CLAIM FOR RELIEF

False Claims Act: Reverse False Claims

31 U.S.C. § 3729(a)(1)(G) (formerly 31 U.S.C. § 3729(a)(7))

352. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

353. Defendants violated the first part of 31 U.S.C. § 3729(a)(1)(G) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation material to an obligation to repay risk adjustment payments to which they were not entitled from the Medicare Program.

354. Defendants also violated former 31 U.S.C. § 3729(a)(7) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government. Specifically, Defendants knowingly made, used, or caused to be made or used, a false Risk Adjustment Attestation to conceal, avoid or decrease an obligation to repay risk adjustment payments to which they were not entitled from the Medicare Program.

355. By virtue of the said false record, statement, and other acts of concealment and improper avoidance, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment

356. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

357. Defendants have received money from the United States to which Defendants were not entitled, which unjustly enriched Defendants, and for which Defendants must make restitution. Defendants received such money by claiming and retaining Medicare risk adjustment payments based on invalid risk adjustment data. In equity and good conscience, such money belongs to the United States and to the Medicare Program.

1 358. The United States is entitled to recover such money from Defendants in an amount
2 to be determined at trial.

3 **SIXTH CLAIM FOR RELIEF**

4 **Payment by Mistake**

5 359. The United States repeats and re-alleges the allegations contained in Paragraphs 1
6 to 340 above as though they are fully set forth herein.

7 360. The United States paid money to Defendants as a result of a mistaken
8 understanding. Specifically, the United States paid Defendants claims for risk
9 adjustment payments under the mistaken understanding that such claims were based on
10 valid risk adjustment data. Had the United States known the truth, it would not have
11 paid such claims. Payment was therefore by mistake.

12 361. As a result of such mistaken payments, the United States has sustained damages
13 for which Defendants are liable in the amount to be determined at trial.

14 **PRAYER**

15 **WHEREFORE**, the United States requests that judgment be entered in its favor
16 and against Defendants as follows:

17 362. On Claims I, II, III, and IV (False Claims Act), against all Defendants jointly and
18 severally, for the amount of the United States' damages, trebled as required by law,
19 together with the maximum civil penalties allowed by law, costs, post-judgment interest,
20 and such other and further relief as the Court may deem appropriate;

21 363. On Claim V (Unjust Enrichment), against all Defendants jointly and severally, for
22 an amount equal to the monies that Defendants obtained from the United States without
23 right and by which Defendants have been unjustly enriched, plus costs, pre- and post-
24 judgment interest, and such other and further relief as the Court may deem appropriate;
25 and

26 364. On Claim VI (Payment By Mistake), against Defendants for an amount equal to
27 the United States' damages, plus costs, pre- and post-judgment interest, and such other
28 and further relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States of America hereby demands a trial by jury.

Dated: November 17, 2017

Respectfully submitted,

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EXHIBIT 1

Contract with Eligible Medicare Advantage (MA) Organization Pursuant to
 Sections 1851 through 1859 of the Social Security Act for the Operation
 of a Medicare Advantage Coordinated Care Plan(s)

CONTRACT 14-10251.1

Between

Centers for Medicare & Medicaid Services (hereinafter referred to as CMS)

and

UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.,
 (hereinafter referred to as the MA Organization)

CMS and the MA Organization, an entity which has been determined to be an eligible Medicare Advantage Organization by the Administrator of the Centers for Medicare & Medicaid Services under 42 CFR 422.503, agree to the following for the purposes of sections 1851 through 1859 of the Social Security Act (hereinafter referred to as the Act).

(NOTE: Citations indicated in brackets are placed in the text of this contract to note the regulatory authority for certain contract provisions. All references to Part 422 are to 42 CFR Part 422.)

You must check off AND initial each required Addendum type to reflect the coverage offered under the H (or R) number associated with this contract

<u>Addendum Type</u>	<u>Initials</u>
☒ Part D Addendum	_____
☐ EGWP ("800 Series") MA-PD Addendum	_____
☐ EGWP ("800 Series") MA-Only Addendum	_____
☐ Variances/Waivers (Provided directly to Demonstration Organizations by CMS)	_____
☐ Regional Preferred Provider Organization Addendum (Provided directly to RPPOs by CMS)	_____

Final March 31, 2019

Article I

Term of Contract

The term of this contract shall be from the date of signature by CMS' authorized representative through December 31, 2010, after which this contract may be renewed for successive one-year periods in accordance with 42 CFR 422.505(c) and as discussed in Paragraph A in Article VII below. [422.505]

This contract governs the respective rights and obligations of the parties as of the effective date set forth above, and supersedes any prior agreements between the MA Organization and CMS as of such date. MA organizations offering Part D also must execute an Addendum to the Medicare Managed Care Contract Pursuant to Sections 1860D-1 through 1860D-42 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan (hereafter the "Part D Addendum"). For MA Organizations offering MA-PD plans, the Part D Addendum governs the rights and obligations of the parties relating to the provision of Part D benefits, in accordance with its terms, as of its effective date.

Article II

Coordinated Care Plan

A. The Medicare Advantage Organization agrees to operate one or more coordinated care plans as defined in 42 CFR 422.4(a)(1)(ii-iv), including at least one MA-PD plan as required under 42 CFR 422.4(c), as described in its final Plan Benefit Package (PBP) bid submission (benefit and price bid) proposal as approved by CMS and as attested to in the Medicare Advantage Attestation of Benefit Plan and Price, and in compliance with the requirements of this contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.).

B. Except as provided in paragraph (C) of this Article, this contract is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract and any regulations or policies implementing or interpreting such statutory provisions.

C. CMS will not implement, other than at the beginning of a calendar year, requirements under 42 CFR Part 422 that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute. [422.521]

D. This contract is in no way intended to supersede or modify 42 CFR, Part 422. Failure to reference a regulatory requirement in this contract does not affect the applicability of such requirements to the MA organization and CMS.

E. The MA organization must comply with all applicable requirements as described in CMS regulations and guidance implementing the Medicare Improvements for Patients and Providers Act of 2008.

Article III

Final Amended 2009

Functions To Be Performed By Medicare Advantage Organization

A. PROVISION OF BENEFITS

1. The MA Organization agrees to provide enrollees in each of its MA plans the basic benefits as required under §422.101 and, to the extent applicable, supplemental benefits under §422.102 and as established in the MA Organization's final benefit and price bid proposal as approved by CMS and listed in the MA Organization Plan Assertion of Benefit Plan and Price, which is attached to this contract. The MA Organization agrees to provide access to such benefits as required under subpart C in a manner consistent with professionally recognized standards of health care and according to the access standards stated in §422.112.

2. The MA Organization agrees to provide post-hospital extended care services, should an MA enrollee elect such coverage, through a skilled nursing home facility according to the requirements of section 1852(f) of the Act and §422.133. A skilled nursing home facility is a facility in which an MA enrollee resided at the time of admission to the hospital, a facility that provides services through a continuing care retirement community, a facility in which the spouse of the enrollee is residing at the time of the enrollee's discharge from the hospital, or hospital, or wherever the enrollee resides immediately before admission for extended care services.

[422.133; 422.504(a)(3)]

B. ENROLLMENT REQUIREMENTS

1. The MA Organization agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of part 422.

2. The MA Organization shall comply with the provisions of §422.110 concerning prohibitions against discrimination in beneficiary enrollment, other than in enrolling eligible beneficiaries in a CMA-approved special needs plan that exclusively enrolls special needs individuals as consistent with §§422.2, 422.4(a)(1)(c) and 422.52.

[422.504(a)(2)]

C. BENEFICIARY PROTECTIONS

1. The MA Organization agrees to comply with all requirements in subpart M of part 422, governing coverage determinations, grievances, and appeals. [422.504(a)(7)]

2. The MA Organization agrees to comply with the confidentiality and enrollee record accuracy requirements in §422.118.

3. **Beneficiary Financial Protections.** The MA Organization agrees to comply with the following requirements:

(a) Each MA Organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the MA Organization. To meet this requirement the MA Organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the Organization's providers from holding any beneficiary enrollee liable for payment of any fees that are the legal obligation of the MA Organization, and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the MA Organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA Organization, to provide services to the organization's beneficiary enrollees. [422.504(g)(1)]

(b) The MA Organization must provide for continuation of enrollee health care benefits-

(i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of the MA Organization's insolvency, through the date of discharge. [422.504(g)(2)]

(c) In meeting the requirements of this section (C), other than the provider contract requirements specified in paragraph (C)(3)(a) of this Article, the MA Organization may use--

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS. [422.504(g)(3)]

D. PROVIDER PROTECTIONS

1. The MA Organization agrees to comply with all applicable provider requirements in 42 CFR Part 422 Subpart E, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. [422.504(h)(6)]

2. Prompt Payment.

(a) The MA Organization must pay 95 percent of "clean claims" within 30 days of receipt if they are claims for covered services that are not furnished under a written agreement between the organization and the provider.

(i) The MA Organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2) and 1842(e)(2) of the Act.

(ii) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request. [422.520(a)]

(b) Contracts or other written agreements between the MA Organization and its providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA Organization and the relevant provider. [422.520(b)]

(c) If CMS determines, after giving notice and opportunity for hearing, that the MA Organization has failed to make payments in accordance with subparagraph (2)(a) of this section, CMS may provide--

(i) For direct payment of the sums owed to providers; and

(ii) For appropriate reduction in the amounts that would otherwise be paid to the MA Organization, to reflect the amounts of the direct payments and the cost of making those payments. [422.520(c)]

E. QUALITY IMPROVEMENT PROGRAM

1. The MA Organization agrees to operate, for each plan that it offers, an ongoing quality improvement program as stated in accordance with Section 1852(e) of the Social Security Act and 42 CFR 422.152.

2. Chronic Care Improvement Program

(a) Each MA organization must have a chronic care improvement program and must establish criteria for participation in the program. The CCIP must have a method for identifying enrollees with multiple or sufficiently severe chronic conditions who meet the criteria for participation in the program and a mechanism for monitoring enrollees' participation in the program.

(b) Plans have flexibility to choose the design of their program, however, in addition to meeting the requirements specified above, the CCIP selected must be relevant to the plan's MA population. MA organizations are required to submit annual reports on their CCIP program to CMS.

3. Performance Measurement and Reporting: The MA Organization shall measure performance under its MA plans using standard measures required by CMS, and report (at the organization level) its performance to CMS. The standard measures required by CMS during the term of this contract will be uniform data collection and reporting instruments, to include the Health Plan and Employer Data Information Set (HEDIS), Consumer Assessment of Health Plan Satisfaction (CAHPS) survey, and Health Outcomes Survey (HOS). These measures will address clinical areas, including effectiveness of care, enrollee perception of care and use of services, and non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics. [422.152(b)(1), (e)]

4. Utilization Review

(a) An MA Organization for an MA coordinated care plan must use written protocols for utilization review and policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and have in effect mechanisms to detect both underutilization and overutilization of services. [422.152(b)]

(b) For MA regional preferred provider organizations (RPPOs) and MA local preferred provider organizations (LPPOs) that are offered by an organization that is not licensed or organized under State law as an HMOs, if the MA Organization uses written protocols for utilization review, those policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and include mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation. [422.152(c)]

5. Information Systems

(a) The MA Organization must:

(i) Maintain a health information system that collects, analyzes and integrates the data necessary to implement its quality improvement program,

(ii) Ensure that the information entered into the system (particularly that received from providers) is reliable and complete,

(iii) Make all collected information available to CMS. [422.152(f)(1)]

6. External Review

The MA Organization will comply with any requests by Quality Improvement Organizations to review the MA Organization's medical records in connection with appeals of discharges from hospitals, skilled nursing facilities, and home health agencies.

F. COMPLIANCE PLAN

The MA Organization agrees to implement a compliance plan in accordance with the requirements of §422.503(b)(4)(vi) [422.503(b)(4)(vi)]

G. COMPLIANCE DEEMED ON THE BASIS OF ACCREDITATION

CMS may deem the MA Organization to have met the quality improvement requirements of §1852(e) of the Act and §422.152, the confidentiality and accuracy of enrollee records requirements of §1852(f) of the Act and §422.118, the anti-discrimination requirements of §1852(b) of the Act and §422.110, the access to services requirements of §1852(d) of the Act and §422.112, and the advance directives requirements of §1852(i) of the Act and §422.128, the provider participation requirements of §1852(j) of the Act and 42 CFR Part 422, Subpart J, and the applicable requirements described in §422.165, if the MA Organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by CMS and the accreditation organization used the standards approved by CMS for the purposes of assessing the MA Organization's compliance with Medicare requirements. The provisions of §422.156 shall govern the MA Organization's use of deemed status to meet MA program requirements.

H. PROGRAM INTEGRITY

1. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS of any integrity items related to payments from governmental entities, both federal and state, for healthcare or prescription drug services. These items include any investigations, legal actions or matters subject to arbitration brought involving the MA Organization (or MA Organization's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.

2. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS in the event the MA Organization or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent activities or is sanctioned under any Federal program involving the provision of health care or prescription drug services.

I. MARKETING

1. The MA Organization may not distribute any marketing materials, as defined in 42 CFR 422.80(b) and in the Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans and Prescription Drug Plans (Medicare Marketing Guidelines), unless they have been filed

with and nor disapproved by CMS in accordance with §422.80. The file and use process set out at §422.80(a)(2) must be used, unless the MA organization notifies CMS that it will not use this process.

2. CMS and the MA Organization shall agree upon language setting forth the benefits, exclusions and other language of the Plan. The MA Organization bears full responsibility for the accuracy of its marketing materials. CMS, in its sole discretion, may order the MA Organization to print and distribute the agreed upon marketing materials, in a format approved by CMS. The MA Organization must disclose the information to each enrollee electing a plan as outlined in 42 CFR 422.111.

3. The MA Organization agrees that any advertising material, including that labeled promotional material, marketing materials, or supplemental literature, shall be truthful and not misleading. All marketing materials must include the Contract number. All membership identification cards must include the Contract number on the front of the card.

4. The MA Organization must comply with the Medicare Marketing Guidelines, as well as all applicable statutes and regulations, including and without limitation Section 1851(h) of the Act and 42 CFR §§422.80, 422.111 and 422.50. Failure to comply may result in sanctions as provided in 42 CFR Part 422 Subpart O.

Article IV

CMS Payment to MA Organization

A. The MA Organization agrees to develop its annual benefit and price bid proposal and submit to CMS all required information on premiums, benefits, and cost sharing, as required under 42 CFR Part 422 Subpart F. ~~§422.504(a)(10)~~

B. Methodology. CMS agrees to pay the MA Organization under this contract in accordance with the provisions of section 1855 of the Act and 42 CFR Part 422 Subpart G. ~~§422.504(a)(9)~~

C. Attestation of payment data (Attachments A, B, and C)

As a condition for receiving a monthly payment under paragraph B of this article, and 42 CFR Part 422 Subpart G, the MA Organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on the forms attached hereto as Attachment A (enrollment attestation) and Attachment B (risk adjustment data) which attest to *(based on best knowledge, information and belief, as of the date specified on the attestation form)* the accuracy, completeness, and truthfulness of the data identified on these attachments. The Medicare Advantage Plan Attestation of Benefit Plan and Price must be signed and attached to the executed version of this contract.

1. Attachment A requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest based on best knowledge, information, and belief that each enrollee for whom the MA Organization is requesting payment is validly enrolled, or was validly enrolled during the period for which payment is requested, in an MA plan offered by the MA Organization. The MA Organization

shall submit completed enrollment attestation forms to CMS, or its contractor, on a monthly basis. (NOTE: The forms included as attachments to this contract are for reference only. CMS will provide instructions for the completion and submission of the forms in separate documents. MA Organizations should not take any action on the forms until appropriate CMS instructions are made available.)

2. Attachment B requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must *attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) that the risk adjustment data it submits to CMS under §422.310 are accurate, complete, and truthful*. The MA Organization shall make annual attestations to this effect for risk adjustment data on Attachment B and according to a schedule to be published by CMS. If such risk adjustment data are generated by a related entity, contractor, or subcontractor of an MA Organization, such entity, contractor, or subcontractor must also attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) the accuracy, completeness, and truthfulness of the data. [422.504(b)]

3. The Medicare Advantage Plan Attestation of Benefit Plan and Price (an example of which is attached hereto as Attachment C) requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest *(based on best knowledge, information and belief, as of the date specified on the attestation form) that the information and documentation comprising the bid submission proposal is accurate, complete, and truthful and fully conforms to the Bid Form and Plan Benefit Package requirements, and that the benefits described in the CMS-approved proposed bid submission agree with the benefit package the MA Organization will offer during the period covered by the proposed bid submission*. This document is being sent separately to the MA Organization and must be signed and attached to the executed version of this contract, and is incorporated herein by reference. [422.504(d)]

Article V

MA Organization Relationship with Related Entities, Contractors, and Subcontractors

A. Notwithstanding any relationship(s) that the MA Organization may have with related entities, contractors, or subcontractors, the MA Organization maintains full responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. [422.504(i)(1)]

B. The MA Organization agrees to require all related entities, contractors, or subcontractors to agree that--

(1) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to this contract, and

(2) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent information for any particular contract period for 10 years from the final

date of the contract period or from the date of completion of any audit, whichever is later
[422.504(i)(2)]

C. The MA Organization agrees that all contracts or written arrangements into which the MA Organization enters with providers, related entities, contractors, or subcontractors (first tier and downstream entities) shall contain the following elements:

- (1) Enrollee protection provisions that provide—
 - (a) Consistent with Article III(C), arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and
 - (b) Consistent with Article III(C), provision for the continuation of benefits.
 - (2) Accountability provisions that indicate that the MA Organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph D of this article.
 - (3) A provision requiring that any services or other activity performed by a related entity, contractor or subcontractor in accordance with a contract or written agreement between the related entity, contractor, or subcontractor and the MA Organization will be consistent and comply with the MA Organization's contractual obligations to CMS.
- [422.504(i)(3)]

D. If any of the MA Organization's activities or responsibilities under this contract with CMS is delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:

- (1) Written arrangements must specify delegated activities and reporting responsibilities
 - (2) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA Organization determine that such parties have not performed satisfactorily.
 - (3) Written arrangements must specify that the performance of the parties is monitored by the MA Organization on an ongoing basis
 - (4) Written arrangements must specify that either—
 - (a) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA Organization; or
 - (b) The credentialing process will be reviewed and approved by the MA Organization and the MA Organization must audit the credentialing process on an ongoing basis.
 - (5) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions
- [422.504(i)(4)]

E. If the MA Organization delegates selection of the providers, contractors, or subcontractors to another organization, the MA Organization's written arrangements with that organization must state that the MA Organization retains the right to approve, suspend, or terminate any such arrangement. [422.504(i)(5)]

F. As of the date of this contract and throughout its term, the MA Organization

- (1) Agrees that any physician incentive plan it operates meets the requirements of §422.208, and
- (2) Has assured that all physicians and physician groups that the MA Organization's physician incentive plan places at substantial financial risk have adequate stop-loss protection in accordance with §422.208(f) [422.208]

Article VI

Records Requirements

A. MAINTENANCE OF RECORDS

- 1. The MA Organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that--
 - (a) Are sufficient to do the following:
 - (i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the benefit and price bid) of the MA Organization.
 - (ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the MA Organization.
 - (iii) Enable CMS to audit and inspect any books and records of the MA Organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.
 - (iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the benefit and price bid proposal.
 - (v) Establish component rates of the benefit and price bid for determining additional and supplementary benefits.
 - (vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and
 - (b) Include at least records of the following:
 - (i) Ownership and operation of the MA Organization's financial, medical, and other record keeping systems
 - (ii) Financial statements for the current contract period and six prior periods.
 - (iii) Federal income tax or informational returns for the current contract period and six prior periods
 - (iv) Asset acquisition, lease, sale, or other action
 - (v) Agreements, contracts (including, but not limited to, with related or unrelated prescription drug benefit managers) and subcontracts
 - (vi) Franchise, marketing, and management agreements.
 - (vii) Schedules of charges for the MA Organization's fee-for-service patients.
 - (viii) Matters pertaining to costs of operations.
 - (ix) Amounts of income received, by source and payment.
 - (x) Cash flow statements.
 - (xi) Any financial reports filed with other Federal programs or State authorities.
- [422.504(d)]

2. Access to facilities and records. The MA Organization agrees to the following:

(a) The Department of Health and Human Services (HHS), the Comptroller General, or their designee may evaluate, through inspection or other means--

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the MA Organization; and

(iii) The enrollment and disenrollment records for the current contract period and ten prior periods.

(b) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, documents, papers, patient care documentation, and other records of the MA Organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(c) The MA Organization agrees to make available, for the purposes specified in section 4(A) of this article, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require, in a manner that meets CMS record maintenance requirements.

(d) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the final date of the contract period or completion of audit, whichever is later unless:

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA Organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or fraud or similar fault by the MA Organization, in which case the retention may be extended to 10 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) HHS, the Comptroller General, or their designee determines that there is a reasonable possibility of fraud, in which case they may inspect, evaluate, and audit the MA Organization at any time. [422.504(e)]

B. REPORTING REQUIREMENTS

1. The MA Organization shall have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information as described in the remainder of this section (B). [422.516(a)]

2. The MA Organization agrees to submit to CMS certified financial information that must include the following:

(a) Such information as CMS may require demonstrating that the organization has a fiscally sound operation, including:

(i) The cost of its operations;

(ii) A description, submitted to CMS annually and within 120 days of the end of the fiscal year, of significant business transactions (as defined in §422.500) between the MA Organization and a party in interest showing that the costs of the transactions listed in paragraph 12(a)(v) of

- this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
- (iii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements;
 - (iv) A combined financial statement for the MA Organization and a party in interest if either of the following conditions is met:
 - (aa) Thirty-five percent or more of the costs of operation of the MA Organization go to a party in interest;
 - (bb) Thirty-five percent or more of the revenue of a party in interest is from the MA Organization. **[422.516(h)]**
 - (v) ~~Requirements for combined financial statements.~~
 - (aa) The combined financial statements required by paragraph (2)(a)(iv) must display in separate columns the financial information for the MA Organization and each of the parties in interest.
 - (bb) Inter-entity transactions must be eliminated in the consolidated column.
 - (cc) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.
 - (dd) Upon written request from the MA Organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in paragraph (2)(a)(v) with respect to a particular entity. **[422.516(e)]**
 - (vi) A description of any loans or other special financial arrangements the MA Organization makes with contractors, subcontractors, and related entities.
 - (h) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA Organization. **[422.504(f)(1)(ii)]**
 - (e) Patterns of utilization of the MA Organization's services.
3. The MA Organization agrees to participate in surveys required by CMS and to submit to CMS all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:
- (a) The benefits covered under the MA plan;
 - (b) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan;
 - (c) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;
 - (d) Plan quality and performance indicators for the benefits under the plan including –
 - (i) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;
 - (ii) Information on Medicare enrollee satisfaction;
 - (iii) The patterns of utilization of plan services;
 - (iv) The availability, accessibility, and acceptability of the plan's services;
 - (v) Information on health outcomes and other performance measures required by CMS;
 - (vi) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS, and

- (vii) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;
- (e) Information about beneficiary appeals and their disposition;
- (f) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;
- (g) Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program. [422.504(f)(2)]
- 4. The MA Organization agrees to provide to its enrollees and upon request, to any individual eligible to elect an MA plan, all informational requirements under §422.64 and upon an enrollee's request, the financial disclosure information required under §422.516. [422.504(f)(3)]
- 5. Reporting and disclosure under ERISA.
 - (a) For any employees' health benefits plan that includes an MA Organization in its offerings, the MA Organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the MA Organization) under the Employee Retirement Income Security Act of 1974 (ERISA).
 - (b) The MA Organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. [422.516(d)]
- 6. Electronic communication. The MA Organization must have the capacity to communicate with CMS electronically. [422.504(b)]
- 7. Risk Adjustment data. The MA Organization agrees to comply with the requirements in §422.310 for submitting risk adjustment data to CMS. [422.504(a)(8)]

Article VII

Renewal of the MA Contract

- A. Renewal of contract. In accordance with §422.505, following the initial contract period, this contract is renewable annually only if:
 - (1) The MA Organization has not provided CMS with a notice of intention not to renew; [422.506(a)]
 - (2) CMS and the MA Organization reach agreement on the bid under 42 CFR Part 422, Subpart F; and [422.505(d)]
 - (3) CMS informs the MA Organization that it authorizes a renewal.
- B. Nonrenewal of contract.
 - (1) Nonrenewal by the Organization.
 - (a) In accordance with §422.506, the MA Organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason, provided it meets the time frames for doing so set forth in subparagraphs (b) and (c) of this paragraph.
 - (b) If the MA Organization does not intend to renew its contract, it must notify--
 - (i) CMS, in writing, by the first Monday in June of the year in which the contract would end, pursuant to §422.506

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of all alternatives available for obtaining Medicare services within the service area including alternative MA plans, Medigap options, and original Medicare and prescription drug plans and must receive CMS approval prior to issuance.

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a CMS-approved notice in one or more newspapers of general circulation in each community located in the MA Organization's service area.

(c) CMS may accept a nonrenewal notice submitted after the applicable annual nonrenewal notice deadline if –

(i) The MA Organization notifies its Medicare enrollees and the public in accordance with subparagraph (1)(b)(ii) and (1)(b)(iii) of this section, and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(d) If the MA Organization does not renew a contract under subparagraph (1), CMS will not enter into a contract with the Organization for 2 years from the date of contract separation unless there are special circumstances that warrant special consideration, as determined by CMS. [422.506(a)]

(2) CMS decision not to renew.

(a) CMS may elect not to authorize renewal of a contract for any of the following reasons.

(i) The MA Organization's level of enrollment, growth in enrollment, or insufficient number of contracted providers is determined by CMS to threaten the viability of the organization under the MA program and/or be an indicator of beneficiary dissatisfaction with the MA plan(s) offered by the organization.

(ii) For any of the reasons listed in §422.510(a) [Article VIII, section (B)(1)(a) of this contract], which would also permit CMS to terminate the contract.

(iii) The MA Organization has committed any of the acts in §422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under 42 CFR Part 122 Subpart C.

(iv) The MA Organization did not submit a benefit and price bid or the benefit and price bid was not acceptable [422.505(d)].

(b) Notice. CMS shall provide notice of its decision whether to authorize renewal of the contract as follows:

(i) To the MA Organization by May 1 of the contract year, except in the event of (2)(a)(iv) above, for which notice will be sent by September 1.

(ii) To the MA Organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(iii) To the general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(c) Notice of appeal rights. CMS shall give the MA Organization written notice of its right to reconsideration of the decision not to renew in accordance with § 422.644.
[422.506(b)]

Article VIII

Modification or Termination of the Contract

A. Modification or Termination of Contract by Mutual Consent

1. This contract may be modified or terminated at any time by written mutual consent.

(a) If the contract is modified by written mutual consent, the MA Organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within time frames specified by CMS. [422.508(a)(2)]

(b) If the contract is terminated by written mutual consent, except as provided in section (A)(2) of this Article, the MA Organization must provide notice to its Medicare enrollees and the general public as provided in section B(2)(b)(iii) and B(2)(b)(iii) of this Article. [422.508(a)(1)]

2. If this contract is terminated by written mutual consent and replaced the day following such termination by a new MA contract, the MA Organization is not required to provide the notice specified in section B of this article
[422.508(b)]

B. Termination of the Contract by CMS or the MA Organization

1. Termination by CMS

(a) CMS may terminate a contract for any of the following reasons:

(i) The MA Organization has failed substantially to carry out the terms of its contract with CMS.

(ii) The MA Organization is carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of 42 CFR Part 427.

(iii) CMS determines that the MA Organization no longer meets the requirements of 12 CFR Part 422 for being a contracting organization.

(iv) There is credible evidence that the MA Organization committed or participated in false, fraudulent or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

(v) The MA Organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists.

(vi) The MA Organization substantially fails to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals.

(vii) The MA Organization fails to provide CMS with valid risk adjustment data as required under §422.310 and 423.229(b)(3).

(viii) The MA Organization fails to implement an acceptable quality improvement program as required under 42 CFR Part 422 Subpart D.

(ix) The MA Organization substantially fails to comply with the prompt payment requirements in §422.520.

(x) The MA Organization substantially fails to comply with the service access requirements in §422.112.

(xi) The MA Organization fails to comply with the requirements of §422.208 regarding physician incentive plans.

(xii) The MA Organization substantially fails to comply with the marketing requirements in 422.80.

(b) Notice. If CMS decides to terminate a contract for reasons other than the grounds specified in section (B)(1)(a) above, it will give notice of the termination as follows:

(i) CMS will notify the MA Organization in writing 90 days before the intended date of the termination.

(ii) The MA Organization will notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The MA Organization will notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(c) Immediate termination of contract by CMS.

(i) For terminations based on violations prescribed in paragraph (B)(1)(a)(i) of this article, CMS will notify the MA Organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA Organization covering the period of the month following the contract termination.

(ii) CMS will notify the MA Organization's Medicare enrollees in writing of CMS' decision to terminate the MA Organization's contract. This notice will occur no later than 30 days after CMS notifies the plan of its decision to terminate this contract. CMS will simultaneously inform the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA Organizations in a similar geographic area and original Medicare.

(iii) CMS will notify the general public of the termination no later than 30 days after notifying the MA Organization of CMS' decision to terminate this contract. This notice will be published in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(d) Corrective action plan.

(i) General. Before terminating a contract for reasons other than the grounds specified in section (B)(1)(a)(v) of this article, CMS will provide the MA Organization with reasonable opportunity, not to exceed time frames specified at 42 CFR Part 422 Subpart N, to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(ii) Exception. If a contract is terminated under section (B)(1)(a)(v) of this article, the MA Organization will not have the opportunity to submit a corrective action plan.

(c) Appeal rights. If CMS decides to terminate this contract, it will send written notice to the MA Organization informing it of its termination appeal rights in accordance with 42 CFR Part 422 Subpart K. [422.510]

2. Termination by the MA Organization

(a) Cause for termination. The MA Organization may terminate this contract if CMS fails to substantially carry out the terms of the contract.

(b) Notice. The MA Organization must give advance notice as follows:

(i) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA Organization is requesting contract termination.

(ii) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA and MA-PD plans, PDP plans, Medigap options, and original Medicare and must receive CMS approval.

(iii) To the general public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA Organization's geographic area.

(c) Effective date of termination. The effective date of the termination will be determined by CMS and will be at least 90 days after the date CMS receives the MA Organization's notice of intent to terminate.

(d) CMS' liability. CMS' liability for payment to the MA Organization ends as of the first day of the month after the last month for which the contract is in effect, but CMS shall make payments for amounts owed prior to termination but not yet paid.

(e) Effect of termination by the organization. CMS will not enter into an agreement with the MA Organization for a period of two years from the date the Organization has terminated this contract, unless there are circumstances that warrant special consideration, as determined by CMS. [422.512]

Article IX

Requirements of Other Laws and Regulations

A. The MA Organization agrees to comply with--

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law: the False Claims Act (31 USC 3729 et seq.), and the anti-kickback statute (section 1128B(b) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164. [422.504(b)]

B. The MA Organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, notwithstanding any relationships that the MA organization may have with related entities, contractors, or subcontractors. [422.504(i)]

C. In the event that any provision of this contract conflicts with the provisions of any statute or regulation applicable to an MA Organization, the provisions of the statute or regulation shall have full force and effect.

Article X

Severability

The MA Organization agrees that, upon CMS' request, this contract will be amended to exclude any MA plan or State-licensed entity specified by CMS, and a separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made. [422.504(k)]

Article XI

Miscellaneous

- A. Definitions. Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 422.
- B. Alteration to Original Contract Terms. The MA Organization agrees that it has not altered in any way the terms of this contract presented for signature by CMS. The MA Organization agrees that any alterations to the original text the MA Organization may make to this contract shall not be binding on the parties.
- C. Approval to Begin Marketing and Enrollment. The MA Organization agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part C marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications for contracting with an entity qualified to perform such functions on the MA Organization's Sponsor's behalf and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the MA Organization must:
 - 1) establish and test physical connectivity to the CMS data center;
 - 2) acquire user identifications and passwords;
 - 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS; and
 - 4) check and receive transaction status information.
- D. Incorporation of Applicable Addenda. All addenda checked off and initialed on the cover sheet of this contract by the MA Organization are hereby incorporated by reference.

In witness whereof, the parties hereby execute this contract

FOR THE MA ORGANIZATION

Printed Name

Title

Signature

Date

Organization

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES

Teresa DeCaro, R.N., MS
Acting Director
Medicare Drug and Health Plan Contract
Administration Group
Center for Drug and Health Plan Choice

Date

ATTACHMENT A

**ATTESTATION OF ENROLLMENT INFORMATION
RELATING TO CMS PAYMENT
TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (HOSP), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This attestation shall not be considered a waiver of the MA Organization's right to seek payment adjustments from CMS based on information or data which does not become available until after the date the MA Organization submits this attestation.

1. The MA Organization has reported to CMS for the month of (INDICATE MONTH AND YEAR) all new enrollments, disenrollments, and appropriate changes in enrollees' status with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The MA Organization has reviewed the CMS monthly membership report and reply listing for the month of (INDICATE MONTH AND YEAR) for the above-stated MA plans and has reported to CMS any discrepancies between the report and the MA Organization's records. For those portions of the monthly membership report and the reply listing to which the MA Organization raises no objection, the MA Organization, through the certifying CEO/COO, will be deemed to have attested, based on best knowledge, information, and belief as of the date indicated below, to its accuracy, completeness, and truthfulness.

(INDICATE TITLE (CEO, COO, or delegate))

on behalf of

UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.
(INDICATE MA ORGANIZATION)

DATE

20

ATTACHMENT B

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (H0251), the MA Organization hereby requests payment

under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS during the period of (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS ENCOUNTER) risk adjustment data available to the MA Organization with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

(INDICATE TITLE (CEO, CFO, or delegate))

on behalf of

UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC.,
(INDICATE MA ORGANIZATION)

DATE

[SAMPLE - DO NOT USE - THIS DOCUMENT WILL BE SENT DIRECTLY TO THE MAO THROUGH HPMS]

ATTACHMENT C – Medicare Advantage Plan Attestation of Benefit Plan and Price

<Legal Entity Name>

<Contract # >

Date: <XX/XX/XXXX>

I attest that the following plan numbers as established in the final Plan Benefit Package (PBP) will be operated by the above-stated organization and made available to eligible Medicare beneficiaries in the approved service area during program year 2010

Plan ID	Segment ID	Version	Plan Name	Plan Type	Transaction Type	MA Premium	Part D Premium	CMS Approval Date	Effective Date
<XXX>	<X>	<X>	<Plan Name>	<Plan Type>	<Transaction Type>	S<Plan Premium>	S<Part D Premium>	<XX/XX/XX>	<XX/XX/XX>
<XXX>	<X>	<X>	<Plan Name>	<Plan Type>	<Transaction Type>	S<Plan Premium>	S<Part D Premium>	<XX/XX/XX>	<XX/XX/XX>
<XXX>	<X>	<X>	<Plan Name>	<Plan Type>	<Transaction Type>	S<Plan Premium>	S<Part D Premium>	<XX/XX/XX>	<XX/XX/XX>

CEO

<Name of CEO>
<Title>
<Address 1>
<Address 2>
<City, State Zip>
<Phone #>

Date

CFO

<Name of CFO>
<Title>
<Address 1>
<Address 2>
<City, State Zip>
<Phone #>

Date

EXHIBIT D-2

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Attorneys for UnitedHealth Defendants

**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et*
al.,

Defendants.

CASE NO. 2:16-cv-08697-MWF-SSx

**UNITEDHEALTH'S ANSWER TO
UNITED STATES' AMENDED
COMPLAINT-IN-PARTIAL-
INTERVENTION AND
COUNTERCLAIM**

1 Having filed a notice of intervention pursuant to 31 U.S.C. § 3730(b)(4), the
2 United States alleges in its Amended Complaint-In-Partial-Intervention and
3 Demand for Jury Trial (the “Government’s Amended Complaint” or “Amended
4 Complaint”) the allegations below. Defendants UnitedHealth Group Incorporated,
5 United HealthCare Services, Inc., UnitedHealthcare, Inc., UnitedHealthcare
6 Insurance Company, Ovations, Inc., Optum, Inc., OptumInsight, Inc.,
7 AmeriChoice of New Jersey, Inc., AmeriChoice of New York, Inc., Arizona
8 Physicians IPA, Inc., Care Improvement Plus of Maryland, Inc., Care
9 Improvement Plus of Texas Insurance Company, Care Improvement Plus South
10 Central Insurance Company, Care Improvement Plus Wisconsin Insurance
11 Company, Optum Insurance Co., Citrus Health Care, Inc., Health Plan of Nevada,
12 Inc., Medica HealthCare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford
13 Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., PacifiCare Life and
14 Health Insurance Company, PacifiCare of Arizona, Inc., PacifiCare of Colorado,
15 Inc., PacifiCare of Nevada, Inc., Physicians Health Choice of Texas, LLC,
16 Preferred Care Partners, Inc., Rocky Mountain Health Maintenance Organization,
17 Incorporated, Sierra Health and Life Insurance Company, Inc., Symphonix Health
18 Insurance, Inc., UHC of California (f.k.a. PacifiCare of California), United Health
19 Care Ins. Co. and United New York, Unison Health Plan of Tennessee, Inc.,
20 UnitedHealthcare Benefits of Texas, Inc. (f.k.a. PacifiCare of Texas, Inc.),
21 UnitedHealthcare Community Plan of Ohio, Inc. (f.k.a. Unison Health Plan of
22 Ohio, Inc.), UnitedHealthcare Community Plan of Texas, L.L.C. (f.k.a. Evercare of
23 Texas, L.L.C.), UnitedHealthcare Community Plan, Inc. (f.k.a. UnitedHealthcare
24 of the Great Lakes Health Plan, Inc.), UnitedHealthcare Insurance Company of
25 New York, UnitedHealthcare of Alabama, Inc., UnitedHealthcare of Arizona, Inc.,
26 UnitedHealthcare of Arkansas, Inc., UnitedHealthcare of Florida, Inc.,
27 UnitedHealthcare of Georgia, Inc., UnitedHealthcare of New England, Inc.,
28 UnitedHealthcare of New York, Inc., UnitedHealthcare of North Carolina, Inc.,

UnitedHealthcare of Ohio, Inc., UnitedHealthcare of Oklahoma, Inc. (f.k.a. PacifiCare of Oklahoma, Inc.), UnitedHealthcare of Oregon, Inc. (f.k.a. PacifiCare of Oregon, Inc.), UnitedHealthcare of Pennsylvania, Inc. (f.k.a. Unison Health Plan of Pennsylvania, Inc.), UnitedHealthcare of Tennessee, Inc., UnitedHealthcare of the Midlands, Inc., UnitedHealthcare of the Midwest, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc. (f.k.a. PacifiCare of Washington, Inc.), UnitedHealthcare of Wisconsin, Inc., and UnitedHealthcare Plan of the River Valley, Inc. (collectively, “UnitedHealth”) generally deny each and every allegation except those hereinafter specifically admitted.

On February 2, 2018, the Court granted in part and denied in part the UnitedHealth Defendants’ motion to dismiss. Dkt. 212. This Order dismissed, with leave to amend, the Government’s Second, Third, and Fourth Claims for Relief. On February 26, 2018, the Government notified the Court and the parties that it had “elected not to file a Second Amended Complaint-in-Intervention in this action.” Dkt. 217 at 2. Therefore, the only surviving claims against the UnitedHealth Defendants are the First, Fifth, and Sixth Claims for Relief. There are many allegations that clearly relate to the dismissed claims that are now surplusage and do not require a response. Notwithstanding that and while preserving all of its rights, UnitedHealth denies claims or allegations that do not relate to the Government’s First, Fifth, and Sixth Claims for Relief. UnitedHealth further answers the numbered paragraphs as follows:

INTRODUCTION

1. Paragraph 1 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 1 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 1 vary therefrom or

1 with other applicable statutory or decisional law, UnitedHealth denies those
2 allegations.

3 2. Paragraph 2 contains no allegations with respect to a particular
4 Defendant or claim, and therefore no response is required. However, to the extent
5 Paragraph 2 purports to summarize and/or describe the provisions of the Medicare
6 program, UnitedHealth states that the Medicare statute and regulations speak for
7 themselves, and to the extent that the allegations in Paragraph 2 vary therefrom or
8 with other applicable statutory or decisional law, UnitedHealth denies those
9 allegations.

10 3. Paragraph 3 contains no allegations with respect to a particular
11 Defendant or claim, and therefore no response is required. However, to the extent
12 Paragraph 3 purports to summarize and/or describe the provisions of the Medicare
13 program, UnitedHealth states that the Medicare statute and regulations speak for
14 themselves, and to the extent that the allegations in Paragraph 3 vary therefrom or
15 with other applicable statutory or decisional law, UnitedHealth denies those
16 allegations.

17 4. Paragraph 4 contains no allegations with respect to a particular
18 Defendant or claim, and therefore no response is required. However, to the extent
19 Paragraph 4 purports to summarize and/or describe the provisions of the Medicare
20 program, UnitedHealth states that the Medicare statute and regulations speak for
21 themselves, and to the extent that the allegations in Paragraph 4 vary therefrom or
22 with other applicable statutory or decisional law, UnitedHealth denies those
23 allegations.

24 5. Paragraph 5 contains no allegations with respect to a particular
25 Defendant or claim, and therefore no response is required. However, to the extent
26 Paragraph 5 purports to summarize and/or describe the provisions of the Medicare
27 program, UnitedHealth states that the Medicare statute and regulations speak for
28 themselves, and to the extent that the allegations in Paragraph 5 vary therefrom or

1 with other applicable statutory or decisional law, UnitedHealth denies those
2 allegations.

3 6. To the extent that Paragraph 6 contains legal conclusions, no response
4 is required. Paragraph 6 contains no allegations with respect to a particular
5 Defendant or claim, and therefore no response is required. However, to the extent
6 Paragraph 6 purports to summarize and/or describe the provisions of the Medicare
7 program or the Ninth Circuit's order in *United States ex rel. Swoben v.*
8 *UnitedHealthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016), UnitedHealth states that
9 the Medicare regulations and the order speak for themselves, and to the extent that
10 the allegations in Paragraph 6 vary therefrom or with other applicable statutory or
11 decisional law, UnitedHealth denies those allegations.

12 7. UnitedHealth admits that for many years, UnitedHealth Group
13 Incorporated has owned Medicare Advantage ("MA") Organizations that have
14 enrolled more MA beneficiaries than any other entity, and offers Medicare
15 Advantage Plans ("MA Plans") and prescription drug plans ("PD Plans") to
16 millions of elderly and disabled Medicare beneficiaries throughout the United
17 States. UnitedHealth also admits that in or around March 2017, approximately
18 229,000 Medicare beneficiaries in the Central District of California were enrolled
19 in MA Plans offered by UHC of California and Sierra Health and Life Insurance
20 Company, Inc. UnitedHealth denies the remaining allegations in Paragraph 7.

21 8. Paragraph 8 refers to the Complaint, a legal document, which speaks
22 for itself and to which no response is required. UnitedHealth denies the remaining
23 allegations in Paragraph 8.

24 9. UnitedHealth admits that some of the UnitedHealth Defendants
25 collectively received billions of dollars from the Medicare program each year in
26 relation to the Medicare beneficiaries enrolled in the Defendant MA
27 Organizations' Plans. UnitedHealth admits that certain Defendants conducted
28 programs and engaged in activities designed to improve the completeness of risk

adjustment data submitted on behalf of Defendant MA Organizations.

UnitedHealth denies the remaining allegations in Paragraph 9.

10. UnitedHealth admits that certain Defendants have conducted a Chart Review Program since in or about 2005. UnitedHealth admits that this program improved the completeness of risk adjustment data submitted for Defendant MA Organizations and that risk adjustment payments increased as a result. UnitedHealth denies the remaining allegations in Paragraph 10.

11. To the extent that Paragraph 11 contains legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 11.

12. To the extent that Paragraph 12 contains legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 12.

13. To the extent that Paragraph 13 contains legal conclusions, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the Government's estimations. UnitedHealth denies the remaining allegations in Paragraph 13.

14. To the extent the allegations in Paragraph 14 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 14 states legal conclusions to which no response is required. To the extent that Paragraph 14 contains any factual allegations regarding UnitedHealth, such allegations are denied.

15. Paragraph 15 states legal conclusions to which no response is required. To the extent that Paragraph 15 contains any factual allegations regarding UnitedHealth, such allegations are denied.

16. UnitedHealth admits that some of the UnitedHealth Defendants paid some of its provider groups on a capitated basis and others on a fee-for-service basis. UnitedHealth also admits that some of the UnitedHealth Defendants entered

1 into value-based agreements with some of its fee-for-service providers.

2 UnitedHealth denies the remaining allegations in Paragraph 16.

3 17. UnitedHealth admits that pursuant to some of the UnitedHealth
4 Defendants' contractual arrangements with capitated and certain other providers,
5 some of the UnitedHealth Defendants paid a percentage share of the payments that
6 some of the UnitedHealth Defendants received from the Medicare Program for the
7 beneficiaries under those providers' care. UnitedHealth denies the remaining
8 allegations in Paragraph 17.

9 18. Paragraph 18 states legal conclusions to which no response is
10 required. UnitedHealth denies the remaining allegations in Paragraph 18.

11 **JURISDICTION AND VENUE**

12 19. Paragraph 19 states legal conclusions to which no response is
13 required.

14 20. Paragraph 20 states legal conclusions to which no response is
15 required. To the extent a response is required, UnitedHealth admits that at least
16 one of the Defendants transacts business in the Central District of California.

17 21. Paragraph 21 states legal conclusions to which no response is
18 required. To the extent a response is required, UnitedHealth admits that at least
19 one of the Defendants can be found in, resides in, and transacts business in this
20 District. UnitedHealth denies the remaining allegations in Paragraph 21.

21 **PARTIES**

22 **I. Plaintiffs**

23 22. Paragraph 22 refers to the Complaint, a legal document, which speaks
24 for itself and to which no response is required. To the extent Paragraph 22
25 purports to summarize and/or describe the provisions of the Medicare program,
26 UnitedHealth states that the Medicare statute and regulations speak for themselves,
27 and to the extent that the allegations in Paragraph 22 vary therefrom or with other
28 applicable statutory or decisional law, UnitedHealth denies those allegations.

UnitedHealth admits that the United States filed its notice of partial intervention in this action on February 14, 2017.

23. UnitedHealth admits that the *qui tam* plaintiff (“Relator”), Benjamin Poehling, initiated this action by filing a complaint under the *qui tam* provisions of the False Claims Act (“FCA”) against UnitedHealth in March 2011. UnitedHealth admits that from 2004 through the end of 2012, Poehling was the Director of Finance for UnitedHealthcare. UnitedHealth denies the characterization of its Chart Review Program as a “revenue-generating activit[y].” UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 23; therefore, such allegations are denied.

II. Defendants

24. UnitedHealth admits that UnitedHealth Group Incorporated is a publicly traded Delaware corporation and that it, along with some of its affiliates, have offices in various locations throughout the United States, including in the Central District of California. UnitedHealth denies the remaining allegations in Paragraph 24.

25. UnitedHealth admits that some of its MA Organizations offer one or more MA Plans and some also offer PD Plans. UnitedHealth admits that in or around 2008, UnitedHealth Group Incorporated had approximately 1.5 million beneficiaries enrolled in MA Plans operated by its affiliate entities and millions of beneficiaries enrolled in PD Plans operated by its affiliate entities. UnitedHealth admits that in or around 2009, UnitedHealth Group Incorporated had approximately 1.8 million beneficiaries enrolled in MA operated by its affiliate entities and millions of beneficiaries enrolled in PD Plans operated by its affiliate entities. UnitedHealth admits that in or around 2010, UnitedHealth Group Incorporated had approximately 2.1 million beneficiaries in MA Plans operated by its affiliate entities and millions of beneficiaries in PD Plans operated by its

1 affiliate entities. UnitedHealth admits that in or around 2011, UnitedHealth Group
2 Incorporated had approximately 2.2 million beneficiaries in MA Plans operated by
3 its affiliate entities and millions of beneficiaries in PD Plans operated by its
4 affiliate entities. UnitedHealth admits that in or around 2012, UnitedHealth Group
5 Incorporated had approximately 2.6 million beneficiaries in MA Plans operated by
6 its affiliate entities and millions of beneficiaries in PD Plans operated by its
7 affiliate entities. UnitedHealth denies the remaining allegations in Paragraph 25.

8 26. To the extent the allegations in Paragraph 26 relate to claims that have
9 been dismissed, they are surplusage and should be stricken. UnitedHealth admits
10 that the following entities named as Defendants in this action have had or have
11 previously had one or more agreements with the Government at some point since
12 2005 to offer MA and/or PD Plans to Medicare beneficiaries under Parts C and D
13 of the Medicare Program, and received payments from the Government pursuant to
14 these agreements: Citrus Health Care, Inc., which was a Florida corporation;
15 Health Plan of Nevada, Inc., which is a Nevada corporation; Medica HealthCare
16 Plans, Inc., which is a Florida corporation; and Physicians Health Choice of Texas,
17 LLC, which is a Texas limited liability company doing business as Physicians
18 Health Choice. UnitedHealth denies the remaining allegations in Paragraph 26.

19 27. UnitedHealth admits that United HealthCare Services, Inc. is a
20 Minnesota corporation and a direct subsidiary of UnitedHealth Group
21 Incorporated. UnitedHealth also admits that PacifiCare Health Systems, LLC and
22 PacifiCare Health Plan Administrators, Inc. merged into United HealthCare
23 Services, Inc. UnitedHealth denies the remaining allegations in Paragraph 27.

24 28. UnitedHealth admits that Ovations, Inc. is a Delaware corporation and
25 a direct subsidiary of United HealthCare Services, Inc. and an indirect subsidiary
26 of UnitedHealth Group Incorporated. UnitedHealth denies the remaining
27 allegations in Paragraph 28.

29. UnitedHealth admits that UnitedHealthcare, Inc. is a Delaware corporation. UnitedHealth admits that various UnitedHealthcare subsidiaries operate health benefit plans and provide healthcare benefits to Medicare beneficiaries under the MA Program. UnitedHealth denies the remaining allegations in Paragraph 29.

30. UnitedHealth admits that Optum, Inc. and OptumInsight, Inc. are Delaware corporations and indirect subsidiaries of UnitedHealth Group Incorporated. UnitedHealth admits that in 2011, OptumInsight became the successor to Ingenix, Inc. Paragraph 30 also refers to the Complaint, a legal document, which speaks for itself and to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 30.

31. Paragraph 31 states legal conclusions to which no response is required. To the extent Paragraph 31 contains any factual allegations, such allegations are denied.

32. Paragraph 32 states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 32.

33. UnitedHealth admits that, starting in 2007, its risk adjustment submission process was primarily performed within Ingenix and then within Ingenix's successor, Optum. UnitedHealth admits that Ingenix and then Optum submitted risk adjustment data to CMS' Risk Adjustment Processing System (RAPS) via IRADS. UnitedHealth admits that Ingenix and then Optum performed operational functions for Chart Review, Claims Verification, and Risk Adjustment Coding Compliance Review ("RACCR") programs. UnitedHealth admits that Ingenix and then Optum performed certain activities relating to risk adjustment from its office in the Central District of California and elsewhere. UnitedHealth denies the remaining allegations in Paragraph 33.

1 34. Paragraph 34 states legal conclusions to which no response is
2 required. Paragraph 34 also refers to the Complaint, a legal document, which
3 speaks for itself and to which no response is required.

4 35. UnitedHealth admits that Ingenix and then Optum also performed risk
5 adjustment-related services for third parties, who owned and operated their own
6 MA Organizations and offered their own Plans. UnitedHealth admits that these
7 third parties were sometimes referred to as Optum's commercial clients.
8 UnitedHealth admits that Ingenix and then Optum submitted risk adjustment data
9 to the Government on behalf of certain commercial clients. UnitedHealth admits
10 that Ingenix and then Optum conducted Chart Review and other programs for
11 certain commercial clients. UnitedHealth admits that Ingenix and then Optum
12 performed risk adjustment related work for certain commercial clients from offices
13 in this District and elsewhere. UnitedHealth denies the remaining allegations in
14 Paragraph 35.

15 36. UnitedHealth admits that in or around 2005 it acquired PacifiCare
16 Health Systems, PacifiCare of Arizona, Inc., incorporated in Arizona; PacifiCare
17 of California, incorporated in California; PacifiCare of Colorado, Inc., incorporated
18 in Colorado; PacifiCare of Nevada, Inc., incorporated in Nevada; PacifiCare of
19 Oklahoma, Inc., incorporated in Oklahoma; PacifiCare of Oregon, Inc.,
20 incorporated in Oregon; PacifiCare of Texas, Inc. incorporated in Texas; and
21 PacifiCare of Washington, incorporated in Washington. UnitedHealth also admits
22 that at various points in time, PacifiCare plans were referred to as Secure Horizons.
23 UnitedHealth admits that the aforementioned entities are indirect subsidiaries of
24 UnitedHealth Group Incorporated. UnitedHealth admits that in or around 2011,
25 PacifiCare of California became UHC of California. UnitedHealth denies the
26 remaining allegations in Paragraph 36.

27 37. UnitedHealth admits that PacifiCare Health Systems, LLC and
28 PacifiCare Health Plan Administrators, Inc. merged into United HealthCare

Services, Inc. in or around 2005. UnitedHealth admits that all PacifiCare MA Organizations and their successors were direct or indirect subsidiaries of UnitedHealth Group Incorporated. Paragraph 37 also refers to the Complaint, a legal document, which speaks for itself and to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 37.

38. UnitedHealth admits that prior to its acquisition of PacifiCare, PacifiCare had an office in Cypress, California. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 38; therefore, such allegations are denied. Additionally, Paragraph 38 states a legal conclusion to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 38.

39. UnitedHealth admits that in or around 2011, it acquired a share of WellMed Medical Management, Inc. In or around 2011, UnitedHealth also acquired entities such as Physician's Health Choice of Texas, LLC and Citrus Health Care, Inc., which operated in Texas, Florida, New Mexico, and Arkansas. UnitedHealth admits that at the time of the acquisition, Citrus Health Care, Inc. was a Florida corporation and a subsidiary of PHC Holdings of Florida, Inc. UnitedHealth denies the remaining allegations in Paragraph 39.

40. UnitedHealth admits that for many years, WMMI had affiliates that directly managed the provision of healthcare services, including WellMed Networks, Inc., WellMed Networks Inc. of Florida, WellMed Medical Management of Florida Inc., and WellMed Medical Group, PA. UnitedHealth admits that after the acquisition, WMMI became part of the UnitedHealth Group Incorporated group called OptumCare. UnitedHealth admits that WellMed's integrated health care delivery system includes more than 10,000 contracted physicians who provide healthcare to hundreds of thousands of Medicare beneficiaries in Texas and Florida, including those beneficiaries enrolled in

UnitedHealth's MA Plans. UnitedHealth denies the remaining allegations in Paragraph 40.

41. Paragraph 41 refers to the Complaint, a legal document, which speaks for itself and to which no response is required. To the extent Paragraph 41 contains any factual allegations, such allegations are denied.

DEFENDANTS' EXECUTIVES AND OTHER EMPLOYEES

42. To the extent Paragraph 42 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 42 with the exception of those specifically admitted below:

- Kyle Anderson was the Director of Financial Planning and Analysis at UnitedHealthcare from in or around 2009 to 2015.
- Jason Bainbridge worked for UnitedHealthcare in or around 2012.
- From in or around 2011 to 2015, Paul Balthazor was the Chief Financial Officer of UnitedHealthcare Community & State.
- Marc Beckmann worked for UnitedHealthcare Medicare & Retirement.
- In or around 2008, Jon Bird worked for Ingenix's Risk Adjustment Group, became Director of Revenue Projections in or around 2010, and became the Vice President of Risk Adjustment and Quality Analytics at Optum in or around 2013.
- Gail Boudreaux became the Executive Vice President of UnitedHealthcare in or around 2008.
- Tracey Bradberry was an Operations Manager at Ingenix from around 2008 to 2012, and that since 2012, she has served as an Associate Director of Operations at Optum.
- Patty Brennan began working at Ingenix in or around 2008 as a Compliance Manager for Risk Adjustment Programs. In or around

2009, Brennan became the Director of Retrospective Services at Ingenix. In or around 2013, Brennan became the Vice President of Retrospective Services at Optum.

- In or around 2009, Jonathan Bunker was the President of Sierra Health and Life Insurance Company, Inc. and the President of Health Plan of Nevada, Inc. In or around 2013 Bunker became the Chief Executive Officer for UnitedHealthcare's Southwest Region.
- Barbara Carlson was a Senior Regulatory Affairs Analyst at UnitedHealthcare in 2011.
- Shelly Cranley served as the Director of Regulatory Affairs for UnitedHealthcare.
- Keith Dobbins has been UnitedHealthcare's Deputy General Counsel since at least in or around 2014.
- From around 2012 to 2015, Juliet Domb was a Strategic Relationship Analyst at Optum. Domb served as an administrative assistant to Larry Renfro.
- Jeffrey Dumcum was the Chief Financial Officer at PacifiCare, and became a Director of Finance at UnitedHealth following PacifiCare's acquisition. In or around 2007, Dumcum became a Senior Vice President at Ingenix (later Optum).
- Karen Erickson has been an Executive Vice President at Optum since in or around 2011, and that she was Optum's Chief Administrative Officer in or around 2011.
- Ronnie Grower was a Vice President of Market Consultation at Ingenix from around 2008 to 2009, and a Vice President of Account Management at Ingenix from around 2009 to 2010.
- Joseph Hafermann was the Chief Financial Officer of Secure Horizons in or around 2007.

- 1 • Kimberly Halva was an attorney for UnitedHealthcare Medicare &
2 Retirement in or around 2009 and served as UnitedHealthcare
3 Medicare & Retirement's Finance and Clinical Compliance Officer
4 from in or around 2010 to 2013.
- 5 • In or around 2010 to 2013, Mary Hammond was an Associate
6 Director of Strategy and Support at UnitedHealthcare Medicare &
7 Retirement.
- 8 • In or around 2008 to 2013, Charles Hanson was a Vice President of
9 Underwriting and Finance at UnitedHealthcare Medicare &
10 Retirement.
- 11 • Steve Hemsley is currently the Executive Chairman of UHG's Board
12 of Directors, and that he was formerly Chief Executive Officer of
13 UHG from in or around 2006 to 2017.
- 14 • Pam Holt was a Manager of Network Operations at UnitedHealthcare.
- 15 • Scott Hughes was a Senior Project Manager at Optum beginning in or
16 around 2012.
- 17 • Michael (Mike) Jacobson was a Business Analyst Consultant at
18 OptumInsight.
- 19 • Donald James was a Director of Program Strategy at Optum from in
20 or around 2012 to 2015.
- 21 • Thad Johnson is the current Chief Legal Officer at UnitedHealthcare.
- 22 • Joseph Keen was a Vice President and Chief Compliance Audit
23 Officer for UnitedHealthcare in or around 2011.
- 24 • Gerald (Jerry) Knutson was the Chief Financial Officer at Ovations
25 from in or around 2003 to 2009 and the Chief Financial Officer of
26 OptumInsight from in or around 2009 to 2012.

- John (Jack) Larsen was the Chief Executive Officer of UnitedHealthcare Medicare & Retirement and at one time was the Chief Financial Officer of UnitedHealthcare Medicare & Retirement.
- In or around 2010, Rebecca Martin became the Director of Encounter Operations at Optum.
- In or around 2013, 2014, and 2015, Jay Matushak was a Vice President of Finance for UnitedHealthcare Medicare & Retirement.
- Michael McCarthy was a Regional Vice President for Southern California for UnitedHealthcare in or around 2013.
- Bill Miller was the Chief Executive Officer of OptumInsight from in or around 2012 to 2017.
- Eric Murphy was President of Payer Solutions at Optum.
- Randall Myers worked for PacifiCare and then for Ingenix and then Optum as a Director of Encounter Operations.
- Steve Nelson has been the Chief Executive Officer of UnitedHealthcare since in or around 2017, and that from in or around 2014 to 2017, he was the Chief Executive Officer of UnitedHealthcare Medicare & Retirement.
- Jennifer O'Brien was the Chief Medicare Compliance Officer of Ovation.
- Karin O'Hara worked at UnitedHealthcare Community & State.
- David Orbuch was the Chief Compliance Officer for PSMG.
- Karen Petroff was the Senior Vice President of Business Development at Optum.
- Cynthia (Cindy) Polich was the President of UnitedHealthcare Medicare & Retirement.

- Janice Redmond was Senior Vice President of Provider Outreach at Optum until in or around 2012, when she became Vice President of Market Consultation for Optum's Western Region.
- In or around 2013, Anne Reis was an Associate Director of Revenue for UnitedHealthcare Medicare & Retirement.
- In or around 2009 to 2011, Larry Renfro served as the Chief Executive Officer of Ovations and the Chief Executive Officer of the Public & Senior Markets Group. Renfro is currently the Chief Executive Officer of Optum and has been in this position since in or around July 2011. Renfro has been the Vice Chairman of UHG since in or around November 2014.
- Sandy Rick was a Senior Regulatory Affairs Analyst at UnitedHealthcare.
- Kara Rios was the Chief Financial Officer of AmeriChoice.
- Justin Roth was the Chief Financial Officer of Evercare.
- Daniel Schumacher was the Chief Financial Officer of UnitedHealthcare.
- Melissa Sedor was a Director of Accounting at UnitedHealthcare.
- Matt Shors is UHG's Senior Deputy General Counsel.
- Marianne Short is UHG's Executive Vice President and Chief Legal Officer.
- Andy Slavitt was the Chief Executive Officer for OptumInsight and an Executive Vice President for Optum.
- Scott Theisen was the Chief Financial Officer of UnitedHealthcare Medicare & Retirement from in or around 2010 to 2013.
- Brian Thompson has been the Chief Executive Officer of UnitedHealthcare Medicare & Retirement since in or around 2017, and that from in or around 2013 to 2017, he was the Chief Financial

Officer of UnitedHealthcare Medicare & Retirement. Brian Thompson was also previously the Chief Financial Officer of UnitedHealthcare Community & State.

- Carol Thompson was a National Manager for Risk Adjustment Programs at Ingenix until in or around 2009, a Manager of ChartSync operations at Ingenix from in or around 2009 to 2011, a Manager of Encounter Operations at Optum from in or around 2011 to 2013 and an Analyst of Encounter Operations at Optum from in or around 2013 to 2014.
- Lee Valenta was the Chief Financial Officer, the Chief Operating Officer, the Chief Scientific Officer, and an Executive Vice President at OptumInsight.
- Karen Wagor was the Manager of the National Medical Coder Team and the National Coding Trainer at Ingenix and then Optum and that she previously worked at PacificCare.
- John Way was Chief Financial Officer of SecureHorizons.
- Timothy Wicks served in a senior management position at Optum.

THE MEDICARE PROGRAM

I. The Medicare Statute

43. Paragraph 43 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 43 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 43 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 43 also states legal conclusions to which no response is required.

44. Paragraph 44 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent

Paragraph 44 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 44 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 44 also states legal conclusions to which no response is required.

45. Paragraph 45 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 45 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 45 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 45 also states legal conclusions to which no response is required.

46. Paragraph 46 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 46 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 46 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Additionally, Paragraph 46 refers to the Complaint, a legal document, which speaks for itself and to which no response is required. Paragraph 46 also states legal conclusions to which no response is required.

47. Paragraph 47 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 47 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 47 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 47 also states legal conclusions to which no response is required.

48. Paragraph 48 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 48 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 48 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 48 refers to the Complaint, a legal document, which speaks for itself and to which no response is required.

49. Paragraph 49 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 49 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, Medicare regulations, Medicare guidance documents, and the FCA speak for themselves, and to the extent that the allegations in Paragraph 49 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 49 also states legal conclusions to which no response is required.

50. To the extent Paragraph 50 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 50 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 50 also states legal conclusions to which no response is required.

51. To the extent Paragraph 51 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 51 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 51 also states legal conclusions to which no response is required.

1 52. Paragraph 52 contains no allegations with respect to a particular
2 Defendant or claim, and therefore no response is required. However, to the extent
3 Paragraph 52 purports to summarize and/or describe the provisions of the Medicare
4 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
5 extent that the allegations in Paragraph 52 vary therefrom or with other applicable
6 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 52
7 also states legal conclusions to which no response is required.

8 53. Paragraph 53 contains no allegations with respect to a particular
9 Defendant or claim, and therefore no response is required. However, to the extent
10 Paragraph 53 purports to summarize and/or describe the provisions of the Medicare
11 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
12 extent that the allegations in Paragraph 53 vary therefrom or with other applicable
13 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 53
14 also states legal conclusions to which no response is required.

15 **II. Medicare Parts C and D Risk Adjustment Payments**

16 54. Paragraph 54 contains no allegations with respect to a particular
17 Defendant or claim, and therefore no response is required. However, to the extent
18 Paragraph 54 purports to summarize and/or describe the provisions of the Medicare
19 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
20 extent that the allegations in Paragraph 54 vary therefrom or with other applicable
21 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 54
22 also states legal conclusions to which no response is required.

23 55. Paragraph 55 contains no allegations with respect to a particular
24 Defendant or claim, and therefore no response is required. However, to the extent
25 Paragraph 55 purports to summarize and/or describe the provisions of the Medicare
26 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
27 extent that the allegations in Paragraph 55 vary therefrom or with other applicable
28

1 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 55
2 also states legal conclusions to which no response is required.

3 56. Paragraph 56 contains no allegations with respect to a particular
4 Defendant or claim, and therefore no response is required. However, to the extent
5 Paragraph 56 purports to summarize and/or describe the provisions of the Medicare
6 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
7 extent that the allegations in Paragraph 56 vary therefrom or with other applicable
8 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 56
9 also states legal conclusions to which no response is required.

10 57. Paragraph 57 contains no allegations with respect to a particular
11 Defendant or claim, and therefore no response is required. However, to the extent
12 Paragraph 57 purports to summarize and/or describe the provisions of the Medicare
13 program, UnitedHealth states that the Medicare statute, Medicare regulations, and
14 Medicare guidance documents speak for themselves, and to the extent that the
15 allegations in Paragraph 57 vary therefrom or with other applicable statutory or
16 decisional law, UnitedHealth denies those allegations. Paragraph 57 also states
17 legal conclusions to which no response is required.

18 58. Paragraph 58 contains no allegations with respect to a particular
19 Defendant or claim, and therefore no response is required. However, to the extent
20 Paragraph 58 purports to summarize and/or describe the provisions of the Medicare
21 program, UnitedHealth states that the Medicare statute and regulations speak for
22 themselves, and to the extent that the allegations in Paragraph 58 vary therefrom or
23 with other applicable statutory or decisional law, UnitedHealth denies those
24 allegations.

25 59. Paragraph 59 contains no allegations with respect to a particular
26 Defendant or claim, and therefore no response is required. However, to the extent
27 Paragraph 59 purports to summarize and/or describe the provisions of the Medicare
28 program, UnitedHealth states that the Medicare statute speaks for itself, and to the

1 extent that the allegations in Paragraph 59 vary therefrom or with other applicable
2 statutory or decisional law, UnitedHealth denies those allegations.

3 60. Paragraph 60 contains no allegations with respect to a particular
4 Defendant or claim, and therefore no response is required. However, to the extent
5 Paragraph 60 purports to summarize and/or describe the provisions of the Medicare
6 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
7 extent that the allegations in Paragraph 60 vary therefrom or with other applicable
8 statutory or decisional law, UnitedHealth denies those allegations.

9 61. Paragraph 61 contains no allegations with respect to a particular
10 Defendant or claim, and therefore no response is required. However, to the extent
11 Paragraph 61 purports to summarize and/or describe the provisions of the Medicare
12 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
13 extent that the allegations in Paragraph 61 vary therefrom or with other applicable
14 statutory or decisional law, UnitedHealth denies those allegations.

15 62. Paragraph 62 contains no allegations with respect to a particular
16 Defendant or claim, and therefore no response is required. However, to the extent
17 Paragraph 62 purports to summarize and/or describe the provisions of the Medicare
18 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
19 extent that the allegations in Paragraph 62 vary therefrom or with other applicable
20 statutory or decisional law, UnitedHealth denies those allegations.

21 63. Paragraph 63 contains no allegations with respect to a particular
22 Defendant or claim, and therefore no response is required. However, to the extent
23 Paragraph 63 purports to summarize and/or describe the provisions of the Medicare
24 program, UnitedHealth states that the Medicare statute speaks for itself, and to the
25 extent that the allegations in Paragraph 63 vary therefrom or with other applicable
26 statutory or decisional law, UnitedHealth denies those allegations. The final
27 sentence of Paragraph 63 describes the Complaint, a legal document, which speaks
28 for itself and to which no response is required.

64. Paragraph 64 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 64 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 64 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 64 also states legal conclusions to which no response is required.

65. Paragraph 65 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 65 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 65 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

DEFENDANTS' AGREEMENTS

I. The Annual Parts C and D Agreements

66. Paragraph 66 states legal conclusions to which no response is required. To the extent Paragraph 66 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 66 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth admits that certain entities named as Defendants in this action entered into one or more agreements with the Government since 2005 to offer MA and/or PD Plans to Medicare beneficiaries under Parts C and D of the Medicare Program.

67. To the extent Paragraph 67 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute speaks for itself, and to the extent that the allegations in Paragraph 67 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies

1 those allegations. Paragraph 67 also states legal conclusions to which no response
2 is required.

3 68. To the extent the allegations in Paragraph 68 relate to claims that have
4 been dismissed, they are surplusage and should be stricken. To the extent
5 Paragraph 68 purports to describe a document or documents, such documents
6 speak for themselves and, as such, no response is required. UnitedHealth denies
7 the remaining allegations in Paragraph 68. Paragraph 68 also states legal
8 conclusions to which no response is required.

9 69. To the extent Paragraph 69 purports to describe a document or
10 documents, such documents speak for themselves and, as such, no response is
11 required. UnitedHealth denies the remaining allegations in Paragraph 69.

12 70. To the extent Paragraph 70 purports to describe a document or
13 documents, such documents speak for themselves and, as such, no response is
14 required. UnitedHealth denies the remaining allegations in Paragraph 70.

15 71. To the extent the allegations in Paragraph 71 relate to claims that have
16 been dismissed, they are surplusage and should be stricken. To the extent
17 Paragraph 71 purports to describe a document or documents, such documents
18 speak for themselves and, as such, no response is required. UnitedHealth denies
19 the remaining allegations in Paragraph 71.

20 72. Paragraph 72 contains no allegations with respect to a particular
21 Defendant or claim, and therefore no response is required. To the extent Paragraph
22 72 purports to describe a document or documents, such documents speak for
23 themselves and, as such, no response is required. UnitedHealth denies the
24 remaining allegations in Paragraph 72.

25 **II. The Electronic Data Interchange Agreements**

26 73. To the extent Paragraph 73 purports to summarize and/or describe the
27 provisions of the Medicare program, UnitedHealth states that the Medicare statute
28 and regulations speak for themselves, and to the extent that the allegations in

Paragraph 73 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. To the extent Paragraph 73 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 73 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 73.

74. To the extent Paragraph 74 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 74.

75. To the extent Paragraph 75 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 75 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 75.

76. To the extent Paragraph 76 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 76 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 76.

77. To the extent Paragraph 77 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 77 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 77.

78. To the extent Paragraph 78 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 78 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 78.

79. To the extent Paragraph 79 purports to describe a document or documents, such documents speak for themselves and, as such, no response is

1 required. Paragraph 79 also states legal conclusions to which no response is
2 required. UnitedHealth denies the remaining allegations in Paragraph 79.

3 80. To the extent Paragraph 80 purports to describe a document or
4 documents, such documents speak for themselves and, as such, no response is
5 required. Paragraph 80 also states legal conclusions to which no response is
6 required. UnitedHealth denies the remaining allegations in Paragraph 80.

7 81. To the extent Paragraph 81 purports to describe a document or
8 documents, such documents speak for themselves and, as such, no response is
9 required. Paragraph 81 also states legal conclusions to which no response is
10 required. UnitedHealth denies the remaining allegations in Paragraph 81.

11 82. Paragraph 82 contains no allegations with respect to a particular
12 Defendant or claim, and therefore no response is required. To the extent Paragraph
13 82 purports to describe a document or documents, such documents speak for
14 themselves and, as such, no response is required. UnitedHealth denies the
15 remaining allegations in Paragraph 82.

16 **III. The Ingenix/Optum Service Agreements**

17 83. To the extent Paragraph 83 purports to describe a document or
18 documents, such documents speak for themselves and, as such, no response is
19 required. UnitedHealth denies the remaining allegations in Paragraph 83.

20 84. To the extent Paragraph 84 purports to describe a document or
21 documents, such documents speak for themselves and, as such, no response is
22 required. UnitedHealth denies the remaining allegations in Paragraph 84.

23 85. To the extent Paragraph 85 purports to describe a document or
24 documents, such documents speak for themselves and, as such, no response is
25 required. UnitedHealth denies the remaining allegations in Paragraph 85.

26 86. To the extent Paragraph 86 purports to describe a document or
27 documents, such documents speak for themselves and, as such, no response is
28 required. UnitedHealth denies the remaining allegations in Paragraph 86.

DEFENDANTS' DATA INTEGRITY OBLIGATIONS

I. Obligation to Submit Valid Diagnoses

87. Paragraph 87 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 87 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance, including the Medicare Managed Care Manual and the 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide ("2008 RA Participant Guide"), speak for themselves, and to the extent that the allegations in Paragraph 87 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 87. Paragraph 87 also states legal conclusions to which no response is required.

88. Paragraph 88 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 88 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 88 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 88. Paragraph 88 also states legal conclusions to which no response is required.

89. Paragraph 89 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 89 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 89 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies

1 those allegations. UnitedHealth denies the remaining allegations in Paragraph 89.
2 Paragraph 89 also states legal conclusions to which no response is required.

3 90. Paragraph 90 contains no allegations with respect to a particular
4 Defendant or claim, and therefore no response is required. However, to the extent
5 Paragraph 90 purports to summarize and/or describe the provisions of the Medicare
6 program, UnitedHealth states that the Medicare statute, regulations, and guidance
7 speak for themselves, and to the extent that the allegations in Paragraph 90 vary
8 therefrom or with other applicable statutory or decisional law, UnitedHealth denies
9 those allegations. UnitedHealth denies the remaining allegations in Paragraph 90.
10 Paragraph 90 also states legal conclusions to which no response is required.

11 91. Paragraph 91 contains no allegations with respect to a particular
12 Defendant or claim, and therefore no response is required. However, to the extent
13 Paragraph 91 purports to summarize and/or describe the provisions of the Medicare
14 program, UnitedHealth states that the Medicare statute, regulations, and guidance
15 speak for themselves, and to the extent that the allegations in Paragraph 91 vary
16 therefrom or with other applicable statutory or decisional law, UnitedHealth denies
17 those allegations. UnitedHealth denies the remaining allegations in Paragraph 91.

18 92. Paragraph 92 contains no allegations with respect to a particular
19 Defendant or claim, and therefore no response is required. However, to the extent
20 Paragraph 92 purports to summarize and/or describe a document or documents,
21 such documents speak for themselves and, as such, no response is required.
22 UnitedHealth denies the remaining allegations in Paragraph 92.

23 93. Paragraph 93 contains no allegations with respect to a particular
24 Defendant or claim, and therefore no response is required. However, to the extent
25 Paragraph 93 purports to summarize and/or describe the provisions of the Medicare
26 program, UnitedHealth states that the Medicare statute, regulations, and guidance
27 speak for themselves, and to the extent that the allegations in Paragraph 93 vary
28

therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 93.

94. Paragraph 94 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 94 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 94 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 94.

II. Obligation to Implement an Effective Compliance Program

95. Paragraph 95 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 95 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 95 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 95.

96. Paragraph 96 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 96 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 96 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 96.

97. Paragraph 97 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 97 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance

1 speak for themselves, and to the extent that the allegations in Paragraph 97 vary
2 therefrom or with other applicable statutory or decisional law, UnitedHealth denies
3 those allegations. UnitedHealth denies the remaining allegations in Paragraph 97.

4 **III. Obligation to Attest to Validity of Risk Adjustment Data**

5 98. To the extent the allegations in Paragraph 98 relate to claims that have
6 been dismissed, they are surplusage and should be stricken. Paragraph 98 contains
7 no allegations with respect to a particular Defendant or claim, and therefore no
8 response is required. However, to the extent Paragraph 98 purports to summarize
9 and/or describe the provisions of the Medicare program, UnitedHealth states that
10 the Medicare statute, regulations, and guidance speak for themselves, and to the
11 extent that the allegations in Paragraph 98 vary therefrom or with other applicable
12 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 98
13 also states legal conclusions to which no response is required.

14 99. To the extent the allegations in Paragraph 99 relate to claims that have
15 been dismissed, they are surplusage and should be stricken. Paragraph 99 contains
16 no allegations with respect to a particular Defendant or claim, and therefore no
17 response is required. However, to the extent Paragraph 99 purports to summarize
18 and/or describe the provisions of the Medicare program, UnitedHealth states that
19 the Medicare statute, regulations, and guidance speak for themselves, and to the
20 extent that the allegations in Paragraph 99 vary therefrom or with other applicable
21 statutory or decisional law, UnitedHealth denies those allegations. Paragraph 99
22 also states legal conclusions to which no response is required. UnitedHealth denies
23 the remaining allegations in Paragraph 99.

24 100. To the extent the allegations in Paragraph 100 relate to claims that
25 have been dismissed, they are surplusage and should be stricken. Paragraph 100
26 contains no allegations with respect to a particular Defendant or claim, and
27 therefore no response is required. However, to the extent Paragraph 100 purports
28 to summarize and/or describe the provisions of the Medicare program,

UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 100 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 100 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 100.

101. To the extent the allegations in Paragraph 101 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 101 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 101 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 101 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 101 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 101.

102. To the extent the allegations in Paragraph 102 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 102 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 102 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 102 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 102 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 102.

IV. Obligation to Delete Invalid Diagnoses

103. Paragraph 103 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent

Paragraph 103 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 103 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 103 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 103.

104. Paragraph 104 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 104 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 104 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 104 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 104.

105. To the extent the allegations in Paragraph 105 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 105 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 105 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 105 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 105 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 105.

106. Paragraph 106 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent

Paragraph 106 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 106 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 106 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 106.

107. Paragraph 107 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 107 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute, regulations, and guidance speak for themselves, and to the extent that the allegations in Paragraph 107 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. Paragraph 107 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 107.

108. Paragraph 108 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 108 purports to summarize and/or describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 108 also states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 108.

109. Paragraph 109 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 109 purports to summarize and/or describe a document or documents or data archive, such documents and data archive speak for themselves and, as such, no response is required. Paragraph 109 also states legal conclusions to which no

1 response is required. UnitedHealth denies the remaining allegations in Paragraph
2 109.

3 110. Paragraph 110 contains no allegations with respect to a particular
4 Defendant or claim, and therefore no response is required. However, to the extent
5 Paragraph 110 purports to summarize and/or describe the provisions of the
6 Medicare program, UnitedHealth states that the Medicare statute, regulations, and
7 guidance speak for themselves, and to the extent that the allegations in Paragraph
8 110 vary therefrom or with other applicable statutory or decisional law,
9 UnitedHealth denies those allegations. Paragraph 110 also states legal conclusions
10 to which no response is required. UnitedHealth denies the remaining allegations in
11 Paragraph 110.

12 111. Paragraph 111 contains no allegations with respect to a particular
13 Defendant or claim, and therefore no response is required. However, to the extent
14 Paragraph 111 purports to summarize and/or describe the provisions of the
15 Medicare program, UnitedHealth states that the Medicare statute, regulations, and
16 guidance speak for themselves, and to the extent that the allegations in Paragraph
17 111 vary therefrom or with other applicable statutory or decisional law,
18 UnitedHealth denies those allegations. UnitedHealth denies the remaining
19 allegations in Paragraph 111.

20 112. Paragraph 112 contains no allegations with respect to a particular
21 Defendant or claim, and therefore no response is required. However, to the extent
22 Paragraph 112 purports to summarize and/or describe the provisions of the
23 Medicare program, UnitedHealth states that the Medicare statute, regulations, and
24 guidance speak for themselves, and to the extent that the allegations in Paragraph
25 112 vary therefrom or with other applicable statutory or decisional law,
26 UnitedHealth denies those allegations. UnitedHealth denies the remaining
27 allegations in Paragraph 112.
28

1 113. UnitedHealth admits that Rebecca Martin knew how to make deletes
2 in RAPS. UnitedHealth admits that certain other employees knew the difference
3 between “open-period” and “closed-period” deletes. UnitedHealth denies the
4 remaining allegations in Paragraph 113.

5 114. Paragraph 114 states legal conclusions to which no response is
6 required. To the extent that Paragraph 114 contains any factual allegations
7 regarding UnitedHealth, such allegations are denied. UnitedHealth denies the
8 remaining allegations in Paragraph 114.

9 **THE FALSE CLAIMS ACT**

10 115. To the extent the allegations in Paragraph 115 relate to claims that
11 have been dismissed, they are surplusage and should be stricken. Paragraph 115
12 contains no allegations with respect to a particular Defendant or claim, and
13 therefore no response is required. However, to the extent Paragraph 115 purports
14 to summarize and/or describe the provisions of the FCA, UnitedHealth states that
15 the FCA speaks for itself, and to the extent that the allegations in Paragraph 115
16 vary therefrom or with other applicable statutory or decisional law, UnitedHealth
17 denies those allegations. UnitedHealth denies the remaining allegations in
18 Paragraph 115. Paragraph 115 also states legal conclusions to which no response
19 is required.

20 116. To the extent the allegations in Paragraph 116 relate to claims that
21 have been dismissed, they are surplusage and should be stricken. Paragraph 116
22 contains no allegations with respect to a particular Defendant or claim, and
23 therefore no response is required. However, to the extent Paragraph 116 purports
24 to summarize and/or describe the provisions of the FCA or the Fraud Enforcement
25 and Recovery Act of 2009 (“FERA”), UnitedHealth states that the FCA and FERA
26 speak for themselves, and to the extent that the allegations in Paragraph 116 vary
27 therefrom or with other applicable statutory or decisional law, UnitedHealth denies
28 those allegations. UnitedHealth denies the remaining allegations in Paragraph 116.

1 117. To the extent the allegations in Paragraph 117 relate to claims that
2 have been dismissed, they are surplusage and should be stricken. Paragraph 117
3 contains no allegations with respect to a particular Defendant or claim, and
4 therefore no response is required. However, to the extent Paragraph 117 purports
5 to summarize and/or describe the provisions of the FCA or FERA, UnitedHealth
6 states that the FCA and FERA speak for themselves, and to the extent that the
7 allegations in Paragraph 117 vary therefrom or with other applicable statutory or
8 decisional law, UnitedHealth denies those allegations. UnitedHealth denies the
9 remaining allegations in Paragraph 117.

10 118. Paragraph 118 contains no allegations with respect to a particular
11 Defendant or claim, and therefore no response is required. However, to the extent
12 Paragraph 118 purports to summarize and/or describe the provisions of the FCA or
13 FERA, UnitedHealth states that the FCA and FERA speak for themselves, and to
14 the extent that the allegations in Paragraph 118 vary therefrom or with other
15 applicable statutory or decisional law, UnitedHealth denies those allegations.
16 Paragraph 118 also states legal conclusions to which no response is required.
17 UnitedHealth denies the remaining allegations in Paragraph 118.

18 119. Paragraph 119 contains no allegations with respect to a particular
19 Defendant or claim, and therefore no response is required. However, to the extent
20 Paragraph 119 purports to summarize and/or describe the provisions of the FCA or
21 FERA, UnitedHealth states that the FCA and FERA speak for themselves, and to
22 the extent that the allegations in Paragraph 119 vary therefrom or with other
23 applicable statutory or decisional law, UnitedHealth denies those allegations.
24 UnitedHealth denies the remaining allegations in Paragraph 119.

25 120. Paragraph 120 contains no allegations with respect to a particular
26 Defendant or claim, and therefore no response is required. However, to the extent
27 Paragraph 120 purports to describe the provisions of the FCA, UnitedHealth states
28 that the FCA speaks for itself, and to the extent that the allegations in Paragraph

120 vary therefrom or with other applicable statutory or decisional law, such as *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 120.

121. Paragraph 121 contains no allegations with respect to a particular Defendant or claim, and therefore no response is required. However, to the extent Paragraph 121 purports to summarize and/or describe the provisions of the FCA and the Bipartisan Budget Act of 2015, Public Law 114-74 (No. 2, 2015) (“BBA”), UnitedHealth states that the FCA and BBA speak for themselves, and to the extent that the allegations in Paragraph 121 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 121.

THE FACTS

122. UnitedHealth admits that since at least 2005, certain Defendants conducted a Chart Review program in which millions of medical records were reviewed. To the extent Paragraph 122 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 122.

I. Defendants Knew That Many Provider-Reported Diagnoses Were Invalid And That They Were Obligated To Undertake Good Faith Efforts To Identify And Delete Them¹

123. UnitedHealth admits that in connection with its acquisition of PacifiCare in 2005, UnitedHealth retained some PacifiCare employees who had experience performing work relating to risk adjustment. UnitedHealth denies the remaining allegations in Paragraph 123.

¹ The headings and sub-headings throughout the Amended Complaint do not constitute well-pleaded allegations of fact and therefore require no response.

1 124. UnitedHealth admits that Jeffrey Dumcum, Stephanie Will, Pam Holt,
2 and Pam Leal were former employees of PacifiCare who worked in risk
3 adjustment. UnitedHealth admits that Dumcum joined UnitedHealth as Director of
4 Finance at UnitedHealthcare; that Will joined UnitedHealth as Manager of
5 Finance; that Holt joined UnitedHealth as Manager of Network Operations at
6 UnitedHealthcare; and that Leal joined UnitedHealth as Director of Network
7 Management at UnitedHealthcare. UnitedHealth is without knowledge or
8 information sufficient to form a belief as to the truth or falsity of the remaining
9 allegations in Paragraph 124 regarding Holt and Leal's positions at PacifiCare
10 before they joined UnitedHealth; therefore, such allegations are denied.

11 UnitedHealth denies the remaining allegations in Paragraph 124.

12 125. UnitedHealth admits that from 2005 to 2007, Dumcum and Gardner
13 worked at the PacifiCare office in Santa Ana, California, and Holt and Leal worked
14 at the PacifiCare office in Cypress, California. UnitedHealth admits that in March
15 2007, Holt and Leal transferred to an office in Santa Ana, California.

16 UnitedHealth denies the remaining allegations in Paragraph 125.

17 126. To the extent Paragraph 126 purports to describe a document or
18 documents, such documents speak for themselves and, as such, no response is
19 required. UnitedHealth is without knowledge or information sufficient to form a
20 belief as to the truth or falsity of the remaining allegations in Paragraph 126;
21 therefore, such allegations are denied. UnitedHealth denies the remaining
22 allegations in Paragraph 126.

23 127. UnitedHealth admits that the Industry Collaboration Effort ("ICE")
24 was a volunteer, multi-disciplinary team of providers, health plans, associations,
25 state and federal agencies, and accrediting bodies working collaboratively to
26 improve healthcare regulatory compliance through education of the public.
27 UnitedHealth admits that ICE had a Risk Adjustment Data Acquisition &
28 Reporting ("RADAR") team. UnitedHealth further admits that after UnitedHealth

1 acquired PacifiCare, some former PacifiCare employees participated in ICE and its
2 RADAR team. UnitedHealth admits that Leal was the President and a member of
3 the Board of Directors of ICE around or before 2007. To the extent Paragraph 127
4 purports to describe a document or documents, such documents speak for
5 themselves and, as such, no response is required. UnitedHealth denies the
6 remaining allegations in Paragraph 127.

7 128. To the extent Paragraph 128 purports to describe a document or
8 documents, such documents speak for themselves and, as such, no response is
9 required. UnitedHealth denies the remaining allegations in Paragraph 128.

10 129. To the extent Paragraph 129 describes these documents, such
11 documents speak for themselves and, as such, no response is required.
12 UnitedHealth is without knowledge or information sufficient to form a belief as to
13 the truth or falsity of the remaining allegations in Paragraph 129; therefore, such
14 allegations are denied. UnitedHealth denies the remaining allegations in Paragraph
15 129.

16 130. To the extent Paragraph 130 purports to describe a document or
17 documents, such documents speak for themselves and, as such, no response is
18 required. UnitedHealth is without knowledge or information sufficient to form a
19 belief as to the truth or falsity of the remaining allegations in Paragraph 130;
20 therefore, such allegations are denied. UnitedHealth denies the remaining
21 allegations in Paragraph 130.

22 131. To the extent Paragraph 131 purports to describe a document or
23 documents, such documents speak for themselves and, as such, no response is
24 required. UnitedHealth is without knowledge or information sufficient to form a
25 belief as to the truth or falsity of the remaining allegations in Paragraph 131;
26 therefore, such allegations are denied.

27 132. UnitedHealth admits that the former PacifiCare employees were
28 aware that CMS could audit the diagnoses MA Organizations submitted for risk

1 adjustment payments. UnitedHealth denies the remaining allegations in Paragraph
2 132.

3 133. To the extent Paragraph 133 purports to describe a document or
4 documents, such documents speak for themselves and, as such, no response is
5 required. UnitedHealth is without knowledge or information sufficient to form a
6 belief as to the truth or falsity of the remaining allegations in Paragraph 133;
7 therefore, such allegations are denied. UnitedHealth denies the remaining
8 allegations in Paragraph 133.

9 134. To the extent Paragraph 134 purports to describe a document or
10 documents, such documents speak for themselves and, as such, no response is
11 required. UnitedHealth denies the remaining allegations in Paragraph 134.

12 135. UnitedHealth admits that after UnitedHealth's acquisition of
13 PacifiCare, Jeff Dumcum gave presentations to various UnitedHealth employees
14 regarding provider coding. To the extent Paragraph 135 purports to describe
15 documents, the documents speak for themselves and, as such, no response is
16 required. UnitedHealth is without knowledge or information sufficient to form a
17 belief as to the truth or falsity of the remaining allegations in Paragraph 135;
18 therefore, such allegations are denied. UnitedHealth denies the remaining
19 allegations in Paragraph 135.

20 136. To the extent Paragraph 136 purports to describe a document or
21 documents, such documents speak for themselves and, as such, no response is
22 required. UnitedHealth denies the remaining allegations in Paragraph 136.

23 137. UnitedHealth admits that in or about 2007, certain risk adjustment
24 operations moved to Ingenix. Additionally, UnitedHealth admits that Ingenix
25 served commercial clients. To the extent Paragraph 137 purports to describe a
26 document or documents, such documents speak for themselves and, as such, no
27 response is required. UnitedHealth denies the remaining allegations in Paragraph
28 137.

1 138. To the extent Paragraph 138 purports to describe a document or
2 documents, such documents speak for themselves and, as such, no response is
3 required. UnitedHealth is without knowledge or information sufficient to form a
4 belief as to the truth or falsity of the allegations in Paragraph 138; therefore, such
5 allegations are denied. UnitedHealth denies the remaining allegations in Paragraph
6 138.

7 139. UnitedHealth admits that it implemented an internal data validation
8 program on or about 2007 or 2008. To the extent Paragraph 139 purports to
9 describe a document or documents, the documents speak for themselves and, as
10 such, no response is required. UnitedHealth denies the remaining allegations in
11 Paragraph 139.

12 140. To the extent Paragraph 140 purports to describe a document or
13 documents, such documents speak for themselves and, as such, no response is
14 required. UnitedHealth is without knowledge or information sufficient to form a
15 belief as to the truth or falsity of the allegations in Paragraph 140; therefore, such
16 allegations are denied. UnitedHealth denies the remaining allegations in Paragraph
17 140.

18 141. UnitedHealth admits that CMS performed RADV audits.
19 UnitedHealth admits that Ingenix and then Optum performed IDV and RACCR to
20 review provider-reported diagnoses. To the extent Paragraph 141 purports to
21 describe a document or documents, such documents speak for themselves and, as
22 such, no response is required. UnitedHealth denies the remaining allegations in
23 Paragraph 141.

24 142. To the extent Paragraph 142 purports to describe a document or
25 documents, such documents speak for themselves and, as such, no response is
26 required. UnitedHealth denies the remaining allegations in Paragraph 142.

27 143. UnitedHealth admits that Ingenix implemented an internal data
28 validation program in or around 2007 or 2008. To the extent Paragraph 143

purports to describe a document or documents, the documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 143.

144. To the extent Paragraph 144 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 144.

145. To the extent Paragraph 145 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 145.

146. To the extent Paragraph 146 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 146.

147. UnitedHealth admits that Larry Renfro was the Chief Executive Officer of PSMG in or around May 2010. To the extent Paragraph 147 contains legal conclusions, no response is required. To the extent Paragraph 147 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Additionally, to the extent Paragraph 147 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 147 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 147.

148. UnitedHealth admits that Kimberly Halva was UnitedHealth Medicare & Retirement's Finance Compliance Officer from 2010 to 2013. UnitedHealth admits that Scott Theisen was the Chief Financial Officer of UnitedHealthcare Medicare & Retirement from in or around 2010 to 2013. To the extent Paragraph 148 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 148

contains legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 148.

149. To the extent Paragraph 149 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 149.

150. To the extent the allegations in Paragraph 150 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 150 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth admits that, since in or around 2008, certain provider groups submitted attestations to some of the UnitedHealth Defendants certifying that the diagnoses that they reported to some of the UnitedHealth Defendants were valid and met CMS's requirements. UnitedHealth denies the remaining allegations in Paragraph 150.

151. To the extent Paragraph 151 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 151.

152. To the extent Paragraph 152 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent a response is required, UnitedHealth denies the allegations in Paragraph 152.

153. To the extent Paragraph 153 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 153.

154. To the extent Paragraph 154 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 154.

1 155. To the extent Paragraph 155 purports to describe a document or
2 documents, such documents speak for themselves and, as such, no response is
3 required. UnitedHealth denies the remaining allegations in Paragraph 155.

4 156. To the extent Paragraph 156 purports to describe a document or
5 documents, such documents speak for themselves and, as such, no response is
6 required. UnitedHealth denies the remaining allegations in Paragraph 156.

7 157. UnitedHealth admits that UnitedHealthcare Medicare & Retirement
8 implemented the program eventually known as the RACCR program in or about
9 2009. To the extent Paragraph 157 purports to describe a document or documents,
10 such documents speak for themselves and, as such, no response is required. To the
11 extent Paragraph 157 states a legal conclusion, no response is required.
12 UnitedHealth denies the remaining allegations in Paragraph 157.

13 158. UnitedHealth admits that its Claims Verification (“CV”) program was
14 implemented in phases, that Phase I of the CV Program was performed in or
15 around 2010, and that Phase II of the CV Program was performed in or around late
16 2011 or early 2012. To the extent Paragraph 158 purports to describe a document
17 or documents, such documents speak for themselves and, as such, no response is
18 required. UnitedHealth denies the remaining allegations in Paragraph 158.

19 159. To the extent Paragraph 159 purports to describe a document or
20 documents, such documents speak for themselves and, as such, no response is
21 required. UnitedHealth denies the remaining allegations in Paragraph 159.

22 160. To the extent Paragraph 160 purports to describe a document or
23 documents, such documents speak for themselves and, as such, no response is
24 required. UnitedHealth denies the remaining allegations in Paragraph 160.

25 161. To the extent that Paragraph 161 contains legal conclusions, no
26 response is required. To the extent Paragraph 161 purports to describe a document
27 or documents, such documents speak for themselves and, as such, no response is
28 required. UnitedHealth denies the remaining allegations in Paragraph 161.

1 162. To the extent Paragraph 162 purports to describe a document or
2 documents, such documents speak for themselves and, as such, no response is
3 required. UnitedHealth denies the remaining allegations in Paragraph 162.

4 163. To the extent that Paragraph 163 contains legal conclusions, no
5 response is required. To the extent Paragraph 163 purports to describe a document
6 or documents, such documents speak for themselves and, as such, no response is
7 required. UnitedHealth denies the remaining allegations in Paragraph 163.

8 **II. Chart Reviews and Claims Verification**

9 **A. United's "Look One Way" Chart Review Program**

10 164. UnitedHealth admits that as part of its Chart Review Program, coders
11 reviewed beneficiaries' medical records. To the extent Paragraph 164 purports to
12 describe a document or documents, such documents speak for themselves and, as
13 such, no response is required. UnitedHealth denies the remaining allegations in
14 Paragraph 164.

15 165. UnitedHealth admits that some of the UnitedHealth Defendants have
16 performed some form of Chart Review since 2005. UnitedHealth admits that
17 Dumcum and Will became key participants in the Chart Review Program and that
18 Will was the Program Manager of the Chart Review Program. UnitedHealth is
19 without knowledge or information as to the identity of the "other former
20 PacificCare employees sufficient to form a belief as to the truth or falsity of the
21 remaining allegations in Paragraph 165; therefore, such allegations are denied.
22 UnitedHealth denies the remaining allegations in Paragraph 165.

23 166. UnitedHealth admits that hundreds of thousands of charts were
24 reviewed over the first few years of the Chart Review Program. To the extent
25 Paragraph 166 purports to describe a document or documents, such documents
26 speak for themselves and, as such, no response is required. UnitedHealth denies
27 the remaining allegations in Paragraph 166.

28

1 167. UnitedHealth admits that UnitedHealth Group Incorporated acquired
2 AIM Healthcare Services, Inc. in or around 2009. UnitedHealth admits that in or
3 about 2010, Ingenix developed ChartSync—an in-house chart review computer
4 database system that allowed coders to review medical records electronically—and
5 that in or about 2012 and 2011, Ingenix opened offices in the Philippines and
6 India, respectively, where coders could review codes. UnitedHealth denies the
7 remaining allegations in Paragraph 167.

8 168. To the extent Paragraph 168 purports to describe a document or
9 documents, such documents speak for themselves and, as such, no response is
10 required. UnitedHealth denies the remaining allegations in Paragraph 168.

11 169. To the extent Paragraph 169 purports to describe a document or
12 documents, such documents speak for themselves and, as such, no response is
13 required. UnitedHealth denies the remaining allegations in Paragraph 169.

14 170. UnitedHealth admits that Ingenix and then Optum or their vendors
15 obtained medical records from fee-for-service providers in numerous places in the
16 United States. UnitedHealth admits that Ingenix and then Optum or their vendors
17 sent some of these medical records to coders employed in Tennessee, India, and
18 the Philippines. UnitedHealth admits that Ingenix and then Optum hired coding
19 vendors located in various locations within and outside of the United States to
20 review medical records. UnitedHealth denies the remaining allegations in
21 Paragraph 170.

22 171. UnitedHealth admits chart review was conducted by or on behalf of
23 certain physician groups, including WellMed and Southwest Medical Associates.
24 UnitedHealth denies the remaining allegations in Paragraph 171.

25 172. To the extent Paragraph 172 purports to describe a document or
26 documents, such documents speak for themselves and, as such, no response is
27 required. UnitedHealth denies the remaining allegations in Paragraph 172.
28

1 173. To the extent Paragraph 173 purports to describe a document or
2 documents, such documents speak for themselves and, as such, no response is
3 required. UnitedHealth denies the remaining allegations in Paragraph 173.

4 174. To the extent Paragraph 174 purports to describe a document or
5 documents, such documents speak for themselves and, as such, no response is
6 required. UnitedHealth denies the remaining allegations in Paragraph 174.

7 175. UnitedHealth admits that its Chart Review Program was conducted
8 according to an annual cycle. To the extent Paragraph 175 purports to describe a
9 document or documents, such documents speak for themselves and, as such, no
10 response is required. UnitedHealth denies the remaining allegations in Paragraph
11 175.

12 176. UnitedHealth admits that some of the UnitedHealth Defendants had
13 revenue estimates for the Chart Review Program. UnitedHealth admits that some
14 of the UnitedHealth Defendants identified more codes supported by records
15 through subsequent reviews. To the extent Paragraph 176 purports to describe a
16 document or documents, such documents speak for themselves and, as such, no
17 response is required. UnitedHealth denies the remaining allegations in Paragraph
18 176.

19 177. To the extent the allegations in Paragraph 177 relate to claims that
20 have been dismissed, they are surplusage and should be stricken. To the extent
21 Paragraph 177 states legal conclusions, no response is required. UnitedHealth
22 denies the remaining allegations in Paragraph 177.

23 **B. United Knew It Was Obligated To Look Both Ways At The**
24 **Results Of Its Chart Reviews And Make DELETES As Well As**
25 **ADDS**

26 178. To the extent Paragraph 178 purports to describe a document, the
27 document speaks for itself and, as such, no response is required. UnitedHealth is
28 without knowledge or information sufficient to form a belief as to the truth or

1 falsity of Poehling's discussions and the allegations in Paragraph 178.

2 UnitedHealth denies the remaining allegations in Paragraph 178.

3 179. UnitedHealth denies that there were problems related to the diagnoses
4 reported by providers paid on a fee-for-service basis. To the extent Paragraph 179
5 purports to describe a document, the document speaks for itself and, as such, no
6 response is required. UnitedHealth is without knowledge or information sufficient
7 to form a belief as to the truth or falsity of the remaining allegations in Paragraph
8 179; therefore, such allegations are denied. UnitedHealth denies the remaining
9 allegations in Paragraph 179.

10 180. To the extent Paragraph 180 purports to describe a document or
11 documents, such documents speak for themselves and, as such, no response is
12 required. UnitedHealth is without knowledge or information sufficient to form a
13 belief as to the truth or falsity of the allegations in Paragraph 180; therefore, such
14 allegations are denied.

15 181. To the extent Paragraph 181 purports to describe a document or
16 documents, such documents speak for themselves and, as such, no response is
17 required. UnitedHealth is without knowledge or information sufficient to form a
18 belief as to the truth or falsity of the allegations in Paragraph 181; therefore, such
19 allegations are denied. UnitedHealth denies the remaining allegations in Paragraph
20 181.

21 182. To the extent Paragraph 182 purports to describe a document or
22 documents, such documents speak for themselves and, as such, no response is
23 required. UnitedHealth denies the remaining allegations in Paragraph 182.

24 183. To the extent Paragraph 183 purports to describe a document or
25 documents, such documents speak for themselves and, as such, no response is
26 required. UnitedHealth denies the remaining allegations in Paragraph 183.

27

28

1 184. To the extent Paragraph 184 purports to describe a document, the
2 document speaks for itself and, as such, no response is required. UnitedHealth
3 denies the remaining allegations in Paragraph 184.

4 185. To the extent Paragraph 185 purports to describe a document, the
5 document speaks for itself and, as such, no response is required. To the extent
6 Paragraph 186 states legal conclusions, no response is required. UnitedHealth
7 denies the remaining allegations in Paragraph 185.

8 186. UnitedHealth admits that Paul Bihm was a Vice President of General
9 Management at Optum in or around 2011. To the extent Paragraph 186 purports to
10 describe a document, the document speaks for itself and, as such, no response is
11 required. UnitedHealth denies the remaining allegations in Paragraph 186.

12 187. To the extent Paragraph 187 purports to describe a document or
13 documents, such documents speak for themselves and, as such, no response is
14 required. UnitedHealth denies the remaining allegations in Paragraph 187.

15 188. UnitedHealth admits that Eric Murphy was the President of Payer
16 Solutions at Optum in or around December 2011. To the extent Paragraph 188
17 purports to describe a document or documents, such documents speak for
18 themselves and, as such, no response is required. UnitedHealth denies the
19 remaining allegations in Paragraph 188.

20 189. To the extent Paragraph 189 purports to describe a document or
21 documents, such documents speak for themselves and, as such, no response is
22 required. UnitedHealth denies the remaining allegations in Paragraph 189.

23 190. UnitedHealth admits that William Miller was the Chief Executive
24 Officer of OptumInsight in or around September 2012. To the extent Paragraph
25 190 purports to describe a document or documents, such documents speak for
26 themselves and, as such, no response is required. To the extent Paragraph 190
27 states legal conclusions, no response is required. UnitedHealth denies the
28 remaining allegations in Paragraph 190.

1 191. UnitedHealth admits that prior to 2012, coders reviewed medical
2 records at providers' offices if the coder could not review the records electronically
3 because the provider did not want UnitedHealth to copy the record. UnitedHealth
4 further admits that UnitedHealthcare Medicare & Retirement made a policy
5 decision to stop this practice. To the extent Paragraph 191 purports to describe a
6 document or documents, such documents speak for themselves and, as such, no
7 response is required. UnitedHealth denies the remaining allegations in Paragraph
8 191.

9 192. To the extent Paragraph 193 purports to describe a document or
10 documents, such documents speak for themselves and, as such, no response is
11 required. UnitedHealth denies the remaining allegations in Paragraph 193.

12 193. To the extent Paragraph 193 purports to describe a document or
13 documents, such documents speak for themselves and, as such, no response is
14 required. UnitedHealth denies the remaining allegations in Paragraph 193.

15 194. To the extent Paragraph 194 purports to describe a document or
16 documents, such documents speak for themselves and, as such, no response is
17 required. UnitedHealth denies the remaining allegations in Paragraph 194.

18 195. To the extent Paragraph 195 purports to describe a document or
19 documents, such documents speak for themselves and, as such, no response is
20 required. UnitedHealth is without knowledge or information sufficient to form a
21 belief as to the truth or falsity of the remaining allegations in Paragraph 195;
22 therefore, such allegations are denied.

23 **C. United's Short-lived "Look Both Ways" Claims Verification**
24 **Program**

25 196. To the extent Paragraph 196 purports to describe a document or
26 documents, such documents speak for themselves and, as such, no response is
27 required. UnitedHealth denies the remaining allegations in Paragraph 196.
28

1 197. To the extent Paragraph 197 purports to describe a document or
2 documents, such documents speak for themselves and, as such, no response is
3 required. UnitedHealth denies the remaining allegations in Paragraph 197.

4 198. To the extent Paragraph 198 purports to describe a document or
5 documents, such documents speak for themselves and, as such, no response is
6 required. UnitedHealth denies the remaining allegations in Paragraph 198.

7 199. To the extent Paragraph 199 purports to describe a document or
8 documents, such documents speak for themselves and, as such, no response is
9 required. UnitedHealth denies the remaining allegations in Paragraph 199.

10 200. To the extent Paragraph 200 purports to describe a document or
11 documents, such documents speak for themselves and, as such, no response is
12 required. UnitedHealth denies the remaining allegations in Paragraph 200.

13 201. UnitedHealth admits that in or around 2012, UnitedHealthcare
14 Medicare & Retirement sent letters to capitated providers. To the extent Paragraph
15 201 purports to describe a document or documents, such documents speak for
16 themselves and, as such, no response is required. UnitedHealth denies the
17 remaining allegations in Paragraph 201.

18 202. UnitedHealth admits that UnitedHealthcare Medicare & Retirement
19 and Optum developed and implemented CV in phases over several years.
20 UnitedHealth admits that when there was a discrepancy between the provider-
21 reported diagnoses and the diagnosis codes identified by the coder as part of the
22 Chart Review Program, Optum undertook an additional review of the medical
23 record. UnitedHealth admits Optum did not delete diagnosis codes that were found
24 to be adequately supported by the medical record. To the extent Paragraph 202
25 purports to describe a document or documents, such documents speak for
26 themselves and, as such, no response is required. To the extent Paragraph 202
27 states legal conclusions, no response is required. UnitedHealth denies the
28 remaining allegations in Paragraph 202.

203. UnitedHealth admits that Optum did not generally contact providers during the CV process. UnitedHealth denies the remaining allegations in Paragraph 203.

204. To the extent Paragraph 204 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 204 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 204.

205. UnitedHealth denies the allegations in Paragraph 205.

206. To the extent Paragraph 206 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 206.

207. UnitedHealth admits that as part of Phase I, Ingenix sometimes contacted providers to determine whether or not there were additional medical records for particular beneficiaries. To the extent Paragraph 207 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 207.

208. UnitedHealth admits that Optum began conducting Phase II of its CV Program in approximately mid-2011 and that Phase II was completed in approximately early 2012. To the extent Paragraph 208 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 208 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 208.

209. UnitedHealth admits that Optum began the Phase III pilot in or about mid-2012. UnitedHealth admits that the Phase III pilot included a review of approximately 5,000 charts relating to encounters that took place in calendar year 2011. To the extent Paragraph 209 purports to describe a document or documents,

1 such documents speak for themselves and, as such, no response is required.

2 UnitedHealth denies the remaining allegations in Paragraph 209.

3 210. To the extent Paragraph 210 purports to describe a document or
4 documents, such documents speak for themselves and, as such, no response is
5 required. UnitedHealth denies the remaining allegations in Paragraph 210.

6 211. UnitedHealth admits that the CV Program continued to evolve after
7 research regarding how to structure the CV Program to best meet the goals of
8 identifying diagnosis codes that were unsupported by the medical record.
9 UnitedHealth admits that, as a result of that research, UnitedHealthcare Medicare
10 & Retirement added an expert-level review to the CV process. UnitedHealth
11 admits that UnitedHealthcare Medicare & Retirement discontinued its CV Program
12 in 2014. UnitedHealth denies the remaining allegations in Paragraph 211.

13 212. UnitedHealth admits that certain eligibility criteria were applied to
14 determine eligibility for inclusion in the CV Program. To the extent Paragraph 212
15 purports to describe a document, the document speaks for itself and, as such, no
16 response is required. To the extent Paragraph 213 states legal conclusions, no
17 response is required. UnitedHealth denies the remaining allegations in Paragraph
18 212.

19 213. UnitedHealth admits that, in or about 2013, UnitedHealthcare
20 Medicare & Retirement decided to add an expert-level review to the CV process.
21 To the extent Paragraph 213 purports to describe a document, the document speaks
22 for itself and, as such, no response is required. UnitedHealth denies the remaining
23 allegations in Paragraph 213.

24 214. To the extent Paragraph 214 states legal conclusions, no response is
25 required. UnitedHealth denies the remaining allegations in Paragraph 214.

26 215. To the extent Paragraph 215 purports to describe a document or
27 documents, such documents speak for themselves and, as such, no response is
28 required. UnitedHealth denies the remaining allegations in Paragraph 215.

216. To the extent Paragraph 216 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 216.

217. To the extent Paragraph 217 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 217.

218. To the extent Paragraph 218 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 218.

219. To the extent Paragraph 219 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 219.

220. To the extent Paragraph 220 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 220.

221. UnitedHealth admits that Marybeth Meyer assumed Mr. Poehling's role after he left the Company. To the extent Paragraph 221 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 221.

222. To the extent Paragraph 222 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 222.

223. UnitedHealth admits that, before UnitedHealthcare Medicare & Retirement discontinued the CV Program, UnitedHealthcare Medicare & Retirement and Optum sought guidance from CMS about the retroactivity of a proposed regulation requiring MA Organizations to design all medical record reviews to validate diagnoses submitted to CMS ("Proposed Rule"). To the extent

Paragraph 223 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 223.

224. UnitedHealth admits that Larry Renfro, the Chief Executive Officer of Optum, contacted senior government employees at CMS, including the Administrator of CMS, to ask whether UnitedHealth had an obligation to perform CV before the effective date of the Proposed Rule. To the extent Paragraph 224 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 224.

225. UnitedHealth admits that on April 8, 2014, Renfro spoke with the CMS Administrator regarding UnitedHealth's obligation to perform CV in light of the Proposed Rule. To the extent Paragraph 225 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 225.

226. UnitedHealth admits that Nelson, Schumacher, Erickson, and Johnson went to Washington, D.C. on April 29, 2014 to speak with CMS employees responsible for the Medicare Advantage Program, including Cheri Rice, the Director of the Medicare Plan Payment Group at CMS. To the extent Paragraph 226 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 226 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 226.

227. To the extent Paragraph 227 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 227.

228. To the extent the allegations in Paragraph 228 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent

Paragraph 228 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 228.

229. UnitedHealth admits that the Department of Justice sent a letter to UnitedHealth's counsel after Rice sent her May 2 email. To the extent Paragraph 229 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 229.

230. To the extent Paragraph 230 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 230.

231. UnitedHealth admits that UnitedHealthcare Medicare & Retirement decided to discontinue its CV Program on or about May 27, 2014. To the extent Paragraph 231 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 231.

232. UnitedHealth denies the allegations in Paragraph 232.

233. UnitedHealth admits that Optum continued performing chart review for UnitedHealthcare after CV was discontinued. To the extent Paragraph 233 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 233.

234. To the extent Paragraph 234 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 234.

D. United Failed to Delete Diagnoses Invalidated By Its Own Chart Review Program

235. To the extent Paragraph 235 purports to describe a document, the document speaks for itself and, as such, no response is required. To the extent

Paragraph 235 states legal conclusions, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 235; therefore, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 235.

236. To the extent that Paragraph 236 contains legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 236.

237. To the extent that Paragraph 237 contains legal conclusions, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 237; therefore, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 237.

238. To the extent Paragraph 238 purports to describe the Complaint, the Complaint is a legal document that speaks for itself and, as such, no response is required. To the extent that Paragraph 238 contains any factual allegations regarding UnitedHealth, such allegations are denied. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 238; therefore, such allegations are denied. To the extent that Paragraph 238 contains legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 238.

III. The RACCR Program

239. UnitedHealth admits that some of the UnitedHealth Defendants conducted the Chart Review and RACCR Programs. To the extent Paragraph 239 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 239.

**A. Defendants Knew That Their Financially-Incentivized Providers
Were Reporting Invalid Codes**

240. UnitedHealth admits that some of the UnitedHealth Defendants have arrangements that are value-based either in full or in part with providers, and to the extent Paragraph 240 purports to describe the contracts underlying these arrangements, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 240.

241. UnitedHealth admits that UnitedHealthcare Medicare & Retirement implemented RACCR to address and safeguard against potentially inaccurate coding by provider groups whose revenue was tied to risk adjustment revenue from CMS. To the extent Paragraph 241 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 241.

242. UnitedHealth admits Ingenix implemented an internal data validation program in or about 2007 or 2008. UnitedHealth admits that UnitedHealthcare Medicare & Retirement implemented the program eventually known as RACCR on or about 2009. UnitedHealth admits that the stated goal of RACCR is to address and safeguard against potentially inaccurate coding by provider groups whose revenue is tied to risk adjustment revenue from CMS. UnitedHealth denies the remaining allegations in Paragraph 242.

243. To the extent Paragraph 243 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 243.

**B. UnitedHealthcare Structured The RACCR Program To Limit
The Number Of Invalid Diagnosis Codes It Identified**

244. To the extent Paragraph 244 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 244.

245. UnitedHealth denies the allegations in Paragraph 245.

246. To the extent Paragraph 246 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 246; therefore, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 246.

247. UnitedHealth admits that for DOS 2008, 2009, and 2010 RACCR reviews, Optum defined outliers as HCCs that provider groups coded with a prevalence frequency of greater than 300% of the Optum National Rate (sometimes referred to as the national prevalence rate). UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations in Paragraph 247; therefore, such allegations are denied. To the extent Paragraph 247 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 247.

248. UnitedHealth admits that for DOS 2011 and DOS 2012 RACCR reviews, Optum defined outliers as HCCs that provider groups coded with a prevalence frequency greater than two standard deviations of the Optum National Rate, which for those DOS years was calculated based on data from all providers classified as Tier 1 provider groups. UnitedHealth denies the remaining allegations in Paragraph 248.

249. UnitedHealth admits that some of its capitated providers are located in the Central District of California. UnitedHealth admits that Exhibit 14 lists capitated providers involved in RACCR reviews that are also located in the Central District of California. UnitedHealth denies the remaining allegations in Paragraph 249.

250. UnitedHealth admits that the sample size for 2011 and 2012 dates of service RACCR reviews was set at 50 beneficiaries per provider group per HCC selected for review. To the extent Paragraph 250 purports to describe a document

1 or documents, such documents speak for themselves and, as such, no response is
2 required. UnitedHealth denies the remaining allegations in Paragraph 250.

3 251. UnitedHealth admits that RACCR reviews focused on provider groups
4 where the HCCs selected for RACCR reviews did not attain a validation rate of
5 greater than 80%. To the extent Paragraph 251 states legal conclusions, no
6 response is required. UnitedHealth denies the remaining allegations in Paragraph
7 251.

8 252. UnitedHealth admits that for DOS 2008 and 2009 RACCR reviews,
9 Optum increased the number of members whose charts were reviewed for HCCs
10 that did not validate at greater than 80% based on the initial sample and that it
11 called this process an “incremental sample.” UnitedHealth admits that RACCR
12 reviews focused on provider groups where the HCCs selected for RACCR reviews
13 did not attain a validation rate of greater than 80%. To the extent Paragraph 252
14 purports to describe a document or documents, such documents speak for
15 themselves and, as such, no response is required. To the extent Paragraph 252
16 states legal conclusions, no response is required. UnitedHealth denies the
17 remaining allegations in Paragraph 252.

18 253. UnitedHealth admits that for DOS 2008 through DOS 2011,
19 lookbacks focused on instances in which an HCC validated at 80% or less at the
20 provider group level during RACCR sample reviews. To the extent Paragraph 253
21 purports to describe a document or documents, such documents speak for
22 themselves and, as such, no response is required. UnitedHealth denies the
23 remaining allegations in Paragraph 253.

24 **C. Despite Its Limited Scope, The RACCR Program Confirmed That**
25 **Financially Incentivized Providers Were Submitting Invalid**
26 **Diagnosis Codes**

27 254. UnitedHealth denies the allegations in Paragraph 254.
28

255. To the extent Paragraph 255 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 255.

256. To the extent Paragraph 256 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 256.

257. To the extent Paragraph 257 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 257.

258. To the extent Paragraph 258 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 258.

259. To the extent Paragraph 259 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 259 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 259.

260. To the extent Paragraph 260 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 260; therefore, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 260.

261. To the extent Paragraph 261 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 261 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 261.

262. To the extent Paragraph 262 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 262.

263. To the extent Paragraph 263 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 263.

264. To the extent Paragraph 264 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 264.

**D. UnitedHealthcare Knew It Was Obligated To Delete Invalid
Diagnosis Codes Identified Through The RACCR Reviews**

265. To the extent Paragraph 265 states legal conclusions, no response is required. To the extent Paragraph 265 purports to describe a document, the document speaks for itself and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 265.

266. UnitedHealth admits that Optum deleted diagnosis codes for DOS 2008 through DOS 2013 as a result of its RACCR reviews. To the extent Paragraph 266 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 266 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 266.

267. To the extent Paragraph 267 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 267 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 267.

268. To the extent Paragraph 268 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 268.

269. To the extent Paragraph 269 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 269.

270. To the extent Paragraph 270 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 270.

271. To the extent Paragraph 271 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 271.

272. Paragraph 272 states legal conclusions to which no response is required. To the extent that Paragraph 272 contains any factual allegations, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 272.

273. Paragraph 273 states legal conclusions to which no response is required. To the extent Paragraph 273 contains any factual allegations, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 273.

**E. Defendants Failed To Follow Their Own RACCR Protocol
Requiring 100 Percent Reviews**

274. UnitedHealth admits that for DOS 2008 through DOS 2011, lookbacks focused on instances in which an HCC validated at 80% or less at the provider group level during RACCR sample reviews. To the extent Paragraph 274 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 274.

275. Paragraph 275 contains no allegations with respect to a particular Defendant or claim and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 275.

276. To the extent Paragraph 276 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 276 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 276.

277. To the extent Paragraph 277 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 277 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 277.

278. To the extent Paragraph 278 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 278.

279. To the extent Paragraph 279 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 279.

F. Even After Identifying Miscoding By Providers, Defendants Failed To Delete Invalid Codes

280. To the extent Paragraph 280 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 280; therefore, such allegations are denied. UnitedHealth denies the remaining allegations in Paragraph 280.

281. To the extent Paragraph 281 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 281 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 281.

**G. UnitedHealthcare Medicare & Retirement Discontinued 100
Percent Reviews And Converted The RACCR Program Into A
Revenue Generating Program**

282. UnitedHealth admits that during the first half of 2014,
UnitedHealthcare Medicare & Retirement made changes to the RACCR Program.
To the extent Paragraph 282 states legal conclusions, no response is required.
UnitedHealth denies the remaining allegations in Paragraph 282.

283. UnitedHealth admits that beginning with DOS 2012,
UnitedHealthcare Medicare & Retirement refocused RACCR such that it did not
require providers to conduct lookback reviews. UnitedHealth denies the remaining
allegations in Paragraph 283.

284. To the extent Paragraph 284 purports to describe a document or
documents, such documents speak for themselves and, as such, no response is
required. UnitedHealth denies the remaining allegations in Paragraph 284.

285. UnitedHealth admits that beginning with DOS 2013 RACCR reviews,
UnitedHealthcare Medicare & Retirement used a different methodology to select
medical records. UnitedHealth denies the remaining allegations in Paragraph 285.

286. To the extent Paragraph 286 purports to describe a document or
documents, such documents speak for themselves and, as such, no response is
required. UnitedHealth denies the remaining allegations in Paragraph 286.

287. Paragraph 287 states legal conclusions to which no response is
required. To the extent Paragraph 287 contains any factual allegations, such
allegations are denied. UnitedHealth denies the remaining allegations in Paragraph
287.

288. UnitedHealth admits that during the first half of 2014,
UnitedHealthcare Medicare & Retirement made changes to the RACCR Program.
UnitedHealth denies the remaining allegations in Paragraph 288.

H. RACCR-Related Falsehoods In UnitedHealthcare's And Optum's Attestations

289. To the extent the allegations in Paragraph 289 relate to claims that have been dismissed, they are surplusage and should be stricken. UnitedHealthcare admits that it has submitted Risk Adjustment Attestations to the Medicare Program. UnitedHealth admits that Optum approved these Attestations before they were submitted.

290. To the extent the allegations in Paragraph 290 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 290 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 290 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 290.

291. To the extent the allegations in Paragraph 291 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 291 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 291 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 291.

292. To the extent the allegations in Paragraph 292 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 292 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 292 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 292.

IV. Defendants' False Risk Adjustment Attestations

293. To the extent the allegations in Paragraph 293 relate to claims that have been dismissed, they are surplusage and should be stricken. UnitedHealth

1 admits that UnitedHealthcare is required to submit a truthful Risk Adjustment
2 Attestation to the Medicare Program. UnitedHealthcare admits that it has
3 submitted Risk Adjustment Attestations to the Medicare Program. UnitedHealth
4 admits that Optum and Ingenix employees reviewed and approved these
5 Attestations and that Ovations and UnitedHealthcare employees reviewed and
6 signed these Attestations. To the extent Paragraph 293 states legal conclusions, no
7 response is required. UnitedHealth denies the remaining allegations in Paragraph
8 293.

9 294. To the extent the allegations in Paragraph 294 relate to claims that
10 have been dismissed, they are surplusage and should be stricken. To the extent
11 Paragraph 294 purports to describe a document or documents, such documents
12 speak for themselves and, as such, no response is required. UnitedHealth denies
13 the remaining allegations in Paragraph 294.

14 295. To the extent the allegations in Paragraph 295 relate to claims that
15 have been dismissed, they are surplusage and should be stricken. To the extent
16 Paragraph 295 states legal conclusions, no response is required. To the extent
17 Paragraph 295 purports to describe a document or documents, such documents
18 speak for themselves and, as such, no response is required. UnitedHealth denies
19 the remaining allegations in Paragraph 295.

20 **A. Defendants' Internal Attestation Approval Process**

21 296. To the extent the allegations in Paragraph 296 relate to claims that
22 have been dismissed, they are surplusage and should be stricken. To the extent
23 Paragraph 296 purports to describe a document or documents, such documents
24 speak for themselves and, as such, no response is required. UnitedHealth denies
25 the remaining allegations in Paragraph 296.

26 297. To the extent the allegations in Paragraph 297 relate to claims that
27 have been dismissed, they are surplusage and should be stricken. To the extent
28 Paragraph 297 purports to describe a document or documents, such documents

1 speak for themselves and, as such, no response is required. To the extent
2 Paragraph 297 purports to summarize and/or describe the provisions of the
3 Medicare program, UnitedHealth states that the Medicare statute and regulations
4 speak for themselves, and to the extent that the allegations in Paragraph 297 vary
5 therefrom or with other applicable statutory or decisional law, UnitedHealth denies
6 those allegations. To the extent Paragraph 297 states legal conclusions, no
7 response is required.

8 298. To the extent the allegations in Paragraph 298 relate to claims that
9 have been dismissed, they are surplusage and should be stricken. To the extent
10 Paragraph 298 purports to describe a document or documents, such documents
11 speak for themselves and, as such, no response is required. UnitedHealth denies
12 the remaining allegations in Paragraph 298.

13 299. To the extent the allegations in Paragraph 299 relate to claims that
14 have been dismissed, they are surplusage and should be stricken. Paragraph 299
15 states legal conclusions to which no response is required. To the extent Paragraph
16 299 purports to describe a document or documents, such documents speak for
17 themselves and, as such, no response is required. UnitedHealth denies the
18 remaining allegations in Paragraph 299.

19 300. To the extent the allegations in Paragraph 300 relate to claims that
20 have been dismissed, they are surplusage and should be stricken. Paragraph 300
21 states legal conclusions to which no response is required. To the extent Paragraph
22 300 purports to describe a document or documents, such documents speak for
23 themselves and, as such, no response is required. UnitedHealth denies the
24 remaining allegations in Paragraph 300.

25 301. To the extent the allegations in Paragraph 301 relate to claims that
26 have been dismissed, they are surplusage and should be stricken. Paragraph 301
27 states legal conclusions to which no response is required. To the extent Paragraph
28 301 purports to describe a document or documents, such documents speak for

1 themselves and, as such, no response is required. UnitedHealth denies the
2 remaining allegations in Paragraph 301.

3 302. To the extent the allegations in Paragraph 302 relate to claims that
4 have been dismissed, they are surplusage and should be stricken. Paragraph 302
5 states legal conclusions to which no response is required. To the extent Paragraph
6 302 purports to describe a document or documents, such documents speak for
7 themselves and, as such, no response is required. UnitedHealth denies the
8 remaining allegations in Paragraph 302.

9 303. To the extent the allegations in Paragraph 303 relate to claims that
10 have been dismissed, they are surplusage and should be stricken. Paragraph 303
11 states legal conclusions to which no response is required. To the extent Paragraph
12 303 purports to describe a document or documents, such documents speak for
13 themselves and, as such, no response is required. UnitedHealth denies the
14 remaining allegations in Paragraph 303.

15 304. To the extent the allegations in Paragraph 304 relate to claims that
16 have been dismissed, they are surplusage and should be stricken. Paragraph 304
17 states legal conclusions to which no response is required. To the extent Paragraph
18 304 purports to describe a document or documents, such documents speak for
19 themselves and, as such, no response is required. UnitedHealth denies the
20 remaining allegations in Paragraph 304.

21 305. To the extent the allegations in Paragraph 305 relate to claims that
22 have been dismissed, they are surplusage and should be stricken. Paragraph 305
23 states legal conclusions to which no response is required. To the extent Paragraph
24 305 purports to describe a document or documents, such documents speak for
25 themselves and, as such, no response is required. UnitedHealth denies the
26 remaining allegations in Paragraph 305.

27 306. To the extent the allegations in Paragraph 306 relate to claims that
28 have been dismissed, they are surplusage and should be stricken. To the extent

Paragraph 306 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 306.

307. To the extent the allegations in Paragraph 307 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 307 states legal conclusions to which no response is required. To the extent Paragraph 307 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 307.

308. To the extent the allegations in Paragraph 308 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 308 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 308.

B. The False Attestations Submitted To The Government

309. To the extent the allegations in Paragraph 309 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 309 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 309.

310. To the extent the allegations in Paragraph 310 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 310 states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 310.

311. To the extent the allegations in Paragraph 311 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 311 purports to describe a document or documents, such documents

1 speak for themselves and, as such, no response is required. UnitedHealth denies
2 the remaining allegations in Paragraph 311.

3 312. To the extent the allegations in Paragraph 312 relate to claims that
4 have been dismissed, they are surplusage and should be stricken. To the extent
5 Paragraph 312 purports to describe a document or documents, such documents
6 speak for themselves and, as such, no response is required. UnitedHealth denies
7 the remaining allegations in Paragraph 312.

8 313. To the extent the allegations in Paragraph 313 relate to claims that
9 have been dismissed, they are surplusage and should be stricken. To the extent
10 Paragraph 313 purports to describe a document or documents, such documents
11 speak for themselves and, as such, no response is required. UnitedHealth denies
12 the remaining allegations in Paragraph 313.

13 314. To the extent the allegations in Paragraph 314 relate to claims that
14 have been dismissed, they are surplusage and should be stricken. To the extent
15 Paragraph 314 purports to describe a document or documents, such documents
16 speak for themselves and, as such, no response is required. UnitedHealth denies
17 the remaining allegations in Paragraph 314.

18 315. To the extent the allegations in Paragraph 315 relate to claims that
19 have been dismissed, they are surplusage and should be stricken. To the extent
20 Paragraph 315 purports to describe a document or documents, such documents
21 speak for themselves and, as such, no response is required. UnitedHealth denies
22 the remaining allegations in Paragraph 315.

23 316. To the extent the allegations in Paragraph 316 relate to claims that
24 have been dismissed, they are surplusage and should be stricken. Paragraph 316
25 states legal conclusions to which no response is required. UnitedHealth denies the
26 remaining allegations in Paragraph 316.

27 317. To the extent the allegations in Paragraph 317 relate to claims that
28 have been dismissed, they are surplusage and should be stricken. To the extent

Paragraph 317 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 317.

318. To the extent the allegations in Paragraph 318 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 318 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 318.

319. To the extent the allegations in Paragraph 319 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 319 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 319.

320. To the extent the allegations in Paragraph 320 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 320 states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 320.

321. To the extent the allegations in Paragraph 321 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 321 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 321.

322. To the extent the allegations in Paragraph 322 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 322 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 322 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 322.

323. To the extent the allegations in Paragraph 323 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 323 states legal conclusions to which no response is required. To the extent Paragraph 323 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 323.

324. To the extent the allegations in Paragraph 324 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 324 states legal conclusions to which no response is required. To the extent Paragraph 324 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 324.

325. To the extent the allegations in Paragraph 325 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 325 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 325 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 325.

326. To the extent the allegations in Paragraph 326 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 326 states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 326.

327. To the extent the allegations in Paragraph 327 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 327 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 327 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 327.

V. Diagnoses Solely Determine Risk Adjustment Payments Based On Health Status

328. Paragraph 328 contains no allegations with respect to a particular Defendant or claim and, as such, no response is required. To the extent Paragraph 328 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 328 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

329. Paragraph 329 contains no allegations with respect to a particular Defendant or claim and, as such, no response is required. To the extent Paragraph 329 states legal conclusions, no response is required. To the extent Paragraph 329 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 329 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

330. To the extent the allegations in Paragraph 330 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 330 contains no allegations with respect to a particular Defendant or claim and, as such, no response is required. To the extent Paragraph 330 states legal conclusions, no response is required. To the extent Paragraph 330 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 330 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

331. UnitedHealth admits that UnitedHealthcare Medicare & Retirement submitted delete transactions to RAPS as a result of its RACCR and CV Programs. To the extent Paragraph 331 purports to describe a document or documents, such

documents speak for themselves and, as such, no response is required. To the extent Paragraph 331 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 331.

332. To the extent Paragraph 332 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. Paragraph 332 states legal conclusions to which no response is required. UnitedHealth denies the remaining allegations in Paragraph 332.

333. UnitedHealth is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in Paragraph 333; therefore, such allegations are denied. To the extent Paragraph 333 states legal conclusions, no response is required. UnitedHealth denies the remaining allegations in Paragraph 333.

334. Paragraph 334 contains no allegations with respect to a particular Defendant or claim and, as such, no response is required. To the extent Paragraph 334 states legal conclusions, no response is required. To the extent Paragraph 334 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 334 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

335. To the extent the allegations in Paragraph 335 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 335 states legal conclusions to which no response is required. To the extent Paragraph 335 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 335 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 335.

336. To the extent the allegations in Paragraph 336 relate to claims that have been dismissed, they are surplusage and should be stricken. Paragraph 336 states legal conclusions to which no response is required. To the extent Paragraph 336 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 336 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations. UnitedHealth denies the remaining allegations in Paragraph 336.

337. To the extent the allegations in Paragraph 337 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 337 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. To the extent Paragraph 337 purports to summarize and/or describe the provisions of the Medicare program, UnitedHealth states that the Medicare statute and regulations speak for themselves, and to the extent that the allegations in Paragraph 337 vary therefrom or with other applicable statutory or decisional law, UnitedHealth denies those allegations.

338. To the extent the allegations in Paragraph 338 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 338 states legal conclusions, no response is required. To the extent Paragraph 338 purports to describe a document or documents, such documents speak for themselves and, as such, no response is required. UnitedHealth denies the remaining allegations in Paragraph 338.

339. To the extent the allegations in Paragraph 339 relate to claims that have been dismissed, they are surplusage and should be stricken. To the extent Paragraph 339 states legal conclusions, no response is required. To the extent Paragraph 339 purports to describe a document or documents, such documents

1 speak for themselves and, as such, no response is required. UnitedHealth denies
2 the remaining allegations in Paragraph 339.

3 340. To the extent the allegations in Paragraph 340 relate to claims that
4 have been dismissed, they are surplusage and should be stricken. To the extent
5 Paragraph 340 states legal conclusions, no response is required. To the extent
6 Paragraph 340 purports to describe a document or documents, such documents
7 speak for themselves and, as such, no response is required. UnitedHealth denies
8 the remaining allegations in Paragraph 340.

9 **FIRST CLAIM FOR RELIEF**

10 **False Claims Act: Reverse False Claims**

11 **31 U.S.C. § 3729(a)(1)(G) (formerly 31 U.S.C. § 3729(a)(7))**

12 341. UnitedHealth incorporates its responses to each and every allegation
13 set forth above as if fully stated herein.

14 342. Paragraph 342 states legal conclusions to which no response is
15 required. To the extent Paragraph 342 contains any factual allegations, such
16 allegations are denied.

17 343. Paragraph 343 states legal conclusions to which no response is
18 required. To the extent Paragraph 343 contains any factual allegations, such
19 allegations are denied.

20 **SECOND CLAIM FOR RELIEF**

21 **False Claims Act: Presentation of False or Fraudulent Claims**

22 **31 U.S.C. § 3729(a)(1)(A) (formerly 31 U.S.C. § 3729(a)(1))**

23 344. The Second Claim for Relief has been dismissed, and therefore no
24 response is required.

25 345. The Second Claim for Relief has been dismissed, and therefore no
26 response is required.

27 346. The Second Claim for Relief has been dismissed, and therefore no
28 response is required.

1 347. The Second Claim for Relief has been dismissed, and therefore no
2 response is required.

3 **THIRD CLAIM FOR RELIEF**

4 **False Claims Act: Making or Using False Records or Statements**

5 **31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2))**

6 348. The Third Claim for Relief has been dismissed, and therefore no
7 response is required.

8 349. The Third Claim for Relief has been dismissed, and therefore no
9 response is required.

10 350. The Third Claim for Relief has been dismissed, and therefore no
11 response is required.

12 351. The Third Claim for Relief has been dismissed, and therefore no
13 response is required.

14 **FOURTH CLAIM FOR RELIEF**

15 **False Claims Act: Reverse False Claims**

16 **31 U.S.C. § 3729(a)(1)(G) (formerly 31 U.S.C. § 3729(a)(7))**

17 352. The Fourth Claim for Relief has been dismissed, and therefore no
18 response is required.

19 353. The Fourth Claim for Relief has been dismissed, and therefore no
20 response is required.

21 354. The Fourth Claim for Relief has been dismissed, and therefore no
22 response is required.

23 355. The Fourth Claim for Relief has been dismissed, and therefore no
24 response is required.

25 **FIFTH CLAIM FOR RELIEF**

26 **Unjust Enrichment**

27 356. UnitedHealth incorporates its responses to each and every allegation
28 set forth above as if fully stated herein.

1 357. Paragraph 357 states legal conclusions to which no response is
2 required. To the extent Paragraph 357 contains any factual allegations, such
3 allegations are denied.

4 358. Paragraph 358 states legal conclusions to which no response is
5 required. To the extent Paragraph 358 contains any factual allegations, such
6 allegations are denied.

7 **SIXTH CLAIM FOR RELIEF**

8 **Payment by Mistake**

9 359. UnitedHealth incorporates its responses to each and every allegation
10 set forth above as if fully stated herein.

11 360. Paragraph 360 states legal conclusions to which no response is
12 required. To the extent Paragraph 360 contains any factual allegations, such
13 allegations are denied.

14 361. Paragraph 361 states legal conclusions to which no response is
15 required. To the extent Paragraph 361 contains any factual allegations, such
16 allegations are denied.

17 **PRAYER**

18 **WHEREFORE**, the United States requests that judgment be entered in its
19 favor and against Defendants as follows:

20 362. Paragraph 362 contains a prayer for relief to which no response is
21 required. To the extent a response is required, UnitedHealth denies any remaining
22 allegations in the Amended Complaint and denies that the United States is entitled
23 to any relief whatsoever against UnitedHealth.

24 363. Paragraph 363 contains a prayer for relief to which no response is
25 required. To the extent a response is required, UnitedHealth denies any remaining
26 allegations in the Amended Complaint and denies that the United States is entitled
27 to any relief whatsoever against UnitedHealth.

28

364. Paragraph 364 contains a prayer for relief to which no response is required. To the extent a response is required, UnitedHealth denies any remaining allegations in the Amended Complaint and denies that the United States is entitled to any relief whatsoever against UnitedHealth.

GENERAL DENIAL

UnitedHealth denies each and every allegation in the United States' Complaint-In-Partial-Intervention that has not been admitted or responded to specifically. To the extent any allegations of fact remain unanswered, they are denied by UnitedHealth. UnitedHealth further denies that the United States is entitled to any of the relief sought in the Prayer for Relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

UnitedHealth pleads the following affirmative defenses and reserves the right to assert additional affirmative defenses to the extent that such defenses become known as a result of discovery or otherwise:

1. The United States' claims are barred, in whole or in part, by the statute of limitations.

2. The United States' claims are barred, in whole or in part, by the doctrine of estoppel.

3. The United States knew and approved of the particulars of UnitedHealth's claims for payment before such claims were presented but after UnitedHealth had alerted the United States to UnitedHealth's understanding of applicable Medicare Program requirements.

4. The conduct of the United States negates the materiality of any alleged misrepresentations by Defendants and thus, the United States and Relators cannot recover under the Amended Complaint against Defendants.

5. UnitedHealth is not vicariously liable for the acts alleged in the Complaint.

6. UnitedHealth is not liable to the extent that the United States failed to take adequate measures to mitigate damages.

7. The United States ratified, or otherwise consented to, the transactions and occurrences that are the subject of this action.

8. The United States' claims are barred, in whole or in part, by the doctrines of course of performance, course of dealing, and usage of trade. UnitedHealth's submissions to the United States during contract negotiations and modifications and its compliance efforts were consistent with its course of performance, its course of dealing, and usage of trade.

9. The United States' claims are barred, in whole or in part, by the existence of an express contract.

10. The United States' claims are barred, in whole or in part, because of its assumption of risk.

11. The United States' claims are barred, in whole or in part, because any recovery would result in unjust enrichment.

12. Every equitable claim is barred by the doctrine of unclean hands.

13. The United States' claims are barred because UnitedHealth made no express or implied false certification.

14. The United States at all times relevant to the Amended Complaint knew of the conduct allegedly engaged in by UnitedHealth and thus, the United States and Relators cannot recover under the Amended Complaint.

15. The services and products reimbursed by the United States under Medicare were worth what the government paid.

16. The United States' claims based on alleged conduct by UnitedHealth are barred, in whole or in part, by the fact that the United States has suffered no actual injury. The United States' claims based on alleged conduct by UnitedHealth are barred, in whole or in part, because of the prior public disclosures of the core allegations upon which the Amended Complaint's "false claims" allegations

1 purport to be based and/or because Relators are not an “original source” of the
2 information, as defined in the statutes therein, such that they are not entitled to
3 pursue this action or be awarded any recovery, nor the does the Court have
4 jurisdiction.

5 17. The United States’ causes of action and allegations in the Complaint
6 are vague, ambiguous and uncertain.

7 18. The United States’ claims against one or more Defendants are
8 misjoined with the United States’ claims against other Defendants and must be
9 severed.

10 19. Damages and claims for which the United States seeks relief in the
11 Complaint, if any, were caused by the acts, errors or omissions or other fault of
12 third parties and/or contributed to and/or other fault of third parties, for whose
13 conduct UnitedHealth was not responsible.

14 20. The United States’ alleged damages are speculative, uncertain, or
15 contingent and are not recoverable.

16 21. To the extent any damages are awarded against UnitedHealth, they
17 must be reduced pursuant to 31 U.S.C. § 3729(a)(2).

18 22. UnitedHealth reserves the right to add additional defenses as
19 discovery progresses.

COUNTERCLAIM

Defendants AmeriChoice of New Jersey, Inc., AmeriChoice of New York, Inc., Arizona Physicians IPA, Inc., Care Improvement Plus of Maryland, Inc., Care Improvement Plus of Texas Insurance Company, Care Improvement Plus South Central Insurance Company, Care Improvement Plus Wisconsin Insurance Company, Optum Insurance Co., Citrus Health Care, Inc., Health Plan of Nevada, Inc., Medica HealthCare Plans, Inc., Oxford Health Plans (CT), Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (NY), Inc., PacifiCare Life and Health Insurance Company, PacifiCare of Arizona, Inc., PacifiCare of Colorado, Inc., PacifiCare of Nevada, Inc., Physicians Health Choice of Texas, LLC, Preferred Care Partners, Inc., Rocky Mountain Health Maintenance Organization, Incorporated, Sierra Health and Life Insurance Company, Inc., Symphonix Health Insurance, Inc., United HealthCare of California, Inc., UHC of California (f.k.a. PacifiCare of California), United Health Care Ins. Co. and United New York, Unison Health Plan of Tennessee, Inc., UnitedHealthcare Benefits of Texas, Inc. (f.k.a. PacifiCare of Texas, Inc.), UnitedHealthcare Community Plan of Ohio, Inc. (f.k.a. Unison Health Plan of Ohio, Inc.), UnitedHealthcare Community Plan of Texas, L.L.C. (f.k.a. Evercare of Texas, L.L.C.), UnitedHealthcare Community Plan, Inc. (f.k.a. UnitedHealthcare of the Great Lakes Health Plan, Inc.), UnitedHealthcare Insurance Company, UnitedHealthcare Insurance Company of New York, UnitedHealthcare of Alabama, Inc., UnitedHealthcare of Arizona, Inc., UnitedHealthcare of Arkansas, Inc., UnitedHealthcare of Florida, Inc., UnitedHealthcare of Georgia, Inc., UnitedHealthcare of New England, Inc., UnitedHealthcare of New York, Inc., UnitedHealthcare of North Carolina, Inc., UnitedHealthcare of Ohio, Inc., UnitedHealthcare of Oklahoma, Inc. (f.k.a. PacifiCare of Oklahoma, Inc.), UnitedHealthcare of Oregon, Inc. (f.k.a. PacifiCare of Oregon, Inc.), UnitedHealthcare of Pennsylvania, Inc. (f.k.a. Unison Health Plan of Pennsylvania, Inc.), UnitedHealthcare of Tennessee, Inc., UnitedHealthcare of

the Midlands, Inc., UnitedHealthcare of the Midwest, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc. (f.k.a. PacifiCare of Washington, Inc.), UnitedHealthcare of Wisconsin, Inc., and UnitedHealthcare Plan of the River Valley, Inc. (collectively, “UnitedHealth MA Plans”)² state, allege, and request the following in the character of a counterclaim against Plaintiff the United States of America (“United States” or “Government”):

1. The responses and affirmative defenses contained in the Answer to the United States’ Amended Complaint-in-Partial-Intervention described above are incorporated by reference in this Counterclaim as if fully set forth herein.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1367, as well as Federal Rule of Civil Procedure 13. To the extent jurisdiction and venue are proper under the Complaint, jurisdiction and venue are also proper under the Counterclaims, which arise out of the same transactions and occurrences alleged in the Complaint.

PARTIES

3. Plaintiff and Counter-Defendant United States of America has sued UnitedHealth on behalf of the United States Department of Health and Human Services (“HHS”).

4. The following Defendant and Counter-Plaintiff Medicare Advantage (“MA”) Organizations entered into one or more agreements with the Government during the relevant time period to offer MA Plans and/or Medicare Part D Plans to Medicare beneficiaries under Parts C and D of the Medicare Program, presented claims to the Government for risk adjustment payments under Parts C and D of the Medicare Program, and received risk adjustment payments from the Government.

² Should the Government substitute additional MA Plans as parties in this action in the place of erroneously named entities in its Amended Complaint, such additional MA Plans would constitute Counter-Plaintiffs as well.

1 a. Defendant and Counter-Plaintiff AmeriChoice of New Jersey, Inc., a
2 New Jersey corporation.

3 b. Defendant and Counter-Plaintiff AmeriChoice of New York, Inc., a
4 New York corporation.

5 c. Defendant and Counter-Plaintiff Arizona Physicians IPA, Inc., an
6 Arizona corporation.

7 d. Defendant and Counter-Plaintiff Care Improvement Plus of Maryland,
8 Inc., a Maryland corporation.

9 e. Defendant and Counter-Plaintiff Care Improvement Plus of Texas
10 Insurance Company, a Texas corporation insurance company.

11 f. Defendant and Counter-Plaintiff Care Improvement Plus South
12 Central Insurance Company, an Arkansas corporation insurance company.

13 g. Defendant and Counter-Plaintiff Care Improvement Plus Wisconsin
14 Insurance Company, a Wisconsin corporation insurance company.

15 h. Defendant and Counter-Plaintiff Citrus Health Care, Inc., a Florida
16 corporation.

17 i. Defendant and Counter-Plaintiff Health Plan of Nevada, Inc., a
18 Nevada corporation.

19 j. Defendant and Counter-Plaintiff Medica HealthCare Plans, Inc., a
20 Florida corporation.

21 k. Defendant and Counter-Plaintiff Oxford Health Plans (CT), Inc., a
22 Connecticut corporation.

23 l. Defendant and Counter-Plaintiff Oxford Health Plans (NJ), Inc., a
24 New Jersey corporation.

25 m. Defendant and Counter-Plaintiff Oxford Health Plans (NY), Inc., a
26 New York corporation.

27 n. Defendant and Counter-Plaintiff PacifiCare Life and Health Insurance
28 Company, an Indiana corporation insurance company.

1 o. Defendant and Counter-Plaintiff PacifiCare of Arizona, Inc., an
2 Arizona corporation.

3 p. Defendant and Counter-Plaintiff PacifiCare of Colorado, Inc., a
4 Colorado corporation.

5 q. Defendant and Counter-Plaintiff PacifiCare of Nevada, Inc., a Nevada
6 corporation.

7 r. Defendant and Counter-Plaintiff Physicians Health Choice of Texas,
8 LLC, a Texas limited liability company.

9 s. Defendant and Counter-Plaintiff Preferred Care Partners, Inc., a
10 Florida corporation.

11 t. Defendant and Counter-Plaintiff Sierra Health and Life Insurance
12 Company, Inc., a Nevada corporation.

13 u. Defendant and Counter-Plaintiff Symphonix Health Insurance, Inc.,
14 an Illinois corporation insurance company.

15 v. Defendant and Counter-Plaintiff United HealthCare of California,
16 Inc., a California corporation.

17 w. Defendant and Counter-Plaintiff UHC of California, a California
18 corporation.

19 x. Defendant and Counter-Plaintiff Unison Health Plan of Tennessee,
20 Inc., a Tennessee corporation.

21 y. Defendant and Counter-Plaintiff UnitedHealthcare Benefits of Texas,
22 Inc., a Texas corporation.

23 z. Defendant and Counter-Plaintiff UnitedHealthcare Community Plan
24 of Ohio, Inc., an Ohio corporation.

25 aa. Defendant and Counter-Plaintiff UnitedHealthcare Community Plan
26 of Texas, L.L.C., a Texas limited liability company.

27 bb. Defendant and Counter-Plaintiff UnitedHealthcare Community Plan,
28 Inc., a Michigan corporation.

1 cc. Defendant and Counter-Plaintiff UnitedHealthcare Insurance
2 Company, a Connecticut corporation insurance company.

3 dd. Defendant and Counter-Plaintiff UnitedHealthcare Insurance
4 Company of New York, a New York corporation insurance company.

5 ee. Defendant and Counter-Plaintiff UnitedHealthcare of Alabama, Inc.,
6 an Alabama corporation.

7 ff. Defendant and Counter-Plaintiff UnitedHealthcare of Arizona, Inc., an
8 Arizona corporation.

9 gg. Defendant and Counter-Plaintiff UnitedHealthcare of Arkansas, Inc.,
10 an Arkansas corporation.

11 hh. Defendant and Counter-Plaintiff UnitedHealthcare of Florida, Inc., a
12 Florida corporation.

13 ii. Defendant and Counter-Plaintiff UnitedHealthcare of Georgia, Inc., a
14 Georgia corporation.

15 jj. Defendant and Counter-Plaintiff UnitedHealthcare of New England,
16 Inc., a Rhode Island corporation.

17 kk. Defendant and Counter-Plaintiff UnitedHealthcare of New York, Inc.,
18 a New York corporation.

19 ll. Defendant and Counter-Plaintiff UnitedHealthcare of North Carolina,
20 Inc., a North Carolina corporation.

21 mm. Defendant and Counter-Plaintiff UnitedHealthcare of Ohio, Inc., an
22 Ohio corporation.

23 nn. Defendant and Counter-Plaintiff UnitedHealthcare of Oklahoma, Inc.,
24 an Oklahoma corporation.

25 oo. Defendant and Counter-Plaintiff UnitedHealthcare of Oregon, Inc., an
26 Oregon corporation.

27 pp. Defendant and Counter-Plaintiff UnitedHealthcare of Pennsylvania,
28 Inc., a Pennsylvania corporation.

1 qq. Defendant and Counter-Plaintiff UnitedHealthcare of Tennessee, Inc.,
2 a Tennessee corporation.

3 rr. Defendant and Counter-Plaintiff UnitedHealthcare of the Midlands,
4 Inc., a Nebraska corporation.

5 ss. Defendant and Counter-Plaintiff UnitedHealthcare of the Midwest,
6 Inc., a Missouri corporation.

7 tt. Defendant and Counter-Plaintiff UnitedHealthcare of Utah, Inc., a
8 Utah corporation.

9 uu. Defendant and Counter-Plaintiff UnitedHealthcare of Washington,
10 Inc., a Washington corporation.

11 vv. Defendant and Counter-Plaintiff UnitedHealthcare of Wisconsin, Inc.,
12 a Wisconsin corporation.

13 ww. Defendant and Counter-Plaintiff UnitedHealthcare Plan of the River
14 Valley, Inc., an Illinois corporation.

15 **FACTUAL ALLEGATIONS**

16 **I. Medicare Advantage Contracts**

17 **A. Medicare Advantage and CMS's "Risk Adjustment" Model**

18 5. The Medicare Act establishes a federal health insurance program for
19 disabled and elderly individuals. Traditional Medicare beneficiaries are often
20 referred to as fee-for-service ("FFS") beneficiaries because they receive healthcare
21 from a network of healthcare providers, including doctors and hospitals, whom the
22 federal government—through the Centers for Medicare and Medicaid Services
23 ("CMS")—reimburses based on the claims those providers submit for the services
24 they provide.

25 6. Congress created the Medicare Advantage program to allow
26 individuals eligible for traditional Medicare instead to receive healthcare benefits
27 through private insurance plans like the UnitedHealth MA Plans.

28

1 7. As with other types of health insurance, it costs more on average to
2 insure individuals who are projected to be sicker during the coverage period than it
3 does to insure individuals who are projected to be healthier during that same
4 period. Therefore, CMS adjusts the amount it pays to Medicare Advantage
5 organizations to reflect the projected health status of the MA plan's enrollees.

6 8. CMS designed and implemented a "risk adjustment" model to
7 determine how much to pay an MA plan in a given year. The model is designed to
8 predict how much it will cost an MA plan to care for the group of senior citizens
9 who are enrolled in that MA plan, based on an analysis of CMS's costs to care for
10 people with the same health conditions in traditional Medicare. The model relies
11 on medical diagnosis codes, which are numerical codes that correspond to illnesses
12 or medical conditions diagnosed by medical professionals. CMS uses the
13 diagnosis codes it receives from the physicians and other medical professionals
14 who treat traditional Medicare beneficiaries on a FFS basis to determine how much
15 it costs CMS to provide care for beneficiaries with a particular medical condition.
16 CMS then uses that data to predict how much it will cost an MA plan to insure an
17 individual with the same diagnosis code. CMS assumes that MA plans will see a
18 similar relationship between diagnosis codes and medical costs for the patients
19 enrolled in MA plans, and so it uses the analysis of its own FFS program codes and
20 costs to adjust MA plans' payment amounts as well.

21 9. CMS has long known that a substantial number of the diagnosis codes
22 in its own FFS claims data reflect conditions that are not sufficiently documented
23 in patients' corresponding medical charts. CMS thus has known that if it tried to
24 verify each reported diagnosis code by looking at the underlying medical records,
25 it would not always find specific entries in the medical charts that reflect the
26 specific diagnosis reported to CMS. It has recognized, however, that attempting to
27 verify all the diagnosis codes would be operationally difficult and, indeed, so
28

expensive as to be cost prohibitive. Instead, CMS includes supported and unsupported diagnosis codes alike in its calculations.

10. Using both supported and unsupported diagnosis codes to determine the average costs associated with medical conditions, rather than using just supported diagnosis codes, has the effect of lowering the average costs associated with the conditions. That reflects, among other things, the fact that patients who do not have a given condition (and whose diagnosis codes for that condition would therefore be unsupported) generally do not require the same level of healthcare services as patients who actually suffer from it. And because CMS does not distinguish between its supported and unsupported codes, the lower costs that CMS incurs for a FFS patient *without* a given condition (and whose diagnosis code for that condition is therefore unsupported) results on average in a lower payment to an MA plan for a patient who *does* have that condition (and a supported diagnosis code to go with it). This means that the payments CMS makes to MA plans are lower than they would be if CMS used only supported diagnosis codes in calculating its own average costs for a given condition.

11. Accordingly, by using unverified FFS codes to determine payment amounts, CMS already has reduced its per-code payment *in a way that accounts for the presence of unsupported diagnosis codes in claims data*. If CMS also required MA plans to delete all codes that are not supported in provider-submitted codes, such that they received payments only for supported codes even as CMS continued calculating payment amounts using both its supported and unsupported FFS codes, CMS would receive a windfall and the MA plans would be improperly underpaid.

B. Medical Chart Reviews

12. In the MA program, physicians and other healthcare providers submit diagnosis codes to the MA organizations, who in turn submit them to CMS.

1 13. MA organizations are not required or expected to double-check all
2 diagnosis codes they receive from providers in claims submissions. Doing so
3 would be logistically difficult, if not impossible, for the same reasons CMS chose
4 not to double-check its FFS codes when determining how much to adjust its
5 payments for specific diagnosis codes. CMS both expects and accepts that some
6 portion of data submitted by MA organizations—like CMS’s own FFS data—
7 would not be supported in the medical chart if one were to compare codes
8 submitted in claims to underlying medical records.

9 14. MA organizations are permitted to perform their own reviews of
10 certain medical charts if they choose to do so—and often do. Specialists in coding
11 diagnoses (known as “coders”) review the medical charts and determine what
12 codes are supported by the charts. MA organizations then submit those additional
13 diagnosis codes to CMS to demonstrate that the particular patients may require
14 more care in the successive period.

15 15. CMS never has issued any rules or regulations addressing the scope of
16 MA organizations’ reviews of medical charts. For example, there is no rule or
17 regulation requiring that MA plans perform a so-called “two-way look,” in which
18 their coders would not only affirmatively identify codes that should be submitted
19 but also validate the diagnosis codes *already* submitted by physicians and other
20 medical professionals.

21 16. Instead, CMS fully expects that MA organizations’ chart reviews will
22 result in a net increase in the number of diagnosis codes that MA plans submit for
23 risk adjustment purposes. In fact, *because* CMS anticipates that MA
24 organizations’ chart reviews will lead MA plans to identify more codes than they
25 would if they relied just on submissions by doctors and other health professionals
26 (as CMS does in the traditional Medicare program), CMS makes an across-the-
27 board reduction in its payments to MA plans. In 2018, for example, this
28 reduction—known as the “Coding Intensity Adjustment” because it adjusts for MA

1 plans' tendency to record diagnosis codes with more "intensity" than FFS
2 providers—will reduce MA plans' payments by 5.91 percent. CMS has studied the
3 issue and expressly found that the Coding Intensity Adjustment fully accounts for
4 the difference in coding practices between the MA and traditional Medicare
5 programs.

6 **C. Contract and Bid Process**

7 17. MA plans enter into annual contracts with CMS in which they agree
8 to provide insurance benefits to patients for the coming year in exchange for
9 payment from CMS.

10 18. The payment provision of these contracts provides that the MA plans
11 will develop an annual benefit and price bid proposal and submit that information
12 to CMS.

13 19. An MA plan's bid must reflect the MA organization's estimate of the
14 payment it will require to provide the benefits covered by Medicare Parts A and B
15 to a Medicare enrollee "with a national average risk profile." This payment
16 estimate must include "all estimated revenue required by the plan, including
17 administrative costs and return on investment."

18 20. To make these estimates, an MA plan must be able to calculate
19 anticipated revenues and expenses, including the cost of providing care to the
20 beneficiaries enrolled in the MA plan. In doing so, MA plans take into account
21 CMS's calculations about the relative amount it will cost to care for patients with
22 individual conditions, as well as "actuarial" assumptions, which are projections
23 about the number of beneficiaries with particular conditions that will enroll in the
24 plan during the year.

25 21. In deciding whether to accept an MA plan's bid, CMS is required by
26 law to determine whether the bid "reasonably and equitably reflects the plan's
27 estimated revenue requirements for providing the benefits under the plan." If the
28 bid does *not*, CMS cannot accept it.

22. If CMS accepts the bid (after determining that it is reasonable and equitable), CMS then agrees to pay the MA organization under the contract in accordance with the MA organization's bid and based on the submitted risk adjustment data and other amounts published by CMS.

D. CMS Told United and the Industry that MA Plans Are Not Required to Perform Chart Reviews that Include Efforts to Validate Previously Submitted Diagnosis Codes (Two-Way Looks)

23. As noted above, none of the thousands of rules and regulations issued by CMS requires MA plans to conduct chart reviews that "look both ways" or otherwise make their diagnosis data conform to a higher standard of accuracy than CMS itself utilizes with respect to its FFS data.

24. In fact, CMS told UnitedHealth that just the opposite is true.

25. For example, in 2014 CMS considered and then affirmatively decided *not* to finalize a proposed rule that would have prohibited MA organizations from performing reviews that only looked for additional diagnosis codes (known as "one-way" reviews).

26. In addition, UnitedHealth repeatedly made clear that it was not performing two-way reviews and sought specific guidance on the issue from CMS. CMS consistently confirmed that two-way reviews were not, and are not, required.

27. For example, in 2009, UnitedHealth explained to government auditors that its chart review program did not seek to verify diagnosis codes received from medical providers through the review of medical records. The government auditors never stated or even suggested that UnitedHealth was violating any rule or CMS contract by failing to verify the diagnosis codes UnitedHealth had received from providers, and the resulting audit did not find that UnitedHealth was out of compliance with any rule, regulation or contractual requirement.

28. Moreover, starting in 2011, the UnitedHealth MA Plans informed CMS each year in their bids that they made no effort to validate the diagnosis

1 codes they used in the bids by reviewing medical records: “As part of the
2 preparation of the bids, we did not attempt to validate any actual or projected risk
3 scores through a review of applicable medical records. . . .”

4 29. CMS did not advise a single UnitedHealth MA Plan that its failure to
5 validate provider-submitted codes was inappropriate or that validation of risk
6 scores based on a review of the medical records was required; rather, CMS
7 accepted these bids and paid the UnitedHealth MA Plans for the services provided.

8 30. In fact, during conversations between UnitedHealth and CMS over the
9 course of the spring and early summer of 2014, CMS confirmed multiple times that
10 “two-way” looks were not required.

11 31. Specifically, CMS told UnitedHealth that unless and until a proposed
12 rule governing the review of medical records became final, MA plans did not, and
13 do not, have an affirmative obligation to confirm whether diagnosis codes
14 submitted by physicians are supported in the medical records.

15 32. The UnitedHealth MA Plans memorialized this understanding,
16 including in subsequent bids and risk adjustment data attestations they provided to
17 CMS under the contracts.

18 **II. The UnitedHealth MA Plans Submitted Bids and Performed Contracts**
19 **In Reliance on the Government’s Representations and Conduct**

20 33. During the relevant period, the UnitedHealth MA Plans based their
21 bids on the understanding that they did not need to perform chart reviews to
22 identify unsupported codes from physicians, just as CMS does not look for
23 unsupported codes when calculating its average costs in the FFS program.

24 34. The lack of an obligation to perform chart reviews to identify
25 unsupported codes was an assumption underlying the UnitedHealth MA Plans’
26 bids. The UnitedHealth MA Plans took this lack of an obligation into account in
27 estimating the amounts they would need to bid in order to meet their revenue
28 requirements. CMS accepted these bids knowing that it had not imposed an

1 obligation to perform such reviews and that the assumptions on which the
2 UnitedHealth MA Plans' bids rested—which CMS was required by law to review
3 and, if appropriate, approve—did not include the performance of such two-way
4 looks.

5 **III. The Department of Justice Files Suit Against UnitedHealth**

6 35. *Qui tam* relator Benjamin Poehling filed this False Claims Act
7 ("FCA") case in 2011. The Department of Justice ("DOJ") investigated Poehling's
8 allegations for more than 6 years, during which time the case remained under seal.

9 36. DOJ formally intervened in the case and filed a Complaint-In-Partial-
10 Intervention on May 16, 2017. DOJ filed an Amended Complaint on November
11 17, 2017.

12 37. In its Amended Complaint, DOJ makes assertions directly contrary to
13 the guidance and instructions from CMS regarding the UnitedHealth MA Plans'
14 obligations to review medical records.

15 38. Despite knowing that CMS considered, and then rejected, a rule that
16 would have required MA plans conducting any review of medical records to
17 validate diagnosis codes previously submitted by providers, DOJ now claims that
18 the UnitedHealth MA Plans "were obligated to 'look both ways' at the results of
19 their chart reviews and delete unsupported provider-diagnoses." Moreover, despite
20 knowing that CMS told the UnitedHealth MA Plans that they had no obligation to
21 look for unsupported diagnosis codes during the course of any chart review, DOJ
22 now claims that the UnitedHealth MA Plans had a legal obligation to do so.

23 **CAUSES OF ACTION**

24 **Count 1: Breach of Contract**

25 39. The UnitedHealth MA Plans repeat and re-allege the allegations
26 contained in Paragraphs 1 to 38 above as though they are fully set forth herein.

1 40. During all time periods relevant for the Government's Amended
2 Complaint, CMS and certain UnitedHealth MA Plans had in place contracts
3 relating to the UnitedHealth MA Plans' participation in Medicare Part C.

4 41. The UnitedHealth MA Plans performed their obligations under their
5 contracts.

6 42. As part of the contract formation process, the UnitedHealth MA Plans
7 were required to submit bid proposals. CMS approved and accepted those bid
8 proposals, and agreed to pay the UnitedHealth MA plans based on their approved
9 bids.

10 43. The bids CMS approved and accepted were premised on the
11 understanding, and in some instances specified, that the UnitedHealth MA Plans
12 were not performing medical chart reviews to identify unsupported codes (i.e.
13 "two-way looks").

14 44. DOJ's Amended Complaint claims that the UnitedHealth MA Plans
15 were required to perform two-way looks, despite the fact that CMS previously
16 advised the UnitedHealth MA Plans that two-way looks were unnecessary and not
17 required. DOJ now seeks, after the fact, to alter fundamental assumptions built
18 into the UnitedHealth MA Plans' bids and, thus, their contracts with CMS.

19 45. The instant lawsuit improperly seeks to deprive the UnitedHealth MA
20 Plans of compensation they earned in exchange for providing insurance coverage
21 to millions of MA plan beneficiaries, on the ground that the UnitedHealth MA
22 Plans did not perform two-way looks or otherwise validate provider-submitted
23 codes. Depriving the UnitedHealth MA Plans of compensation on that ground
24 constitutes a breach of the terms of the contracts between the UnitedHealth MA
25 Plans and CMS. In addition, DOJ effectively seeks to withhold payment for
26 services already provided by the UnitedHealth MA Plans.

46. As a result of such breach, the UnitedHealth MA Plans have suffered damages and are entitled to recover for these damages in an amount to be determined at trial.

Count 2: Breach of Covenant of Good Faith and Fair Dealing

47. The UnitedHealth MA Plans repeat and re-allege the allegations contained in Paragraphs 1 to 46 above as though they are fully set forth herein.

48. During all time periods relevant for the Government's Amended Complaint, CMS and certain of the UnitedHealth MA Plans had in place legally enforceable contracts relating to the UnitedHealth MA Plans' participation in Medicare Part C. Every contract imposes a duty of good faith and fair dealing upon the parties in performance and enforcement of the contract.

49. The UnitedHealth MA Plans performed their obligations under their contracts.

50. In suing the UnitedHealth MA Plans for not performing two-way looks and other measures to review and delete codes, the Government breached the duty of good faith and fair dealing by demanding that the UnitedHealth MA Plans perform functions not required by the contracts or else face significant liability.

51. The Government further breached the covenant of good faith and fair dealing by continuing to accept benefits from the UnitedHealth MA Plans based on the parties' contracts, while simultaneously pursuing treble-damages recovery for payments it made pursuant to those contracts, in a manner designed to secure the benefits of its contracts with the UnitedHealth MA Plans without paying for those benefits.

52. As a result of any such breach of the covenant of good faith and fair dealing, the UnitedHealth MA Plans have suffered damages and are entitled to recover for these damages in an amount to be determined at trial.

Count 3: Fraudulent Inducement

53. The UnitedHealth MA Plans repeat and re-allege the allegations contained in Paragraphs 1 to 52 above as though they are fully set forth herein.

54. CMS made representations to the UnitedHealth MA Plans regarding the terms of the UnitedHealth MA Plans' contracts, both in the context of express contract negotiations and otherwise.

55. CMS expressly represented that the UnitedHealth MA Plans were not required to conduct two-way looks to verify and delete diagnosis codes.

56. CMS's past assertions on that point were legally correct. Nevertheless, DOJ now asserts that two-way looks *were* required. If DOJ's assertion is accurate—and the UnitedHealth MA Plans were required to conduct two-way looks when conducting chart reviews—then CMS's prior representations to the UnitedHealth MA Plans were false and lulled the UnitedHealth MA Plans into continuing to enter into contracts with CMS under false pretenses. Indeed, while the UnitedHealth MA Plans continue to believe that two-way looks were not, and are not, required during the course of chart reviews, if CMS knew, or was reckless in not knowing, that the UnitedHealth MA Plans were required to conduct two-way looks, then it deliberately deceived the UnitedHealth MA Plans.

57. CMS knew, and intended, that the UnitedHealth MA Plans would rely on CMS's representations and omissions regarding two-way looks.

58. The UnitedHealth MA Plans justifiably relied on CMS's representations and omissions in preparing their bids and entering into their contracts.

59. If the Government's current assertions are correct, and the UnitedHealth MA Plans were required to perform two-way looks, then CMS's prior representations and omissions fraudulently induced the UnitedHealth MA Plans to enter into their contracts with CMS.

60. As a result of CMS's fraudulent statements and omissions, the UnitedHealth MA Plans have suffered damages and are entitled to recover for these damages in an amount to be determined at trial.

Count 4: Negligent Misrepresentation

61. The UnitedHealth MA Plans repeat and re-allege the allegations contained in Paragraphs 1 to 60 above as though they are fully set forth herein.

62. CMS expressly represented to the UnitedHealth MA Plans on certain occasions that the UnitedHealth MA Plans would not be required under the contracts to conduct two-way looks or take other steps to verify and delete codes that CMS itself does not take.

63. CMS's past assertions on that point were legally correct. Nevertheless, DOJ now asserts that two-way looks *were* required. The UnitedHealth MA Plans therefore assert, in the alternative, that if two-way looks were required, then CMS's prior representations were false and negligent, and the UnitedHealth MA Plans were ignorant of the two-way look requirement.

64. CMS intended that the UnitedHealth MA Plans would rely on CMS's representations that the UnitedHealth MA Plans would not be required under the contracts to conduct two-way looks.

65. The UnitedHealth MA Plans justifiably relied on CMS's representations in preparing their bids and entering into their contracts.

66. If the Government's current assertions are correct, and the UnitedHealth MA Plans were required to perform two-way looks, then CMS negligently misrepresented the UnitedHealth MA Plans' medical record review obligations.

67. As a result of CMS's negligent misrepresentations, the UnitedHealth MA Plans have suffered damages and are entitled to recover for these damages in an amount to be determined at trial.

Count 5: Promissory Estoppel

68. The UnitedHealth MA Plans repeat and re-allege the allegations contained in Paragraphs 1 to 67 above as though they are fully set forth herein.

69. CMS clearly and unambiguously promised the UnitedHealth MA Plans that the UnitedHealth MA Plans would not be required to conduct two-way looks in their chart reviews.

70. The UnitedHealth MA Plans foreseeably and reasonably relied on CMS's representations in preparing their bids, which would have been higher if CMS had not promised that two-way looks would not be required.

71. As a result of CMS's promises, the UnitedHealth MA Plans have suffered damages and are entitled to recover for these damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the UnitedHealth MA Plans request that the Amended Complaint be dismissed with prejudice and that the relief sought in same be denied. The UnitedHealth MA Plans further request that the counterclaims be granted and that the Court grant the relief sought in each of the counterclaims, costs, and disbursements of this litigation including attorney's fees, and such other and further relief in favor of the UnitedHealth MA Plans as this Court deems just and proper.

Dated: March 23, 2018

Respectfully submitted,

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EXHIBIT D-3

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**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et*
al.,

Defendants.

CASE NO. 2:16-cv-08697-MWF (SSx)

**STATEMENT OF GENUINE
DISPUTES OF MATERIAL FACT
IN OPPOSITION TO PLAINTIFFS'
MOTION FOR PARTIAL
SUMMARY JUDGMENT**

Date: September 17, 2018
Time: 10:00 a.m.
Courtroom: 5A
Judge: Hon. Michael W. Fitzgerald

UnitedHealth Group, Inc. (“United” or “UnitedHealth”) submits this Statement of Genuine Disputes and Additional Uncontroverted Facts under Local Rule 56-2 in response to the United States’ and relator Benjamin Poehling’s [Proposed] Statement of Uncontroverted Facts and Conclusions of Law.

PLAINTIFFS’ UNCONTROVERTED FACTS	UNITED’S RESPONSE
A. Medicare Parts A, B, and C	
1. Medicare is a federal health insurance program for the elderly and disabled, <i>see</i> 42 U.S.C. § 1395 <i>et seq.</i> , administered by the Centers for Medicare and Medicaid Services (“CMS”), an agency of the United States Department of Health and Human Services (“HHS”).	Undisputed.
2. Medicare Part A “covers medical services furnished by hospitals and other institutional care providers.” <i>Ne. Hosp. Corp. v. Sebelius</i> , 657 F.3d 1, 2 (D.C. Cir. 2011) (citing 42 U.S.C. §§ 1395c to 1395i-5).	Undisputed.
3. Medicare Part B “is an optional supplemental insurance program that pays for items and services not covered by Part A, including outpatient physician services,” as well as “clinical laboratory tests, and durable medical equipment,” among other things. <i>Id.</i> at 2 (citing 42 U.S.C. §§ 1395j to 1395w-4).	Undisputed.
4. Medicare Part C, now known as Medicare Advantage, allows people to opt out of Parts A and B and instead enroll in health insurance plans offered by private insurers, the Medicare	Undisputed.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
Advantage Organizations ("MAOs"). <i>See</i> 42 U.S.C. §§ 1395w-21 to 1395w-29.	
5. MAOs "must provide enrollees the benefits and services (other than hospice care) that are available to people . . . under Medicare Parts A and B, <i>see</i> 42 U.S.C. § 1395w-22(a)(1), and may also offer supplemental benefits approved by the Secretary of [HHS], <i>see</i> 42 U.S.C. § 1395w-22(a)(3)." <i>Matthews v. Leavitt</i> , 452 F.3d 145, 146 n.1 (2d Cir. 2006).	Undisputed.
6. Pursuant to contracts with CMS, MAOs receive monthly payments from Medicare for each beneficiary enrolled in their Medicare Advantage (MA or Part C) plans and Prescription Drugs (PD or Part D) plans. <i>See, e.g.</i> Medicare Advantage Contract Between United Healthcare of California and CMS ("MA Contract"), 2011, Article IV, CMS Payment to MA Organization (Exhibit 1). ¹	Undisputed.
7. Under Parts A and B, CMS pays providers directly for medical services rendered to beneficiaries under a "fee-for-service" regime. <i>Methodist Hosp. of Sacramento v. Shalala</i> , 38 F.3d 1225, 1227 (D.C. Cir. 1994).	Undisputed.

¹ "United" is used herein to refer to all of the United Defendants in this action. Exhibits 1-8 are attached to the Declaration of Cheri Rice. Exhibits 9-15 are attached to the United States' and Relator Poehling's Request for Judicial Notice.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
8. In contrast, under Part C, MAOs contract with providers to render services to the beneficiaries enrolled in their plans and pay those providers. For each beneficiary in a MA plan, CMS pays the MAO a monthly base amount (which CMS and the MAO agree to before the start of the payment year) which is adjusted for each beneficiary based on that beneficiary's risk score. 42 U.S.C. § 1395w-23(a)(1)(A).	Undisputed.
9. The adjusted amount is based on the characteristics of each beneficiary, including "such risk factors as age, ... gender, ... and such other factors as the Secretary determines to be appropriate, including adjustment for health status." <i>Id.</i> § 1395w-23(a)(1)(C)(i).	Undisputed.
10. Under this "risk adjustment" system, MAOs are paid the predicted cost of providing benefits to a given beneficiary (regardless of the services, if any, actually provided to the beneficiary).	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. Although it is undisputed that "risk adjustment" payments are not made to cover services already provided to the beneficiary, United disputes the remainder of the statement as incomplete. In determining the "predicted cost of providing benefits to a given beneficiary," CMS' objective is to obtain "[r]isk scores [that] are consistent across both fee-for-service and Medicare Advantage settings," Declaration of David J. Schindler, July 23, 2018 ("Schindler Decl.") Ex. 1,

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
	2010 Rate Announcement, at AR4336, such that “[r]isk scores for beneficiaries with the same diagnoses and characteristics should be identical” in the MA and traditional Medicare programs, Schindler Decl. Ex. 2, GAO, <i>Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments</i>, at AR12043 (January 2013); <i>see also</i> Schindler Decl. Ex. 3, Gregory C. Pope et al., <i>Evaluation of the CMS-HCC Risk Adjustment Model: Final Report</i>, at AR011889, AR011892 (March 2011) (explaining that the CMS-HCC model is intended to “pay plans appropriately for their expected <i>relative</i> costs” and that “[t]he predicted costs from the risk adjustment models are . . . converted to relative risk factors so that payment adjustments can be made <i>relative</i> to the average Medicare beneficiary”) (emphasis added); <i>see also id.</i> at AR011892 (explaining that the cost predictions are designed to be accurate at the group level rather than for an individual beneficiary).
11. MAOs thus receive more for providing benefits to older and sicker people, and less for younger and healthier ones.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United does not dispute that the risk adjustment system was designed to pay MAOs more for caring for older and sicker people and less for younger and healthier people, as compared to the average FFS beneficiary in the same area. However,

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PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
	MAOs do not always receive more money for providing benefits to sicker people in practice because patients' diagnoses are not always fully captured in the data reported to CMS. <i>See, e.g.,</i> Schindler Decl. Ex. 4, Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare Advantage at 103-04, in <i>Report to Congress: Medicare and Health Care Delivery System</i> (Chapter 4), Washington, DC (June 2012) (finding inconstant coding of chronic conditions from year to year in both FFS and MA data); Schindler Decl. Ex. 5, Richard Kronick & W. Pete Welch, Measuring Coding Intensity in the Medicare Advantage Program, <i>Medicare & Medicaid Research Review</i>, 4(2), at E5 (2014) ("FFS coding is known to be both incomplete and variable. . . . [as] evidenced by lack of persistence in coding of chronic conditions"); Schindler Decl. Ex. 6, Deposition of Jeffrey Grant at 88:11-24 (March 20, 2018) ("March Grant Dep.") (Q: "Okay, and have you formed your own opinion?" A: "I have." Q: "And what is that opinion? . . ." THE WITNESS [A]: "That there is a degree of error in doctors' coding, that the codes on claims are not perfect." Q: "In the sense that the codes on claims do not capture everything in the medical chart? . . ." THE WITNESS [A]: "That is one potential problem"). To the extent this statement suggests otherwise, it is disputed.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
12. Adjusting the monthly payments based on risk factors is the Secretary's method of ensuring "actuarial equivalence" between the average payments that CMS would expect to make under fee-for-service Medicare, and the payments that CMS makes to MAOs for covering an individual with the same characteristics. <i>Id.</i>	Disputed. This statement is argumentative and a legal conclusion that requires no response. To the extent a response is required, however, United disputes as incomplete Plaintiffs' characterization of the risk factor-based payment adjustments as the Secretary's method of ensuring "actuarial equivalence." Although 42 U.S.C. § 1395w-23(a)(1)(C)(i) imposes a requirement that the Secretary adjust the risk factor-based payments "so as to ensure actuarial equivalence," United disputes that the risk adjustment factors (coefficients) calculated by the Secretary comply with the statutory mandate, or that the Secretary's calculated risk adjustment factors would be legally compliant if plans had to delete unsupported codes when CMS does not audit its own data and has not implemented a mechanism to account for its own errors. <i>See Opp. to Mot. for Part. Sum. J.</i> at 3-4, 14, 21-26.
B. The Risk Adjustment Payment System	
13. When Congress established Part C, it directed the Secretary of HHS to implement "a risk adjustment methodology that accounts for variations in per capita costs based on	Undisputed.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
health status and other demographic factors.” <i>Id.</i> § 1395w-23(a)(3)(C)(i). ²	
14. The Secretary has broad discretion under this provision to adopt a methodology and determine how to adjust payment levels based on the health status of Medicare beneficiaries.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. This statement is also argumentative and a legal conclusion that requires no response. United disputes as inaccurate Plaintiffs’ legal characterization regarding the Secretary’s alleged discretion with respect to her ability to deviate from the requirement of actuarial equivalence. <i>See</i> Opp. to Mot. for Part. Sum. J. at 3-4, 14, 21-22, 24-25.
15. Since 2004, the Secretary has used the Hierarchical Condition Category (HCC) model to determine these amounts under Part C.	Undisputed , except that this model was only fully applicable to payments beginning in 2007.
16. The Secretary has used a similar model (the RxHCC model) to risk adjust for health status under Part D. <i>See</i> 42 C.F.R. § 423.329(b)(1), (2).	Undisputed.
17. HCC is a complex regression model that collects and analyzes payment data in order to assign estimated costs to certain characteristics of Medicare beneficiaries such as age, gender, and health status.	Undisputed , provided that “payment data” refers to CMS’s unaudited FFS claims data.
18. The model includes a set of	Undisputed.

² Part C was established by the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 299 (Aug. 25, 1997).

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
multipliers – that is, “coefficients” – used to determine “the marginal (additional) cost” of each medical “condition or demographic factor (<i>e.g.</i>, age/sex group, Medicaid status, disability status).” Medicare Managed Care Manual, Pub. 100-16, Chapter 7, § 70.1 (June 7, 2013) (Exhibit 5).	
19. The multipliers are determined based on data included in claims submitted to CMS by providers for payments for their services to beneficiaries under Parts A and B of the Medicare Program. <i>See</i> Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, at 17 (Feb. 15, 2013) (Exhibit 6).	Undisputed.
20. For each Part C beneficiary, the multipliers are added to form a “risk score” and then computed against the negotiated base (fixed) monthly rate to determine how much CMS will pay an MAO for insuring that beneficiary.³	Disputed. The CMS-HCC risk adjustment model does not purport to predict the precise medical expenses for a given beneficiary in any given year. The model’s explanatory power (as measured by R-squared) of

³ For example, a 72-year-old woman living independently without a disability would have “demographic” characteristics (*i.e.*, age, sex, institutional and disability statuses) assigned a coefficient of 0.348 in 2014. Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, Table 1, at 67 (Exhibit 7). If the woman had no diagnosed conditions, an MAO would be paid 34.8% of its base rate. If the beneficiary had diabetes without complications, another 0.118 would be added to her score, which would become 0.466 (0.348 + 0.118). *Id.* Her expected healthcare costs would be 46.6% as much as the average beneficiary, and an MAO would thus be paid 46.6% of its base rate for covering her. A diagnosis of multiple sclerosis would add another 0.556 to her risk score, for a total of 1.022 (0.348 for demographics + 0.118 for diabetes without complications + 0.556 for

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	individual variation in beneficiaries' expenditures was approximately 11 percent for the v12 model. Schindler Decl. Ex. 3, Evaluation of the CMS-HCC Risk Adjustment Model: Final Report, at AR011892-895; Schindler Decl. Ex. 7, Deposition of Jeffrey Grant at 320: 9-16 (May 16, 2018) ("May Grant Dep.") (A: "You're trying to predict large groups of people accurately. You're not trying to predict one individual's cost accurately. You're trying to get a reasonable relative risk score for people that have health conditions, people that don't have health conditions, people that have a mix of health conditions.")
21. MAOs submit diagnosis codes to CMS so the agency can apply the multipliers for each beneficiary's health status.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United disputes the suggestion that MAOs submit diagnosis codes only for the purpose of CMS's applying "multipliers" for each beneficiary's health status. MAOs submit diagnoses codes to CMS for a variety of reasons. Per 42 C.F.R. § 422.310(f)(1), CMS may use risk adjustment data, which includes

multiple sclerosis). *Id.* at 68. Her expected healthcare costs would now be 102.2% as much as the average beneficiary, and an MAO would receive 102.2% of its base rate for covering her. Thus, when an MAO submits a diagnosis code that maps to an HCC for a beneficiary, that code increases the amount paid to the MAO for coverage. *See* 2000 Rule, 65 Fed. Reg. at 40268 (explaining that the diagnosis data is a claim for payment); *see generally* Defendants' Mem. in Support of Cross-Mot. for Summ. J. and in Opp'n to Plaintiff's Mot. for Summ. J., *United Healthcare Ins. Co. v. Hargan*, CV 16-157-RMC, Dkt. 57-1, at 14-16 (D.D.C. filed Dec. 4, 2017) ("APA case") (Exhibit 13).

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	diagnosis codes, for a range of purposes described in § 422.310(f)(1)(i)-(ix), including but not limited to “conduct[ing] quality review and improvement activities,” and “update[ing] risk adjustment models.” Only one of the nine purposes listed is “[t]o determine the risk adjustment factors used to adjustment payments. . . .” Additionally, the risk scores of beneficiaries who switch from Medicare FFS to MA in a given year are not determined from data submitted by the MA plan. <i>Cf.</i> Schindler Decl. Ex. 8, Brad Piper & Hillary Millican, Medicare Advantage Risk Score Primer: What You Need to Know About Diagnoses Supporting Risk Scores and Revenue Payment Timing at 2, <i>Milliman White Paper</i> , (Oct. 2017).
22. Since 2004, they have submitted the codes through CMS’s Risk Adjustment Processing System (“RAPS”).	Undisputed.
23. In the last several years, they submit the codes through RAPS and CMS’ Encounter Data System (“EDS”).	Undisputed.
24. Each RAPS submission includes only a few data fields: the beneficiary’s identification number, the date of the medical encounter, the type of healthcare provider, and the diagnosis code(s) reported by the provider for that encounter. <i>See, e.g.,</i> 2013	Disputed. United disputes this statement to the extent that it implies that providers are the only acceptable source of diagnosis codes reported on RAPS submissions. MAOs are permitted to submit diagnosis code(s) not reported by the provider. <i>See, e.g.,</i>

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Medicare Managed Care Manual, Pub. 100-16, chapter 7 at § 120.2.3 (Exhibit 5).	Schindler Decl. Ex. 9, CMS, 2012 <i>Regional Technical Assistance Participant Guide: Encounter Data</i> , §§ 2.4.3, 3.5.7, 3.5.7.1, 3.5.7.2 (Aug. 6-7, 2012); <i>see also</i> Schindler Decl. Ex. 7, May Grant Dep. at 163: 14–18 (Q: “Okay. The same question with respect to pulling charts for review. Is that an appropriate activity for MA plans to engage in?” MS. KRIEG: “Object to the question.” A: “Yes”). The remainder of the statement is undisputed.
25. RAPS also has a field called a “Delete Indicator” that allows MAOs to delete invalid diagnosis codes that were previously submitted and thereby retract the claim for payment for those invalid diagnoses. <i>Id.</i>	Undisputed.
26. A diagnosis that has been deleted in RAPS will not cause an increase in the risk score or risk adjusted payment that otherwise would have been based on the deleted diagnosis code.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United disputes this statement to the extent it implies that every diagnosis code submitted in RAPs affects payment. Not all diagnosis codes submitted in RAPs affect risk scores and thereby payments. The rest of the statement is undisputed.
27. When an MAO acquires information about invalid diagnoses after payment is made, it can still delete the invalid diagnosis codes through RAPS, and CMS will reconcile	Disputed. United disputes the suggestion that it is always possible for an MAO to delete diagnosis codes submitted through RAPs. Until 2014, there was no formal process in place

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its payments as part of a routine process. 42 C.F.R. § 422.310(g)(2)(ii).	for deleting diagnosis codes during the closed period. <i>See</i> Schindler Decl., Ex. 10, CMS, <i>Guidance for Reporting and Returning Medicare Advantage Organization and/or Sponsor Identified Overpayments to the Centers for Medicare & Medicaid Services (CMS)</i>, (Feb. 18, 2015) (announcing the process for reporting and returning overpayments beginning on January 1, 2015). United also disputes that CMS consistently reconciles or otherwise adjusts payments when plans do submit deletions.
28. EDS works much the same way with respect to the deletion of invalid diagnosis codes. <i>See</i> CMS 2012 Regional Technical Assistance Participant Guide, Encounter Data, at 3-32 to 3-33 (Exhibit 8).	Disputed. This statement is unclear as to what is meant by “much the same way” such that United cannot meaningfully assess the statement. For purposes of this motion the statement is disputed.
C. Part C and D Payment Data Integrity Requirements and Obligations	
29. MAOs have a financial incentive to submit as many risk-adjusting diagnoses as possible to generate as much payment as possible.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. United does not dispute that MAOs are paid in part based on the risk-adjusting diagnoses they submit to CMS and that they therefore have a financial incentive to submit complete risk adjustment data reflecting all of the diagnoses supported by the medical record. However, United disputes that MAOs have a financial incentive to submit “as

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	many risk-adjusting codes as possible."
30. Accordingly, to ensure that payments are based on valid diagnosis data and are not improperly inflated, payment integrity requirements and obligations are imposed on MAOs.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged "fact" is also argumentative and a legal conclusion that requires no response.
31. These requirements and obligations are contractual as well as regulatory, and apply to all United MAOs and to entities related to these MAOs, including, the non-MAO United Defendants in this action. <i>See</i> Section D(5) of Article V of the MA Contract (Exhibit 1) (if any MAO responsibility is delegated to another entity, "all contracts or written agreements must specify that the related entity, contractor or subcontractor must comply with all applicable Medicare laws, regulations, and CMS instructions"); <i>see also</i> 42 C.F.R. §422.504(i)(3)(iii), (4)(v) (Part C) (requiring related entities and contractors to comply with the MAO's contractual obligations to CMS and to comply with all applicable Medicare laws, regulations, and CMS instructions); 42 C.F.R. § 423.505(i)(3)(iii), (iv) (Part D) (same).	Disputed. The alleged "fact" is argumentative and a legal conclusion that requires no response. United also objects on the grounds that the term "These requirements" is vague.
32. One of the most fundamental payment integrity requirements is that diagnoses must be substantiated by the beneficiaries' medical records to be valid and one of the most important	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged "fact" is also argumentative and a legal

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payment integrity obligations is that MAOs and their related entities and contractors delete unsubstantiated diagnoses when they have information, knowledge or a belief about them.	conclusion that requires no response.
33. In order to participate in the Part C and Part D programs, the Defendant MAOs were required to agree in writing to comply with Part C and D regulations and other terms and conditions. 42 C.F.R. §§ 422.503, 422.504 (Part C); 42 C.F.R. §§ 423.504, 423.505 (Part D).	Disputed. The alleged “fact” is argumentative and a legal conclusion that requires no response.
34. Each year, one or more executives of defendant UnitedHealthcare, Inc. or its affiliates or predecessors entered into these contracts with CMS on behalf of the Defendant MAOs. <i>See e.g.</i> Signature Attestation page at the end of Exhibit 1.	Disputed. United does not dispute that its executives signed Risk Adjustment Attestations. However, United objects on the grounds that the term “Each year” and “these contracts” is vague. Although unclear what Plaintiffs mean by “these contracts,” United also disputes that its “executives . . . entered into these contracts with CMS on behalf of the Defendant MAOs.”
35. During the payment years at issue in this case, the contracts obligated defendants to operate their Part C and D plans “in compliance with the requirements of [the] contract[s] and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.)” and to comply with “Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse,” including the False Claims Act. <i>See,</i>	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited contract. However, the interpretation of the contract is a legal conclusion that United disputes and that requires no response. This statement is also disputed as incomplete and misleading. The portion of the contracts only partially quoted by the government deals with MA plans’ agreements to operate a particular type of MA plan (a coordinated care plan, as opposed to

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<i>e.g.</i>, Section A of Article II and Section A(1) of Article IX of the Part C contract, which is part of Exhibit 1.⁴	one of two other categories of MA plans – private FFS plans or MSA plans, <i>see</i> Schindler Decl. Ex. 11, 2017 Manual Chapter 1, §§ 20.1, 20.2; 42 C.F.R. § 422.4(a)) and the provision of services to beneficiaries as part of that “Coordinated Care Plan.” Ex. 1 to Decl. of Cheri Rice, at 6. That “coordinated care plan” governs the medical services that the plan is required to provide to its members, the conditions under which those services must be available, the providers through whom the plan will provide them, and so forth, and various requirements that apply to coordinated care type MA plans in particular. <i>See</i> 42 C.F.R. 422.4(a)(1); Schindler Decl. Ex. 11, 2017 Manual Chapter 1, § 20.2. It does not extend, however, to the manner in which CMS will pay the plan. The terms governing that issue are instead set out in Article IV, governing “CMS Payment to MA Organization.” <i>See</i> Opp. to Mot. for Part. Sum. J. at 33-36.
36. The contracts also required defendants to implement an effective compliance program in accordance with the Part C and D compliance regulations. <i>See, e.g.</i>, Section F of Art. III of the MA Contract and Section J of Art. II of the Part D Addendum, also	Disputed. United does not dispute that pursuant to the referenced MA Contract, the MAO defendants agreed to implement a compliance program in accordance with Part C and D compliance regulations. However, the interpretation of the contract is a legal

⁴ The Attestation of Benefit Plan, which is part of the contract, also requires compliance with the Medicare Managed Care Manual and other documents issued by CMS. This Attestation is included as part of Exhibit 1.

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part of Exhibit 1.	conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30.
37. Since 2005, the Part C compliance regulation itself has obligated United to monitor for noncompliance with CMS requirements, identify compliance risks, and respond to and correct compliance problems, including taking "affirmative steps to address errors" in the data it submitted for payments. <i>United States ex rel. Swoben v. United Healthcare Ins. Co.</i>, 848 F.3d 1161, 1174 (9th Cir. 2016) (citing 42 C.F.R. § 422.503(b)(4)(vi), (vi)(F), (vi)(G) (2005)); <i>see also</i> 42 C.F.R., § 423.504(b)(4)(vi), (vi)(F), (vi)(G) (2007) (Part D compliance regulation setting forth same requirements).	Disputed. United does not dispute that the language that appears in quotation marks appears in the sources that are cited. However, the interpretation of these regulations and case law is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 46-49.
38. The compliance regulations state that the MAO "must conduct appropriate corrective actions (for example, repayment of overpayments . . .)." 42 C.F.R. § 422.503(b)(4)(vi)(G)(2); <i>see also</i> 42 C.F.R., § 423.504(b)(4)(vi)(G)(2) (Part D) (same).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the interpretation of these regulations is a legal conclusion that United disputes and that requires no response. Further, this factual allegation is disputed as incomplete. 42 C.F.R. § 422.503(b)(4)(vi)(G)(2) states that an MAO "must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section." 42 C.F.R. § 422.503(b)(4)(vi)(G)(1) states,

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	"If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct." The analogous Part D regulations provide similarly. To the extent Plaintiffs' statement suggests otherwise, the cited regulations do not impose an obligation on MAOs to delete unsupported codes. <i>See Opp. to Mot. for Part. Sum. J. at 30.</i>
13 39. In 2013, the obligation to 14 withdraw erroneous risk adjustment 15 data was also reiterated in the Medicare 16 Managed Care Manual, which, as noted 17 above, was expressly incorporated into 18 all of the contracts. <i>See, e.g., 2013</i> 19 <i>Medicare Managed Care Manual, Pub.</i> 20 <i>100-16, chapter 7 at § 40 (Exhibit 5)</i> 21 <i>(stating: "If upon conducting an</i> 22 <i>internal review of submitted diagnosis</i> 23 <i>codes, the plan sponsor [or MAO]</i> 24 <i>determines that any ICD-9-CM</i> 25 <i>diagnosis codes that have been</i> 26 <i>submitted do not meet risk adjustment</i> 27 <i>submission requirements, the plan</i> 28 <i>sponsor [or MAO] is responsible for</i> <i>deleting the submitted ICD-9-CM</i> <i>diagnosis codes as soon as possible").</i>	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited Medicare Managed Care Manual. However, the interpretation of the contract and Medicare Managed Care Manual is a legal conclusion that United disputes and that requires no response. Further, Plaintiffs mischaracterize the meaning of the cited provisions, which describe a responsibility to delete codes <i>if</i> a plan chooses to undertake an internal review of previously submitted codes <i>and</i> that review determines that submitted codes do not meet the risk adjustment submission requirements. <i>See Opp. to Mot. for Part. Sum. J. at 40.</i> To the extent Plaintiffs' statement suggests otherwise, the cited Manuals do not impose an obligation on MAOs to delete unsupported codes. Finally, the Manual is a guidance

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	document that does not impose any legal obligations on plans and that United did not agree to comply with in its contract with CMS. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-33.
40. In addition, in accordance with 42 C.F.R. § 422.504(l) (Part C), the contracts obligated an officer of each United MAO to annually attest to the accuracy, completeness, and truthfulness of the diagnosis data submitted for risk adjustment payments based on best knowledge, information, and belief. <i>See</i> Section D.2 of Article IV of the MA Contract (Exhibit 1). ⁵	Disputed. Plaintiffs mischaracterize the cited regulation and contracts. The contracts and applicable regulation provide that a chief executive officer, a chief financial officer, "or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer" can sign. 42 C.F.R. § 422.504(l); Pls.' Mem. of P. & A. in Supp. of Pls.' Mot. for Partial Summ. J., ECF No. 234-1 ("Mem.") Ex. 1 at 11, ECF No. 234-3.
41. This regulatory and contractual obligation also applied to each related entity and contractor that generated (that is, submitted) risk adjustment data for the United MAOs, including defendant Optum (and its predecessor, Ingenix). <i>Id.</i>	Disputed. The alleged "fact" is a legal conclusion that that requires no response.
42. Importantly, this contractual and regulatory attestation requirement imposed affirmative duties on the MAOs and their related entities and contractors.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. The alleged "fact" is also argumentative and a legal conclusion that requires no response. United further objects on the grounds that the term "affirmative duties" is

⁵ The Part D regulations include a similar attestation requirement for diagnoses submitted for risk adjustment payments under the prescription drug program. Under the applicable Part D regulation, these attestations are referred to as certifications. 42 C.F.R. § 423.505(k).

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	vague and ambiguous.
43. As explained by the Ninth Circuit and “as CMS has long made clear,” to attest to the accuracy, completeness, and truthfulness of their risk adjustment data submitted to CMS, MAOs have always had a duty to take actions to ensure the accuracy, completeness, and truthfulness of the data and are responsible for “making good faith efforts” to certify the accuracy, completeness, and truthfulness of the data. <i>Swoben</i>, 848 F.3d at 1174 (citing 65 Fed. Reg. at 40,268); <i>see also</i> 2004 Manual (Exhibit 4), § 111.7 (discussing this requirement).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the interpretation of case law and the underlying regulations and Managed Care Manual are legal conclusions that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 31-33, 46-49. Further, in each year since 2014, United has submitted its risk adjustment data attestations subject to certain clarifications, including the understanding that it was not obligated to perform two-ways looks. In 2014, United explained that it had suspended the “process through which [it] review[s] certain medical records to determine the accuracy of risk adjustment diagnoses and submit[s] appropriate deletes” while it considered whether to make changes. <i>See</i> Schindler Decl. Ex. 12, Email from Steve Nelson to Cheri Rice dated April 30, 2014, produced at MARA1296259. In 2015 and 2016, United clarified that it “previously had a process through which [it] reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes” but that it “ended this process and informed [CMS] of that decision.” Schindler Decl. Ex. 13, Email from Steve Nelson to Cheri Rice dated June 26, 2015, produced at MARA2152278; Schindler

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	Decl. Ex. 14, Email from Cheri Rice to Johanna Kreisel dated June 7, 2016, produced at USBP000498420. It further clarified that the decision remained operative and explicitly communicated that United “did not use [its] previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record.” <i>See</i> Schindler Decl. Ex. 13, Email from Steve Nelson to Cheri Rice dated June 26, 2015, produced at MARA2152278; Schindler Decl. Ex. 14, Email from Cheri Rice to Johanna Kreisel dated June 7, 2016, produced at USBP000498420. United also made similar qualifications in its bid assumptions that CMS reviewed and approved prior to the parties executing the contracts here at issue. <i>See, e.g.,</i> Schindler Decl. Ex. 49, MA Supporting Documentation for CY2015 Bid, UHC of California, Inc., Contract No. H0543-001-000, dated Aug. 5, 2014 (emphasis added) (providing: “We . . . adjusted projected risk scores to account for changes in our medical record review processes. Specifically, <i>based on multiple conversations with CMS and CMS’s treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process</i>”); <i>see also</i> Opp. to Mot. for Part. Sum. J. at 36-38.
44. Thus, MAOs and their related	Disputed. The alleged “fact” is a legal

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entities and contractors cannot turn blind eyes to information about the invalidity of their diagnosis data or act with reckless disregard or deliberate ignorance of the falsity of the data and one of the affirmative duties or actions that MAOs and their related entities and contractors must undertake because of the attestation requirement is to correct or withdraw erroneous data. <i>Id.</i> at 1174.	conclusion that United disputes and that requires no response.
45. The Medicare Managed Care Manual has long specified that diagnosis data must be substantiated by the beneficiaries' medical records – a requirement that has been in every version of the Manual since at least 2001. <i>See, e.g.</i>, 2001 Manual (Exhibit 3), §§ 110.3, 110.4 (requiring diagnosis data to “be substantiated by the hospital’s medical record”); 2004 Manual (Exhibit 4), §§ 111.1, 111.4, 111.8 and Exhibit 30 [to the Manual] (Aug. 13, 2004) (“a medical record must substantiate all diagnostic information provided to CMS”); 2013 Manual (Exhibit 5), § 40 (“All diagnosis codes submitted must be documented in the medical record”).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited sources. However, the rest of the statement, including the interpretation of the Medicare Managed Care Manuals, is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-36, 39.
46. The Manual, in accordance with federal regulation, also has long specified that diagnoses be coded according to <i>International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting</i> and the ICD Guidelines have long specified that the	Disputed. The effect and interpretation of the Manual and ICD Guidelines are legal conclusions that United disputes and that require no response. Further, United disputes the contention that “the ICD Guidelines have long specified that the medical record must substantiate the diagnosis coding.” In

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medical record must substantiate the diagnosis coding. <i>See, e.g.</i>, 2013 Manual § 40 (Exhibit 5); <i>see also</i> 45 C.F.R. §§ 162.103, 162.1000(a) and 162.1002(a)(1), (b)(1), (c)(2)(i) (by which the Secretary of HHS adopted certain “code sets as the standard medical data code sets[.]” including the ICD-9-CM (Ninth Edition) until it was superseded in October 2015 by the ICD-10-CM (Tenth Edition), and made their use mandatory for “covered entities,” which includes health plans and providers).	addition, the Manuals do not impose legal obligations and United did not contractually agree to comply with the Manuals in connection with submission of risk adjustment data or payment. <i>See</i> Opp. to Mot. for Part. Sum. J. at 32-41.
47. The Ninth Edition of the ICD Guidelines (effective during many of the years at issue here), “published by the United States Government” and “required for reporting diagnoses and diseases to all . . . [CMS] programs,” included the requirement of medical record documentation to substantiate diagnosis coding. Joint Appendix of Rulemaking Record Excerpts from APA case, ICD-9-CM Coding Guidelines, Preface at 1 (Exhibit 15); <i>see also id.</i> at 5 (explaining “[t]he importance of consistent, complete documentation in the medical record,” without which accurate diagnosis coding “is a difficult, if not impossible, task”).	Disputed. United does not dispute that the language that appears in quotation marks appears in the source that is cited. However, the effect and interpretation of the ICD Guidelines are legal conclusions that United disputes and that require no response. Further, United disputes Plaintiff’s contention that “[t]he Ninth Edition of the ICD Guidelines . . . included the requirement of medical record documentation to substantiate diagnosis coding.” <i>See</i> Opp. to Mot. for Part. Sum. J. at 39.
48. The Tenth Edition of the ICD Guidelines does the same. ICD-10-CM Official Guidelines for Coding and Reporting FY 2018, at 1 (Exhibit 16) (“importance of consistent, complete	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited source. However, the effect and interpretation of the ICD Guidelines are legal

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documentation in the medical record cannot be overemphasized").	conclusions that United disputes and that require no response. Further, United disputes Plaintiff's contention that the Tenth Edition of the ICD Guidelines included a requirement of medical record documentation to substantiate diagnosis coding. <i>See</i> Opp. to Mot. for Part. Sum. J.
49. Moreover, pursuant to their MA Contracts, the Defendant MAOs agreed "to comply with the requirements in § 422.310 for submitting risk adjustment data to CMS" and could be terminated if they "fail[ed] to provide CMS with valid risk adjustment data as required under § 422.310 and 423.329(b)(3)." <i>See</i> Section B.7 of Art. VI and Section B.1(a)(vii) of Article VIII of the MA Contract. ⁶	Disputed. United does not dispute that the language that appears in quotation marks appears in the MA Contract. However, the interpretation of the contract is a legal conclusion that United disputes and that requires no response.
50. One of the requirements of § 422.310 (a Part C regulation) pertains to the "[v]alidation of risk adjustment data."	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310. However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31.
51. Section 422.310(e) also establishes the medical record as the source for determining the validity of risk adjustment data: "MA	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310(e). However, the

⁶ The contracts are also subject to termination when "[t]here is credible evidence that the MA Organization committed or participated in false, fraudulent or abusive activities affecting the Medicare program, including the submission of false or fraudulent data." *See, e.g.,* Section B.1(a)(iv) of Article VIII of the MA Contract (Exhibit 1).

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organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS."	interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31.
52. "There may be penalties for submission of false data." 42 C.F.R. § 422.310(e). ⁷	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.310(e). However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. <i>See</i> 30-31.
53. Similarly, the regulation relating to CMS' risk adjustment data validation (RADV) audits refers to the medical records as the source for validating diagnoses in order "to ensure risk adjusted payment integrity and accuracy." 42 C.F.R. § 422.311(a).	Disputed. United does not dispute that the language that appears in quotation marks appears in 42 C.F.R. § 422.311(a). However, the interpretation of the regulation is a legal conclusion that United disputes and that requires no response. This "fact" is also disputed as incomplete and potentially misleading. The provision Plaintiffs' cite discusses data validation in the specific context of Risk Adjustment Data Validation (RADV) audits rather than a general obligation to validate risk adjustment data. <i>See</i> Opp. to Mot. for Part. Sum. J. at 30-31. The entirety of the quoted subsection states: "In accordance with § 422.2 [Definitions] and § 422.310(e), the Secretary annually conducts RADV audits to ensure risk adjusted payment

⁷ Section 423.329(b)(3) addresses the collection of data for Part D risk adjustment based on health status. It references the requirements of section 422.310.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
	integrity and accuracy.” 42 C.F.R. § 422.311(a). To the extent Plaintiffs’ statement suggests otherwise, it is disputed.
54. And, because the medical record is the “source of truth” for the determining the validity of risk adjustment data, United’s MA Contracts, in accordance with 42 C.F.R. § 422.504(e)(2), provided the government with the right to audit, evaluate, and inspect “medical records,” “patient care documentation, and other records” in the possession or control of the United MAOs, related entities, and contractors that relate to the “determination of amounts payable under the contract[s].” <i>See, e.g.</i>, Section A.2(b), (d) of Article VI of the MA Contract (Exhibit 1).	Disputed. United does not dispute that the language that appears in quotation marks appears in the cited contract and regulation. The rest of the statement is argumentative and a legal conclusion that United disputes and requires no response. Additionally, Plaintiffs have mischaracterized the meaning of the quoted language; the cited contract does not give “the government” a right; rather it provides that “HHS, the Comptroller General, or their designees may audit, evaluate, or inspect. . . medical records. . . patient care documentation, and other records of the MA Organization, . . . and determination of amounts payable under the contract. . .” Mem. Ex. 1 at 13, ECF No. 234-3; 42 C.F.R. § 422.504(e)(2) (providing similarly).
55. During the relevant time period, 2009-2017, the United Defendants were also bound by the terms and conditions of Electronic Data Interchange (“EDI”) Agreements.	Disputed. This statement is a legal conclusion that United disputes and requires no response.
56. The United MAOs and any related entity or contractor that submitted risk adjustment data on their behalf (here Optum and its predecessor, Ingenix) were required to execute these agreements in order to submit the data,	Disputed. This statement is a legal conclusion that United disputes and requires no response.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
including diagnoses, to CMS' RAPS and EDS and to receive payments. <i>See, e.g.,</i> Electronic Data Interchange Agreement Between United and CMS (Exhibit 2); <i>see also</i> 2004 Manual (Exhibit 4), § 111.6.1 (discussing this requirement).	
57. Pursuant to the EDI Agreements, the defendant MAOs and Optum (and its predecessor, Ingenix) agreed that they were responsible for all risk adjustment data submitted by themselves, their employees, and agents and that "[b]ased on best knowledge, information, and belief, [they would] submit risk adjustment data that are accurate, complete, and truthful." <i>Id.</i> at Sections A.1 and 5.	Disputed. Plaintiffs have misquoted the language in the cited EDI Agreements. The EDI Agreements state that the MAO will be responsible "for all Medicare encounter data submitted to CMS by itself, its employees, or its agents," and that, "Based on best knowledge, information, and belief, [the MAO] will submit encounter data that are accurate, complete, and truthful." Mem. Ex. 2 at 43. Further, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
58. Moreover, they agreed to "correct risk adjustment data discrepancies." <i>Id.</i> at Section A.11.	Disputed. Plaintiffs have misquoted the language in cited EDI Agreements. The source refers to "research[ing] and correct[ing] encounter data discrepancies." Mem. Ex. 2 at 43. Further, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
59. Of equal significance, pursuant to the EDI Agreements, they also agreed that the government had the	Disputed. United does not dispute that the language that appears in quotation marks appears in the EDI Agreements.

PLAINTIFFS' UNCONTROVERTED FACTS	UNITED'S RESPONSE
right to "audit and confirm" the data submitted by them and that they would provide the government with access to "medical records related to the eligible organization's submissions" in order for the government to audit data and confirm that the submitted-diagnosis were supported by the medical records. <i>Id.</i> at Section A.4.	However, the interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
60. Thus, the EDI Agreements also established the medical records as the "source of truth" for validating diagnosis data and Defendants' entitlement to payments.	Disputed. Plaintiffs have failed to provide any support for this purported uncontroverted fact as required by Local Rule 56-3. Plaintiffs' interpretation of the EDI Agreements is a legal conclusion that United disputes and that requires no response. <i>See</i> Opp. to Mot. for Part. Sum. J. at 42.
61. Any conclusion of law that is deemed a finding of fact is incorporated herein by this reference.	Disputed. To the extent any conclusion of law is deemed a finding of fact, United objects.

**ADDITIONAL MATERIAL FACTS AND EVIDENCE THAT PRECLUDES
PARTIAL SUMMARY JUDGMENT**

United presents the following additional material facts and evidence in opposition to the United States' and Ben Poehling's Motion for Partial Summary Judgment. As set forth in the Declaration of Abid R. Qureshi submitted pursuant to Federal Rule of Civil Procedure 56(d), filed concurrently, United expects to develop additional evidence on many of the factual matters that support the arguments in its Opposition through ongoing discovery in this litigation. See Declaration of Abid R. Qureshi, July 23, 2018.

**UNITED'S ADDITIONAL
MATERIAL FACTS AND
SUPPORTING EVIDENCE:**

A. Additional Material Facts Establishing the Impact of Diagnosis Coding Discrepancies on the Payment Rates Calculated by CMS

62. In determining the predicted cost of providing benefits to a given beneficiary, CMS' objective is to obtain "[r]isk scores [that] are consistent across both fee-for-service and Medicare Advantage settings, Schindler Decl. Ex. 1, 2010 Rate Announcement, at AR4336, such that "[r]isk scores for beneficiaries with the same diagnoses and characteristics should be identical" in the MA and traditional Medicare programs, Schindler Decl. Ex. 2, GAO, *Medicare Advantage: Substantial Excess Payments Underscore Need for CMS to Improve Accuracy of Risk Score Adjustments*, at AR12043.

63. In both traditional Medicare and Medicare Advantage providers sometimes submit diagnosis codes that

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	do not correspond perfectly with patients' medical charts. <i>See, e.g.,</i> Schindler Decl. Ex. 15, Presentation from Division of Payment Validation at CMS0005886 (internal CMS presentation acknowledging that "In FFS Medicare, some portion of diagnoses on FFS claims are not documented in medical records."); Schindler Decl. Ex. 7, May Grant Dep. at 233:4-17 ("Q: So you are aware that there are errors [in FFS data], but you don't know the amount or extent because you believe there's no systematic study evaluating this issue? ... A: Again, 'aware' is a strong term. I would say it is my firm belief, having processed data for years, that any data set has errors in it. My experience with data would say that every data set you ever deal with that is a very large data set has some degree of error and the only question is what that degree of error is. And unless you study it, it is not knowable what that degree of error is.")	
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21	64. CMS has acknowledged that the FFS claims data it collects in the traditional Medicare program contains unsupported diagnosis codes. <i>See supra</i> 63.	
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25	65. Yet, when CMS calibrates the CMS-HCC risk adjustment model, it does not attempt to correct for those discrepancies by auditing the FFS claims data to confirm that the	
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1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	diagnosis codes are properly supported	
5	by medical records. <i>See</i> Schindler	
6	Decl. Ex. 15, Presentation from	
7	Division of Payment Validation at	
8	CMS0005887; Schindler Decl. Ex. 16,	
9	FOIA Agenda at CMS0006200	
10	("...we've got another documentation	
11	standard for risk adjustment, which	
12	reflects a certain level of codes that	
13	aren't documented in a medical	
14	record").	
15	66. Instead, when CMS uses its own	
16	data to calculate the average	
17	incremental relative cost of having a	
18	particular condition, it assumes that	
19	every diagnosis code in its claims data	
20	represents an individual who actually	
21	has the condition in question. <i>See</i>	
22	Schindler Decl. Ex. 17, Pope et al.,	
23	Risk Adjustment of Medicare	
24	Capitation Payments Using the CMS-	
25	HCC Model, at AR11867, <i>Health Care</i>	
26	<i>Financing Review</i> , 25(4) (Summer	
27	2004); Schindler Decl. Ex. 18, 2010	
28	RADV Rule, at AR2826.	
	67. The existence of these "zero	
	cost" conditions affects the overall	
	average, incremental risk coefficient	
	that the model calculates for that	
	particular condition. <i>See</i> Schindler	
	Decl. Ex. 7, May Grant Dep. at 229:3-	
	231:15 (Q: "Mr. Grant, is that sort of	
	what the purpose is of slide 2? You're	
	referencing a healthy personal	
	mistakenly coded as sick and then	
	assigning the relative cost to that	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	individual?" . . . "A. Yes. So this is	
5	again, with the God-like power to	
6	know everybody's cost, I know that	
7	these healthy people coded as sick cost	
8	the same as all the other healthy people	
9	and I magically already know they all	
10	cost \$500, an unknowable fact when	
11	running a risk adjustment calibration,	
12	but in this world I've created I know	
13	this. And so I have two people thrown	
14	into the sick category from a coding	
15	perspective, but from a cost perspective	
16	appropriately residing in the healthy	
17	category . . . And as you see from this -	
18	- and this is only -- by the way, it's a	
19	one-directional look at this, I will point	
20	out too, just looking at the incorrect	
21	coding, not going the other direction.	
22	The incorrectly -- incorrectly coded as	
23	sick, not healthy, incorrectly coded as	
24	healthy. It's not a robust presentation	
25	that has both sides. It's a one sided --	
26	. . . And then we just walk through it	
27	and say we haven't thrown any sick	
28	people into the healthy category	
	erroneously, so healthy people still cost	
	500 bucks apiece. But by virtue [sic]	
	adding two healthy people into the sick	
	population, you lower the perceived	
	average cost of the sick population....	
	Q: "So what is the principle that you're	
	illustrating with this example?" A:	
	"That if there is a pattern of	
	overreporting of diagnosis codes in fee	
	for service, then that pattern would	
	result in a underprediction of the	
	disease-related factors in the	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	model")	
5	68. CMS's own Division of Payment	
6	Validation used a simplified	
7	hypothetical to explain this concept	
8	internally to senior CMS leaders. In	
9	the slide presentation attached as	
10	Schindler Decl. Ex. 15, they	
11	hypothesized a scenario in which,	
12	when calibrating the CMS-HCC model,	
13	CMS identifies four FFS beneficiaries	
14	with the diagnosis code for diabetes	
15	and determines that the aggregate	
16	incremental healthcare costs for the	
17	four beneficiaries the following year	
18	were \$12,000. <i>Id.</i> at CMS0005888. In	
19	that scenario, CMS would conclude	
20	that the average per-patient cost	
21	associated with diabetes is \$3,000, and	
22	it would set the diabetes risk coefficient	
23	accordingly. <i>Id.</i> But, the presentation	
24	explained, suppose further that one of	
25	these diagnosis codes was a false	
26	positive; the beneficiary did not in fact	
27	have diabetes. That means that the	
28	\$12,000 was in reality attributable to	
	just three beneficiaries, such that the	
	true per-patient cost of diabetes was	
	actually \$4,000 ($\$12,000 \div 3$	
	beneficiaries). <i>Id.</i> at CMS0005888-89.	
	By averaging the cost over the four	
	beneficiaries with the diagnosis code,	
	rather than just the three beneficiaries	
	who actually have diabetes, CMS's	
	model produces a lower average	
	incremental cost (and associated risk	
	coefficient) than it would have done if	
	the diagnosis codes in the FFS data had	

UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
been perfectly accurate. As the CMS presentation put it, "Inclusion of undocumented diagnoses [in the FFS data] tends to reduce risk adjustment values." <i>Id.</i> at CMS0005888.	
69. Jeffrey Grant, one of CMS's risk adjustment experts, used a similar hypothetical when explaining to senior CMS officials that "Plans must submit like FFS to be paid full costs of sick population." Schindler Decl. Ex. 19, PowerPoint Presentation at 3, produced by UnitedHealth at USBP000011428; <i>see also</i> Schindler Decl. Ex. 20, Email from Jeffrey Grant to Thomas E. Hutchison dated May 29, 2009, produced at USBP000011424, attaching Schindler Decl. Ex. 19.	
70. In addition to recognizing the impact of coding discrepancies on payment rates internally, CMS also orally instructed MA plans that "if they stuck to how the data comes in to FFS, they would be paid correctly." Schindler Decl. Ex. 20 at USBP000011426 ("Plans were told that if they stuck to how the data comes in to FFS, they would be paid correctly."); Schindler Decl. Ex. 7, May Grant Dep. at 207:20-208:17 (testifying that CMS provided oral instructions to MA plans stating that "if they submitted data like fee for service, they would be paid equivalent to the calibration.")	
B. Additional Material Facts Establishing CMS Recognition Of The Need	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	To Assess MA Plans' Diagnosis Codes In Light Of The Codes Submitted In	
5	Traditional Medicare	
6	<i>1. The Coding Intensity Adjustment</i>	
7	71. Because MA risk adjustment is	
8	based on diagnosis codes, MA plans	
9	have an incentive "to find and report as	
10	many diagnoses as can be supported by	
11	the medical record"—to code with high	
12	"intensity." Schindler Decl. Ex. 5,	
13	Kronick & Welch, <i>supra</i> , at E3-E4.	
14	72. By contrast, reimbursement	
15	under traditional FFS Medicare	
16	generally is not tied to diagnoses, so	
17	the incentive for comprehensive coding	
18	is weaker. <i>See id.</i> at E3.	
19	73. MA plans therefore arrange for	
20	"chart reviews" to look for diagnoses	
21	documented in their beneficiaries'	
22	charts that a provider failed to code in	
23	claims data.	
24	74. CMS has long known that MA	
25	plans engage in chart review activities	
26	and, in effect, code more completely.	
27	<i>See, e.g.,</i> Schindler Decl. Ex. 21, 2009	
28	Advance Notice at AR004229-31	
	("CMS understands that MA plans	
	have made efforts to identify enrollees'	
	conditions and may be coding more	
	completely than FFS.")	
	75. Although CMS officials have	
	recognized that this is "an appropriate	
	activity for MA plans to engage in,"	
	<i>see, e.g.,</i> Schindler Decl. Ex. 7, May	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	Grant Dep. at 163:14-18, CMS also	
5	recognized that the divergent financial	
6	incentives between MA and traditional	
7	Medicare can lead to different coding	
8	patterns that affect risk adjustment	
9	payments.	
10	76. Medicare experts have long	
11	recognized that "for the purposes of	
12	creating an equitable MA payment	
13	system, the relevant question is	
14	whether MA risk scores are	
15	systematically different than those risk	
16	scores would be in FFS, and not which	
17	set of scores is more accurate" in an	
18	absolute sense. Schindler Decl. Ex. 5,	
19	Kronick & Welch, at E4 (emphasis	
20	added); Schindler Decl. Ex. 7, May	
21	Grant Dep. at 174:21 – 175:8 ("[T]hey	
22	are using accuracy not to talk about	
23	whether any specific diagnosis code in	
24	fee-for-services or managed care is	
25	accurate. It is to compare – to have	
26	comparable diagnoses. So it is	
27	accuracy of risk adjustment, really, not	
28	accuracy of coding . . . when they say	
	"inaccurate" they are not referring to	
	the accuracy or inaccuracy of any	
	specific code on any specific claim or	
	any specific RAP submission. They're	
	talking about comparable types of	
	data."); <i>id.</i> at 182:6-8 ("[T]he	
	definition of accuracy here," is that MA	
	plans "would be paid consistently with	
	how the model is calibrated.")	
	77. Congress understands this, too,	
	and in 2006 it instructed CMS to	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	analyze any “ <i>differences</i> in coding	
5	patterns between Medicare Advantage	
6	plans and providers under part A and B	
7	[i.e., traditional FFS Medicare].”	
8	Schindler Decl. Ex. 22, Pub. L. No.	
9	109-171, § 5301(b)(2), 120 Stat. 4, 51	
10	(2006) (emphasis added).	
11	78. Congress further said that, “to	
12	ensure payment accuracy,” CMS	
13	should adjust MA beneficiaries’ risk	
14	scores in light of those different coding	
15	patterns. <i>Id.</i>	
16	79. As recognized by the United	
17	States Government Accountability	
18	Office (“GAO”): “Risk scores for	
19	beneficiaries with the same diagnoses	
20	and characteristics should be identical,	
21	regardless of whether the beneficiaries	
22	are in an MA plan or Medicare FFS.”	
23	Schindler Decl. Ex. 2, GAO,	
24	<i>Substantial Excess Payments</i>	
25	<i>Underscore Need for CMS to Improve</i>	
26	<i>Accuracy of Risk Score Adjustments</i> , at	
27	AR012043; <i>see also</i> Schindler Decl.	
28	Ex. 6, March Grant Dep. at 117:7-18	
	(agreeing with this statement).	
	80. In other words, “the implicit	
	assumption in the design of the MA	
	payment system” is that if “Jane Doe	
	would have a risk score of 1.0 if she	
	were in FFS,” then “she would have	
	had the same risk score of 1.0 if she	
	were enrolled in MA.” Schindler Decl.	
	Ex. 5, Kronick & Welch, at E4; <i>See</i>	
	<i>also</i> Schindler Decl. Ex. 6, March	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	Grant Dep. at 122:2-23 (agreeing with this statement).	
5	81. Requiring MA plans to delete	
6	diagnosis codes that are unsupported	
7	even though CMS does not do the same	
8	for its FFS population would violate	
9	this fundamental risk adjustment	
10	requirement: it would result in an MA	
11	beneficiary having a lower risk score	
12	than an identical FFS beneficiary,	
13	resulting in a lower payment. <i>See,</i>	
14	<i>generally</i> , Schindler Decl. Ex. 19,	
15	USBP000011428 at 3 ("Plans must submit like FFS to be paid full costs of sick populations"); <i>see also</i> Schindler Decl. Ex. 7, May Grant Dep. at 274:22- 277:16	
16	82. CMS began imposing a	
17	downward adjustment to MA plans'	
18	risk scores in 2010, calculated to	
19	replicate the risk score-adjusted	
20	payments that would have resulted had	
21	plans not engaged in different coding activities. Schindler Decl. Ex. 1, 2010 Rate Announcement, at AR4334.	
22	83. CMS explained that, because the	
23	risk adjustment model is calibrated on FFS data,	
24	MA plans must code the way	
25	Medicare Part A and B providers do	
26	in order for risk adjustments to be	
27	valid. This means that MA	
28	<i>organizations are coding</i> <i>"accurately" when they are coding</i>	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	<i>in a manner similar to fee-for-</i>	
5	<i>service coding used on the</i>	
6	<i>beneficiaries to whom MA plan</i>	
7	<i>enrollees are being compared. In</i>	
8	<i>this sense, "differences" in coding</i>	
9	<i>patterns, regardless of the source,</i>	
10	<i>would make the MA plan coding</i>	
11	<i>"inaccurate" for purposes of</i>	
12	<i>implementing risk adjustment.</i>	
13	<i>Id. at AR4335 (emphases added).</i>	
14	84. CMS noted that several members	
15	of Congress had expressly recognized	
16	this relative notion of accuracy.	
17	Senator Grassley, for instance, had	
18	explained that the intensity adjustment	
19	provision was intended to address	
20	"coding that is inaccurate or	
21	incomplete for the purpose of	
22	establishing risk scores that are	
23	consistent across both fee-for-service	
24	and Medicare Advantage settings, even	
25	if such coding is accurate or complete	
26	for other purposes." <i>Id. at AR4336.</i>	
27	85. CMS has applied the Coding	
28	Intensity Adjustment in every year	
	since 2010. 42 U.S.C. § 1395w-	
	23(a)(1)(C)(ii).	
	86. CMS has never found that higher	
	MA coding intensity reflects the	
	inclusion of codes unsupported by	
	medical records; to the contrary, it has	
	said the data "fail[] to show a	
	systematic correlation between coding	
	pattern differences and errors in the	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	reporting of documented coding.”	
5	Schindler Decl. Ex. 1, 2010 Rate	
6	Announcement, at AR4337.	
7	87. Nevertheless, CMS continues to	
8	recognize that “to ensure payment	
9	accuracy,” it must account for	
10	“differential coding patterns in MA and	
11	FFS.” Schindler Decl. Ex. 23, 2014	
12	Rate Announcement, at AR4865.	
13	88. Each year, CMS reduces by a	
14	certain percentage the risk adjustment	
15	payments that an MA plan would	
16	otherwise have received based on the	
17	diagnosis codes it had submitted, in	
18	order to account for the MA plans’	
19	more complete coding. In 2017, for	
20	example, United expects that CMS will	
21	reduce its payment to United by	
22	approximately \$2.9 billion through its	
23	application of the Coding Intensity	
24	Adjustment. See Schindler Decl. Ex.	
25	24, Declaration of Mary Murley ¶ 9	
26	(July 23, 2018).	
27	89. CMS has found that “our	
28	methodology results in an accurate	
	measure of the coding differential	
	between FFS and MA.” Schindler	
	Decl. Ex. 25, 2013 Rate	
	Announcement, at AR4712.	
	90. Jeffrey Grant, one of only two	
	CMS officials deposed in this case to	
	date, testified that assuming the coding	
	intensity adjustment fully offsets any	
	activities that the plan undertakes to	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	code more completely, an MA plan	
5	would be <i>underpaid</i> if it were to audit	
6	just 25 percent of its members' charts	
7	(or even fewer) and delete any	
8	unsupported codes it found, while	
9	CMS continued its policy of not	
10	deleting such codes in the FFS data that	
11	it uses to calibrate its model. <i>See</i>	
12	Schindler Decl. Ex. 7, May Grant Dep.	
13	at 274:22-277:22 (Q: "Well, I want you	
14	now to assume, sir, in this hypothetical	
15	world that the coding intensity adjuster	
16	that we talked about earlier, I want you	
17	to assume that it fully offsets any	
18	activities that the plan undertakes to	
19	code more completely, chart reviews,	
20	home visits, whatever, but they're	
21	completely offset by the coding	
22	intensity adjuster. If the plan were to	
23	submit only the codes of people who	
24	are truly sick, to use your presentation	
25	example [Exhibit 1017], then that plan	
26	would be <i>underpaid</i> ." A: "In a	
27	hypothetical word that you are	
28	creating . . . in that world, in theory,	
	yes . . ." Q: "Mr. Grant, I want you to	
	again assume that the coding intensity	
	adjuster fully offsets all the activities	
	that a plan might undertake to code	
	more fully. I also want you to assume	
	that a plan audits every one of its charts	
	and deletes every unsupported code.	
	The problem that you highlight in your	
	slide presentation, Exhibit 1017, would	
	still exist in that scenario?" A: "In my	
	opinion, if you could have that	
	scenario, yes." Q: "The problem	

UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
would still exist?" A: "The problem would still exist if you have that scenario." Q: "Okay. Now I'd like to change the assumption slightly. Once again, the coding intensity adjuster fully offsets all activities that the plan undertakes that code more fully, but now the plan audits 50 percent of a chart, of its charts, and deletes the unsupported codes in that set. Would the problem still exist?" A: "Okay, we have multiple assumptions right? So we have the assumption that overcoding is the bias in the data. We have the assumption of perfect adjustment for plan coding activities. To a degree, it exists. It exists to a smaller amount." Q: "Same assumption regarding the coding intensity adjuster, but now the plan is auditing 25 percent of its charts and deleting the unsupported codes. Does the problem still exist? . . . " A: "Again, assumption of overcoding, endemic in fee for service, and assumption of plan – plan coding activities being 100 percent offset in theory it exists to the degree that diagnosis codes are deleted.")	
91. United performed chart reviews that covered significantly more than 25 percent of United's beneficiaries in 2009-2017. Schindler Decl. Ex. 52, Declaration of Jon Bird ¶ 6 (July 23, 2018).	

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	92. Jeffrey Grant also testified that in his view he did not believe it was “improper” or “fraud” for a plan to perform one-way reviews that add additional diagnosis codes supported in the charts, without looking at whether previously submitted coded lack such support. Schindler Decl. Ex. 7, May Grant Dep. at 307:11-310:16 (Q: “Mr. Grant, I believe you testified earlier there was at least one plan for which you recall HRP performed a chart review while you were there; is this correct?” A: “Well there’s . . . more than one plan that we performed chart reviews for, yes.” Q: “Yeah. For the purpose of adding codes, you recall at least one plan?” A: “Yes.” Q: “And do you recall the identity of the plan?” A: “I do.” Q: “Okay. What is the identity?” A: “It was Coventry.” Q: “And in connection with that project, were you the relationship manager with Coventry?” A: “I was the overall relationship manager for Coventry, like all clients . . .” Q: “Is it fair to say that you were involved in that engagement?” A: “Right. And I oversaw all of our client engagements. I was the senior vice president for client services. I had client services that did the day-to-day for any client, and then if it was a special project that involved special skills, we might have people that were further managing the relationship with respect to that skill set because it required specialized	
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1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	skill.” Q: “Understood. The one	
5	instance in which you recalled in which	
6	there were review of charts to add	
7	codes, do you recall whether there were	
8	any efforts to reconcile those codes	
9	against previously submitted claims	
10	data?” A: “So from a coding	
11	perspective, we did totally blind	
12	coding, so the coders had no idea what	
13	was previously submitted. We did	
14	have the capacity not to duplicate	
15	submit [sic] diagnoses. We weren’t	
16	going one for one and trying to look at	
17	claims data and see if every claim was	
18	one-for-one backed by a diagnosis on	
19	that date.” Q: “As part of this effort,	
20	did HRP compare the codes identified	
21	in the blind coding effort against the	
22	claims data that was submitted by	
23	providers and delete codes that HRP’s	
24	coders did not identify?” . . . A: “I’m	
25	not sure. I believe we may have done –	
26	not systematically, not on a large-scale	
27	basis, but I believe there were cases	
28	where we did.” Q: “And at that time,	
	did you have a belief that not engaging	
	in such a systematic effort was	
	improper?” . . . A: “At that time, no.”	
	Q: “Okay. At that time, did you think it	
	was fraud?” A: “No, I did not	
	knowingly participate in [a] fraudulent	
	activity [laughter].” ⁸	

⁸ The prepared transcript of Mr. Grant’s deposition states: “No, I did not knowingly participate in the fraudulent activity.” United believes the transcript contains an error: Mr. Grant’s oral testimony on this issue did not contain the word “the” in describing “fraudulent activity.” Instead United understands Mr. Grant testified “I did not knowingly participate in a fraudulent

1 UNITED'S ADDITIONAL 2 MATERIAL FACTS AND 3 SUPPORTING EVIDENCE:	
4 93. Mr. Grant explained that in his 5 view, an MA plan's submission of an 6 unsupported code would be improper 7 only if it was making the "very specific 8 submission of a very specific data 9 element ... that [it] know[s] is 10 wrong.") <i>See id.</i> at 321:21-23.	
11 2. The RADV FFS Adjuster	
12 94. The purpose of Risk Adjustment 13 Data Validation ("RADV") audits is to 14 recover "overpayments." <i>See</i> Schindler 15 Decl. Ex. 18, 2010 RADV Rule, at 16 AR2819 ("Under the RADV audit 17 process we plan to recover the 18 overpayments identified during the 19 RADV audit.") (emphasis added).	
20 95. When CMS initiates a RADV 21 audit for a plan, it selects a sample of 22 the plan's enrollees for the audited 23 year, collects those enrollees' medical	

24 activity." On July 21, 2018, United requested that the court reporter review the video and revise the transcript to correct the error. The court reporter, however, declined to do so. United respectfully disagrees with the court reporter's decision not to revise the transcript. Prior to this statement and based on his experience at Health Risk Partners ("HRP")—a company Mr. Grant described as akin to "a risk adjustment support company" and where Mr. Grant worked from 2008-2010, Schindler Decl. Ex. 6, March Grant Dep. at 27:4-9—Mr. Grant testified that when HRP performed chart reviews for at least one MA plan whose relationship Grant managed, HRP did not engage in a systematic effort to compare the codes identified during chart review against the claims data submitted by providers and delete codes that HRP's coders did not identify. Mr. Grant further testified that he did not find this improper, which United believes implies he did not think it was fraudulent. Mr. Grant was not discussing a specific fraudulent incident. United therefore believes that Mr. Grant's oral testimony only makes sense given the context if he testified that he "did not knowingly participate in a fraudulent activity." For the Court's convenience and determination, United is submitting excerpts of Mr. Grant's video-taped deposition testimony at Schindler Decl. Ex. 59.

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	records, and then assesses whether	
5	those records adequately support the	
6	enrollees' diagnosis codes. Schindler	
7	Decl. Ex. 26, Final RADV	
8	Methodology, at AR5312-13.	
9	96. In 2008, CMS announced that it	
10	would eventually start using its RADV	
11	audit findings to make "plan-level	
12	payment adjustments," meaning that it	
13	would extrapolate the results from the	
14	audited sample of the plan's	
15	beneficiaries to all of a plan's enrollees	
16	producing payment adjustment for the	
17	plan's entire contract with CMS.	
18	Schindler Decl. Ex. 43, Announcement	
19	of CY 2009 Parts C and D Rates and	
20	Policies, at 22 (Apr. 7, 2008).	
21	97. MA plans objected, and by 2010,	
22	CMS acknowledged a possible	
23	problem with defining	
24	"overpayment[s]" to include all	
25	payments resulting from unsupported	
26	diagnosis codes submitted by MA	
27	plans—namely, that the FFS data used	
28	to calibrate the risk adjustment model	
	contained coding discrepancies of its	
	own, meaning that MA payment	
	amounts already accounted for the	
	existence of some unsupported codes.	
	<i>See</i> Schindler Decl. Ex. 18, 2010	
	RADV Rule, at AR2826.	
	98. As commenters pointed out,	
	CMS needed to assess the discrepancy	
	rate in the FFS data and compare it to	
	the discrepancy rate of a given MA	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	plan before it could determine whether	
5	the plan had been overpaid. <i>See, e.g.,</i>	
6	Schindler Decl. Ex. 27, Public	
7	Comments of Aetna on the Proposed	
8	2009 RADV Rule at AR2627;	
9	Schindler Decl. Ex. 28, Public	
10	Comments of AHIP on the Proposed	
11	2009 RADV Rule at AR2744-45.	
12	99. Jeffrey Grant made this same	
13	point to CMS officials in 2009, while	
14	working at Health Risk Partners. <i>See</i>	
15	Schindler Decl. Ex. 19,	
16	USBP000011428 at 3 ("Plans must	
17	submit like FFS to be paid full costs of	
18	sick populations).	
19	100. CMS acknowledged that there	
20	was "potential merit" in this concern	
21	and said it was "currently studying this	
22	issue." Schindler Decl. Ex. 18, 2010	
23	RADV Rule, at AR2826.	
24	101. The issue received intensified	
25	scrutiny after CMS proposed a RADV	
26	sampling and adjustment-calculation	
27	methodology that did not account for	
28	unsupported FFS codes. Schindler	
	Decl. Ex. 29, Proposed RADV	
	Methodology, at AR5020-22.	
	102. Numerous commenters pointed	
	out that this omission was a serious	
	flaw. <i>See, e.g.,</i> Schindler Decl. Ex. 30,	
	Public Comments of Aetna on the	
	Proposed RADV Methodology, at	
	AR5053-57; Schindler Decl. Ex. 31,	
	Public Comments of Humana on the	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	Proposed RADV Methodology, at	
5	AR5105-08; Schindler Decl. Ex. 32,	
6	Public Comments of United on the	
7	Proposed RADV Methodology, at	
8	AR5205-07.	
9	103. Among them was the American	
10	Academy of Actuaries, which stated	
11	that it was inappropriate to develop risk	
12	coefficients "with FFS data that ...	
13	were not validated or audited for	
14	accuracy" but then "apply those factors	
15	only to MA data that are validated."	
16	Schindler Decl. Ex. 33, Public	
17	Comments of the American Academy	
18	of Actuaries on the Proposed RADV	
19	Methodology, at AR5235-36. Doing so,	
20	it said, could result in "systematic	
21	underpayment." <i>Id.</i> at AR5236.	
22	104. Multiple commenters also noted	
23	that this approach would violate the	
24	statutory requirement that risk	
25	adjustment ensure "actuarial	
26	equivalence." <i>See, e.g.,</i> Schindler	
27	Decl. Ex. 30, Public Comments of	
28	Aetna at AR5053-54; Schindler Decl.	
	Ex. 31, Public Comments of Humana,	
	at AR5114 (Humana); see also 42	
	U.S.C. § 1395w-23(a)(1)(C)(i).	
	105. CMS officials acknowledged	
	that the commenters were right, stating	
	in internal CMS documents:	
	"The industry has argued that in	
	the RADV audits we are holding	
	them to a standard of perfection	
	for diagnosis coding but that	

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	physician claims in FFS	
5	Medicare often include	
6	diagnoses that aren't supported	
7	in the medical record. And this	
8	wouldn't matter except that we	
9	use FFS claims data to develop	
10	our risk adjusters for Medicare	
11	Advantage. So when we estimate	
12	the relative cost of any given	
13	condition, we use diagnosis and	
14	cost data from FFS Medicare. So	
15	implicit in all of the adjustments	
16	we make to plans payments to	
17	account for the relative risk of	
18	their populations, are the factors	
19	that we developed using FFS	
20	data. ... [f]or our payments to	
21	be as accurate as possible, we	
22	should be using the same	
23	standard for both... To answer	
24	this issue, we can incorporate a	
25	FFS adjuster that estimates how	
26	much higher the plans payment	
27	would be if the model had been	
28	built using perfect data. This	
	factor would reduce the	
	estimated RADV overpayments	
	due from each plan. We think	
	this approach makes sense and	
	from a technical point of view	
	is the right thing to do.")	
	Schindler Decl. Ex. 16, FOIA	
	Agenda, at CMS0006200-01	
	(emphasis added).	
	106. When CMS published a revised	
	RADV methodology in February 2012,	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	it said that in determining any contract-	
5	level payment adjustments, it would	
6	apply a "FFS adjuster." Schindler	
7	Decl. Ex. 26, Final RADV	
8	Methodology, at AR5314.	
9	107. CMS explained that "[t]he FFS	
10	adjuster" would "account[] for the fact	
11	that the documentation standard used in	
12	RADV audits to determine [an MA]	
13	contract's payment error (medical	
14	records) is different from the	
15	documentation standard used to	
16	develop the Part C risk-adjustment	
17	model (FFS claims)." <i>Id.</i> at AR5314-	
18	15.	
19	108. If the effect of the unsupported	
20	codes in CMS's data is greater than or	
21	equal to the effect of the unsupported	
22	codes in the plan's data, the audit will	
23	conclude with a finding that there has	
24	been no overpayment such that "the	
25	final recovery amount is equal to zero."	
26	<i>Id.</i> at AR5314.	
27	109. CMS stated that the "amount of	
28	the adjuster" would "be calculated by	
	CMS based on a RADV-like review of	
	records submitted to support FFS	
	claims data." <i>Id.</i> at AR5315.	
	110. CMS has not yet published a	
	FFS adjuster or the FFS payment error	
	rate, despite publishing the relevant	
	methodology over six years ago. <i>See</i>	
	<i>Id.</i> at AR5314.	
	C. Additional Material Facts Establishing the Link Between This Motion	

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	and United's Pending Administrative Challenges To The Government's Current Overpayment Theory	
5	111. In 2014, in connection with CMS's proposal of regulations about the "Reporting and returning of overpayments," multiple MA plans urged CMS to make explicit in its overpayment regulation the point that it had already recognized in its audit regulation: That "an overpayment cannot exist for an MA organization's particular contract unless CMS's payments to the [plan] as a whole are inaccurate in light of an appropriate Fee-for-Service Adjuster that is applied to the entire contract." Schindler Decl. Ex. 34, Public Comments of Humana on the Overpayment Rule, at AR907.	
16	112. United explained to the agency that, "[u]nder the Proposed Rule, [MA plans] will be undercompensated for the relative risk of their membership if they delete diagnosis codes from claims that are unsupported in a medical record and CMS does not simultaneously account for the equivalent diagnoses in FFS data." Schindler Decl. Ex. 35, Public Comments of United on the Overpayment Rule, at AR1041.	
25	113. CMS refused, announcing in its final rule (known as the "Overpayment Rule") that any undocumented diagnosis code would result in an overpayment to an MA plan: "[A] risk adjustment diagnosis that has been	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	submitted for payment but is found to	
5	be invalid because it does not have	
6	supporting medical record	
7	documentation would result in an	
8	overpayment," regardless of the errors	
9	in the agency's own FFS data.	
10	Schindler Decl. Ex. 36, Overpayment	
11	Rule, at AR1313.	
12		
13	114. The agency made no attempt to	
14	reconcile that view with its prior	
15	recognition of the need for a FFS	
16	adjuster when identifying	
17	overpayments through RADV audits.	
18	Instead, it argued that MA plans'	
19	contracts with CMS required them to	
20	"certify (based on best knowledge,	
21	information, and belief) the accuracy,	
22	completeness, and truthfulness of the	
23	risk adjustment data they submit to	
24	CMS." <i>Id.</i> ; see 42 C.F.R. § 422.504(l).	
25	It also asserted that the agency had a	
26	"long-standing risk adjustment data	
27	requirement that a diagnosis submitted	
28	to CMS by an MA organization for	
	payment purposes must be supported	
	by medical record documentation."	
	Schindler Decl. Ex. 36, Overpayment	
	Rule, at AR1314-15.	
	115. United subsequently brought an	
	Administrative Procedure Act suit	
	challenging the Overpayment Rule in	
	the U.S. District Court for the District	
	of Columbia. United has argued there	
	that unless CMS implements a	
	mechanism to account for unsupported	
	diagnosis codes in CMS's own FFS	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	data, requiring MA plans to delete	
5	unsupported codes in their provider-	
6	submitted data would violate CMS's	
7	statutory obligation under 42 U.S.C.	
8	§ 1395w-23(a)(1)(C)(i) to "ensure	
9	actuarial equivalence" between the MA	
10	and traditional Medicare programs.	
11	<i>See</i> Schindler Decl. Ex. 37, APA	
12	United Opening Br. at 8 (ECF 47-1).	
13	116. In addition, United has argued	
14	that requiring deletions by MA plans	
15	without comparable adjustments in the	
16	FFS data would violate CMS's	
17	statutory obligation to "us[e] the same	
18	methodology" when calculating risk	
19	scores of patients in the traditional	
20	Medicare program that it "expect[s] to	
21	be applied in making payments to MA	
22	plans. 42 U.S.C. § 1395w-23(b)(4).	
23	<i>See</i> Schindler Decl. Ex. 37, APA	
24	United Opening Br.	
25	117. In response, CMS has argued	
26	that the Overpayment Rule does not	
27	present a proper opportunity to	
28	challenge its present view that every	
	unsupported diagnosis code submitted	
	by an MA plan results in an	
	overpayment and must therefore be	
	deleted. Schindler Decl., Ex. 40, APA	
	CMS Reply Br., at 5-9 (ECF 64).	
	118. Relying on the same contractual,	
	regulatory, and sub-regulatory	
	provisions the government has invoked	
	here, CMS has argued there that MA	
	plans have long been required to delete	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	all unsupported codes they identified,	
5	and that the Overpayment Rule	
6	therefore changed nothing. <i>Id.</i>	
7	119. United has argued in turn that	
8	the contracts, manuals, and regulations	
9	are at best ambiguous, that they can	
10	and should be read in a manner	
11	consistent with CMS's adoption of a	
12	FFS Adjuster, and that if they are not	
13	read that way—and instead read to	
14	require deletion of all unsupported	
15	codes in MA data without any	
16	adjustment for the FFS data—then the	
17	provisions at issue would be unlawful	
18	in light of the statutory provisions	
19	discussed above. Schindler Decl. Ex.	
20	39, APA United Resp. Br., at 28-39	
21	(ECF 60).	
22	120. The parties completed summary	
23	judgment briefing in February (totaling	
24	over 200 pages), and Judge Collyer has	
25	scheduled argument for August 8,	
26	2018.	
27	D. Additional Material Facts Demonstrating that CMS Communicated to	
28	United that Two-Way Looks Were Not Required	
	121. Given the “volume and variety”	
	of diagnosis codes, CMS has	
	recognized that the presence of at least	
	some unsupported codes is	
	“inevitable.” Schindler Decl. Ex. 41,	
	2001 Medicare Managed Care Manual	
	§ 110.2, at AR5349.	
	122. In 2014, CMS considered and	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	then affirmatively decided not to	
5	finalize a proposed rule that would	
6	have prohibited MA organizations from	
7	performing reviews that only looked	
8	for additional diagnosis codes (known	
9	as "one-way" reviews). <i>See</i> Schindler	
10	Decl. Ex. 42, 79 Fed Reg 1918, 2000	
11	(January 10, 2014) (proposed medical	
12	record review rule); Schindler Decl.	
13	Ex. 36, 79 Fed Reg 29844, 29926 (May	
14	23, 2014) (finalized rule without	
15	medical record review component).	
16	123. During conversations between	
17	United and CMS over the course of the	
18	spring and early summer of 2014, CMS	
19	confirmed multiple times that "two-	
20	way" looks were not required. <i>See</i>	
21	Schindler Decl. Ex. 44, Deposition of	
22	Larry Renfro at 134:1 – 137:6 (May 6,	
23	2016) ("Renfro Dep.") (describing a	
24	conversation between Larry Renfro, the	
25	CEO of Optum, and then-Deputy	
26	Administrator of CMS Jonathan	
27	Blum); Renfro Dep. at 150:21 – 151:10	
28	(describing a telephone conversation	
	between Mr. Renfro and Marilyn	
	Tavener, then-Administrator of CMS,	
	on April 8, 2014); Schindler Decl. Ex.	
	45, MARA2160500 (reflecting the	
	same April 8, 2014 conversation	
	between Ms. Tavener and Mr. Renfro	
	regarding the implications of the	
	proposed rule); Schindler Decl. Ex. 46,	
	MARA1998459 (coordinating by email	
	an in-person meeting between senior	
	officials at CMS and United regarding	
	United's obligations in light of the	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	proposed medical record review rule);	
5	Schindler Decl. Ex. 47,	
6	MARA2157039 (T. Johnson notes	
7	from April 29, 2014 meeting between	
8	United and CMS officials).	
9	124. Specifically, in March 2014,	
10	Deputy Administrator of CMS	
11	Jonathan Blum told Larry Renfro, CEO	
12	of Optum (a United affiliate), that	
13	unless and until CMS adopted a	
14	regulation requiring MA plans to use	
15	their chart reviews to look both ways,	
16	there was no obligation for plans to do	
17	so. Schindler Decl. Ex. 44, Renfro	
18	Dep. at 134:1 – 137:6 (including	
19	testimony by Mr. Renfro that Mr. Blum	
20	“told me that at this point [the proposed	
21	rule]’s not in effect. As a result of not	
22	being in effect, we shouldn’t be doing	
23	it,” referring to United’s claims	
24	verification program).	
25	125. CMS Administrator Marilyn	
26	Tavener told Mr. Renfro the same	
27	thing in a subsequent telephone	
28	conversation. <i>See id.</i> at 150:21 –	
	151:10; 160:9 – 163:17 (including	
	testimony by Mr. Renfro paraphrasing	
	Ms. Tavener’s telling him that “If the	
	proposed rule goes into effect January	
	1, 2015, [United] should be doing	
	normal business, which means [United]	
	d[id] not have to be doing claims	
	verification”); <i>see also</i> Schindler Decl.	
	Ex. 45, MARA2160500 (reflecting the	
	same April 8, 2014 conversation	
	between Ms. Tavener and Mr. Renfro	

1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	regarding the implications of the	
5	proposed rule).	
6	126. On April 29, 2014, UnitedHealth	
7	sent four executives to meet with no	
8	fewer than five top officials from CMS:	
9	the new Deputy Administrator and	
10	Director of the Center for Medicare,	
11	Sean Cavanaugh; the Director of the	
12	Medicare Plan Payment Group, Cheri	
13	Rice; the Deputy Director of Medicare	
14	Parts C and D, Cynthia Tudor; the	
15	Special Assistant at CMS, Dan Farmer;	
16	and the Director of the Division of	
17	Capitated Plan Audits, Financial	
18	Services Group. Schindler Decl. Ex.	
19	47, MARA2157039 (T. Johnson notes	
20	from April 29, 2014 meeting between	
21	United and CMS officials).	
22	127. As Ms. Tavenner acknowledged	
23	during her deposition, Mr. Renfro set	
24	up this meeting between United and	
25	CMS to obtain clarification regarding	
26	United's obligations in light of the	
27	proposed rule. . See Deposition of	
28	Marilyn B. Tavenner at 126:15-127:10	
	(February 28, 2018) ("Tavenner Dep.")	
	(Q: You testified a moment ago you	
	said "I understand your concern,"	
	okay? What was the concern that you	
	understood Mr. Renfro to be expressing	
	to you? A: It's basically what's written	
	here. He was getting ready to sign an	
	attestation. He was unclear about what	
	to do with the records that he had	
	reviewed, and it didn't really get into as	
	much detail as was in this email, but it	

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	was enough where the proposed rule, the fact that he wanted to sign for validation, he needed an answer. I referred him to the staff. Q: And he needed an answer about whether it was appropriate for United to cease looking for diagnosis codes to delete, correct? MR. FREEBORNE: Objection to form. A: He was looking for an answer about what he was supposed to do with the records he had reviewed, because he wanted to sign the attestation, and he wanted to make sure he did it correctly.”); <i>see also</i> Schindler Decl. Ex. 46, MARA1998459 (coordinating by email an in-person meeting between senior officials at CMS and United to “confirm [United’s] understanding”).	
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16	128. During that meeting, CMS told United that unless and until a proposed rule governing the review of medical records became final, MA plans did not, and do not, have an affirmative obligation to confirm whether diagnosis codes submitted by physicians are supported in the medical records. <i>See</i> Schindler Decl. Ex. 47, MARA2157039 (T. Johnson notes from April 29, 2014 meeting between United and CMS officials, noting that “CMS representatives reiterated that, under CMS regulations, MA plans were not required to design their chart review programs for overall accuracy until the proposed rule is finalized” and that Cheri Rice of CMS stated that “until the proposed rule relating to	
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1	UNITED'S ADDITIONAL	
2	MATERIAL FACTS AND	
3	SUPPORTING EVIDENCE:	
4	medical records review was finalized,	
5	MA plans do not have a proactive	
6	responsibility to confirm whether	
7	diagnoses submitted by physicians are	
8	correct").	
9	129. United MA Plans memorialized	
10	this understanding, including in	
11	subsequent bids and risk adjustment	
12	data attestations they provided to CMS	
13	under the contracts. <i>See, e.g.,</i>	
14	Schindler Decl. Ex. 12,	
15	MARA1296259 (April 30, 2014 email	
16	from S. Nelson to C. Rice (CMS)	
17	regarding 2012 DOS risk adjustment	
18	data attestation, noting that CMS	
19	confirmed "that MA plans are . . . not	
20	currently required to design their	
21	medical record reviews to determine	
22	the accuracy of risk adjustment	
23	diagnoses"); Schindler Decl. Ex. 13,	
24	MARA2152278 (June 26, 2015 email	
25	from S. Nelson to C. Rice regarding	
26	2013 DOS risk adjustment data	
27	attestation, noting "During our	
28	conversations last year before the	
	proposed rule was withdrawn, CMS	
	confirmed to us that the proposed	
	requirements would not apply until the	
	effective date of the rule, and that MA	
	plans were thus not required to design	
	their medical record reviews to	
	determine the accuracy of risk	
	adjustment diagnoses); Schindler Decl.	
	Ex. 20, USBP000498420 (June 7, 2016	
	email from S. Nelson to C. Rice	
	regarding 2014 risk adjustment data	
	attestation, providing similarly);	

UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
Schindler Decl. Ex. 49, MA Supporting Documentation for CY2015 Bid, UHC of California, Inc., Contract No. H0543-001-000, at 8, dated Aug. 5, 2014 (emphasis added) (providing: "We . . . adjusted projected risk scores to account for changes in our medical record review processes. Specifically, <i>based on multiple conversations with CMS and CMS's treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process</i>").	
E. Additional Material Facts Demonstrating That Under the Government's Reading of the Contract, United's Bid Limitations Stating that United Was Not Validating Codes Were Incorporated Into the Contract's Payment Scheme As Well	
130. Article II of the MA contracts incorporates the "final Plan Benefit Package (PBP) bid submission (benefit and price bid proposal as approved by CMS. Rice Decl. Ex. 1, at 6.	
131. CMS requires MAOs to explain the assumptions underlying their bids, provide supporting documentation for their bids, and have an actuary certify that the assumptions are reasonable. <i>See, e.g., Schindler Decl. Ex. 51, Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contracy Year 2014, at 95-110 (Apr. 5, 2013).</i>	

1	UNITED'S ADDITIONAL MATERIAL FACTS AND SUPPORTING EVIDENCE:	
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4	132. Starting at least as early as 2011, United's final Plan Benefit Package each year explicitly stated: "[C]onsistent with our prior year activities ... [a]s part of the preparation of the bids, we did not attempt to validate any actual or projected risk scores through a review of applicable medical records or of the systems used to submit RAF data to CMS." Schindler Decl. Ex. 50, MA Supporting Documentation for CY2012 Bid, Pacificare of California, Inc., Contract No. H0543-007-000, at 5, dated June 5, 2011; <i>see also</i> Schindler Decl. Ex. 49, MA Supporting Documentation for CY2015 Bid, UHC of California, Inc., Contract No. H0543-001-000, at 8, dated Aug. 5, 2014 (stating in 2015 bid submission that "the health plan has decided to cease one of its prior processes that identified and deleted certain diagnosis codes through the medical record review process").	
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20	133. CMS reviewed and approved United's bid submission prior to execution of the final contract. <i>See</i> 42 C.F.R. 422.256(b).	
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1 Dated: July 23, 2018

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EXHIBIT D-4

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

No. CV 16-08697 MWF (SSx)

AMENDED JOINT RULE 26(f)
REPORT

DATE: April 9, 2018
TIME: 11 a.m.
COURTROOM: 5A

The Parties submit this amended Joint Report to the Court regarding the Rule 26(f) conference that counsel for the Parties conducted by telephone on December 8, 2017. At the Rule 26(f) conference, the Parties discussed the topics set forth in Rule 26(f), along with the topics set forth in the Court's February 28, 2018 Order Setting Scheduling Conference. The Parties then submitted a Joint Report on December 22, 2017 (Dkt. No. 191), which this Report updates and supersedes. The Parties' respective positions regarding each topic are set forth in detail below.

A. Statement of the Case

United States and Relator's Position: This is a civil fraud action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, as well as for restitution and common law damages, for monies unlawfully obtained and retained by Defendant UnitedHealth Group, Inc. and various of its direct and indirect subsidiaries ("Defendants") involved in Parts C and D of the Medicare Program.¹ Pursuant to its First Claim for Relief set forth in its First Amended Complaint ("FAC"), filed on November 17, 2017 (Dkt. No. 171), the United States alleges that Defendants violated 31 U.S.C. § 3729(a)(1)(G), known as the "reverse false claims" provision, by knowingly (as "knowingly" is defined by 31 U.S.C. § 3729(b)(1)) concealing or knowingly and improperly avoiding their obligations to repay significant sums of money to the Medicare Program.² Specifically, for over a decade, Defendants have been knowingly concealing and knowingly and improperly avoiding their contractual and regulatory obligations to repay risk adjustment payments to which they were not entitled from the Medicare Program. In particular, Defendants failed

¹ On February 12, 2018, this Court issued an Order granting Defendants' motion to dismiss the United States' Second, Third, and Fourth Claims for Relief under the False Claims Act but denying the motion as to the United States' First, Fifth, and Sixth Claims for Reliefs. (Dkt. No. 212) Accordingly, this statement about the case focuses on the First, Fifth, and Sixth Claims for Relief.

² On May 16, 2017, Plaintiff-Relator Benjamin Poehling filed his Second Amended Complaint (Dkt. No. 117) against Defendants. He is not pursuing any claims beyond those asserted by the United States.

1 to comply with their well-established contractual and regulatory obligations to
2 delete, withdraw, retract, or correct invalid diagnoses submitted by them to the
3 Medicare Program for risk adjustment payments based on the health status of
4 beneficiaries in their Medicare Advantage plans or to otherwise return to the
5 Medicare Program the overpayments based on the invalid diagnoses. On
6 information and belief, Defendants continue to engage in this unlawful conduct.

7 Pursuant to its Fifth Claim for Relief, the United States alleges that, based on
8 the same wrongful conduct, Defendants have been unjustly enriched by receiving
9 risk adjustment payments to which they were not entitled and must make
10 restitution. Pursuant to the Sixth Claim for Relief, the United States seeks to
11 recover the overpayments because they were paid by the United States based on
12 the mistaken belief that Defendants' diagnosis data was valid.

13 The United States' claims relate in part to Defendants' very large national
14 Chart Review Program, which they have conducted annually since 2005. The
15 United States alleges that Defendants systematically ignored the negative results of
16 their chart reviews, *i.e.*, results showing that diagnoses submitted by them for risk
17 adjustment payments were not supported by their beneficiaries' medical records,
18 and failed to comply with their obligations to delete the unsubstantiated diagnoses.
19 The United States Court of Appeals for the Ninth Circuit, in *United States ex rel.*
20 *Swoben v. UnitedHealthcare Ins. Co.*, 848 F.3d 1161, 1175-76 (9th Cir. 2016),
21 held that this type of conduct – turning a blind eye to information about
22 unsupported diagnoses – constitutes reckless disregard and deliberate ignorance
23 toward the truth or falsity of the data submitted to the Medicare Program. On
24 information and belief, Defendants have continued to ignore the negative results of
25 their Chart Review Program and, thus, have continued to avoid repaying the
26 Medicare Program overpayments based on invalid diagnoses. The United States
27 seeks to recover all overpayments due to Defendants' violation of the FCA.

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1 In addition, the United States’ claims relate to Defendants’ disregard of
2 information from their Risk Adjustment Coding Compliance Review (“RACCR”)
3 Program about invalid diagnoses reported to them by their financially-incentivized
4 capitated and gainsharing providers. The United States alleges that Defendants
5 knew that these providers had a financial incentive to report invalid diagnoses to
6 increase risk adjustment payments and, based on the results of the RACCR
7 Program, that the providers actually or likely over-reported diagnoses, but
8 Defendants nonetheless continued to submit diagnoses from these providers and
9 knowingly and improperly avoided repaying Medicare for risk adjustment
10 payments based on invalid diagnoses from these providers.

11 UnitedHealth’s Position: This case arises from the United States’ and
12 Relator’s effort to change the rules governing obligations of Medicare Advantage
13 (“MA”) plans to verify data submitted by third-party healthcare providers. The
14 United States claims that UnitedHealth was obligated to undertake efforts to verify
15 diagnostic data from third-party healthcare providers that the government itself
16 does not undertake with respect to beneficiaries it insures under traditional
17 Medicare. UnitedHealth believes that the United States is seeking to impose
18 obligations that simply did not, and do not, exist. UnitedHealth submitted bids to
19 care for a population of beneficiaries based on a set of statutory and regulatory
20 rules administered by the Centers for Medicare and Medicaid Services (“CMS”).
21 Those rules include CMS’s risk adjustment methodology, which already reduces
22 the amount that UnitedHealth and other MA plans receive in a way that builds in
23 and reflects the existence of unsupported diagnosis codes. In addition, CMS
24 applies a statutory coding intensity adjustor, reducing payments to MA plans, to
25 account for Chart Review activities and other differences in coding patterns
26 between MA plans and CMS FFS data. UnitedHealth has not been overpaid,
27 unjustly enriched, or paid by mistake under those rules; to the contrary, requiring
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UnitedHealth to delete unsupported diagnosis codes would result in UnitedHealth being *underpaid*.

Furthermore, UnitedHealth was transparent with CMS about the extent to which it was reviewing diagnosis codes submitted to it by providers, and CMS officials confirmed it was not required to do so-called “two-way looks” to double-check provider submissions. This suit is a misguided attempt to second guess that CMS guidance and oversight of the MA program, pursuing a windfall for the United States and Relator by forcing UnitedHealth to suffer a loss for playing by the rules CMS originally set up more than a decade after the fact. UnitedHealth has therefore asserted counterclaims for (1) Breach of Contract; (2) Breach of Covenant of Good Faith and Fair Dealing; (3) Fraudulent Inducement; (4) Negligent Misrepresentation; and (5) Promissory Estoppel.

B. Subject Matter Jurisdiction

United States and Relator’s Position: This Court has subject matter jurisdiction over Plaintiffs’ claims pursuant to 28 U.S.C. §§ 1331, 1345, & 1367(a) and 31 U.S.C. § 3732(a)-(b). The Court does not possess subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1367 or Federal Rule of Civil Procedure 13 over Defendants’ counterclaims.

UnitedHealth’s Position: As to the counterclaims, this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1367, as well as Federal Rule of Civil Procedure 13. To the extent jurisdiction is proper under the Complaint, it is also proper under the counterclaims, which arise out of the same transactions and occurrences alleged in the Complaint.

C. Legal Issues

United States and Relator’s Position: Many, if not most, of the key legal issues presented by this case have already been decided by the Ninth Circuit in its opinion in *Swoben*, including that (1) Defendants were not entitled to risk adjustment payments for diagnoses unsubstantiated by their beneficiaries’ medical

1 records, 848 F.3d at 1168 (“Each diagnosis code submitted must be supported by a
2 properly documented medical record”) (citations omitted); (2) Defendants were
3 obligated to exercise due diligence to ensure the validity of the diagnosis data they
4 submitted for risk adjustment payments and to take affirmative steps to address
5 errors in the diagnosis data they submitted for such payments, *id.* at 1174 (“The
6 defendants’ contention that they were under no obligation to take affirmative steps
7 to address errors . . . ignores § 422.503, which since 2005 has required Medicare
8 Advantage organizations to have effective compliance programs in place,
9 including ‘procedures for internal monitoring and auditing’ and for ‘ensuring
10 prompt response to detected offenses’”) (citing 42 C.F.R. § 422.503(b)(4)(vi),
11 (vi)(F), (vi)(G) (2005)); (3) Defendants were obligated to withdraw diagnoses
12 unsupported by their beneficiaries’ medical records, *id.* at 1185 n. 8 (“[I]f a
13 Medicare Advantage organization relied on medical record X to justify submitting
14 a particular diagnosis code to CMS initially, and the retrospective reviewer
15 concludes X does not support that diagnosis, then the code should be withdrawn”);
16 and (4) Defendants acted with actual knowledge that the diagnoses they submitted
17 were false when they withheld known errors from CMS and acted with reckless
18 disregard and deliberate ignorance about the falsity of the data submitted to CMS
19 when they turned a blind eye to the errors and did not withdraw them, *id.* at 1175-
20 76. The Court also rejected Defendants’ argument that, because CMS does not
21 verify diagnoses submitted under different parts of the Medicare Program (which
22 pay providers based on services rendered, not diagnoses submitted), Defendants
23 are entitled to risk adjustment payments based on diagnoses unsubstantiated by
24 their beneficiaries’ medical records. 848 F.3d at 1179 (rejecting this so-called
25 “actuarial equivalence” argument for “multiple reasons”).

26 In addition, in its February 12, 2018 opinion on Defendants’ Motion to
27 Dismiss (“MTD”) (Dkt. No. 212), this Court held that the United States’ FAC
28 adequately and “extensively alleges how central the diagnostic data is to the risk

1 adjustment payments CMS makes to Defendants” and “that the Government’s
2 FAC contains enough factual allegations of the effect of the submission of invalid
3 diagnosis codes on the Government’s risk adjustment payments, and on
4 Defendants’ retention of risk adjustment payment to which they are not entitled, to
5 satisfy the *Escobar* [materiality] standard.” Order on MTD at 19-20. This Court
6 further held that, with respect to the Government’s claims based on the second part
7 of the reverse false claims provision, 31 U.S.C. § 3729(a)(1)(G), “[t]he
8 Government has adequately pled facts showing that the Defendants have
9 knowingly avoided obligations to repay CMS by failing to delete invalid diagnosis
10 codes, and that such failure was material” and that “the issue here is . . . the
11 specific invalid diagnosis codes that Defendants submitted and failed to delete
12 despite information available to them.” *Id.* at 20-21. Accordingly, both the Ninth
13 Circuit and this Court have recognized the direct link between the invalid
14 diagnoses submitted by Defendants and the risk adjusted payments by Medicare.
15 *Swoben*, 848 F.3d at 1167-68 (“diagnoses codes contribute to an enrollee’s risk
16 score, which is used to adjust a base payment rate”); Order on MTD at 15 (“not
17 only do various contractual and regulatory materials require Defendants to submit
18 accurate diagnostic data, but that data is central to the calculation of the amount of
19 money CMS pays to Defendants”). Moreover, the Government believes that,
20 consistent with the Ninth Circuit in *Swoben*, this Court has recognized that
21 Defendants had a legal obligation to repay CMS by deleting invalid diagnosis
22 codes, including diagnoses unsubstantiated by the beneficiaries’ medical records.
23 *Id.*

24 Very recently, on March 23, 2018, Defendants filed an Answer to the FAC.
25 The Answer includes 21 enumerated affirmative defenses, some of which raise
26 new legal and factual issues. For example, Defendants contend that the wrongful
27 conduct alleged in the FAC was the fault of third parties (affirmative defense 19)
28 and that they are “not vicariously liable for the acts alleged in the” FAC

1 (affirmative defense 5), although Defendants also contend that they made a
2 voluntary disclosure to the Department of Justice of their wrongful conduct
3 pursuant to 31 U.S.C. § 3729(a)(2) (affirmative defense 21) and, thus, if they are
4 liable, their liability is limited to only double (not treble) damages. Defendants
5 also contend that the Government failed to mitigate damages (affirmative defense
6 6) although Defendants, in 2012, represented to the Department of Justice that they
7 were developing a program to delete unsubstantiated diagnoses and would do so
8 (FAC ¶ 190) and despite the fact that Defendants never informed CMS about the
9 specific unsubstantiated diagnoses that they failed to delete. *See* Order on MTD at
10 21 (“[G]eneralized knowledge does not amount to actual knowledge of specific
11 invalid diagnoses. Without such actual knowledge, CMS could not know how it
12 should change the risk adjustment payments.”) Other new issues raised by
13 Defendants’ affirmative defenses include, but are not limited to, that the “services
14 and products reimbursed by the United States under Medicare were worth what the
15 government paid” (affirmative defense 15), the Court does not possess subject
16 matter jurisdiction because the Relator is not an “original source” (affirmative
17 defense 16), and the Government’s claims against one or more Defendants are
18 improperly joined with its claims against other Defendants and must be severed
19 (affirmative defense 17). Plaintiffs are currently evaluating all 21 affirmative
20 defenses and presently anticipates moving to strike some of them under Rule
21 12(f)(2). Plaintiffs will need to conduct discovery relating to at least some of
22 Defendants’ affirmative defenses (depending on which remain), which may add
23 significantly to the amount of discovery that they need to conduct in this action.
24 For example, one of Defendants’ affirmative defenses is that “[t]he services and
25 products reimbursed by the United States under Medicare were worth what the
26 government paid” (affirmative defense 15). If the Court does not strike this
27 defense, then Plaintiffs would have to conduct extensive discovery about the
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1 services and products that Defendants provided and whether they were worth what
2 the Government paid.

3 Moreover, on March 23, 2018, Defendants filed five counterclaims against
4 the Government. Defendants' counterclaims appear to be based in large part on
5 their meritless "actuarial equivalence" argument. Defendants seek to avoid their
6 legal obligations to delete diagnoses unsubstantiated by their chart reviews and to
7 retain payments for the invalid diagnoses. This is based on their legally erroneous
8 and entirely unreasonable interpretation of the terms "actuarial equivalence" and
9 "same methodology" in that part of the Medicare Statute relating to payments to
10 Medicare Advantage organizations ("MAOs"). There is nothing in the Medicare
11 Statute, including the use of those terms in the Statute, which entitles Defendants
12 to risk adjustment payments based on invalid diagnosis data. Defendants were
13 never entitled to payments based on invalid data and had longstanding contractual
14 and regulatory obligations to delete invalid diagnoses submitted by them for such
15 payments. Their attempt to avoid their obligations and keep substantial sums (at
16 least over one billion dollars for just four years) of Medicare funds and taxpayer
17 dollars to which they were never entitled should be summarily rejected by this
18 Court.

19 Plaintiffs believe that an early ruling by the Court on this "actuarial
20 equivalence" legal issue will streamline discovery and resolution of this case.
21 Alternatively, if Defendants are not asserting their "actuarial equivalence"
22 argument in this case as they appear to represent in their statement of the legal
23 issues (below), then they should stipulate that they are not asserting this argument
24 here and withdraw their numerous and burdensome document requests relating to
25 this issue.

26 The counterclaims also appear to be based on Defendants' contention that, in
27 2014, CMS purportedly misled them to believe that they could ignore the negative
28 results of their chart reviews – the results showing the diagnoses that were

1 unsubstantiated by the beneficiaries' charts – and avoid their obligation to delete
2 the invalid diagnoses. The Ninth Circuit, in *Swoben*, already rejected this
3 argument. It explained that, although CMS decided in 2014 not to finalize the
4 proposed rule prohibiting MAOs from designing chart reviews to only identify
5 diagnoses for additional payments, CMS made clear that MAOs remained
6 responsible for ensuring the validity of their data to avoid receiving or retaining
7 overpayments. 848 F.3d at 1169-70. The Ninth Circuit further explained that, in
8 2014, CMS finalized a regulation that had the same effect as the proposed
9 regulation because it required the return of overpayments resulting from the
10 submission of diagnoses that are unsupported by the beneficiaries' medical
11 records. *Id.* at 1185 n.4.³ Furthermore, according to Defendants' own senior
12 executives, in 2014, CMS told them that they could not ignore information about
13 invalid diagnoses from their reviews of medical records and that CMS could not
14 advise Defendants about their compliance with laws regarding their overpayment
15 obligations. (FAC ¶ 226 & 228-29).

16 The Government presently anticipates moving to dismiss the counterclaims.
17 Among other deficiencies with these counterclaims, it appears that Defendants'
18 alleged damages are anticipatory, contingent, and unripe in that they are premised
19 on this Court issuing a judgment requiring Defendants to repay the overpayments
20 due to their failure to delete invalid diagnosis data. The primary intent of

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22 ³ The regulation that CMS finalized in 2014 is often referred to as the
23 Overpayment Rule, 42 C.F.R. § 422.326. It is the regulation that Defendants
24 challenge in their Administrative Procedure Act ("APA") case. That regulation
25 was issued pursuant to the Patient Protection and Affordable Care Act ("ACA"),
26 42 U.S.C. § 1320a-7k(d), which requires MAOs to report and return overpayments
27 no later than 60 days after their identification of the overpayments; otherwise, their
28 late overpayments become "obligations" under the FCA and the MAOs are subject
to liability under the reverse false claims provision of the FCA even if they
returned the overpayments after 60 days. The resolution of the APA case will not
resolve this FCA case. *See UnitedHealthcare Ins. Co. v. Price*, 2017 WL 2623783,
at 2-3 (D.D.C. June 14, 2017). This case does not involve the Overpayment Rule
because Defendants were not just late in returning the overpayments; they never
returned the overpayments. Nonetheless, in this case, Defendants are demanding
the production of documents relating to the Overpayment Rule.

Defendants' meritless counterclaims appears to be to divert the Government's resources from focusing on its document production and other efforts in this matter.

Pursuant to Rule 12(a)(2), the Government's response to the counterclaims is due within 60 days after service of the counterclaims on the United States Attorney, to and including May 22, 2018. The Government and Relator also seek the same 60 days to move to strike some or all of the affirmative defenses. Plaintiffs recently sent Defendants a proposed stipulation that Plaintiffs will file their motions to dismiss and to strike by May 22, 2018; Defendants may file their oppositions by June 11, 2018; Plaintiffs may file their replies by June 25, 2018; and the motions shall be heard on July 9, 2018. If Defendants do not agree to this stipulation, Plaintiffs will file an application with this Court seeking this relief.

In addition to issues identified elsewhere in this Report, including Section M, Plaintiffs anticipate that other legal issues may arise as discovery continues.

UnitedHealth's Position: This case centers on a dispute about the reciprocal contractual, regulatory, and statutory obligations of MA plans and CMS in the MA program. As the Parties, as well as this Court, have previously recognized, the "central" issues in the dispute are currently being litigated in an Administrative Procedures Act suit in the District of Columbia. See Order Denying Motion to Transfer at 4, ECF No. 154 (noting the government's agreement that "'identical arguments' . . . are 'central' to the cases"); see also *UnitedhealthCare Ins. Co. v. Hargan*, No. CV-16-RMC (D.D.C.).⁴ Those issues include whether MA plans are required to attempt to delete all unsupported diagnosis codes submitted to them by providers, even though the model CMS uses to determine payment amounts is based in part on unsupported codes that CMS itself collects in the Medicare Part A and B programs. CMS has acknowledged in the APA suit that it knowingly uses

⁴ Upon the resignation of former Secretary of Health and Human Services Thomas Price, UnitedHealth's APA action was automatically re-captioned with the name of Acting Secretary Eric Hargan.

1 unsupported diagnosis codes to estimate its expected costs for Medicare patients
2 whose care it pays for directly under Medicare Parts A and B. UnitedHealth has
3 argued that CMS’ choice has direct implications for the types of risk adjustment
4 data it collects from MA plans. Specifically, Congress has required CMS to use
5 the “same methodology” to determine payment amounts in the MA program, 42
6 U.S.C. § 1395w-23(b)(4), and has directed CMS to “ensure actuarial equivalence”
7 between the two programs, 42 U.S.C. § 1395w-23(a)(1)(C)(i). In light of those
8 statutory requirements, UnitedHealth believes that CMS cannot require MA plans
9 to use a different approach to the diagnosis codes they submit than the one CMS
10 itself uses, such as by requiring MA plans to delete all unsupported codes, unless
11 CMS also provides a means of adjusting for the different methodologies.

12 UnitedHealth and the United States have already fully briefed cross-motions
13 for summary judgment in the APA case addressing those issues. UnitedHealth
14 believes it would be inappropriate, inefficient, and a waste of judicial resources to
15 attempt to litigate those same issues here while they are already pending before the
16 APA court. If the APA court upholds the validity of the regulation there based on
17 a rejection of UnitedHealth’s arguments described above, UnitedHealth will not
18 seek to re-litigate the regulation’s validity here. If the APA court finds the
19 regulation *invalid*, then at that point the Parties will be able to address the
20 implications of such a decision for the United States’ claims here. The extent to
21 which the “actuarial equivalence” and “same methodology” requirements will need
22 to be addressed by this Court, and the timing of any such consideration by this
23 Court, thus depends on the outcome in the APA case. UnitedHealth remains
24 willing to discuss those issues with the United States in an attempt to avoid
25 unnecessary and inefficient briefing on the United States’ contemplated motion for
26 partial summary judgment on this issue (and has been open to such discussions
27 since the United States first raised the prospect of a motion for partial summary
28 judgment on this issue in November 2017).

1 Depending on how the APA case is resolved, there may also be other FCA-
2 and fact-specific issues to resolve in this case, including:

3 (i) Whether a physician's subjective clinical judgment regarding
4 diagnostic coding may give rise to a false claim under the FCA;

5 (ii) Whether any regulatory or contractual violations UnitedHealth did
6 commit were committed "knowingly," in light of the regulatory landscape and the
7 government's knowledge and approval of UnitedHealth's chart review processes;

8 (iii) Whether any alleged noncompliance was material to payment under
9 the FCA or the United States' unjust enrichment or payment by mistake claims;

10 (iv) Whether the acts of UnitedHealth resulted in damages actionable
11 under the FCA or claims of unjust enrichment and payment by mistake; and

12 (v) Whether the United States can sustain claims for unjust enrichment
13 and payment by mistake when valid contracts between the parties existed.

14 The United States has taken the position here, as it did on remand in
15 *Swoben*, that the Ninth Circuit's *Swoben* decision resolves many of these questions
16 in the United States' favor. That is incorrect. The Ninth Circuit's decision arose
17 following a dismissal on Rule 8 and 9(b) grounds, and resolved only the narrow set
18 of issues that were actually at issue there. Specifically, the Parties there disputed
19 the extent of detail that Rule 9(b) requires at the pleading stage in a case like this
20 one, and also the extent of the verification obligations imposed by the "best
21 knowledge, information, and belief" standard contained in the contractual
22 attestation. *See Swoben*, 848 F.3d 1178-79. The Ninth Circuit expressly *declined*
23 to address whether the United States' allegations stated a claim under the reverse
24 false claims provision. *Id.* at 1172 n.6. Accordingly, *Swoben* is of minimal
25 guidance now that this Court has dismissed the United States' attestation-based
26 claims (Dkt. 212), and the only FCA claim remaining is based on a theory that was
27 not addressed by the Ninth Circuit.

28

1 In addition, contrary to the United States’ contention, in granting in part
2 UnitedHealth’s motion to dismiss on February 12, 2018 (Dkt. 212), the Court did
3 not “recognize[] that [UnitedHealth] had a legal obligation to repay CMS by
4 deleting invalid diagnosis codes”—the Court merely held that, at this stage (where
5 factual allegations must be accepted as true), the FAC contained sufficient
6 allegations to plead materiality under the United States’ remaining causes of
7 action. (Order on MTD at 20-21.)

8 The United States also fundamentally misconstrues UnitedHealth’s
9 counterclaims and affirmative defenses. UnitedHealth’s counterclaims and
10 affirmative defenses do not rely on the actuarial equivalence issues being
11 separately litigated in the APA case. Rather, UnitedHealth’s counterclaims are
12 based on the fact that CMS failed to issue any rule or otherwise make clear any
13 requirement to perform two-way looks, affirmatively represented to UnitedHealth
14 that two-way looks were not required, knew that UnitedHealth understood it was
15 not under an obligation to perform two-way looks and relied on that understanding
16 in calculating its bids and entering into MA contracts with CMS, and continued to
17 enter into and pay UnitedHealth under such contracts. Yet the United States, years
18 after the fact, seeks to alter the fundamental assumptions built into UnitedHealth’s
19 bids, and thus, their contracts with CMS. The United States’ conduct under these
20 circumstances gives rise to UnitedHealth’s valid assertion of counterclaims
21 consisting of breach of contract, breach of the covenant of good faith and fair
22 dealing, fraudulent inducement, negligent misrepresentation, and promissory
23 estoppel. UnitedHealth is prepared to litigate any motions to dismiss and/or strike
24 its counterclaims and affirmative defenses.

25 **D. Parties, Evidence, etc.**

26 **1. Parties**

27 The Parties are Plaintiff United States of America, Relator Benjamin
28 Poehling, and Defendants UnitedHealth Group Incorporated, United HealthCare

Services, Inc., UnitedHealthcare, Inc., Ovations, Inc., Optum, Inc., and OptumInsight, Inc., as well as the numerous Medicare Advantage Organizations identified in paragraph 26 of the FAC. The full list of Defendants' parents and subsidiaries is available in UnitedHealth's Corporate Disclosure Statement, Dkt. No. 129, and UnitedHealth's Notice of Interested Parties, Dkt. 130.

2. Percipient Witnesses

United States and Relator's Position: Plaintiffs, at this early stage of the litigation and subject to the factual record developed during discovery, identify the following potential percipient witnesses in this case: The individuals identified in Plaintiffs' Initial Disclosures (served on Defendants on December 22, 2017) as individuals likely to have discoverable information that the Government and Relator may use to support their claims; Relator Benjamin Poehling; the current and former executives and employees of Defendants identified in paragraph 42 of the FAC; the individuals identified and/or described in the Declaration of Carol Wallack in Support of the United States' Opposition to United's Motion to Transfer, Dkt. No. 138-1; the current and former employees of the incentivized providers listed in Exhibits 14 and 15 of the FAC; the chart reviewers and diagnosis coders who reviewed charts and coded diagnoses as part of Defendants' Chart Review, Claims Verification, and RACCR Programs; certain current and former employees of CMS and its contractors, including Palmetto and ARDX; and certain current and former participants in a managed care industry group called the Industry Collaboration Effort ("ICE").

UnitedHealth's Position: In addition to the witnesses identified by the United States and the individuals identified in UnitedHealth's Initial Disclosures (served on the United States on December 22, 2017) as those likely to have discoverable information that UnitedHealth may use to support its claims and defenses, UnitedHealth anticipates, subject to the factual record developed during discovery, that the following may be key witnesses in this action: (1) Marilyn

1 Tavenner, the former Administrator of CMS; (2) Jonathan Blum, the former
2 Principal Deputy Administrator and Director of CMS; (3) Sean Cavanaugh, the
3 former Deputy Administrator and Director of CMS; (4) Cheri Rice, the Acting
4 Deputy Director of the Center for Medicare at CMS; (5) Jeffrey Grant, the former
5 Division Director, Capitated Payment; (6) Dan Farmer, the former Special
6 Assistant at CMS; (7) Julia Gorner, Director, Division of Capitated Plan Audits at
7 CMS; (8) Cynthia Tudor, Deputy Center Director, Parts C and D at CMS; (9)
8 Lateefah Hughes, the former Acting Deputy Group Director of Payment Policy and
9 Financial Management at CMS; (10) Tom Hutchinson, the former Director of the
10 Medicare Plan Payment Group at CMS; (11) Sean Creighton, the former Deputy
11 Group Director of Payment Policy and Financial Management at CMS; (12)
12 Jennifer Harlow, the Acting Director and Deputy Director of Medicare Plan
13 Payment Group, Division of Payment Systems at CMS; (13) Jonathan Smith, the
14 Director of the Medicare Plan Payment Group, Division of Retiree Drug Subsidy at
15 CMS; (14) current and former government officials who (a) devised the MA risk
16 adjustment methodology; (b) reviewed UnitedHealth's annual MA plan bids
17 setting forth its proposed capitated payment amounts; (c) established CMS'
18 average cost and risk calculations within specific geographic regions; (d)
19 developed the methodology CMS uses for its own audits of MA plans; and (e) set
20 forth diagnosis coding and medical documentation criteria used by the government
21 itself in auditing health plans; and (15) UnitedHealth employees who will testify to
22 the fact that they believed, and still believe, that UnitedHealth was paid properly
23 and never submitted false statements or claims and did not knowingly and
24 improperly retain any overpayments or avoid or decrease any obligations.

25 **3. Key Documents**

26 United States and Relator's Position: Plaintiffs, at this early stage of the
27 litigation and subject to the factual record developed during discovery, identify the
28 following potential key categories of documents in this case: The documents and

1 electronically stored information (“ESI”) identified in Plaintiffs’ Initial Disclosures
2 as documents and ESI that the Government and Relator may use to support their
3 claims; the documents referenced in the FAC; documents relating to Defendants’
4 Chart Review, Claims Verification, and RACCR Programs; documents relating to
5 Defendants’ knowledge (as that term is defined by the FCA) about inaccurate or
6 untruthful diagnoses submitted by providers, including diagnoses unsubstantiated
7 by the providers’ medical records; documents relating to Defendants’ obligation to
8 submit accurate and truthful risk adjustment data to Medicare for risk adjustment
9 payments, including the obligation to submit diagnoses substantiated by
10 beneficiaries’ medical records; documents relating to Defendants’ obligation to
11 retract, withdraw, or delete inaccurate or untruthful risk adjustment data submitted
12 to Medicare, including the obligation to retract, withdraw, or delete diagnoses
13 unsubstantiated by beneficiaries’ medical records; documents relating to
14 Defendants’ submission of inaccurate or untruthful risk adjustment data to
15 Medicare; documents relating to Defendants’ failure to retract, withdraw, or delete
16 inaccurate or untruthful risk adjustment data; documents relating to Defendants’
17 contracts and other agreements with CMS and their attestations; medical records
18 from the RACCR “financially incentivized” providers relating to the beneficiaries
19 whose diagnoses are at issue; documents regarding liability accruals and reserves
20 that one or more of the Defendants took relating to their Chart Review, Claims
21 Verification, and RACCR Programs; documents relating to Defendants’
22 communications with CMS about the above-mentioned issues; and documents
23 related to damages.

24 UnitedHealth’s Position: UnitedHealth anticipates, subject to the factual
25 record developed during discovery, that the key categories of documents in this
26 action include: (1) the documents and electronically stored information (“ESI”)
27 identified in UnitedHealth’s Initial Disclosures as documents and ESI that
28 UnitedHealth may use to support its claims and defenses; (2) documents

1 demonstrating that UnitedHealth was transparent with the government about its
2 claims verification program; (3) documents demonstrating that there was no
3 statutory or regulatory requirement for MA plans to “look both ways”; (4)
4 documents demonstrating that UnitedHealth did not knowingly retain any alleged
5 overpayments; and (5) documents demonstrating that the allegedly fraudulent
6 conduct was not material to payment.

7 **E. Damages**

8 United States and Relator’s Position: At this time, Plaintiffs’ damages
9 calculations for both its Chart Review and RACCR damages analyses do not
10 involve sampling or extrapolation. Rather, at this time, Plaintiffs intend to identify
11 the specific diagnoses that Defendants failed to delete. In addition, Defendants’
12 contention below that the FCA damages in this case should be reduced by an
13 undefined “benefit” conferred by them to the Medicare Program is unfounded.
14 There was no benefit to the Medicare Program from Defendants’ receipt and
15 retention of payments based on invalid data.

16 Furthermore, contrary to Defendants assertion below, Plaintiffs do not seek
17 Defendants’ assistance in determining their damages theories. However, Plaintiffs
18 do seek and have a right to obtain the data and related information in Defendants’
19 possession that Plaintiffs need to calculate all of the damages to the Medicare
20 Program.

21 Chart Review Damages: In this action, the Government seeks to recover its
22 damages for the 2009 payment year and all subsequent years during which
23 Defendants knowingly avoided their obligation to delete diagnoses invalidated by
24 their own chart reviews. To date, the Government has data to determine its
25 damages for payment years 2011 to 2014. Assuming that the Court will schedule
26 this action for trial for early 2020, the Government will limit its damages claim for
27 purpose of that trial to five additional payment years: 2009, 2010, and 2015 to
28

2017.⁵ Accordingly, the Government is now seeking to obtain from Defendants the data for those additional payment years. Based on experience from the investigation, as recounted below, it will take Defendants a significant amount of time to produce the data for the other five years and, thus, for the Government to perform the damages analyses.

In the investigation of this matter, Defendants produced data and other information for the Government to assess its damages for four of the years at issue, the 2011 to 2014 payment years. The Government requested this data from Defendants in July 2015. It took Defendants one year, until July 2016, to produce the data for all four years. In addition, after July 2016, Defendants continued to provide supplement data and information necessary to perform the damages analysis. According to a December 2, 2016 letter from Defendants to the Government, for those four years, Defendants' initial production included 47 files containing 828 million rows of data and totaling 150 GB of data and subsequent productions included 60 supplemental and replacement files totaling an additional 150 GB of data. This was not surprising as Defendants have conducted millions of chart reviews. (FAC ¶ 169)

As alleged in paragraph 237 of the FAC, the Government determined that, for 2011 to 2014, Defendants failed to repay the Medicare Program at least \$1.1 billion by failing to look both ways and delete diagnoses invalidated by their Chart Review Program. These damages are based on (1) a comparison of the results of Defendants' chart reviews for those four years with the diagnoses they submitted for payment for those years in order to identify the unsubstantiated diagnoses that should have been deleted, as alleged in paragraph 235 of the FAC, and (2) a computation of the overpayments made to Defendants based on those invalid diagnoses.

⁵ To the extent that Defendants are continuing to ignore the negative results of their current chart reviews and failing to delete the invalid diagnoses, the Government reserves its right to recover the damages for payment years after 2017.

1 On October 5, 2017, the United States served Defendants with its First
2 Request for Production of Documents, which includes specific requests for the
3 chart review and other data required to conduct the damages analyses for the 2009,
4 2010, and 2015 to 2017 payment years. To date, Defendants have not produced
5 any of the requested data. In a letter dated March 7, 2018, Defendants stated that
6 they anticipate producing data for 2015 to 2017 payment years by April 27, 2018,
7 but that they reserve their right to modify what years are included and the data that
8 Defendants will produce for the 2016 and 2017 payment years will not be
9 complete. Defendants have not stated when they will produce the data for the 2009
10 and 2010 payment years.

11 Defendants are refusing to provide complete chart review and other data for
12 the later payment years and to comply with Rule 26(e)'s requirement that
13 discovery responses be supplemented or corrected if they are incomplete or
14 incorrect. In a recent letter, Defendants state that they will not produce any chart
15 review and other data necessary to assess damages after January 31, 2018.
16 However, for the 2016 payment year, pursuant to a deadline set by CMS,
17 Defendants (and other MAOs) are allowed to submit diagnoses to the Medicare
18 Program until August 2, 2018. Thus, for that year, Defendants currently may be
19 performing chart reviews in order to submit additional diagnoses to increase
20 payments and they may continue to perform chart reviews and submit those
21 additional diagnoses until August 2, 2018. Similarly, for the 2017 payment year,
22 Defendants (and other MAOs) are allowed to submit diagnoses until September 14,
23 2018. Thus, for that year, Defendants also currently may be performing chart
24 reviews in order to submit additional diagnoses to increase payments and they may
25 continue to perform chart review and submit the additional codes until September
26 14, 2018. Accordingly, in order to obtain complete and accurate data to assess
27 damages for payment years 2016 and 2017, Defendants must provide the
28 Government with (i) the results of and other information about any chart reviews

1 relating to those years that were performed after January 31, 2018 and (ii) any
2 supplemental or corrected data relating to the beneficiaries whose charts were
3 reviewed for those years (for example, supplemental data would include any
4 additional diagnoses submitted by providers for those beneficiaries for those
5 years). Because Defendants have refused to do this, the Government will move to
6 compel the production of complete and accurate data for the 2016 and 2017
7 payment years.

8 In addition, since at least 2014, Defendants have submitted diagnoses
9 through two separate systems to CMS, the Risk Adjustment Processing System
10 (RAPS) and the Encounter Data Processing System (EDPS). Defendants have two
11 separate databases that they use to report into each system. Defendants' database
12 that submits diagnoses to RAPS is called IRADS. It includes data about all of the
13 beneficiaries in Defendants' MA Plans, including the beneficiaries whose charts
14 were reviewed in Defendants' Chart Review Program. This data includes, among
15 many other things, the dates of services of the medical encounters that the
16 beneficiaries had with providers, information identifying the providers, and the
17 diagnoses submitted by the providers. Defendants' database that submits
18 diagnoses to EDPS includes additional information about the beneficiaries, the
19 providers, and the beneficiaries' health status. That additional data is likely to be
20 very useful in assessing damages.

21 In its October 2017 Document Request, the Government requested data from
22 both of Defendants' databases, IRADS and the database that submits to EDPS, in
23 order to ensure that it has complete and accurate data to perform its damages
24 analyses. So far, Defendants have not agreed to provide the data from their
25 database that submits to EDPS. Accordingly, the Government will move to
26 compel its production.

27 After the requested documents and data are produced, the Government will
28 conduct the damages analyses for the 2009, 2010, 2015 to 2017 payment years.

1 The Government will present its damages pursuant to Rule 26(a)(2) relating to the
2 disclosure of expert testimony.

3 For the Government to even attempt to make its initial damages expert
4 disclosures by June 28, 2019 (the date proposed by Plaintiffs for initial expert
5 disclosures), Defendants need to complete their production of the chart review and
6 other data necessary to compute damages by September of 2018. In order for their
7 productions to be deemed complete, Defendants must provide all information
8 necessary for the Government to understand and interpret the data that they
9 produce. It is the Government's understanding that Defendants will insist that the
10 Government obtain this explanatory information through formal discovery
11 (interrogatories and depositions). Obtaining this information through formal
12 discovery will significantly add to the time and effort necessary for the
13 Government to make its initial damages expert disclosures.

14 RACCR Damages: Defendants themselves estimated the amount of the
15 overpayments they would have to return to the United States as a result of the
16 RACCR Program in the tens of millions of dollars per year during the time period
17 before they started phasing out the program. In December 2017, Plaintiffs served
18 Defendants with interrogatories to obtain the information necessary to conduct the
19 first phase of their determination of these overpayments. The interrogatories seek
20 information necessary to identify which financially-incentivized (capitated and
21 gainsharing) providers coded excessive numbers of diagnoses (more than three
22 times the average rate), including those providers who were included in the
23 RACCR Program and failed Defendants' sample validation test. The
24 interrogatories also seek information about the diagnoses that these providers
25 coded at these excessively high rates and the beneficiaries for whom they coded
26 these diagnoses. Defendants have not yet provided all of the information requested
27 by the interrogatories. After Defendants complete their provision of this
28 information (and assuming the information that Defendants provide is sufficient),

1 Plaintiffs plan to conduct the second phase of their overpayment analysis, which
2 will require obtaining medical records from the outlier providers and conducting
3 medical record reviews to determine the invalid diagnoses that Defendants should
4 have deleted. Defendants have not stated when they will complete their responses
5 to these interrogatories.

6 Defendants' Alleged Damages: Based on Defendants' counterclaims, it
7 appears that their purported damages are contingent entirely on their paying
8 damages to the Government in this action. Accordingly, at this time, Plaintiffs do
9 not believe that there will be a need to conduct separate damages analyses
10 pertaining to Defendants' counterclaims. However, because Defendants have
11 failed to provide any description of their purported damages or even a description
12 of their theory of damages either in their pleading setting forth their counterclaims
13 or in this report, Plaintiffs do not know whether their belief is correct. If it is
14 incorrect, Plaintiffs will need additional time to conduct fact and expert witness
15 discovery relating to Defendants' damages. Pursuant to Rule 26(e)(1)(B), the
16 Court should order Defendants to supplement their Rule 26(a)(1)(A) initial
17 disclosures to describe their damages as well as to list the witnesses and documents
18 supporting their counterclaims.

19 UnitedHealth's Position: UnitedHealth denies that it owes any damages
20 alleged in the FAC. UnitedHealth will have an alternate theory as to how damages
21 should be calculated if liability is established in light of the contracts and
22 reimbursement methodology and the FCA measure of damages, which take into
23 account the benefit already conferred on the government. UnitedHealth anticipates
24 challenging the propriety of sampling and extrapolation and asserting that a fee-
25 for-service adjustor must be applied to account for unsupported codes in the
26 diagnostic data of fee-for-service beneficiaries.

27
28

1 At this point in the litigation, UnitedHealth does not have sufficient
2 information to estimate damages associated with its counterclaims against the
3 United States regarding its obligations under the MA program.

4 UnitedHealth notes that the United States and Relator's position above on
5 Damages details discovery-related issues instead of setting forth "[t]he realistic
6 range of provable damages," as required by the Court's Order Setting Scheduling
7 Conference. UnitedHealth addresses the United States' mischaracterization of
8 these discovery issues below in the proper section, Status of Discovery (Section I).
9 The notion that the United States needs significantly more time to conduct routine
10 discovery in a case it brought—despite the advantages of a multi-year
11 investigation, detailed responses to dozens of complex (and sometimes improper
12 and nonsensical) interrogatories, more than 20 Civil Investigative Demand oral
13 examinations, over 630,000 documents produced by UnitedHealth during the
14 investigation and in *Swoben*, 6 document productions totaling nearly 66,000
15 documents already in this litigation, and 5 spreadsheets of over 125,000 lines of
16 data produced by UnitedHealth in response to the United States' First Set of
17 Written Interrogatories to Defendants—rings hollow.

18 The United States chose to bring this lawsuit, and it cannot now complain
19 about conducting routine discovery to which UnitedHealth is entitled and that
20 UnitedHealth needs to defend itself. The United States effectively is seeking
21 UnitedHealth's assistance in not only determining what their theory of damages is,
22 but also in determining whether there are any damages (there are not). This is
23 wholly improper and does not justify the United States delaying discovery or
24 failing to meet its discovery obligations.

25 **F. Insurance**

26 Coverage is available to UnitedHealth for certain claims in the FAC under
27 UnitedHealth's insurance policies, and UnitedHealth has agreed to make certain
28 documents relating to those policies available to Plaintiffs.

G. Motions

The United States and Relator's Position: As explained in Section C (Legal Issues), the Government presently anticipates filing a motion to dismiss Defendants' counterclaims. In addition, the Government and the Relator presently anticipate filing a separate motion to strike certain of Defendants' affirmative defenses. As explained in Sections E (Damages) and I (Status of Discovery), Defendants refuse to produce certain very relevant documents and Plaintiffs presently anticipate moving to compel the production of these documents.

In addition, the Government reserves the right to seek leave to (i) add any Medicare Advantage Organizations (or Part D Sponsors) directly or indirectly owned, affiliated with, or controlled by UnitedHealth Group that should be included in the list of such organizations set forth in paragraph 26 of the FAC; and, (ii) if necessary to recover its damages, to add any other entities affiliated with UnitedHealth Group that owned, controlled, or managed the Medicare Advantage Organizations. Information that has recently come to Plaintiffs attention indicates that some Medicare Advantage Organizations (or Part D Sponsors) directly or indirectly owned, affiliated with, or controlled by UnitedHealth Group may not have been expressly named in the FAC or may have been identified incorrectly. As needed, Plaintiffs will seek to stipulate with Defendants to amend the FAC to address these types of issues.

In addition to the motions identified in Section M, Plaintiffs anticipate considering additional motions as issues arise throughout the litigation. Plaintiffs may also file motions to exclude certain documents as evidence for use both in supporting summary judgment motions and at trial.

UnitedHealth's Position: UnitedHealth has engaged in good-faith discussions and negotiations on all issues raised by the United States during the course of discovery either to resolve or narrow any areas of disagreement between the Parties. Those discussions and negotiations are ongoing, and UnitedHealth is

1 committed to working with the United States to avoid or limit the necessity for
2 seeking intervention from the Court.

3 In addition, UnitedHealth reserves the right to seek leave to amend its
4 counterclaims to add or substitute any Medicare Advantage Organizations (or Part
5 D sponsors) that may subsequently be added or substituted by the United States in
6 its FAC.

7 Both Parties reserve the right to file non-dispositive pretrial motions,
8 including but not limited to motions related to discovery disputes, motions *in*
9 *limine*, and motions to exclude experts. Dispositive motions are addressed below.

10 **H. Manual for Complex Litigation**

11 The Parties do not believe the Manual for Complex Litigation should be
12 utilized in this case.

13 **I. Status of Discovery**

14 *The United States and Relator's Statement:*

15 In July 2017, the Court provided that “the Parties may engage in written
16 discovery (document requests and interrogatories) and may do so before a Rule
17 26(f) conference.” (Dkt. No. 133) Defendants have served the Government with
18 two sets of document requests and the Relator with one set of document requests.
19 The Government has also served Defendants with two sets of document requests.
20 The Government has also served Defendants with several interrogatories to which
21 Defendants are responding by producing documents.

22 *Government's Production of Documents:* The Government fully appreciates
23 that Defendants have a right to obtain documents and other information relevant to
24 the claims and defenses that are appropriately a part of this case. The Government
25 has been and will continue to be fully cooperative with Defendants in that regard.

26 The Government has been working cooperatively with Defendants in
27 responding to their 97 separate document requests (the total number in both sets),
28 which cover a very wide range of documents on many subject matters. The

1 Government spent many hours working with Defendants in the drafting of
2 mutually-agreeable proposed protective orders relating to the treatment of
3 confidential documents and other information and relating to the non-waiver of
4 privilege and protected documents. These protective orders were entered by the
5 Court on January 16, 2018. (Dkt. Nos. 197 & 198) In addition, on a regular basis
6 over the last six months, the Government has been in contact with Defendants
7 about their document collection and production activities through emails, letters,
8 telephone calls, and meetings. The Government spent many hours providing
9 Defendants with an extensive amount of information about its document collection
10 efforts and document review protocols and discussing these efforts and protocols
11 with Defendants' counsel. The Government identified its numerous document
12 custodians and multi-access email accounts from which it has collected documents,
13 and the Parties have agreed to provide titles and dates of employment for each of
14 their document custodians. The Government also identified the search terms used
15 to collect potentially responsive documents in the custodians' electronic files. In
16 addition, the Government provided Defendants with detailed information about its
17 Technology Assisted Review methodology being used to identify the responsive
18 documents in its enormous collection of electronic documents.

19 The Government also has spent many hours responding to Defendants'
20 requests that it expand its efforts to locate and collect documents, revise its search
21 terms for collecting electronic documents, and revise its Technology Assisted
22 Review methodology. The Government has complied with many of these requests.
23 The Government has also compromised and tried to minimize the burden of
24 discovery disputes needed to be resolved by the Court by agreeing to produce
25 documents relating to various issues that are irrelevant to this case, including, for
26 example, documents relating to CMS' methodology for conducting administrative
27 audits and the calculation of the statutory coding intensity adjustment that applies
28

1 to all MAOs. (However, the Government may still file one or more motions as
2 necessary to limit or prevent such wasteful discovery.)

3 The Government has also agreed to produce documents and privilege logs
4 on a rolling basis. In addition, it has agreed to prioritize the production of various
5 documents at Defendants' request so long as it is given reasonable notice and
6 Defendants' also agree to requests by the Government to prioritize the production
7 of certain documents such as the production of the data necessary to perform the
8 Government's damages analyses.

9 In response to Defendants' document requests, the United States has so far
10 collected over four terabytes of data, constituting over five million documents,
11 from more than 150 custodians at CMS and other parts of the Department of
12 Health and Human Services ("HHS"). The United States is still in the process of
13 collecting documents in response to Defendants' requests that it expand the search
14 terms that it is using to collect potentially responsive documents and expects to
15 collect a substantial amount of additional documents within the next several
16 months. In response to other requests made by Defendants, the United States is
17 also continuing to identify additional document custodians, including custodians at
18 the Office of the Secretary of HHS.

19 The United States must review all of the documents that it has collected and
20 will collect over the next several months. It must review these documents for
21 responsiveness, confidentiality (for example, for patient identifiable data and
22 information relating to other insurance companies which participate in the
23 Medicare Advantage Program), and privilege. To expedite the task of reviewing
24 and producing responsive, non-privileged documents, the United States is utilizing
25 targeted searches, Technology Assisted Review, and manual review. Even
26 utilizing these methods, however, the task of identifying responsive, non-
27 privileged documents and determining which of those are confidential is enormous.
28 The Government currently estimates that there are at least 500,000 documents that

1 its attorneys must manually review for privilege and this does not include the
2 manual, eyes-on privilege review that will need to be conducted for documents that
3 the Government has not yet collected. Contrary to Defendants’ assertion below,
4 Relator’s counsel cannot perform this privilege review of Government documents.
5 Government attorneys must exclusively perform this review. Furthermore,
6 contrary to Defendants’ assertion below, the Government is not inappropriately
7 relying on the deliberative process privilege or applying the privilege too broadly.
8 *See NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 150 (1975) (privilege protects
9 documents that “reflect[] advisory opinions, recommendations and deliberations
10 comprising part of a process by which governmental decisions and policies are
11 formulated”); *Hongsermeier v. Commissioner of Internal Revenue*, 621 F.3d 890,
12 904 (9th Cir. 2010) (privilege protects documents that are “predecisional” and
13 “deliberative”).

14 The Government’s initial goal was to make rolling productions of
15 documents on a regular basis throughout 2018 and to substantially complete its
16 production by the end of 2018. This goal was premised on the hope that
17 Defendants would agree to withdraw at least some of its requests for irrelevant
18 documents, but they have not. In addition, this goal was premised on the hope that
19 the Court would agree with the Government’s proposal that fact witness
20 depositions by both Parties commence after both Parties substantially complete
21 their document productions. However, over the last several months, Defendants
22 diverted the Government’s resources because of their insistence that they conduct
23 expedited depositions of certain Government witnesses. This was exacerbated by a
24 change in Defendants’ position in insisting that the Government also produce
25 documents relating to these witnesses on an expedited basis even though neither
26 Defendants’ deposition notice nor subpoena relating to these witnesses had
27 requested such documents. In order to accommodate the noticed depositions of
28 two senior Government witnesses (including a former Administrator of CMS),

1 which went forward notwithstanding the Government's objection that they were
2 premature, the Government had to interrupt its document collection and review
3 efforts in response to Defendants' 97 document requests (sets one and two) in
4 order to prioritize the collection, review and production of documents relating to
5 these two deponents. This has impeded the Government's document review and
6 production efforts.

7 Furthermore, the Government's resources are now being diverted by
8 responding to Defendants' counterclaims and affirmative defenses. Government
9 counsel is now focused on preparing motions to dismiss the counterclaims and
10 strike some of the affirmative defenses.

11 To date, the Government has produced approximately 10,000 documents.
12 The tasks of identifying responsive documents and conducting manual, "eyes-on"
13 privilege and confidentiality reviews have consumed and will continue to consume
14 significant Government's resources until these reviews are completed. The
15 Government proposes that phased discovery, with fact witness depositions
16 commencing in November 2018, would significantly facilitate its completion of the
17 production of documents. If Defendants continue to expedite the depositions of
18 Government witnesses, the Government's resources will be diverted to defending
19 those depositions and producing attendant documents and, thus, discovery will
20 proceed in a piecemeal fashion. This diversion will be in addition to the diversion
21 caused by moving to dismiss Defendants' counterclaims and strike their
22 affirmative defenses. This diversion will further delay the Government's
23 completion of its production of documents.

24 It should not be surprising to Defendants that it would require significant
25 time for the Government to produce documents in response to their numerous and
26 broad requests. In the investigation, the approximately 600,000 documents
27 produced by Defendants were produced over a 4 year time period, from December
28 2012 to December 2016. Furthermore, the Government also believes that

Defendants will not substantially complete their document production in this action until at least the end of 2018.

Relator's Production of Documents: Relator has served his responses and objections to Defendants' document requests and is in the process of making a relatively small production of non-privileged, relevant documents. Following his departure from UnitedHealth in 2012, Relator gave UnitedHealth all non-privileged documents in his possession generated in the course of and directly related to his work at UnitedHealth (that is, UnitedHealth's documents). Moreover, pursuant to agreements between UnitedHealth and Relator, he destroyed all such UnitedHealth documents in his possession other than his performance reviews.

Defendants' Production of Documents: Plaintiffs presently anticipate moving to compel Defendants' production of various documents that they have refused to produce. As explained in Section E (Damages), this includes chart review and other data that is necessary to assess damages for payment years 2016 and 2017. As another example, this includes documents from the electronic and hard copy files of Steve Hemsley, the Chief Executive Officer of UnitedHealth Group from 2006 to 2017, and Janis Leafgren, Mr. Hemsley's Administrative Assistant, who (for instance) sent and received emails on behalf of Mr. Hemsley. On March 27, 2018, Defendants sent the Government a letter stating that it needs some undefined amount of additional time to decide whether it will produce documents from these relevant custodians' files. However, Mr. Hemsley engaged in activities relevant to this case. Among other things, Mr. Hemsley chaired Defendants' Risk Adjustment Advisory Board (FAC ¶ 42); the executives who managed Defendants' Medicare Advantage Plans regularly reported to Mr. Hemsley with respect to risk adjustment payment-related issues (*id.*); according to a 2011 documents produced by Defendants, Mr. Hemsley was "significantly involved in the oversight and management of" Defendants' "Medicare business"

(*id.*); and, Mr. Hemsley was aware of risk adjustment payment compliance issues (*id.* at ¶¶ 154 & 188). Moreover, Mr. Hemsley was intimately involved in the decision to terminate Defendants’ Claims Verification Program and revert to ignoring the negative results of Defendants’ chart reviews and failing to delete the diagnoses invalidated by those reviews. Mr. Hemsley is the one who directed Messrs. Renfro, Johnson, Nelson, and Schumacher and Ms. Erickson to speak with CMS about Defendants’ termination of their Claims Verification Program. (FAC ¶¶ 224-26, 230-31, & 234) Defendants have provided no valid justification for not searching these custodians’ files.

Plaintiffs also anticipate that they may challenge many of Defendants’ privilege assertions, including privilege assertions pertaining to the rendering of non-legal advice, the attendance of Defendants’ attorneys at business meetings to shield those meetings from discovery, and the participation of Defendants’ attorneys in non-legal communications to shield those communications from discovery.

UnitedHealth’s statement:

UnitedHealth’s statement on the collection and production of documents:

The United States opted to bring this lawsuit, yet it now balks at the notion of meeting its discovery obligations and allowing UnitedHealth to pursue discovery to which UnitedHealth is entitled so that it may properly and effectively defend itself. The United States complains about its resources being “diverted” by other standard litigation matters—such as defending depositions and responding to counterclaims and affirmative defenses—and attempts to justify its failure to meet its original document production deadline because of these “diverted resources.” Despite the advantage of conducting a multi-year investigation related to this matter, the United States curiously now appears to claim that it lacks the resources to properly litigate this matter and to meet its discovery deadlines. The notion that Plaintiffs—which currently have thirteen government attorneys and twenty active

1 attorneys for Relator (including twelve partners)—lack the resources to conduct
2 routine discovery in a timely manner is absurd.

3 Prior to filing the FAC, DOJ investigated this matter for more than five
4 years. During that time, UnitedHealth produced over 600,000 documents,
5 compiled detailed responses to dozens of complex interrogatories, and produced
6 more than twenty witnesses for Civil Investigative Demand oral examinations. In
7 *United States ex rel. Swoben v. Secure Horizons*, Case No. CV-09-5013 JFW
8 (JEMx), UnitedHealth produced over 34,000 documents, which are also responsive
9 in this case. The United States, in contrast, made two small productions totaling
10 less than 600 documents, the majority of which were publically available and re-
11 produced from another action.

12 In response to the United States' Complaint in this case, UnitedHealth has
13 been collecting documents from 118 custodians and 7 email distribution lists and
14 has collected approximately 70 million documents to date. In addition to the more
15 than 634,000 documents produced during the investigation and the *Swoben*
16 litigation, UnitedHealth has produced over 65,845 documents in this litigation. On
17 January 29, 2018, UnitedHealth produced 5 spreadsheets of over 125,000 lines of
18 data requested by the United States in its First Set of Written Interrogatories to
19 Defendants. UnitedHealth has also produced two privilege logs thus far—in
20 addition to the more than ten it produced during the investigation—and intends to
21 continue producing privilege logs on a monthly basis.

22 In contrast, the United States failed to produce a single document until late
23 February 2018—and only did so at the direction of Magistrate Judge Segal after
24 initially refusing to comply with its discovery obligations related to the depositions
25 of Marilyn Tavenner and Jeffrey Grant. The United States' first two productions
26 consisted of 893 documents total. Although the United States' deadline for its first
27 Technology Assisted Review production was the week of March 19, it failed to
28 make its production until March 28, when it produced approximately 9,500

1 documents—approximately one-sixth of the number of documents produced by
2 UnitedHealth in this litigation alone. UnitedHealth also notes that Relator has yet
3 to produce a single document in this matter, despite UnitedHealth serving
4 document requests on Relator on January 19, 2018.

5 UnitedHealth has already agreed that the United States need not log certain
6 categories of likely privileged documents (such as communications with the
7 Department of Justice or the Office of General Counsel), so the United States’
8 assertion that it will have to review over 500,000 documents (and counting) for
9 privilege is not primarily tied to attorney-client or work product privilege concerns.
10 Rather, it is the product of the United States’ inappropriately broad view of the
11 qualified deliberative process privilege, as demonstrated by the United States’ first
12 privilege log that it produced on March 30, 2018. The United States has asserted
13 deliberative process privilege over every single document on that log for which
14 CMS is a custodian—approximately eighty percent of the entire log. This
15 specious, over-expansive view is nothing more than a strategic attempt to yet again
16 deprive UnitedHealth of key information that UnitedHealth needs to defend itself
17 in a lawsuit that the United States chose to bring. For example, the United States
18 brazenly attempts to assert deliberative process privilege over documents the
19 government itself produced previously in response to a FOIA request. In response
20 to that request, these documents were produced partially redacted, suggesting they
21 had already undergone review by the relevant government agency outside of this
22 litigation and deemed appropriate for public disclosure.

23 UnitedHealth has also provided the United States with information regarding
24 its document collection efforts and document review protocols and will continue to
25 work cooperatively with the United States on discovery. UnitedHealth engaged in
26 good-faith negotiations with the United States and exchanged detailed information
27 about its Technology Assisted Review protocol, and the Parties have now agreed
28 on respective Technology Assisted Review protocols. While UnitedHealth

1 proposed that the Parties exchange additional information, including custodians’
2 job titles and employment history, regarding custodians on December 20, 2017, the
3 United States was not prepared to do so.

4 UnitedHealth’s statement regarding data productions: The United States’
5 Damages section (Section E, above) is replete with inaccuracies and misleading
6 statements, and it is highly inappropriate for a Rule 26(f) Joint Report. To avoid
7 any prejudice resulting from the United States’ tactics, UnitedHealth will briefly
8 respond to set the record straight, but UnitedHealth does not believe this Joint
9 Report is the proper vehicle to respond to each and every one of the United States’
10 assertions.

11 UnitedHealth has been working diligently and devoting substantial
12 resources—in addition to the overlapping resources it is expending to respond to
13 other document requests and interrogatories, deposing witnesses, moving to
14 dismiss the FAC, answering the United States’ 364-paragraph FAC, and
15 developing its counterclaims, among other things—to collect and produce data
16 responsive to various requests by the United States. UnitedHealth agreed to the
17 United States’ request that UnitedHealth prioritize dates of service years 2014
18 through 2016 and will be making a significant production on April 27, 2018, the
19 government’s unilaterally imposed deadline. Per the United States’ request,
20 UnitedHealth also agreed to produce the requested data for dates of service years
21 2008 and 2009 after April 27, 2018. UnitedHealth has been transparent with the
22 United States about its data productions, and the United States’ claim otherwise is
23 preposterous. The United States appears to be dictating how much time
24 UnitedHealth is going to require to produce responsive data to its extremely broad
25 data requests, but UnitedHealth clearly is better positioned to make that
26 determination. Accordingly, UnitedHealth has in good-faith proposed a discovery
27 schedule that not only meets the United States’ unilaterally imposed April 27, 2018
28

1 deadline but also gives UnitedHealth sufficient time to satisfy its discovery
2 obligations.

3 **J. Discovery Plan**

4 **1. Rule 26(a) Initial Disclosures – Rule 26(f)(3)(A)**

5 The Parties made their initial disclosures on December 22, 2017.

6 United States and Relator's Position: In their initial disclosures, Plaintiffs
7 provided Defendants with the results of their estimation of damages for the four
8 payment years (2011 to 2014) for their violations of the FCA relating to their chart
9 reviews. These results are also described in paragraphs 235 and 237 of the FAC.
10 At this time, Plaintiffs claim a work product privilege with respect to the analyses
11 underlying this damages estimate. In accordance with Rule 26(a)(2), the United
12 States and Relator will make their expert damages disclosures at the time set forth
13 in the Schedule entered by the Court.

14 As previously explained, Defendants have not produced documents and data
15 required to compute damages due to their one-way chart reviews for payment years
16 2009, 2010, 2015, 2016, and 2017.⁶ In addition, Defendants have agreed to
17 provide certain information responsive to the Government's interrogatories
18 concerning Defendants' RACCR program, but have not yet done so. Once
19 Defendants have completed their provision of information responsive to the
20 Government's interrogatories, Plaintiffs will use that information to propound
21 subpoenas to third-party providers who participated in Defendants' RACCR
22 program, to enable Plaintiffs to obtain and review medical records in the
23 possession of those third-party providers.

24 The United States proposes that it will comply with the requirements
25 imposed by Rule 26(a)(1)(A)(iii) when it makes its damages expert witness(es)
26 disclosures pursuant to Rule 26(a)(2)(B). The United States needs sufficient time

27 ⁶ If Defendants' unlawful one-way Chart Review Program has continued past
28 payment year 2017, the United States reserves its right to recover the additional
damages.

(approximately nine months) to perform all the work, including, but not limited to, the document review and data analyses, necessary in order to compute damages and make its damages expert witness(es) disclosures after Defendants complete their production of the required documents and data (assuming that the Defendants also cooperate in producing the data in a usable format).

UnitedHealth's Position: The United States' discussion in this section is once again largely unnecessary and inappropriate in a Joint Report. The Parties exchanged initial disclosures on December 22, 2017 and will revise or supplement as required as the matter moves forward.

UnitedHealth continued to work diligently and to devote substantial resources to collect and produce data sought by the United States, and UnitedHealth will be making a significant production of data on April 27, 2018. Again, the notion that the United States needs significantly more time to conduct routine discovery and develop its damages theory and analysis is baseless. The United States chose to file this lawsuit after the benefit of a multi-year investigation, detailed responses to dozens of complex interrogatories, numerous Civil Investigative Demand oral examinations, and UnitedHealth's production of hundreds of thousands of documents. The United States must now engage in timely discovery and cannot continue to delay meeting its obligations.

2. Subjects and Timing of Discovery – Rule 26(f)(3)(B)

The Parties' positions as to the specific dates for Non-Expert and Expert Discovery Cut-Off are set forth below and in Exhibit A. The Parties' positions as to the subjects on which discovery may be needed, and whether discovery should be conducted in phases or be limited to or focused on particular issues, are as follows:

United States and Relator's Position: Certain key issues in this case are purely legal issues because the underlying facts are undisputed and most of those legal issues have already been decided by the Ninth Circuit in *Swoben*. Discovery

1 is therefore unnecessary to resolve these legal issues. In particular, the
2 “materiality” of Defendants’ submission of false risk adjustment data is a purely
3 legal issue as are Defendants’ legal obligations to delete unsubstantiated diagnoses.
4 In addition, Defendants’ “actuarial equivalence” argument (if Defendants are
5 making it in this case) raises a purely legal issue about the meaning of that term as
6 used in Part C of Medicare Statute. Accordingly, discovery relating to the
7 “materiality” issue, Defendants’ contractual and regulatory obligations to delete
8 invalid diagnoses, and the “actuarial equivalence” issue should be precluded or, at
9 a minimum, limited by the Court pursuant to Rule 26(b)(1).

10 Plaintiffs believe that discovery, including third party discovery, should
11 focus on the results of Defendants’ medical record reviews conducted as part of
12 their Chart Review, Claims Verification, and RACCR Programs; Defendants’
13 knowledge (as that term is defined by the FCA) about inaccurate or untruthful
14 diagnoses submitted by providers, including diagnoses unsubstantiated by the
15 providers’ medical records; Defendants’ knowledge (as that term is defined by the
16 FCA) about their obligation to submit accurate and truthful risk adjustment data to
17 Medicare for risk adjustment payments, including the obligation to submit
18 diagnoses substantiated by beneficiaries’ medical records; Defendants’ knowledge
19 (as that term is defined by the FCA) about their obligation to retract, withdraw, or
20 delete inaccurate or untruthful risk adjustment data submitted to Medicare,
21 including the obligation to retract, withdraw, or delete diagnoses unsubstantiated
22 by beneficiaries’ medical records; Defendants’ submission of inaccurate or
23 untruthful risk adjustment data to Medicare; Defendants’ processes and procedures
24 for submitting risk adjustment data to CMS and for withdrawing, retracting, or
25 deleting such data; Defendants’ failure to retract, withdraw, or delete inaccurate or
26 untruthful risk adjustment data; Defendants’ communications with CMS about the
27 above-mentioned issues; Defendants’ contractual and financial relationship with
28 their “incentivized” capitated and gainsharing providers; the unsubstantiated and

1 invalid diagnoses that incentivized providers reported to Defendants and
2 Defendants submitted to CMS for risk adjustment payments; any affirmative
3 defenses that remain after the government and relator's motion to strike; and
4 damages.

5 Plaintiffs propose that discovery proceed in phases and we describe these
6 phases in detail below. Both Rules 16(c)(2)(F) and 26(d)(3) and the Court's
7 February 28, 2018 Order Setting Scheduling Conference contemplate the use of
8 phased discovery. Phased discovery is particularly appropriate in very large and
9 complex cases such as this.

10 Plaintiffs believe that this approach is warranted to ensure that this very
11 large case be conducted in the manner most efficient for the Court, the Parties,
12 third parties, and witnesses. Plaintiffs also strongly believe that fact witness
13 depositions should begin after (i) the Court resolves the Government's motion to
14 dismiss Defendants' counterclaims, the Plaintiffs' motion to strike Defendants'
15 affirmative defenses, and the motion for partial summary judgment on Defendants'
16 "actuarial equivalence" argument (unless Defendants stipulate that they are not
17 making this argument in this case); (ii) the Parties produce substantially all
18 relevant documents to each other relating to the fact witnesses; and (iii) privilege
19 issues and issues relating to the appropriate scope of discovery are resolved.
20 Otherwise, there is a significant risk that (i) significant time will be spent deposing
21 witnesses about issues relating to counterclaims that are later dismissed on legal
22 grounds by the Court and/or defenses that the Court strikes or disposes of on the
23 Government's motion for partial summary judgment; (ii) the Parties will seek to
24 depose the same witnesses multiple times because, subsequent to their depositions,
25 additional documents relating to the witnesses (or the topics on which they were
26 deposed) were collected and produced; and (iii) the Court will be unnecessarily
27 burdened with multiple motions for protective orders and motions to compel. By
28 making this request for phased discovery, the Government does not seek to prevent

1 Defendants from obtaining any needed and relevant evidence, as Defendants may
2 pursue all reasonable discovery efforts they desire. The Government simply seeks
3 to ensure that discovery is conducted in the most efficient manner possible as
4 appropriate for litigation of this magnitude.

5 In addition, Defendants' proposal that non-expert discovery be cut-off on
6 January 28, 2019 is not realistic and is extremely prejudicial to Plaintiffs. This
7 deadline will force Plaintiffs to take depositions of fact witnesses before
8 Defendants produce documents relevant to their depositions. It will also force the
9 Government to focus on defending depositions rather than completing its
10 document production. In addition, this January 28, 2019 deadline will not provide
11 the Government with sufficient time to analyze the chart review and other data that
12 Defendants produce in order for the Government to assess damages and to obtain
13 the additional information it needs to understand and interpret the data. As
14 previously stated, the Government will need to obtain this information by deposing
15 fact witnesses and serving interrogatories on Defendants. This deadline also will
16 not provide Plaintiffs with sufficient time to determine the overpayments due to the
17 incentivized providers' invalid diagnoses, which, as previously stated, requires that
18 Plaintiffs subpoena medical records and other documents from these providers and
19 then review the medical records.

20 Furthermore, Defendants' argument that Magistrate Judge Segal already
21 decided that phased discovery should not occur in this case is incorrect. Magistrate
22 Judge Segal allowed Defendants to conduct the depositions of only two
23 Government witnesses over the Government's objection that the depositions were
24 premature. Defendants represented to Magistrate Judge Segal that they would not
25 re-depose those witnesses a second time in this matter. Magistrate Judge Segal did
26 not hold a Rule 16(b) Scheduling Conference or consider the phased discovery
27 plan set forth by Plaintiffs below.

28

Phase One:

- The Parties should focus on the completion of production of documents; the resolution of objections to the production of documents based on relevancy, burden, etc.; and the resolution of privileges being asserted to withhold the production of documents. It is likely that the Court's intervention may be required to resolve objections and privilege issues and, thus, that the Parties will need to brief these issues. Resolution of these objections and privilege issues before fact witness depositions will streamline such depositions and ensure that they are conducted appropriately.
- By April 30, 2018, Defendants must disclose in writing whether they will rely on an advice of counsel, and/or good faith reliance defense, and describe their defense(s) in sufficient detail to permit Plaintiffs to conduct relevant discovery. Disclosure of this information under the proposed deadline will permit Plaintiffs to seek additional discovery on these issues during phase one, including documents over which Defendants waive privilege, as applicable, through assertion of the defense(s).
- By September 30, 2018, Defendants must complete their production of documents and data responsive to the one-way chart review damages-related discovery requests that have been served. After the production of the data, Defendants should work cooperatively with Plaintiffs to explain and answer questions concerning the data produced, including explaining the format and source of the data, and any abbreviations. The Court's imposition of this intermediate deadline on Defendants ensures that Plaintiffs will have sufficient time to review Defendants' production of documents and data needed to compute damages, to clarify or resolve any issues, to take depositions of fact witnesses knowledgeable about such documents and data, to propound and receive answers to interrogatories about such documents and data, and to prepare the required disclosures of damages expert

1 witness(es) before opening expert reports are due.

- 2 • The Parties may take discovery relating to the preservation, collection, and
3 production of documents, including the Defendants' production of data
4 requested by Plaintiffs in order to compute damages.
- 5 • The Parties may serve subpoenas on third parties in order to obtain
6 documents from them. Plaintiffs have already done so. For example,
7 Defendants objected to producing documents and data about the results of
8 their chart reviews on the ground that the results were in the possession of
9 third-parties. Consequently, Plaintiffs served third party subpoenas on three
10 companies that Defendants employed to review medical records as part of its
11 Chart Review Program in order to obtain the results of these reviews. But
12 then, two of the companies responded that Defendants directed them to
13 provide the documents and data to Defendants and the companies have not
14 yet produced the chart review results to Plaintiffs. In addition, Plaintiffs will
15 seek medical records from incentivized providers who were outliers (i.e.,
16 diagnosed certain medical conditions at unusually high rates) and whose
17 diagnoses had high invalidation rates based on the results of Defendants'
18 RACCR reviews. Plaintiffs have sought information (through
19 interrogatories) from Defendants identifying the beneficiaries whom those
20 incentivized providers diagnosed with those conditions in order to serve the
21 providers with subpoenas for those beneficiaries' medical records, and
22 Defendants have agreed to provide certain information responsive to those
23 interrogatories. Until Defendants complete their provision of information
24 necessary to identify these beneficiaries, Plaintiffs cannot serve the
25 providers with the subpoenas requesting their medical records. Review of
26 those medical records will enable the Plaintiffs to identify the
27 unsubstantiated diagnoses that Defendants submitted to the Medicare
28 Program but deliberately ignored or recklessly disregarded.

- The Parties may also propound interrogatories on each other. Plaintiffs propose that each side may, without seeking leave of Court, serve up to 30 interrogatories relating to the Government's claims in this action. Plaintiffs further state that they will seek the Court's permission to serve additional interrogatories relating to Defendants' counterclaims that are not dismissed and the affirmative defenses that remain after the Court rules on their motions.
- The Parties may also serve requests for admissions, which number should not be limited.
- Plaintiffs anticipate that Phase I will be the principal phase for written and document discovery, although the Parties will not be precluded, prior to the close of fact discovery, from submitting additional discovery requests to address discrete issues that arise or become clear later in the litigation, or to establish the authenticity and admissibility of documentary evidence if those evidentiary issues cannot be resolved cooperatively.

Phase Two:

- During this phase, the Parties should focus on conducting fact witness depositions. Plaintiffs estimate that, with respect to their claims (not Defendants counterclaims or affirmative defenses), they will need at least 100 hours for depositions of fact witnesses and at least an additional 14 hours for depositions of corporate entities conducted pursuant to Rule 30(b)(6) (such depositions and topics may be the subject of more than one notice) and propose that this phase of discovery start November 1, 2018 and end by May 31, 2019. This estimate of the number of hours for and the time it will take for fact witness depositions is based on the assumptions that (i) Defendants will work informally and cooperatively with Plaintiffs to provide the information necessary for Plaintiffs to understand Defendants' data relating to damages (otherwise additional time would be needed to depose

1 fact witnesses knowledgeable about the data; and (ii) there are no major
2 issues concerning the authenticity and admissibility of documents (which
3 would also require additional time to depose fact witnesses). This estimate
4 also does not include fact witness depositions relating to Defendants'
5 counterclaims or affirmative defenses. In addition, if Defendants fail to
6 work informally and cooperatively with Plaintiffs to provide the information
7 necessary for Plaintiffs to understand and interpret the chart review and
8 other data Defendants provide to determine damages, Plaintiffs seek an
9 additional 25 hours for depositions of witnesses who can provide this
10 information.

- 11 • Plaintiffs agree that the customary limitations regarding the duration of
12 depositions (seven hours) should remain, and that no individual will be
13 deposed more than once without a showing of good cause and leave of court.
14 However, Plaintiffs believe that, on the whole, fact witness depositions
15 should be limited by the number of total hours and not by the number of
16 witnesses. Plaintiffs need to depose many fact witnesses, but we believe that
17 many of them can be deposed in less than a full day. Defendants' request
18 that the Court limit the number of fact witness depositions to ten deponents
19 (with the Parties having the option to stipulate to more) is unreasonable.
20 The Government's use of the testimony it took during the investigation is
21 limited to impeachment and Defendants are currently producing additional
22 documents relating to those deponents. Accordingly, Plaintiffs must re-
23 depose many of those fact witnesses in this litigation. Furthermore, there are
24 many important fact witnesses that the Government did not depose during
25 the investigation. Defendants' proposed ten-deponent limit is also
26 undermined by the Parties' estimate that each of them will call numerous
27 witnesses at trial.
28

Phase Three:

- By June 28, 2019, approximately four weeks after the close of fact witness depositions, the Parties should make expert testimony disclosures pursuant to Rule 26(a)(2) addressing issues on which they bear the burden of proof. At this time, Plaintiffs anticipate that their disclosures will include experts on risk adjustment under Parts C and D of the Medicare Program; experts on diagnosis coding; and damages experts. However, because the Court has not yet had the opportunity to rule on various issues, Plaintiffs' disclosures may include other types of experts. Because of this uncertainty, it is also difficult to estimate the amount of time needed to conduct expert discovery, but Plaintiffs' current estimate is that responsive expert reports would be due by July 31, 2019, approximately four weeks after the opening expert reports, and expert depositions would be completed by September 30, 2019, approximately a month before summary judgment briefing. Accordingly, at this time, Plaintiffs estimate that expert discovery can be completed by September 30, 2019. Expert depositions should also be limited to 7 hours for each expert. In addition, as previously stated, Plaintiffs' ability to make their initial damages expert disclosures will depend on Defendants' timely production of the requested documents and data.

UnitedHealth's Position: The staged discovery process proposed by the United States appears intended to prevent UnitedHealth from obtaining the evidence it believes necessary to defend this case: the proposed restrictions and controls on discovery advocated by the United States will frustrate UnitedHealth from securing relevant and necessary evidence promptly. In this case, the United States already possesses a vast amount of documentary and testimonial information it obtained from UnitedHealth and other sources. UnitedHealth anticipates needing extensive discovery from the United States in order to prepare its defenses and counterclaims, including discovery relating to: the manner in which risk

1 adjustment factors are calculated; CMS' knowledge of UnitedHealth's and other
2 MA Plans' chart reviews and its awareness of industry-wide diagnostic coding
3 error rates and data verification practices during the relevant time period; any
4 attempts by the United States to calculate a Medicare fee-for-service error rate;
5 information concerning what those error rates are and their impact on payment
6 calculations; the United States' analysis of the assumptions and disclosures
7 contained in UnitedHealth's bids; the meaning of the "reasonable diligence"
8 standard; the decision not to finalize the medical record review rule; meetings and
9 communications between UnitedHealth and CMS regarding its obligations to
10 perform a "two-way-look" in light of this proposed rule; and the May 2014
11 overpayment rule. UnitedHealth will also seek discovery, including third-party
12 discovery, to identify what information, if any, Relator possesses, how Relator
13 obtained that information, and the source of that information. UnitedHealth
14 expressly reserves the right to conduct discovery on additional subjects and from
15 additional persons or entities as necessary and appropriate, and to make
16 appropriate objections to discovery requests.

17 UnitedHealth does not believe that phasing of discovery is necessary or
18 appropriate in this case and respectfully submits that it is an improper attempt by
19 the United States to impede UnitedHealth's efforts to defend itself. Rather than
20 lead to a more efficient discovery process, the United States' proposal would
21 prejudice UnitedHealth, and lead to both protracted discovery and increased costs.
22 For example, if UnitedHealth is unable to depose certain witnesses at the outset, it
23 will suffer delay in its attempt to effectively outline the scope of necessary
24 documents and other materials it may need.

25 Moreover, phased discovery would further delay UnitedHealth's access to
26 key fact witnesses and prejudice its ability to mount an effective defense in this
27 action. As noted above, for over five years, UnitedHealth has produced over
28 600,000 documents, compiled detailed responses to dozens of complex

1 interrogatories, and produced more than twenty witnesses for Civil Investigative
2 Demand oral examinations. While document productions are ongoing,
3 UnitedHealth requires the ability to take testimony of a number of current and
4 former government executives to effectively begin the defense of this action and to
5 identify potential other sources of documents and relevant information. However,
6 by the United States’ proposal, UnitedHealth would be precluded from doing so for
7 another *seven months*. Such an imbalance in the Parties’ access to witnesses is
8 antithetical to the spirit and purpose of the discovery rules, which advocate for
9 liberal and expeditious discovery and mutual knowledge of all relevant facts. For
10 similar reasons, Judge Segal noted during the Parties’ informal discovery
11 conference on November 20, 2017, that there is no such rule in the Federal Rules
12 that says a party is entitled to complete written discovery or to resolve written
13 discovery prior to the beginning of depositions. And, indeed, the Federal Rules of
14 Civil Procedure do not contemplate the proposed phasing of discovery the United
15 States advocates. During the Parties’ informal discovery conference on February
16 8, 2018, Judge Segal again noted that delayed or phased discovery is not “built-in”
17 in federal court and, when it is permitted, it is usually “with both parties’
18 agreement about the usefulness of phasing.” See February 8, 2018 Telephonic
19 Conf. Tr. 25:16-20. Otherwise, if one side is able to dictate the phasing of
20 discovery, it “can be used as a strategy point in a case” and gamesmanship. See *id.*
21 25:21-23.

22 The United States’ suggestion that depositions should only begin after the
23 Court resolves its forthcoming motion to dismiss UnitedHealth’s counterclaims,
24 motion to strike UnitedHealth’s affirmative defenses, and motion for partial
25 summary judgment is similarly unjustified. The United States in essence seeks a
26 stay of depositions during the pendency of the motions, which is not provided for
27 in the Federal Rules—otherwise, a case could be pending for months before
28 significant progress in the litigation is made. Similarly, the United States’

1 conclusory and generalized assertion that there will be privilege issues does not
2 justify postponing the commencement of depositions. Privilege issues exist in
3 most cases, yet most cases do not stall the commencement of depositions for close
4 to a year and a half after a complaint is filed, particularly where one side has
5 already had access to more than twenty witnesses. The propriety of a privilege
6 assertion cannot be addressed in a vacuum; it is typically best addressed in the
7 context of a specific question and the assertion of privilege in response. The
8 ordinary course is to resolve questions about the assertion of privilege in the
9 specific contexts in which they arise, so that the Court has a specific topic to
10 address.

11 UnitedHealth has only recently been afforded the opportunity to conduct
12 affirmative discovery to defend itself from the United States' baseless claims.
13 UnitedHealth is entitled to continue the process of reaching symmetry in the
14 discovery of factual information through depositions. During the December 18,
15 2017 telephonic conference before Judge Segal regarding The United States'
16 Motion for a Protective Order, Judge Segal stated that the United States had not
17 made a showing of undue burden or good cause sufficient to prevent UnitedHealth
18 from proceeding with depositions as laid out in the Federal Rules of Civil
19 Procedure. Judge Segal also stated that a pending motion for partial summary
20 judgment generally does not justify postponing depositions and that would be "the
21 exception and not the common practice." See December 18, 2017 Telephonic
22 Conf. Tr. 14:11-16. During the Parties' informal discovery conference on
23 February 8, 2018, Judge Segal again stated that UnitedHealth "ha[s] a right to
24 notice depositions" and reiterated that she likely would not enter a protective order
25 because there is "nothing in the rules that would justify it here." See February 8,
26 2018 Telephonic Conf. Tr. 26:23-27:1. Consistent with Judge Segal's admonition
27 that "given the complexity of this case . . . [it is not] inappropriate for a defendant
28 to be moving quickly to try and gather information and prepare its defenses"

UnitedHealth should be permitted to continue deposing government witnesses. See *id.* 27:8-10.

Phased discovery would also introduce significant disputes regarding whether certain discovery should or should not have been conducted during a particular phase – disputes for which there is no case law or guidance in the Federal Rules. Moreover, UnitedHealth does not agree to disclose whether it will rely on any specific defense by any date unilaterally imposed by the United States. Such a deadline is not mandated by the Federal Rules of Civil Procedure.

Finally, the United States’ proposed imposition of a unilateral deadline on UnitedHealth to complete production of documents responsive to damages-related discovery requests by September 2018 is unreasonable and inequitable, particularly in light of the fact that the United States has only just begun to produce documents in this matter. UnitedHealth is willing to work cooperatively with the United States to engage in mutual exchanges of information and to comply with its obligations under the Federal Rules.

3. Electronically Stored Information – Rule 26(f)(3)(C)

The Parties are aware of their duties regarding the preservation of discoverable information. The Parties have taken reasonable measures to comply with those duties as required by the Federal Rules of Civil Procedure and the Local Rules. The Parties have met and conferred pursuant to Federal Rule of Civil Procedure 26(f), and each represented that steps have been taken to preserve evidence relevant to this litigation. The Parties have agreed to a protocol for the exchange of Electronically Stored Information.

4. Privilege Issues – Rule 26(f)(3)(D)

The Parties negotiated a protective order governing non-waiver of privilege and protected material. Magistrate Judge Segal entered the order on January 16, 2018. (Dkt. No. 198)

1 **5. Changes to Federal and Local Rules – Rule 26(f)(3)(E)**

2 United States and Relator's Position: The changes that we propose are set
3 forth in our proposed discovery plan set forth in Section J.2 above.

4 UnitedHealth's Position: UnitedHealth reiterates that phased discovery is
5 inappropriate in this case. Exhibit A, and Subsections K and L below, address
6 UnitedHealth's position on the timing of discovery and proposed discovery
7 deadlines. UnitedHealth disagrees with the United States' hour-based calculation
8 of depositions. UnitedHealth's position is that each side will likely need more than
9 the 10 depositions permitted by the Federal Rules without leave, and that the
10 Parties should meet-and-confer as the need for additional depositions matures.
11 UnitedHealth agrees with the United States' proposal of 30 interrogatories by the
12 United States and Relator jointly and 30 interrogatories by UnitedHealth.

13 **6. Other Orders – Rule 26(f)(3)(F)**

14 United States and Relator's Position: As discussed above, Plaintiffs request
15 that the Court issue an order, pursuant to Rule 16(b)(3)(B)(i) and 16(c)(2)(F),
16 modifying the timing of initial disclosures under Rule 26(a)(1)(A)(iii) relating to
17 damages. The Government also provided Defendants with a proposed stipulation
18 and order relating to the scope of expert disclosures and discovery in order to
19 streamline that part of the case. The Government hopes that Defendants will agree
20 to this.

21 Pursuant to Rule 16(b)(3)(B)(ii), Plaintiffs also request that the Court limit
22 the scope of discovery to only factual issues and preclude discovery relating to
23 purely legal issues, including materiality, Defendants' legal obligations to delete
24 invalid diagnoses, and actuarial equivalence. In addition, pursuant to Rule
25 16(c)(2)(C), Plaintiffs believe it may benefit the case to make rulings in advance
26 on the authenticity and admissibility of certain evidence. This would include
27 evidence that may be relied upon for summary judgment motions as well as trial.

28

1 Accordingly, Plaintiffs request that the Parties be permitted to file motions relating
2 to authenticity and admissibility of documents at any time.

3 UnitedHealth's Position: UnitedHealth objects to the limiting of discovery
4 pursuant to Rule 16(b)(3)(B)(ii). UnitedHealth believes that CMS would not have
5 acted differently or sought repayment from UnitedHealth had it learned that
6 UnitedHealth allegedly retained overpayments and is entitled to discovery on this
7 topic, including discovery of facts which are relevant to UnitedHealth's ability to
8 establish this and other defenses, including the views of CMS employees about the
9 ambiguous regulatory requirements here at issue, which is relevant to scienter.

10 **K. Discovery Cut-Off**

11 United States and Relator's Position:

12 Plaintiffs propose that the non-expert discovery cut-off date be May 31,
13 2019.

14 UnitedHealth's Position:

15 UnitedHealth proposes that the non-expert discovery cut-off date be January
16 28, 2019.

17 **L. Expert Discovery**

18 The Parties agree to disclose expert witnesses consistent with the Federal
19 Rules of Civil Procedure, the Local Rules, and any order entered by this Court.
20 Plaintiffs' position with respect to the timing of expert witness disclosures (June
21 28, 2019 for initial disclosures and July 31, 2019 for rebuttal disclosures) and the
22 expert discovery cut-off date (September 30, 2019) are set forth in Section J.2
23 above (its discovery plan) and Exhibit A.

24 UnitedHealth proposes the following dates for expert witness disclosures
25 and expert discovery cut-off under Rule 26(a)(2).

26	Expert Disclosure – Initial	February 25, 2019
27	Expert Disclosure – Rebuttal	March 25, 2019
28	Completion of Expert Discovery	April 22, 2019

M. Dispositive Motions

The United States and Relator's Statement: The United States presently anticipates filing a motion to dismiss Defendants' counterclaims and the United States and Relator presently anticipate filing a motion to strike some of Defendants' affirmative defenses. The United States also intends to file a motion for partial summary judgment on Defendants' "actuarial equivalence" argument (unless Defendants stipulate that they are not asserting it in this case) because it presents a purely legal issue which can be adjudicated at this time and should be adjudicated at this time to avoid wasteful discovery. The United States may file other motions, including motions for summary judgment or partial summary judgment, on other issues concerning liability, damages, and issues raised in Defendants' Answer to the FAC. Plaintiffs may also file motions *in limine* because certain issues or defenses may be determined earlier on by such motions, especially with respect to the authenticity and/or admissibility of certain documents created by Defendants for purposes of litigation.

Plaintiffs propose that the last date to hear summary judgment motions be November 4, 2019.

UnitedHealth's Statement: UnitedHealth will oppose the United States' motion to dismiss and motion to strike. As noted above in Section C, UnitedHealth and the United States have already fully briefed cross-motions for summary judgment in the APA case addressing "actuarial equivalence" and it would be inappropriate, inefficient, and a waste of judicial resources to attempt to litigate those same issues here. In addition, as noted above in Section J, the United States has only recently begun to produce documents in this case. Accordingly, the filing of any summary judgment motion is drastically premature at this point in the litigation. UnitedHealth anticipates filing motions or cross motions for summary judgment, at the appropriate time and after the Parties have had the opportunity to conduct meaningful discovery.

UnitedHealth proposes the last date to hear summary judgment motions be May 20, 2019.

N. Settlement/Alternative Dispute Resolution (ADR)

The United States' Statement: In October 2016, pursuant to a request made by Defendants, the United States made a presentation to Defendants about their liability under the False Claims Act. After this presentation, Defendants' counsel notified the United States that it was not interested in discussing a settlement of this matter.

UnitedHealth's Position: In October 2016, the United States made a presentation concerning this case in which it refused even to acknowledge UnitedHealth's myriad defenses and asserted no formal settlement demand; accordingly, UnitedHealth did not make any settlement offer either. Based on the one-sided presentation the United States made in October 2016 and other discussions, UnitedHealth respectfully believes that settlement discussions are unlikely to be productive at this time.

A Notice to the Parties of Court-Directed ADR Program was entered on November 22, 2016, when this action was transferred to this Court. Dkt. No. 54. Pursuant to Local Rule 16-15.2, the Parties are filing concurrently a Request: ADR Procedure Selection. The Parties have agreed on ADR Procedure No. 3 (private dispute resolution).

O. Trial Estimate

The United States and Relator's Position: Plaintiffs estimate that their presentation of their claims at trial will take approximately 10-15 days and include approximately 25-30 witnesses (including experts), depending on whether the Court agrees that certain key issues are purely legal issues, the Court's resolution of dispositive motions, the Court's resolution of evidentiary issues prior to trial, the Parties' stipulation to the authenticity and admissibility of documents, and the Parties' admission of undisputable facts. Plaintiffs estimate that Defendants'

1 presentation of their defenses should take an equal or less number of days.

2 Accordingly, Plaintiffs have estimated a total of 20-30 days.

3 If the Court does not dismiss all of Defendants' counterclaims prior to trial,
4 Plaintiffs request that any trial relating to any of those claims be severed and
5 separate from the trial of their claims against Defendants, especially considering
6 their apparent contingent nature. At this time, Plaintiffs do not have an estimate
7 for the duration of a trial relating to the counterclaims.

8 UnitedHealth's Position: UnitedHealth estimates that the trial will take 24
9 to 32 days, including presentations by both sides. UnitedHealth anticipates calling
10 25-30 witnesses at trial, including experts.

11 UnitedHealth opposes the United States' request to sever or bifurcate
12 UnitedHealth's counterclaims at trial. The United States fails to provide any
13 substantive basis for its premature request to sever and bifurcate.

14 The Parties reserve their rights to modify these estimates as the case
15 progresses and to ask for additional time for rebuttal witnesses.

16 **P. Trial Counsel**

17 United States: Edward Crooke, Carol Wallack, Justin Draycott, Paul
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24 Abid R. Qureshi.

25 **Q. Independent Expert or Master**

26 At this time, the Parties do not anticipate a need for an independent expert or
27 master.

28

R. Timetable

The Parties' completed Schedule of Pretrial and Trial Dates is attached as Exhibit A.

S. Other Issues

At this time, the Parties do not have other issues.

Respectfully submitted,

Dated: April 2, 2018

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Attestation

I hereby attest that the other signatories listed, on whose behalf the filing is submitted, concur in the filing's content and have authorized the filing.

Dated: April 2, 2018

/S/ John E. Lee

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JUDGE MICHAEL W. FITZGERALD
SCHEDULE OF PRETRIAL AND TRIAL DATES WORKSHEET

Case No.	16-08697			
Case Name	United States ex rel. Poehling v. UnitedHealth Group, Inc. et al.			
Matter	** Plaintiff(s) Date: mo / day / year	Defendant(s) Date mo / day / year	Court Order	
☒ Jury Trial or ☐ Court Trial (Tuesday at 8:30 a.m.) Duration Estimate _____ Days	2/18/2020; duration estimate = 20-30 days	8/27/2019; duration estimate = 24-32 days		
Final Pretrial Conference (LR 16) and Hearing on Motions in/ to/ vaine (Monday at 11:00 a.m. -- <u>three (3)</u> weeks before trial date) Motions in/ to/ vaine must be filed <u>three (3)</u> weeks before this date; oppositions are due <u>two (2)</u> weeks before this date. no reply briefs	1/27/2020	8/5/2019		
Event	Weeks Before Trial	Plaintiff(s) Date mo / day / year	Defendant(s) Date mo / day / year	Court Order
Last Date to Hear Motion to Amend Pleadings / Add Parties		10/29/2018	10/29/2018	
Non-Expert Discovery Cut-Off (at least 4 weeks before last date to hear motions)	13	5/31/2019	1/28/2019	
Expert Disclosures (Initial)		6/28/2019	2/25/2019	
Expert Disclosures (Rebuttal)		7/31/2019	3/25/2019	
Expert Discovery Cut-Off	14 *	9/30/2019	4/22/2019	
Last Date to Hear Motions (Monday at 10:00 a.m.)	14	11/4/2019	5/20/2019	
Last Date to Conduct Settlement Conference	12	12/26/2019	6/3/2019	
<u>For Jury Trial</u> • File Memorandum of Contents of Fact and Law, LR 16-4 • File Exhibit and Witness Lists, LR 16-5.E • File Status Report Regarding Settlement • File Motions in/ to/ vaine	6	1/6/2020	7/15/2019	
<u>For Jury Trial</u> • Lodge Pretrial Conference Order, LR 16-7 • File Agreed Set of Jury Instructions and Verdict Forms • File Statement Regarding Disputed Instructions, Verdicts, etc. • File Oppositions to Motions in/ to/ vaine	5	1/13/2020	7/22/2019	
<u>For Court Trial</u> • Lodge Findings of Fact and Conclusions of Law, LR 16-2, and Summaries of Direct Testimony	3			

* The parties may choose to cut off expert discovery prior to MSJ briefing.

** If the Court dismisses Defendant's counterclaims, Plaintiff's may raise their proposed dates and estimated trial duration.

ADR (LR 16-16) Selection:

☐ Attorney Settlement Officer Panel☒ Private Mediation☐ Magistrate Judge (with Court approval)

EXHIBIT D-5

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et al.*,

Defendants.

No. CV 16-08697 FMO (SSx)

JOINT STIPULATION RE UNITED
STATES' MOTION TO COMPEL
DISCOVERY

DISCOVERY MATTER
Special Master Suzanne H. Segal

Date: April 29, 2021

Time: 1:00 p.m.

Discovery cutoff date: December 6, 2021

Pretrial conference date: February 3, 2023

Trial Date: February 21, 2023

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I. INTRODUCTORY STATEMENTS

A. United States

This dispute arises out of UnitedHealth Group’s (“UnitedHealth” or “UHG”) refusal to reasonably respond to two discovery requests served by the United States that address central issues of this case. The United States’ Interrogatory No. 14 (“Interrogatory 14”) and Request for Production No. 147 (“Request 147”) together seek to discover UnitedHealth’s contentions about the diagnosis codes that the United States alleges UnitedHealth improperly failed to delete.

The central issue in this case is whether UnitedHealth improperly failed to delete diagnosis codes from its Medicare Part C risk adjustment submissions, after its own medical record reviews indicated that diagnoses it had previously submitted to CMS were, in fact, not supported by medical records. Pursuant to the rules and regulations governing Medicare Part C, Medicare Advantage Organizations (“MAOs”) such as UnitedHealth submit to CMS diagnosis codes associated with every beneficiary, which adjust that beneficiary’s risk score. As alleged in the Amended Complaint, the diagnosis codes that MAOs submit determine the payment that MAOs receive from CMS, and CMS requires that MAOs only submit diagnosis codes that are unambiguously supported by the beneficiaries’ medical records. (Declaration of Gregory Mason (“Mason Decl.”), Ex. C, United States’ Am. Compl., ECF No. 171, at ¶ 4). Because MAOs submit only diagnosis data, not the underlying medical records, MAOs must exercise due diligence and expressly certify that the diagnosis codes they have submitted for risk adjustment payments are accurate and truthful. *Id.* at ¶ 5. When an MAO discovers that a previously submitted diagnosis code was not supported by medical records, it is required to delete it in CMS’s risk adjustment payment system. *Id.* at ¶ 103.

As alleged in this case, UnitedHealth significantly increased the amount of risk adjustment payments it received from CMS by implementing medical record review programs, through which it collected millions of medical records from providers and employed coders to review those medical records and mine them for additional diagnosis

1 codes that the providers themselves did not report or record. *Id.* at ¶ 10. Although
2 UnitedHealth relied on its medical record reviews to submit additional diagnosis codes
3 and increase its risk adjustment payment from CMS, it systematically ignored medical
4 record reviews when they indicated that diagnosis codes UnitedHealth had previously
5 submitted to CMS were not supported by beneficiaries' medical records. *Id.* at ¶ 12.

6 In response to UnitedHealth's Interrogatory No. 1, the United States has identified
7 every diagnosis code that it contends UnitedHealth submitted to CMS to increase its risk
8 adjustment payments, and then improperly failed to delete when UnitedHealth's own
9 reviewers found no support for the diagnosis code in the beneficiary's medical records.
10 For each diagnosis code on the United States' list: (1) the diagnosis code was submitted
11 by UnitedHealth to CMS and was required, by regulation, to be supported by an underlying
12 medical record; (2) that medical record went through UnitedHealth's medical record
13 review program; and (3) UnitedHealth's own reviewers did not find the diagnosis code to
14 be supported by medical records. That is, each diagnosis code on the United States' list is
15 associated with a medical chart that UnitedHealth has already thoroughly reviewed, and
16 in none of those reviews found support for the diagnosis code in question. However,
17 UnitedHealth never deleted any of these diagnosis codes.

18 After the United States identified its list of all diagnosis codes it contends are at
19 issue, it served Interrogatory 14 and Request 147 to discover UnitedHealth's contentions
20 about the very same diagnosis codes. In particular, the United States seeks to discover
21 whether UnitedHealth contends that any of the diagnosis codes on the United States' list
22 were supported by medical records, despite not being found during any of UnitedHealth's
23 reviews of the associated medical records. The United States further seeks to discover
24 factual information related to UnitedHealth's medical record reviews.

25 Interrogatory 14 asks UnitedHealth to, with respect to every diagnosis code on the
26 United States' list: (A) identify which of those diagnosis codes, if any, UnitedHealth
27 contends were supported by a medical record, as well as the specific medical record
28 UnitedHealth contends provides such support, and (B) identify every medical record

1 review that UnitedHealth conducted (and the results of that review) for every code that
2 UnitedHealth contends it was not obligated to delete or otherwise return payment for,
3 regardless of whether the basis for UnitedHealth's contention is claimed support in an
4 underlying medical record or some other defense. (Mason Decl., Ex. A, UHG's Resps.
5 and Objs. to Interrog. 14). Request 147, as written, relatedly requests all medical records
6 associated with the diagnosis codes on the United States' list. (Mason Decl., Ex. B, UHG's
7 Resps. and Objs. to Req. 147). Importantly, as a result of the meet and confer process
8 following UnitedHealth's responses and objections to Request 147, the United States
9 agreed to limit its request for medical records to only those records associated with the
10 diagnosis codes that UnitedHealth contends were supported (*i.e.*, the medical records
11 UnitedHealth identifies in response to Part A of Interrogatory 14).

12 This discovery is an appropriate use of contention interrogatories, seeks factual
13 information regarding UnitedHealth's contentions and defenses, will substantially narrow
14 the issues for trial and the scope of document discovery, avoid wasteful trial preparation,
15 and possibly expedite the resolution of this case.

16 UnitedHealth initially refused to provide any response to either Interrogatory 14 or
17 Request 147. (Mason Decl., Ex. A; Mason Decl., Ex. B). Subsequently, UnitedHealth
18 agreed to produce some (but not all) of the underlying medical records, but that offer is
19 hollow without identifying which codes UnitedHealth contends are supported by medical
20 records (*i.e.*, responding to Interrogatory 14). Simply producing millions of medical
21 records alone does nothing to illuminate UnitedHealth's contentions.

22 UnitedHealth's position is unreasonable, would undermine the utility of contention
23 interrogatories, and would cause wasteful inefficiencies in discovery. Because
24 Interrogatory 14 is an appropriate contention interrogatory, UnitedHealth should be
25 compelled to answer it. Furthermore, UnitedHealth should be compelled to produce all
26 medical records associated with the diagnosis codes that UnitedHealth contends were
27 supported. Therefore, the Court should grant the United States' Motion and order a full
28 response to Interrogatory No. 14 and Request 147.

B. UnitedHealth

The government's motion to compel seeks to require United to conduct burdensome and extensive analysis United itself has not conducted, and may never conduct, much of it expert, in order to make the government's case for it. The government should have conducted this analysis while the matter was under investigation and *before* it filed its complaint, but the government failed to do so. The government should not now be permitted to abuse the discovery process in an ill-conceived attempt to cure fundamental defects in its case.

The core of this dispute centers on whether, under the guise of a contention interrogatory (Interrogatory 14A), the government may compel United to: (a) retain coding experts to review the list of approximately 28 million diagnosis codes the government alleges United knew were unsupported and was required to delete; (b) identify which medical records in United's possession, if any, correspond to those diagnosis codes; (c) direct the coding experts to review the resulting tens of millions of medical records to search for entries that correspond to the diagnosis codes on the government's list; and (d) provide the government now with the results of the coding experts' conclusions as to which codes among the 28 million are in fact supported – and thus necessarily (by omission) also which codes the experts conclude are *not* supported by the medical charts.

The Federal Rules, and numerous cases, make clear that the government cannot compel United to undertake this work. First, despite the government's strenuous insistence that Interrogatory 14A only seeks "facts" underlying United's defense, the reality is that only an expert can reach a conclusion as to which of the codes on the government's list are supported. The government's interrogatory thus does not seek disclosure of some underlying facts, it unabashedly seeks the *results* of that expert analysis, long in advance of when expert reports would be due, despite the fact that United might choose never to perform the expert analysis that the government now seeks. Second, aside from seeking to compel United to perform expert analysis, the government's interrogatory improperly seeks to shift the burden of proof in this case by requiring United to conduct extensive

1 analysis it has not undertaken in order to determine which of the 28 million diagnosis
2 codes on the government's list are supported, when it is the government's burden to prove
3 that all 28 million diagnosis codes are unsupported. United has repeatedly offered to
4 produce all the medical records in its possession to the government, which will allow the
5 government to conduct the expert analysis it seeks to compel United to perform. That is
6 all that is required under the Federal Rules.

7 Moreover, while United may contend at trial that the diagnosis codes on the
8 government's list are generally supported since they reflect the independent coding
9 decisions of medical providers, United has no obligation or burden to prove that point.
10 United is perfectly entitled simply to contest whatever evidence the government intends
11 to present to support its contention that all 28 million diagnosis codes are unsupported. To
12 the extent that United chooses to proffer expert testimony regarding any of diagnosis codes
13 on the government's list, it will make that disclosure when required by the scheduling
14 order in this case—not during fact discovery.

15 Interrogatory 14B is likewise improper. That interrogatory seeks to compel United
16 to conduct new, complex, analysis to help fill another hole in the government's case – its
17 allegation that United allegedly *knew* that the codes on the government's list were
18 unsupported. The government alleges that United possessed this knowledge because
19 United's coders allegedly reviewed the medical records that correspond to the 28 million
20 diagnosis codes on the government's list. In order to prove this allegation for the
21 government, Interrogatory 14B asks United, with respect to each of the 28 million codes,
22 to determine whether a United coder in fact reviewed the corresponding medical chart,
23 match the chart to the corresponding code on the government's list, and provide the results
24 of that chart review. United has not conducted such an analysis, and this analysis in no
25 way relates to any contention United is making or any defense United intends to advance
26 in this case. It is the government, not United, that alleges that United reviewed the medical
27 records corresponding to these 28 million codes, and it is the government that must
28 conduct the analysis to prove it. United has already produced to the government all the

1 datasets that contain the relevant information that United would need to conduct this
2 analysis; hence, the government already has all the information necessary to analyze that
3 data for itself. The Federal Rules require nothing more.

4 In response to RFP 147, United has offered to produce all the medical records in its
5 possession from the relevant time period that were subject to United's chart review, and
6 that offer remains open. Instead, the government asks United to produce only those
7 medical charts that correspond to codes United contends are supported in its response to
8 Interrogatory 14A. As recrafted, RFP 147 thus stands or falls with this Court's ruling as
9 to that interrogatory. If the court agrees with United that it need not respond to
10 Interrogatory 14A, then there will be no responsive records to produce.

11 United's positions are neither novel nor unfair. The relevant rules provide deadlines
12 for expert disclosures, witness lists, and pretrial exchange of exhibits. But even in complex
13 cases with millions of documents, parties are not required to identify during fact discovery
14 the specific evidence they intend to introduce at trial, much less on cross-examination, nor
15 to provide expert disclosures in response to alleged contention interrogatories. These rules
16 apply equally to the government, and there is no unfairness in requiring the government
17 to adhere to them.

18 **II. PROCEDURAL AND FACTUAL BACKGROUND**

19 **A. United States**

20 **1. The United States' Requests**

21 Interrogatory 14 is a contention interrogatory requesting that UnitedHealth identify
22 factual information regarding its contentions about the diagnosis codes at issue in this case.

23 **INTERROGATORY NO. 14:** For each Diagnosis set forth in the
24 United States' Response to Defendants' Interrogatory No. 11 that You
25 contend You were not obligated to delete or otherwise return payment
26 received for the Diagnosis to the Medicare Program, identify (A) all
27 documentation in each Chart(s), if any, that You contend supports that
28 Diagnosis, Including for each the Beneficiary (by name, HIC Number,

1 and date of birth), Date(s) of Service, Diagnosis Code(s), HCC(s)
2 and/or RxHCC(s), Provider (by individual name, group name, address,
3 NPI, Tax ID(s), and Provider ID); and (B) each Medical Record
4 Review(s) of the Chart(s) corresponding to that Diagnosis, Including
5 for each its date(s), type(s) (i.e., whether the Medical Record Review
6 was conducted as part of Chart Review, Internal Data Validation,
7 RACCR, Claims Verification, HQ-PAFs, or other UHG Medical
8 Record Review program), Chart Barcode, Load Date(s), and each
9 Diagnosis Code for which support was found, identified, validated, or
10 recorded in the Medical Record Review.

11 (Mason Decl., Ex. A). That is, for every diagnosis code on the United States' list of
12 diagnosis codes UnitedHealth improperly failed to delete that UnitedHealth disputes it was
13 obligated to delete, it must identify: (A) "all documentation in each Chart(s), if any, that
14 You contend supports that Diagnosis" and (B) "each Medical Record Review(s) of the
15 Chart(s) corresponding to that Diagnosis." *Id.* Part B effectively asks UnitedHealth to
16 identify every medical record review it conducted of any charts associated with every code
17 on the United States' list – assuming, of course, that UnitedHealth disputes it was obligated
18 to delete, regardless of the basis for that dispute, each of the codes. *Id.*

19 Request 147 seeks the production of all medical records associated with the
20 diagnosis codes on the United States' list:

21 **REQUEST FOR PRODUCTION NO. 147:**

22 All Chart(s) corresponding to, associated with, or related to each
23 Beneficiary, from each DOS Year(s) in which that Beneficiary is listed
24 in the United States' Response to Defendants' Interrogatory No. 1
25 (Including the United States' First Supplemental Response served on
26 August 17, 2020, the United States' Amended First Supplemental
27 Response served on October 13, 2020, the United States' Second
28 Supplemental Response served on October 30, 2020, and any other

subsequent responses).

(Mason Decl., Ex. B). As indicated above, the United States has agreed to limit this request to production of only those medical records UnitedHealth contends support a diagnosis code on the United States' list.

2. UnitedHealth's Response

In its Response, UnitedHealth refused to answer the Interrogatory:

Pursuant to and on the basis of these objections, UnitedHealth responds that this Interrogatory is an improper contention interrogatory that impermissibly seeks to shift the burden of proving an essential element of the government's False Claims Act case on to UnitedHealth and seeks expert opinion. UnitedHealth therefore does not intend to further respond to this Interrogatory.

(Mason Decl., Ex. A). UnitedHealth also refused to produce any documents responsive to Request 147:

Based upon its General and Specific Objections, UnitedHealth does not intend to produce documents responsive to this Request.

(Mason Decl., Ex. B).

In an effort to resolve this discovery dispute, the United States sought a meet and confer with UnitedHealth. See Mason Decl., ¶ 4. UnitedHealth indicated that it would produce the responsive medical records in its possession (but not those in its control that are in the possession of UnitedHealth's third party contractors), which would, according to UnitedHealth, amount to an estimated 21 million charts and take approximately 8 months to collect and produce. (Mason Decl., ¶ 6). UnitedHealth also stated that it would respond to Interrogatory 14 only by referring to those millions of charts, and would not otherwise supplement its response to the Interrogatory. *Id.*

During the meet and confer process, the United States proposed to resolve the dispute by offering a reasonable period of time during fact discovery for UnitedHealth to substantively answer the Interrogatory by identifying the diagnosis codes it contends were

1 supported by medical records, and limiting the document production to only those charts,
2 if any, associated with the diagnosis codes that UnitedHealth contends were supported.
3 (Mason Decl., ¶ 5).

4 UnitedHealth's position is that it is entitled to present evidence at trial – through
5 percipient witnesses or expert opinion testimony – that certain diagnosis codes on the
6 United States' list were supported by a medical record, without ever answering
7 Interrogatory 14 or otherwise identifying which diagnosis codes it believes are supported
8 by medical records during fact discovery.

9 **B. UnitedHealth**

10 1. Procedural and Factual Background

11 a. *The Government's Theory of the Case, United's Defenses, and*
12 *the Government's Response to United's First Interrogatory*

13 This case centers around the government's contention that United failed to delete
14 diagnosis codes that providers treating United beneficiaries had transmitted to United and
15 that United passed on to CMS, but that United allegedly subsequently came to know were
16 unsupported by the corresponding medical charts. In simplest terms, the government
17 alleges that United retained monies it was not entitled to retain, knew that it had thereby
18 received overpayments from the government, and then failed to return those monies.

19 The instant dispute centers on a list of 28 million diagnosis codes that this Court
20 ordered the government to create in order to comply with its obligation to identify, with
21 specificity, the diagnosis codes it contends United knew were "invalid" (i.e. unsupported
22 by any medical record), and thus represented overpayments that United was required to
23 return by deleting the codes. Each of the diagnosis codes set forth on the government's list
24 of 28 million allegedly false diagnosis codes was originally submitted by providers to
25 United on claim forms. For each diagnosis code, a coder in the provider's office, who is
26 familiar with the provider's documentation practices and handwriting, the particular
27 medical conditions that the provider may specialize in, and often the patient herself, made
28 an affirmative determination that the code at issue was in fact supported by the patient's
medical record.

1 Providers have no incentive to identify all of the appropriate diagnosis codes for a
2 patient because providers are generally not paid based on diagnosis codes (rather, they are
3 paid for rendering a particular service or providing treatment). In recognition of the fact
4 that provider coding is incomplete and does not fully reflect the complete health status of
5 a patient, United and other Medicare Advantage Plans have chart review programs that
6 look for codes to submit that are supported in the medical record. No one, including the
7 government, claims that chart reviews themselves are improper. To avoid biasing its
8 coders, United instructs its chart review coders to review a medical record “blind,”
9 meaning the coder does not have any knowledge regarding what diagnosis codes a
10 provider submitted on a claims form for that same patient. Chart review coders have a
11 finite amount of time to review what often amounts to very lengthy medical records and
12 do their best to identify the codes they see supported by the medical record they are
13 reviewing.

14 In some cases, a chart review coder reviewing a medical record for a particular
15 beneficiary may not identify a diagnosis code that the provider or provider’s coder
16 submitted on the claim form. Contrary to the government’s assertion, in none of those
17 instances is the United chart review coder making an affirmative determination that the
18 provider submitted a code that was not supported in the medical record. The coder cannot
19 make such a determination as the coder does not have any knowledge as to which codes
20 the provider originally submitted on the claim. At worst, the government might argue that
21 a chart review coder’s failure to list a diagnosis code creates an *implication* that the code
22 *might* not be supported by the particular chart the coder reviewed. At best, the code is
23 supported in the medical record and simply was overlooked by the United coder.

24 There are many reasons why a chart review coder conducting a “blind” review of a
25 medical record may not identify a diagnosis code submitted on the claim when that
26 diagnosis code is, in fact, supported in the medical record. To take a simple example, a
27 United coder may not be familiar with the provider’s handwriting, and thus may miss
28 perfectly valid diagnosis codes identified by the provider’s own staff. More than that,

1 coding requires judgment and interpretation of both the medical record and the complex
2 and myriad coding rules. Two coders may look at the same chart and observe different
3 things. The fact that a second coder does not identify all of the codes originally identified
4 by an initial coder thus does not render the original codes false or unsupported.
5 Alternatively, the second coder may well have made an error and missed some entry in
6 the medical record that documents the diagnosis code at issue. Nevertheless, the
7 government's theory is that every single time there is a discrepancy between an affirmative
8 coding decision by the provider that a code is supported and the coding results of United's
9 blind chart reviews, the provider's decision to code that particular code was necessarily
10 incorrect and the code was not supported.

11 In addition to proving that the diagnosis codes at issue were false, the government
12 also has to prove that United *knew* that the 28 million codes at issue were unsupported.
13 The government's list of codes, of course, did not exist prior to this litigation. Hence, the
14 government cannot allege that anyone at United had allegedly reviewed that list and
15 determined it contained unsupported codes. Instead, the government's theory of
16 knowledge appears to rest on its allegation that with respect to each of the 28 million codes
17 at issue, a United coder had reviewed the very medical chart associated with the specific
18 diagnosis code and by not identifying the code in that coder's coding results, thereby knew
19 the provider's code on the list was unsupported. As the government itself describes the
20 factual underpinning of this theory, "each diagnosis code on the United States' list is
21 associated with a medical chart that UnitedHealth has already thoroughly reviewed."
22 *United States' Portion, Section I.A. at 2.*

23 United has made clear throughout this matter that it vigorously disputes the
24 government's theory of the case, both as a legal and factual matter. As the Special Master
25 is aware, one of United's legal defenses, based on the statutory "actuarial equivalence"
26 mandate, is that it cannot be required to delete codes that it knows are unsupported unless
27 it knows that its rate of unsupported codes exceeds the rate in CMS's data. And as a factual
28 matter, United argues that for many reasons, including that the payment amounts to

1 Medicare Advantage Plans that CMS calculates already account for the existence of
2 unsupported codes, the presence of unsupported codes in a Medicare Advantage Plan's
3 data does not necessarily result in overpayment. *See* United Motion to Compel Medical
4 Records, concurrently filed on April 12, 2021. Hence, even if United somehow had
5 knowledge that a particular code on the government's list was unsupported, that would not
6 translate into knowledge that United was overpaid or was improperly retaining monies it
7 was not entitled to retain.

8 But United also disputes the government's underlying factual theory of "falsity"—
9 that simply because a United coder conducting a "blind" review did not identify a code
10 that a provider submitted on a claim form, the code must be unsupported and thus
11 "invalid."^{1,2} This should come as no surprise to the government. As early as its Motion to
12 Dismiss (Dkt. 182), United "vigorously dispute[d] the suggestion that merely because a
13 retrospective chart reviewer doing a 'blind' chart review did not identify every diagnosis
14 code that the provider's own coder had found, the provider's own codes were necessarily
15 wrong or suspect." Ex. M, Dkt. 182 at 6, n.3. United further explained that it would be
16 "remarkable" if a chart review coder conducting a "blind" review "consistently captured
17 every code that was supported in a given patient's chart." *Id.* To be sure, given the sheer
18 number of codes at issue here and the prevalent level of unsupported diagnosis codes
19 industry wide (including in CMS's own data) some number of the 28 million codes are
20 undoubtedly unsupported. But because each of the codes the government alleges United

21
22 ¹ The only government witness deposed on this topic to date made clear that he
23 agreed with United's position. Jeffrey Grant, a senior CMS official who oversaw creation
24 of the risk adjustment program, explained that even in his view, an MA plan's submission
25 of an unsupported code would be improper only if it was making the "very specific
26 submission of a very specific data element . . . that [it] know[s] is wrong." Ex. L, Grant
27 Dep. 321:21–23. He further stated that performing one-way reviews that add diagnosis
28 codes supported in the charts, without looking at whether previously submitted codes lack
such support, would not create the requisite knowledge. *Id.* at 322:18–323:15.

² Starting with Exhibit L, citations to "Ex." materials refer to exhibits to the Declaration of David J. Schindler filed herewith.

1 was required to delete was submitted to United by a provider who treated the patient,
2 United believes that the majority of the codes are likely supported by medical charts, and
3 that each code individually is, as a matter of probability, more likely to be supported than
4 not. United certainly denies that *all* of the codes are unsupported.

5 On January 3, 2020, United issued its First Interrogatory to the government, which
6 asked the government to identify each diagnosis code for the relevant payment years that
7 the government alleged United “knowingly and improperly failed to delete . . . or
8 otherwise return to the Medicare Program [as an] overpayment.” Ex. E. United issued that
9 interrogatory because the government had failed to allege in the Complaint which codes
10 were allegedly unsupported and United needed to know which codes, as a factual matter,
11 are at issue. After being ordered to do so, the government ultimately made four productions
12 of data collectively identifying 28 million diagnosis codes the government alleges are
13 false. The most recent production, completing this list, was in December 2020.

14 The government did not review a single medical record to create its list of 28
15 million diagnosis codes at issue, and it does not know whether the diagnosis codes on its
16 list are in fact unsupported. Instead, as the government candidly admits in its portion of
17 the Joint Stipulation, *see United States’ Portion, Section I.A. at 2*, the government created
18 its list by simply comparing the codes that United had received from providers and
19 submitted to CMS to the codes identified by United’s chart review coders who allegedly
20 reviewed the medical charts corresponding to those codes, and then listing all of the codes
21 that the provider had submitted but which the chart reviewer did not identify. In
22 responding to United’s First Interrogatory, the government set forth allegations only of
23 historical facts: it is a list of codes that the government alleges a United chart reviewer did
24 not identify when coding a chart. Not having reviewed a single medical record, the
25 government’s response did not reflect any medical coding analysis or conclusions as to
26 whether either the provider’s coding, or the results of United chart review coding, was in
27 fact correct under applicable coding guidelines.

b. *Interrogatory 14 and RFP 147*

On November 4, 2020, the government issued the instant discovery requests, both of which relate to medical records that correspond to the approximately 28 million diagnosis codes the government alleges represent overpayments that United was required to delete.

Interrogatory 14

Interrogatory 14 has two subparts, A and B,³ both of which apply to “each Diagnosis set forth in the United States’ Response to Defendants’ Interrogatory No. 1 that you contend you were not obligated to delete or otherwise return payment received for the Diagnosis to the Medicare Program.” Ex. N, United States’ Fourth Set of Interrogatories. For the universe of diagnosis codes United contends it was not obligated to delete, Subpart 14A asks United to identify “all documentation in each Chart(s), if any, that You contend supports that Diagnosis, Including for each the Beneficiary (by name, HIC Number, and date of birth), Date(s) of Service, Diagnosis Code(s), HCC(s) and/or RxHCC(s), Provider (by individual name, group name, address, NPI, Tax ID(s), and Provider ID.” *Id.* As the Special Master knows, United contends that it was not obligated to delete *any* of the 28 million diagnosis codes on the government’s list, regardless of whether some of those codes are not supported by a medical record. Hence, Interrogatory 14A requires United to identify and gather the over 20 million medical records corresponding to each of the 28 million codes on the government’s list and then to hire expert coders to review those tens of millions of charts to determine whether each code on the government’s list is or is not supported by the medical chart, and if it is, to point the government to the relevant portions of the medical record containing that documentation.

Subpart 14B requests that, for the universe of diagnosis codes United contends it

³ While not at issue in the current Joint Stipulation, United notes for the record and has made clear to the government that Interrogatory 14 contains two discrete subparts, A and B, which are separate lines of inquiry and therefore separate interrogatories.

1 was not obligated to delete, United identify “each Medical Record Review(s) of the
2 Chart(s) corresponding to that Diagnosis, Including for each its date(s), type(s) (i.e.,
3 whether the Medical Record Review was conducted as part of Chart Review, Internal Data
4 Validation, RACCR, Claims Verification, HQ-PAFs, or other UHG Medical Record
5 Review program), Chart Barcode, Load Date(s), and each Diagnosis Code for which
6 support was found, identified, validated, or recorded in the Medical Record Review.” *Id.*
7 As with Interrogatory 14A, this request requires United to engage in a massive and
8 complex matching analysis for the government to look for every instance in which any of
9 the government’s 28 million codes might have been the subject of a Medical Record
10 Review, and to set forth the results of such chart reviews. The government seeks to have
11 United perform this matching exercise to create evidence to buttress the government’s
12 claim that United had knowledge that the 28 million diagnosis codes on the government’s
13 list were unsupported and, therefore, constituted overpayments.

14
15 *RFP 147*

16 RFP 147 seeks “[a]ll Chart(s) corresponding to, associated with, or related to each
17 Beneficiary, from each DOS Year(s) in which that Beneficiary is listed in the United
18 States’ Response to Defendants’ Interrogatory No. 1.” Ex. O, United States’ Eighth Set of
19 Requests for Production. As written, this request encompassed every medical chart
20 relating to every beneficiary who appears on the government’s list from the years in
21 question – regardless of whether that chart had ever been reviewed by United or was even
22 associated with the particular diagnosis code submission that the government alleges
23 should have been deleted. On its face, RFP 147 would have required the production of
24 many tens of millions of medical charts. On January 29, 2021, the government attempted
25 to “narrow RFP 147 to only require production of the medical records associated with the
26 codes that UHG contends were supported.” *See* Ex. P, Jan. 29, 2021 email correspondence
27 between counsel for United and counsel for the United States and Relator. Specifically, as
28 the government clarifies its position in its portion of this Joint Stipulation, its request is

1 now limited to those medical records “UnitedHealth identifies in response to Part A of
2 Interrogatory 14.” *United States’ Portion, Section I.A. at 3*. RFP 147 is, therefore,
3 dependent entirely on whether United is required to respond to Interrogatory 14A; if the
4 Court agrees that United is not required to hire experts to engage in the coding reviews
5 that responding to Interrogatory 14A would require, then there would be no medical
6 records responsive to RFP 147 as now recrafted by the government.

7 On December 4, 2020, United issued its Responses & Objections to Interrogatory
8 14 and RFP 147 (“Responses”). *See* Exs. A, B. United objected to Interrogatory 14 and
9 RFP 147 on several grounds, including most importantly that Interrogatory 14 is an
10 impermissible contention interrogatory because (1) it seeks to improperly shift the burden
11 of proof for a main element of the government’s False Claims Act case to United and (2)
12 it seeks expert opinion, which is outside the scope of a proper contention interrogatory.
13 *See id.*

14 *c. United’s Efforts to Avoid This Dispute*

15 Since December 4, 2020, the parties have engaged in four meet and confers and
16 exchanged numerous correspondence regarding United’s Responses. Despite the parties’
17 best efforts, the parties have been unable to reach a resolution regarding the discovery
18 requests.

19 With respect to Interrogatory 14, United stood on its objection that it is not required
20 to conduct new and burdensome analysis for the government that United has not done for
21 itself, especially since the government has the burden of proving that the 28 million codes
22 are unsupported and that United knew they were unsupported. United has also reiterated
23 that Interrogatory 14A, in particular, is an improper attempt to require United to disclose
24 expert opinion and conclusions in the guise of fact discovery.

25 At the same time, United explained that it has either already produced, or is willing
26 to produce, all of the information that would allow the government to undertake each of
27 these analyses for itself. With respect to Interrogatory 14A, United has offered to produce
28 to the government every single medical record in United’s possession that United reviewed

1 as part of its chart review program, to allow the government to determine for itself which
2 of the codes on its list are or are not supported. *See* Ex. Q, Dec. 31, 2020 email
3 correspondence from A. Qureshi to counsel for the United States and Relator. With respect
4 to Interrogatory 14B, United offered to point the government to all of the data that United
5 has already produced that the government can use to attempt to match the codes on its list
6 to charts that United reviewed, and to the results of those reviews. *Id.* That would be the
7 very same data that United itself would use were it compelled to conduct this analysis for
8 the government. The government has turned down both proposals, insisting that United
9 conduct the complex analyses required to respond to Interrogatories 14A and 14B for the
10 government. *See* Exs. R, P, Jan. 21, 2021 and Jan. 29, 2021 email correspondence between
11 counsel for United and counsel for the United States and Relator.

12 With respect to RFP 147, the government's positions have vacillated dramatically
13 over time. As written, RFP 147 required United to produce all medical records in its
14 possession, custody, or control pertaining to any of the beneficiaries whose codes appear
15 on the government's list for the year in question – regardless of whether United reviewed
16 or possessed those records, and regardless of whether the charts corresponded to the
17 diagnosis codes appearing on the government's list. That request would have required
18 United to gather tens of millions of records, many from third party providers and many
19 with little to no relevance to this case. United therefore has proposed to the government
20 that instead it will produce all medical records in its possession that were subject to a chart
21 review. United's proposal would provide the government with all the materials necessary
22 to perform the expert coding analysis the government wishes United to perform for it.
23 United estimated and informed the government that even this proposal would entail
24 producing between 15 and 21 million medical records. *See* Ex. Q, Dec. 31, 2020 email
25 correspondence counsel for United and counsel for the United States and Relator.

26 When United originally proposed to produce all medical records in its possession,
27 the government expressed concern that United's proposal was too *narrow* because it did
28 not include medical records that may be in United's custody or control rather than in its

1 possession. See Ex. S, Jan. 6, 2021 email correspondence between counsel for United and
2 counsel for the United States and Relator. United explained in response that it did not
3 currently intend to collect medical records from third parties but that, if it did in the future,
4 it would provide those to the government.

5 On January 29, 2021, the government made an about face, this time suggesting that
6 United's offer was *too broad*.⁴ Ex. P, Jan. 29, 2021 email correspondence between counsel
7 for United and counsel for the United States and Relator. As the government describes its
8 current position, the government now asks that United produce "only those records
9 associated with the diagnosis codes that UnitedHealth contends were supported (i.e., the
10 medical records UnitedHealth identifies in response to Part A of Interrogatory 14)." *United*
11 *States' Portion, Section I.A. at 3*. Producing the subset of medical records now requested
12 by the government would therefore require United to first conduct the coding review of
13 the 28 million codes on the government's list that Interrogatory 14A would require.

14 Unfortunately, despite numerous meet and confers and the informal conference
15

16 ⁴ In its portion of the Joint Stipulation, the government writes that "as a result of the
17 meet and confer process following UnitedHealth's responses and objections to RFP 147,
18 the United States *agreed to limit* its request for medical records to only those records
19 associated with the diagnosis codes that UnitedHealth contends were supported (i.e., the
20 medical records UnitedHealth identifies in response to Part A of Interrogatory 14)." *United*
21 *States' Portion, Section I.A. at 3* (emphasis added). The government mischaracterizes the
22 facts. While the government's January 29 counter-proposal in theory does limit RFP 147,
23 the government proposed to limit the RFP at its own initiative and not in response to any
24 request by United. In fact, United is more than prepared to and has already agreed to
25 produce all of the medical records in its possession that were subject to a chart review for
26 the relevant time period. United does not need the government to narrow RFP 147 further.
27 And the government's suggestion that doing so is less burdensome to United is
28 disingenuous. The government is really attempting to narrow RFP 147, not because it
wants to create less burden for United, but because it wants United to go through the
exercise of identifying which charts United contends support the diagnosis codes at issue
so the government does not have to review any medical records. If anything, this
narrowing of RFP 147 is more burdensome for United because it requires United to have
an expert conduct extensive analysis in order to respond.

1 held before the Court, the parties remain at an impasse.

2 **III. ARGUMENT**

3 **A. United States**

4 1. Interrogatory 14

5 The United States is entitled to discover UnitedHealth's contentions about the
6 diagnosis codes at issue in this case during fact discovery. The United States is likewise
7 entitled to discover the facts surrounding each medical record review that UnitedHealth
8 conducted associated with every diagnosis code on the United States' list that
9 UnitedHealth contends it was not obligated to delete, regardless of which specific defense
10 it is relying on for that contention. Because Interrogatory 14 is a proper contention
11 interrogatory and UnitedHealth has asserted no proper objections supporting its refusal to
12 respond, the Court should compel UnitedHealth to answer fully Interrogatory 14. The
13 United States is likewise entitled to discover the facts surrounding each medical record
14 review that UnitedHealth conducted associated with every diagnosis code that
15 UnitedHealth disputes.

16 a. *Interrogatory 14 Is a Proper Contention Interrogatory.*

17 Interrogatory 14 is a proper interrogatory because it seeks factual information
18 relating to UnitedHealth's contentions about issues central to this case. *See* Fed. R. Civ.
19 P. 33(b) ("An interrogatory is not objectionable merely because it asks for an opinion or
20 contention that relates to fact or the application of law to fact"). Contention
21 interrogatories "can be most useful in narrowing and sharpening the issues, which is a
22 major purpose of discovery." Fed. R. Civ. P. 33 (Advisory Committee Notes); *see also*
23 *Boston v. ClubCorp USA, Inc.*, No. CV 18-3746 PSG (SS), 2019 WL 1873293, at *8 (C.D.
24 Cal. Mar. 11, 2019) (Segal, M.J.) ("Courts generally approve of appropriately-timed
25 contention interrogatories because they may serve several beneficial purposes, including
26 narrowing the issues, avoiding wasteful preparation, and, it is hoped, expedit[ing] a
27 resolution of the litigation.") (internal citations omitted).

28 Interrogatory 14 is a straightforward contention interrogatory that asks

1 UnitedHealth to identify its contentions about the diagnosis codes on the United States’
2 list, *i.e.*, the diagnosis codes that the United States has put in issue through its affirmative
3 allegations. Each diagnosis code on the United States’ list previously went through
4 UnitedHealth’s medical record review program, and UnitedHealth’s own reviewers did
5 not find support for the diagnosis code in the associated medical records. The United
6 States is entitled to discover if UnitedHealth now contends that there is support in a
7 medical record for any of the diagnosis codes on the United States’ list. And for each
8 diagnosis code that UnitedHealth contends is supported by medical records, the United
9 States is entitled to discover the documentation and medical records that UnitedHealth
10 contends support that diagnosis code. (Interrogatory 14(A)). Furthermore, for every
11 diagnosis code on the United States’ list (*i.e.*, every diagnosis code the United States
12 alleges UnitedHealth was obligated to delete because, in part, UnitedHealth subjected it to
13 a comprehensive medical record review), that UnitedHealth contends it was not obligated
14 to delete, the United States is entitled to discover the facts surrounding those medical
15 record reviews (Interrogatory 14(B)).

16 If UnitedHealth does not contend that any of the diagnosis codes on the United
17 States’ list were supported by medical records or will not otherwise dispute its obligation
18 to delete specific codes, it should say so in response to Interrogatory 14. That would not
19 only be burden-free, it would substantially narrow the issues in the case. However, if
20 UnitedHealth seeks to present evidence or argue that certain diagnosis codes on the United
21 States’ list were supported by medical records, it must disclose those contentions and their
22 factual basis during fact discovery. (Interrogatory 14(A)). Similarly, if UnitedHealth
23 disputes its obligation to delete any of the diagnosis codes at issue, the United States is
24 entitled to the factual information regarding the medical record reviews UnitedHealth
25 conducted with respect to those diagnosis codes. (Interrogatory 14(B)). *ClubCorp USA,*
26 *Inc.*, 2019 WL 1873293, at *7 (“The purpose of interrogatories is to facilitate trial
27 preparation, to provide facts, to narrow the issues, **and to reduce the chance of surprise.**”)
28 (emphasis added). UnitedHealth is not permitted to surprise the United States at trial by

1 arguing that certain diagnosis codes were in fact supported by medical records, or
2 disputing the results of its own medical record reviews, without ever disclosing those
3 contentions or the facts supporting them during fact discovery.

4 *b. UnitedHealth's Objections That Interrogatory 14 Improperly*
5 *Shifts the Burden of Proof Is Meritless.*

6 UnitedHealth's principal rationale for refusing to respond to Interrogatory 14 is its
7 baseless objection that a plaintiff may not propound a contention interrogatory on a matter
8 in which the defendant does not bear the burden of proof at trial. (Mason Decl., Ex. A,
9 UHG's Resps. and Objs. to Interrog. 14 ("A party bearing the burden of proof cannot
10 propound an interrogatory that effectively requires the responding party to prove the
11 propounding party's case by shifting the burden of proof.")). According to UnitedHealth,
12 Interrogatory 14 is improper "in that it seeks to improperly shift the burden of proof for a
13 main element of the government's False Claims Act case to UnitedHealth." *Id.*

14 The question of burden of proof does not determine whether information is
15 discoverable, nor whether an interrogatory is proper. On the contrary, "the ultimate burden
16 . . . does not dictate the scope of discovery." *SPH America, LLC v. Research In Motion*
17 *Ltd*, No. 13-CV-2320 CAB (KSC), 2016 WL 6305414, *2 (S.D. Cal. Aug. 16, 2016).
18 "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any
19 party's claim **or defense** and proportional to the needs of the case." Fed. R. Civ. P.
20 26(b)(1) (emphasis added). UnitedHealth wrongly seeks to rewrite Rule 26(b)(1) to only
21 allow a plaintiff to discover information relevant to a defense upon which the defendant
22 bears the burden of proof.

23 Furthermore, "[n]owhere in the Federal Rules of Civil Procedure is it required that
24 a party who carries the ultimate burden on an issue at trial must establish a prima facie
25 case before it is entitled to discover information the other party may use to rebut the prima
26 facie case." *McKesson Information Solutions, LLC v. Epic Systems Corp.*, 242 FRD 689,
27 692 (N.D. Ga. 2007); *see also Jackson v. Equifax Inf. Servs. LLC*, No. 1:13-cv-02382-CC-
28 RGV, 2014 WL 12862681, at *3 (N.D. Ga. Sept. 26, 2014) ("contention interrogatories
are properly used to narrow and sharpen the issues before the Court and may be used to

1 discover the legal and factual bases of an opposing party's defenses, even if the party does
2 not bear any burden of proof on the issues to which those defenses relate"); *Linde v. Arab*
3 *Bank PLC*, No. CV-04-2799 (NG)(VVP), 2012 WL 957970, at *2 (E.D.N.Y. Mar. 21,
4 2012) (rejecting "the proposition that contention interrogatories may only explore a party's
5 'contentions' concerning issues on which the party bears the burden of proof"); *Moses v.*
6 *Halstead*, 236 F.R.D. 667, 674 (D. Kan. 2006) ("This Court has noted that such
7 interrogatories are helpful in that they may narrow and define the issues for trial and enable
8 the propounding party to determine the proof required to rebut the responding party's
9 claim or defense.").

10 Because Interrogatory 14 asks for the factual basis of UnitedHealth's defenses in
11 this case, it is a proper contention interrogatory notwithstanding that it is the United States'
12 burden of proof to establish that UnitedHealth improperly failed to delete the diagnosis
13 codes on its list. Interrogatory 14(A) simply requires UnitedHealth to state whether it
14 intends to present evidence, as one of its defenses, that certain of the diagnosis codes on
15 the United States' list are supported in those codes' underlying medical records and
16 identify the records that support that contention. Likewise, Interrogatory 14(B) only asks
17 for factual information about medical record reviews UnitedHealth has already conducted;
18 it does not require any additional analysis by UnitedHealth whatsoever.

19 Moreover, contention interrogatories are routinely permitted where they seek to
20 discover the factual basis for a party's denial of an allegation in a pleading. *See, e.g.,*
21 *GEICO v. Prushanksy*, 12-80556-Civ, 2013 WL 12077495, at *3 (S.D. Fla. Jan. 4, 2013)
22 ("The Court overrules the objection as the interrogatory simply seeks the factual basis for
23 GEICO's denial of paragraph 31 of the Counterclaim, which paragraph states how GEICO
24 allegedly breached its duty of good faith. There is no burden shifting, and this is a proper
25 contention interrogatory."); *Fridkin v. Minn. Mut. Life Ins. Co., Inc.*, No. 97 C 0332, 1998
26 WL 42322, at *5 (N.D. Ill. Jan. 29, 1998) (compelling a response to a contention
27 interrogatory that sought "the bases for Minnesota Mutual's denial of certain allegations
28 in Plaintiffs' Amended Complaint"); *Am. Gen. Life Ins. Co. v. Billard*, No. C10-1012,

2011 WL 13136619, at *3 (N.D. Iowa May 2, 2011) (ordering a full response to a contention interrogatory and related requests for production seeking “the factual basis for the denial of those paragraphs of the Complaint that are denied by the Billard Answer” and the production of any document “which proves or disproves any fact upon which Defendant bases its denial”); *Barkley v. Life Ins. Co. of N. Am.*, No. 3-07-CV-1498-M, 2008 WL 450138, at *1 (N.D. Tex. Feb. 19, 2008) (ordering a response to a contention interrogatory seeking “the basis for each of the denials expressed in Defendant’s Original Answer”), *as modified* (N.D. Tex. Mar. 12, 2008); *Schaap v. Exec. Indus., Inc.*, 130 F.R.D. 384, 388 (N.D. Ill. 1990) (ordering responses to contention interrogatories inquiring into the basis of Executive’s denials of certain allegations of the complaint, so as to “clarify, narrow, and sharpen the issues” and “ensure mutual access to all relevant facts”).

Just as in the cases cited above, Interrogatory 14 seeks the factual basis for the denial of an allegation in a pleading, specifically UnitedHealth’s denial of Paragraph 342 of the United States’ Amended Complaint. (Mason Decl., Ex. D, UnitedHealth’s Answer to Amend. Compl., ECF No. 223, at ¶ 342 (“Paragraph 342 states legal conclusions to which no response is required. To the extent Paragraph 342 contains any factual allegations, such allegations are denied.”)). UnitedHealth denied the factual allegations in the United States’ contention that UnitedHealth “knowingly and improperly failed to delete . . . the invalid diagnoses that had been submitted to the Medicare Program for risk adjustment payments which were made by the Medicare Program or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses.” *Id.* Moreover, UnitedHealth’s Interrogatory No. 1 (which sought and elicited the United States’ list of diagnosis codes that are the subject of this litigation), specifically sought the factual bases for the United States’ contention in Paragraph 342 of the Amended Complaint. (Mason Decl., Ex. E, UnitedHealth’s Interrog. No. 1). Because the United States’ Interrogatory 14 asks for the factual basis regarding which diagnosis codes on that list UnitedHealth contends were supported, it asks for UnitedHealth’s factual basis for denying the allegations in Paragraph 342. The United States is entitled to discover the

1 factual basis for UnitedHealth's denial of Paragraph 342 of the Complaint, and
2 Interrogatory 14 is therefore a proper contention interrogatory.

3 c. *UnitedHealth's Objection That Interrogatory 14 Improperly*
4 *Requests the Early Production of UnitedHealth's Expert*
Opinions Is Meritless.

5 The other objection that UnitedHealth relies on to support its refusal to answer
6 Interrogatory 14 is equally meritless. UnitedHealth contends that Interrogatory 14 is an
7 "improper contention interrogatory because it seeks expert opinion, not facts, which is
8 outside the scope of a proper contention interrogatory." (Mason Decl., Ex. A, UHG's
9 Resps. And Objects. to Interrog. 14).

10 This objection fundamentally misapprehends the information the United States is
11 seeking. Interrogatory 14 is a proper contention interrogatory because it requests only
12 information regarding the underlying facts (*i.e.*, the existence and source of medical record
13 support, as contended by UnitedHealth, for any of the diagnosis codes identified by the
14 United States), not any expert opinion about those facts. *See Amgen Inc. v. Sandoz Inc.*,
15 No. 14-cv-04741, 2017 WL 1352052, *2 (N.D. Cal. Apr. 13, 2017) (holding that
16 interrogatories "are not improper to the extent they seek only facts, not how an expert
17 would construe those facts"); *D&D Techs. (USA), Inc. v. Safetech Hardware Inc.*, 2013
18 WL 12142955, at *2 (C.D. Cal. Nov. 8, 2013) (ordering responding party to supplement
19 responses to interrogatories that sought "the legal and factual bases for [d]efendant's
20 contentions"); *Bayer Healthcare Pharm., Inc. v. River's Edge Pharm., LLC*, No.:
21 1:11-cv-1634-HLM, 2015 WL 11142425, at *7 (N.D. Ga. July 31, 2015), *report and*
22 *recommendation adopted*, 2015 WL 11142428 (N.D. Ga. Sept. 22, 2015) (The
23 "[i]nterrogatory ... did not ask for the expert's opinion or a conclusion of law, which, of
24 course, would have been rightfully objectionable. Rather, the interrogatory asked which
25 facts and legal theories Plaintiffs intend to rely on.").

26 Here, the interrogatory asks for UnitedHealth to identify facts – which diagnosis
27 codes it contends are supported by medical records, which medical records provide such
28 support, and the medical record reviews that UnitedHealth previously conducted of those

1 records. Contrary to UnitedHealth's meritless objection, the interrogatory does not ask
2 UnitedHealth to describe "how an expert would construe those facts." *See Amgen Inc.*, at
3 *2. Nor does it ask for UnitedHealth to describe "expert's opinion or a conclusion of law."
4 *See Bayer Healthcare Pharm., Inc.*, at *7. "The fact that an expert would ultimately put
5 the facts together to support the legal theory in an opinion is of no consequence as to
6 whether a responding party must timely supplement such an interrogato[r]y." *Id.*

7 UnitedHealth itself previously argued regarding its Interrogatory No. 1 that "[t]he
8 fact that the . . . Interrogatory may seek information that has been provided to an expert or
9 that relates to the subject of expert analysis does not provide . . . an excuse to avoid
10 responding . . . in full with the information reasonably available to it at the time of its
11 response." (Mason Decl., Ex. F, Ltr. From A. Qureshi dated March 17, 2020 at p. 4 (citing
12 *Menell v. Rialto Unified Sch. Dist.*, No. EDCV 15-2124-VAP (KKx), 2016 WL 3452920,
13 at *4 (C.D. Cal. June 20, 2016) ("The Court notes expert analysis does not relieve
14 Defendant of its obligation to investigate and provide information reasonably available to
15 it."))).

16 For these same reasons, any potential expert analysis UnitedHealth may propound
17 related to the issue of whether underlying medical records support specific diagnosis
18 codes, or related expert conclusions about any impact of that support, does not relieve
19 UnitedHealth of its obligation to timely investigate and provide during fact discovery
20 information reasonably available to it. In that same vein, Interrogatory 14(B) merely asks
21 UnitedHealth to identify every medical record review it conducted of any charts associated
22 with the diagnosis codes on the United States' list that UnitedHealth disputes.

23 Interrogatory 14 is therefore a proper contention interrogatory that does not call for
24 expert opinion.

25 *d. UnitedHealth's Proposed Response Under Fed. R. Civ. P.*
26 *33(d) is Improper.*

27 During the party's meet and confer process and the informal conference with
28 Special Master Segal, UnitedHealth suggested that, notwithstanding its initial
Interrogatory Response, it would respond to Interrogatory 14 by generally referencing

1 some tens of millions of medical records that it would eventually produce to the United
2 States. Not only does this not even address the response requested by Interrogatory 14(B),
3 but with respect to 14(A), this is an unreasonable position and does not satisfy
4 UnitedHealth's discovery obligations, because UnitedHealth's **contentions** cannot
5 possibly be found in underlying medical records. The documents do not speak for
6 themselves and do not contain any discernible clue as to what UnitedHealth's contentions
7 might be. Only UnitedHealth can say what its contentions are.

8 A party may answer interrogatories by reference to underlying documents only "if
9 the burden of deriving or ascertaining the answer will be substantially the same for either
10 party" and only if the responding party "specif[ies] the records that must be reviewed, in
11 sufficient detail to enable the interrogating party to locate and identify them as readily as
12 the responding party could." Fed. R. Civ. P. 33(d). Neither of those conditions are
13 satisfied here, where the United States has asked for UnitedHealth's **contentions**, and
14 UnitedHealth proposes responding with a blanket reference to tens of millions of
15 underlying medical records, without identifying, importantly, which of those tens of
16 millions of medical records it contends support one or more of the diagnosis codes on the
17 United States' list. UnitedHealth's proposed elaborate guessing game does not comport
18 with its discovery obligations.

19 For this very reason, Fed. R. Civ. P. 33(d) does not permit a party to respond to
20 contention interrogatories by reference to underlying documents. "[D]ocuments
21 themselves rarely, if ever, reveal contentions of fact or law . . . Only plaintiff can identify
22 its own contentions and the burden on defendants to try and divine plaintiff's contentions
23 from documents obviously imposes a greatly unequal burden on defendants . . . [and] a
24 mixture of contention interrogatories and requests for statements of fact . . . do not lend
25 themselves to answer by use of Rule 33(d)." *U.S. S.E.C. v. Elfindopan, S.A.*, 206 F.R.D.
26 574, 576-77 and n. 5 (M.D. N.C. 2002); *see also United States ex rel. Dougherty v. Guild*
27 *Mortg. Co.*, No. 16cv2909-JAH(BLM), 2020 WL 3542391, at *5 (S.D. Cal. June 30, 2020)
28 ("Merely directing Defendant to hundreds of loan records and citing to the general HUD

underwriting and origination requirements does not suffice to alert Defendant to what the Government's allegations are or what evidence it has to support its claims."); *Moeller v. Taco Bell Corp.*, No. C 02-5849 PJH (JL), 2008 WL 11454816, at *2 (N.D. Cal. Aug. 28, 2008) (party cannot rely on the document production option of FRCP 33(d) to respond to a contention interrogatory); *United States ex rel. Landis v. Tailwind Sports Corp.*, 317 F.R.D. 592, 594 (D.D.C. 2016) (same); *In re Ford Motor Co. DPS6 Powershift Transmission Prod. Liab. Litig.*, No. 2:18-ML-02814 AB (FFM), 2019 WL 6486048, at *2 (C.D. Cal. Oct. 17, 2019) (same); *Johnson Marcraft, Inc v. W. Sur. Co.*, No. 3:15-CV-01482, 2016 WL 3655299, at *2 (M.D. Tenn. July 8, 2016) (same).

UnitedHealth itself previously argued regarding its Interrogatory No. 1 that it is improper to answer a contention interrogatory by reference to documents: "The government's attempt at directing UnitedHealth to root through UnitedHealth's own documents to ascertain what diagnosis codes the government contends are at issue is improper and contrary to the requirements of the Federal Rules and applicable case law." (Mason Decl., Ex. F, Ltr. From A. Qureshi dated March 17, 2020 at p. 6 (citing *See Dancy v. Scribner*, No. 1:07-cv-00716-OWW-SMS PC, 2009 WL 3567850, at *2 (E.D. Cal. Oct. 27, 2009) ("This requires Plaintiff to answer Defendants' interrogatories with specificity. Plaintiff may not provide vague information or direct Defendants to comb through his exhibits to answer their own interrogatories."))). For these same reasons, UnitedHealth's proposal under Fed. R. Civ. P. 33(d) is improper.

Therefore, UnitedHealth may not properly respond to Interrogatory 14 simply by referring to tens of millions of medical records.

e. Compelling A Response to Interrogatory No. 14 Promotes Fairness and Efficiency.

A response to Interrogatory 14 will promote efficiency, because it will potentially narrow the issues in the case. If UnitedHealth is not defending this case by arguing that the diagnosis codes at issue were supported by medical records, it is wasteful for UnitedHealth to withhold that information now and force the parties and the Court to expend resources litigating that aspect of the case. It will also streamline document

1 discovery – UnitedHealth’s proposal to produce 21 million medical records in response to
2 Request 147 is not only unnecessary, but would unreasonably and exponentially expand
3 the scope of discovery and the schedule set in this case. If UnitedHealth responds to
4 Interrogatory 14(A), then the parties can agree to the production of only the subset of those
5 medical records, if any, associated with the diagnosis codes UnitedHealth contends were
6 supported. It makes no sense to require the production of 21 million records (which
7 UnitedHealth estimates will take approximately 8 months), when only a subset of those
8 records may ultimately be relevant to this litigation. More importantly, even if
9 UnitedHealth produced all 21 million records, that production is meaningless if it refuses
10 to identify which of those records it contends supports one of the diagnosis codes at issue
11 in this case.

12 Likewise, compelling an answer to Interrogatory 14 will avoid unfair surprise not
13 contemplated by the Federal Rules. UnitedHealth’s position is that it may (or may not)
14 present percipient witnesses and expert opinion testimony at trial to show that certain
15 diagnosis codes were supported by medical records, without ever identifying those
16 diagnosis codes or the associated medical records during fact discovery. This would put
17 the United States in the untenable position of having to rebut a defense that it never had
18 an opportunity to probe or otherwise prepare for during fact discovery. That is trial by
19 ambush, and not how civil discovery works. For this reason, it is not sufficient to wait
20 until UnitedHealth eventually provides this information in pretrial disclosures or expert
21 reports, which come long after the close of fact discovery.

22 Finally, compelling an answer to Interrogatory 14 would be consistent with Court’s
23 prior ruling on UnitedHealth’s Interrogatory No. 1, which required the United States to
24 expend extraordinary efforts to compile a list of each and every diagnosis code that the
25 United States contends is at issue in this case. In support of its position on Interrogatory
26 No. 1, UnitedHealth argued that “[i]n order to defend itself, United is entitled to know,
27 with specificity, which diagnosis codes it allegedly knew were false and affirmatively
28 chose not to delete.” (Mason Decl., Ex. G, UnitedHealth’s Counter-Proposal Regarding

UHC of California's First Interrogatory, at 1). Just as the United States was required to disclose which diagnosis codes it contends are unsupported, UnitedHealth should be required to disclose which codes it contends are supported by the medical records. This is not tit for tat; it is simply what discovery properly requires in this case. It would not only be inconsistent to require that the United States identify each diagnosis code at issue, and then not allow the United States to learn UnitedHealth's position as to those very same codes, but it would eviscerate the very purpose of what discovery was designed to do in a case, namely, narrow the issues for trial and eliminate the opportunity for the presentation of surprise evidence.

2. Request 147

The United States is entitled to the production of medical records associated with all of the diagnosis codes at issue in this case and Request 147 is thus a proper document request. UnitedHealth has asserted no proper basis for refusing to produce documents in its possession, custody, or control.

Because UnitedHealth has now agreed to produce *all* responsive documents in its possession, the parties' dispute at this point is much narrower. The United States continues to believe that it is unnecessary to incur the burden and delay of producing all records, when only a subset of the responsive records may be relied upon by UnitedHealth. Accordingly, the United States submits that, after UnitedHealth answers Interrogatory 14 and identifies every diagnosis code that it contends was supported by medical records, it must produce all medical records in its possession, custody, or control, that relate to the diagnosis codes that UnitedHealth contends were supported by medical records.

B. UnitedHealth

1. The Government's Motion to Compel on Interrogatory 14A
Should Be Denied

a. *Interrogatory 14A is an Improper Attempt to Use a Contention Interrogatory to Compel United to Perform the Expert Analysis that the Government Failed to Perform Before Filing Suit*

Interrogatory 14A does not seek to ferret out United's contentions of fact in this

1 case. Interrogatory 14A instead seeks to compel United to perform expert analysis in a
2 thinly veiled attempt to overcome a fundamental flaw in the government's case: namely,
3 having created and advanced a list of 28 million diagnosis codes it claims were
4 unsupported (and, therefore, "false"), the government now realizes that it failed to do the
5 work necessary to support that allegation. Instead of doing the work, under the guise of a
6 contention interrogatory, the government seeks to compel United to retain expert coders
7 to review the list of 28 million codes the government created and to endeavor to find
8 support for each of those diagnosis codes in the medical records pertaining to the
9 underlying beneficiaries corresponding to diagnosis codes on the government's list. Put
10 simply, the government seeks to compel United to do the expert work the government
11 should have done before filing this case and before promulgating a list of 28 million codes
12 it contends are unsupported.

13 It is well settled that contention interrogatories "are improper [when] they ask the
14 respondent to provide an expert opinion." *Amgen Inc. v. Sandoz Inc.*, No. 14-cv-04741-
15 RS (MEJ), 2017 WL1352052, at *2 (C.D. Cal. Apr. 13, 2017); *Montgomery v. Wal-Mart*
16 *Stores, Inc.*, No. 12cv3057-JLS (DHB), 2015 WL 11233384, at *6 (S.D. Cal. July 17,
17 2015); *Finjan, Inc. v. ESET, LLC*, No. 17CV183 CAB (BGS), 2018 WL 4772124, at*4
18 (S.D. Cal. Oct. 3, 2018). Courts in the Ninth Circuit have specifically held that while
19 interrogatories are proper "to the extent they seek only facts," interrogatories cannot
20 require a responding party to demonstrate "how an expert would construe those facts." See
21 *Amgen Inc.*, 2017 WL 1352052, at *2 (a contention interrogatory, which required the
22 respondent to show why the patented mechanism was nonobvious, impermissibly required
23 expert testimony); *Qualcomm Inc. v. Apple Inc.*, No. 3:17-CV-02398-DMS-MDD, 2018
24 WL 5829940, at *1 (S.D. Cal. Nov. 7, 2018).

25 The government does not appear to dispute this legal proposition. Instead, it insists
26 that Interrogatory 14A seeks only "facts." That claim grossly mischaracterizes the
27 complex, expert-driven process required to determine that a code is supported by a medical
28 record. To generate the list the government commands, United will need to retain expert

1 coders to review each of the 28 million diagnosis codes and then to compare those codes
2 to any of the medical records corresponding to the beneficiaries (patients) at issue.
3 Determining whether any or all of the 28 million codes are supported by a particular entry
4 in any of the relevant medical records cannot be done by lay people or lawyers. It must be
5 done by someone with specialized training and experience in risk adjustment coding:
6 namely, an expert. Put simply, interrogatory 14A falls squarely and unquestionably in the
7 realm of expert analysis and expert opinion, and any answer to Interrogatory 14A will be
8 expert opinion governed by Fed. R. Evid. 702. Interrogatory 14A is therefore procedurally
9 and substantively improper.

10 (A) Whether a Diagnosis Code Is Supported in a Medical
Record Requires Expert Opinion

11 Whether a diagnosis code is or is not supported in a medical record is an opinion,
12 not a fact, and, in any event, is a determination that only a coder can make.

13 To begin with, as the government's own documents recognize, coding involves the
14 exercise of judgment as to which different coders may disagree; whether a particular
15 diagnosis code is supported or not by a medical chart *is not a fact*. For example, in a
16 November 20, 2015 memorandum from the U.S. Department of Health and Human
17 Services ("HHS") Office of the Inspector General, HHS recognized that "[m]edical record
18 review consists of evaluating risk adjustment data to see if it supports the reported CMS-
19 HCC. While criteria does exist, in some cases, the medical reviewer must use their
20 judgment to make a decision." Ex. T, USBP060643694 (Confidential) at 1. The
21 government has also recognized that "[i]t is entirely possible for two different reviewers
22 to look at a medical record and come to opposite conclusions." *Id.*; *see also* Ex. U,
23 USBP059844500 (Confidential) at 2 (June 2011 email exchange in which a CMS
24 employee discusses appeals related to "RADV reviews of medical records" and states:
25 "everything stands or falls on what each side asserts is in the record (note, I didn't say—
26 what IS in the record. It is much more nuanced than that since coding is far from bench
27 science . . . it's fairly subjective at times"); Ex. V, USBP059164283(AEO) at 12 (February
28 2004 draft report regarding "Medicare+Choice Risk Adjustment Data Validation for CY

2001 Payments,” acknowledging the existence of “coding differences” that can be due to many factors, including “differences in interpretation of clinical documentation, differences in interpreting coding guidelines and judgment between coders”); Ex. W, 2018 Benefit Year Protocols at 91 (explaining that, in its Risk Adjustment Data Validation (“RADV”) audits, CMS employs a process called “Inter-Rater Reliability” or “IRR,” which is a “quality control measure to determine the accuracy of the abstraction diagnoses by Primary Coders when compared to Senior Coders. Medical records reviewed by the Primary Coder and sampled for IRR are then re-reviewed by a Senior Coder. The comparison of HCCs assigned to diagnoses found between the Primary Coder and the Senior Coder are then used to determine the Primary Coder’s IRR consistency measure”).⁵

Moreover, regardless of whether properly characterized as “art” or “science,” determining whether a particular diagnosis code is properly abstracted from a medical record undoubtedly requires expertise and specialized training. The government knows this. Each year, as part of its RADV audits, the government retains expert coders to conduct medical record reviews on behalf of the government to determine whether a diagnosis code submitted by a Medicare Advantage Plan is supported in a medical record. As part of this process, CMS provides these RADV coders with guidance for reviewing the underlying medical record documentation to identify potential support for a diagnosis code. This guidance provides that the “reviewers must first apply their expertise in documentation and official coding guidelines to each scenario.” Ex. Y, CMS RADV

⁵ Numerous experts within the healthcare industry have likewise recognized that coding is an art not a science and requires the exercise of judgment. *See* Ex. X, *Achieving Coding Consistency* at 1 (“[c]oding professionals know that the act of coding is not black and white—there is room for interpretation. A coder’s background and training, among other factors, will greatly influence the way he or she assigns codes”); *see id.* (quoting a coding manager as saying: “Coding is much more of an art than it is a science . . . So [coding professionals] definitely have a lot of room for interpretation.”); *see id.* (quoting a vice president of health information management at a healthcare company as saying: “[A] coder doesn’t just use books and resources, they also have to use their head, use their logic, their common sense, to make some decisions.”)).

1 Guidance at 6. The “reviewers” are certified and trained coding experts CMS retains to
2 conduct these RADV audits. *See* Ex. Z, RA Participant Guide at 159 (describing how CMS
3 uses “Medical Record Review Contractors (MRRCs)” in RADV that utilize “certified
4 coders to abstract diagnosis codes”). They are not lay people.

5 The application of expertise and guidance to interpret a medical record is
6 necessarily analysis, not fact. Moreover, this is expertise a lay person does not possess and
7 guidance a lay person does not understand and cannot interpret. One could not hand a lay
8 person a voluminous medical record and ask them to determine whether the record
9 adequately supports coding pythorax without fistula (ICD 10 code J86.9) or amyotrophic
10 lateral sclerosis (ICD-10 code G12.21) because the lay person has no training in reading
11 highly technical medical charts and would have no understanding of the “official coding
12 guidelines” that apply to the abstraction and selection from among thousands of possible
13 diagnosis codes.⁶

14 Numerous courts have thus recognized that only a coder qualified as an expert by
15 the court can testify as to whether a diagnosis code is supported in the record. *See, e.g.,*
16 *United States ex rel. Desrosiers v. Thaller*, No. 12-22445-CIV-LENARD/SELTZER,
17 2016 U.S. Dist. LEXIS 151220, at *6–7, *12–13 (S.D. Fla. Nov. 1, 2016) (holding that
18 professionally certified coder expert opinion that “57 of the 121 cases lacked sufficient
19 documentation to support the procedure coded” was not outside the expert’s area of
20

21 ⁶ In fact, there is no single comprehensive source of “official coding guidelines”
22 that detail how to accurately code diagnoses in the risk adjustment context. Rather, there
23 are multiple organizations and industry-accepted sources regarding risk adjustment
24 coding. For instance, CMS in-part relies upon official ICD Coding guidance as well as the
25 views of certifying bodies. Common sources of risk adjustment coding guidance include
26 the American Academy of Professional Coders (“AAPC”), which educates coders
27 primarily in physician-based settings, including AAPC Certified Risk Adjustment Coder
28 course guidance, and the American Health Information Association (“AHIMA”), which
educates coders primarily in hospital settings. CMS guidance expressly directs Medicare
Advantage plans to industry organizations for risk adjustment coding guidance. *See* Ex. Z,
RA Participant Guide at 155.

1 expertise in False Claims Act case concerning allegedly unnecessary and up coded medical
2 procedures); *United States ex rel. Armfield v. Gills*, No. 8:07-cv-2374-T-27TBM, 2012
3 WL 12918274, at *2 (M.D. Fla. July 6, 2012) (party advancing a coding expert—and court
4 agreeing she was qualified—to testify regarding improperly coded claims because she was
5 a certified professional coder and had twenty-five years of experience in medical coding
6 and billing); *Counts v. Pollock*, No. 3:18-cv-1072-J-39JBT, 2020 WL 5534444, at *2
7 (M.D. Fla. Aug. 21, 2020) (party advancing an expert—and court agreeing he was
8 qualified—to testify regarding whether plaintiff’s medical bills were properly coded
9 because “[h]e has numerous credentials, certifications, and recognitions in the field of
10 medical billing and coding”); *see also id.*, at *3 (finding that the coding expert’s testimony
11 is proper opinion testimony and would aid the jury because “[t]he ordinary juror is not
12 expected to have knowledge regarding [certain medical] codes, meaning expert testimony
13 regarding [medical] coding is appropriate”).

14 (B) Interrogatory 14A Asks for Expert Analysis and
15 Conclusions

16 Because responding to Interrogatory 14A would require expert analysis, it is not a
17 proper contention interrogatory. *Qualcomm* is persuasive on this point. In a patent
18 licensing dispute brought by Apple against Qualcomm, Qualcomm requested that Apple
19 “identify all patent license agreements concerning any of the Apple Accused
20 Functionalities that Apple contends are comparable to a license Apple would have taken
21 in a hypothetical negotiation in this case including certain details regarding those
22 comparable licenses.” *Qualcomm Inc.*, 2018 WL 5829940, at *1. Concluding that
23 “[w]hether a particular patent license is comparable to one that might be taken in a
24 hypothetical negotiation is considered to be a matter of expert opinion” and would
25 therefore be outside the scope of a contention interrogatory, the court held that Apple
26 would “not be required, in connection with this dispute, to provide the *opinions of its*
27 *experts* regarding the comparability of these licenses to that which may be taken in the
28 hypothetical negotiation.” *Id.* at 2 (emphasis added).

The government argues that an interrogatory that seeks “only information regarding

1 the underlying facts” and not ““how an expert would construe those facts”” is proper.
2 *United States’ Portion, Section III.A.1.c. at 25* (quoting *Amgen Inc.*, 2017 WL 1352052,
3 *2). But Interrogatory 14A does no such thing. Interrogatory 14A clearly seeks disclosure
4 of a coding expert’s ultimate opinion and conclusion: whether a diagnosis code is
5 supported by the medical chart under applicable coding guidelines, and if so, by which
6 entry. Use of a contention interrogatory for that purpose is improper.

7 (C) The Government’s Attempt to Equate Interrogatory 14A
8 with United’s First Interrogatory is Meritless

9 Lacking a persuasive argument that Interrogatory 14A does not seek the results of
10 expert analysis and conclusions, the government attempts to equate Interrogatory 14A
11 with United’s First Interrogatory, to which this Court required the government to respond.
12 *See United States’ Portion, Section III.A.1.e. at 28–29*. In fact, there is no similarity
13 whatsoever between the information sought by the government in its interrogatory and the
14 information it was required to disclose in response to United’s.

15 United’s First Interrogatory asked the government, as the plaintiff that brought this
16 action, to identify the diagnosis codes that it alleges constituted overpayments that United
17 knew of but failed to delete. In responding to United’s interrogatory, the government did
18 not review a single medical record to determine for itself whether any of the diagnosis
19 codes at issue are in fact supported by the medical chart in accordance with applicable
20 coding guidelines. Indeed, the government had not even requested a single medical chart
21 from United prior to undertaking its response to United’s Interrogatory. RFP 147, also at
22 issue in this motion, is its first such request. Instead, as the government acknowledges in
23 its portion of the Joint Stipulation, consistent with the flawed theory of liability it pled in
24 its complaint, the government’s response to United’s interrogatory consists of a list of
25 codes that the government claims that United submitted for payment but that its chart
26 review coders did not identify when conducting a chart review. *See United States’ Portion,*
27 *Section III.A.1.a. at 20*. While the government may have used expert data analysts to assist
28 in creating its list, its response consists of its allegations regarding historical facts: the
subset of previously submitted codes that United’s coders allegedly did not identify when

1 performing their chart reviews. United's interrogatory did not ask the government to
2 review medical charts or engage in diagnosis coding, and the government's response did
3 not disclose any expert opinions or conclusions.

4 Interrogatory 14A, by contrast, expressly asks United to identify which codes on
5 the government's list are in fact supported by the underlying medical records. As explained
6 above, only a trained coder can make that determination, and Interrogatory 14A thus
7 requires the disclosure of an expert's conclusions. There is no parallelism whatsoever
8 between the government's response to United's interrogatory and the government's
9 Interrogatory 14A.

10 The government's argument also overlooks the different obligations imposed on
11 plaintiffs and defendants. The government chose to bring this case and alleges that United
12 has retained billions of dollars in overpayments. A plaintiff cannot avoid informing the
13 defendant of the alleged overpayments it is seeking to recover. No countervailing duty is
14 imposed on defendants, who are fully entitled to put the government to its proof and to
15 wait to make its decisions about whether to conduct potential expert analysis for the time
16 when expert disclosures are required.

17 (D) United will Make Any Expert Analysis it Conducts
18 Available to the Government Through Expert Discovery

19 Because Interrogatory 14A improperly seeks expert discovery, United cannot be
20 compelled to respond to it, now or in the future. Interrogatories may not be used to seek
21 expert disclosures. As United has made clear to the government on multiple occasions,
22 however, to the extent that United has an expert conduct analysis of medical records to
23 identify whether support for any of the diagnosis codes at issue exists that it plans to use
24 at trial, United will disclose this analysis according to the Order Granting Stipulation
25 Regarding Expert Discovery entered by the Court on May 17, 2018 (Dkt. 233). That Order
26 sets forth the parties obligations with respect to expert disclosures, and the government
27 cannot require United to make expert disclosures during fact discovery. *See* Ex. AA,
28 Expert Discovery Stipulation.

b. *Interrogatory 14A is Improper Because it Would Require United to Conduct New and Time-Consuming Analysis that it Has Not and May Never Undertake and Reverses the Burden of Proof.*

Interrogatory 14A is also improper because it impermissibly seeks to require United to undertake extensive investigation and analysis it has not conducted and would shift the government's burden of proving falsity onto United. Interrogatory 14A is entirely inconsistent with United's discovery obligations and antithetical to the basic tenet of civil litigation: the plaintiff must prove its own case and cannot force the defendant to meet this burden instead. Therefore, United should not be required to respond.

It is well settled that a party cannot craft "interrogatories that require a party to make extensive investigations, research, or compilation or evaluation of data for the opposing party." 8B Wright, Miller & Marcus, Federal Practice and Procedure § 2174 (3d ed. 2013). Likewise, a party does not have a "duty to search out new information in response to interrogatories." *See* 7 Moore's Federal Practice - Civil § 33.102 (2021); *see also, City of Las Cruces v. United States*, No. CV 17-809 JCH/GBW, 2021 WL 330062, at *8 (D.N.M. Feb. 1, 2021) ("A party responding to an interrogatory 'is not required to make an extensive investigation'" (citation omitted); *Behrazfar v. Unisys Corp.*, No. SACV 08-0850-AG(RCX), 2009 WL 10673197, at *4 (C.D. Cal. June 3, 2009) (party need not respond to an interrogatory that would require extensive analysis that would include "at least 10 hours per employee . . . and cost more than \$600,000.00").

It is equally well established that in responding to an interrogatory "a party cannot ordinarily be forced to prepare its opponent's case," 8B Wright, Miller & Marcus, Federal Practice and Procedure § 2174 (3d ed. 2013), or "do the interrogating party's investigation for him." *City of Las Cruces*, 2021 WL 330062, at *8 (citations omitted). An interrogatory thus cannot be used to compel the responding party to create analysis that would prove elements of the case as to which the propounding party has the burden.

Interrogatory 14A runs afoul of these principles. Responding to the interrogatory would undoubtedly require United to undertake an extensive investigation and analysis for the government that United has not performed already (and may very well never perform),

1 and create new information. United has not reviewed the relevant medical records to
2 determine whether the codes on the government's list are, or are not, supported by those
3 medical records, and indeed may never do so. Yet, in order to respond to the government's
4 interrogatory, United would now have to retain hundreds of coders to review
5 approximately 20 million charts and to determine which of the codes on the government's
6 list of 28 million codes is or is not supported. If that is not an extensive investigation,
7 nothing is, and United cannot be compelled to undertake this work for the government.
8 *See Melder v. Allstate Corp.*, No. CV 03-2499, 2007 WL 9777975, at *4 (E.D. La. Nov.
9 5, 2007) (denying motion to compel Allstate to disclose insurance scores and credit scores
10 by "zip code, policy type [and] policy form," because Allstate did not keep that
11 information in that form and responding would require Allstate to undertake extensive
12 analysis and prepare its opponent's case for it.)

13 The analysis the government wishes to compel United to undertake would likewise
14 reverse the burden of proof and require United to prepare the government's case for it.
15 The government admits that "it is the United States' burden of proof to establish that
16 UnitedHealth improperly failed to delete the diagnosis codes on its list," *United States'*
17 *Portion, Section III.A.1.b. at 22*, and that includes first proving that the codes on its list
18 are in fact unsupported. Instead of accepting United's proposal to produce all medical
19 records in its possession so that the government can review them, Interrogatory 14A would
20 require United to review all of the codes on the government's list and identify for the
21 government which codes are supported. In doing so, United would thus necessarily be also
22 identifying (by the codes not included on its list) which codes were *not* supported, thereby
23 potentially producing evidence that the government could use to prove one element of the
24 government's case for it. The government cannot compel United to do this. *See In re*
25 *Facebook, Inc.*, No. MDL 12-2389, 2016 WL 5080152, at *4 (S.D.N.Y. July 7, 2016)
26 (ruling that defendant in a securities case did not have to respond to an interrogatory on a
27 "complicated matter" that "would amount to a collection of information akin to
28 Defendants' affirmative defense," reasoning that "[i]t would be inappropriate to require

1 Plaintiffs to devise a theory for an element which is not required for their prima facie
2 case”); *Allstate Corp.*, 2007 WL 9777975, at *4 (interrogatory cannot require the
3 defendant to undertake analysis that would prepare the plaintiff’s case for it).

4 It would be no answer to argue that Interrogatory 14A requires United to undertake
5 a coding review only as to those diagnostic codes that it contends are supported. To begin
6 with, because all of the diagnosis codes were submitted by providers, United believes that
7 *each* code, taken by itself, is presumptively valid and more likely than not supported by
8 the underlying medical record. Moreover, because the list of codes is not something that
9 United created, the only way that United could determine which of the 28 million codes
10 on the government’s list are or are not in fact supported would be by reviewing every
11 single one of them. And if United responded to Interrogatory 14A by reviewing only a
12 partial list of codes, it risks the government later attempting to prevent United from
13 introducing evidence at trial that other codes, too, are supported. As a practical matter,
14 therefore, responding to Interrogatory 14A would require United to review every single
15 code on the government’s list.

16 The cases relied on by the government, *United States’ Portion, Section III.A.1.b. at*
17 *21–22*, merely stand for the unremarkable proposition that a party may be required by an
18 interrogatory to provide reasonably available facts, even if those facts are relevant to an
19 issue as to which the propounding party has the burden. *See, e.g., McKesson Info. Sols.,*
20 *LLC v. Epic Sys. Corp.*, 242 F.R.D. 689, 692 (N.D. Ga. 2007) (requiring party to disclose
21 the date of its invention). None of those cases reject, or even discuss, the rule that a party
22 responding to an interrogatory request may not be compelled to conduct new time-
23 consuming *analysis* that it has not already conducted in order to prepare the other party’s
24 case for it.

25 2. The Government’s Motion to Compel a Response to
26 Interrogatory 14B Should Be Denied

27 As with Interrogatory 14A, Interrogatory 14B also seeks to require United to
28 undertake new, complex analysis, this time to assist the government in proving a different

1 element of its case – knowledge. The government’s theory of the case is that not only are
2 all the diagnosis codes on its list of 28 million codes unsupported, but that United *knew*
3 the codes were unsupported. And the government’s theory is that United knew the codes
4 were unsupported because with respect to each code on the government’s list, one of
5 United coders had allegedly reviewed the medical chart corresponding to the same
6 beneficiary, same date of service, and same provider, and yet had not identified the code
7 in the coder’s blinded coding results. In order to prove this theory, the government needs
8 to properly match a specific diagnosis code submitted by a provider on a claim to its
9 corresponding medical record reviewed by a United chart review coder and to the results
10 of that review. United for its part denies that its coders necessarily reviewed the medical
11 records, or portions of medical records, corresponding to the provider-submitted codes on
12 the government’s list. Moreover, establishing that a United coder reviewed a medical chart
13 that may have been the same chart relied upon by the provider when submitting the initial
14 code is not a premise of any aspect of United’s defense and does not form the basis of any
15 contention United may advance in this case.

16 In order to establish this critical and disputed aspect of the government’s theory of
17 liability, Interrogatory 14B requires United to take every single diagnosis code in the
18 government’s list of 28 million codes, and undertake the complex exercise, which United
19 has not conducted already, of matching the codes on the list to the charts reviewed by
20 United’s coders, and for ones that match, to report the results of the coding review (among
21 other details). As the government admits, *United States’ Portion, Section I.A. at 3*, the
22 Interrogatory requires United to do this for every code on its list, “regardless of whether
23 the basis for UnitedHealth’s contention [that it was not required to delete the code] is
24 claimed support in an underlying medical record or some other defense.”⁷ Interrogatory

25
26 ⁷ Although this request relates to those codes that United contends “it was not
27 obligated to delete or otherwise return payment received for,” as the Court is aware
28 United’s legal position in this case is that it was not obligated to delete *any* of the codes
on the government’s list. Interrogatory 14B thus requires United to conduct this matching
analysis for every one of the 28 million codes listed by the government.

1 14B is an improper interrogatory to which United should not be compelled to respond.

2 To begin with, although the government's portion of the Joint Stipulation repeatedly
3 refers to Interrogatory 14 as a "contention interrogatory," *see, e.g., United States' Portion,*
4 *Section I.A. at 3*, that characterization is wholly inapplicable to Interrogatory 14B. It is the
5 government who contends that United reviewed the medical charts corresponding to all
6 the codes on the government's list. United has not made any such contention, and no
7 defense United has raised or would raise in this case would depend on United proving that
8 the codes on the government's list correspond to the precise charts that United's coders
9 reviewed. Even if Interrogatory 14B had sought only existing factual information, that
10 information would be the facts underlying *the government's* contention, not United's
11 contention. Interrogatory 14B is thus not a valid contention interrogatory – it is simply a
12 naked attempt to get United to undertake an extensive and difficult matching exercise that
13 it has not conducted in order to prepare the government's case for it.

14 Even if Interrogatory 14B were actually a contention interrogatory, it is improper
15 for the same reasons that Interrogatory 14A is improper: it impermissibly forces United to
16 perform the government's analysis for it and shifts the burden of proving knowledge,
17 according to the government's theory, onto United. As discussed above, an interrogatory
18 cannot affirmatively force a responding party to perform a complicated analysis on behalf
19 of the propounding party. *See City of Las Cruces*, 2021 WL 330062, at *8 ("A party
20 responding to an interrogatory 'is not required to make an extensive investigation' or 'do
21 the interrogating party's investigation for him.'" (citations omitted)). If United is forced to
22 match diagnosis codes at issue to medical record reviews of records for the same date of
23 service, it would have to perform analysis it otherwise would not perform and has no need
24 to perform. Nor can the government shift the burden of proving an element of the
25 government's case—in this instance, knowledge—onto United. *See In re Facebook, Inc.*,
26 2016 WL 5080152, at *4.

27 United has repeatedly offered to respond to Interrogatory 14B by pointing the
28 government to the data that United has already produced and that the government can use

1 to conduct the matching analysis for itself. Tellingly, despite the fact that it has all the
2 tools and data necessary to perform the matching exercise it seeks to compel United to
3 perform, the government does not wish to perform that analysis itself. The government
4 bears the burden of proving its case and cannot compel United to create new information,
5 and conduct new and complicated analysis and investigations, in order to prepare the
6 government's case for it. That is particularly true where the government could do the work
7 on its own, yet apparently refuses to do so.

8 3. The Government's Motion to Compel Regarding RFP 147
9 Should Be Denied

10 The government has repeatedly rejected United's good-faith proposals to respond
11 to RFP 147. Specifically, United has offered to produce all of the medical charts in its
12 possession that went through United's chart reviews. After months of insisting that this
13 proposal, which United estimates would result in producing approximately 20 million
14 charts, was too *narrow*, the government now complains that this offer is too *broad* and
15 that United should produce only those "medical records UnitedHealth identifies in
16 response to Part A of Interrogatory 14." *United States' Portion, Section I.A. at 3.*

17 As now recast by the government, RFP 147 stands or falls with the Court's ruling
18 as to Interrogatory 14A. Because the government's proposal makes United's obligation to
19 respond to RFP 147 dependent on United's response to Interrogatory 14A, if the Court
20 agrees that United is not required to respond to that interrogatory then there would be no
21 medical records responsive to the government's recast version of RFP 147.

22 4. The Government's Claims of Sandbagging and Unfair Surprise
23 Are Baseless

24 United is not trying to hide the ball from the government and has no intention of
25 putting the government in the position of "having to rebut a defense that it never had an
26 opportunity to probe or otherwise prepare for." *United States' Portion, Section III.A.1.e.*
27 *at 28.* With respect to Interrogatory 14B, the government has all the information it needs
28 to perform the analysis, and derive the information, it seeks. In that regard, there is no

1 risk of surprise—provided the government is willing to do the work. Similarly, with
2 respect to Interrogatory 14A, United is prepared to produce all the medical records in its
3 possession, which would allow the government to perform the expert analysis of
4 determining which of its 28 million codes is supported or unsupported. In that way, the
5 government would certainly be prepared to rebut any defense United might mount that
6 was predicated on an analysis of the 28 million codes and/or a review of medical records
7 corresponding to the 28 million codes. Yet, here again, the government simply does not
8 want to do the work now that it should have done before bringing this case.

9 In any event, United simply has not determined whether and to what extent it will
10 introduce evidence at trial demonstrating that certain of the codes on the government's
11 list are supported as part of its defense, and so has not done the expert analysis that
12 would be required to respond to Interrogatory 14A.

13 To be completely clear, should United retain an expert to testify at trial that some,
14 or all, of the 28 million codes on the government's list are supported by specific medical
15 records that the expert reviews, that information will be produced during expert
16 discovery in a manner that provides the government sufficient time to prepare a rebuttal,
17 consistent with its obligations under the relevant discovery rules and under the Order
18 Granting Stipulation Regarding Expert Discovery. See, e.g., Fed. R. Civ. P. 26(a)(2); see
19 also Ex. AA, Expert Discovery Stipulation.

20 United's agreement to produce all the medical records in its possession also
21 disposes of the government's fear that a percipient witness might refer to one or more
22 medical charts as part of his/her testimony. Not surprisingly, given that the trial in this
23 case is nearly 2 years out, and given that fact discovery is still ongoing, United has not
24 endeavored to compile a list of exhibits it intends to use at trial. Yet, as long as United's
25 ultimate exhibits have been produced to the government during discovery, the government
26 has no basis to claim unfair surprise. This is true even though there are millions of charts
27 potentially at issue. For example, even in complex cases with millions of produced
28 documents, the parties have no obligation to disclose in advance of pretrial disclosures

1 which particular emails they intend to introduce at trial, especially those that will be used
2 during cross-examination. *See* Fed. R. Civ. P. 26(a)(3). The parties instead bear their own
3 responsibilities for developing their own cases based on their own review of the documents
4 produced. These rules apply equally to medical records as they do to emails. Moreover,
5 the government cannot complain about the massive scope of discovery in this case since
6 it is the government alone that framed the size of the case and who has put 28 million
7 codes at issue.

8 5. The Government’s Alternative Request that United Be
9 Foreclosed From Introducing Evidence at Trial Lacks Any
10 Foundation

11 Finally, the Court should reject outright the government’s request that “if
12 UnitedHealth is not compelled” to respond to the government’s requests, the Court should
13 issue an “Order foreclosing UnitedHealth from later introducing such evidence” at trial.
14 *United States’ Portion, Section IV at 46.*

15 To begin with, the government makes this request only in one sentence of the
16 Conclusion section of its portion of the Joint Stipulation. It does not address this request
17 in the body of its brief and provides literally no legal authority to support it. Under well-
18 established principles, the request is thus not adequately presented and the Court should
19 not address it on the merits. As the Central District has summarized the Ninth Circuit’s
20 treatment of analogous briefing deficiencies, “issues raised in a brief that are not supported
21 by argument are deemed abandoned.” *Fabricant v. United States*, No. CR 03-01257-
22 RSWL-1, 2015 WL 5923481, at *4 (C.D. Cal. Oct. 8, 2015) (citing *Martinez-Serrano v.*
23 *I.N.S.*, 94 F.3d 1256, 1259 (9th Cir. 1996) (citing *Acosta-Huerta v. Estelle*, 7 F.3d 139,
24 144 (9th Cir. 1992))). “Furthermore, issues referred to in the appellant’s statement of the
25 case but not discussed in the body of the brief are waived.” *Id.* “The Ninth Circuit has even
26 refused to consider constitutional matters that were neither briefed nor argued, but merely
27 asserted in conclusory terms.” *Id.* (citing *United States v. Mateo-Mendez*, 215 F.3d 1039,
28 1043 (9th Cir. 2000)). Under these principles, an argument raised for the first time in the

1 Conclusion of a brief, without any argument, is likewise waived. *See Erwin v. Shinseki*,
2 No. 09-1530, 2011 WL 1563942, at *6 (Vet. App. Apr. 27, 2011) (refusing to consider an
3 argument raised only in the “Conclusion” section of Erwin’s brief).

4 There is also no basis for the government’s request. United has not resisted
5 producing documents or data to the government. United has instead objected, on legal
6 grounds, to undertaking new analysis for the government as part of an interrogatory
7 response to help prepare the government’s case for it. And it has also objected that it may
8 not be required to disclose expert analysis or conclusions in response to an interrogatory.
9 If the Court agrees with these arguments, there would be no basis for punishing United for
10 prevailing by then precluding it at trial from introducing relevant and admissible evidence,
11 should it choose to do so.

12 Finally, unlike situations where a party objects, on the grounds of burden, to producing,
13 in response to a request for production, the only evidence that would permit the
14 requesting party to prove certain facts, and then attempting to capitalize on that refusal at
15 trial, United is merely objecting to undertaking the government’s trial preparation for it.
16 United has offered to produce to the government all of the medical records in United’s
17 possession that were subject to United chart reviews, and the government can review
18 those medical records to conduct its own expert analysis of whether some or, as it
19 alleges, all of the codes on its list are in fact unsupported. And United has already
20 produced to the government, and has offered to point the government to, all of the data
21 that would enable the government to conduct for itself the matching exercise it wishes to
22 compel United to undertake in response to Interrogatory 14B. United’s position does not
23 prevent the government from attempting to meet its burdens of proof in this case, and
24 there is thus no reason whatsoever to preclude United from introducing any evidence of
25 its own at trial.

26 **IV. PROPOSED RESOLUTION/CONCLUSION**

27 **A. United States**

28 The United States respectfully requests that the Court grant the United States’

Motion to Compel a Response to Interrogatory No. 14 and the production of all medical charts associated with any diagnosis codes UnitedHealth contends are supported by medical records, in response to Request for Production No. 147. Alternatively, if UnitedHealth is not compelled to disclose its contentions and produce the medical records it contends support a diagnosis code, the United States requests an Order foreclosing UnitedHealth from later introducing such evidence on the ground that it failed to produce it during fact discovery.

B. UnitedHealth

The Court should deny the government's Motion to Compel and not require United to respond to Interrogatory 14 or RFP 147, now or in the future.

Dated: April_16, 2021

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Optum, Inc.; and OptumInsight, Inc.

19 Attestation

20 I hereby attest that the other signatories listed, on whose behalf the filing is
21 submitted, concur in the filing's content and have authorized the filing.
22

23 Dated: April 16, 2021

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27
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EXHIBIT D-6

FILED
CLERK, U.S. DISTRICT COURT

MAY 28 2021

CENTRAL DISTRICT OF CALIFORNIA

BY: ydr DEPUTY

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WESTERN DIVISION
UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel.
BENJAMIN POEHLING,

Plaintiffs,

vs.

UNITED HEALTH GROUP, INC., et. al.

Defendants.

Case No. CV 16-8697 FMO (SSx)

ORDER DENYING WITHOUT PREJUDICE
PLAINTIFF'S MOTION TO COMPEL RE
INTERROGATORY NO. 14 AND REQUEST
FOR PRODUCTION NO. 147

On April 16, 2021, Plaintiff United States (the "government") filed a motion to compel (the "Motion" or "MTC") seeking an order regarding Defendant United Health Group, Inc. and related entities ("UnitedHealth" or "UHG") to provide a supplemental response to Interrogatory No. 14 ("Interrogatory 14") and Request for Production No. 147 ("RFP 147" or "Request 147"). The parties submitted a Joint Stipulation in connection with the Motion. Each party also filed a Supplemental Memorandum. On May 20, 2021, the Special Master held a Zoom hearing on the

1 Motion. For the reasons discussed below, the Motion is DENIED without prejudice
2 to renewing the motion at a later stage in the litigation.
3

4 5 I. FACTUAL AND PROCEDURAL BACKGROUND

6
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8 The government contends that UnitedHealth has refused to reasonably
9 respond to two discovery requests that address whether UnitedHealth improperly
10 failed to delete diagnosis codes from its Medicare Part C risk adjustment submission.
11 According to the government, UnitedHealth systematically ignored medical record
12 reviews when it indicated that diagnosis codes UnitedHealth previously submitted
13 to CMS were not supported by beneficiaries' medical records.
14
15

16 The government contends that it has identified every diagnosis code that
17 UnitedHealth submitted to CMS to increase its risk adjustment payments and then
18 improperly failed to delete when UnitedHealth's own review found no support for
19 the diagnosis code in the medical records. The government asserts that Interrogatory
20 14 and Request 147 are intended to discover UnitedHealth's contentions about the
21 very same diagnosis codes. The government seeks to discover whether
22 UnitedHealth contends that any of the diagnosis codes on the government's list were
23 supported by medical records, despite not being found during any of UnitedHealth's
24 reviews of the associated medical records.
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1 Interrogatory 14 asked UnitedHealth to, with respect to every diagnosis code
2 on the government's list, (a) identify which code is supported by a medical record
3 and (b) identify every medical record review that UnitedHealth conducted. (MTC
4 at 5-7). Request 147 requests all medical records associated with the diagnosis codes
5 on the government's list. (Id. at 7).

6
7
8 In response to Interrogatory 14, UnitedHealth objected on the grounds that
9 "this Interrogatory is an improper contention interrogatory that impermissibly seeks
10 to shift the burden of proving an essential element of the government's False Claims
11 Act case on to UnitedHealth and seeks expert opinion." (Id. at 8). In response to
12 Request 147, UnitedHealth stated: "Based upon its General and Specific Objections,
13 UnitedHealth does not intend to produce documents responsive to this Request."
14

15
16 At the meet and confer on this issue, UnitedHealth indicated that it would
17 produce the responsive medical records in its possession. This production, however,
18 would require a production of approximately 21 million charts and take 8 months to
19 produce. This proposal did not resolve the discovery dispute.
20
21

22 The government asserts that, as it was required to provide a list of 28 million
23 diagnosis codes to comply with its obligation to identify the diagnosis codes it
24 contends UnitedHealth knew were invalid, UnitedHealth should now explain
25 whether medical records do or do not support these codes. (Id. at 9).
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28

1 According to UnitedHealth, Interrogatory 14A requires it to identify the over
2 20 million medical records corresponding to each of the 28 million codes on the
3 government's list and then to hire experts to review those charts to determine
4 whether each code on the government's list is or is not supported by the medical
5 chart. Subpart 14B requests that UnitedHealth "[i]dentify each Medical record
6 Review(s) of the chart(s) corresponding to that Diagnosis, etc." According to UHG,
7 this request would also require it to engage in a massive and complex matching
8 analysis. RFP 147 seeks the documents that relate to the answer required in
9 Interrogatory 14.
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15 II. INTERROGATORY 14 REQUIRES EXPERT ANALYSIS TO
16 RESPOND
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18

19 Although the government argues that Interrogatory 14 is "only seeking facts,"
20 it would be impossible for anyone other than an expert to provide a reliable answer.
21 Only an expert -- or someone with specialized knowledge -- could do a fair
22 comparison of the medical records and the diagnosis codes to determine if the
23 medical record supported the code. It is also undeniable that the interrogatory would
24 impose a tremendous burden on the responding party to prepare an answer that does
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1 not currently exist. For these reasons, Interrogatory 14 is an improper interrogatory
2 at this stage of the proceedings.

3
4 Contention interrogatories may be improper “[when] they ask the respondent
5 to provide an expert opinion.” Amgen Inc. v. Sandoz Inc., 2017 WL 1352052, at *2
6 (C.D. Cal. April 13, 2017); Montgomery v. Wal-Mart Stores, Inc., 2015 WL
7 11233384, at *6 (S.D. Cal. July 17, 2015). In addition, a court has discretion to
8 delay an answer to a contention interrogatory until designated discovery is complete
9 or at some other time. See Capacchione v. Charlotte-Mecklenburg Sch., 182 F.R.D.
10 486, 489 (W.D.N.C.1998) (stating that “[d]ue to the nature of contention
11 interrogatories, they are more appropriately used after a substantial amount of
12 discovery has been conducted - typically, at the end of the discovery period”). In
13 general, courts prefer to defer answers to contention interrogatories that are
14 propounded prematurely. See e.g., Everett v. USAir Group, Inc., 165 F.R.D. 1, 3
15 (D.D.C. 1995) (denying without prejudice motion to compel response to contention
16 interrogatory on grounds that interrogatory served too early in discovery process);
17 B. Braun Medical, Inc. v Abbott Lab., 155 F.R.D. 525, 527 (E.D. Pa. 1994) (“[T]here
18 is considerable support to defer answering contention interrogatories until the end of
19 the discovery period.”).

20
21 In the present action, the request seeks the application of expert knowledge to
22 facts, i.e., the medical records. This interrogatory cannot be answered until after
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expert discovery is completed and only if UnitedHealth intends to assert a defense based upon this information. Indeed, parties generally provide this type of information through expert testimony. See United States ex rel. Desrosiers v. Thaller, 2016 WL 6441548, at *4-6 (S.D. Fla. Nov. 1, 2016) (whether medical codes submitted for reimbursement were proper was subject of expert testimony); Counts v. Pollock, 2020 WL 5534444, at *2 (M.D. Fla. August 21, 2020) (providing expert testimony on whether plaintiff's medical bills were properly coded); United States ex rel Armfield v. Gills, 2012 WL 12918274, at * 2 (M.D. Fla. 2012) (qualifying expert for testimony regarding improperly coded claims). Accordingly, this interrogatory is improper at this stage of the proceedings because it would require expert analysis to respond.

It is also undeniable that preparation of the response to the request would be extremely burdensome and costly. It would require UnitedHealth to pay for and create an analysis for 20 million documents. Ordinarily, a respondent is not required to undertake investigation and analysis to prepare a response to an interrogatory. See Behrazfar v. Unisys Corp., 2009 WL 10673197, at *4 (C.D. Cal. June 3, 2009) (party need not respond to an interrogatory that would require extensive analysis and cost). While this analysis and cost may be necessary at some point in the litigation, the Special Master concludes that it is premature to order UHG to undertake this analysis now.

1 UnitedHealth has stated that if it discloses during the expert discovery phase
2 that it has retained an expert to testify at trial that the 28 million codes on the
3 government's list are supported by medical records, that information will be
4 produced in a manner that provides the government sufficient time to prepare a
5 rebuttal. (MTC at 42). Nothing more is required during this phase of the litigation.
6
7 Because Request 14 is a contention interrogatory and requires expert analysis,
8 UnitedHealth is not required to prepare a response at this time.
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12 III. REQUEST 147 IS DEPENDENT UPON A RESPONSE TO
13 INTERROGATORY 14 AND THEREFORE IS
14 DENIED WITHOUT PREJUDICE
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18 Request 147 seeks: "All Chart(s) corresponding to, associated with, or related
19 to each Beneficiary, from each DOS Year(s) in which that Beneficiary is listed in
20 the United States Response to Defendants' Interrogatory No. 1 (Including the United
21 States' First Supplemental Response served on August 17, 2020, the United States
22 Amended First Supplemental Response served on October 13, 2020, the United
23 States' Second Supplemental Response served on October 30, 2020, and any other
24 subsequent responses)." (Mason Decl., Ex. B). The government agreed to limit this
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1 request to production of only those medical records UHG contends supports a
2 diagnosis code on the government's list. (MTC at 7-8).

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4 During the meet and confer process, UnitedHealth offered to produce the
5 responsive medical records in its possession which would amount to an estimated
6 21 million charts and take 8 months to collect and produce. This would allow the
7 government to review the medical records that UnitedHealth reviewed as part of its
8 chart review program and the government could then determine which of the codes
9 on its list are or are not supported. (MTC at 17). At the hearing on the MTC,
10 counsel for the government argued that at a minimum the medical records should be
11 produced to allow the government to review the medical evidence underlying
12 UnitedHealth's codes. Production of these records would allow the government to
13 determine for itself which of the codes on its list are supported or are not supported.
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18 However, in the Motion itself, the government asserted the following: "After
19 the United States identified its list of all diagnosis codes it contends are at issue, it
20 served Interrogatory 14 and Request 147 to discover UnitedHealth's contentions
21 about the very same diagnosis codes. In particular, the United States seeks to
22 discovery whether UnitedHealth contends that any of the diagnosis codes on the
23 United States' list were supported by medical records, despite not being found
24 during any of UnitedHealth's reviews of the associated medical records. The United
25 States further seeks to discover factual information related to UnitedHealth's
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1 medical record reviews.” (MTC at 2, ll. 18-24). The United States also noted:
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3 “Request 147, as written, relatedly requests all medical records associated with the
4 diagnosis codes on the United States’ list. (citation omitted). Importantly, as a result
5 of the meet and confer process . . . the United States agreed to limit its request for
6 medical records to only those records associated with the diagnosis codes that
7 UnitedHealth contends were supported (i.e., the medical records UnitedHealth
8 identifies in response to Part A of Interrogatory 14).” (MTC at 3, ll. 5-11) . . .
9
10 “Subsequently, UnitedHealth agreed to produce some (but not all) of the underlying
11 medical records, but that offer is hollow without identifying which codes
12 UnitedHealth contends are supported by medical records (i.e., responding to
13 Interrogatory 14). Simply producing millions of medical records alone does nothing
14 to illuminate UnitedHealth’s contentions.” (MTC at 3, ll. 17-21).

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18 As UHG observed, “RFP 147 is . . . dependent entirely on whether United is
19 required to Interrogatory 14A; if the Court agrees that United is not required to hire
20 experts to engage in the coding reviews that responding to Interrogatory 14A would
21 require, then there would be no medical records responsive to RFP 147 as now
22 recrafted by the government.” (MTC at 16, ll. 2-6). UHG, as part of the meet and
23 confer efforts, offered to produce to the government every medical record in
24 United’s possession that United reviewed as part of its chart review program, to
25 allow the government to determine for itself which of the codes on its list are or are
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1 not supported. (MTC at 16, ll. 25-28; 17, ll. 1-2). The government rejected this
2 offer. UHG contends that the government's position regarding Request 147 has
3 "vacillated dramatically over time." (MTC at 17, ll. 12-13). At the hearing on the
4 MTC, the government did take a position that contradicted the government's prior
5 arguments in the MTC, i.e., the government argued that a response to Request 147
6 would be meaningful even without a response to Interrogatory 14.

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8
9 The Special Master finds that the inconsistency in the government's
10 arguments undermines their persuasiveness. The Special Master concludes that if
11 the two discovery requests are related and linked as the government originally
12 argued, then the Order should be consistent regarding both requests. Accordingly,
13 the MTC is DENIED without prejudice as it pertains to Request 147. The
14 government may renew Request 147 if the requested documents are relevant to
15 UHG's defenses asserted at a later phase of the action.
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21 IT IS SO ORDERED.

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24 **DATE: May 28, 2021**

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DocuSigned by:
Hon. Suzanne Segal (Ret.)
2B75618C7FET+g5B
Hon. Suzanne H. Segal (Ret.)

PROOF OF SERVICE

RE: United States ex rel. Pochling v. United Health Group, Inc., et al.
Case ID: KEERX

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES:

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and am not a party to the within action. My business address is 633 West 5th Street, Suite 1000 Los Angeles, CA 90071

On June 1 2021 I served the **ORDER DENYING WITHOUT PREJUDICE PLAINTIFF'S MOTION TO COMPEL RE INTERROGATORY NO. 14 AND REQUEST FOR PRODUCTION NO. 147** on the following parties. Placing a true copy to all parties as follows:

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- ☐ BY U.S. MAIL: I caused such envelope(s), with postage fully prepaid, to be placed in the U.S. Mail at Los Angeles, California.
- ☐ BY FACSIMILE: I caused such document to be sent via facsimile to each person.
- ☒ BY ELECTRONIC MAIL: I caused such document to be sent via electronic mail to each person.
- ☐ BY PERSONAL SERVICE: I caused such envelope to be delivered by hand to the office of the addressee.
- ☒ STATE: I declare under penalty of perjury under the laws of the State of California that the above is true and correct.
- ☐ FEDERAL: I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on June 1, 2021 at Los Angeles, California.


Alisa Martinez
Signature Resolution

EXHIBIT D-7

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**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et*
al.,

Defendants.

CASE NO. CV 16-08697 FMO (SSx)

**DEFENDANT UHC OF
CALIFORNIA'S FIRST
INTERROGATORY TO THE
GOVERNMENT**

Assigned to Hon. Fernando Manzano
Olguin

DISCOVERY MATTER

PROPOUNDING PARTY: Defendant UHC of California

RESPONDING PARTY: Plaintiff United States Government

SET NO.: ONE (1)

TO THE RESPONDING PARTY AND TO ITS ATTORNEYS OF RECORD:

Please take notice that pursuant to Rule 33 of the Federal Rules of Civil Procedure and Rule 33-1 of the Local Civil Rules of the United States District Court for the Central District of California, Defendant UHC of California, by and through its undersigned attorneys, submits the following First Interrogatory to the Government (“Interrogatory”). UnitedHealth requests that the Government respond separately in writing to the following Interrogatory within thirty (30) days of service. The Definitions and Instructions set forth below shall govern the following Interrogatory, as well as responses to the Interrogatory.

DEFINITIONS

As used herein, the following terms and phrases shall have the following meanings:

1. The applicable definitions and rules of construction set forth in the Federal Rules of Civil Procedure and the local rules are incorporated herein by reference.

2. **“Beneficiary”** or **“Member”** shall mean an individual enrolled in a Medicare Advantage Plan.

3. **“CMS HCC”** means an HCC that is used for Medicare Part C.

4. **“Complaint”** shall mean the United States’ Amended Complaint-In-Partial Intervention And Demand For Jury Trial filed by the Government in this case on November 17, 2017, and any forthcoming amended complaints filed by the Government in this case.

5. **“Diagnosis Code(s)”** shall mean an ICD-9-CM or ICD-10 CM diagnosis code.

6. **“Date of Service Year(s)”** shall mean the year or years during which a Beneficiary had a medical encounter with a healthcare provider.

7. **“HCC”** shall mean a hierarchical condition category associated with one or more diagnosis codes (ICD-9-CM or ICD-10-CM codes) that represent the disease component of the beneficiary risk scores that are applied to Medicare Advantage payments.

8. **“Date of Service”** shall mean the date of a medical encounter or, if the encounter lasted more than 24 hours, the start and end dates for the encounter.

9. **“Each”** includes the word “every” and **“every”** includes the word “each,” **“any”** includes the word “all” and **“all”** includes the word “any,” **“and”** includes the word “or” and **“or”** includes the word “and,” as necessary to bring within the scope of each Request information that might otherwise be construed to be outside its scope.

10. **“Government”** shall mean the United States, its agencies, departments, components, agents, representatives, contractors, attorneys, consultants, and all other Persons acting on its behalf, including, but not limited to, any component of the United States Department of Justice, the United States Department of Health and Human Services, the Centers for Medicare & Medicaid Services, and all subdivisions and components thereof.

11. **“HIC Number”** shall mean a Beneficiary’s Health Insurance Claim Number.

12. **“NPI”** or **“National Provider Identifier”** shall mean the unique 10-digit identification number CMS issues to covered healthcare Providers.

13. **“Person”** shall mean natural persons, proprietorships, corporations, public corporations, municipal corporations, the federal government and all departments and agencies thereof, state governments, local governments, other governmental agencies, political subdivisions, partnerships, groups, associations or organizations.

1 14. **“Provider”** shall mean any provider of healthcare services including
2 individual providers such as physicians, physicians assistants, laboratories, medical
3 equipment providers, and nurse practitioners; institutional providers such as
4 hospitals and clinics; provider groups such as groups of physicians or associations
5 of physicians with other provider types; and any other type of providers of healthcare
6 services or items. “Provider” includes fee-for-service Providers, providers with
7 Gainshare Arrangements, and Providers with Capitation arrangements. “Provider”
8 also includes any past or present employee, contractor, or agent of any Provider. The
9 term “Provider” shall be given the broadest possible meaning when responding to
10 these Requests.

11 15. **“Provider ID”** shall mean the unique identifier(s) used to differentiate
12 the Provider in one or more of UnitedHealth’s Risk Adjustment Databases.

13 16. **“RxHCC”** means an HCC used for Medicare Part D.

14 17. **“Tax ID”** shall mean the nine-digit identification number used by the
15 Internal Revenue Service (IRS) for tax purposes.

16 18. **“United”** or **“UnitedHealth”** shall mean all the Defendants listed in
17 Your Complaint.

18 19. **“You”** and **“Your”** shall mean the Government and all Persons acting
19 on its behalf.

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INSTRUCTIONS

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2 1. In accordance with the Federal Rules of Civil Procedure, Your
3 obligation to respond to the Interrogatory is continuing. If you receive or discover
4 information after serving a response to the Interrogatory, You should supplement
5 Your responses promptly.

6 2. Whenever appropriate, the singular form of a word shall be interpreted
7 as plural, and vice versa. Similarly, the use of the present tense of a verb shall be
8 considered to include within its meaning the future and past tense, and vice versa.

9 3. The Interrogatory should be construed so as to include all time periods
10 relevant to the allegations and claims for damages contained in Your Complaint.

11 4. Whenever the conjunction “and” is used, it is also to be interpreted
12 disjunctively, and conversely; whenever the disjunctive ‘or’ is used, it is also to be
13 interpreted conjunctively.

14 5. Each Interrogatory is to be construed independently and not in
15 reference to any other Interrogatory for purposes of limiting the scope of the
16 Interrogatory. The answer to an Interrogatory shall not be supplied by referring to
17 the answer to another interrogatory unless the answer to the referenced interrogatory
18 supplies a complete and accurate answer to the Interrogatory being answered.

19 6. You are to produce all responsive information that are in Your
20 possession, custody or control, or in the possession, custody, or control of any of
21 Your agents, representatives, and consultants. Without limiting the term “control,”
22 responsive information is deemed to be within Your control if You have ownership,
23 possession, or custody or the information, or the right to secure the information from
24 any person. If You do not have responsive information in Your possession, custody,
25 or control, You must state so and answer the Interrogatory in part if You have part
26 of the responsive information.

27 7. If a claim of privilege is asserted in objecting to the Interrogatory, or
28 any sub-part thereof, and an answer is not provided on the basis of such assertion,

1 furnish the following information with respect to the Interrogatory as to which the
2 claim of privilege is asserted: (a) the nature of the privilege (including work product)
3 that is being claimed; and (b) the general topic of the information claimed to be
4 privileged to the extent possible in a manner consistent with the claimed privilege.

5 8. Whenever an Interrogatory calls for information with respect to “each”
6 one of a particular type or class of claims, matters, events, persons, or entities, of
7 which there is more than one, You are required to separately list, set forth, or identify
8 for each thereof all of the information requested.

9 9. If any meaning of any term in any Interrogatory is unclear to You,
10 without waiver of UnitedHealth’s right to seek a full and complete response to the
11 Interrogatory, You shall assume a reasonable meaning, state what the assumed
12 meaning is, and respond to the Interrogatory according to the assumed meaning.

13
14 **INTERROGATORY**

15 **INTERROGATORY NO. 1**

16 Identify for Date of Service Years 2008–2016 the Beneficiary (by name, HIC
17 Number, and date of birth), Date of Service, Diagnosis Code(s), CMS HCC(s) or
18 RxHCC(s), and Provider (by individual name, group name, address, NPI, Tax ID(s),
19 and Provider ID), that corresponds to each and every Diagnosis Code You allege
20 UnitedHealth “knowingly and improperly failed to delete . . . or otherwise return to
21 the Medicare Program [as an] overpayment.” United States’ Complaint ¶ 342, Dkt.
22 171.

1 Dated: January 3, 2020

2 LATHAM & WATKINS LLP
3 DAVID J. SCHINDLER
4 DANIEL MERON
5 KATHRYN H. RUEMMLER
6 ABID R. QURESHI

7 By



8 David J. Schindler
9 Attorneys for UnitedHealth
10 Defendants
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PROOF OF SERVICE

I am employed in the County of Los Angeles, State of California. I am over the age of 18 years and not a party to this action. My business address is Latham & Watkins LLP, 355 South Grand Avenue, Suite 100, Los Angeles, CA 90071-1560.

On **January 3, 2020**, I caused the service of a true copy of the following document described as:

UHC OF CALIFORNIA'S FIRST INTERROGATORY TO THE GOVERNMENT

to be served in the following manner:

BY ELECTRONIC MAIL

The above-described document was transmitted via electronic mail to the following party pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E) on **January 3, 2020**:

SEE ATTACHED SERVICE LIST

I declare that I am employed in the office of a member of the Bar of, or permitted to practice before, this Court at whose direction the service was made and declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on **January 3, 2020**, at Los Angeles, California.



David J. Schindler

SERVICE LIST

United States District Court
CASE NO. CV 16-08697 FMO (SSx)

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et al.*,

Defendants.

No. CV 16-08697 FMO

UNITED STATES' RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S SECOND SET OF
INTERROGATORIES TO THE
GOVERNMENT

PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.

RESPONDING PARTY: UNITED STATES OF AMERICA

SET NUMBER: TWO

Preliminary Statement

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and Rule 33 of the Local Civil Rules of the United States District Court for the Central District of California, the United States of America (“United States” or “government”), through its undersigned counsel, hereby provides its responses and objections to Defendant UHC of California’s (“UnitedHealth” or “Defendant”) Second Set of Interrogatories (“Second Set of Interrogatories”), dated February 4, 2021. The responses set forth herein are based on information now known to the United States and its undersigned attorneys, and will be revised, corrected, supplemented, amended, and clarified to the extent required by Rule 26 as discovery proceeds.

General Objections

The following objections apply to each and every separately numbered Interrogatory and are incorporated by reference to the extent applicable into the objection to each Interrogatory.

1. UnitedHealth’s Interrogatories are inconsistent with the spirit and letter of the Federal Rules of Civil Procedure (“Federal Rules”), which explain that an interrogatory ought to narrow and sharpen issues for trial. See Fed. R. Civ. P. 33 Advisory Committee’s Note. UnitedHealth’s extensive Interrogatories do just the opposite by asking the United States to respond to vague and illogical mischaracterizations of its arguments, and seeking vast amounts of information without the objective to narrow and sharpen issues for trial. For example, the Interrogatories demand that the United States (i) survey all CMS and HHS-OIG Individuals (as defined by UnitedHealth’s Second Set of Interrogatories, Definitions 4 and 12) to determine if anyone ever held a particular belief between 2008–2017; (ii)

1 reply to convoluted hypotheticals by stating what CMS and HHS-OIG Individuals
2 believe CMS would have done if it had known certain information during the period
3 2008–2017; and (iii) identify “all evidence and material facts” it relies on for its
4 contentions while discovery in this matter is still ongoing.

5 2. The United States objects to the Second Set of Interrogatories to the
6 extent they are vague, ambiguous, overbroad, unduly burdensome, or seek to impose
7 requirements upon the United States beyond those called for or permitted by the
8 Federal Rules, the Local Civil Rules of the United States District Court for the
9 Central District of California (“Local Rules”), or any order of the Court. The United
10 States responds below pursuant to its obligations under the Federal Rules and the
11 Local Rules, namely that the United States has taken and is continuing to undertake
12 reasonable efforts to identify information responsive to the Interrogatories.

13 3. The United States objects to the Second Set of Interrogatories to the
14 extent that a response requires disclosure of information protected by an applicable
15 privilege or protection, including, but not limited to, the attorney-client privilege,
16 work product doctrine, deliberative process privilege, law enforcement privilege,
17 common interest privilege, or investigative files privilege, and protections afforded
18 by Fed. R. Civ. P. 26(b), or any other applicable privilege. The United States will not
19 respond in such a way as to disclose such protected information, and inadvertent
20 identification or disclosure of privileged information by the United States shall not be
21 a waiver of any applicable privilege. Under Federal Rule of Evidence 502, Federal
22 Rule of Civil Procedure 26(b)(5)(B), other related sources of law, and the Court’s
23 Revised Protective Order Governing Non-Waiver of Privilege and Protected Material,
24 Dkt. 412, the government reserves any and all rights to claw back privileged
25 information it inadvertently discloses in response to the Second Set of Interrogatories.

26 4. The United States submits these responses subject to, without intending
27 to waive, but expressly reserving the right to object to other discovery procedures
28 involving or relating to the subject matter of the information in responses to the

1 Second Set of Interrogatories. The United States reserves the right to object on any
2 ground, at any time, to such other or supplemental requests as the Defendants may
3 propound involving or relating to the subject matter of the Second Set of
4 Interrogatories.

5 5. The United States reserves the right to supplement its responses to the
6 Second Set of Interrogatories at any time to the extent provided by the Federal Rules.

7 6. The assertion of the same, similar, or additional specific objections to the
8 Second Set of Interrogatories does not and should not be construed to waive or
9 modify any of the United States' general objections.

10 7. The United States objects to the Second Set of Interrogatories to the
11 extent they require the United States to draw legal conclusions, comment on the
12 merits of any affirmative defenses, or otherwise seek to impose any requirements
13 beyond those established by the Federal Rules or the Local Rules.

14 8. The United States objects to the Second Set of Interrogatories to the
15 extent that they contain multiple subparts numbered as a single Interrogatory. By
16 responding, the United States in no way waives its right to object that UnitedHealth
17 has exceeded the maximum number of interrogatories permitted under the Federal
18 Rules.

19 9. The United States objects to the Second Set of Interrogatories to the
20 extent they purport to require the United States to gather information in the
21 possession or custody of Government components beyond HHS-OIG and CMS on
22 the grounds that they are unduly burdensome and overbroad and that they seek
23 information not relevant to the claims or defenses in this action and disproportionate
24 to the needs of this case.

25 10. The United States objects to the Second Set of Interrogatories to the
26 extent they purport to require the United States to gather information in the
27 possession or custody of HHS-OIG where HHS-OIG is not the relevant agency for
28 payment purposes and therefore the Interrogatories are unduly burdensome,

1 overbroad, and seek information not relevant to the claims or defenses in this action
2 and disproportionate to the needs of this case.

3 11. To the extent the United States produces information or documents in
4 further response to these Interrogatories, it does not admit that the information or
5 documents are true, accurate, authentic, relevant, or admissible in this action. The
6 United States reserves the right to challenge on evidentiary grounds any information
7 or documents produced in response to these Interrogatories.

8 12. The fact that the United States has answered any part of all or any
9 particular interrogatory is not intended to and shall not be construed to be a waiver by
10 the United States of all or part of any objection to any interrogatory.

11 **Specific Objections to the Definitions and Instructions**

12 The United States objects to the Definitions and Instructions to the extent they
13 (i) seek to impose burdens on the United States that are different from, are
14 inconsistent with, or exceed those imposed by the Federal Rules and the Local Rules,
15 (ii) are vague or ambiguous, and/or (iii) render the Second Set of Interrogatories
16 overly broad, unduly burdensome, not proportionate to the needs of the case, and not
17 relevant. The United States further objects to the Second Set of Interrogatories to the
18 extent UnitedHealth has failed to define vague, ambiguous, and confusing terms.

19 **Definition 2:** The United States objects to the definition of “Believed” (Definition 2)
20 as vague, confusing, ambiguous, and irrelevant to the extent it is used in conjunction
21 with “CMS” or “HHS-OIG.” As entities, CMS and HHS-OIG cannot hold Beliefs.
22 The United States will interpret any Interrogatories involving “Believed” to apply
23 exclusively to individuals. The United States further objects because the Beliefs of
24 any individual CMS or HHS-OIG employee is irrelevant to any claim or defense in
25 this matter as CMS and HHS-OIG speak through official pronouncements. The
26 United States also objects to the definition of “Believed” in that “suppose” means
27 something different than “hold something as an opinion” or “think,” and this
28 definition encompassing two different meanings therefore renders UnitedHealth’s

1 Second Set of Interrogatories confusing and self-contradictory. The United States
2 will interpret “Believed” as to hold something as an opinion or to think.

3 **Definitions 3, 10, and 11:** The United States objects to the terms “CMS” (Definition
4 3), “Government” (Definition 10), and “HHS-OIG” (Definition 11) as overbroad and
5 irrelevant to the extent they include current and former contractors or consultants.
6 CMS and HHS-OIG speak through official pronouncements and do not speak through
7 its contractors or consultants, making information provided by contractors and
8 consultants overbroad and irrelevant for the purpose of responding to the Second Set
9 of Interrogatories. The United States objects to the definition of “Government”
10 (Definition 10) to the extent it includes any branch, agency, department, agent,
11 representative, contractor, attorney, consultant, or person acting on its behalf not
12 relevant to this action. This definition is plainly unreasonable, unduly burdensome,
13 and disproportionate to the needs of the case, in that it seeks to require the United
14 States to provide information not currently in the possession, custody, or control of
15 CMS or HHS-OIG. Subject to and without waiving these objections, the United
16 States interprets “Government” to mean CMS and HHS-OIG. To the extent the
17 United States interprets the use of “Government” in a specific Interrogatory as
18 directed at one, but not all, of the above components, the United States will state its
19 interpretation in its response. The United States further objects to the inclusion of
20 “attorneys” in the definitions to the extent that the inclusion of “attorneys” requires
21 the United States to gather information from attorneys within CMS’s Office of the
22 General Counsel (“OGC”), the Office of Counsel for the Inspector General
23 (“OCIG”), or the Department of Justice (“DOJ”). The United States is not searching
24 for, collecting, or providing information or materials from any attorney within OGC,
25 OCIG, or DOJ.

26 **Definitions 4 and 12:** The United States objects to the terms “CMS Individual”
27 (Definition 4) and “HHS-OIG Individual” (Definition 12) as irrelevant, unduly
28 burdensome, and beyond the scope of permissible discovery to the extent they

1 include all current or former contractors or current or former subcontractors, and
2 therefore demand that the United States obtain information from, or respond on
3 behalf of, persons or entities not reasonably accessible to the United States and over
4 whom the United States has no control. The United States further objects to the terms
5 “CMS Individual” and “HHS-OIG Individual” as overly broad and unduly
6 burdensome to the extent they include all current employees of each agency, which
7 includes thousands of people who are unlikely to have information relevant to these
8 interrogatories. The United States objects to the terms “CMS Individual” and “HHS-
9 OIG Individual” as overly broad and unduly burdensome to the extent they include
10 all former employees of each agency, and therefore purport to require the United
11 States to obtain information from, or to respond on behalf of, persons or entities not
12 reasonably accessible to the United States and over whom the United States has no
13 control. It is plainly unreasonable for the United States to survey each and every
14 current and former employee of CMS and/or HHS-OIG. The United States further
15 objects to the inclusion of “attorneys” in the definitions to the extent the inclusion of
16 “attorneys” requires the United States to gather information from attorneys within
17 OGC, OCIG, or DOJ. The United States is not searching for, collecting, or providing
18 information or materials from any attorney within OGC, OCIG, or DOJ.

19 **Definition 17:** The United States objects to the definition of “Person” (Definition
20 17) to the extent it is defined to mean “the federal government and all departments
21 and agencies thereof, state governments, local governments, [and] other
22 governmental agencies[.]” This definition is plainly unreasonable, unduly
23 burdensome, and disproportionate to the needs of the case, in that it seeks to require
24 the United States to provide information not currently in the possession, custody, or
25 control of CMS and HHS-OIG. Furthermore, the United States objects to the extent
26 each definition includes former CMS contractors for whom the United States
27 presently has no reasonable belief they possess or control non-duplicative information
28 relevant to any claim or defense in this case.

1 **Definition 18:** The United States objects to the definition of “Proposed Medical
2 Record Review Rule” (Definition 18) to the extent that it is overly broad, vague, and
3 misleading in that the definition cites to provisions of a proposed rule beyond the
4 proposed addition to 42 C.F.R. § 422.310(e). The United States will interpret
5 “Proposed Medical Record Review Rule” to only include the language at 79 Fed.
6 Reg. 1918, 2000 related to 42 C.F.R. § 422.310(e).

7 **Definitions 6 and 19:** The United States objects to the definitions of “Concerning”
8 (Definition 6) and “Relating to” and “regarding” (Definition 19) because the
9 definitions render the Second Set of Interrogatories vague, ambiguous, confusing,
10 overly broad, unduly burdensome, and disproportionate to the needs of the case.
11 Indeed, these terms are defined to seek any piece of information that in some way—
12 no matter how remote, indirect, or tangential—mentions or references matters set
13 forth in the Interrogatory. The United States responds to the Second Set of
14 Interrogatories by using these terms and the verbs constituting their definitions as
15 limited by the constraining adverb “directly.”

16 **Definition 22:** The United States objects to the definition of “Time Period”
17 (Definition 22) to the extent it seeks information outside the scope of the Parties’
18 agreement relating to a discovery cut-off date of May 16, 2017, with the exception of
19 discovery relating to CMS’s proposed rule *Medicare and Medicaid Programs; Policy*
20 *and Technical Changes to the Medicare Advantage, Medicare Prescription Drug*
21 *Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-*
22 *Service, and Medicaid Managed Care Programs for Years 2020 and 2021* (“Proposed
23 Rule”) and underlying FFS Adjuster Study. See August 9, 2019 D. Schindler email
24 to R. McAuliffe.

25 **Definition 24:** The United States objects to the definition of “You” and “Your”
26 (Definition 24) as overly broad to the extent these terms are intended to encompass
27 any agency, office, employee, agent, representative, officer, or contractor of either the
28 legislative or judicial branch, and insofar as these terms are defined to include

1 executive branch agencies and offices not relevant to this action. This is plainly
2 unreasonable, unduly burdensome, and disproportionate to the needs of the case, in
3 that it seeks to require the United States to provide information not currently in the
4 possession, custody, or control of CMS and HHS-OIG. Subject to and without
5 waiving these objections, the United States will interpret this term to mean CMS and
6 HHS-OIG. When appropriate, the United States will identify whether it is
7 interpreting “You” and “Your” as either CMS, HHS-OIG, or both in the context of
8 each specific Interrogatory.

9 **Instruction 3:** The United States objects to Instruction 3 as vague and ambiguous.
10 For the purposes of responding to these Interrogatories, the United States will
11 construe the relevant time period as January 1, 2004 through May 16, 2017, in
12 accordance with the parties’ agreed-upon discovery timeframe. However, with
13 respect to Interrogatory 6, the United States will construe the relevant time period as
14 January 1, 2004 to June 30, 2019, in accordance with the parties’ agreed-upon
15 discovery timeframe pertaining to discovery relating to CMS’s proposed rule
16 *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare*
17 *Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for*
18 *the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care*
19 *Programs for Years 2020 and 2021* (“Proposed Rule”) and underlying FFS Adjuster
20 Study. See August 9, 2019 D. Schindler email to R. McAuliffe.

21 **Instruction 5:** The United States objects to Instruction 5 to the extent it seeks to
22 impose burdens upon the United States beyond those called for or permitted by the
23 Federal Rules or the Local Rules.

24 **Instruction 6:** The United States objects to Instruction 6 to the extent it seeks to
25 impose burdens upon the United States beyond those called for or permitted by the
26 Federal Rules or the Local Rules.

27 **Instruction 7:** The United States objects to Instruction 7 to the extent it seeks to
28 impose burdens upon the United States beyond those called for or permitted by the

1 Federal Rules or the Local Rules. The United States will assert any applicable
2 privileges and specify the material to which it applies per Fed. R. Civ. P. 26(b)(5)(A)
3 for all information responsive to an Interrogatory to which the United States has
4 agreed to produce but which is withheld on the basis of a privilege or protection.
5 **Instruction 8:** The United States objects to Instruction 8 to the extent it requires the
6 United States to identify “each” instance of duplicative, redundant, or repetitive
7 information.

8 **Specific Objections and Responses**

9 **INTERROGATORY NO. 2:** For each Diagnosis Code You identified in response
10 to UHC of California’s First Interrogatory, Identify all evidence and material facts
11 upon which You rely, or intend to rely, to support Your contention that these
12 Diagnosis Codes are “not supported by the beneficiaries’ medical records,” “false,”
13 or “invalid.” United States’ Am. Compl. ¶¶ 103, 342, Dkt. 171.

14 **Objections:** The United States incorporates by reference each of its General
15 Objections and Specific Objections to the Definitions and Instructions as if stated
16 herein. The United States objects to this Interrogatory as overly broad and unduly
17 burdensome to the extent it improperly requires the United States to lay out “all
18 evidence and material facts” of its case. *See Tubbs v. Sacramento Cty. Jail*, No.
19 CIVS060280LKKGGHP, 2008 WL 863974, at *1 (E.D. Cal. Mar. 28, 2008) (“‘Each
20 and every fact’ interrogatories pose problems for a responding party and a reviewing
21 court. Parties are not tasked with laying out every jot and tittle of their evidentiary
22 case in response to interrogatories.”); *Lucero v. Valdez*, 240 F.R.D. 591, 594 (D.N.M.
23 2007) (“Contention interrogatories should not require a party to provide the
24 equivalent of a narrative account of its case, including every evidentiary fact, details
25 of testimony of supporting witnesses, and the contents of supporting documents.”);
26 *Aldapa v. Fowler Packing Co. Inc.*, 310 F.R.D. 583, 591 (E.D. Cal. 2015).

27 The United States further objects that the Interrogatory calls for the disclosure
28 of information protected by privilege, insofar as it requests the identification of

1 evidence upon which the United States relies or intends to rely, which is protected by
2 the attorney work product doctrine. The United States further objects to this
3 Interrogatory on the ground that it is premature given that discovery is ongoing and
4 the material facts and evidence in this case are still being developed through
5 discovery. The United States further objects to this Interrogatory on the ground that
6 it is not required to identify its trial witnesses and exhibits at this stage in the
7 litigation, and will identify its evidence in accordance with the Federal Rules, and it is
8 not obligated to, and will not, identify “all evidence” in response to this Interrogatory.
9 By responding to this Interrogatory, the United States does not represent that it has
10 identified all material facts related to the topics requested, and reserves the right to
11 supplement or amend its responses and objections to this Interrogatory if it discovers
12 new, relevant, and responsive information. The United States further objects to this
13 Interrogatory on the ground that it calls for materials protected from disclosure by the
14 Order Granting Stipulation Regarding Expert Discovery entered by the Court on May
15 17, 2018, Dkt. 233. The United States further objects to this Interrogatory to the
16 extent it seeks the premature disclosure of expert opinion testimony, which is outside
17 the scope of a proper contention interrogatory.

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States responds as follows. Every Diagnosis Code included in the United States’
20 response to Interrogatory 1 was submitted to UnitedHealth as part of a claim from or
21 beneficiary encounter with a provider (“Provider Claim or Encounter”) and later
22 submitted by UnitedHealth to CMS for risk adjustment purposes. The medical
23 records associated with the Provider Claim or Encounter for every Diagnosis Code
24 included in the United States’ response to Interrogatory 1 were reviewed in
25 UnitedHealth’s process of reviewing medical records and abstracting or identifying
26 Diagnosis Codes for the purpose of submitting additional Diagnosis Codes to CMS
27 for risk adjustment payments (“Chart Review” or “Chart Review Program”). For
28 every Diagnosis Code included in the United States’ response to Interrogatory 1,

1 UnitedHealth's Chart Review did not identify that Diagnosis Code as one that was
2 supported by that medical record after review.

3 In its Chart Review Program, UnitedHealth instructed its Chart Review coders
4 to look for all medical conditions purportedly documented in the records, record all
5 Diagnosis Codes identifying those conditions, and report all of those Diagnosis Codes
6 to UnitedHealth. UnitedHealth coders were trained, qualified, and/or certified to
7 accurately identify Diagnosis Codes supported by the medical record, in accordance
8 with the Ninth or the Tenth Edition of the *International Classification of Diseases*
9 *(ICD) Clinical Modification Guidelines for Coding and Reporting* ("ICD
10 Guidelines"). UnitedHealth relied on its coders' accuracy to submit to CMS
11 Diagnosis Codes that were supported by the medical record but were not previously
12 submitted to UnitedHealth based on a Provider Claim or Encounter. UnitedHealth
13 attested to the validity of all of these additional submitted Diagnosis Codes based on
14 its Chart Review results. UnitedHealth's coders were required to meet quality
15 benchmarks of at least 95% for accuracy—defined as completeness in identifying all
16 risk adjusting Diagnosis Codes that were supported by the medical record in
17 accordance with ICD Guidelines—when reviewing and coding a medical record.

18 UnitedHealth conducted additional medical record reviews (through Quality
19 Assurance programs, Recode projects, Claims Verification, etc.) of many of the
20 medical records associated with Diagnosis Codes included in the United States'
21 response to Interrogatory 1. For example, in UnitedHealth's "Recode Project,"
22 UnitedHealth re-reviewed medical records that had already been through the Chart
23 Review Program. In the Recode Project, UnitedHealth liberalized its coding
24 standards in order to identify additional Diagnosis Codes that had not been submitted
25 by the provider, nor been found during Chart Review. None of these additional
26 medical record reviews found support in the beneficiary's medical records for any of
27 the Diagnosis Codes included in the United States' response to Interrogatory 1.

28 The United States will supplement its response to this Interrogatory as

1 appropriate.

2 **INTERROGATORY NO. 3:** For each Diagnosis Code You identified in response
3 to UHC of California's First Interrogatory, state in detail every material fact relating
4 to Your contention that UnitedHealth had Knowledge that these Diagnosis Codes
5 were "not supported by the beneficiaries' medical records," "false," or "invalid,"
6 including but not limited to the specific individuals at UnitedHealth who You contend
7 had such Knowledge. United States' Am. Compl. ¶¶ 103, 342, Dkt. 171.

8 **Objections:** The United States incorporates by reference each of its General
9 Objections and Specific Objections to the Definitions and Instructions as if stated
10 herein. The United States objects to this Interrogatory as overly broad and unduly
11 burdensome to the extent it improperly requires the United States to "state in detail
12 every material fact" of its evidentiary case. *See Tubbs v. Sacramento Cty. Jail*, No.
13 CIVS060280LKKGGHP, 2008 WL 863974, at *1 (E.D. Cal. Mar. 28, 2008) ("Each
14 and every fact' interrogatories pose problems for a responding party and a reviewing
15 court. Parties are not tasked with laying out every jot and tittle of their evidentiary
16 case in response to interrogatories."); *Lucero v. Valdez*, 240 F.R.D. 591, 594 (D.N.M.
17 2007) ("Contention interrogatories should not require a party to provide the
18 equivalent of a narrative account of its case, including every evidentiary fact, details
19 of testimony of supporting witnesses, and the contents of supporting documents.");
20 *Aldapa v. Fowler Packing Co. Inc.*, 310 F.R.D. 583, 591 (E.D. Cal. 2015).

21 The United States further objects to this Interrogatory on the ground that it is
22 premature given that discovery is ongoing and the material facts in this case are still
23 being developed through discovery. By responding to this Interrogatory, the United
24 States does not represent that it has identified every material fact related to the topics
25 requested, and reserves the right to supplement or amend its responses and objections
26 to this Interrogatory if it discovers new, relevant, and responsive information. The
27 United States further objects to this Interrogatory on the ground that it calls for
28 materials protected from disclosure by the Order Granting Stipulation Regarding

1 Expert Discovery entered by the Court on May 17, 2018, Dkt. 233. The United
2 States further objects to this Interrogatory to the extent it seeks the premature
3 disclosure of expert opinion testimony, which is outside the scope of a proper
4 contention interrogatory.

5 The United States also objects to this Interrogatory on the ground that it is
6 really two separate interrogatories—one seeking material facts underlying a
7 contention and another seeking the identity of knowledgeable witnesses. *See Safeco*
8 *of Am. v. Rawstron*, 181 F.R.D. 441, 445 (C.D. Cal. 1998); *see also Ott v. Mortg.*
9 *Inv'rs Corp. of Ohio*, No. 3:14-CV-00645-ST, 2015 WL 691643, at *1 (D. Or. Feb.
10 17, 2015) (“[O]nce a subpart of an interrogatory introduces a line of inquiry that is
11 separate and distinct from the inquiry made by the portion of the interrogatory that
12 precedes it, the subpart must be considered a separate interrogatory no matter how it
13 is designated.”). The Interrogatory requests that the United States: (1) identify “every
14 material fact relating to [the United States’] contention that UnitedHealth had
15 Knowledge that these Diagnosis Codes were ‘not supported by the beneficiaries’
16 medical records,’ ‘false,’ or ‘invalid,’” and (2) identify “the specific individuals at
17 UnitedHealth who [the United States] contend[s] had such Knowledge.”
18 UnitedHealth has therefore issued at least four interrogatories out of the 25
19 interrogatories permitted under the Federal Rules. By responding to this
20 Interrogatory, the United States in no way waives its right to object if UnitedHealth
21 exceeds the maximum number of permitted interrogatories.

22 The United States objects to this Interrogatory as premature, in that it requires
23 the United States to identify individuals who had Knowledge of relevant facts prior to
24 the completion of fact discovery, and in particular prior to the depositions of
25 UnitedHealth and individual witnesses under Federal Rule of Civil Procedure 30.
26 The United States will supplement its response to this Interrogatory as appropriate.
27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States hereby incorporates its response to Interrogatory 2 into this response and

1 further states that UnitedHealth had Knowledge, as defined by 31 U.S.C. §
2 3729(b)(1)(A), of all of the facts set forth in the United States' response to
3 Interrogatory 2. In addition, UnitedHealth designed, implemented, and maintained
4 the database systems that contained all of the information necessary to determine that
5 Diagnosis Codes it had previously submitted to CMS were not found by
6 UnitedHealth's coders to have support in the beneficiaries' medical records, and
7 UnitedHealth deliberately ignored or recklessly disregarded the information in its
8 own databases. UnitedHealth received and maintained data from Provider Claims
9 and Encounters and also maintained the data containing the results of its Chart
10 Review Program. UnitedHealth had the ability to compare the results of every Chart
11 Review to the diagnosis data UnitedHealth had received from Provider Claims and
12 Encounters and then submitted to CMS for risk adjustment. UnitedHealth was able
13 to, and frequently did, analyze its Chart Review data to assess whether an HCC was
14 unique as to a specific beneficiary in a specific DOS year. UnitedHealth had
15 Knowledge that it must act in good faith and exercise due diligence in its submission
16 of Diagnosis Codes to CMS, and that it must, and did, expressly certify that the
17 Diagnosis Codes it submits for risk adjustment payments are accurate and truthful to
18 the best of its Knowledge. UnitedHealth did not review the results of its Chart
19 Review program in good faith or exercise due diligence in order to obtain and submit
20 true and accurate risk adjustment data to CMS. Instead, UnitedHealth systematically
21 and deliberately ignored the results of Chart Reviews that showed that Diagnosis
22 Codes received by UnitedHealth from Provider Claims and Encounters and then
23 submitted to CMS were not supported by the beneficiaries' medical records.
24 UnitedHealth knowingly and improperly avoided comparing the Diagnosis Codes
25 from Provider Claims and Encounters submitted by UnitedHealth to CMS for risk
26 adjustment with the results of Chart Review. UnitedHealth acted with reckless
27 disregard or deliberate ignorance of the truth or falsity of whether the Diagnosis
28 Codes it had submitted to CMS for risk adjustment were supported by the

1 beneficiaries' medical records.

2 UnitedHealth designed the Chart Review program at issue, and had Knowledge
3 of all relevant facts about the Chart Review program, including that UnitedHealth
4 instructed its Chart Review coders to look for all medical conditions purportedly
5 documented in the medical records, record all Diagnosis Codes identifying those
6 conditions, and report all of those Diagnosis Codes to UnitedHealth. UnitedHealth
7 therefore had Knowledge that every Diagnosis Codes included in the United States'
8 response to Interrogatory 1 was not found to be supported by any review of the
9 medical records. Nor has UnitedHealth contended that any of the Diagnosis Codes
10 included in the United States' response to Interrogatory 1 was in fact supported by a
11 medical record. UnitedHealth had Knowledge that its Claims Verification program
12 and other internal audit programs demonstrated that many Diagnosis Codes
13 UnitedHealth received from Provider Claims and Encounters and submitted to CMS
14 for risk adjustment were not found to have support in a medical record. Furthermore,
15 UnitedHealth had Knowledge that CMS's Risk Adjustment Data Validation audits of
16 select UnitedHealth Medicare Advantage Plans as well as HHS-OIG's Risk
17 Adjustment Data Validation audits of Pacificare of Texas and Pacificare of California
18 demonstrated that many Diagnosis Codes UnitedHealth received from Provider
19 Claims and Encounters and submitted to CMS for risk adjustment were not supported
20 by a medical record. From its own Internal Data Validation ("IDV") Program and
21 Risk Adjustment Coding Compliance Review ("RACCR"), UnitedHealth also had
22 Knowledge of inaccuracies in the Diagnosis Codes it received from Provider Claims
23 and Encounters, which UnitedHealth in turn submitted to CMS for risk adjustment.
24 UnitedHealth recklessly disregarded and deliberately ignored that IDV and RACCR
25 showed that significant percentages of the Diagnosis Codes reported to UnitedHealth
26 from Provider Claims and Encounters were not supported by the beneficiaries'
27 medical records.

28 Answering now the second and distinct part of this Interrogatory, the United

1 States states that the following UnitedHealth individuals have such Knowledge in that
2 they acted with actual knowledge, deliberate ignorance, or reckless disregard of the
3 truth or falsity of whether the Diagnosis Codes included in the United States'
4 response to Interrogatory 1 were supported by the beneficiaries' medical records:

- 5 • Anita Westrup
- 6 • Benjamin Poehling
- 7 • Bill Miller
- 8 • Brian Lund
- 9 • Brian Thompson
- 10 • Carol Thompson
- 11 • Charlie Tran
- 12 • Chris Webb
- 13 • Christen Connell
- 14 • Cynthia Polich
- 15 • Dan Schumacher
- 16 • Don James
- 17 • Gail Boudreaux
- 18 • Jack Larsen
- 19 • Janice Redmond
- 20 • Jason Bainbridge
- 21 • Jay Matushak
- 22 • Jeff Dumcum
- 23 • Jim Colhour
- 24 • Jim Higgins
- 25 • John Martinez
- 26 • Jon Bird
- 27 • Karen Erickson
- 28 • Karen Petroff

- 1 • Karin O'Hara
- 2 • Kathleen Baker
- 3 • Keith Dobbins
- 4 • Kevin Sommerfield
- 5 • Kim Halva
- 6 • Kyle Anderson
- 7 • Larry Renfro
- 8 • Lee Valenta
- 9 • Marc Beckmann
- 10 • Marianne Short
- 11 • Mary Hammond
- 12 • MaryBeth Meyer
- 13 • Matt Shors
- 14 • Melissa Sedor
- 15 • Mike Jacobson
- 16 • Natasha Walker
- 17 • Nick Chiechi
- 18 • Patty Brennan
- 19 • Paul Balthazor
- 20 • Paul Bihm
- 21 • Randy Meyers
- 22 • Rebecca Martin
- 23 • Ronnie Grower
- 24 • Ryan Maddox
- 25 • Sanjeev Balsara
- 26 • Scott Hughes
- 27 • Scott Theisen
- 28 • Stephanie Gardner (Will)

- 1 • Steve Hemsley
- 2 • Steve Nelson
- 3 • Thad Johnson
- 4 • Thomas MacDougal
- 5 • Thomas Paul
- 6 • Tim Noel
- 7 • Tim Spaeth
- 8 • Vinh Troung-son
- 9 • William Hnath

10 The United States will supplement its response to this Interrogatory as appropriate.

11 **INTERROGATORY NO. 4:** State in detail every material fact Concerning Your
12 contention that UnitedHealth had Knowledge of “overpayments based on invalid
13 diagnoses,” United States’ Am. Compl. ¶ 342, Dkt. 171, including but not limited to
14 the specific individuals at UnitedHealth who You contend had such Knowledge.

15 **Objections:** The United States incorporates by reference each of its General
16 Objections and Specific Objections to the Definitions and Instructions as if stated
17 herein. The United States objects to this Interrogatory as overly broad and unduly
18 burdensome to the extent it improperly requires the United States to “state in detail
19 every material fact” of its evidentiary case. *See Tubbs v. Sacramento Cty. Jail*, No.
20 CIVS060280LKKGGHP, 2008 WL 863974, at *1 (E.D. Cal. Mar. 28, 2008) (“‘Each
21 and every fact’ interrogatories pose problems for a responding party and a reviewing
22 court. Parties are not tasked with laying out every jot and tittle of their evidentiary
23 case in response to interrogatories.”); *Lucero v. Valdez*, 240 F.R.D. 591, 594 (D.N.M.
24 2007) (“Contention interrogatories should not require a party to provide the
25 equivalent of a narrative account of its case, including every evidentiary fact, details
26 of testimony of supporting witnesses, and the contents of supporting documents.”);
27 *Aldapa v. Fowler Packing Co. Inc.*, 310 F.R.D. 583, 591 (E.D. Cal. 2015).

28 The United States further objects to this Interrogatory on the ground that it is

1 premature given that discovery is ongoing and the material facts in this case are still
2 being developed through discovery. By responding to this Interrogatory, the United
3 States does not represent that it has identified every material fact related to the topics
4 requested, and reserves the right to supplement or amend its responses and objections
5 to this Interrogatory if it discovers new, relevant, and responsive information. The
6 United States further objects to this Interrogatory on the ground that it calls for
7 materials protected from disclosure by the Order Granting Stipulation Regarding
8 Expert Discovery entered by the Court on May 17, 2018, Dkt. 233. The United
9 States further objects to this Interrogatory to the extent it seeks the premature
10 disclosure of expert opinion testimony, which is outside the scope of a proper
11 contention interrogatory.

12 The United States also objects to this Interrogatory on the ground that it is
13 really two separate interrogatories—one seeking material facts underlying a
14 contention and another seeking the identity of knowledgeable witnesses. *See Safeco*
15 *of Am. v. Rawstron*, 181 F.R.D. 441, 445 (C.D. Cal. 1998); *see also Ott v. Mortg.*
16 *Inv'rs Corp. of Ohio*, No. 3:14-CV-00645-ST, 2015 WL 691643, at *1 (D. Or. Feb.
17 17, 2015) (“[O]nce a subpart of an interrogatory introduces a line of inquiry that is
18 separate and distinct from the inquiry made by the portion of the interrogatory that
19 precedes it, the subpart must be considered a separate interrogatory no matter how it
20 is designated.”); *McCarthy v. Paine Webber Grp., Inc.*, 168 F.R.D. 448, 450 (D.
21 Conn. 1996) (observing that contention interrogatories “are distinct from
22 interrogatories that request identification of witnesses or documents that bear on the
23 allegations” (citing *In re Convergent Technologies Securities Litig.*, 108 F.R.D. 328,
24 332-33 (N.D. Cal. 1985)). The Interrogatory requests that the United States: (1)
25 identify “every material fact Concerning [the United States’] contention that
26 UnitedHealth had Knowledge of ‘overpayments based on invalid diagnoses,’” and (2)
27 identify “the specific individuals at UnitedHealth who [the United States] contend[s]
28 had such Knowledge.” UnitedHealth has therefore issued at least six interrogatories

1 out of the 25 interrogatories permitted under the Federal Rules. By responding to this
2 Interrogatory, the United States in no way waives its right to object if UnitedHealth
3 exceeds the maximum number of permitted interrogatories.

4 The United States objects to this Interrogatory as premature, in that it requires
5 the United States to identify individuals who had Knowledge of relevant facts prior to
6 the completion of fact discovery, and in particular prior to the depositions of
7 UnitedHealth and individual witnesses under Fed. R. Civ. P. 30. The United States
8 will supplement its response to this Interrogatory as appropriate.

9 **Response:** Subject to and without waiving the foregoing objections, the United
10 States hereby incorporates its responses to Interrogatories 2 and 3 into this response
11 and further states that UnitedHealth had Knowledge, as defined by 31 U.S.C. §
12 3729(b)(1)(A), of all of the facts set forth in the United States' response to
13 Interrogatories 2 and 3. Furthermore, UnitedHealth had Knowledge that the
14 Diagnosis Codes it submitted to CMS for each beneficiary determined the risk
15 adjustment payment CMS made to UnitedHealth for that beneficiary. UnitedHealth
16 had Knowledge that the risk-adjusting Diagnosis Codes that it submitted for each
17 beneficiary increased the risk adjustment payment CMS made to UnitedHealth for
18 that beneficiary, and that the risk-adjusting Diagnosis Codes that UnitedHealth
19 submitted as deletes or otherwise removed or corrected would cause CMS to reduce
20 the risk adjustment payment it made to UnitedHealth for that beneficiary.
21 UnitedHealth further had Knowledge that CMS's risk adjustment program requires
22 data accuracy and that it is permitted to only submit Diagnosis Codes that are
23 supported by the beneficiaries' medical records, as evidenced by the design and
24 implementation of its Chart Review Program, which reviewed records for additional
25 supported Diagnosis Codes. UnitedHealth had Knowledge that it was not entitled to
26 receive or retain risk adjustment payments based on Diagnosis Codes that are not
27 supported by a beneficiary's medical record. UnitedHealth had Knowledge that it
28 must act in good faith and exercise due diligence in its submission of Diagnosis

1 Codes to CMS, and that it must, and did, expressly certify that the Diagnosis Codes it
2 submits for risk adjustment payments are accurate and truthful to the best of its
3 Knowledge. UnitedHealth had Knowledge that it was required to implement a
4 compliance program, which must include measures that prevent, detect, and correct
5 non-compliance with CMS's program requirements as well as measures that prevent,
6 detect, and correct fraud, waste, and abuse. UnitedHealth had Knowledge that it was
7 required to delete Diagnosis Codes that were not supported by the medical record.

8 The following UnitedHealth individuals have such Knowledge in that they
9 acted with actual knowledge, deliberate ignorance, or reckless disregard of the truth
10 or falsity of whether the UnitedHealth had improperly received or retained
11 overpayments based on the Diagnosis Codes included in the United States' response
12 to Interrogatory 1:

- 13 • Anita Westrup
- 14 • Benjamin Poehling
- 15 • Bill Miller
- 16 • Brian Lund
- 17 • Brian Thompson
- 18 • Carol Thompson
- 19 • Charlie Tran
- 20 • Chris Webb
- 21 • Christen Connell
- 22 • Cynthia Polich
- 23 • Dan Schumacher
- 24 • Don James
- 25 • Gail Boudreaux
- 26 • Jack Larsen
- 27 • Janice Redmond
- 28 • Jason Bainbridge

- 1 • Jay Matushak
- 2 • Jeff Dumcum
- 3 • Jim Colhour
- 4 • Jim Higgins
- 5 • John Martinez
- 6 • Jon Bird
- 7 • Karen Erickson
- 8 • Karen Petroff
- 9 • Karin O'Hara
- 10 • Kathleen Baker
- 11 • Keith Dobbins
- 12 • Kevin Sommerfield
- 13 • Kim Halva
- 14 • Kyle Anderson
- 15 • Larry Renfro
- 16 • Lee Valenta
- 17 • Marc Beckmann
- 18 • Marianne Short
- 19 • Mary Hammond
- 20 • MaryBeth Meyer
- 21 • Matt Shors
- 22 • Melissa Sedor
- 23 • Mike Jacobson
- 24 • Natasha Walker
- 25 • Nick Chiechi
- 26 • Patty Brennan
- 27 • Paul Balthazor
- 28 • Paul Bihm

- 1 • Randy Meyers
- 2 • Rebecca Martin
- 3 • Ronnie Grower
- 4 • Ryan Maddox
- 5 • Sanjeev Balsara
- 6 • Scott Hughes
- 7 • Scott Theisen
- 8 • Stephanie Gardner (Will)
- 9 • Steve Hemsley
- 10 • Steve Nelson
- 11 • Thad Johnson
- 12 • Thomas MacDougal
- 13 • Thomas Paul
- 14 • Tim Noel
- 15 • Tim Spaeth
- 16 • Vinh Troung-son
- 17 • William Hnath

18 The United States will supplement its response to this Interrogatory as appropriate.

19 **INTERROGATORY NO. 5:** Separately for each of the years 2008 to 2017,
20 Identify all CMS Individuals and HHS-OIG Individuals who Believed or expressed in
21 writing that CMS would not have paid or continued entering into MA contracts with
22 UnitedHealth if CMS had known that UnitedHealth was not “compar[ing] all chart
23 reviews to the provider reported diagnoses and delet[ing] all of the invalid provider-
24 reported diagnoses that they previously had submitted to the Medicare Program.”
25 United States’ Am. Compl. ¶ 185, Dkt. 171.

26 **Objections:** The United States incorporates by reference each of its General
27 Objections and Specific Objections to the Definitions and Instructions as if stated
28 herein. The United States further objects that this Interrogatory is overly broad,

1 unduly burdensome, vague, confusing, and ambiguous. This Interrogatory is overly
2 broad and unduly burdensome because on its face it seeks to require the United States
3 to investigate the communications and beliefs of all of the thousands of current and
4 former CMS employees, current and former HHS-OIG employees, as well as current
5 and former CMS and HHS-OIG contractors, for a period of nearly a decade. This is
6 plainly unreasonable. The United States objects that the Interrogatory is
7 disproportionate to the needs of this case because the potential relevance is
8 outweighed by the enormous burden sought by the Interrogatory. Further, the United
9 States objects that this Interrogatory is irrelevant because Government agencies,
10 including CMS and HHS-OIG, act through official policy and regulations and not the
11 beliefs or impressions of individual government agency employees. For the purposes
12 of responding to this Interrogatory, the United States has undertaken a reasonable
13 inquiry to identify information responsive to this Interrogatory, but objects to the
14 Interrogatory insofar as it purports to require the United States to identify “every”
15 CMS and HHS-OIG Individual who held a Belief and reiterates its statement that
16 CMS and HHS-OIG only act through official policy and regulations, not through the
17 private Beliefs of its employees. The United States’ Response to this Interrogatory
18 should not be interpreted or construed to represent or otherwise reflect the official
19 position of CMS or HHS-OIG.

20 The United States objects to the inclusion of current and former HHS-OIG
21 employees and contractors as irrelevant because, as the language of the Interrogatory
22 itself recognizes, it is CMS that makes MA payment and contract decisions, and
23 HHS-OIG does not make Risk Adjustment payment or contracting decisions. The
24 subjective beliefs and written expressions of HHS-OIG employees and/or contractors
25 about whether “CMS” would have paid or whether “CMS” would have entered into
26 contracts with UnitedHealth is not relevant to any claim or defense in this case.
27 Therefore, for purposes of responding to this Interrogatory, the United States will not
28 include “HHS-OIG Individuals.”

1 The United States further objects to the Interrogatory in that it asks the United
2 States to search every piece of writing by a given individual, to determine whether
3 they ever “expressed in writing” the topic sought by the Interrogatory. Such an
4 endeavor is overly broad, unduly burdensome, and not proportional to the needs of
5 the case. Moreover, the United States reiterates that any such writings, if they exist,
6 do not reflect the official position of CMS or HHS-OIG. The United States therefore
7 interprets “expressed in writing” to mean official and public pronouncements on
8 behalf of CMS.

9 The United States objects to this Interrogatory to the extent that it seeks
10 information from after May 16, 2017, the parties’ agreed-upon discovery cut-off. For
11 the purposes of responding to this Interrogatory, the United States interprets this
12 Interrogatory as seeking information only up to May 16, 2017. The United States
13 also objects to this Interrogatory as vague, confusing, and ambiguous because it
14 requires CMS individuals to recall whether they held beliefs or made written
15 statements speculating about what “CMS” would or would not have done in the
16 specified years based on information that the agency did not possess in those years.

17 The United States further objects on the ground that the Interrogatory is vague,
18 confusing, and unduly burdensome because it seeks a separate answer for each year
19 for what an individual “Believed” at the time and to the extent the Interrogatory
20 requires the United States to determine, year by year from 2008–2017, when a given
21 Belief began or ended. For the purpose of responding to this Interrogatory, the
22 United States will interpret “Believed” to mean that the personal belief was held at
23 some point during the relevant time period.

24 The United States further objects that this Interrogatory is vague, confusing,
25 and ambiguous because the phrase “that CMS would not have paid” is undefined and
26 unclear. Because the Interrogatory places no limitation on the phrase “would not
27 have paid,” the United States interprets that phrase to mean that CMS would not have
28 made any payments to UnitedHealth for any plans and any beneficiaries, regardless

1 of whether the beneficiaries were the subject of Chart Reviews and regardless of
2 whether the diagnoses submitted by UnitedHealth were supported or unsupported.
3 The United States further objects that this Interrogatory is vague, confusing, and
4 ambiguous because the phrase “would not have . . . continued entering into MA
5 contracts with UnitedHealth” is undefined and unclear. Because the Interrogatory
6 places no limitation on the phrase “would not have . . . continued entering into MA
7 contracts,” the United States interprets that phrase to mean that CMS would have
8 terminated all existing contracts and ceased entering into any new MA contracts with
9 UnitedHealth.

10 The United States objects that this Interrogatory is vague, confusing, and
11 ambiguous because it cites one sentence from one paragraph of the United States’
12 Amended Complaint and incorrectly contorts it into a distorted version of the United
13 States’ theory of UnitedHealth’s liability under the False Claims Act. The United
14 States alleges that UnitedHealth failed to delete invalid diagnosis codes that it had
15 Knowledge (as defined by the False Claims Act) were not supported by medical
16 records, and therefore knowingly avoided its obligation to pay CMS. This
17 Interrogatory is vague, ambiguous, confusing, and irrelevant because it focuses on the
18 design of UnitedHealth’s Chart Reviews rather than on UnitedHealth’s failure to
19 delete known invalid diagnosis codes. *See* MTD Order, Dkt. 212 at 21 (“As the
20 Government argues, the issue here is not the one-way Chart Review generally, but the
21 specific invalid diagnosis codes that Defendants submitted and failed to delete despite
22 information available to them.”). The United States objects to this Interrogatory as
23 inaccurate, improper, and misleading to the extent that it implies or suggests that the
24 United States’ Amended Complaint alleges that particular CMS Individuals held the
25 belief that CMS should terminate payments to or cease continuing to enter into MA
26 contracts with UnitedHealth when the cited portion of the complaint merely alleges in
27 part that “Defendants should and could have compared the results of *all* Chart
28 Reviews to the provider-reported diagnoses and deleted all of the invalid provider-

1 reported diagnoses that they previously had submitted to the Medicare Program.”
2 Am. Compl. ¶ 185, Dkt. 171.

3 The United States objects to this Interrogatory to the extent that it implies a
4 legal conclusion. Specifically, the United States objects to this Interrogatory as being
5 irrelevant and contrary to law insofar as it implies or suggests that termination of
6 payment or discontinuance of contracts is a requirement of materiality under the False
7 Claims Act. It is not. See MTD Order, Dkt. 212, at 20–21 (“[t]he Government has
8 adequately pled facts showing that the Defendants have knowingly avoided
9 obligations to repay CMS by failing to delete invalid diagnosis codes, and that such
10 failure was material”); see also *United States ex rel. Campie v. Gilead Sciences, Inc.*,
11 862 F.3d 890, 906 (9th Cir. 2017). This Interrogatory is vague, confusing, and
12 ambiguous because it mischaracterizes the United States’ position regarding
13 materiality under the False Claims Act, which is set forth in its Opposition to the
14 Motion to Dismiss, Dkt 194.

15 The United States further objects to this Interrogatory to the extent that it seeks
16 information protected from disclosure by an applicable privilege or protection.

17 **Response:** Subject to and without waiving the foregoing objections, the United
18 States responds that based on the information available, separately for each year in
19 the period 2008 through 2017, it has not identified any CMS individuals who
20 believed or expressed in writing that CMS would have stopped all payments to
21 UnitedHealth for all beneficiaries (whether or not their charts were reviewed) and all
22 diagnoses (whether those diagnoses were supported and unsupported) or would have
23 terminated all contracts with UnitedHealth and ceased entering into new contracts
24 with UnitedHealth if CMS had known that UnitedHealth was not “compar[ing] all
25 chart reviews to the provider reported diagnoses and delet[ing] all of the invalid
26 provider-reported diagnoses that they previously had submitted to the Medicare
27 Program.” The United States further responds that UnitedHealth led CMS to believe
28 that UnitedHealth was not deliberately ignoring the negative results of its Chart

1 Review Program that showed UnitedHealth that diagnoses it had submitted to CMS
2 for payment were invalid. CMS had no actual knowledge of the specific invalid
3 diagnosis codes submitted by UnitedHealth until the United States pursued its
4 investigation of the matter underlying this litigation. In this case, CMS is pursuing
5 the overpayments associated with the invalid diagnoses uncovered in the United
6 States' investigation. The United States will supplement its response to this
7 Interrogatory as appropriate.

8 **INTERROGATORY NO. 6:** For each CMS Individual or HHS-OIG Individual
9 who participated in or was involved in—including but not limited to drafting,
10 analyzing, revising, commenting on, or reviewing—the Study Underlying CMS's
11 Proposed Rule, provide a description, including the Time Period, of his or her
12 participation or involvement. This Interrogatory should be construed to cover the time
13 period January 1, 2004 to June 30, 2019.

14 **Objections:** The United States incorporates by reference each of its General
15 Objections and Specific Objections to the Definitions and Instructions as if stated
16 herein. The United States objects to the time period of this Interrogatory to the extent
17 it goes beyond the publication date (November 1, 2018) of the Study Underlying
18 CMS's Proposed Rule as overbroad, unduly burdensome, and irrelevant. Identifying
19 individuals who reviewed the Study Underlying CMS's Proposed Rule after it was
20 published has no bearing on the pre-publication development of the Study. Consistent
21 with its Objections to Definitions 3, 10, and 11, the United States interprets this
22 Interrogatory to exclude attorneys and is not searching for, collecting, or providing
23 information or materials from any attorney within OGC, OCIG, or DOJ.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States responds as follows:

- 26 • The following individuals reviewed the Study: Jennifer Lazio (October 2017–
27 November 1, 2018); Jennifer Harlow (July 2018–November 1, 2018); Joanne
28 Davis (January 2018–October 2018); Carolyn Kapustij (May 2018–October

2018).

- The following individuals reviewed and commented on the Study: Delois J. Newkirk (2017–November 1, 2018); Blake Pelzer (September 2018–November 1, 2018); Paul Spitalnic (October 2017–November 1, 2018); Richard Coyle (September 2018); Abby Woodroffe (March 2018); Jesse Levy (March 2018).
- The following individuals conducted analysis for the Study: Michelle Hill (2017—November 1, 2018); Richard Griffith (June 2018 to August 2018).
- The following individuals drafted, analyzed, revised, commented on, and reviewed the Study: Jonathan Smith (January 2017–November 1, 2018), Hans Dutt (January 2017–November 1, 2018).

The United States will supplement its response to this Interrogatory as appropriate.

INTERROGATORY NO. 7: Separately for each of the years 2008 to 2017, Identify all CMS Individuals and HHS-OIG Individuals who Believed or expressed in writing that the existence of unsupported codes in CMS’s FFS Medicare data has the capacity to impact Risk Adjustment payments to MA Plans.

Objections: The United States incorporates by reference each of its General Objections and Specific Objections to the Definitions and Instructions as if stated herein. The United States objects to this Interrogatory as overly broad, unduly burdensome, vague, confusing, and ambiguous. This Interrogatory is overly broad and unduly burdensome because on its face it seeks to require the United States to investigate the communications and beliefs of all of the thousands of current and former CMS employees, current and former HHS-OIG employees, as well as current and former CMS and HHS-OIG contractors for a period of nearly a decade. This is plainly unreasonable. The United States objects that the Interrogatory is disproportionate to the needs of this case because the potential relevance is outweighed by the enormous burden sought by the Interrogatory. Further, the United States objects that this Interrogatory is irrelevant because Government agencies, including CMS and HHS-OIG, act through official policy and regulations and not the

1 beliefs or impressions of individual government agency employees. For the purposes
2 of responding to this Interrogatory, the United States has undertaken a reasonable
3 inquiry to identify information responsive to this Interrogatory, but objects to the
4 Interrogatory insofar as it purports to require the United States to identify “every”
5 CMS and HHS-OIG individual who held a Belief and reiterates its statement that
6 CMS and HHS-OIG only act through official policy and regulations, not through the
7 private Beliefs of its employees. The inclusion of any individuals in response to this
8 Interrogatory should not be interpreted or construed to mean that these individuals
9 represent or otherwise reflect the official position of CMS or HHS-OIG.

10 The United States further objects to the Interrogatory in that it asks the United
11 States to search every piece of writing by a given individual, to determine whether
12 they ever “expressed in writing” the topic sought by the Interrogatory. Such an
13 endeavor is overly broad, unduly burdensome, and not proportional to the needs of
14 the case. Moreover, the United States reiterates that any such writings, if they exist,
15 do not reflect the official position of CMS or HHS-OIG. The United States therefore
16 interprets “expressed in writing” to mean official and public pronouncements on
17 behalf of CMS. The United States objects to this Interrogatory as irrelevant and
18 overly broad to the extent it seeks information about the beliefs and written
19 expressions of HHS-OIG employees and/or contractors because HHS-OIG does not
20 make Risk Adjustment payment decisions for CMS. Therefore, for purposes of
21 responding to this Interrogatory, the United States will not include “HHS-OIG
22 Individuals.”

23 The United States objects to this Interrogatory to the extent that it seeks
24 information from after May 16, 2017, the parties’ agreed-upon discovery cut-off. For
25 the purposes of responding to this Interrogatory, the United States interprets this
26 Interrogatory as seeking information only up to May 16, 2017.

27 The United States further objects on the ground that the Interrogatory is vague,
28 confusing, and unduly burdensome because it seeks a separate answer for each year

1 for what an individual “Believed” at the time and to the extent the Interrogatory
2 requires the United States to determine, year by year from 2008–2017, when a given
3 Belief began or ended. For the purpose of responding to this Interrogatory, the
4 United States will interpret “Believed” to mean that the belief was held at some point
5 during the relevant time period.

6 The United States further objects that the Interrogatory is vague and ambiguous
7 because the terms “codes,” “unsupported,” “existence,” “has the capacity to,” and
8 “impact” are not defined terms. The United States interprets “codes” to mean any
9 data element relevant to a claim when the claim is submitted to CMS for payment.
10 This includes but is not limited ICD-9 and ICD-10 Diagnosis Codes. The United
11 States interprets “unsupported” to mean, in the context of Diagnosis Codes, that
12 Diagnosis Codes were not supported by the medical record. The United States
13 interprets “existence” to mean that something was included in the coding in CMS’s
14 FFS Medicare claims data at the time the FFS data was incorporated into the CMS
15 HCC Risk Adjustment Model. The United States interprets “has the capacity to” to
16 mean that something could potentially, theoretically, or in principle, affect Risk
17 Adjustment payments, regardless of whether it did, in fact, affect Risk Adjustment
18 payments. The United States interprets the term “impact” to include any potential
19 effect whatsoever on Risk Adjustment payments, regardless of whether the effect was
20 significant or insignificant, and regardless of whether the effect resulted in a higher
21 payment or a lower payment to MA Plans.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States identifies the following individuals who Believed or expressed in writing that
24 any inaccuracies, including but not limited to Diagnosis Codes supported by a
25 medical record that were not submitted to CMS or Diagnosis Codes that were
26 submitted to CMS but were not supported by a medical record, in Medicare Fee-For-
27 Service data that existed within that data when it was used to calibrate the Risk
28 Adjustment model, could potentially, theoretically, or in principle, have some effect

1 on the risk adjustment payments made to MA plans, whether the effect occurred in
2 fact or not, whether the Diagnosis Codes were risk adjusting or not, whether the risk
3 adjusting Diagnosis Code was unique or not (with “unique” meaning that the
4 Diagnosis Code was the only risk adjusting Diagnosis Code mapping to a given HCC
5 within the relevant Part C HCC Risk Adjustment Model for a given beneficiary in a
6 given date of service year), whether the effect on risk adjustment payments was
7 significant or not, whether the effect resulted in increased or decreased payments to
8 MA plans. Individuals who Believed or expressed this in writing include the
9 following:

- 10 • Jonathan Smith
- 11 • Cheri Rice
- 12 • Monica Reed Asante
- 13 • Rebecca Paul
- 14 • Ashley Franzel
- 15 • Jennifer Lazio
- 16 • Paul Spitalnic
- 17 • Blake Pelzer
- 18 • Carolyn Kapustij
- 19 • Jennifer Lazio
- 20 • Richard Coyle
- 21 • Jennifer Harlow
- 22 • Hans Dutt

23 The United States will supplement its response to this Interrogatory as appropriate.

24 **INTERROGATORY NO. 8:** Separately for each of the years 2008 to 2017, Identify
25 all CMS Individuals and HHS-OIG Individuals who drafted, revised, analyzed, or
26 commented on language included in CMS’s Announcements regarding Medicare
27 Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies
28 indicating that MA organizations are coding “accurately” when they are coding in a

1 manner similar to or reflecting the coding used on the beneficiaries in FFS Medicare
2 to whom MA Plan enrollees are being compared. See, e.g., CMS's April 7, 2008,
3 April 6, 2009, and April 1, 2013 Announcements for Calendar Years (CYs) 2009,
4 2010, and 2014 Medicare Advantage Capitation Rates and Medicare Advantage and
5 Part D Payment Policies at 20, 20–21, and 30, respectively.

6 **Objections:** The United States incorporates by reference each of its General
7 Objections and Specific Objections to the Definitions and Instructions as if stated
8 herein. The United States objects to this Interrogatory as irrelevant to the extent that
9 the language referenced from CMS's Annual Announcements is not relevant to a
10 claim or defense in this case. The United States objects to this Interrogatory as
11 vague, confusing, and ambiguous because it mischaracterizes CMS's responses to
12 comments in the Annual Announcements. The United States further objects to this
13 Interrogatory as confusing, vague, and ambiguous to the extent that the Interrogatory
14 does not specifically state the language subject to the inquiry for each year. Further,
15 the United States objects that the Interrogatory's demand to provide information
16 separately for each of the years 2008–2017 is disproportionate to the needs of this
17 case because the potential relevance is outweighed by the enormous burden placed on
18 the United States by this request. Therefore, the United States will not provide the
19 requested information separately for each year.

20 The United States objects to this Interrogatory to the extent that it seeks
21 information from after May 16, 2017, the parties' agreed-upon discovery cut-off. For
22 the purposes of responding to this Interrogatory, the United States interprets this
23 Interrogatory as seeking information only up to May 16, 2017.

24 The United States further objects to this Interrogatory to the extent that it seeks
25 information protected from disclosure by an applicable privilege or protection.
26 Consistent with its Objections to Definitions 3, 10, and 11, the United States
27 interprets this Interrogatory to exclude attorneys and is not searching for, collecting,
28 or providing information or materials from any attorney within OGC, OCIG, or DOJ.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States responds that after a reasonable inquiry, it has identified the following
3 individuals as responsive to the Interrogatory:

- 4 • Anne Calinger
- 5 • Ilina Chaudhuri
- 6 • Julie Gover
- 7 • Jennifer Harlow
- 8 • Anne Hornsby
- 9 • Joanne Kong
- 10 • Thomas Kornfield
- 11 • Rebecca Paul
- 12 • Monica Reed-Asante
- 13 • Cheri Rice
- 14 • Kay Schneider
- 15 • Julie Uebersax

16 The United States will supplement its response to this Interrogatory as appropriate.

17 **INTERROGATORY NO. 9:** Identify all CMS Individuals and HHS-OIG
18 Individuals who participated in or were involved—including but not limited to
19 drafting, developing, analyzing, revising, commenting on, reviewing, or issuing—
20 CMS's Proposed Medical Record Review Rule and the decision not to finalize the
21 Proposed Medical Record Review Rule articulated in the May 23, 2014 Final Rule.

22 **Objections:** The United States incorporates by reference each of its General
23 Objections and Specific Objections to Definitions set forth above. The United States
24 further objects that this Interrogatory is overly broad, unduly burdensome, vague,
25 confusing and ambiguous.

26 The United States also objects to this Interrogatory to the extent that it contains
27 multiple discrete subparts that count as separate Interrogatories. *See Safeco of Am. v.*
28 *Rawstron*, 181 F.R.D. 441, 445 (C.D. Cal. 1998); *see also Ott v. Mortg. Inv'rs Corp.*

1 of *Ohio*, No. 3:14-CV-00645-ST, 2015 WL 691643, at *1 (D. Or. Feb. 17, 2015)
2 (“[O]nce a subpart of an interrogatory introduces a line of inquiry that is separate and
3 distinct from the inquiry made by the portion of the interrogatory that precedes it, the
4 subpart must be considered a separate interrogatory no matter how it is designated.”).
5 The Interrogatory requests that the United States: (1) identify “all CMS Individuals
6 and HHS-OIG Individuals who participated in or were involved—including but not
7 limited to drafting, developing, analyzing, revising, commenting on, reviewing, or
8 issuing—CMS’s Proposed Medical Record Review Rule” and (2) identify all CMS
9 Individuals and HHS-OIG involved in “the decision not to finalize the Proposed
10 Medical Record Review Rule articulated in the May 23, 2014 Final Rule.”
11 UnitedHealth has therefore issued at least 12 interrogatories out of the 25
12 interrogatories permitted under the Federal Rules. By responding to this
13 Interrogatory, the United States in no way waives its right to object if UnitedHealth
14 exceeds the maximum number of permitted interrogatories.

15 The United States objects that this Interrogatory is vague and ambiguous
16 because the terms “participated in,” “involved,” “reviewing,” and “issuing” are not
17 defined terms. The United States will interpret each of these terms to have their
18 ordinary meaning. The United States interprets “participated in” and “involved” to
19 mean actively take part in something. The United States interprets “reviewing” to
20 mean examine something formally with the possibility or intention of instituting
21 change, if necessary. The United States interprets “issuing” to mean publishing in the
22 Federal Register official and public pronouncements on behalf of CMS. Based on
23 these objections, the United States will not identify any individuals who only
24 received the language of the proposed rule or individuals who were only involved in
25 the CMS clearance process of the entire rule to the extent those individuals are not
26 otherwise responsive to the Request as defined above.

27 The United States further objects to this Interrogatory to the extent that it seeks
28 information protected from disclosure by an applicable privilege or protection.

1 Consistent with its Objections to Definitions 3, 10, and 11, the United States
2 interprets this Interrogatory to exclude attorneys and is not searching for, collecting,
3 or providing information or materials from any attorney within OGC, OCIG, or DOJ.

4 **Response:** Subject to and without waiving the foregoing objections, the United
5 States responds that after a reasonable inquiry, it has identified the following
6 Individuals as responsive to the Interrogatory:

- 7 • Jon Blum
- 8 • Maricruz Bonfante
- 9 • Shawn Braxton
- 10 • Nora Castro
- 11 • Sean Cavanaugh
- 12 • Ilina Chaudhuri
- 13 • Tim Englehardt
- 14 • Kellie Simons (Gombeski)
- 15 • Julie Gover
- 16 • Jennifer Harlow
- 17 • Debra Hennessy
- 18 • Anne Hornsby
- 19 • Amanda Johnson
- 20 • Whitney Johnson
- 21 • Marie Manteuffel
- 22 • Christopher McClintick
- 23 • Cheri Rice
- 24 • Kay Schneider
- 25 • Marilyn Tavenner
- 26 • Cynthia Tudor
- 27 • Julie Uebersax
- 28 • Jim Wickliffe

1 The United States will supplement its response to this Interrogatory as appropriate.

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Dated: April 21, 2021

Respectfully submitted,

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PROOF OF SERVICE BY ELECTRONIC MAIL

I am over the age of 18 and not a party to the action entitled U.S. *ex rel.* Poehling v. UnitedHealth Group, Inc., CV-16-8697 FMO. I am employed by the Department of Justice, Civil Division. My business address is 175 N Street NE, Room 10.224, Washington, D.C. 20002.

On April 21, 2021, I served the foregoing PLAINTIFF UNITED STATES' RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S SECOND SET OF INTERROGATORIES TO THE GOVERNMENT on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: April 21, 2021.

Place of e-mailing: Washington, D.C.

Person(s) and/or Entity(s) to whom e-mailed:

See attached page

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 21, 2021, at Washington, D.C.



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EXHIBIT D-9

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21 FOR THE CENTRAL DISTRICT OF CALIFORNIA
22 WESTERN DIVISION

23 UNITED STATES OF AMERICA *ex*
24 *rel.* BENJAMIN POEHLING,

25 Plaintiffs,

26 v.

27 UNITEDHEALTH GROUP, INC., *et al.*,

28 Defendants.

No. CV 16-08697 FMO (SSx)

UNITED STATES' RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S REQUESTS FOR
ADMISSION TO THE GOVERNMENT
(SET NO. TWO)

PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.

RESPONDING PARTY: UNITED STATES OF AMERICA

SET NUMBER: TWO

Preliminary Statement

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure (“Federal Rules”) and Rule 36 of the Local Civil Rules of the United States District Court for the Central District of California, the United States of America (“United States” or “government”), through its undersigned counsel, provides these responses and objections to Defendant UHC of California’s (“UnitedHealth” or “Defendant”) Requests for Admission (Set No. Two), dated August 27, 2019 (“Second Requests”). The objections and responses set forth herein are based on information now known to the United States and its undersigned attorneys, and will be revised, corrected, supplemented, amended, and clarified to the extent required by Rule 26 as discovery proceeds.

General Objections

The following objections apply to each and every separately numbered Request and are incorporated by reference to the extent applicable into the objection to each Request.

1. The United States objects to the Second Requests to the extent they are vague, ambiguous, overbroad, unduly burdensome, or seek to impose requirements upon the United States beyond those called for or permitted by the Federal Rules of Civil Procedure, the Local Civil Rules of the United States District Court for the Central District of California, or any order of the Court. The United States responds below pursuant to its obligations under the Federal Rules and the Local Civil Rules, namely that the United States has taken and is continuing to undertake reasonable efforts to identify information responsive to the Requests.

1 2. The United States objects to the Second Requests to the extent they seek the
2 disclosure of information concerning the United States' investigation of this matter as
3 well as the United States' investigation in *United States of America ex rel. Swoben v.*
4 *SCAN Health Plan, et al.*, CV 09-5013 (JEMx), 2017 U.S. Dist. LEXIS 174308 (C.D.
5 Cal. Oct. 5, 2017) ("Swoben"). This includes, but is not limited to, the United States'
6 investigative efforts, its assessments of facts and allegations, its deliberative
7 processes concerning actions taken regarding this matter and *Swoben*, and other
8 information generated before and after the commencement of both this litigation and
9 *Swoben*. The United States objects on the grounds that such information is
10 privileged, work product protected, not relevant to claims or defenses, and not
11 proportional to the needs of the case.

12 3. The United States objects to logging the following information withheld on the
13 basis of privilege regarding both this and the *Swoben* action: (a) communications
14 between or among attorneys at the United States Department of Justice (DOJ),
15 including, but not limited to, attorneys at DOJ's Civil Division and the United States
16 Attorneys' Offices both during the Government's pre-complaint investigation and
17 after the Government commenced action; (b) communications between or among
18 attorneys at DOJ and attorneys at the United States Department of Health & Human
19 Services (HHS) both during the Government's pre-complaint investigation and after
20 the Government commenced action; (c) communications between or among attorneys
21 at DOJ and counsel for Relator James Swoben and/or counsel for Relator Benjamin
22 Poehling during the Government's pre-complaint investigation and after the
23 Government commenced action; (d) work product or other privileged documents
24 generated by or sent to or from attorneys for DOJ, HHS, Relator James Swoben
25 and/or Relator Benjamin Poehling and any of agents or contractors for said attorneys
26 both during the Government's pre-complaint investigation and after the Government
27 commenced action. The United States asserts this objection on the grounds that such
28 effort would impose undue and extraordinary burdens on the United States, seek

1 information not relevant to the claims and defenses in this action, and be
2 disproportionate to the needs of this case.

3 4. Pursuant to Rule 36, any admissions contained herein are for purposes of the
4 present action only and shall not be taken as admissions for any other purpose,
5 including for purposes of any other case.

6 5. By making the accompanying responses and objections to Defendant's Second
7 Requests, the government does not waive, and hereby expressly reserves, its right to
8 assert any and all objections as to the admissibility of any documents, testimony, or
9 information into evidence in this action, or in any other proceedings, on any and all
10 grounds including, but not limited to, competency, relevancy, materiality, privilege,
11 or admissibility. Further, the government makes the responses and objections herein
12 without in any way implying that it considers the Second Requests to be relevant or
13 material to the subject matter of this action.

14 6. The United States objects to the below Second Requests to the extent that a
15 response to such Request requires disclosure of information protected from disclosure
16 by an applicable privilege or protection, including, but not limited to, the attorney-
17 client privilege, work product doctrine, deliberative process privilege, law
18 enforcement privilege, common interest privilege, or investigative files privilege, and
19 protections afforded by Fed. R. Civ. P. 26(b), or any other applicable privilege. The
20 United States will not respond in such a way as to disclose such protected
21 information, but inadvertent identification or disclosure of privileged information by
22 the United States shall not be a waiver of any applicable privilege. Under Federal
23 Rule of Evidence 502, Federal Rule of Civil Procedure 26(b)(5)(B), other related
24 sources of law, and the Court's order regarding inadvertent disclosure of privileged
25 information [Doc. 198], the government reserves any and all rights to claw back
26 privileged information it inadvertently discloses in response to the Requests.

27 7. The United States submits these responses subject to, without intending to
28 waive, but expressly reserving the right to object to other discovery procedures

1 involving or relating to the subject matter of the information in responses to the
2 Second Requests. The United States reserves the right to object on any ground, at any
3 time, to such other or supplemental requests as the Defendants may propound
4 involving or relating to the subject matter of these Requests.

5 8. The United States objects to the Second Requests to the extent they are based
6 on inaccurate assumptions or misstatements of fact or misconstructions of law.
7 Nothing herein is intended to concede the accuracy of the assumptions, facts, or law
8 underlying the Second Requests.

9 9. The United States reserves the right to supplement its responses to each and
10 every Request at any time, up to and including trial, as provided by the Federal Rules.

11 10. The assertion of the same, similar, or additional objections to the below
12 Second Requests does not and should not be construed to waive or modify any of the
13 United States' general objections.

14 11. The United States objects to the Second Requests to the extent they require
15 the United States to draw legal conclusions, comment on the merits of any affirmative
16 defenses, or otherwise seek to impose any requirements beyond those established by
17 the Federal Rules or the Local Rules.

18 **Specific Objections to the Definitions and Instructions**

19 The United States objects to the Definitions and Instructions to the extent they
20 (i) seek to impose burdens on the United States that are different from, inconsistent
21 with, or exceed those imposed by the Federal Rules of Civil Procedure and the Local
22 Civil Rules, (ii) are vague or ambiguous, and/or (iii) render the Second Requests
23 overly broad, unduly burdensome, not proportionate to the needs of the case, and not
24 relevant. The United States further objects to the Second Requests to the extent they
25 use terms not defined by UnitedHealth.

26 **Definitions 5, 9, and 14:** The United States objects to the definition of
27 "Government" (Definition 9) to the extent it includes any branch, agency,
28 department, agent, representative, contractor, attorney, consultant, or person acting on

1 its behalf not relevant to this action. This definition is plainly unreasonable. Subject
2 to and without waiving these objections, the United States interprets “Government” to
3 mean CMS for purposes of the Second Requests. The United States further objects to
4 the term “Person” (Definition 14) to the extent it is defined to mean “the federal
5 government and all departments and agencies thereof, state governments, local
6 governments, other governmental agencies.” The United States objects to the
7 definitions of “CMS” (Definition 5), “Government” (Definition 9), and “Person”
8 (Definition 14) as unduly burdensome and disproportionate to the needs of the case to
9 the extent they require the United States to provide information not currently in the
10 possession, custody, or control of CMS, HHS Office of the Secretary and Immediate
11 Office of the Secretary and HHS-OIG. Furthermore, the United States objects to the
12 extent each definition includes former CMS contractors for whom the United States
13 presently has no reasonable belief they possess or control non-duplicative information
14 relevant to any claim or defense in this case.

15 **Definitions 10 and 16:** The United States objects to the definitions of “including,”
16 “relating to,” and “regarding” as rendering the Second Requests vague, ambiguous,
17 confusing, overly broad, and unduly burdensome and disproportionate to the needs of
18 the case. Indeed, these terms as defined to seek any piece of information that in some
19 way – no matter how remote, indirect, or tangential – mentions or references matters
20 set forth in the Request. The United States responds to these Second Requests by
21 using these terms and the verbs constituting their definitions as limited by the
22 constraining adverb “directly.”

23 **Definition 11:** The United States objects to the definition of “March 2014 Meeting”
24 to the extent that it includes a specific date in March that has not been established by
25 the evidence in this matter.

26 **Definition 12:** The United States objects to the definition of “Spring 2014 Phone
27 Call” to the extent that it includes specific dates in March and April that have not
28 been established by the evidence in this matter.

1 **Definition 13:** The United States also objects to the definition of “Medicare
2 Advantage Organization” and “MAO” (Definition 13) to the extent it is inconsistent
3 with the definition provided by 42 U.S.C. § 1395w-28(a)(1). For the purpose of
4 responding to the Requests, the United States shall use the definition of MA Plans
5 provided by 42 U.S.C. § 1395w-28(b)(1) and the definition of MAO provided by 42
6 U.S.C. § 1395w-28(a)(1).

7 **Definition 18:** The United States objects to the definition of “State” to the extent it
8 seeks to impose burdens on the United States that are different from, inconsistent
9 with, or exceed those imposed by the Federal Rules of Civil Procedure and the Local
10 Civil Rules.

11 **Definition 22:** The United States objects to the definition of “you” and “your” to the
12 extent these terms are intend to encompass any agency, office, employee, agent,
13 representative, officer, or contractor of either the legislative or judicial branch, and
14 insofar as these terms are defined to include executive branch agencies and offices
15 not relevant to this action. This is plainly unreasonable. Subject to and without
16 waiving these objections, the United States will interpret this term to mean CMS.

17 **Instruction 3:** The United States objects to Instruction 3 as vague and construes
18 each request to include the time period from January 1, 2004 through May 16, 2017.

19 **Instructions 4:** The United States objects to Instruction 4 to the extent it seeks to
20 impose burdens upon the United States beyond those called for or permitted by the
21 Federal Rules or the Local Rules for the Central District of California. The United
22 States will respond to unobjectionable Requests or portions of Requests to the best of
23 its present ability. The United States submits these responses subject to, without
24 intending to waive, but expressly reserving the right to revise, correct, supplement or
25 clarify any of the responses herein at any time up to and including trial. Said
26 responses are at all times without prejudice subject to such additional or different
27 information that discovery or further investigation may disclose.

28 **Instruction 5:** The United States objects to Instruction 5 to the extent it seeks to

1 impose burdens upon the United States beyond those called for or permitted by the
2 Federal Rules or the Local Rules for the Central District of California.

3 **Instruction 6:** The United States objects to Instruction 6 to the extent it seeks to
4 impose burdens upon the United States beyond those called for or permitted by the
5 Federal Rules or the Local Rules for the Central District of California. The United
6 States will assert any applicable privileges and specify the material to which it applies
7 per Fed. R. Civ. P. 25(b)(5)(A) for all information responsive to a request to which
8 the United States has agreed to produce but which is withheld on the basis of a
9 privilege or protection.

Specific Objections and Responses to Requests for Admission

REQUEST FOR ADMISSION NO. 18: Admit that during the March 2014 Meeting, Jonathan Blum met Larry Renfro in person.

Objection: The United States incorporates its General Objections and Specific Objections to the Definitions and Instructions as if stated herein, including but not limited to, its specific objections to the definition of “March 2014 Meeting.” The United States objects to this Request to the extent it calls for information that is already in UnitedHealth’s possession, custody, or control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth is using this information to mischaracterize or misinterpret the facts. The United States objects to this Request to the extent it seeks information not relevant to a claim or defense in this case.

Response: Subject to and without waiving the foregoing objections, including regarding the specific date implicated, the United States admits this Request.

REQUEST FOR ADMISSION NO. 19: Admit that Larry Renfro requested the March 2014 Meeting with Jonathan Blum.

Objection: The United States incorporates its General Objections and Specific Objections to the Definitions and Instructions as if stated herein, including but not limited to, its specific objections to the definition of “March 2014 Meeting.” The United States objects to this Request to the extent it calls for information that is already in UnitedHealth’s possession, custody, or control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth is using this information to mischaracterize or misinterpret the facts. The United States objects to this Request to the extent it seeks information not relevant to a claim or defense in this case.

Response: Subject to and without waiving the foregoing objections, including regarding the specific date implicated, the United States admits this Request to the extent that Larry Renfro requested a meeting with Jonathan Blum during this general time frame although Mr. Blum did not know the topic of the requested meeting ahead of time.

1 **REQUEST FOR ADMISSION NO. 20:** Admit that the March 2014 Meeting
2 between Jonathan Blum and Larry Renfro took place in Washington, D.C.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein, including but not
5 limited to, its specific objections to the definition of “March 2014 Meeting.” The
6 United States objects to this Request to the extent it calls for information that is
7 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
8 UnitedHealth and to the extent that UnitedHealth is using this information to
9 mischaracterize or misinterpret the facts. The United States objects to this Request to
10 the extent it seeks information not relevant to a claim or defense in this case.

11 **Response:** Subject to and without waiving the foregoing objections, including
12 regarding the specific date implicated, the United States admits this Request.

13 **REQUEST FOR ADMISSION NO. 21:** Admit that no other Person attended the
14 March 2014 Meeting between Jonathan Blum and Larry Renfro.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definitions of “Person” and “March 2014
18 Meeting.” The United States objects to this Request to the extent it calls for
19 information that is already in UnitedHealth’s possession, custody, or control, or is
20 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
21 information to mischaracterize or misinterpret the facts. The United States objects to
22 this Request to the extent it seeks information not relevant to a claim or defense in
23 this case.

24 **Response:** Subject to and without waiving the foregoing objections, including
25 regarding the specific date implicated, the United States admits this Request.

26 **REQUEST FOR ADMISSION NO. 22:** Admit that Jonathan Blum took notes
27 during the March 2014 Meeting with Larry Renfro.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “March 2014 Meeting.” The
3 United States objects to this Request to the extent it calls for information that is
4 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
5 UnitedHealth and to the extent that UnitedHealth is using this information to
6 mischaracterize or misinterpret the facts.

7 **Response:** Subject to and without waiving the foregoing objections, including
8 regarding the specific date implicated, the United States denies this Request.

9 **REQUEST FOR ADMISSION NO. 23:** Admit that after the March 2014
10 Meeting between Jonathan Blum and Larry Renfro, Jonathan Blum took notes about
11 or otherwise memorialized the meeting in writing.

12 **Objection:** The United States incorporates its General Objections and Specific
13 Objections to the Definitions and Instructions as if stated herein, including but not
14 limited to, its specific objections to the definition of “March 2014 Meeting.” The
15 United States also objects to this Request to the extent that the undefined phrase “or
16 otherwise memorialized” is vague and ambiguous. For the purposes of this Request,
17 the United States defines “memorialized” as put in writing.

18 **Response:** Subject to and without waiving the foregoing objections, including
19 regarding the specific date implicated, the United States denies this Request.

20 **REQUEST FOR ADMISSION NO. 24:** Admit that after the March 2014
21 Meeting between Jonathan Blum and Larry Renfro, Jonathan Blum had
22 Communications with the Government regarding the meeting.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definitions of “March 2014 Meeting” and
26 “Government.” The United States objects to this Request to the extent it seeks
27 disclosure of information that is protected from disclosure by an applicable privilege
28 or protection, including the attorney-client privilege, attorney work-product doctrine,

1 deliberative process privilege, and/or investigative files privilege. For the purposes
2 of this Request, the United States will interpret the definition of “Government” to
3 include only CMS.

4 **Response:** Subject to and without waiving the foregoing objections, including
5 regarding the specific date implicated, the United States admits this Request.

6 **REQUEST FOR ADMISSION NO. 25:** Admit that during the March 2014
7 Meeting, Jonathan Blum discussed UnitedHealth’s Claims Verification Program with
8 Larry Renfro.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein, including but not
11 limited to, its specific objections to the definition of “March 2014 Meeting.” The
12 United States also objects to this Request to the extent that the undefined term
13 “discussed” is vague and ambiguous. For purposes of this Request, the United States
14 defines “discussed” as a back and forth conversation on a particular topic. The
15 United States further objects to this Request to extent it is duplicative of Requests for
16 Admission Nos. 29 and 30. The United States also objects to this Request to the
17 extent it calls for information that is already in UnitedHealth’s possession, custody, or
18 control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth
19 is using this information to mischaracterize or misinterpret the facts.

20 **Response:** Subject to and without waiving the foregoing objections, including
21 regarding the specific date implicated, the United States denies this Request. To the
22 extent it is possible Larry Renfro raised the topic of Claims Verification at this time,
23 Jonathan Blum did not have a sufficient understanding of UnitedHealth’s processes to
24 engage in a discussion with Mr. Renfro.

25 **REQUEST FOR ADMISSION NO. 26:** Admit that during the March 2014
26 Meeting, Jonathan Blum discussed the Proposed Medical Record Review Rule with
27 Larry Renfro.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “March 2014 Meeting.” The
3 United States also objects to this Request to the extent that the undefined term
4 “discussed” is vague and ambiguous. For purposes of this Request, the United States
5 defines “discussed” as a back and forth conversation on a particular topic. The
6 United States also objects to this Request to the extent it calls for information that is
7 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
8 UnitedHealth and to the extent that UnitedHealth is using this information to
9 mischaracterize or misinterpret the facts.

10 **Response:** Subject to and without waiving the foregoing objections, including
11 regarding the specific date implicated, the United States admits that Larry Renfro
12 asked Jonathan Blum for clarification regarding the Proposed Medical Record
13 Review Rule during their one-on-one meeting in approximately March 2014. The
14 United States denies the remainder of this Request.

15 **REQUEST FOR ADMISSION NO. 27:** Admit that during the March 2014
16 Meeting, Larry Renfro asked Jonathan Blum what new requirements the Proposed
17 Medical Record Review Rule would impose on MAOs.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of “March 2014 Meeting” and
21 “MAO.” The United States objects to this Request to the extent it calls for
22 information that is already in UnitedHealth’s possession, custody, or control, or is
23 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
24 information to mischaracterize or misinterpret the facts. The United States objects to
25 this Request to the extent it calls for any legal conclusion.

26 **Response:** Subject to and without waiving the foregoing objections, including
27 regarding the specific date implicated, the United States admits that Larry Renfro
28 asked Jonathan Blum for clarification regarding the Proposed Medical Record

1 Review Rule during their one-on-one meeting in approximately March 2014.

2 **REQUEST FOR ADMISSION NO. 28:** Admit that during the March 2014
3 Meeting, Larry Renfro told Jonathan Blum that the Proposed Medical Record
4 Review Rule would require MAOs to conduct Two-Way Looks beginning January 1,
5 2015.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definition of “March 2014 Meeting” and
9 “MAO.” The United States objects to this Request to the extent it calls for
10 information that is already in UnitedHealth’s possession, custody, or control, or is
11 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
12 information to mischaracterize or misinterpret the facts. The United States objects to
13 this Request to the extent it calls for any legal conclusion.

14 **Response:** Subject to and without waiving the foregoing objections, including
15 regarding the specific date implicated, the United States admits that Larry Renfro
16 asked Jonathan Blum for clarification regarding the Proposed Medical Record
17 Review Rule during their one-on-one meeting in approximately March 2014.
18 However, the United States responds that, after a reasonable inquiry, it lacks
19 sufficient information to admit or deny the remainder of this Request.

20 **REQUEST FOR ADMISSION NO. 29:** Admit that during the March 2014
21 Meeting, Larry Renfro told Jonathan Blum that UnitedHealth had been conducting a
22 Claims Verification Program.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of “March 2014 Meeting.” The
26 United States objects to this Request to extent it is duplicative of Request for
27 Admission Nos. 25 and 30. The United States also objects to this Request to the
28 extent it calls for information that is already in UnitedHealth’s possession, custody, or

1 control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth
2 is using this information to mischaracterize or misinterpret the facts.

3 **Response:** Subject to and without waiving the foregoing objections, including
4 regarding the specific date implicated, the United States responds that, after a
5 reasonable inquiry, it lacks sufficient information to admit or deny this Request. To
6 the extent it is possible Larry Renfro raised the topic of Claims Verification at this
7 time, Jonathan Blum did not have a sufficient understanding of UnitedHealth's
8 processes to engage in a discussion with Mr. Renfro.

9 **REQUEST FOR ADMISSION NO. 30:** Admit that during the March 2014
10 Meeting, Larry Renfro told Jonathan Blum that UnitedHealth had been conducting a
11 Claims Verification Program since approximately 2012.

12 **Objection:** The United States incorporates its General Objections and Specific
13 Objections to the Definitions and Instructions as if stated herein, including but not
14 limited to, its specific objections to the definition of "March 2014 Meeting." The
15 United States objects to this Request to extent it is duplicative of Request for
16 Admission Nos. 25 and 29. The United States also objects to this Request to the
17 extent it calls for information that is already in UnitedHealth's possession, custody, or
18 control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth
19 is using this information to mischaracterize or misinterpret the facts.

20 **Response:** Subject to and without waiving the foregoing objections, including
21 regarding the specific date implicated, the United States responds that, after a
22 reasonable inquiry, it lacks sufficient information to admit or deny this Request. To
23 the extent it is possible Larry Renfro raised the topic of Claims Verification at this
24 time, Jonathan Blum did not have a sufficient understanding of UnitedHealth's
25 processes to engage in a discussion with Mr. Renfro.

26 **REQUEST FOR ADMISSION NO. 31:** Admit that during the March 2014
27 Meeting, Jonathan Blum told Larry Renfro there was no then-current requirement for
28 MAOs to conduct Two-Way Looks when conducting reviews of a Member's

1 medical records.

2 **Objection:** The United States incorporates its General Objections and Specific
3 Objections to the Definitions and Instructions as if stated herein, including but not
4 limited to, its specific objections to the definition of “March 2014 Meeting” and
5 “MAO.” The United States also objects to this Request to the extent that the
6 undefined phrase “reviews of a Member’s medical records” is vague and ambiguous.
7 The United States interprets this phrase to mean Chart Review for purposes of this
8 request. The United States objects to this Request to the extent it calls for
9 information that is already in UnitedHealth’s possession, custody, or control, or is
10 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
11 information to mischaracterize or misinterpret the facts. The United States objects to
12 this Request to the extent it calls for any legal conclusion.

13 **Response:** Subject to and without waiving the foregoing objections, including
14 regarding the specific date implicated, the United States denies this Request.

15 **REQUEST FOR ADMISSION NO. 32:** Admit that during the March 2014
16 Meeting, Larry Renfro asked Jonathan Blum whether UnitedHealth should conduct
17 its Claims Verification Program before the Proposed Medical Record Review Rule
18 took effect.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “March 2014 Meeting.” The
22 United States objects to this Request to the extent it calls for information that is
23 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
24 UnitedHealth and to the extent that UnitedHealth is using this information to
25 mischaracterize or misinterpret the facts. The United States objects to this Request to
26 the extent it calls for any legal conclusion.

27 **Response:** Subject to and without waiving the foregoing objections, including
28 regarding the specific date implicated, the United States admits that Larry Renfro

1 asked Jonathan Blum for clarification regarding the Proposed Medical Record
2 Review Rule during their one-on-one meeting in approximately March 2014. To the
3 extent it is possible Larry Renfro raised the topic of Claims Verification at this time,
4 Jonathan Blum did not have a sufficient understanding of UnitedHealth's processes to
5 engage in a discussion with Mr. Renfro.

6 **REQUEST FOR ADMISSION NO. 33:** Admit that during the March 2014
7 Meeting, Larry Renfro asked Jonathan Blum whether UnitedHealth should conduct
8 Two-Way Looks when conducting reviews of a Member's medical records before
9 the Proposed Medical Record Review Rule took effect.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition of "March 2014 Meeting." The
13 United States also objects to this Request to the extent that the undefined phrase
14 "reviews of a Member's medical records" is vague and ambiguous. The United
15 States interprets this phrase to mean Chart Review for purposes of this request. The
16 United States objects to this Request to the extent it calls for information that is
17 already in UnitedHealth's possession, custody, or control, or is otherwise available to
18 UnitedHealth and to the extent that UnitedHealth is using this information to
19 mischaracterize or misinterpret the facts. The United States objects to this Request to
20 the extent it calls for any legal conclusion.

21 **Response:** Subject to and without waiving the foregoing objections, including
22 regarding the specific date implicated, the United States admits that Larry Renfro
23 asked Jonathan Blum for clarification regarding the Proposed Medical Record
24 Review Rule during their one-on-one meeting in approximately March 2014. To the
25 extent it is possible Larry Renfro raised the topic of UnitedHealth's Chart Review,
26 Jonathan Blum did not have a sufficient understanding of UnitedHealth's processes to
27 engage in a discussion with Mr. Renfro.

28 **REQUEST FOR ADMISSION NO. 34:** Admit that during the March 2014

1 Meeting, Jonathan Blum told Larry Renfro he would look into Renfro's question
2 about whether UnitedHealth should continue to conduct Two-Way Looks in its
3 Claims Verification Program before the Proposed Medical Record Review Rule went
4 into effect.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of "March 2014 Meeting." The
8 United States also objects to this Request to the extent that the undefined phrases
9 "look into" and "continue" are vague and ambiguous. The United States objects to
10 this Request to the extent it calls for information that is already in UnitedHealth's
11 possession, custody, or control, or is otherwise available to UnitedHealth and to the
12 extent that UnitedHealth is using this information to mischaracterize or misinterpret
13 the facts. The United States objects to this Request to the extent it calls for any legal
14 conclusion.

15 **Response:** Subject to and without waiving the foregoing objections, including
16 regarding the specific date implicated, the United States admits that Jonathan Blum
17 agreed to follow-up with individuals from CMS's staff regarding Larry Renfro's
18 request for clarity regarding the Proposed Medical Record Review Rule. However,
19 the United States denies the remainder of this Request.

20 **REQUEST FOR ADMISSION NO. 35:** Admit that Jonathan Blum spoke to
21 Larry Renfro via telephone during the Spring 2014 Phone Call.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein, including but not
24 limited to, its specific objections to the definition of "Spring 2014 Phone Call." The
25 United States objects to this Request to the extent it calls for information that is
26 already in UnitedHealth's possession, custody, or control, or is otherwise available to
27 UnitedHealth and to the extent that UnitedHealth is using this information to
28 mischaracterize or misinterpret the facts.

1 **Response:** Subject to and without waiving the foregoing objections, including
2 regarding the specific date implicated, the United States admits this Request.

3 **REQUEST FOR ADMISSION NO. 36:** Admit that Jonathan Blum spoke to
4 Larry Renfro during the Spring 2014 Phone Call to discuss UnitedHealth's Claims
5 Verification Program.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definition of "Spring 2014 Phone Call." The
9 United States also objects to this Request to the extent that the undefined term
10 "discuss" is vague and ambiguous. For purposes of this Request, the United States
11 defines "discuss" as a back and forth conversation on a particular topic. The United
12 States objects to this Request to the extent it calls for information that is already in
13 UnitedHealth's possession, custody, or control, or is otherwise available to
14 UnitedHealth and to the extent that UnitedHealth is using this information to
15 mischaracterize or misinterpret the facts.

16 **Response:** Subject to and without waiving the foregoing objections, including
17 regarding the specific date implicated, the United States admits that Jonathan Blum
18 spoke with Larry Renfro by telephone as a follow-up to their earlier in-person
19 meeting. However, to the extent it is possible Larry Renfro raised the topic of
20 UnitedHealth's Claims Verification Program, Jonathan Blum did not have a sufficient
21 understanding of UnitedHealth's processes to engage in a discussion with Mr.
22 Renfro.

23 **REQUEST FOR ADMISSION NO. 37:** Admit that Jonathan Blum spoke to
24 Larry Renfro during the Spring 2014 Phone Call to discuss conducting Two-Way
25 Looks when conducting reviews of a Member's medical records.

26 **Objection:** The United States incorporates its General Objections and Specific
27 Objections to the Definitions and Instructions as if stated herein, including but not
28 limited to, its specific objections to the definition of "Spring 2014 Phone Call." The

1 United States also objects to this Request to the extent that the undefined phrase
2 “reviews of a Member’s medical records” is vague and ambiguous. The United
3 States interprets this phrase to mean Chart Review for purposes of this request. The
4 United States also objects to this Request to the extent that the undefined term
5 “discuss” is vague and ambiguous. For purposes of this Request, the United States
6 defines “discuss” as a back and forth conversation on a particular topic. The United
7 States objects to this Request to the extent it calls for information that is already in
8 UnitedHealth’s possession, custody, or control, or is otherwise available to
9 UnitedHealth and to the extent that UnitedHealth is using this information to
10 mischaracterize or misinterpret the facts. The United States objects to this Request to
11 the extent it calls for any legal conclusion.

12 **Response:** Subject to and without waiving the foregoing objections, including
13 regarding the specific date implicated, the United States admits that Jonathan Blum
14 spoke with Larry Renfro by telephone as a follow-up to their earlier in-person
15 meeting. However, the United States denies the remainder of this Request.

16 **REQUEST FOR ADMISSION NO. 38:** Admit that Jonathan Blum took notes
17 during the Spring 2014 Phone Call.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of “Spring 2014 Phone Call.”

21 **Response:** Subject to and without waiving the foregoing objections, including
22 regarding the specific date implicated, the United States denies this Request.

23 **REQUEST FOR ADMISSION NO. 39:** Admit that after the Spring 2014 Phone
24 Call, Jonathan Blum took notes about or otherwise memorialized the meeting in
25 writing.

26 **Objection:** The United States incorporates its General Objections and Specific
27 Objections to the Definitions and Instructions as if stated herein, including but not
28 limited to, its specific objections to the definition of “Spring 2014 Phone Call.” The

1 United States also objects to this Request to the extent that the undefined phrases “or
2 otherwise memorialized” and “the meeting” are vague and ambiguous. For the
3 purposes of this Request, the United States defines “memorialized” as put in writing
4 and “the meeting” as a phone call between Mr. Renfro and Mr. Blum in
5 approximately Spring 2014.

6 **Response:** Subject to and without waiving the foregoing objections, including
7 regarding the specific date implicated, after a reasonable inquiry, the United States
8 responds that it lacks sufficient information to admit or deny this Request. To the
9 extent the United States identifies any writing by Mr. Blum regarding the phone call
10 between Mr. Renfro and Mr. Blum in approximately Spring 2014, it will supplement
11 this Response.

12 **REQUEST FOR ADMISSION NO. 40:** Admit that after the Spring 2014 Phone
13 Call, Jonathan Blum had Communications with the Government about the Spring
14 2014 Phone Call.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definition of “Spring 2014 Phone Call” and
18 “Government.” The United States objects to this Request to the extent it seeks
19 disclosure of information that is protected from disclosure by an applicable privilege
20 or protection, including the attorney-client privilege, attorney work-product doctrine,
21 deliberative process privilege, and/or investigative files privilege. For the purposes
22 of this Request, the United States will interpret the definition of “Government” to
23 include only CMS.

24 **Response:** Subject to and without waiving the foregoing objections, including
25 regarding the specific date implicated, after a reasonable inquiry, the United States
26 responds that it lacks sufficient information to admit or deny this Request.

27 **REQUEST FOR ADMISSION NO. 41:** Admit that no other Person from the
28 Government participated in the Spring 2014 Phone Call.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definitions of “Spring 2014 Phone Call,”
4 “Government,” and “Person.” For the purposes of this Request, the United States
5 will interpret the definition of “Government” to include only CMS. The United
6 States objects to this Request to the extent it calls for information that is already in
7 UnitedHealth’s possession, custody, or control, or is otherwise available to
8 UnitedHealth and to the extent that UnitedHealth is using this information to
9 mischaracterize or misinterpret the facts.

10 **Response:** Subject to and without waiving the foregoing objections, including
11 regarding the specific date implicated, the United States admits this Request.

12 **REQUEST FOR ADMISSION NO. 42:** Admit that Jonathan Blum did not Audio
13 Record the Spring 2014 Phone Call.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein, including but not
16 limited to, its specific objections to the definition of “Spring 2014 Phone Call.”

17 **Response:** Subject to and without waiving the foregoing objections, including
18 regarding the specific date implicated, the United States admits this Request.

19 **REQUEST FOR ADMISSION NO. 43:** Admit that the Government did not
20 Audio Record the Spring 2014 Phone Call.

21 **Objection:** The United States incorporates its General Objections and Specific
22 Objections to the Definitions and Instructions as if stated herein, including but not
23 limited to, its specific objections to the definitions of “Spring 2014 Phone Call” and
24 “Government.” The United States further objects to this request because it is unduly
25 burdensome for the United States to determine the actions of all “agencies,
26 departments, components, agents, representatives, contractors, attorneys, consultants,
27 and all other Persons acting on its behalf.”

28 **Response:** Subject to and without waiving the foregoing objections, including

1 regarding the specific date implicated, the United States admits that Jonathan Blum
2 did not audio record the phone call, but after a reasonable inquiry, the United States
3 responds that it lacks sufficient information to admit or deny this Request with
4 respect to the entire United States Government.

5 **REQUEST FOR ADMISSION NO. 44:** Admit that during the Spring 2014
6 Phone Call, Jonathan Blum told Larry Renfro that MAOs other than UnitedHealth
7 were asking if MAOs were required to conduct Two-Way Looks before the Proposed
8 Medical Record Review Rule took effect.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein, including but not
11 limited to, its specific objections to the definitions of “Spring 2014 Phone Call” and
12 “MAO.” The United States objects to this Request to the extent it calls for
13 information that is already in UnitedHealth’s possession, custody, or control, or is
14 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
15 information to mischaracterize or misinterpret the facts. The United States objects to
16 this Request to the extent it calls for any legal conclusion.

17 **Response:** Subject to and without waiving the foregoing objections, including
18 regarding the specific date implicated, the United States responds that, after a
19 reasonable inquiry, it lacks sufficient information to admit or deny this Request.

20 **REQUEST FOR ADMISSION NO. 45:** Admit that during the Spring 2014
21 Phone Call, Jonathan Blum told Larry Renfro that the Proposed Medical Record
22 Review Rule was not retroactive.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of “Spring 2014 Phone Call.” The
26 United States objects to this Request to the extent it calls for information that is
27 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
28 UnitedHealth and to the extent that UnitedHealth is using this information to

1 mischaracterize or misinterpret the facts. The United States objects to this Request to
2 the extent it calls for any legal conclusion.

3 **Response:** Subject to and without waiving the foregoing objections, including
4 regarding the specific date implicated, the United States denies this Request.

5 Jonathan Blum responded to Larry Renfro's inquiry simply by telling him to read the
6 Proposed Medical Record Rule.

7 **REQUEST FOR ADMISSION NO. 46:** Admit that Marilyn Tavenner spoke on
8 the phone with Larry Renfro on April 8, 2014.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein. The United States
11 objects to this Request to the extent it seeks information not relevant to a claim or
12 defense in this case. The United States objects to this Request to the extent it calls for
13 information that is already in UnitedHealth's possession, custody, or control, or is
14 otherwise available to UnitedHealth as it is duplicative of information sought and
15 obtained by UnitedHealth in the February 28, 2018 deposition of Marilyn Tavenner.
16 The United States additionally objects to the extent that UnitedHealth is using this
17 information to mischaracterize or misinterpret the facts.

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
20 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
21 information to admit or deny whether a telephone call took place on April 8, 2014.

22 **REQUEST FOR ADMISSION NO. 47:** Admit that Larry Renfro requested the
23 April 8, 2014 call with Marilyn Tavenner.

24 **Objection:** The United States incorporates its General Objections and Specific
25 Objections to the Definitions and Instructions as if stated herein. The United States
26 objects to this Request to the extent it calls for information that is already in
27 UnitedHealth's possession, custody, or control, or is otherwise available to
28 UnitedHealth as it is duplicative of information sought and obtained by UnitedHealth

1 in the February 28, 2018 deposition of Marilyn Tavenner. The United States
2 additionally objects to the extent that UnitedHealth is using this information to
3 mischaracterize or misinterpret the facts.

4 **Response:** Subject to and without waiving the foregoing objections, the United
5 States admits that Larry Renfro requested a call with Marilyn Tavenner in the Spring
6 of 2014, but after a reasonable inquiry, responds that it lacks sufficient information to
7 admit or deny whether a telephone call took place on April 8, 2014. Ms. Tavenner's
8 recollection is consistent with her testimony in her February 28, 2018 deposition, "I
9 remember being approached by Larry to discuss a concern he had about the process
10 that involved a review of charts."

11 **REQUEST FOR ADMISSION NO. 48:** Admit that Marilyn Tavenner spoke on
12 the phone with Larry Renfro on April 8, 2014 regarding the Proposed Medical
13 Record Review Rule.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein. The United States
16 objects to this Request to the extent it calls for information that is already in
17 UnitedHealth's possession, custody, or control, or is otherwise available to
18 UnitedHealth as it is duplicative of information sought and obtained by UnitedHealth
19 in the February 28, 2018 deposition of Marilyn Tavenner. The United States
20 additionally objects to the extent that UnitedHealth is using this information to
21 mischaracterize or misinterpret the facts.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
24 Spring of 2014 regarding the Proposed Medical Record Review Rule, but after a
25 reasonable inquiry, responds that it lacks sufficient information to admit or deny
26 whether a telephone call took place on April 8, 2014.

27 **REQUEST FOR ADMISSION NO. 49:** Admit that Marilyn Tavenner took notes
28 during her April 8, 2014 phone call with Larry Renfro.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein.

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
5 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
6 information to admit or deny whether a telephone call took place on April 8, 2014.
7 Further, after a reasonable inquiry, the United States responds that it lacks sufficient
8 information to admit or deny whether Ms. Tavenner took notes during her phone call
9 with Mr. Renfro, but can state that it was not Ms. Tavenner's practice to take notes
10 during phone calls. If the United States identifies notes taken by Ms. Tavenner
11 during her call with Mr. Renfro in the Spring of 2014, it will supplement this
12 Response.

13 **REQUEST FOR ADMISSION NO. 50:** Admit that after the April 8, 2014
14 telephone call between Marilyn Tavenner and Larry Renfro, Marilyn Tavenner took
15 notes about or otherwise memorialized the meeting in writing.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein. The United States
18 also objects to this Request to the extent that the undefined phrase "or otherwise
19 memorialized" is vague and ambiguous. For the purposes of this Request, the United
20 States defines "memorialized" as put in writing.

21 **Response:** Subject to and without waiving the foregoing objections, the United
22 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
23 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
24 information to admit or deny whether a telephone call took place on April 8, 2014.
25 Further, after a reasonable inquiry, the United States responds that it lacks sufficient
26 information to admit or deny whether Ms. Tavenner memorialized the call in writing
27 after the call. To the extent the United States identifies writing by Ms. Tavenner
28 regarding her call with Mr. Renfro in the Spring of 2014, it will supplement this

1 Response.

2 **REQUEST FOR ADMISSION NO. 51:** Admit that after the April 8, 2014
3 telephone call between Marilyn Tavenner and Larry Renfro, Marilyn Tavenner had
4 Communications with the Government about the call.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of “Government.” The United
8 States objects to this Request to the extent it seeks disclosure of information that is
9 protected from disclosure by an applicable privilege or protection, including the
10 attorney-client privilege, attorney work-product doctrine, deliberative process
11 privilege, and/or investigative files privilege. For the purposes of this Request, the
12 United States will interpret the definition of “Government” to include only CMS.

13 **Response:** Subject to and without waiving the foregoing objections, the United
14 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
15 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
16 information to admit or deny whether a telephone call took place on April 8, 2014.
17 Further, the United States admits that following this telephone call with Larry Renfro,
18 Ms. Tavenner communicated with CMS regarding the call.

19 **REQUEST FOR ADMISSION NO. 52:** Admit that no other Person participated
20 in the April 8, 2014 call between Marilyn Tavenner and Larry Renfro.

21 **Objection:** The United States incorporates its General Objections and Specific
22 Objections to the Definitions and Instructions as if stated herein, including but not
23 limited to, its specific objections to the definition of “Person.”

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
26 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
27 information to admit or deny whether a telephone call took place on April 8, 2014 or
28 whether any other person participated in the call.

1 **REQUEST FOR ADMISSION NO. 53:** Admit that Marilyn Tavenner did not
2 Audio Record the April 8, 2014 call between Marilyn Tavenner and Larry Renfro.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
7 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
8 information to admit or deny whether a telephone call took place on April 8, 2014.
9 Further, the United States admits that Ms. Tavenner was not in the habit of audio
10 recording any of her telephone calls. To the extent the United States identifies an
11 audio recording made by Ms. Tavenner of her call with Mr. Renfro in Spring 2014, it
12 will supplement this Response.

13 **REQUEST FOR ADMISSION NO. 54:** Admit that the Government did not
14 Audio Record the April 8, 2014 call between Marilyn Tavenner and Larry Renfro.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definition “Government.” The United States
18 further objects to this request because it is unduly burdensome for the United States
19 to determine the actions of all “agencies, departments, components, agents,
20 representatives, contractors, attorneys, consultants, and all other Persons acting on its
21 behalf.”

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
24 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
25 information to admit or deny whether a telephone call took place on April 8, 2014.
26 Further, the United States admits that Ms. Tavenner was not in the habit of audio
27 recording any of her telephone calls, but after a reasonable inquiry, responds that it
28 lacks sufficient information to admit or deny this Request with respect to the entire

1 United States Government.

2 **REQUEST FOR ADMISSION NO. 55:** Admit that Marilyn Tavenner spoke on
3 the phone with Larry Renfro on April 8, 2014 regarding whether UnitedHealth was
4 obligated at that time to perform Two-Way Looks.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein. The United States
7 also objects to this Request to the extent that the undefined term “obligated” is vague
8 and ambiguous. The United States objects to this Request to the extent it calls for
9 information that is already in UnitedHealth’s possession, custody, or control, or is
10 otherwise available to UnitedHealth as it is duplicative of information sought and
11 obtained by UnitedHealth in the February 28, 2018 deposition of Marilyn Tavenner.
12 The United States additionally objects to the extent that UnitedHealth is using this
13 information to mischaracterize or misinterpret the facts. The United States objects to
14 this Request to the extent it calls for any legal conclusion.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
17 Spring of 2014 regarding the Proposed Medical Record Review Rule, but after a
18 reasonable inquiry, responds that it lacks sufficient information to admit or deny
19 whether a telephone call took place on April 8, 2014. Further, the United States
20 responds that after a reasonable inquiry, it lacks sufficient information to admit or
21 deny the remainder of this Request. Ms. Tavenner’s recollection is consistent with
22 her testimony in her February 28, 2018 deposition, “That he [Larry Renfro] was
23 asking me about something that was in the proposed rule that related to chart review,
24 and giving me his ideas on what he thought it meant, and I listened to him, and then I
25 referred him to our staff.”

26 **REQUEST FOR ADMISSION NO. 56:** Admit that Jonathan Blum spoke to
27 Marilyn Tavenner prior to April 8, 2014 about Mr. Blum’s March 2014 Meeting with
28 Larry Renfro.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition of “March 2014 Meeting.”

4 **Response:** Subject to and without waiving the foregoing objections, including
5 regarding the specific dates implicated, the United States responds that after a
6 reasonable inquiry, it lacks sufficient information to admit or deny this Request.

7 **REQUEST FOR ADMISSION NO. 57:** Admit that Jonathan Blum spoke to
8 Marilyn Tavenner prior to April 8, 2014 about Mr. Blum’s Spring 2014 Phone Call
9 with Larry Renfro.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition of “Spring 2014 Phone Call.”

13 **Response:** Subject to and without waiving the foregoing objections, including
14 regarding the specific dates implicated, the United States responds that after a
15 reasonable inquiry, it lacks sufficient information to admit or deny this Request.

16 **REQUEST FOR ADMISSION NO. 58:** Admit that Marilyn Tavenner told Larry
17 Renfro on April 8, 2014 that she spoke to Jonathan Blum about Blum’s Spring 2014
18 Phone Call with Renfro.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “Spring 2014 Phone Call.” The
22 United States objects to this Request to the extent it calls for information that is
23 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
24 UnitedHealth and to the extent that UnitedHealth is using this information to
25 mischaracterize or misinterpret the facts.

26 **Response:** Subject to and without waiving the foregoing objections, including
27 regarding the specific dates implicated, the United States responds that after a
28 reasonable inquiry, it lacks sufficient information to admit or deny this Request.

1 **REQUEST FOR ADMISSION NO. 59:** Admit that Marilyn Tavenner told Larry
2 Renfro on April 8, 2014 that she spoke to Jonathan Blum about Blum's Spring 2014
3 Phone Call with Renfro regarding UnitedHealth's Claims Verification Program.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition of "Spring 2014 Phone Call." The
7 United States further objects to this Request to extent it is duplicative of Request for
8 Admission No. 58. The United States objects to this Request to the extent it calls for
9 information that is already in UnitedHealth's possession, custody, or control, or is
10 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
11 information to mischaracterize or misinterpret the facts.

12 **Response:** Subject to and without waiving the foregoing objections, including
13 regarding the specific dates implicated, the United States responds that after a
14 reasonable inquiry, it lacks sufficient information to admit or deny this Request.

15 **REQUEST FOR ADMISSION NO. 60:** Admit that Larry Renfro asked Marilyn
16 Tavenner on April 8, 2014 if she agreed with Jonathan Blum that there was no
17 requirement that UnitedHealth perform Two-Way Looks before the Proposed
18 Medical Record Review Rule went into effect.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein. The United States
21 objects to this Request to the extent that it purports to set forth a statement of
22 Jonathan Blum which has not been established by the evidence in this matter. The
23 United States objects to this Request to the extent it calls for information that is
24 already in UnitedHealth's possession, custody, or control, or is otherwise available to
25 UnitedHealth as it is duplicative of information sought and obtained by UnitedHealth
26 in the February 28, 2018 deposition of Marilyn Tavenner. The United States
27 additionally objects to the extent that UnitedHealth is using this information to
28 mischaracterize or misinterpret the facts. The United States objects to this Request to

1 the extent it calls for any legal conclusion.

2 **Response:** Subject to and without waiving the foregoing objections, the United
3 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
4 Spring of 2014 regarding the Proposed Medical Record Review Rule, but after a
5 reasonable inquiry, responds that it lacks sufficient information to admit or deny
6 whether a telephone call took place on April 8, 2014. The United States denies the
7 remainder of this Request. Ms. Tavenner's recollection is consistent with the
8 testimony in her February 28, 2018 deposition, "That he [Larry Renfro] was asking
9 me about something that was in the proposed rule that related to chart review, and
10 giving me his ideas on what he thought it meant, and I listened to him, and then I
11 referred him to our staff."

12 **REQUEST FOR ADMISSION NO. 61:** Admit that Larry Renfro asked Marilyn
13 Tavenner on April 8, 2014 whether UnitedHealth had to perform Two-Way Looks
14 prior to the implementation of the Proposed Medical Record Review Rule.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein. The United States
17 also objects to this Request to the extent that the undefined phrase "prior to the
18 implementation" is vague and ambiguous. The United States objects to this Request
19 to the extent it calls for information that is already in UnitedHealth's possession,
20 custody, or control, or is otherwise available to UnitedHealth as it is duplicative of
21 information sought and obtained by UnitedHealth in the February 28, 2018 deposition
22 of Marilyn Tavenner. The United States additionally objects to the extent that
23 UnitedHealth is using this information to mischaracterize or misinterpret the facts.
24 The United States objects to this Request to the extent it calls for any legal
25 conclusion.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
28 Spring of 2014 regarding the Proposed Medical Record Review Rule, but after a

1 reasonable inquiry, responds that it lacks sufficient information to admit or deny
2 whether a telephone call took place on April 8, 2014. Further, the United States
3 responds that after a reasonable inquiry, it lacks sufficient information to admit or
4 deny the remainder of this Request. Ms. Tavenner's recollection is consistent with
5 the testimony in her February 28, 2018 deposition, "That he [Larry Renfro] was
6 asking me about something that was in the proposed rule that related to chart review,
7 and giving me his ideas on what he thought it meant, and I listened to him, and then I
8 referred him to our staff."

9 **REQUEST FOR ADMISSION NO. 62:** Admit that Marilyn Tavenner told Larry
10 Renfro on April 8, 2014 that MAOs were not required to conduct Two-Way Looks
11 prior to the implementation of the Proposed Medical Record Review Rule.

12 **Objection:** The United States incorporates its General Objections and Specific
13 Objections to the Definitions and Instructions as if stated herein, including but not
14 limited to, its specific objections to the definition "MAO." The United States also
15 objects to this Request to the extent that the undefined phrase "prior to the
16 implementation" is vague and ambiguous. The United States objects to this Request
17 to the extent it calls for information that is already in UnitedHealth's possession,
18 custody, or control, or is otherwise available to UnitedHealth as it is duplicative of
19 information sought and obtained by UnitedHealth in the February 28, 2018 deposition
20 of Marilyn Tavenner. The United States additionally objects to the extent that
21 UnitedHealth is using this information to mischaracterize or misinterpret the facts.
22 The United States objects to this Request to the extent it calls for any legal
23 conclusion.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States denies this Request. Ms. Tavenner's recollection is consistent with the
26 testimony in her February 28, 2018 deposition in response to questioning seeking to
27 illicit the same information. See Tavenner Dep. at 133:8-15 (Q: At any point did you
28 tell Mr. Renfro that UnitedHealth did not have an obligation to delete diagnosis codes

1 it knew to be unsupported by the medical record? A: We did not have that level of
2 detail in the conversation. In the conversation, he was just talking about he was
3 unclear what to do with the proposed rule sitting there.”), 111:2-6 (“Q: Okay. Do
4 you recall telling him that two-way looks were not required because this proposed
5 rule was not yet in effect? A: No. I recall sending him to the staff to ask that
6 question.”), 116:14- 117: 1 (“Q: With respect to the conversation you had with Mr.
7 Renfro, if his recollection of that conversation he had with you was that you told him
8 that United was not required to delete – to look for deletions because the proposed
9 rule was not yet in effect, would he be inaccurate? A: I told that I could not make
10 that decision, that that decision would be something he would have to discuss with
11 the staff and Medicare Advantage, and I sent him to those people.”)

12 **REQUEST FOR ADMISSION NO. 63:** Admit that Larry Renfro asked Marilyn
13 Tavenner on April 8, 2014 if he should talk to anyone else at CMS to confirm that
14 MAOs were not required to perform Two Way Looks prior to the implementation of
15 the Proposed Medical Record Review Rule.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definitions of “CMS” and “MAO.” The
19 United States also objects to this Request to the extent that the undefined phrase
20 “prior to the implementation” is vague and ambiguous. The United States objects to
21 this Request to the extent it calls for information that is already in UnitedHealth’s
22 possession, custody, or control, or is otherwise available to UnitedHealth as it is
23 duplicative of information sought and obtained by UnitedHealth in the February 28,
24 2018 deposition of Marilyn Tavenner. The United States additionally objects to the
25 extent that UnitedHealth is using this information to mischaracterize or misinterpret
26 the facts. The United States objects to this Request to the extent it calls for any legal
27 conclusion.

28 **Response:** Subject to and without waiving the foregoing objections, including

1 regarding the specific date implicated, the United States denies this Request.

2 **REQUEST FOR ADMISSION NO. 64:** Admit that Marilyn Tavenner told Larry
3 Renfro on April 8, 2014 that Renfro did not need to talk to anyone else at CMS to
4 confirm that MAOs were not required to perform Two-Way Looks prior to the
5 implementation of the Proposed Medical Record Review Rule.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definitions of “CMS” and “MAO.” The
9 United States also objects to this Request to the extent that the undefined phrase
10 “prior to the implementation” is vague and ambiguous. The United States objects to
11 this Request to the extent it calls for information that is already in UnitedHealth’s
12 possession, custody, or control, or is otherwise available to UnitedHealth as it is
13 duplicative of information sought and obtained by UnitedHealth in the February 28,
14 2018 deposition of Marilyn Tavenner. The United States additionally objects to the
15 extent that UnitedHealth is using this information to mischaracterize or misinterpret
16 the facts.

17 **Response:** Subject to and without waiving the foregoing objections, the United
18 States denies this Request.

19 **REQUEST FOR ADMISSION NO. 65:** Admit that Larry Renfro told Marilyn
20 Tavenner on April 8, 2014 that UnitedHealth was concerned that other MAOs were
21 not performing Two-Way Looks.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein, including but not
24 limited to, its specific objections to the definition of “MAO.” The United States
25 objects to this Request to the extent it calls for information that is already in
26 UnitedHealth’s possession, custody, or control, or is otherwise available to
27 UnitedHealth as it is duplicative of information sought and obtained by UnitedHealth
28 in the February 28, 2018 deposition of Marilyn Tavenner. The United States

1 additionally objects to the extent that UnitedHealth is using this information to
2 mischaracterize or misinterpret the facts.

3 **Response:** Subject to and without waiving the foregoing objections, including
4 regarding the specific date implicated, the United States responds that after a
5 reasonable inquiry, it lacks sufficient information to admit or deny the Request as
6 written.

7 **REQUEST FOR ADMISSION NO. 66:** Admit that Marilyn Tavenner told Larry
8 Renfro on April 8, 2014 that UnitedHealth was not required to perform Two-Way
9 Looks for dates of service years 2012, 2013, and 2014.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein. The United States
12 further objects to this Request to extent it is duplicative of Request for Admission No.
13 62. The United States objects to this Request to the extent it calls for information that
14 is already in UnitedHealth's possession, custody, or control, or is otherwise available
15 to UnitedHealth as it is duplicative of information sought and obtained by
16 UnitedHealth in the February 28, 2018 deposition of Marilyn Tavenner. The United
17 States additionally objects to the extent that UnitedHealth is using this information to
18 mischaracterize or misinterpret the facts. The United States objects to this Request to
19 the extent it calls for any legal conclusion.

20 **Response:** Subject to and without waiving the foregoing objections, the United
21 States denies this Request.

22 **REQUEST FOR ADMISSION NO. 67:** Admit that Marilyn Tavenner spoke on
23 the phone with Larry Renfro on April 26, 2014.

24 **Objection:** The United States incorporates its General Objections and Specific
25 Objections to the Definitions and Instructions as if stated herein. The United States
26 objects to this Request to the extent it seeks information not relevant to a claim or
27 defense in this case. The United States objects to this Request to the extent it calls for
28 information that is already in UnitedHealth's possession, custody, or control, or is

1 otherwise available to UnitedHealth as it is duplicative of information sought and
2 obtained by UnitedHealth in the February 28, 2018 deposition of Marilyn Tavenner.
3 The United States additionally objects to the extent that UnitedHealth is using this
4 information to mischaracterize or misinterpret the facts.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
7 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
8 information to admit or deny whether a telephone call took place on April 26, 2014.
9 Ms. Tavenner's recollection is consistent with the testimony in her February 28, 2018
10 deposition: "I remember being approached by Larry to discuss a concern he had
11 about the process that involved a review of charts." Tavenner Dep. at 110:3-13.

12 **REQUEST FOR ADMISSION NO. 68:** Admit that Larry Renfro requested the
13 April 26, 2014 call with Marilyn Tavenner.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein. The United States
16 objects to this Request to the extent it calls for information that is already in
17 UnitedHealth's possession, custody, or control, or is otherwise available to
18 UnitedHealth as it is duplicative of information sought and obtained by UnitedHealth
19 in the February 28, 2018 deposition of Marilyn Tavenner. The United States
20 additionally objects to the extent that UnitedHealth is using this information to
21 mischaracterize or misinterpret the facts.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States admits that Larry Renfro requested a call with Marilyn Tavenner in the Spring
24 of 2014, but after a reasonable inquiry, responds that it lacks sufficient information to
25 admit or deny whether a telephone call took place on April 26, 2014. Ms. Tavenner's
26 recollection is consistent with the testimony in her February 28, 2018 deposition, "I
27 remember being approached by Larry to discuss a concern he had about the process
28 that involved a review of charts." Tavenner Dep. at 110:3-13.

1 **REQUEST FOR ADMISSION NO. 69:** Admit that no other Person from the
2 Government participated in the April 26, 2014 call between Marilyn Tavenner and
3 Larry Renfro.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definitions of “Person” and “Government.”

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
9 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
10 information to admit or deny whether a telephone call took place on April 26, 2014 or
11 whether any other person participated in the call.

12 **REQUEST FOR ADMISSION NO. 70:** Admit that Marilyn Tavenner took notes
13 during her April 26, 2014 call with Larry Renfro.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein.

16 **Response:** Subject to and without waiving the foregoing objections, the United
17 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
18 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
19 information to admit or deny whether a telephone call took place on April 26, 2014.
20 Further, after a reasonable inquiry, the United States responds that it lacks sufficient
21 information to admit or deny whether Ms. Tavenner took notes during her phone call
22 with Mr. Renfro, but can state that it was not Ms. Tavenner’s practice to take notes
23 during phone calls. To the extent the United States identifies notes taken by Ms.
24 Tavenner during the Spring 2014 phone call, it will supplement this Response.

25 **REQUEST FOR ADMISSION NO. 71:** Admit that after the April 26, 2014
26 telephone call between Marilyn Tavenner and Larry Renfro, Marilyn Tavenner took
27 notes about or otherwise memorialized the meeting in writing.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein. The United States
2 also objects to this Request to the extent that the undefined phrase “or otherwise
3 memorialized” is vague and ambiguous. For the purposes of this Request, the United
4 States defines “memorialized” as put in writing.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
7 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
8 information to admit or deny whether a telephone call took place on April 26, 2014.
9 Further, after a reasonable inquiry, the United States responds that it lacks sufficient
10 information to admit or deny whether Ms. Tavenner memorialized the call in writing
11 after the call. To the extent the United States identifies writing by Ms. Tavenner
12 regarding her call with Mr. Renfro in the Spring of 2014, it will supplement this
13 Response.

14 **REQUEST FOR ADMISSION NO. 72:** Admit that after the April 26, 2014
15 telephone call between Marilyn Tavenner and Larry Renfro, Marilyn Tavenner had
16 Communications with the Government about the call.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definition of “Government.” The United
20 States objects to this Request to the extent it seeks disclosure of information that is
21 protected from disclosure by an applicable privilege or protection, including the
22 attorney-client privilege, attorney work-product doctrine, deliberative process
23 privilege, and/or investigative files privilege. For the purposes of this Request, the
24 United States will interpret the definition of “Government” to include only CMS.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
27 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
28 information to admit or deny whether a telephone call took place on April 26, 2014.

1 The United States admits the remainder of this Request.

2 **REQUEST FOR ADMISSION NO. 73:** Admit that Marilyn Tavenner did not
3 Audio Record the April 26, 2014 call between Marilyn Tavenner and Larry Renfro.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein.

6 **Response:** Subject to and without waiving the foregoing objections, the United
7 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
8 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
9 information to admit or deny whether a telephone call took place on April 26, 2014.
10 Further, the United States admits that Ms. Tavenner was not in the habit of audio
11 recording any of her telephone calls. To the extent the United States identifies an
12 audio recording made by Ms. Tavenner of her call with Mr. Renfro in Spring 2014, it
13 will supplement this Response.

14 **REQUEST FOR ADMISSION NO. 74:** Admit that the Government did not
15 Audio Record the April 26, 2014 call between Marilyn Tavenner and Larry Renfro.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definition “Government.” The United States
19 further objects to this request because it is unduly burdensome for the United States
20 to determine the actions of all “agencies, departments, components, agents,
21 representatives, contractors, attorneys, consultants, and all other Persons acting on its
22 behalf.”

23 **Response:** Subject to and without waiving the foregoing objections, the United
24 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
25 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
26 information to admit or deny whether a telephone call took place on April 26, 2014.
27 Further, the United States admits that Ms. Tavenner was not in the habit of audio
28 recording any of her telephone calls, but after a reasonable inquiry, responds that it

1 lacks sufficient information to admit or deny this Request with respect to the entire
2 United States Government.

3 **REQUEST FOR ADMISSION NO. 75:** Admit that Marilyn Tavenner told Larry
4 Renfro on April 26, 2014 to request a meeting with CMS.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition “CMS.” The United States objects
8 to this Request to the extent it calls for information that is already in UnitedHealth’s
9 possession, custody, or control, or is otherwise available to UnitedHealth and to the
10 extent that UnitedHealth is using this information to mischaracterize or misinterpret
11 the facts.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
14 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
15 information to admit or deny whether a telephone call took place on April 26, 2014.
16 However, the United States admits that Marilyn Tavenner told Larry Renfro to
17 contact Jonathan Blum during a Spring 2014 phone call.

18 **REQUEST FOR ADMISSION NO. 76:** Admit that Larry Renfro told Marilyn
19 Tavenner on April 26, 2014 that UnitedHealth wanted to meet with CMS no later
20 than April 30, 2014.

21 **Objection:** The United States incorporates its General Objections and Specific
22 Objections to the Definitions and Instructions as if stated herein, including but not
23 limited to, its specific objections to the definition “CMS.”

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States admits that Marilyn Tavenner spoke by telephone with Larry Renfro in the
26 Spring of 2014, but after a reasonable inquiry, responds that it lacks sufficient
27 information to admit or deny whether a telephone call took place on April 26, 2014.
28 Further, after a reasonable inquiry, the United States responds that it lacks sufficient

1 information to admit or deny the remainder of this Request.

2 **REQUEST FOR ADMISSION NO. 77:** Admit that on April 27, 2014, Larry
3 Renfro informed Marilyn Tavenner that UnitedHealth wanted to schedule a meeting
4 with CMS no later than April 30, 2014.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition “CMS.” The United States objects
8 to this Request to the extent it calls for information that is already in UnitedHealth’s
9 possession, custody, or control, or is otherwise available to UnitedHealth and to the
10 extent that UnitedHealth is using this information to mischaracterize or misinterpret
11 the facts.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States denies this Request as written. However, the United States admits that on
14 April 27, 2014 Larry Renfro sent Marilyn Tavenner an email bates labeled
15 MARA1296260. The United States denies that the email bates labeled
16 MARA1296260 specifically requests a meeting, but admits that the email states
17 “Prior to submitting our attestation this Wednesday, we would like to confirm that
18 our understanding is appropriate. Based on our conversation, I believe the
19 appropriate people for this conversation would be Sean Cavanaugh and Cheri Rice.”

20 **REQUEST FOR ADMISSION NO. 78:** Admit that Marilyn Tavenner received
21 an April 27, 2014 email bates labeled MARA1296260 from Larry Renfro requesting
22 a meeting with CMS.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition “CMS.”

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States admits that Marilyn Tavenner received an email from Larry Renfro, dated
28 April 27, 2014, which is bates labeled MARA1296260. The United States denies that

1 the email bates labeled MARA1296260 specifically requests a meeting, but admits
2 that the email states “Prior to submitting our attestation this Wednesday, we would
3 like to confirm that our understanding is appropriate. Based on our conversation, I
4 believe the appropriate people for this conversation would be Sean Cavanaugh and
5 Cheri Rice.”

6 **REQUEST FOR ADMISSION NO. 79:** Admit that UnitedHealth met with CMS
7 on April 29, 2014.

8 **Objection:** The United States incorporates its General Objections and Specific
9 Objections to the Definitions and Instructions as if stated herein, including but not
10 limited to, its specific objections to the definition “CMS.” The United States objects
11 to this Request to the extent it calls for information that is already in UnitedHealth’s
12 possession, custody, or control, or is otherwise available to UnitedHealth and to the
13 extent that UnitedHealth is using this information to mischaracterize or misinterpret
14 the facts.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States admits that UnitedHealth met with certain employees of CMS on April 29,
17 2014.

18 **REQUEST FOR ADMISSION NO. 80:** Admit that CMS prepared a written
19 agenda for the April 29, 2019 meeting between CMS and UnitedHealth.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition “CMS.” The United States will
23 interpret this request as referencing a meeting on April 29, 2014 not 2019.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States denies this Request.

26 **REQUEST FOR ADMISSION NO. 81:** Admit that CMS was aware that the
27 purpose of the April 29, 2014 meeting was to discuss the Proposed Medical Record
28 Review Rule.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition “CMS.” The United States objects
4 to this Request to the extent it calls for information that is already in UnitedHealth’s
5 possession, custody, or control, or is otherwise available to UnitedHealth and to the
6 extent that UnitedHealth is using this information to mischaracterize or misinterpret
7 the facts.

8 **Response:** Subject to and without waiving the foregoing objections, the United
9 States admits that the stated purpose of the April 29, 2014 meeting was ostensibly to
10 discuss the Proposed Medical Record Review Rule.

11 **REQUEST FOR ADMISSION NO. 82:** Admit that some participants in the April
12 29, 2014 meeting participated via videoconference.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein. The United States
15 objects to this Request to the extent it seeks information not relevant to a claim or
16 defense in this case. The United States objects to this Request to the extent it calls for
17 information that is already in UnitedHealth’s possession, custody, or control, or is
18 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
19 information to mischaracterize or misinterpret the facts.

20 **Response:** Subject to and without waiving the foregoing objections, the United
21 States admits this Request.

22 **REQUEST FOR ADMISSION NO. 83:** Admit that some participants in the April
23 29, 2014 meeting participated via teleconference.

24 **Objection:** The United States incorporates its General Objections and Specific
25 Objections to the Definitions and Instructions as if stated herein. The United States
26 objects to this Request to the extent it seeks information not relevant to a claim or
27 defense in this case. The United States objects to this Request to the extent it calls for
28 information that is already in UnitedHealth’s possession, custody, or control, or is

1 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
2 information to mischaracterize or misinterpret the facts.

3 **Response:** Subject to and without waiving the foregoing objections, after a
4 reasonable inquiry, the United States responds that it lacks sufficient information to
5 admit or deny this Request.

6 **REQUEST FOR ADMISSION NO. 84:** Admit that Sean Cavanaugh attended the
7 April 29, 2014 meeting between UnitedHealth and CMS.

8 **Objection:** The United States incorporates its General Objections and Specific
9 Objections to the Definitions and Instructions as if stated herein, including but not
10 limited to, its specific objections to the definition of “CMS.” The United States
11 objects to this Request to the extent it calls for information that is already in
12 UnitedHealth’s possession, custody, or control, or is otherwise available to
13 UnitedHealth and to the extent that UnitedHealth is using this information to
14 mischaracterize or misinterpret the facts.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States admits this Request.

17 **REQUEST FOR ADMISSION NO. 85:** Admit that Cheri Rice attended the April
18 29, 2014 meeting between UnitedHealth and CMS.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “CMS.” The United States
22 objects to this Request to the extent it calls for information that is already in
23 UnitedHealth’s possession, custody, or control, or is otherwise available to
24 UnitedHealth and to the extent that UnitedHealth is using this information to
25 mischaracterize or misinterpret the facts.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States admits this Request.

28 **REQUEST FOR ADMISSION NO. 86:** Admit that Cynthia Tudor attended the

1 April 29, 2014 meeting between UnitedHealth and CMS.

2 **Objection:** The United States incorporates its General Objections and Specific
3 Objections to the Definitions and Instructions as if stated herein, including but not
4 limited to, its specific objections to the definition of “CMS.” The United States
5 objects to this Request to the extent it calls for information that is already in
6 UnitedHealth’s possession, custody, or control, or is otherwise available to
7 UnitedHealth and to the extent that UnitedHealth is using this information to
8 mischaracterize or misinterpret the facts.

9 **Response:** Subject to and without waiving the foregoing objections, the United
10 States admits this Request.

11 **REQUEST FOR ADMISSION NO. 87:** Admit that Dan Farmer attended the
12 April 29, 2014 meeting between UnitedHealth and CMS.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definition of “CMS.” The United States
16 objects to this Request to the extent it calls for information that is already in
17 UnitedHealth’s possession, custody, or control, or is otherwise available to
18 UnitedHealth and to the extent that UnitedHealth is using this information to
19 mischaracterize or misinterpret the facts.

20 **Response:** Subject to and without waiving the foregoing objections, the United
21 States admits this Request.

22 **REQUEST FOR ADMISSION NO. 88:** Admit that Julia Gerner attended the
23 April 29, 2014 meeting between UnitedHealth and CMS.

24 **Objection:** The United States incorporates its General Objections and Specific
25 Objections to the Definitions and Instructions as if stated herein, including but not
26 limited to, its specific objections to the definition of “CMS.” The United States
27 objects to this Request to the extent it calls for information that is already in
28 UnitedHealth’s possession, custody, or control, or is otherwise available to

1 UnitedHealth and to the extent that UnitedHealth is using this information to
2 mischaracterize or misinterpret the facts.

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States denies this Request.

5 **REQUEST FOR ADMISSION NO. 89:** Admit that, other than Sean Cavanaugh,
6 Cheri Rice, Cynthia Tudor, Dan Farmer, and Julia Gerner, no other person from
7 CMS or the Government attended the April 29, 2014 meeting.

8 **Objection:** The United States incorporates its General Objections and Specific
9 Objections to the Definitions and Instructions as if stated herein, including but not
10 limited to, its specific objections to the definitions of “CMS,” “Government,” and
11 “Person.” The United States objects to this Request to the extent it calls for
12 information that is already in UnitedHealth’s possession, custody, or control, or is
13 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
14 information to mischaracterize or misinterpret the facts.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States denies this Request.

17 **REQUEST FOR ADMISSION NO. 90:** Admit that Karen Erickson, Thad
18 Johnson, Steve Nelson, and Dan Schumacher attended the April 29, 2014 meeting
19 between UnitedHealth and CMS.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition of “CMS.” The United States
23 objects to this Request to the extent it calls for information that is already in
24 UnitedHealth’s possession, custody, or control, or is otherwise available to
25 UnitedHealth and to the extent that UnitedHealth is using this information to
26 mischaracterize or misinterpret the facts.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States admits this Request.

1 **REQUEST FOR ADMISSION NO. 91:** Admit that the Government Audio
2 Recorded the April 29, 2014 meeting.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein, including but not
5 limited to, its specific objections to the definition of “Government.” The United
6 States further objects to this request because it is unduly burdensome for the United
7 States to determine the actions of all “agencies, departments, components, agents,
8 representatives, contractors, attorneys, consultants, and all other Persons acting on its
9 behalf.” For the purposes of this Request, the United States will interpret the
10 definition of “Government” to include only CMS.

11 **Response:** Subject to and without waiving the foregoing objections, the United
12 States denies this Request to the extent that none of the individuals identified in
13 Request for Admission No. 89 Audio Recorded the April 29, 2014 meeting.
14 However, after a reasonable inquiry, the United States responds that it lacks sufficient
15 information to admit or deny this Request with respect to CMS or the entire United
16 States Government.

17 **REQUEST FOR ADMISSION NO. 92:** Admit that the Government Video
18 Recorded the April 29, 2014 meeting.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “Government.” The United
22 States further objects to this request because it is unduly burdensome for the United
23 States to determine the actions of all “agencies, departments, components, agents,
24 representatives, contractors, attorneys, consultants, and all other Persons acting on its
25 behalf.” For the purposes of this Request, the United States will interpret the
26 definition of “Government” to include only CMS.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States denies this Request to the extent that none of the individuals identified in

1 Request for Admission No. 89 Video Recorded the April 29, 2014 meeting.

2 However, after a reasonable inquiry, the United States responds that it lacks sufficient
3 information to admit or deny this Request with respect to CMS or the entire United
4 States Government.

5 **REQUEST FOR ADMISSION NO. 93:** Admit that the April 29, 2014 meeting
6 lasted less than one hour.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein. The United States
9 objects to this Request to the extent it seeks information not relevant to a claim or
10 defense in this case. The United States objects to this Request to the extent it calls for
11 information that is already in UnitedHealth's possession, custody, or control, or is
12 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
13 information to mischaracterize or misinterpret the facts.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States admits this Request.

16 **REQUEST FOR ADMISSION NO. 94:** Admit that Sean Cavanaugh took notes
17 during the April 29, 2014 meeting between UnitedHealth and CMS.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of "CMS."

21 **Response:** Subject to and without waiving the foregoing objections, the United
22 States denies this Request.

23 **REQUEST FOR ADMISSION NO. 95:** Admit that after the April 29, 2014
24 meeting between UnitedHealth and CMS, Sean Cavanaugh took notes about or
25 otherwise memorialized the meeting in writing.

26 **Objection:** The United States incorporates its General Objections and Specific
27 Objections to the Definitions and Instructions as if stated herein, including but not
28 limited to, its specific objections to the definition of "CMS." The United States also

1 objects to this Request to the extent that the undefined phrase “or otherwise
2 memorialized” is vague and ambiguous. For the purposes of this Request, the United
3 States defines “memorialized” as put in writing.

4 **Response:** Subject to and without waiving the foregoing objections, the United
5 States denies this Request.

6 **REQUEST FOR ADMISSION NO. 96:** Admit that after the April 29, 2014
7 meeting between UnitedHealth and CMS, Sean Cavanaugh had Communications
8 with the Government about the meeting.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein, including but not
11 limited to, its specific objections to the definitions of “CMS” and “Government.”
12 The United States objects to this Request to the extent it seeks disclosure of
13 information that is protected from disclosure by an applicable privilege or protection,
14 including the attorney-client privilege, attorney work-product doctrine, deliberative
15 process privilege, and/or investigative files privilege. For the purposes of this
16 Request, the United States will interpret the definition of “Government” to include
17 only CMS.

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States admits this Request.

20 **REQUEST FOR ADMISSION NO. 97:** Admit that Cheri Rice took notes during
21 the April 29, 2014 meeting between UnitedHealth and CMS.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein, including but not
24 limited to, its specific objections to the definition of “CMS.”

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States denies this Request.

27 **REQUEST FOR ADMISSION NO. 98:** Admit that after the April 29, 2014
28 meeting between UnitedHealth and CMS, Cheri Rice took notes about or otherwise

1 memorialized the meeting in writing.

2 **Objection:** The United States incorporates its General Objections and Specific
3 Objections to the Definitions and Instructions as if stated herein, including but not
4 limited to, its specific objections to the definition of “CMS.” The United States also
5 objects to this Request to the extent that the undefined phrase “or otherwise
6 memorialized” is vague and ambiguous. For the purposes of this Request, the United
7 States defines “memorialized” as put in writing.

8 **Response:** Subject to and without waiving the foregoing objections, the United
9 States admits this Request to the extent Ms. Rice sent Mr. Nelson a follow up email
10 to the April 29, 2014 meeting, MARA1296257. The United States otherwise denies
11 this Request.

12 **REQUEST FOR ADMISSION NO. 99:** Admit that after the April 29, 2014
13 meeting between UnitedHealth and CMS, Cheri Rice had Communications with the
14 Government about the meeting.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definitions of “CMS” and “Government.”
18 The United States objects to this Request to the extent it seeks disclosure of
19 information that is protected from disclosure by an applicable privilege or protection,
20 including the attorney-client privilege, attorney work-product doctrine, deliberative
21 process privilege, and/or investigative files privilege. For the purposes of this
22 Request, the United States will interpret the definition of “Government” to include
23 only CMS.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States admits this Request.

26 **REQUEST FOR ADMISSION NO. 100:** Admit that Cynthia Tudor took written
27 notes during the April 29, 2014 meeting between UnitedHealth and CMS.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “CMS.”

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States admits that Cynthia Tudor took informal notes during the April 29, 2014
5 meeting.

6 **REQUEST FOR ADMISSION NO. 101:** Admit that after the April 29, 2014
7 meeting between UnitedHealth and CMS, Cynthia Tudor took written notes about or
8 otherwise memorialized the meeting in writing.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein, including but not
11 limited to, its specific objections to the definition of “CMS.” The United States also
12 objects to this Request to the extent that the undefined phrase “or otherwise
13 memorialized” is vague and ambiguous. For the purposes of this Request, the United
14 States defines “memorialized” as put in writing.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States denies this Request.

17 **REQUEST FOR ADMISSION NO. 102:** Admit that after the April 29, 2014
18 meeting between UnitedHealth and CMS, Cynthia Tudor had Communications with
19 the Government about the meeting.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definitions of “CMS” and “Government.”
23 The United States objects to this Request to the extent it seeks disclosure of
24 information that is protected from disclosure by an applicable privilege or protection,
25 including the attorney-client privilege, attorney work-product doctrine, deliberative
26 process privilege, and/or investigative files privilege. For the purposes of this
27 Request, the United States will interpret the definition of “Government” to include
28 only CMS.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States responds that, after a reasonable inquiry, it lacks sufficient information to
3 admit or deny this Request

4 **REQUEST FOR ADMISSION NO. 103:** Admit that Dan Farmer took written
5 notes during the April 29, 2014 meeting between UnitedHealth and CMS.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definition of “CMS.”

9 **Response:** Subject to and without waiving the foregoing objections, the United
10 States responds that, after a reasonable inquiry, it lacks sufficient information to
11 admit or deny this Request. To the extent the United States identifies notes by Mr.
12 Farmer taken during the April 29, 2014 meeting, it will supplement this Response.

13 **REQUEST FOR ADMISSION NO. 104:** Admit that after the April 29, 2014
14 meeting between UnitedHealth and CMS, Dan Farmer took written notes about or
15 otherwise memorialized the meeting in writing.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definition of “CMS.” The United States also
19 objects to this Request to the extent that the undefined phrase “or otherwise
20 memorialized” is vague and ambiguous. For the purposes of this Request, the United
21 States defines “memorialized” as put in writing.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States responds that, after a reasonable inquiry, it lacks sufficient information to
24 admit or deny this Request. To the extent the United States identifies a writing made
25 by Mr. Farmer regarding the April 2014 meeting, it will supplement this Response.

26 **REQUEST FOR ADMISSION NO. 105:** Admit that after the April 29, 2014
27 meeting between UnitedHealth and CMS, Dan Farmer had Communications with the
28 Government about the meeting.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definitions of “CMS” and “Government.”
4 The United States objects to this Request to the extent it seeks disclosure of
5 information that is protected from disclosure by an applicable privilege or protection,
6 including the attorney-client privilege, attorney work-product doctrine, deliberative
7 process privilege, and/or investigative files privilege. For the purposes of this
8 Request, the United States will interpret the definition of “Government” to include
9 only CMS.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States responds that, after a reasonable inquiry, it lacks sufficient information to
12 admit or deny this Request.

13 **REQUEST FOR ADMISSION NO. 106:** Admit that Julia Gerner took written
14 notes during the April 29, 2014 meeting between UnitedHealth and CMS.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definition of “CMS.”

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States denies this Request.

20 **REQUEST FOR ADMISSION NO. 107:** Admit that after the April 29, 2014
21 meeting between UnitedHealth and CMS, Julia Gerner took written notes about or
22 otherwise memorialized the meeting in writing.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of “CMS.” The United States also
26 objects to this Request to the extent that the undefined phrase “or otherwise
27 memorialized” is vague and ambiguous. For the purposes of this Request, the United
28 States defines “memorialized” as put in writing.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States denies this Request.

3 **REQUEST FOR ADMISSION NO. 108:** Admit that after the April 29, 2014
4 meeting between UnitedHealth and CMS, Julia Gorner had Communications with
5 the Government about the meeting.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definitions of “CMS” and “Government.”
9 The United States objects to this Request to the extent it seeks disclosure of
10 information that is protected from disclosure by an applicable privilege or protection,
11 including the attorney-client privilege, attorney work-product doctrine, deliberative
12 process privilege, and/or investigative files privilege. For the purposes of this
13 Request, the United States will interpret the definition of “Government” to include
14 only CMS.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States denies this Request.

17 **REQUEST FOR ADMISSION NO. 109:** Admit that no one from CMS or from
18 the Government took written notes during the April 29, 2014 meeting between
19 UnitedHealth and CMS.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition of “CMS” and “Government.” The
23 United States further objects to this request because it is unduly burdensome for the
24 United States to determine the actions of all “agencies, departments, components,
25 agents, representatives, contractors, attorneys, consultants, and all other Persons
26 acting on its behalf.” For the purposes of this Request, the United States will
27 interpret the definition of “Government” to include only CMS, and will interpret
28 “CMS” to include only those individuals who attended the meeting on April 29,

1 2014. The United States objects to this Request to extent it is duplicative of Request
2 for Admission Nos. 94, 97, 100, 103 and 106.

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States denies this Request to the extent Ms. Tudor took informal notes during the
5 meeting.

6 **REQUEST FOR ADMISSION NO. 110:** Admit that after the April 29, 2014
7 meeting between UnitedHealth and CMS, no one from CMS or from the
8 Government took written notes about or otherwise memorialized the meeting in
9 writing.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definitions of “CMS” and “Government.”
13 The United States further objects to this request because it is unduly burdensome for
14 the United States to determine the actions of all “agencies, departments, components,
15 agents, representatives, contractors, attorneys, consultants, and all other Persons
16 acting on its behalf.” For the purposes of this Request, the United States will
17 interpret the definition of “Government” to include only CMS, and will interpret
18 “CMS” to include only those individuals who attended the meeting on April 29,
19 2014. The United States also objects to this Request to the extent that the undefined
20 phrase “or otherwise memorialized” is vague and ambiguous. For the purposes of
21 this Request, the United States defines “memorialized” as put in writing. The United
22 States objects to this Request to extent it is duplicative of Request for Admission
23 Nos. 95, 98, 101, 104 and 107.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States denies this Request to the extent Ms. Rice sent Mr. Nelson a follow up email to
26 the April 29, 2014 meeting, MARA1296257.

27 **REQUEST FOR ADMISSION NO. 111:** Admit that CMS indicated in the April
28 29, 2014 meeting that CMS understood prior to the meeting that UnitedHealth had

1 asked for the meeting with CMS to receive clarification regarding whether there was
2 a current requirement for MAOs to conduct Two-Way Looks when conducting Chart
3 Reviews.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition “CMS” and “MAO.” For the
7 purposes of this Request, the United States will interpret the definition of “CMS” to
8 include only those individuals who attended the meeting on April 29, 2014. The
9 United States objects to this Request to the extent it calls for information that is
10 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
11 UnitedHealth and to the extent that UnitedHealth is using this information to
12 mischaracterize or misinterpret the facts.

13 **Response:** Subject to and without waiving the foregoing objections, the United
14 States denies this Request.

15 **REQUEST FOR ADMISSION NO. 112:** Admit that UnitedHealth told CMS at
16 the April 29, 2019 meeting that UnitedHealth’s understanding was that MAOs were
17 not required to conduct Two-Way Looks when conducting Chart Reviews prior to the
18 Proposed Medical Record Review Rule taking effect.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition “CMS” and “MAO.” The United
22 States will interpret this request as referencing a meeting on April 29, 2014 not 2019.
23 For the purposes of this Request, the United States will interpret the definition of
24 “CMS” to include only those individuals who attended the meeting on April 29,
25 2014. The United States also objects to this Request to the extent that the undefined
26 phrases “Chart Review” is vague and ambiguous. The United States objects to this
27 Request to the extent it calls for information that is already in UnitedHealth’s
28 possession, custody, or control, or is otherwise available to UnitedHealth and to the

1 extent that UnitedHealth is using this information to mischaracterize or misinterpret
2 the facts. The United States objects to this Request to the extent it calls for any legal
3 conclusion.

4 **Response:** Subject to and without waiving the foregoing objections, the United
5 States admits this Request.

6 **REQUEST FOR ADMISSION NO. 113:** Admit that Steve Nelson asked CMS in
7 the April 29, 2014 meeting whether UnitedHealth had to perform Two-Way Looks
8 when conducting Chart Reviews if the Proposed Medical Record Review Rule was
9 finalized.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition “CMS.” For the purposes of this
13 Request, the United States will interpret the definition of “CMS” to include only
14 those individuals who attended the meeting on April 29, 2014. The United States
15 also objects to this Request to the extent that the undefined phrases “Chart Review” is
16 vague and ambiguous. The United States objects to this Request to the extent it calls
17 for information that is already in UnitedHealth’s possession, custody, or control, or is
18 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
19 information to mischaracterize or misinterpret the facts. The United States objects to
20 this Request to the extent it calls for any legal conclusion.

21 **Response:** Subject to and without waiving the foregoing objections, the United
22 States admits this Request.

23 **REQUEST FOR ADMISSION NO. 114:** Admit that Steve Nelson asked CMS in
24 the April 29, 2014 meeting whether UnitedHealth had an obligation to perform Two-
25 Way Looks when conducting Chart Reviews prior to the implementation of the
26 Proposed Medical Record Review Rule.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein, including but not

1 limited to, its specific objections to the definition “CMS.” For the purposes of this
2 Request, the United States will interpret the definition of “CMS” to include only
3 those individuals who attended the meeting on April 29, 2014. The United States
4 also objects to this Request to the extent that the undefined phrases “Chart Review” is
5 vague and ambiguous. The United States objects to this Request to the extent it calls
6 for information that is already in UnitedHealth’s possession, custody, or control, or is
7 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
8 information to mischaracterize or misinterpret the facts. The United States objects to
9 this Request to the extent it calls for any legal conclusion.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States admits this Request.

12 **REQUEST FOR ADMISSION NO. 115:** Admit that CMS told UnitedHealth in
13 the April 29, 2014 meeting that UnitedHealth was not required to perform Two-Way
14 Looks when conducting Chart Reviews prior to the Proposed Medical Record
15 Review Rule taking effect.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definition “CMS.” For the purposes of this
19 Request, the United States will interpret the definition of “CMS” to include only
20 those individuals who attended the meeting on April 29, 2014. The United States
21 also objects to this Request to the extent that the undefined phrases “Chart Review” is
22 vague and ambiguous. The United States objects to this Request to the extent it calls
23 for information that is already in UnitedHealth’s possession, custody, or control, or is
24 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
25 information to mischaracterize or misinterpret the facts. The United States objects to
26 this Request to the extent it calls for any legal conclusion.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States denies this Request. Further, the United States responds that on May 2, 2014,

1 Cheri Rice sent an email bates labeled MARA2157067 to Steve Nelson stating that
2 "...I would note that regardless of the effective date of the proposed requirement
3 related to medical record reviews, there are other laws that do impose standards,
4 requirements and responsibilities on MA plans in connection with the federal
5 payments they receive from CMS."

6
7
8 Dated: November 4, 2019

Respectfully submitted,

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21 /s/ Jack D. Ross
22 JACK D. ROSS
23 Assistant United States Attorney
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25
26
27
28

PROOF OF SERVICE BY ELECTRONIC MAIL

I am over the age of 18 and not a party to the action entitled U.S. ex rel. Poehling v. UnitedHealth Group, Inc., CV 16-8697 FMO (SSx). I am employed the United States Attorney's Office for the Central District of California. My business address is 300 N. Los Angeles Street, Room 7516, Los Angeles, California 90012.

On November 4, 2019, I served the foregoing UNITED STATES' RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S REQUESTS FOR ADMISSION TO THE GOVERNMENT (SET NO. TWO) on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: November 4, 2019.

Place of e-mailing: Los Angeles, California.

Person(s) and/or Entity(s) to whom e-mailed:

See attached page

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 4, 2019, at Los Angeles, California.

/s/ Jack D. Ross
JACK D. ROSS

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EXHIBIT D-10

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20 UNITED STATES DISTRICT COURT
21 FOR THE CENTRAL DISTRICT OF CALIFORNIA
22 WESTERN DIVISION

23 UNITED STATES OF AMERICA *ex*
24 *rel.* BENJAMIN POEHLING,

25 Plaintiffs,

26 v.

27 UNITEDHEALTH GROUP, INC., *et al.*,

28 Defendants.

No. CV 16-08697 MWF (SSx)

UNITED STATES' RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S REQUESTS FOR
ADMISSION TO THE GOVERNMENT
(SET NO. THREE)

PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.

RESPONDING PARTY: UNITED STATES OF AMERICA

SET NUMBER: THREE

Preliminary Statement

Pursuant to Rules 26 and 36 of the Federal Rules of Civil Procedure (“Federal Rules”) and Rule 36 of the Local Civil Rules of the United States District Court for the Central District of California, the United States of America (“United States” or “government”), through its undersigned counsel, provides these responses and objections to Defendant UHC of California’s (“UnitedHealth” or “Defendant”) Requests for Admission (Set No. Three), dated December 13, 2019 (“Third Requests”). The objections and responses set forth herein are based on information now known to the United States and its undersigned attorneys, and will be revised, corrected, supplemented, amended, and clarified to the extent required by Rule 26 as discovery proceeds.

UnitedHealth’s 104 Requests for Admission in its Third Requests are in large part duplicative of both each other and the 97 Requests for Admission in UnitedHealth’s Second Set of Requests for Admission (“Second Requests”). For example, Request Nos. 165 and 167 are *identical*, and both are duplicative of 163, multiple Requests seek identical information and differ only in minor word changes (e.g. Request Nos. 138 and 139, 140 and 141), and multiple Requests are duplicative of the Second Requests (e.g. Request Nos. 116 and 112). Given the overlap and duplication among the Second and Third Requests and that the Third Request in large part seek information already in UnitedHealth’s possession, it is apparent that the Third Request was designed to burden, harass, and annoy the United States rather than seek information to serve any legitimate purpose. Further numerous Requests seek information already in UnitedHealth’s possession (e.g. Request Nos. 144 and 145) and again appear to be served only to increase the time and resources the United

1 States must spend in responding to discovery rather than facilitate proof on issues that
2 are central to the litigation and to narrow the dispute between the parties. See Fed. R.
3 Civ. P. 36 Advisory Committee's Note.

4 **General Objections**

5 The following objections apply to each and every separately numbered Request
6 and are incorporated by reference to the extent applicable into the objection to each
7 Request.

8 1. The United States objects to the Third Requests to the extent they are vague,
9 ambiguous, overbroad, unduly burdensome, or seek to impose requirements upon the
10 United States beyond those called for or permitted by the Federal Rules of Civil
11 Procedure, the Local Civil Rules of the United States District Court for the Central
12 District of California, or any order of the Court. The United States responds below
13 pursuant to its obligations under the Federal Rules and the Local Civil Rules, namely
14 that the United States has taken and is continuing to undertake reasonable efforts to
15 identify information responsive to the Requests.

16 2. The United States objects to the Third Requests to the extent they seek the
17 disclosure of information concerning the United States' investigation of this matter as
18 well as the United States' investigation in *United States of America ex rel. Swoben v.*
19 *SCAN Health Plan, et al.*, CV 09-5013 (JEMx)), 2017 U.S. Dist. LEXIS 174308
20 (C.D. Cal. Oct. 5, 2017) ("*Swoben*"). This includes, but is not limited to, the United
21 States' investigative efforts, its assessments of facts and allegations, its deliberative
22 processes concerning actions taken regarding this matter and *Swoben*, and other
23 information generated before and after the commencement of both this litigation and
24 *Swoben*. The United States objects on the grounds that such information is
25 privileged, work product protected, not relevant to claims or defenses, and not
26 proportional to the needs of the case.

27 3. The United States objects to logging the following information withheld on the
28 basis of privilege regarding both this and the *Swoben* action: (a) communications

1 between or among attorneys at the United States Department of Justice (DOJ),
2 including, but not limited to, attorneys at DOJ's Civil Division and the United States
3 Attorneys' Offices both during the Government's pre-complaint investigation and
4 after the Government commenced action; (b) communications between or among
5 attorneys at DOJ and attorneys at the United States Department of Health & Human
6 Services (HHS) both during the Government's pre-complaint investigation and after
7 the Government commenced action; (c) communications between or among attorneys
8 at DOJ and counsel for Relator James Swoben and/or counsel for Relator Benjamin
9 Poehling during the Government's pre-complaint investigation and after the
10 Government commenced action; (d) work product or other privileged documents
11 generated by or sent to or from attorneys for DOJ, HHS, Relator James Swoben
12 and/or Relator Benjamin Poehling and any of agents or contractors for said attorneys
13 both during the Government's pre-complaint investigation and after the Government
14 commenced action. The United States asserts this objection on the grounds that such
15 effort would impose undue and extraordinary burdens on the United States, seek
16 information not relevant to the claims and defenses in this action, and be
17 disproportionate to the needs of this case.

18 4. Pursuant to Rule 36, any admissions contained herein are for purposes of the
19 present action only and shall not be taken as admissions for any other purpose,
20 including for purposes of any other case.

21 5. By making the accompanying responses and objections to Defendant's Third
22 Requests, the government does not waive, and hereby expressly reserves, its right to
23 assert any and all objections as to the admissibility of any documents, testimony, or
24 information into evidence in this action, or in any other proceedings, on any and all
25 grounds including, but not limited to, competency, relevancy, materiality, privilege,
26 or admissibility. Further, the government makes the responses and objections herein
27 without in any way implying that it considers the Third Requests to be relevant or
28 material to the subject matter of this action.

1 6. The United States objects to the below Third Requests to the extent that a
2 response to such Request requires disclosure of information protected from disclosure
3 by an applicable privilege or protection, including, but not limited to, the attorney-
4 client privilege, work product doctrine, deliberative process privilege, law
5 enforcement privilege, common interest privilege, or investigative files privilege, and
6 protections afforded by Fed. R. Civ. P. 26(b), or any other applicable privilege. The
7 United States will not respond in such a way as to disclose such protected
8 information, but inadvertent identification or disclosure of privileged information by
9 the United States shall not be a waiver of any applicable privilege. Under Federal
10 Rule of Evidence 502, Federal Rule of Civil Procedure 26(b)(5)(B), other related
11 sources of law, and the Court's order regarding inadvertent disclosure of privileged
12 information [Doc. 198], the government reserves any and all rights to claw back
13 privileged information it inadvertently discloses in response to the Requests.

14 7. The United States submits these responses subject to, without intending to
15 waive, but expressly reserving the right to object to other discovery procedures
16 involving or relating to the subject matter of the information in responses to the Third
17 Requests. The United States reserves the right to object on any ground, at any time,
18 to such other or supplemental requests as the Defendants may propound involving or
19 relating to the subject matter of these Requests.

20 8. The United States objects to the Third Requests to the extent they are based on
21 inaccurate assumptions or misstatements of fact or misconstructions of law. Nothing
22 herein is intended to concede the accuracy of the assumptions, facts, or law
23 underlying the Third Requests.

24 9. The United States reserves the right to supplement its responses to each and
25 every Request at any time, up to and including trial, as provided by the Federal Rules.

26 10. The assertion of the same, similar, or additional objections to the below Third
27 Requests does not and should not be construed to waive or modify any of the United
28 States' general objections.

11. The United States objects to the Third Requests to the extent they require the United States to draw legal conclusions, comment on the merits of any affirmative defenses, or otherwise seek to impose any requirements beyond those established by the Federal Rules or the Local Rules.

Specific Objections to the Definitions and Instructions

The United States objects to the Definitions and Instructions to the extent they (i) seek to impose burdens on the United States that are different from, inconsistent with, or exceed those imposed by the Federal Rules of Civil Procedure and the Local Civil Rules, (ii) are vague or ambiguous, and/or (iii) render the Third Requests overly broad, unduly burdensome, not proportionate to the needs of the case, and not relevant. The United States further objects to the Third Requests to the extent they use terms not defined by UnitedHealth.

Definition 2: The United States objects to the definition of “Actuarial Equivalence” to the extent that it is vague and ambiguous. Subject to and without waiving these objections, for the purposes of responding to these Requests, the United States interprets “Actuarial Equivalence” as used by Congress in 42 U.S.C. § 1395w-23(a)(1)(C)(i).

Definition 6: The United States objects to the definition of “Beneficiary” or “Member” as overly broad. Subject to and without waiving this objection, for the purposes of responding to these Requests the United States interprets these terms to mean individuals enrolled in UnitedHealth's Medicare Advantage (MA) Plans under Part C of the Medicare Program, Prescription Drug (PD) Plans under Part D of the Medicare Program, and MAPD Plans under both Parts C and D of the Medicare Program.

Definitions 10, 21, 28, and 30: The United States objects to the definition of “Government” (Definition 21) to the extent it includes any agency, department, component, agent, representative, contractor, attorney, consultant, or person acting on its behalf not relevant to this action. This definition is plainly unreasonable. Subject

1 to and without waiving these objections, the United States interprets “Government” to
2 mean CMS for purposes of the Third Requests. The United States further objects to
3 the term “Person” (Definition 30) to the extent it is defined to mean “...the federal
4 government and all departments and agencies thereof, state governments, local
5 governments, other governmental agencies....” The United States objects to the
6 definitions of “CMS” (Definition 10), “Government” (Definition 21), “OIG”
7 (Definition 28), and “Person” (Definition 30) as unduly burdensome and
8 disproportionate to the needs of the case to the extent they require the United States
9 to provide information not currently in the possession, custody, or control of CMS
10 and HHS-OIG. Furthermore, the United States objects to the extent each definition
11 includes former CMS contractors for whom the United States presently has no
12 reasonable belief they possess or control non-duplicative information relevant to any
13 claim or defense in this case.

14 **Definition 15:** The United States objects to the definition of “DOJ” as unduly
15 burdensome and disproportionate to the needs of the case to the extent that it includes
16 any agencies components, offices, representatives, contractors, attorneys, consultants, or
17 any person acting on its behalf not relevant to this action. Definition 15 is plainly
18 unreasonable.

19 **Definitions 22 and 33:** The United States objects to the definitions of “including,”
20 “relating to,” and “regarding” as rendering the Third Requests vague, ambiguous,
21 confusing, overly broad, and unduly burdensome and disproportionate to the needs of
22 the case. Indeed, these terms as defined seek any piece of information that in some
23 way – no matter how remote, indirect, or tangential – mentions or references matters
24 set forth in the Request. The United States responds to these Third Requests by using
25 these terms and the verbs constituting their definitions as limited by the constraining
26 adverb “directly.”

27 **Definition 27:** The United States also objects to the definition of “Medicare
28 Advantage Organization” and “MAO” (Definition 27) to the extent it is inconsistent

1 with the definition provided by 42 U.S.C. § 1395w-28(a)(1). For the purpose of
2 responding to the Requests, the United States shall use the definition of MA Plans
3 provided by 42 U.S.C. § 1395w-28(b)(1) and the definition of MAO provided by 42
4 U.S.C. § 1395w-28(a)(1).

5 **Definition 32:** The United States objects to the definition of “Provider” as overbroad
6 and unduly burdensome and disproportionate to the needs of the case to the extent it
7 includes entities or individuals that cannot be used to submit diagnoses for risk
8 adjustment payments.

9 **Definition 34:** The United States objects to the definition of “Risk Adjustment” to the
10 extent it is inconsistent with 42 U.S.C. § 1395w-23 and 42 C.F.R. § 422.308(c)(1).

11 **Definition 35:** The United States objects to the definition of “Risk Adjustment
12 Attestation” as overly broad to the extent this term is intended to encompass all
13 attestations required by 42 C.F.R. § 422.504(l). Subject to and without waiving this
14 objection, the United States will interpret this term to have the meaning set forth in 42
15 C.F.R. § 422.504(l)(2) (“The CEO, CFO, or an individual delegated with the
16 authority to sign on behalf of one of these officers, and who reports directly to such
17 officer, must certify (based on best knowledge, information, and belief) that the data
18 it submits under § 422.310 are accurate, complete, and truthful.”).

19 **Definition 36:** The United States objects to the definition of “State” to the extent it
20 seeks to impose burdens on the United States that are different from, inconsistent
21 with, or exceed those imposed by the Federal Rules of Civil Procedure and the Local
22 Civil Rules.

23 **Definition 40:** The United States objects to the definition of “you” and “your” to the
24 extent these terms are intend to encompass any agency, office, employee, agent,
25 representative, officer, or contractor of either the legislative or judicial branch, and
26 insofar as these terms are defined to include executive branch agencies and offices
27 not relevant to this action. This is plainly unreasonable. Subject to and without
28 waiving these objections, the United States will interpret this term to mean CMS.

1 **Instruction 3:** The United States objects to Instruction 3 as vague and construes
2 each request to include the time period from January 1, 2004 through May 16, 2017.

3 **Instructions 4:** The United States objects to Instruction 4 to the extent it seeks to
4 impose burdens upon the United States beyond those called for or permitted by the
5 Federal Rules or the Local Rules for the Central District of California. The United
6 States will respond to unobjectionable Requests or portions of Requests to the best of
7 its present ability. The United States submits these responses subject to, without
8 intending to waive, but expressly reserving the right to revise, correct, supplement or
9 clarify any of the responses herein at any time up to and including trial. Said
10 responses are at all times without prejudice subject to such additional or different
11 information that discovery or further investigation may disclose.

12 **Instruction 5:** The United States objects to Instruction 5 to the extent it seeks to
13 impose burdens upon the United States beyond those called for or permitted by the
14 Federal Rules or the Local Rules for the Central District of California.

15 **Instruction 6:** The United States objects to Instruction 6 to the extent it seeks to
16 impose burdens upon the United States beyond those called for or permitted by the
17 Federal Rules or the Local Rules for the Central District of California. The United
18 States will assert any applicable privileges and specify the material to which it applies
19 per Fed. R. Civ. P. 25(b)(5)(A) for all information responsive to a request to which
20 the United States has agreed to produce but which is withheld on the basis of a
21 privilege or protection.

Specific Objections and Responses to Requests for Admission

REQUEST FOR ADMISSION NO. 116: Admit that UnitedHealth told CMS at the April 29, 2014 Meeting that UnitedHealth's understanding was that MAOs were not required to conduct Two-Way Looks when conducting Chart Reviews prior to the Proposed Medical Record Review Rule taking effect.

Objection: The United States incorporates its General Objections and Specific Objections to the Definitions and Instructions as if stated herein, including but not limited to, its specific objections to the definitions of "CMS" and "MAO." For the purposes of responding to this Request, the United States will interpret the definition of "CMS" to include only those individuals who attended the meeting on April 29, 2014. The United States objects to this Request as duplicative of Request for Admission No. 112 from the Second Set of Requests. The United States further objects to this Request to the extent it calls for information that is already in UnitedHealth's possession, custody, or control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth is using this information to mischaracterize or misinterpret the facts. The United States objects to this Request to the extent it calls for any legal conclusion.

Response: Subject to and without waiving the foregoing objections, the United States admits this Request.

REQUEST FOR ADMISSION NO. 117: Admit that, other than Sean Cavanaugh, Cheri Rice, Cynthia Tudor, Dan Farmer, and Julie Uebersax, no other person from CMS or the Government attended the April 29, 2014 meeting.

Objection: The United States incorporates its General Objections and Specific Objections to the Definitions and Instructions as if stated herein, including but not limited to, its specific objections to the definitions of "CMS," "Government," and "Person." The United States objects to this Request to the extent it calls for information that is already in UnitedHealth's possession, custody, or control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth is using this

1 information to mischaracterize or misinterpret the facts.

2 **Response:** Subject to and without waiving the foregoing objections, the United
3 States admits this Request.

4 **REQUEST FOR ADMISSION NO. 118:** Admit that, other than Sean Cavanaugh,
5 Cheri Rice, Cynthia Tudor, and Dan Farmer, no other person from CMS or the
6 Government attended the April 29, 2014 meeting.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein, including but not
9 limited to, its specific objections to the definitions of “CMS,” “Government,” and
10 “Person.” The United States objects to this Request to the extent it calls for
11 information that is already in UnitedHealth’s possession, custody, or control, or is
12 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
13 information to mischaracterize or misinterpret the facts.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States denies this Request.

16 **REQUEST FOR ADMISSION NO. 119:** Admit that Julie Uebersax attended the
17 April 29, 2014 meeting.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein. The United States
20 objects to this Request to the extent it calls for information that is already in
21 UnitedHealth’s possession, custody, or control, or is otherwise available to
22 UnitedHealth and to the extent that UnitedHealth is using this information to
23 mischaracterize or misinterpret the facts.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States admits this Request.

26 **REQUEST FOR ADMISSION NO. 120:** Admit that UnitedHealth told CMS at
27 the April 29, 2014 Meeting that UnitedHealth had suspended its Claims Verification
28 Program.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition of “CMS.” For the purposes of
4 responding to this Request, the United States will interpret the definition of “CMS” to
5 include only those individuals who attended the meeting on April 29, 2014. The
6 United States also objects to this Request to the extent that the undefined term
7 “suspended” is vague and ambiguous. For the purposes of responding to this
8 Request, the United States defines the term “suspended” as stopped or delayed
9 temporarily. The United States objects to this Request to the extent it calls for
10 information that is already in UnitedHealth’s possession, custody, or control, or is
11 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
12 information to mischaracterize or misinterpret the facts. The United States further
13 objects to this Request to the extent it calls for any legal conclusion.

14 **Response:** Subject to and without waiving the foregoing objections, after a
15 reasonable inquiry, the United States responds that it lacks sufficient information to
16 admit or deny this Request.

17 **REQUEST FOR ADMISSION NO. 121:** Admit that UnitedHealth told CMS at
18 the April 29, 2014 Meeting that UnitedHealth had suspended its Claims Verification
19 Program based in part on UnitedHealth’s discussions with CMS in March and April
20 2014.

21 **Objection:** The United States incorporates its General Objections and Specific
22 Objections to the Definitions and Instructions as if stated herein, including but not
23 limited to, its specific objections to the definition of “CMS.” For the purposes of
24 responding to this Request, the United States will interpret the definition of “CMS” to
25 include only those individuals who attended the meeting on April 29, 2014. The
26 United States also objects to this Request to the extent that the undefined term
27 “suspended” is vague and ambiguous. For the purposes of responding to this
28 Request, the United States defines the term “suspended” as stopped or delayed

1 temporarily. The United States objects to this Request to the extent it calls for
2 information that is already in UnitedHealth's possession, custody, or control, or is
3 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
4 information to mischaracterize or misinterpret the facts. The United States further
5 objects to this Request to the extent it calls for any legal conclusion.

6 **Response:** Subject to and without waiving the foregoing objections, after a
7 reasonable inquiry, the United States responds that it lacks sufficient information to
8 admit or deny this Request.

9 **REQUEST FOR ADMISSION NO. 122:** Admit that UnitedHealth told CMS at
10 the April 29, 2014 Meeting that UnitedHealth had suspended its Claims Verification
11 Program based in part on the inherent error rate in Fee-For-Service Medicare data.

12 **Objection:** The United States incorporates its General Objections and Specific
13 Objections to the Definitions and Instructions as if stated herein, including but not
14 limited to, its specific objections to the definition of "CMS." For the purposes of
15 responding to this Request, the United States will interpret the definition of "CMS" to
16 include only those individuals who attended the meeting on April 29, 2014. The
17 United States also objects to this Request to the extent that the undefined term
18 "suspended" is vague and ambiguous. For the purposes of responding to this
19 Request, the United States defines the term "suspended" as stopped or delayed
20 temporarily. The United States objects to this Request to the extent the phrase
21 "inherent error rate" is vague and ambiguous as it is undefined and the United States
22 lacks knowledge about what is being requested. The United States objects to this
23 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
24 law to the extent it is compound in that it asks the United States to admit multiple
25 facts in one Request. The United States objects to this Request to the extent it calls
26 for information that is already in UnitedHealth's possession, custody, or control, or is
27 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
28 information to mischaracterize or misinterpret the facts. The United States further

1 objects to this Request to the extent it calls for any legal conclusion.

2 **Response:** Subject to and without waiving the foregoing objections, after a
3 reasonable inquiry, the United States responds that it lacks sufficient information to
4 admit or deny this Request.

5 **REQUEST FOR ADMISSION NO. 123:** Admit that UnitedHealth told CMS at
6 the April 29, 2014 Meeting that UnitedHealth had suspended its Claims Verification
7 Program based in part on the Proposed Medical Record Review Rule.

8 **Objection:** The United States incorporates its General Objections and Specific
9 Objections to the Definitions and Instructions as if stated herein, including but not
10 limited to, its specific objections to the definition of “CMS.” For the purposes of
11 responding to this Request, the United States will interpret the definition of “CMS” to
12 include only those individuals who attended the meeting on April 29, 2014. The
13 United States also objects to this Request to the extent that the undefined terms and
14 phrases “suspended” is vague and ambiguous. For the purposes of responding to this
15 Request, the United States defines the term “suspended” as stopped or delayed
16 temporarily. The United States objects to this Request as improper under Federal
17 Rule of Civil Procedure 36 and applicable case law to the extent it is compound in
18 that it asks the United States to admit multiple facts in one Request. The United
19 States objects to this Request to the extent it calls for information that is already in
20 UnitedHealth’s possession, custody, or control, or is otherwise available to
21 UnitedHealth and to the extent that UnitedHealth is using this information to
22 mischaracterize or misinterpret the facts. The United States further objects to this
23 Request to the extent it calls for any legal conclusion.

24 **Response:** Subject to and without waiving the foregoing objections, after a reasonable
25 inquiry, the United States responds that it lacks sufficient information to admit or deny
26 this Request.

27 **REQUEST FOR ADMISSION NO. 124:** Admit that UnitedHealth told CMS at
28 the April 29, 2014 Meeting about its Claims Verification Program.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition of “CMS.” For the purposes of
4 responding to this Request, the United States will interpret the definition of “CMS” to
5 include only those individuals who attended the meeting on April 29, 2014. The
6 United States also objects to this Request as vague and ambiguous to the extent that it
7 does not specify what UnitedHealth told CMS about its Claims Verification Program.
8 The United States further objects to this Request to the extent it calls for information
9 that is already in UnitedHealth’s possession, custody, or control, or is otherwise
10 available to UnitedHealth and to the extent that UnitedHealth is using this
11 information to mischaracterize or misinterpret the facts.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States admits that UnitedHealth brought up the topic of its internal review processes
14 during the April 29, 2014 meeting, but after a reasonable inquiry, it lacks sufficient
15 information to admit or deny the remainder of this Request.

16 **REQUEST FOR ADMISSION NO. 125:** Admit that UnitedHealth told CMS at
17 the April 29, 2014 Meeting that its Claims Verification Program included a final step,
18 which consisted of a review of Diagnosis Codes by external coding experts.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “CMS.” For the purposes of
22 responding to this Request, the United States will interpret the definition of “CMS” to
23 include only those individuals who attended the meeting on April 29, 2014. The
24 United States objects to this Request to the extent the phrase “external coding
25 experts” is vague and ambiguous as it is undefined and the United States lacks
26 knowledge about what is being requested. The United States further objects to this
27 Request to the extent it calls for information that is already in UnitedHealth’s
28 possession, custody, or control, or is otherwise available to UnitedHealth and to the

1 extent that UnitedHealth is using this information to mischaracterize or misinterpret
2 the facts.

3 **Response:** Subject to and without waiving the foregoing objections, after a
4 reasonable inquiry, the United States responds that it lacks sufficient information to
5 admit or deny this Request.

6 **REQUEST FOR ADMISSION NO. 126:** Admit that UnitedHealth told CMS at
7 the April 29, 2014 Meeting about the number of Diagnosis Codes that UnitedHealth
8 had submitted as Deletes to CMS for 2012 Dates of Service prior to the April 29,
9 2014 Meeting.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition of “CMS.” For the purposes of
13 responding to this Request, the United States will interpret the definition of “CMS” to
14 include only those individuals who attended the meeting on April 29, 2014. The
15 United States objects to this Request to the extent it calls for information that is
16 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
17 UnitedHealth and to the extent that UnitedHealth is using this information to
18 mischaracterize or misinterpret the facts.

19 **Response:** Subject to and without waiving the foregoing objections, after a
20 reasonable inquiry, the United States responds that it lacks sufficient information to
21 admit or deny this Request.

22 **REQUEST FOR ADMISSION NO. 127:** Admit that, at the April 29, 2014
23 Meeting, Cheri Rice asked UnitedHealth how many Diagnosis Codes for 2012 Dates
24 of Service had not yet gone through the entire Claims Verification Program process.

25 **Objection:** The United States incorporates its General Objections and Specific
26 Objections to the Definitions and Instructions as if stated herein. The United States
27 objects to this Request to the extent it calls for information that is already in
28 UnitedHealth’s possession, custody, or control, or is otherwise available to

1 UnitedHealth and to the extent that UnitedHealth is using this information to
2 mischaracterize or misinterpret the facts. The United States further objects to this
3 Request to the extent it is duplicative of Request for Admission No. 136.

4 **Response:** Subject to and without waiving the foregoing objections, after a
5 reasonable inquiry, the United States responds that it lacks sufficient information to
6 admit or deny this Request.

7 **REQUEST FOR ADMISSION NO. 128:** Admit that, at the April 29, 2014
8 Meeting, UnitedHealth told CMS that the number of new and unique Diagnosis
9 Codes for 2012 Dates of Service that had previously been submitted for deletion was
10 approximately 13,000.

11 **Objection:** The United States incorporates its General Objections and Specific
12 Objections to the Definitions and Instructions as if stated herein, including but not
13 limited to, its specific objections to the definition of “CMS.” For the purposes of
14 responding to this Request, the United States will interpret the definition of “CMS” to
15 include only those individuals who attended the meeting on April 29, 2014. The
16 United States also objects to this Request to the extent that the undefined term
17 “submitted for deletion” is vague and ambiguous. For the purposes of responding to
18 this Request, the United States defines “submitted for deletion” as making a Delete.
19 The United States objects to this Request to the extent the phrase “new and unique” is
20 vague and ambiguous as it is undefined and the United States lacks knowledge about
21 what is being requested. The United States objects to this Request to the extent it
22 calls for information that is already in UnitedHealth’s possession, custody, or control,
23 or is otherwise available to UnitedHealth and to the extent that UnitedHealth is using
24 this information to mischaracterize or misinterpret the facts.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States admits that informal notes taken by Cynthia Tudor during the April 29, 2014
27 meeting appear to state “claims new deleted 13K from 2012.” However, the United
28 States responds that, after a reasonable inquiry, it lacks sufficient information to

1 admit or deny the remainder of this Request.

2 **REQUEST FOR ADMISSION NO. 129:** Admit that, at the April 29, 2014
3 Meeting, UnitedHealth told CMS that the number of new and unique Diagnosis
4 Codes for 2012 Dates of Service for which the entire Claims Verification Program
5 process had been completed, but which UnitedHealth had not yet submitted as
6 Deletes, was approximately 8,000.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein, including but not
9 limited to, its specific objections to the definition “CMS.” For the purposes of this
10 Request, the United States will interpret the definition of “CMS” to include only
11 those individuals who attended the meeting on April 29, 2014. The United States
12 objects to this Request to the extent the phrase “new and unique” is vague and
13 ambiguous as it is undefined and the United States lacks knowledge about what is
14 being requested. The United States objects to this Request to the extent it calls for
15 information that is already in UnitedHealth’s possession, custody, or control, or is
16 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
17 information to mischaracterize or misinterpret the facts.

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States admits that informal notes taken by Cynthia Tudor during the April 29, 2014
20 meeting appear to state “8k – completed steps – will delete.” However, the United
21 States responds that, after a reasonable inquiry, it lacks sufficient information to
22 admit or deny the remainder of this Request.

23 **REQUEST FOR ADMISSION NO. 130:** Admit that, at the April 29, 2014
24 Meeting, UnitedHealth told CMS that approximately 8,000 Diagnosis Codes for 2012
25 Dates of Service had not been submitted as Deletes due to UnitedHealth’s suspension
26 of its Claims Verification Program.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein, including but not

1 limited to, its specific objections to the definition of “CMS.” For the purposes of
2 responding to this Request, the United States will interpret the definition of “CMS” to
3 include only those individuals who attended the meeting on April 29, 2014. The
4 United States also objects to this Request to the extent that the undefined term
5 “submitted as deletes” is vague and ambiguous. For the purposes of responding to
6 this Request, the United States defines “submitted as deletes” as making a Delete.
7 The United States also objects to this Request to the extent that the undefined term
8 “suspension” is vague and ambiguous. For the purposes of responding to this
9 Request, the United States defines the term “suspension” as the act of stopping or
10 delaying something temporarily. The United States objects to this Request to the
11 extent it calls for information that is already in UnitedHealth’s possession, custody, or
12 control, or is otherwise available to UnitedHealth and to the extent that UnitedHealth
13 is using this information to mischaracterize or misinterpret the facts.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States admits that informal notes taken by Cynthia Tudor during the April 29, 2014
16 meeting appear to state “8k – completed steps – will delete.” However, the United
17 States responds that, after a reasonable inquiry, it lacks sufficient information to
18 admit or deny the remainder of this Request.

19 **REQUEST FOR ADMISSION NO. 131:** Admit that, at the April 29, 2014
20 Meeting, UnitedHealth told CMS that UnitedHealth estimated that approximately
21 40,000 Diagnosis Codes might be deleted if UnitedHealth were to complete its
22 Claims Verification Program for 2012 Dates of Service.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of “CMS.” For the purposes of
26 responding to this Request, the United States will interpret the definition of “CMS” to
27 include only those individuals who attended the meeting on April 29, 2014. The
28 United States also objects to this Request to the extent that the undefined terms and

1 phrases “might be deleted” and “complete” are vague and ambiguous and the United
2 States lacks knowledge of what is being requested. The United States objects to this
3 Request to the extent it calls for information that is already in UnitedHealth’s
4 possession, custody, or control, or is otherwise available to UnitedHealth and to the
5 extent that UnitedHealth is using this information to mischaracterize or misinterpret
6 the facts.

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States admits that informal notes taken by Cynthia Tudor during the April 29, 2014
9 meeting appear to state “universe in progress 41k – various stages – not finalized.”
10 However, the United States responds that, after a reasonable inquiry, it lacks
11 sufficient information to admit or deny the remainder of this Request.

12 **REQUEST FOR ADMISSION NO. 132:** Admit that, at the April 29, 2014
13 Meeting, UnitedHealth told CMS that the quality assurance process for Chart Review
14 was different from UnitedHealth’s Claims Verification Program.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definition of “CMS.” For the purposes of
18 responding to this Request, the United States will interpret the definition of “CMS” to
19 include only those individuals who attended the meeting on April 29, 2014. The
20 United States also objects to this Request to the extent that the undefined phrase
21 “quality assurance process” is vague and ambiguous and the United States lacks
22 knowledge about what is being requested. The United States objects to this Request
23 to the extent it calls for information that is already in UnitedHealth’s possession,
24 custody, or control, or is otherwise available to UnitedHealth and to the extent that
25 UnitedHealth is using this information to mischaracterize or misinterpret the facts.

26 **Response:** Subject to and without waiving the foregoing objections, after a
27 reasonable inquiry, the United States responds that it lacks sufficient information to
28 admit or deny this Request.

1 **REQUEST FOR ADMISSION NO. 133:** Admit that, at the April 29, 2014
2 Meeting, UnitedHealth told CMS that UnitedHealth's Claims Verification Program
3 was a review of certain Beneficiaries' Charts to identify whether any Diagnosis
4 Codes previously submitted to CMS required submission as Deletes.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of "CMS." For the purposes of
8 responding to this Request, the United States will interpret the definition of "CMS" to
9 include only those individuals who attended the meeting on April 29, 2014. The
10 United States further objects to this Request to the extent it calls for information that
11 is already in UnitedHealth's possession, custody, or control, or is otherwise available
12 to UnitedHealth and to the extent that UnitedHealth is using this information to
13 mischaracterize or misinterpret the facts. The United States also objects to this
14 Request to the extent it is duplicative of Request for Admission No. 134.

15 **Response:** Subject to and without waiving the foregoing objections, after a
16 reasonable inquiry, the United States responds that it lacks sufficient information to
17 admit or deny this Request.

18 **REQUEST FOR ADMISSION NO. 134:** Admit that, at the April 29, 2014
19 Meeting, UnitedHealth told CMS that UnitedHealth's Claims Verification Program
20 was a process to identify whether any Diagnosis Codes previously submitted to CMS
21 required submission as Deletes.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein, including but not
24 limited to, its specific objections to the definition of "CMS." For the purposes of
25 responding to this Request, the United States will interpret the definition of "CMS" to
26 include only those individuals who attended the meeting on April 29, 2014. The
27 United States also objects to this Request to the extent that the undefined term
28 "submission as Deletes" is vague and ambiguous. For the purposes of responding to

1 this Request, the United States defines “submission as Deletes” as making a Delete.
2 The United States objects to this Request to the extent it calls for information that is
3 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
4 UnitedHealth and to the extent that UnitedHealth is using this information to
5 mischaracterize or misinterpret the facts. The United States also objects to this
6 Request to the extent it is duplicative of Request for Admission No. 133.

7 **Response:** Subject to and without waiving the foregoing objections, after a
8 reasonable inquiry, the United States responds that it lacks sufficient information to
9 admit or deny this Request.

10 **REQUEST FOR ADMISSION NO. 135:** Admit that, at the April 29, 2014
11 Meeting, UnitedHealth told CMS that the Chart Review quality assurance process
12 focused on reviewing Diagnosis Codes identified during Chart Review.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definition of “CMS.” For the purposes of
16 responding to this Request, the United States will interpret the definition of “CMS” to
17 include only those individuals who attended the meeting on April 29, 2014. The
18 United States also objects to this Request to the extent that the undefined phrase
19 “quality assurance process” is vague and ambiguous and the United States lacks
20 knowledge about what is being requested. The United States objects to this Request
21 to the extent it calls for information that is already in UnitedHealth’s possession,
22 custody, or control, or is otherwise available to UnitedHealth and to the extent that
23 UnitedHealth is using this information to mischaracterize or misinterpret the facts.

24 **Response:** Subject to and without waiving the foregoing objections, after a
25 reasonable inquiry, the United States responds that it lacks sufficient information to
26 admit or deny this Request.

27 **REQUEST FOR ADMISSION NO. 136:** Admit that, at the April 29, 2014
28 Meeting, Cheri Rice asked UnitedHealth how many Diagnosis Codes for 2012 Dates

1 of Service UnitedHealth had not yet completed review of in its Claims Verification
2 Program.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein. The United States
5 objects to this Request to the extent it calls for information that is already in
6 UnitedHealth's possession, custody, or control, or is otherwise available to
7 UnitedHealth and to the extent that UnitedHealth is using this information to
8 mischaracterize or misinterpret the facts. The United States further objects to this
9 Request to the extent it is duplicative of Request for Admission No. 127.

10 **Response:** Subject to and without waiving the foregoing objections, after a
11 reasonable inquiry, the United States responds that it lacks sufficient information to
12 admit or deny this Request.

13 **REQUEST FOR ADMISSION NO. 137:** Admit that UnitedHealth told CMS at
14 the April 29, 2014 Meeting that UnitedHealth had suspended UnitedHealth's Claims
15 Verification Program pending UnitedHealth's decision regarding whether to no
16 longer continue its Claims Verification Program.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definition of "CMS." For the purposes of
20 responding to this Request, the United States will interpret the definition of "CMS" to
21 include only those individuals who attended the meeting on April 29, 2014. The
22 United States also objects to this Request to the extent that the undefined term
23 "suspended" is vague and ambiguous. For the purposes of responding to this
24 Request, the United States defines the term "suspended" as stopped or delayed
25 temporarily. The United States objects to this Request as improper under Federal
26 Rule of Civil Procedure 36 and applicable case law to the extent it is compound in
27 that it asks the United States to admit multiple facts in one Request. The United
28 States objects to this Request to the extent it calls for information that is already in

1 UnitedHealth's possession, custody, or control, or is otherwise available to
2 UnitedHealth and to the extent that UnitedHealth is using this information to
3 mischaracterize or misinterpret the facts. The United States further objects to this
4 Request to the extent it calls for any legal conclusion.

5 **Response:** Subject to and without waiving the foregoing objections, after a
6 reasonable inquiry, the United States responds that it lacks sufficient information to
7 admit or deny this Request.

8 **REQUEST FOR ADMISSION NO. 138:** Admit that, at the April 29, 2014
9 Meeting, Cheri Rice told UnitedHealth that MAOs do not have to confirm whether
10 Diagnosis Codes submitted by Providers are supported by a Beneficiaries' Chart.

11 **Objection:** The United States incorporates its General Objections and Specific
12 Objections to the Definitions and Instructions as if stated herein, including but not
13 limited to, its specific objections to the definition of "MAO." The United States also
14 objects to this Request to the extent that the undefined term "confirm" is vague and
15 ambiguous. For the purposes of responding to this request, the United States defines
16 "confirm" as establishing the truth or accuracy of something. The United States
17 objects to this Request to the extent it calls for information that is already in
18 UnitedHealth's possession, custody, or control, or is otherwise available to
19 UnitedHealth and to the extent that UnitedHealth is using this information to
20 mischaracterize or misinterpret the facts. The United States further objects to this
21 Request to the extent it calls for any legal conclusion.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States denies this Request.

24 **REQUEST FOR ADMISSION NO. 139:** Admit that, at the April 29, 2014
25 Meeting, Cheri Rice told UnitedHealth that UnitedHealth does not need to confirm
26 whether Diagnosis Codes submitted by Providers are supported by a Beneficiaries'
27 Chart.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein. The United States
2 also objects to this Request to the extent that the undefined term “confirm” is vague
3 and ambiguous. For the purposes of responding to this request, the United States
4 defines “confirm” as establishing the truth or accuracy of something. The United
5 States objects to this Request to the extent it calls for information that is already in
6 UnitedHealth’s possession, custody, or control, or is otherwise available to
7 UnitedHealth and to the extent that UnitedHealth is using this information to
8 mischaracterize or misinterpret the facts. The United States further objects to this
9 Request to the extent it calls for any legal conclusion. The United States objects to
10 this Request as duplicative of Request No. 138.

11 **Response:** Subject to and without waiving the foregoing objections, the United
12 States denies this Request.

13 **REQUEST FOR ADMISSION NO. 140:** Admit that, at the April 29, 2014
14 Meeting, Sean Cavanaugh told UnitedHealth that if an MAO does not have
15 Knowledge that a Diagnosis Code is not documented in a Beneficiary’s Chart, the
16 MAO does not need to submit that Diagnosis Code to CMS as a Delete.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definitions of “CMS” and “MAO.” The
20 United States objects to this Request to the extent it calls for information that is
21 already in UnitedHealth’s possession, custody, or control, or is otherwise available to
22 UnitedHealth and to the extent that UnitedHealth is using this information to
23 mischaracterize or misinterpret the facts. The United States further objects to this
24 Request to the extent it calls for any legal conclusion.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States denies this Request.

27 **REQUEST FOR ADMISSION NO. 141:** Admit that, at the April 29, 2014
28 Meeting, Sean Cavanaugh told UnitedHealth that if UnitedHealth does not have

1 Knowledge that Diagnosis Codes are not documented in a Beneficiary's Chart,
2 UnitedHealth would not need to submit those Diagnosis Codes to CMS as Deletes.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein, including but not
5 limited to, its specific objections to the definitions of "CMS." The United States
6 objects to this Request to the extent it calls for information that is already in
7 UnitedHealth's possession, custody, or control, or is otherwise available to
8 UnitedHealth and to the extent that UnitedHealth is using this information to
9 mischaracterize or misinterpret the facts. The United States further objects to this
10 Request to the extent it calls for any legal conclusion. The United States objects to
11 this Request as duplicative of Request No. 140.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States denies this Request.

14 **REQUEST FOR ADMISSION NO. 142:** Admit that, at the April 29, 2014
15 Meeting, Cheri Rice told UnitedHealth that if an MAO does not have Knowledge that
16 a Diagnosis Code is not documented in a Beneficiary's Chart, then the MAO has not
17 received an Overpayment.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of "MAO." The United States
21 objects to this Request to the extent it calls for information that is already in
22 UnitedHealth's possession, custody, or control, or is otherwise available to
23 UnitedHealth and to the extent that UnitedHealth is using this information to
24 mischaracterize or misinterpret the facts. The United States further objects to this
25 Request to the extent it calls for any legal conclusion.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States denies this Request.

1 **REQUEST FOR ADMISSION NO. 143:** Admit that, at the April 29, 2014
2 Meeting, Cheri Rice told UnitedHealth that if UnitedHealth does not have Knowledge
3 that a Diagnosis Code is not documented in a Beneficiary's Chart, then UnitedHealth
4 has not received an Overpayment.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein. The United States
7 objects to this Request to the extent it calls for information that is already in
8 UnitedHealth's possession, custody, or control, or is otherwise available to
9 UnitedHealth and to the extent that UnitedHealth is using this information to
10 mischaracterize or misinterpret the facts. The United States further objects to this
11 Request to the extent it calls for any legal conclusion. The United States objects to
12 this Request as duplicative of Request No. 142.

13 **Response:** Subject to and without waiving the foregoing objections, the United
14 States denies this Request.

15 **REQUEST FOR ADMISSION NO. 144:** Admit that UnitedHealth submitted a
16 Risk Adjustment Attestation to CMS on April 30, 2014.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definition of "CMS." The United States
20 objects to this Request to the extent it calls for information that is already in
21 UnitedHealth's possession, custody, or control, or is otherwise available to
22 UnitedHealth and to the extent that UnitedHealth is using this information to
23 mischaracterize or misinterpret the facts. The United States further objects to this
24 Request to the extent it calls for any legal conclusion.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States admits this Request.

27 **REQUEST FOR ADMISSION NO. 145:** Admit that UnitedHealth submitted its
28 Risk Adjustment Attestation to CMS on April 30, 2014 electronically.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition of “CMS.” The United States
4 objects to this Request to the extent it seeks information not relevant to a claim or
5 defense in this case. The United States objects to this Request to the extent it calls for
6 information that is already in UnitedHealth’s possession, custody, or control, or is
7 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
8 information to mischaracterize or misinterpret the facts. The United States further
9 objects to this Request to the extent it calls for any legal conclusion.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States admits this Request.

12 **REQUEST FOR ADMISSION NO. 146:** Admit that on April 30, 2014,
13 UnitedHealth informed CMS that UnitedHealth would not Delete Diagnosis Codes
14 that had not completed all steps in its Claims Verification Program at the time that
15 UnitedHealth suspended its Claims Verification Program.

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definition of “CMS.” The United States also
19 objects to this Request to the extent that the undefined term “suspended” is vague and
20 ambiguous. For the purposes of responding to this Request, the United States defines
21 the term “suspended” as stopped or delayed temporarily. The United States objects to
22 this Request to the extent it calls for information that is already in UnitedHealth’s
23 possession, custody, or control, or is otherwise available to UnitedHealth and to the
24 extent that UnitedHealth is using this information to mischaracterize or misinterpret
25 the facts. The United States further objects to this Request to the extent it calls for
26 any legal conclusion.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States admits that Steve Nelson sent an email dated April 30, 2014, MARA1296257,

1 which stated:

2 We currently have a process through which we review certain medical records
3 to determine the accuracy of risk adjustment diagnoses and submit appropriate
4 deletes. This process already has resulted in the identification of and, in some
5 instances, the submission of deletes for 2012 dates of service. But based on the
6 proposed rule, including the preamble, and recent conversations with CMS, we
7 suspended that process for 2012 dates of service while we consider whether to
8 make changes. Pursuant to our discussion, however, we will soon submit for
9 deletion those diagnosis codes that have undergone a complete review and that
10 we have therefore identified as appropriate deletes. In the near future, we will
11 determine whether to continue our review process for the diagnosis codes
12 which were still under review at the time we suspended our process. In the
13 meantime, we will not delete these codes.

14 The United States denies the remainder of this Request.

15 **REQUEST FOR ADMISSION NO. 147:** Admit that on June 26, 2015,
16 UnitedHealth notified CMS that UnitedHealth terminated its Claims Verification
17 Program.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of “CMS.” The United States also
21 objects to this Request to the extent that the undefined term “terminated” is vague and
22 ambiguous. For the purposes of responding to this Request, the United States defines
23 the term “terminated” as caused something to end. The United States objects to this
24 Request to the extent it calls for information that is already in UnitedHealth’s
25 possession, custody, or control, or is otherwise available to UnitedHealth and to the
26 extent that UnitedHealth is using this information to mischaracterize or misinterpret
27 the facts. The United States further objects to this Request to the extent it calls for
28 any legal conclusion.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States admits that Steve Nelson sent an email dated June 26, 2015 to Cheri Rice,
3 MAPL000787445, which stated:

4 As we discussed last year, we previously had a process through which we
5 reviewed certain medical records to determine the accuracy of risk adjustment
6 diagnoses and submitted appropriate deletes. Based on our conversations with
7 CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing
8 consideration of a FFS Adjuster to address diagnoses not supported by a
9 medical record in the context of RADV, we ended this process and informed
10 you of that decision. That decision remains operative for 2013 dates of service.
11 In particular, we did not use our previous process to determine whether
12 diagnosis codes submitted through claims are unsupported in the medical
13 record. We do have a quality assurance process that deletes codes initially
14 identified during chart review and that are later determined to be unsupported.

15 The United States denies the remainder of this Request.

16 **REQUEST FOR ADMISSION NO. 148:** Admit that UnitedHealth did not tell
17 CMS that it was conducting Two-Way Looks when it submitted its MA Part C
18 Supporting Documentation for CY2015 Bid in 2014.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of "CMS." The United States
22 objects to this Request to the extent it calls for information that is already in
23 UnitedHealth's possession, custody, or control, or is otherwise available to
24 UnitedHealth and to the extent that UnitedHealth is using this information to
25 mischaracterize or misinterpret the facts. The United States further objects to this
26 Request to the extent it calls for any legal conclusion.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States responds that UnitedHealth's Bid dated June 2, 2014, USBP000674257, stated:

1 We also adjusted projected risk scores to account for changes in our medical
2 record review processes. Specifically, based on multiple conversations with
3 CMS and CMS's treatment of medical record review in its recent rulemaking
4 process, the health plan has decided to cease one of its prior processes that
5 identified and deleted certain diagnoses codes through the medical record
6 review process.

7 Subject to and without waiving the foregoing objections, after a reasonable inquiry,
8 the United States responds that it lacks sufficient information to admit or deny the
9 remainder of this Request.

10 **REQUEST FOR ADMISSION NO. 149:** Admit that UnitedHealth told CMS it
11 was not conducting Two-Way Looks when it submitted its MA Part C Supporting
12 Documentation for CY2016 Bid in 2015.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definition of "CMS." The United States
16 objects to this Request to the extent it calls for information that is already in
17 UnitedHealth's possession, custody, or control, or is otherwise available to
18 UnitedHealth and to the extent that UnitedHealth is using this information to
19 mischaracterize or misinterpret the facts. The United States further objects to this
20 Request to the extent it calls for any legal conclusion.

21 **Response:** Subject to and without waiving the foregoing objections, after a
22 reasonable inquiry, the United States responds that it lacks sufficient information to
23 admit or deny this Request.

24 **REQUEST FOR ADMISSION NO. 150:** Admit that UnitedHealth told CMS it
25 was not conducting Two-Way Looks when it submitted its MA Part C Supporting
26 Documentation for CY2017 Bid in 2016.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein, including but not

1 limited to, its specific objections to the definition of “CMS.” The United States
2 objects to this Request to the extent it calls for information that is already in
3 UnitedHealth’s possession, custody, or control, or is otherwise available to
4 UnitedHealth and to the extent that UnitedHealth is using this information to
5 mischaracterize or misinterpret the facts. The United States further objects to this
6 Request to the extent it calls for any legal conclusion.

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States admits that UnitedHealth’s Bid dated August 4, 2016, MAPL002840316,
9 stated:

10 In addition, prior to 2014, the health plan had a process of identifying and
11 deleting certain diagnosis codes through the medical record review process.
12 Based on multiple conversations with CMS in 2014 and CMS's treatment of
13 medical record review in its 2014 rulemaking process, the health plan ceased
14 this process in 2014. As a result, we will not reduce projected risk scores to
15 account for our previous process.

16 The United States denies the remainder of this Request.

17 **REQUEST FOR ADMISSION NO. 151:** Admit that Cheri Rice read Steve
18 Nelson’s April 30, 2014 Email.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein. The United States
21 further objects to this Request as vague, ambiguous, overly broad, and unduly
22 burdensome to the extent that it is not limited to a specific period of time. The United
23 States objects to this Request to the extent that UnitedHealth is using this information
24 to mischaracterize or misinterpret the facts. The United States further objects to this
25 Request to the extent it calls for any legal conclusion. The United States further
26 objects to this Request to the extent it is duplicative of Request for Admission Nos.
27 152 and 153.

28 **Response:** Subject to and without waiving the foregoing objections, the United

1 States admits this Request.

2 **REQUEST FOR ADMISSION NO. 152:** Admit that Cheri Rice read Steve
3 Nelson's April 30, 2014 Email on or before May 2, 2014.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein. The United States
6 objects to this Request to the extent that UnitedHealth is using this information to
7 mischaracterize or misinterpret the facts. The United States further objects to this
8 Request to the extent it calls for any legal conclusion. The United States further
9 objects to this Request to the extent it is duplicative of Request for Admission Nos.
10 151 and 153.

11 **Response:** Subject to and without waiving the foregoing objections, the United
12 States admits this Request.

13 **REQUEST FOR ADMISSION NO. 153:** Admit that Cheri Rice read Steve
14 Nelson's April 30, 2014 Email in its entirety on or before May 2, 2014.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein. The United States
17 objects to this Request to the extent that UnitedHealth is using this information to
18 mischaracterize or misinterpret the facts. The United States further objects to this
19 Request to the extent it calls for any legal conclusion. The United States further
20 objects to this Request to the extent it is duplicative of Request for Admission Nos.
21 151 and 152.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States admits this Request.

24 **REQUEST FOR ADMISSION NO. 154:** Admit that Cheri Rice read in Steve
25 Nelson's April 30, 2014 Email that UnitedHealth had suspended its Claims
26 Verification Program.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein. The United States

1 also objects to this Request to the extent that the undefined term “suspended” is
2 vague and ambiguous. For the purposes of responding to this Request, the United
3 States defines the term “suspended” as stopped or delayed temporarily. The United
4 States further objects to this Request as vague, ambiguous, overly broad, and unduly
5 burdensome to the extent that it is not limited to a specific period of time. The United
6 States objects to this Request to the extent that UnitedHealth is using this information
7 to mischaracterize or misinterpret the facts. The United States objects to this Request
8 as improper under Federal Rule of Civil Procedure 36 and applicable case law to the
9 extent it is compound in that it asks the United States to admit multiple facts in one
10 Request. The United States further objects to this Request to the extent it calls for
11 any legal conclusion.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States admits that Cheri Rice read Steve Nelson’s April 30, 2014 email and that the
14 email stated “We currently have a process through which we review certain medical
15 records to determine the accuracy of risk adjustment diagnoses and submit
16 appropriate deletes. ...we suspended that process for 2012 dates of services while
17 we consider whether to make changes.” However, the United States denies the
18 remainder of this Request.

19 **REQUEST FOR ADMISSION NO. 155:** Admit that Cheri Rice read in Steve
20 Nelson’s April 30, 2014 Email that UnitedHealth understood that MAOs were not
21 required to conduct Two-Way Looks.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein, including but not
24 limited to, its specific objections to the definition of “MAO.” The United States also
25 objects to this Request to the extent that the undefined terms “understood” is vague
26 and ambiguous. For purposes of this Request, the United States defines “understood”
27 as “grasped the meaning of.” The United States further objects to this Request as
28 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not

1 limited to a specific period of time. The United States objects to this Request to the
2 extent that UnitedHealth is using this information to mischaracterize or misinterpret
3 the facts. The United States objects to this Request as improper under Federal Rule
4 of Civil Procedure 36 and applicable case law to the extent it is compound in that it
5 asks the United States to admit multiple facts in one Request. The United States
6 objects to this Request to the extent it calls for any legal conclusion.

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States admits that Cheri Rice read Steve Nelson's April 30, 2014 email and that the
9 email stated "Fifth, as we discussed yesterday, CMS recently issued a proposed rule
10 that would, if finalized, require MA plans to design any medical record reviews to
11 determine the accuracy of risk adjustment diagnoses associated with those records.
12 During our conversation yesterday and other recent conversations, CMS confirmed to
13 us that these requirements do not apply until the effective date of the rule, and that
14 MA plans are thus not currently required to design their medical record reviews to
15 determine the accuracy of risk adjustment diagnoses." The United States denies the
16 remainder of this Request.

17 **REQUEST FOR ADMISSION NO. 156:** Admit that after Cheri Rice received
18 Steve Nelson's April 30, 2014 Email, Cheri Rice had Communications with one or
19 more individuals at CMS about the April 30, 2014 Email.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition of "CMS." The United States
23 objects to this Request to the extent it seeks disclosure of information that is protected
24 from disclosure by an applicable privilege or protection, including the attorney-client
25 privilege, attorney work-product doctrine, deliberative process privilege, and/or
26 investigative files privilege. The United States further objects to this Request as
27 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
28 limited to a specific period of time. The United States objects to this Request to the

1 extent that UnitedHealth is using this information to mischaracterize or misinterpret
2 the facts. The United States objects to this Request as improper under Federal Rule
3 of Civil Procedure 36 and applicable case law to the extent it is compound in that it
4 asks the United States to admit multiple facts in one Request.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States admits this Request.

7 **REQUEST FOR ADMISSION NO. 157:** Admit that after Cheri Rice received
8 Steve Nelson's April 30, 2014 Email, Cheri Rice had Communications with DOJ
9 about the April 30, 2014 Email.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objection to the definition of "DOJ." The United States objects
13 to this Request as an improper abuse of Federal Rule of Civil Procedure 36 because
14 by its own terms it specifically seeks disclosure of information that is protected from
15 disclosure by the attorney-client privilege. The United States further objects to this
16 Request as vague, ambiguous, overly broad, and unduly burdensome to the extent
17 that it is not limited to a specific period of time. The United States objects to this
18 Request to the extent that UnitedHealth is using this information to mischaracterize or
19 misinterpret the facts. The United States objects to this Request as improper under
20 Federal Rule of Civil Procedure 36 and applicable case law to the extent it is
21 compound in that it asks the United States to admit multiple facts in one Request.

22 **Response:** Subject to the foregoing objections, the United States does not intend to
23 respond to this Request because responsive information, if any, is protected by the
24 attorney-client privilege.

25 **REQUEST FOR ADMISSION NO. 158:** Admit that after Cheri Rice received
26 Steve Nelson's April 30, 2014 Email, Cheri Rice had Communications with OIG
27 about the April 30, 2014 Email.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “OIG.” The United States
3 further objects to this Request as vague, ambiguous, overly broad, and unduly
4 burdensome to the extent that it is not limited to a specific period of time. The United
5 States objects to this Request to the extent that UnitedHealth is using this information
6 to mischaracterize or misinterpret the facts. The United States objects to this Request
7 as improper under Federal Rule of Civil Procedure 36 and applicable case law to the
8 extent it is compound in that it asks the United States to admit multiple facts in one
9 Request.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States denies this Request.

12 **REQUEST FOR ADMISSION NO. 159:** Admit that Cheri Rice took notes
13 regarding her Communications with one or more individuals at CMS related to Steve
14 Nelson’s April 30, 2014 Email, including such notes before, during, and/or after the
15 Communication(s).

16 **Objection:** The United States incorporates its General Objections and Specific
17 Objections to the Definitions and Instructions as if stated herein, including but not
18 limited to, its specific objections to the definition of “CMS.” The United States
19 objects to this Request to the extent it seeks disclosure of information that is protected
20 from disclosure by an applicable privilege or protection, including the attorney-client
21 privilege, attorney work-product doctrine, deliberative process privilege, and/or
22 investigative files privilege. The United States further objects to this Request as
23 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
24 limited to a specific period of time. The United States objects to this Request to the
25 extent that UnitedHealth is using this information to mischaracterize or misinterpret
26 the facts.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States denies this Request.

1 **REQUEST FOR ADMISSION NO. 160:** Admit that Cheri Rice took notes
2 regarding her Communications with DOJ related to Steve Nelson's April 30, 2014
3 Email, including such notes before, during, and/or after the Communication(s).

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition of "DOJ." The United States
7 objects to this Request as an improper abuse of Federal Rule of Civil Procedure 36
8 because by its own terms it specifically seeks disclosure of information that is
9 protected from disclosure by the attorney-client privilege. The United States further
10 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
11 the extent that it is not limited to a specific period of time.

12 **Response:** Subject to the foregoing objections, the United States does not intend to
13 respond to this Request because responsive information, if any, is protected by the
14 attorney-client privilege.

15 **REQUEST FOR ADMISSION NO. 161:** Admit that Cheri Rice took notes
16 regarding her Communications with OIG related to Steve Nelson's April 30, 2014
17 Email, including such notes before, during, and/or after the Communication(s).

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of "OIG." The United States
21 further objects to this Request as vague, ambiguous, overly broad, and unduly
22 burdensome to the extent that it is not limited to a specific period of time. The United
23 States objects to this Request to the extent that UnitedHealth is using this information
24 to mischaracterize or misinterpret the facts.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States denies this Request.

1 **REQUEST FOR ADMISSION NO. 162:** Admit that Cheri Rice provided some or
2 all of the content of Steve Nelson's April 30, 2014 Email to one or more individuals
3 at CMS.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition of "CMS." The United States
7 objects to this Request to the extent it seeks disclosure of information that is protected
8 from disclosure by an applicable privilege or protection, including the attorney-client
9 privilege, attorney work-product doctrine, deliberative process privilege, and/or
10 investigative files privilege. The United States further objects to this Request as
11 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
12 limited to a specific period of time. The United States objects to this Request to the
13 extent that UnitedHealth is using this information to mischaracterize or misinterpret
14 the facts. The United States objects to this Request to the extent it calls for any legal
15 conclusion. The United States objects to this Request to extent it is duplicative of
16 Request for Admission No. 166.

17 **Response:** Subject to and without waiving the foregoing objections, the United
18 States admits this Request.

19 **REQUEST FOR ADMISSION NO. 163:** Admit that Cheri Rice provided some or
20 all of the content of Steve Nelson's April 30, 2014 Email to DOJ.

21 **Objection:** The United States incorporates its General Objections and Specific
22 Objections to the Definitions and Instructions as if stated herein, including but not
23 limited to, its specific objections to the definition of "DOJ." The United States
24 objects to this Request as an improper abuse of Federal Rule of Civil Procedure 36
25 because by its own terms it specifically seeks disclosure of information that is
26 protected from disclosure by the attorney-client privilege. The United States further
27 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
28 the extent that it is not limited to a specific period of time. The United States objects

1 to this Request to the extent that UnitedHealth is using this information to
2 mischaracterize or misinterpret the facts. The United States objects to this Request to
3 the extent it calls for any legal conclusion. The United States objects to this Request
4 to extent it is duplicative of Request for Admission Nos. 165 and 167.

5 **Response:** Subject to the foregoing objections, the United States does not intend to
6 respond to this Request because responsive information, if any, is protected by the
7 attorney-client privilege.

8 **REQUEST FOR ADMISSION NO. 164:** Admit that Cheri Rice provided some or
9 all of the content of Steve Nelson's April 30, 2014 Email to OIG.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition of "OIG." The United States
13 further objects to this Request as vague, ambiguous, overly broad, and unduly
14 burdensome to the extent that it is not limited to a specific period of time. The United
15 States objects to this Request to the extent that UnitedHealth is using this information
16 to mischaracterize or misinterpret the facts. The United States objects to this Request
17 to the extent it calls for any legal conclusion. The United States objects to this
18 Request to extent it is duplicative of Request for Admission No. 168.

19 **Response:** Subject to and without waiving the foregoing objections, the United
20 States denies this Request.

21 **REQUEST FOR ADMISSION NO. 165:** Admit that Cheri Rice provided Steve
22 Nelson's April 30, 2014 Email to DOJ.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of "DOJ." The United States
26 objects to this Request as an improper abuse of Federal Rule of Civil Procedure 36
27 because by its own terms it specifically seeks disclosure of information that is
28 protected from disclosure by the attorney-client privilege. The United States further

1 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
2 the extent that it is not limited to a specific period of time. The United States objects
3 to this Request to the extent that UnitedHealth is using this information to
4 mischaracterize or misinterpret the facts. The United States objects to this Request to
5 the extent it calls for any legal conclusion. The United States objects to this Request
6 as harassing to extent it is duplicative of Request for Admission No. 163, and
7 identical to Request for Admission No. 167.

8 **Response:** Subject to the foregoing objections, the United States does not intend to
9 respond to this Request because responsive information, if any, is protected by the
10 attorney-client privilege.

11 **REQUEST FOR ADMISSION NO. 166:** Admit that Cheri Rice provided Steve
12 Nelson's April 30, 2014 Email to one or more individuals at CMS.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definition of "CMS." The United States
16 objects to this Request to the extent it seeks disclosure of information that is protected
17 from disclosure by an applicable privilege or protection, including the attorney-client
18 privilege, attorney work-product doctrine, deliberative process privilege, and/or
19 investigative files privilege. The United States further objects to this Request as
20 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
21 limited to a specific period of time. The United States objects to this Request to the
22 extent that UnitedHealth is using this information to mischaracterize or misinterpret
23 the facts. The United States objects to this Request to the extent it calls for any legal
24 conclusion. The United States objects to this Request to extent it is duplicative of
25 Request for Admission No. 162.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States admits this Request.

28 **REQUEST FOR ADMISSION NO. 167:** Admit that Cheri Rice provided Steve

1 Nelson's April 30, 2014 Email to DOJ.

2 **Objection:** The United States incorporates its General Objections and Specific
3 Objections to the Definitions and Instructions as if stated herein, including but not
4 limited to, its specific objections to the definition of "DOJ." The United States
5 objects to this Request as an improper abuse of Federal Rule of Civil Procedure 36
6 because by its own terms it specifically seeks disclosure of information that is
7 protected from disclosure by the attorney-client privilege. The United States further
8 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
9 the extent that it is not limited to a specific period of time. The United States objects
10 to this Request to the extent that UnitedHealth is using this information to
11 mischaracterize or misinterpret the facts. The United States objects to this Request to
12 the extent it calls for any legal conclusion. The United States objects to this Request
13 as harassing to extent it is duplicative of Request for Admission No. 163, and
14 identical to Request for Admission No. 165.

15 **Response:** Subject to the foregoing objections, the United States does not intend to
16 respond to this Request because responsive information, if any, is protected by the
17 attorney-client privilege.

18 **REQUEST FOR ADMISSION NO. 168:** Admit that Cheri Rice provided Steve
19 Nelson's April 30, 2014 Email to OIG.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition of "OIG." The United States
23 further objects to this Request as vague, ambiguous, overly broad, and unduly
24 burdensome to the extent that it is not limited to a specific period of time. The United
25 States objects to this Request to the extent that UnitedHealth is using this information
26 to mischaracterize or misinterpret the facts. The United States objects to this Request
27 to the extent it calls for any legal conclusion. The United States objects to this
28 Request to extent it is duplicative of Request for Admission No. 164.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States denies this Request.

3 **REQUEST FOR ADMISSION NO. 169:** Admit that Cheri Rice's
4 Communications with one or more individuals at CMS regarding the April 30, 2014
5 Email in part related to UnitedHealth's suspension of its Claims Verification
6 Program.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein, including but not
9 limited to, its specific objections to the definition of "CMS." The United States also
10 objects to this Request to the extent that the undefined term "suspension" is vague
11 and ambiguous. For the purposes of responding to this Request, the United States
12 defines the term "suspension" as the act of stopping or delaying something
13 temporarily. The United States objects to this Request to the extent it seeks
14 disclosure of information that is protected from disclosure by an applicable privilege
15 or protection, including the attorney-client privilege, attorney work-product doctrine,
16 deliberative process privilege, and/or investigative files privilege. The United States
17 further objects to this Request as vague, ambiguous, overly broad, and unduly
18 burdensome to the extent that it is not limited to a specific period of time. The United
19 States objects to this Request to the extent that UnitedHealth is using this information
20 to mischaracterize or misinterpret the facts. The United States objects to this Request
21 to the extent it calls for any legal conclusion. The United States objects to this
22 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
23 law to the extent it is compound in that it asks the United States to admit multiple
24 facts in one Request.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States admits that Cheri Rice had Communications with one or more individuals at
27 CMS regarding the April 30, 2014 Email. However, after a reasonable inquiry, the
28 United States responds that it lacks sufficient information to admit or deny the

1 remainder of this Request.

2 **REQUEST FOR ADMISSION NO. 170:** Admit that Cheri Rice's
3 Communications with DOJ regarding the April 30, 2014 Email in part related to
4 UnitedHealth's suspension of its Claims Verification Program.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of "DOJ." The United States also
8 objects to this Request to the extent that the undefined term "suspension" is vague
9 and ambiguous. For the purposes of responding to this Request, the United States
10 defines the term "suspension" as the act of stopping or delaying something
11 temporarily. The United States objects to this Request as an improper abuse of
12 Federal Rule of Civil Procedure 36 because by its own terms it specifically seeks
13 disclosure of information that is protected from disclosure by the attorney-client
14 privilege. The United States further objects to this Request as vague, ambiguous,
15 overly broad, and unduly burdensome to the extent that it is not limited to a specific
16 period of time. The United States objects to this Request to the extent that
17 UnitedHealth is using this information to mischaracterize or misinterpret the facts.
18 The United States objects to this Request to the extent it calls for any legal
19 conclusion. The United States objects to this Request as improper under Federal Rule
20 of Civil Procedure 36 and applicable case law to the extent it is compound in that it
21 asks the United States to admit multiple facts in one Request.

22 **Response:** Subject to the foregoing objections, the United States does not intend to
23 respond to this Request because responsive information, if any, is protected by the
24 attorney-client privilege.

25 **REQUEST FOR ADMISSION NO. 171:** Admit that Cheri Rice's
26 Communications with OIG regarding the April 30, 2014 Email in part related to
27 UnitedHealth's suspension of its Claims Verification Program.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “OIG.” The United States also
3 objects to this Request to the extent that the undefined term “suspension” is vague
4 and ambiguous. For the purposes of responding to this Request, the United States
5 defines the term “suspension” as the act of stopping or delaying something
6 temporarily. The United States further objects to this Request as vague, ambiguous,
7 overly broad, and unduly burdensome to the extent that it is not limited to a specific
8 period of time. The United States objects to this Request to the extent that
9 UnitedHealth is using this information to mischaracterize or misinterpret the facts.
10 The United States objects to this Request to the extent it calls for any legal
11 conclusion. The United States objects to this Request as improper under Federal Rule
12 of Civil Procedure 36 and applicable case law to the extent it is compound in that it
13 asks the United States to admit multiple facts in one Request.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States denies this Request.

16 **REQUEST FOR ADMISSION NO. 172:** Admit that Cheri Rice’s
17 Communications with one or more individuals at CMS regarding the April 30, 2014
18 Email in part related to UnitedHealth’s statement that it understood from CMS that
19 MAOs were not required to conduct Two-Way Looks.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definitions of “CMS” and “MAOs.” The
23 United States also objects to this Request to the extent that the undefined terms
24 “understood” is vague and ambiguous. For purposes of this Request, the United
25 States defines “understood” as “grasped the meaning of.” The United States objects
26 to this Request to the extent it seeks disclosure of information that is protected from
27 disclosure by an applicable privilege or protection, including the attorney-client
28 privilege, attorney work-product doctrine, deliberative process privilege, and/or

1 investigative files privilege. The United States further objects to this Request as
2 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
3 limited to a specific period of time. The United States objects to this Request to the
4 extent it calls for any legal conclusion. The United States objects to this Request to
5 the extent that UnitedHealth is using this information to mischaracterize or
6 misinterpret the facts. The United States objects to this Request as improper under
7 Federal Rule of Civil Procedure 36 and applicable case law to the extent it is
8 compound in that it asks the United States to admit multiple facts in one Request.

9 **Response:** Subject to and without waiving the foregoing objections, the United
10 States admits that Cheri Rice had Communications with one or more individuals at
11 CMS regarding a response to the April 30, 2014 Email. However, after a reasonable
12 inquiry, the United States responds that it lacks sufficient information to admit or
13 deny the remainder of this Request.

14 **REQUEST FOR ADMISSION NO. 173:** Admit that Cheri Rice's
15 Communications with DOJ regarding the April 30, 2014 Email in part related to
16 UnitedHealth's statement that it understood from CMS that MAOs were not required
17 to conduct Two-Way Looks.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definitions of "DOJ," "CMS," and "MAO."
21 The United States also objects to this Request to the extent that the undefined terms
22 "understood" is vague and ambiguous. For purposes of this Request, the United
23 States defines "understood" as "grasped the meaning of". . The United States objects
24 to this Request as an improper abuse of Federal Rule of Civil Procedure 36 because
25 by its own terms it specifically seeks disclosure of information that is protected from
26 disclosure by the attorney-client privilege. The United States further objects to this
27 Request as vague, ambiguous, overly broad, and unduly burdensome to the extent
28 that it is not limited to a specific period of time. The United States further objects to

1 this Request to the extent it calls for any legal conclusion. The United States objects
2 to this Request to the extent that UnitedHealth is using this information to
3 mischaracterize or misinterpret the facts. The United States objects to this Request as
4 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
5 extent it is compound in that it asks the United States to admit multiple facts in one
6 Request.

7 **Response:** Subject to the foregoing objections, the United States does not intend to
8 respond to this Request because responsive information, if any, is protected by the
9 attorney-client privilege.

10 **REQUEST FOR ADMISSION NO. 174:** Admit that Cheri Rice's
11 Communications with OIG regarding the April 30, 2014 Email in part related to
12 UnitedHealth's statement that it understood from CMS that MAOs were not required
13 to conduct Two-Way Looks.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein, including but not
16 limited to, its specific objections to the definitions "OIG," "CMS," and "MAO." The
17 United States also objects to this Request to the extent that the undefined terms
18 "understood" is vague and ambiguous. For purposes of this Request, the United
19 States defines "understood" as "grasped the meaning of." The United States further
20 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
21 the extent that it is not limited to a specific period of time. The United States objects
22 to this Request to the extent it calls for any legal conclusion. The United States
23 objects to this Request to the extent it calls for any legal conclusion. The United
24 States objects to this Request to the extent that UnitedHealth is using this information
25 to mischaracterize or misinterpret the facts. The United States objects to this Request
26 as improper under Federal Rule of Civil Procedure 36 and applicable case law to the
27 extent it is compound in that it asks the United States to admit multiple facts in one
28 Request.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States denies this Request.

3 **REQUEST FOR ADMISSION NO. 175:** Admit that Cheri Rice sent the May 2,
4 2014 Email in response to Steve Nelson's April 30, 2014 Email.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein. The United States
7 objects to this Request to the extent it calls for information that is already in
8 UnitedHealth's possession, custody, or control, or is otherwise available to
9 UnitedHealth and to the extent that UnitedHealth is using this information to
10 mischaracterize or misinterpret the facts. The United States objects to this Request as
11 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
12 extent it is compound in that it asks the United States to admit multiple facts in one
13 Request.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States admits this Request.

16 **REQUEST FOR ADMISSION NO. 176:** Admit that Cheri Rice did not draft the
17 May 2, 2014 Email to Steve Nelson.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein. The United States
20 also objects to this Request to the extent that the undefined term "draft" is vague and
21 ambiguous. For the purposes of responding to this Request, the United States defines
22 the term "draft" as to put something in written form. The United States objects to this
23 Request to the extent it seeks information not relevant to a claim or defense in this
24 case. The United States objects to this Request to the extent it seeks disclosure of
25 information that is protected from disclosure by an applicable privilege or protection,
26 including the attorney-client privilege, attorney work-product doctrine, deliberative
27 process privilege, and/or investigative files privilege. The United States objects to
28 this Request to the extent that UnitedHealth is using this information to

1 mischaracterize or misinterpret the facts. The United States further objects to this
2 Request to extent it is duplicative of Request for Admission No. 177.

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States admits this Request.

5 **REQUEST FOR ADMISSION NO. 177:** Admit that Cheri Rice had assistance
6 with drafting the May 2, 2014 Email to Steve Nelson.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein. The United States
9 also objects to this Request to the extent that the undefined terms “assistance” and
10 “drafting” are vague and ambiguous. For the purposes of responding to this Request,
11 the United States defines the term “drafting” as putting in writing. For the purposes
12 of responding to this Request, the United States defines the term “assistance” as the
13 act of helping someone complete a task. The United States objects to this Request to
14 the extent it seeks information not relevant to a claim or defense in this case. The
15 United States objects to this Request to the extent it seeks disclosure of information
16 that is protected from disclosure by an applicable privilege or protection, including
17 the attorney-client privilege, attorney work-product doctrine, deliberative process
18 privilege, and/or investigative files privilege. The United States objects to this
19 Request to the extent it calls for any legal conclusion. The United States objects to
20 this Request to the extent that UnitedHealth is using this information to
21 mischaracterize or misinterpret the facts. The United States further objects to this
22 Request to extent it is duplicative of Request for Admission No. 176.

23 **Response:** Subject to and without waiving the foregoing objections, the United
24 States admits this Request.

25 **REQUEST FOR ADMISSION NO. 178:** Admit that CMS did not question
26 UnitedHealth’s suspension of its Claims Verification Program.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein, including but not

1 limited to, its specific objections to the definition of “CMS.” The United States also
2 objects to this Request to the extent that the undefined terms “question” and
3 “suspension” are vague and ambiguous. For the purposes of responding to this
4 Request, the United States defines the term “question” as asking about, expressing
5 uncertainty, or subjecting to analysis. For the purposes of responding to this Request,
6 the United States defines the term “suspension” as the act of stopping or delaying
7 something temporarily. The United States objects to this Request to the extent it calls
8 for information that is already in UnitedHealth’s possession, custody, or control, or is
9 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
10 information to mischaracterize or misinterpret the facts. The United States objects to
11 this Request to the extent it calls for any legal conclusion. The United States further
12 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
13 the extent that it is not limited to a specific period of time. The United States further
14 objects to this Request to extent it is duplicative of Request for Admission No. 179.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States denies this Request.

17 **REQUEST FOR ADMISSION NO. 179:** Admit that CMS did not challenge
18 UnitedHealth’s suspension of its Claims Verification Program.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “CMS.” The United States also
22 objects to this Request to the extent that the undefined terms “challenge” and
23 “suspension” are vague and ambiguous. For the purposes of responding to this
24 Request, the United States defines the term “challenge” as to dispute. For the
25 purposes of responding to this Request, the United States defines the term
26 “suspension” as the act of stopping or delaying something temporarily. The United
27 States objects to this Request to the extent it calls for information that is already in
28 UnitedHealth’s possession, custody, or control, or is otherwise available to

1 UnitedHealth and to the extent that UnitedHealth is using this information to
2 mischaracterize or misinterpret the facts. The United States objects to this Request to
3 the extent it calls for any legal conclusion. The United States further objects to this
4 Request as vague, ambiguous, overly broad, and unduly burdensome to the extent
5 that it is not limited to a specific period of time. The United States further objects to
6 this Request to extent it is duplicative of Request for Admission No. 178.

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States denies this Request.

9 **REQUEST FOR ADMISSION NO. 180:** Admit that Steve Nelson met with Sean
10 Cavanaugh on June 10, 2014.

11 **Objection:** The United States incorporates its General Objections and Specific
12 Objections to the Definitions and Instructions as if stated herein. The United States
13 objects to this Request to the extent it seeks information not relevant to a claim or
14 defense in this case. The United States objects to this Request to the extent it calls for
15 information that is already in UnitedHealth's possession, custody, or control, or is
16 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
17 information to mischaracterize or misinterpret the facts.

18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States admits that a June 13, 2014 email bates labeled USBP001366276 reflects that
20 Sean Cavanaugh and Steve Nelson met on June 10, 2014 to discuss topics related to
21 Hep C and Notice to Beneficiaries, but after a reasonable inquiry, the United States
22 lacks sufficient information to admit or deny the remainder of this Request.

23 **REQUEST FOR ADMISSION NO. 181:** Admit that, other than Steve Nelson and
24 Sean Cavanaugh, no other person attended the June 10, 2014 Meeting.

25 **Objection:** The United States incorporates its General Objections and Specific
26 Objections to the Definitions and Instructions as if stated herein, including but not
27 limited to, its specific objections to the definition of "Person." The United States
28 objects to this Request to the extent it seeks information not relevant to a claim or

1 defense in this case. The United States objects to this Request to the extent it calls for
2 information that is already in UnitedHealth's possession, custody, or control, or is
3 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
4 information to mischaracterize or misinterpret the facts.

5 **Response:** Subject to and without waiving the foregoing objections, after a
6 reasonable inquiry, the United States responds that it lacks sufficient information to
7 admit or deny this Request.

8 **REQUEST FOR ADMISSION NO. 182:** Admit that the June 10, 2014 Meeting
9 took place in Person.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein. The United States
12 objects to this Request to the extent it seeks information not relevant to a claim or
13 defense in this case. The United States objects to this Request to the extent it calls for
14 information that is already in UnitedHealth's possession, custody, or control, or is
15 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
16 information to mischaracterize or misinterpret the facts.

17 **Response:** Subject to and without waiving the foregoing objections, after a
18 reasonable inquiry, the United States responds that it lacks sufficient information to
19 admit or deny this Request.

20 **REQUEST FOR ADMISSION NO. 183:** Admit that the June 10, 2014 Meeting
21 took place by videoconference.

22 **Objection:** The United States incorporates its General Objections and Specific
23 Objections to the Definitions and Instructions as if stated herein. The United States
24 objects to this Request to the extent it seeks information not relevant to a claim or
25 defense in this case. The United States objects to this Request to the extent it calls for
26 information that is already in UnitedHealth's possession, custody, or control, or is
27 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
28 information to mischaracterize or misinterpret the facts.

1 **Response:** Subject to and without waiving the foregoing objections, after a
2 reasonable inquiry, the United States responds that it lacks sufficient information to
3 admit or deny this Request.

4 **REQUEST FOR ADMISSION NO. 184:** Admit that the June 10, 2014 Meeting
5 took place by telephone.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein. The United States
8 objects to this Request to the extent it seeks information not relevant to a claim or
9 defense in this case. The United States objects to this Request to the extent it calls for
10 information that is already in UnitedHealth's possession, custody, or control, or is
11 otherwise available to UnitedHealth and to the extent that UnitedHealth is using this
12 information to mischaracterize or misinterpret the facts.

13 **Response:** Subject to and without waiving the foregoing objections, after a
14 reasonable inquiry, the United States responds that it lacks sufficient information to
15 admit or deny this Request.

16 **REQUEST FOR ADMISSION NO. 185:** Admit that the Government Audio
17 Recorded the June 10, 2014 Meeting.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of "Government." The United
21 States further objects to this request because it is unduly burdensome for the United
22 States to determine the actions of all "agencies, departments, components, agents,
23 representatives, contractors, attorneys, consultants, and all other Persons acting on its
24 behalf." The United States objects to this Request to the extent it seeks information
25 not relevant to a claim or defense in this case.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States denies that Sean Cavanaugh Audio Recorded the June 10, 2014 meeting.
28 However, after a reasonable inquiry, the United States responds that it lacks sufficient

1 information to admit or deny this Request with respect to CMS or the entire United
2 States Government.

3 **REQUEST FOR ADMISSION NO. 186:** Admit that the Government Video
4 Recorded the June 10, 2014 Meeting.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of “Government.” The United
8 States further objects to this request because it is unduly burdensome for the United
9 States to determine the actions of all “agencies, departments, components, agents,
10 representatives, contractors, attorneys, consultants, and all other Persons acting on its
11 behalf.” The United States objects to this Request to the extent it seeks information
12 not relevant to a claim or defense in this case.

13 **Response:** Subject to and without waiving the foregoing objections, the United
14 States denies that Sean Cavanaugh Video Recorded the June 10, 2014 meeting.
15 However, after a reasonable inquiry, the United States responds that it lacks sufficient
16 information to admit or deny this Request with respect to CMS or the entire United
17 States Government.

18 **REQUEST FOR ADMISSION NO. 187:** Admit that Sean Cavanaugh took notes
19 during the June 10, 2014 Meeting.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein. The United States
22 objects to this Request to the extent it seeks information not relevant to a claim or
23 defense in this case.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States denies this Request.

26 **REQUEST FOR ADMISSION NO. 188:** Admit that after the June 10, 2014
27 Meeting, Sean Cavanaugh took notes about or otherwise memorialized the meeting in
28 writing.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein. The United States
3 also objects to this Request to the extent that the undefined phrase “or otherwise
4 memorialized” is vague and ambiguous. For the purposes of this Request, the United
5 States defines “memorialized” as put in writing. The United States further objects to
6 this Request as vague, ambiguous, overly broad, and unduly burdensome to the extent
7 that it is not limited to a specific period of time. The United States objects to this
8 Request to the extent it seeks information not relevant to a claim or defense in this
9 case.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States admits that Sean Cavanaugh sent an email to Steve Nelson on June 20, 2014
12 following up on their June 10, 2014 meeting. The United States denies the remainder
13 of this Request.

14 **REQUEST FOR ADMISSION NO. 189:** Admit that after the June 10, 2014
15 Meeting, Sean Cavanaugh had Communications with one or more individuals at CMS
16 about the meeting.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definition of “CMS.” The United States
20 objects to this Request to the extent it seeks disclosure of information that is protected
21 from disclosure by an applicable privilege or protection, including the attorney-client
22 privilege, attorney work-product doctrine, deliberative process privilege, and/or
23 investigative files privilege. The United States further objects to this Request as
24 vague, ambiguous, overly broad, and unduly burdensome to the extent that it is not
25 limited to a specific period of time. The United States objects to this Request to the
26 extent it seeks information not relevant to a claim or defense in this case.

27 **Response:** Subject to and without waiving the foregoing objections, the United
28 States admits this Request.

1 **REQUEST FOR ADMISSION NO. 190:** Admit that after the June 10, 2014
2 Meeting, Sean Cavanaugh had Communications with DOJ about the meeting.

3 **Objection:** The United States incorporates its General Objections and Specific
4 Objections to the Definitions and Instructions as if stated herein, including but not
5 limited to, its specific objections to the definition of “DOJ.” The United States
6 objects to this Request as an improper abuse of Federal Rule of Civil Procedure 36
7 because by its own terms it specifically seeks disclosure of information that is
8 protected from disclosure by the attorney-client privilege. The United States further
9 objects to this Request as vague, ambiguous, overly broad, and unduly burdensome to
10 the extent that it is not limited to a specific period of time. The United States objects
11 to this Request to the extent it seeks information not relevant to a claim or defense in
12 this case.

13 **Response:** Subject to the foregoing objections, the United States does not intend to
14 respond to this Request because responsive information, if any, is protected by the
15 attorney-client privilege.

16 **REQUEST FOR ADMISSION NO. 191:** Admit that after the June 10, 2014
17 Meeting, Sean Cavanaugh had Communications with OIG about the meeting.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of “OIG.” The United States
21 further objects to this Request as vague, ambiguous, overly broad, and unduly
22 burdensome to the extent that it is not limited to a specific period of time. The United
23 States objects to this Request to the extent it seeks information not relevant to a claim
24 or defense in this case.

25 **Response:** Subject to and without waiving the foregoing objections, the United
26 States denies this Request.

1 **REQUEST FOR ADMISSION NO. 192:** Admit that during the June 10, 2014
2 Meeting, Steve Nelson informed Sean Cavanaugh that UnitedHealth discontinued its
3 Claims Verification Program.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein. The United States
6 objects to this Request to the extent it calls for information that is already in
7 UnitedHealth's possession, custody, or control, or is otherwise available to
8 UnitedHealth and to the extent that UnitedHealth is using this information to
9 mischaracterize or misinterpret the facts. The United States objects to this Request to
10 the extent it calls for any legal conclusion.

11 **Response:** Subject to and without waiving the foregoing objections, after a
12 reasonable inquiry, the United States responds that it lacks sufficient information to
13 admit or deny this Request.

14 **REQUEST FOR ADMISSION NO. 193:** Admit that UnitedHealth discontinued
15 UnitedHealth's Claims Verification Program based in part on UnitedHealth's
16 understanding that the Proposed Medical Record Review Rule would not be
17 retroactive.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein. The United States
20 objects to this Request to the extent it calls for information that is already in
21 UnitedHealth's possession, custody, or control, or is otherwise available to
22 UnitedHealth and to the extent that UnitedHealth is using this information to
23 mischaracterize or misinterpret the facts. The United States objects to this Request to
24 the extent it calls for any legal conclusion. The United States objects to this Request
25 because by its nature it calls for the United States to provide information outside of
26 its possession, custody or control about UnitedHealth's motives, of which
27 UnitedHealth should presumably be aware.

28 **Response:** Subject to and without waiving the foregoing objections, the United

1 States responds that it lacks sufficient information to admit or deny this Request
2 because it seeks information regarding UnitedHealth's own beliefs and legal theories.
3 **REQUEST FOR ADMISSION NO. 194:** Admit that UnitedHealth told CMS that
4 UnitedHealth had discontinued UnitedHealth's Claims Verification Program based in
5 part on UnitedHealth's understanding that the Proposed Medical Record Review Rule
6 was not effective until it was finalized.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein, including but not
9 limited to, its specific objections to the definition of "CMS." The United States
10 objects to this Request to the extent it calls for information that is already in
11 UnitedHealth's possession, custody, or control, or is otherwise available to
12 UnitedHealth and to the extent that UnitedHealth is using this information to
13 mischaracterize or misinterpret the facts. The United States further objects to this
14 Request as vague, ambiguous, overly broad, and unduly burdensome to the extent
15 that it is not limited to a specific period of time. The United States objects to this
16 Request to the extent it calls for any legal conclusion. The United States objects to
17 this Request as improper under Federal Rule of Civil Procedure 36 and applicable
18 case law to the extent it is compound in that it asks the United States to admit
19 multiple facts in one Request.

20 **Response:** Subject to and without waiving the foregoing objections, the United
21 States admits that Steve Nelson sent an email dated April 30, 2014, MARA1296257,
22 which stated:

23 Fifth, as we discussed yesterday, CMS recently issued a proposed rule that
24 would, if finalized, require MA plans to design any medical record reviews to
25 determine the accuracy of risk adjustment diagnoses associated with those
26 records. During our conversation yesterday and other recent conversations,
27 CMS confirmed to us that these requirements do not apply until the effective
28 date of the rule, and that MA plans are thus not currently required to design

1 their medical record reviews to determine the accuracy of risk adjustment
2 diagnoses. We currently have a process through which we review certain
3 medical records to determine the accuracy of risk adjustment diagnoses and
4 submit appropriate deletes. This process already has resulted in the
5 identification of and, in some instances, the submission of deletes for 2012
6 dates of service. But based on the proposed rule, including the preamble, and
7 recent conversations with CMS, we suspended that process for 2012 dates of
8 service while we consider whether to make changes. Pursuant to our
9 discussion, however, we will soon submit for deletion those diagnosis codes
10 that have undergone a complete review and that we have therefore identified as
11 appropriate deletes. In the near future, we will determine whether to continue
12 our review process for the diagnosis codes which were still under review at the
13 time we suspended our process. In the meantime, we will not delete these
14 codes.

15 The United States denies the remainder of this Request.

16 **REQUEST FOR ADMISSION NO. 195:** Admit that CMS did not express to
17 UnitedHealth an issue or concern with UnitedHealth's discontinuation of its Claims
18 Verification Program.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of "CMS." The United States also
22 objects to this Request to the extent that the undefined phrases "issue or concern" is
23 vague and ambiguous. The United States objects to this Request to the extent it seeks
24 information not relevant to a claim or defense in this case. The United States objects
25 to this Request to the extent it calls for information that is already in UnitedHealth's
26 possession, custody, or control, or is otherwise available to UnitedHealth and to the
27 extent that UnitedHealth is using this information to mischaracterize or misinterpret
28 the facts. The United States objects to this Request to the extent it calls for any legal

1 conclusion. The United States further objects to this Request as vague, ambiguous,
2 overly broad, and unduly burdensome to the extent that it is not limited to a specific
3 period of time. The United States further objects to this Request to extent it is
4 duplicative of Request for Admission Nos. 178, 179, and 196.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States denies this Request.

7 **REQUEST FOR ADMISSION NO. 196:** Admit that at no time prior to the date on
8 which the Government filed its Complaint has CMS expressed to UnitedHealth an
9 issue or concern with UnitedHealth's discontinuation of its Claims Verification
10 Program.

11 **Objection:** The United States incorporates its General Objections and Specific
12 Objections to the Definitions and Instructions as if stated herein, including but not
13 limited to, its specific objections to the definition of "CMS." The United States also
14 objects to this Request to the extent that the undefined phrases "issue or concern" is
15 vague and ambiguous. The United States objects to this Request to the extent it seeks
16 information not relevant to a claim or defense in this case. The United States objects
17 to this Request to the extent it calls for information that is already in UnitedHealth's
18 possession, custody, or control, or is otherwise available to UnitedHealth and to the
19 extent that UnitedHealth is using this information to mischaracterize or misinterpret
20 the facts. The United States objects to this Request to the extent it calls for any legal
21 conclusion. The United States further objects to this Request to extent it is
22 duplicative of Request for Admission No. 178, 179, and 195.

23 **Response:** Subject to and without waiving the foregoing objections, the United
24 States denies this Request.

25 **REQUEST FOR ADMISSION NO. 197:** Admit that at no time prior to the date on
26 which the Government filed its Complaint has DOJ expressed to UnitedHealth an
27 issue or concern with UnitedHealth's discontinuation of its Claims Verification
28 Program.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definition of “DOJ.” The United States also
4 objects to this Request to the extent that the undefined phrase “issue or concern” is
5 vague and ambiguous. The United States objects to this Request to the extent it seeks
6 information not relevant to a claim or defense in this case. The United States objects
7 to this Request to the extent it calls for information that is already in UnitedHealth’s
8 possession, custody, or control, or is otherwise available to UnitedHealth and to the
9 extent that UnitedHealth is using this information to mischaracterize or misinterpret
10 the facts. The United States objects to this Request to the extent it calls for any legal
11 conclusion. The United States objects to this Request to the extent it suggests the
12 DOJ personnel responsible for investigating and litigating this matter do not act on
13 behalf of their agency client.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States denies this Request.

16 **REQUEST FOR ADMISSION NO. 198:** Admit that at no time prior to the date on
17 which the Government filed its Complaint has OIG expressed to UnitedHealth an
18 issue or concern with UnitedHealth’s discontinuation of its Claims Verification
19 Program.

20 **Objection:** The United States incorporates its General Objections and Specific
21 Objections to the Definitions and Instructions as if stated herein, including but not
22 limited to, its specific objections to the definition of “OIG.” The United States also
23 objects to this Request to the extent that the undefined phrase “issue or concern” is
24 vague and ambiguous. The United States objects to this Request to the extent it seeks
25 information not relevant to a claim or defense in this case. The United States objects
26 to this Request to the extent it calls for information that is already in UnitedHealth’s
27 possession, custody, or control, or is otherwise available to UnitedHealth and to the
28 extent that UnitedHealth is using this information to mischaracterize or misinterpret

1 the facts. The United States objects to this Request to the extent it calls for any legal
2 conclusion.

3 **Response:** Subject to and without waiving the foregoing objections, the United
4 States denies this Request.

5 **REQUEST FOR ADMISSION NO. 199:** Admit that on May 23, 2014, CMS
6 issued the May 23, 2014 Final Rule.

7 **Objection:** The United States incorporates its General Objections and Specific
8 Objections to the Definitions and Instructions as if stated herein, including but not
9 limited to, its specific objections to the definition of “CMS.” The United States
10 objects to this Request to the extent it calls for information that is already in
11 UnitedHealth’s possession, custody, or control, or is otherwise available to
12 UnitedHealth and to the extent that UnitedHealth is using this information to
13 mischaracterize or misinterpret the facts. The United States objects to this Request to
14 the extent it calls for any legal conclusion.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States admits this Request.

17 **REQUEST FOR ADMISSION NO. 200:** Admit that the May 23, 2014 Final Rule
18 did not require MAOs to engage in Two-Way Looks.

19 **Objection:** The United States incorporates its General Objections and Specific
20 Objections to the Definitions and Instructions as if stated herein, including but not
21 limited to, its specific objections to the definition of “MAOs.” The United States
22 objects to this Request to the extent it calls for any legal conclusion. The United
23 States objects to this Request to the extent it calls for information that is already in
24 UnitedHealth’s possession, custody, or control, or is otherwise available to
25 UnitedHealth. The United States objects to this Request to the extent that
26 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
27 particularly in that it mischaracterizes CMS’ statements contained in the Response to
28 Public Comments Section of the May 23, 2014 Final Rule: “However, we emphasize

1 that our decision to not finalize this regulatory proposal does not change CMS’
2 existing contractual requirement that MA organizations must certify (based on best
3 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
4 the risk adjustment data they submit to CMS. Further, this decision does not change
5 the long- standing risk adjustment data requirement that a diagnosis submitted to
6 CMS by an MA organization for payment purposes must be supported by medical
7 record documentation.” 79 Fed. Reg. 29926. The United States objects to this
8 Request to the extent it is duplicative of Request for Admission Nos. 201 and 202.

9 **Response:** Subject to and without waiving the foregoing objections, the United
10 States admits that the May 23, 2014 Final Rule did not include language which
11 specifically required MAOs to conduct Two-Way Looks. However, the United States
12 denies the remainder of this Request particularly in the light of the fact that CMS
13 made very clear in the Final Rule that “our decision to not finalize this regulatory
14 proposal does not change CMS’ existing contractual requirement that MA
15 organizations must certify (based on best knowledge, information, and belief) the
16 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
17 CMS. Further, this decision does not change the long-standing risk adjustment data
18 requirement that a diagnosis submitted to CMS by an MA organization for payment
19 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.

20 **REQUEST FOR ADMISSION NO. 201:** Admit that the May 23, 2014 Final Rule
21 did not require MAOs to confirm that every Diagnosis Code submitted by a Provider
22 is documented in a Beneficiary’s Chart.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of “MAOs.” The United States
26 objects to this Request to the extent it calls for any legal conclusion. The United
27 States objects to this Request to the extent it calls for information that is already in
28 UnitedHealth’s possession, custody, or control, or is otherwise available to

1 UnitedHealth. The United States objects to this Request to the extent that
2 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
3 particularly in that it mischaracterizes CMS' statements contained in the Response to
4 Public Comments Section of the May 23, 2014 Final Rule: "However, we emphasize
5 that our decision to not finalize this regulatory proposal does not change CMS'
6 existing contractual requirement that MA organizations must certify (based on best
7 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
8 the risk adjustment data they submit to CMS. Further, this decision does not change
9 the long- standing risk adjustment data requirement that a diagnosis submitted to
10 CMS by an MA organization for payment purposes must be supported by medical
11 record documentation." 79 Fed. Reg. 29926. The United States objects to this
12 Request to the extent it is duplicative of Request for Admission No. 200 and 202.

13 **Response:** Subject to and without waiving the foregoing objections, the United
14 States admits that the May 23, 2014 Final Rule did not include language which
15 specifically required MAOs to confirm that every Diagnosis Code submitted by a
16 Provider is documented in a Beneficiary's Chart. However, the United States denies
17 the remainder of this Request particularly in the light of the fact that CMS made very
18 clear in the Final Rule that "our decision to not finalize this regulatory proposal does
19 not change CMS' existing contractual requirement that MA organizations must
20 certify (based on best knowledge, information, and belief) the accuracy,
21 completeness, and truthfulness of the risk adjustment data they submit to CMS.
22 Further, this decision does not change the long-standing risk adjustment data
23 requirement that a diagnosis submitted to CMS by an MA organization for payment
24 purposes must be supported by medical record documentation." 79 Fed. Reg. 29926.

25 **REQUEST FOR ADMISSION NO. 202:** Admit that CMS did not finalize the
26 portion of the Proposed Medical Record Review Rule that would have required Two-
27 Way Looks.

28 **Objection:** The United States incorporates its General Objections and Specific

1 Objections to the Definitions and Instructions as if stated herein, including but not
2 limited to, its specific objections to the definition of “CMS.” The United States
3 objects to this Request to the extent it calls for any legal conclusion. The United
4 States objects to this Request to the extent it calls for information that is already in
5 UnitedHealth’s possession, custody, or control, or is otherwise available to
6 UnitedHealth. The United States objects to this Request to the extent that
7 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
8 particularly in that it mischaracterizes CMS’ statements contained in the Response to
9 Public Comments Section of the May 23, 2014 Final Rule: “However, we emphasize
10 that our decision to not finalize this regulatory proposal does not change CMS’
11 existing contractual requirement that MA organizations must certify (based on best
12 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
13 the risk adjustment data they submit to CMS. Further, this decision does not change
14 the long- standing risk adjustment data requirement that a diagnosis submitted to
15 CMS by an MA organization for payment purposes must be supported by medical
16 record documentation.” 79 Fed. Reg. 29926. The United States objects to this
17 Request to the extent it is duplicative of Request for Admission Nos. 200 and 201.
18 **Response:** Subject to and without waiving the foregoing objections, the United
19 States admits that the May 23, 2014 Final Rule did not include language which
20 specifically required MAOs to conduct Two-Way Looks. However, the United States
21 denies the remainder of this Request particularly in the light of the fact that CMS
22 made very clear in the Final Rule that “our decision to not finalize this regulatory
23 proposal does not change CMS’ existing contractual requirement that MA
24 organizations must certify (based on best knowledge, information, and belief) the
25 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
26 CMS. Further, this decision does not change the long-standing risk adjustment data
27 requirement that a diagnosis submitted to CMS by an MA organization for payment
28 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.

1 **REQUEST FOR ADMISSION NO. 203:** Admit that CMS removed the portion of
2 the Proposed Medical Record Review Rule that would have required Two-Way
3 Looks when it finalized the May 23, 2014 Final Rule in part related to comments
4 CMS received.

5 **Objection:** The United States incorporates its General Objections and Specific
6 Objections to the Definitions and Instructions as if stated herein, including but not
7 limited to, its specific objections to the definition of “CMS.” The United States
8 objects to this Request to the extent it calls for any legal conclusion. The United
9 States objects to this Request to the extent it seeks disclosure of information that is
10 protected from disclosure by an applicable privilege or protection, including the
11 attorney-client privilege, attorney work-product doctrine, deliberative process
12 privilege, and/or investigative files privilege. The United States objects to this
13 Request to the extent it calls for information that is already in UnitedHealth’s
14 possession, custody, or control, or is otherwise available to UnitedHealth. The
15 United States objects to this Request to the extent that UnitedHealth is using this
16 information to mischaracterize or misinterpret the facts, particularly in that it
17 mischaracterizes CMS’ statements contained in the Response to Public Comments
18 Section of the May 23, 2014 Final Rule: “However, we emphasize that our decision
19 to not finalize this regulatory proposal does not change CMS’ existing contractual
20 requirement that MA organizations must certify (based on best knowledge,
21 information, and belief) the accuracy, completeness, and truthfulness of the risk
22 adjustment data they submit to CMS. Further, this decision does not change the long-
23 standing risk adjustment data requirement that a diagnosis submitted to CMS by an
24 MA organization for payment purposes must be supported by medical record
25 documentation.” 79 Fed. Reg. 29926. The United States objects to this Request as
26 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
27 extent it is compound in that it asks the United States to admit multiple facts in one
28 Request. The United States objects to this Request to the extent it is duplicative of

1 Request for Admission No. 204.

2 **Response:** Subject to and without waiving the foregoing objections, the United
3 States admits that CMS reviewed the comments it received regarding the Proposed
4 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
5 However, the United States denies the remainder of this Request.

6 **REQUEST FOR ADMISSION NO. 204:** Admit that CMS did not finalize the
7 portion of the Proposed Medical Record Review Rule that would have required Two-
8 Way Looks in part related to comments CMS received.

9 **Objection:** The United States incorporates its General Objections and Specific
10 Objections to the Definitions and Instructions as if stated herein, including but not
11 limited to, its specific objections to the definition of “CMS.” The United States
12 objects to this Request to the extent it calls for any legal conclusion. The United
13 States objects to this Request to the extent it seeks disclosure of information that is
14 protected from disclosure by an applicable privilege or protection, including the
15 attorney-client privilege, attorney work-product doctrine, deliberative process
16 privilege, and/or investigative files privilege. The United States objects to this
17 Request to the extent it calls for information that is already in UnitedHealth’s
18 possession, custody, or control, or is otherwise available to UnitedHealth. The
19 United States objects to this Request to the extent that UnitedHealth is using this
20 information to mischaracterize or misinterpret the facts, particularly in that it
21 mischaracterizes CMS’ statements contained in the Response to Public Comments
22 Section of the May 23, 2014 Final Rule: “However, we emphasize that our decision
23 to not finalize this regulatory proposal does not change CMS’ existing contractual
24 requirement that MA organizations must certify (based on best knowledge,
25 information, and belief) the accuracy, completeness, and truthfulness of the risk
26 adjustment data they submit to CMS. Further, this decision does not change the long-
27 standing risk adjustment data requirement that a diagnosis submitted to CMS by an
28 MA organization for payment purposes must be supported by medical record

1 documentation.” 79 Fed. Reg. 29926. The United States objects to this Request as
2 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
3 extent it is compound in that it asks the United States to admit multiple facts in one
4 Request. The United States objects to this Request to the extent it is duplicative of
5 Request for Admission No. 203.

6 **Response:** Subject to and without waiving the foregoing objections, the United
7 States admits that CMS reviewed the comments it received regarding the Proposed
8 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
9 However, the United States denies the remainder of this Request.

10 **REQUEST FOR ADMISSION NO. 205:** Admit that CMS removed the portion of
11 the Proposed Medical Record Review Rule that would have required Two-Way
12 Looks from the Final Rule in part related to comments CMS received from entities
13 engaged in business related to the Medicare Advantage Program.

14 **Objection:** The United States incorporates its General Objections and Specific
15 Objections to the Definitions and Instructions as if stated herein, including but not
16 limited to, its specific objections to the definition of “CMS.” The United States also
17 objects to this Request to the extent that the undefined phrase “entities engaged in
18 business related to the Medicare Advantage Program” is vague and ambiguous. For
19 purposes of this Request, the United States defines “entities engaged in business
20 related to the Medicare Advantage Program” as MAOs. The United States objects to
21 this Request to the extent it calls for any legal conclusion. The United States objects
22 to this Request to the extent it seeks disclosure of information that is protected from
23 disclosure by an applicable privilege or protection, including the attorney-client
24 privilege, attorney work-product doctrine, deliberative process privilege, and/or
25 investigative files privilege. The United States objects to this Request to the extent it
26 calls for information that is already in UnitedHealth’s possession, custody, or control,
27 or is otherwise available to UnitedHealth. The United States objects to this Request
28 to the extent that UnitedHealth is using this information to mischaracterize or

1 misinterpret the facts, particularly in that it mischaracterizes CMS' statements
2 contained in the Response to Public Comments Section of the May 23, 2014 Final
3 Rule: "However, we emphasize that our decision to not finalize this regulatory
4 proposal does not change CMS' existing contractual requirement that MA
5 organizations must certify (based on best knowledge, information, and belief) the
6 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
7 CMS. Further, this decision does not change the long- standing risk adjustment data
8 requirement that a diagnosis submitted to CMS by an MA organization for payment
9 purposes must be supported by medical record documentation." 79 Fed. Reg. 29926.
10 The United States objects to this Request as improper under Federal Rule of Civil
11 Procedure 36 and applicable case law to the extent it is compound in that it asks the
12 United States to admit multiple facts in one Request. The United States objects to
13 this Request to the extent it is duplicative of Request for Admission Nos. 206, 207
14 and 208.

15 **Response:** Subject to and without waiving the foregoing objections, the United
16 States admits that CMS reviewed the comments it received regarding the Proposed
17 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
18 However, the United States denies the remainder of this Request.

19 **REQUEST FOR ADMISSION NO. 206:** Admit that CMS did not finalize the
20 portion of the Proposed Medical Record Review Rule that would have required Two-
21 Way Looks in part related to comments CMS received from entities engaged in
22 business related to the Medicare Advantage Program.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of "CMS." The United States also
26 objects to this Request to the extent that the undefined phrase "entities engaged in
27 business related to the Medicare Advantage Program" is vague and ambiguous. For
28 purposes of this Request, the United States defines "entities engaged in business

1 related to the Medicare Advantage Program” as MAOs. The United States objects to
2 this Request to the extent it calls for any legal conclusion. The United States objects
3 to this Request to the extent it seeks disclosure of information that is protected from
4 disclosure by an applicable privilege or protection, including the attorney-client
5 privilege, attorney work-product doctrine, deliberative process privilege, and/or
6 investigative files privilege. The United States objects to this Request to the extent it
7 calls for information that is already in UnitedHealth’s possession, custody, or control,
8 or is otherwise available to UnitedHealth. The United States objects to this Request
9 to the extent that UnitedHealth is using this information to mischaracterize or
10 misinterpret the facts, particularly in that it mischaracterizes CMS’ statements
11 contained in the Response to Public Comments Section of the May 23, 2014 Final
12 Rule: “However, we emphasize that our decision to not finalize this regulatory
13 proposal does not change CMS’ existing contractual requirement that MA
14 organizations must certify (based on best knowledge, information, and belief) the
15 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
16 CMS. Further, this decision does not change the long- standing risk adjustment data
17 requirement that a diagnosis submitted to CMS by an MA organization for payment
18 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.
19 The United States objects to this Request as improper under Federal Rule of Civil
20 Procedure 36 and applicable case law to the extent it is compound in that it asks the
21 United States to admit multiple facts in one Request. The United States objects to this
22 Request to the extent it is duplicative of Request for Admission Nos. 205, 207 and
23 208.

24 **Response:** Subject to and without waiving the foregoing objections, the United
25 States admits that CMS reviewed the comments it received regarding the Proposed
26 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
27 However, the United States denies the remainder of this Request.
28

1 **REQUEST FOR ADMISSION NO. 207:** Admit that CMS removed the portion of
2 the Proposed Medical Record Review Rule that would have required Two-Way
3 Looks from the Final Rule in part related to comments CMS received from MAOs.
4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition of “CMS.” The United States
7 objects to this Request to the extent it calls for any legal conclusion. The United
8 States objects to this Request to the extent it seeks disclosure of information that is
9 protected from disclosure by an applicable privilege or protection, including the
10 attorney-client privilege, attorney work-product doctrine, deliberative process
11 privilege, and/or investigative files privilege. The United States objects to this
12 Request to the extent it calls for information that is already in UnitedHealth’s
13 possession, custody, or control, or is otherwise available to UnitedHealth. The
14 United States objects to this Request to the extent that UnitedHealth is using this
15 information to mischaracterize or misinterpret the facts, particularly in that it
16 mischaracterizes CMS’ statements contained in the Response to Public Comments
17 Section of the May 23, 2014 Final Rule: “However, we emphasize that our decision
18 to not finalize this regulatory proposal does not change CMS’ existing contractual
19 requirement that MA organizations must certify (based on best knowledge,
20 information, and belief) the accuracy, completeness, and truthfulness of the risk
21 adjustment data they submit to CMS. Further, this decision does not change the long-
22 standing risk adjustment data requirement that a diagnosis submitted to CMS by an
23 MA organization for payment purposes must be supported by medical record
24 documentation.” 79 Fed. Reg. 29926. The United States objects to this Request as
25 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
26 extent it is compound in that it asks the United States to admit multiple facts in one
27 Request. The United States objects to this Request to the extent it is duplicative of
28 Request for Admission Nos. 205, 206 and 208.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States admits that CMS reviewed the comments it received regarding the Proposed
3 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
4 However, the United States denies the remainder of this Request.

5 **REQUEST FOR ADMISSION NO. 208:** Admit that CMS did not finalize the
6 section of the Proposed Medical Record Review Rule that would have required Two-
7 Way Looks in part related to comments CMS received from MAOs.

8 **Objection:** The United States incorporates its General Objections and Specific
9 Objections to the Definitions and Instructions as if stated herein, including but not
10 limited to, its specific objections to the definition of “CMS.” The United States
11 objects to this Request to the extent it seeks disclosure of information that is protected
12 from disclosure by an applicable privilege or protection, including the attorney-client
13 privilege, attorney work-product doctrine, deliberative process privilege, and/or
14 investigative files privilege. The United States objects to this Request to the extent it
15 calls for any legal conclusion. The United States objects to this Request to the extent
16 it calls for information that is already in UnitedHealth’s possession, custody, or
17 control, or is otherwise available to UnitedHealth. The United States objects to this
18 Request to the extent that UnitedHealth is using this information to mischaracterize or
19 misinterpret the facts, particularly in that it mischaracterizes CMS’ statements
20 contained in the Response to Public Comments Section of the May 23, 2014 Final
21 Rule: “However, we emphasize that our decision to not finalize this regulatory
22 proposal does not change CMS’ existing contractual requirement that MA
23 organizations must certify (based on best knowledge, information, and belief) the
24 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
25 CMS. Further, this decision does not change the long- standing risk adjustment data
26 requirement that a diagnosis submitted to CMS by an MA organization for payment
27 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.
28 The United States objects to this Request as improper under Federal Rule of Civil

1 Procedure 36 and applicable case law to the extent it is compound in that it asks the
2 United States to admit multiple facts in one Request. The United States objects to
3 this Request to the extent it is duplicative of Request for Admission Nos. 205, 206
4 and 207.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States admits that CMS reviewed the comments it received regarding the Proposed
7 Medical Record Review Rule prior to finalizing the May 23, 2014 Final Rule.
8 However, the United States denies the remainder of this Request.

9 **REQUEST FOR ADMISSION NO. 209:** Admit that CMS removed the portion of
10 the Proposed Medical Record Review Rule that would have required Two-Way
11 Looks from the Final Rule in part related to the breadth of the Proposed Medical
12 Record Review Rule.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definition of “CMS.” The United States also
16 objects to this Request to the extent that the undefined term “breadth” is vague and
17 ambiguous. For purposes of this Request, the United States defines “breadth” as the
18 fact of including many different things. The United States objects to this Request to
19 the extent it calls for any legal conclusion. The United States objects to this Request
20 to the extent it seeks disclosure of information that is protected from disclosure by an
21 applicable privilege or protection, including the attorney-client privilege, attorney
22 work-product doctrine, deliberative process privilege, and/or investigative files
23 privilege. The United States objects to this Request to the extent it calls for
24 information that is already in UnitedHealth’s possession, custody, or control, or is
25 otherwise available to UnitedHealth. The United States objects to this Request to the
26 extent that UnitedHealth is using this information to mischaracterize or misinterpret
27 the facts, particularly in that it mischaracterizes CMS’ statements contained in the
28 Response to Public Comments Section of the May 23, 2014 Final Rule: “However,

1 we emphasize that our decision to not finalize this regulatory proposal does not
2 change CMS' existing contractual requirement that MA organizations must certify
3 (based on best knowledge, information, and belief) the accuracy, completeness, and
4 truthfulness of the risk adjustment data they submit to CMS. Further, this decision
5 does not change the long- standing risk adjustment data requirement that a diagnosis
6 submitted to CMS by an MA organization for payment purposes must be supported
7 by medical record documentation." 79 Fed. Reg. 29926. The United States objects
8 to this Request as improper under Federal Rule of Civil Procedure 36 and applicable
9 case law to the extent it is compound in that it asks the United States to admit
10 multiple facts in one Request. The United States objects to this Request to the extent
11 it is duplicative of Request for Admission No. 210.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States denies this Request.

14 **REQUEST FOR ADMISSION NO. 210:** Admit that CMS did not finalize the
15 portion of the Proposed Medical Record Review Rule that would have required Two-
16 Way Looks in part related to the breadth of the Proposed Medical Record Review
17 Rule.

18 **Objection:** The United States incorporates its General Objections and Specific
19 Objections to the Definitions and Instructions as if stated herein, including but not
20 limited to, its specific objections to the definition of "CMS." The United States also
21 objects to this Request to the extent that the undefined term "breadth" is vague and
22 ambiguous. For purposes of this Request, the United States defines "breadth" as the
23 fact of including many different things. The United States objects to this Request to
24 the extent it calls for any legal conclusion. The United States objects to this Request
25 to the extent it seeks disclosure of information that is protected from disclosure by an
26 applicable privilege or protection, including the attorney-client privilege, attorney
27 work-product doctrine, deliberative process privilege, and/or investigative files
28 privilege. The United States objects to this Request to the extent it calls for

1 information that is already in UnitedHealth's possession, custody, or control, or is
2 otherwise available to UnitedHealth. The United States objects to this Request to the
3 extent that UnitedHealth is using this information to mischaracterize or misinterpret
4 the facts, particularly in that it mischaracterizes CMS' statements contained in the
5 Response to Public Comments Section of the May 23, 2014 Final Rule: "However,
6 we emphasize that our decision to not finalize this regulatory proposal does not
7 change CMS' existing contractual requirement that MA organizations must certify
8 (based on best knowledge, information, and belief) the accuracy, completeness, and
9 truthfulness of the risk adjustment data they submit to CMS. Further, this decision
10 does not change the long- standing risk adjustment data requirement that a diagnosis
11 submitted to CMS by an MA organization for payment purposes must be supported
12 by medical record documentation." 79 Fed. Reg. 29926. The United States objects
13 to this Request as improper under Federal Rule of Civil Procedure 36 and applicable
14 case law to the extent it is compound in that it asks the United States to admit
15 multiple facts in one Request. The United States objects to this Request to the extent
16 it is duplicative of Request for Admission No. 209.

17 **Response:** Subject to and without waiving the foregoing objections, the United
18 States denies this Request.

19 **REQUEST FOR ADMISSION NO. 211:** Admit that CMS removed the portion of
20 the Proposed Medical Record Review Rule that would have required Two-Way
21 Looks from the Final Rule in part related to the advisability of implementing the
22 Proposed Rule as drafted.

23 **Objection:** The United States incorporates its General Objections and Specific
24 Objections to the Definitions and Instructions as if stated herein, including but not
25 limited to, its specific objections to the definition of "CMS." The United States also
26 objects to this Request to the extent that the undefined phrase "advisability of
27 implementing" is vague and ambiguous and the United States lacks knowledge about
28 what is requested. The United States objects to this Request to the extent it calls for

1 any legal conclusion. The United States objects to this Request to the extent it seeks
2 disclosure of information that is protected from disclosure by an applicable privilege
3 or protection, including the attorney-client privilege, attorney work-product doctrine,
4 deliberative process privilege, and/or investigative files privilege. The United States
5 objects to this Request to the extent it calls for information that is already in
6 UnitedHealth's possession, custody, or control, or is otherwise available to
7 UnitedHealth. The United States objects to this Request to the extent that
8 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
9 particularly in that it mischaracterizes CMS' statements contained in the Response to
10 Public Comments Section of the May 23, 2014 Final Rule: "However, we emphasize
11 that our decision to not finalize this regulatory proposal does not change CMS'
12 existing contractual requirement that MA organizations must certify (based on best
13 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
14 the risk adjustment data they submit to CMS. Further, this decision does not change
15 the long- standing risk adjustment data requirement that a diagnosis submitted to
16 CMS by an MA organization for payment purposes must be supported by medical
17 record documentation." 79 Fed. Reg. 29926. The United States objects to this
18 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
19 law to the extent it is compound in that it asks the United States to admit multiple
20 facts in one Request. The United States objects to this Request to the extent it is
21 duplicative of Request for Admission No. 212.

22 **Response:** Subject to and without waiving the foregoing objections, the United
23 States denies this Request.

24 **REQUEST FOR ADMISSION NO. 212:** Admit that CMS did not finalize the
25 Proposed Medical Record Review Rule that would have required Two-Way Looks in
26 part related to the advisability of implementing the Proposed Rule as drafted.

27 **Objection:** The United States incorporates its General Objections and Specific
28 Objections to the Definitions and Instructions as if stated herein, including but not

1 limited to, its specific objections to the definitions of “CMS.” The United States also
2 objects to this Request to the extent that the undefined phrase “advisability of
3 implementing” is vague and ambiguous and the United States lacks knowledge about
4 what is requested. The United States objects to this Request to the extent it calls for
5 any legal conclusion. The United States objects to this Request to the extent it seeks
6 disclosure of information that is protected from disclosure by an applicable privilege
7 or protection, including the attorney-client privilege, attorney work-product doctrine,
8 deliberative process privilege, and/or investigative files privilege. The United States
9 objects to this Request to the extent it calls for information that is already in
10 UnitedHealth’s possession, custody, or control, or is otherwise available to
11 UnitedHealth. The United States objects to this Request to the extent that
12 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
13 particularly in that it mischaracterizes CMS’ statements contained in the Response to
14 Public Comments Section of the May 23, 2014 Final Rule: “However, we emphasize
15 that our decision to not finalize this regulatory proposal does not change CMS’
16 existing contractual requirement that MA organizations must certify (based on best
17 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
18 the risk adjustment data they submit to CMS. Further, this decision does not change
19 the long- standing risk adjustment data requirement that a diagnosis submitted to
20 CMS by an MA organization for payment purposes must be supported by medical
21 record documentation.” 79 Fed. Reg. 29926. The United States objects to this
22 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
23 law to the extent it is compound in that it asks the United States to admit multiple
24 facts in one Request. The United States objects to this Request to the extent it is
25 duplicative of Request for Admission No. 211.

26 **Response:** Subject to and without waiving the foregoing objections, the United
27 States denies this Request.
28

1 **REQUEST FOR ADMISSION NO. 213:** Admit that CMS did not finalize the
2 Proposed Medical Record Review Rule that would have required Two-Way Looks in
3 part because CMS thought Two-Way Looks were already required.

4 **Objection:** The United States incorporates its General Objections and Specific
5 Objections to the Definitions and Instructions as if stated herein, including but not
6 limited to, its specific objections to the definition of “CMS.” The United States
7 objects to this Request to the extent it calls for any legal conclusion. The United
8 States objects to this Request to the extent it seeks disclosure of information that is
9 protected from disclosure by an applicable privilege or protection, including the
10 attorney-client privilege, attorney work-product doctrine, deliberative process
11 privilege, and/or investigative files privilege. The United States objects to this
12 Request to the extent it calls for information that is already in UnitedHealth’s
13 possession, custody, or control, or is otherwise available to UnitedHealth. The
14 United States objects to this Request to the extent that UnitedHealth is using this
15 information to mischaracterize or misinterpret the facts, particularly in that it
16 mischaracterizes CMS’ statements contained in the Response to Public Comments
17 Section of the May 23, 2014 Final Rule: “However, we emphasize that our decision
18 to not finalize this regulatory proposal does not change CMS’ existing contractual
19 requirement that MA organizations must certify (based on best knowledge,
20 information, and belief) the accuracy, completeness, and truthfulness of the risk
21 adjustment data they submit to CMS. Further, this decision does not change the long-
22 standing risk adjustment data requirement that a diagnosis submitted to CMS by an
23 MA organization for payment purposes must be supported by medical record
24 documentation.” 79 Fed. Reg. 29926. The United States objects to this Request as
25 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
26 extent it is compound in that it asks the United States to admit multiple facts in one
27 Request. The United States objects to this Request to the extent it is duplicative of
28 Request for Admission No. 214.

1 **Response:** Subject to and without waiving the foregoing objections, the United
2 States denies that CMS identified Two Way Looks as the only manner in which
3 MAOs could comply with their existing regulatory and contractual obligations.
4 However, the United States admits that CMS reaffirmed the existing obligations of
5 MA Organizations in the preamble to the Final Rule: “However, we emphasize that
6 our decision to not finalize this regulatory proposal does not change CMS’ existing
7 contractual requirement that MA organizations must certify (based on best
8 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
9 the risk adjustment data they submit to CMS. Further, this decision does not change
10 the long-standing risk adjustment data requirement that a diagnosis submitted to CMS
11 by an MA organization for payment purposes must be supported by medical record
12 documentation.” 79 Fed. Reg. 29926.

13 **REQUEST FOR ADMISSION NO. 214:** Admit that CMS removed the portion of
14 the Proposed Medical Record Review Rule that would have required Two-Way
15 Looks from the Final Rule in part because CMS thought Two-Way Looks were
16 already required.

17 **Objection:** The United States incorporates its General Objections and Specific
18 Objections to the Definitions and Instructions as if stated herein, including but not
19 limited to, its specific objections to the definition of “CMS.” The United States
20 objects to this Request to the extent it calls for any legal conclusion. The United
21 States objects to this Request to the extent it seeks disclosure of information that is
22 protected from disclosure by an applicable privilege or protection, including the
23 attorney-client privilege, attorney work-product doctrine, deliberative process
24 privilege, and/or investigative files privilege. The United States objects to this
25 Request to the extent it calls for information that is already in UnitedHealth’s
26 possession, custody, or control, or is otherwise available to UnitedHealth. The
27 United States objects to this Request to the extent that UnitedHealth is using this
28 information to mischaracterize or misinterpret the facts, particularly in that it

1 mischaracterizes CMS' statements contained in the Response to Public Comments
2 Section of the May 23, 2014 Final Rule: "However, we emphasize that our decision
3 to not finalize this regulatory proposal does not change CMS' existing contractual
4 requirement that MA organizations must certify (based on best knowledge,
5 information, and belief) the accuracy, completeness, and truthfulness of the risk
6 adjustment data they submit to CMS. Further, this decision does not change the long-
7 standing risk adjustment data requirement that a diagnosis submitted to CMS by an
8 MA organization for payment purposes must be supported by medical record
9 documentation." 79 Fed. Reg. 29926. The United States objects to this Request as
10 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
11 extent it is compound in that it asks the United States to admit multiple facts in one
12 Request. The United States objects to this Request to the extent it is duplicative of
13 Request for Admission No. 213.

14 **Response:** Subject to and without waiving the foregoing objections, the United
15 States denies that CMS identified Two Way Looks as the only manner in which
16 MAOs could comply with their existing regulatory and contractual obligations.
17 However, the United States admits that CMS reaffirmed the existing obligations of
18 MA Organizations in in the preamble to the Final Rule, "However, we emphasize that
19 our decision to not finalize this regulatory proposal does not change CMS' existing
20 contractual requirement that MA organizations must certify (based on best
21 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
22 the risk adjustment data they submit to CMS. Further, this decision does not change
23 the long-standing risk adjustment data requirement that a diagnosis submitted to CMS
24 by an MA organization for payment purposes must be supported by medical record
25 documentation." 79 Fed. Reg. 29926.

26 **REQUEST FOR ADMISSION NO. 215:** Admit that CMS did not finalize the
27 Proposed Medical Record Review Rule that would have required Two-Way Looks in
28 part because CMS thought Two-Way Looks were burdensome for MAOs.

1 **Objection:** The United States incorporates its General Objections and Specific
2 Objections to the Definitions and Instructions as if stated herein, including but not
3 limited to, its specific objections to the definitions of “CMS” and “MAO.” The
4 United States also objects to this Request to the extent that the undefined term
5 “burdensome” is vague and ambiguous. For purposes of this Request, the United
6 States defines “burdensome” as difficult to carry out. The United States objects to
7 this Request to the extent it calls for any legal conclusion. The United States objects
8 to this Request to the extent it seeks disclosure of information that is protected from
9 disclosure by an applicable privilege or protection, including the attorney-client
10 privilege, attorney work-product doctrine, deliberative process privilege, and/or
11 investigative files privilege. The United States objects to this Request to the extent it
12 calls for information that is already in UnitedHealth’s possession, custody, or control,
13 or is otherwise available to UnitedHealth. The United States objects to this Request
14 to the extent that UnitedHealth is using this information to mischaracterize or
15 misinterpret the facts, particularly in that it mischaracterizes CMS’ statements
16 contained in the Response to Public Comments Section of the May 23, 2014 Final
17 Rule: “However, we emphasize that our decision to not finalize this regulatory
18 proposal does not change CMS’ existing contractual requirement that MA
19 organizations must certify (based on best knowledge, information, and belief) the
20 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
21 CMS. Further, this decision does not change the long- standing risk adjustment data
22 requirement that a diagnosis submitted to CMS by an MA organization for payment
23 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.
24 The United States objects to this Request as improper under Federal Rule of Civil
25 Procedure 36 and applicable case law to the extent it is compound in that it asks the
26 United States to admit multiple facts in one Request. The United States objects to
27 this Request to the extent it is duplicative of Request for Admission No. 216.
28 **Response:** Subject to and without waiving the foregoing objections, the United

1 States denies this Request.

2 **REQUEST FOR ADMISSION NO. 216:** Admit that CMS removed the portion of
3 the Proposed Medical Record Review Rule that would have required Two-Way
4 Looks from the Final Rule in part because CMS thought Two-Way Looks were
5 burdensome for MAOs.

6 **Objection:** The United States incorporates its General Objections and Specific
7 Objections to the Definitions and Instructions as if stated herein, including but not
8 limited to, its specific objections to the definitions of “CMS” and “MAO.” The
9 United States also objects to this Request to the extent that the undefined term
10 “burdensome” is vague and ambiguous. For purposes of this Request, the United
11 States defines “burdensome” as difficult to carry out. The United States objects to
12 this Request to the extent it calls for any legal conclusion. The United States objects
13 to this Request to the extent it seeks disclosure of information that is protected from
14 disclosure by an applicable privilege or protection, including the attorney-client
15 privilege, attorney work-product doctrine, deliberative process privilege, and/or
16 investigative files privilege. The United States objects to this Request to the extent it
17 calls for information that is already in UnitedHealth’s possession, custody, or control,
18 or is otherwise available to UnitedHealth. The United States objects to this Request
19 to the extent that UnitedHealth is using this information to mischaracterize or
20 misinterpret the facts, particularly in that it mischaracterizes CMS’ statements
21 contained in the Response to Public Comments Section of the May 23, 2014 Final
22 Rule: “However, we emphasize that our decision to not finalize this regulatory
23 proposal does not change CMS’ existing contractual requirement that MA
24 organizations must certify (based on best knowledge, information, and belief) the
25 accuracy, completeness, and truthfulness of the risk adjustment data they submit to
26 CMS. Further, this decision does not change the long- standing risk adjustment data
27 requirement that a diagnosis submitted to CMS by an MA organization for payment
28 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.

1 The United States objects to this Request as improper under Federal Rule of Civil
2 Procedure 36 and applicable case law to the extent it is compound in that it asks the
3 United States to admit multiple facts in one Request. The United States objects to
4 this Request to the extent it is duplicative of Request for Admission No. 215.

5 **Response:** Subject to and without waiving the foregoing objections, the United
6 States denies this Request.

7 **REQUEST FOR ADMISSION NO. 217:** Admit that CMS did not finalize the
8 Proposed Medical Record Review Rule that would have required Two-Way Looks in
9 part because of the FFS Adjuster.

10 **Objection:** The United States incorporates its General Objections and Specific
11 Objections to the Definitions and Instructions as if stated herein, including but not
12 limited to, its specific objections to the definition of “CMS.” The United States
13 objects to this Request to the extent it calls for any legal conclusion. The United
14 States objects to this Request to the extent it seeks disclosure of information that is
15 protected from disclosure by an applicable privilege or protection, including the
16 attorney-client privilege, attorney work-product doctrine, deliberative process
17 privilege, and/or investigative files privilege. The United States objects to this
18 Request to the extent it calls for information that is already in UnitedHealth’s
19 possession, custody, or control, or is otherwise available to UnitedHealth. The
20 United States objects to this Request to the extent that UnitedHealth is using this
21 information to mischaracterize or misinterpret the facts, particularly in that it
22 mischaracterizes CMS’ statements contained in the Response to Public Comments
23 Section of the May 23, 2014 Final Rule: “However, we emphasize that our decision
24 to not finalize this regulatory proposal does not change CMS’ existing contractual
25 requirement that MA organizations must certify (based on best knowledge,
26 information, and belief) the accuracy, completeness, and truthfulness of the risk
27 adjustment data they submit to CMS. Further, this decision does not change the long-
28 standing risk adjustment data requirement that a diagnosis submitted to CMS by an

1 MA organization for payment purposes must be supported by medical record
2 documentation.” 79 Fed. Reg. 29926. The United States objects to this Request as
3 improper under Federal Rule of Civil Procedure 36 and applicable case law to the
4 extent it is compound in that it asks the United States to admit multiple facts in one
5 Request. The United States objects to this Request to the extent it is duplicative of
6 Request for Admission No. 218.

7 **Response:** Subject to and without waiving the foregoing objections, the United
8 States denies this Request.

9 **REQUEST FOR ADMISSION NO. 218:** Admit that CMS removed the portion of
10 the Proposed Medical Record Review Rule that would have required Two-Way
11 Looks from the Final Rule in part because of the FFS Adjuster.

12 **Objection:** The United States incorporates its General Objections and Specific
13 Objections to the Definitions and Instructions as if stated herein, including but not
14 limited to, its specific objections to the definition of “CMS.” The United States
15 objects to this Request to the extent it calls for any legal conclusion. The United
16 States objects to this Request to the extent it seeks disclosure of information that is
17 protected from disclosure by an applicable privilege or protection, including the
18 attorney-client privilege, attorney work-product doctrine, deliberative process
19 privilege, and/or investigative files privilege. The United States objects to this
20 Request to the extent it calls for information that is already in UnitedHealth’s
21 possession, custody, or control, or is otherwise available UnitedHealth. The United
22 States objects to this Request to the extent that UnitedHealth is using this information
23 to mischaracterize or misinterpret the facts, particularly in that it mischaracterizes
24 CMS’ statements contained in the Response to Public Comments Section of the May
25 23, 2014 Final Rule: “However, we emphasize that our decision to not finalize this
26 regulatory proposal does not change CMS’ existing contractual requirement that MA
27 organizations must certify (based on best knowledge, information, and belief) the
28 accuracy, completeness, and truthfulness of the risk adjustment data they submit to

1 CMS. Further, this decision does not change the long- standing risk adjustment data
2 requirement that a diagnosis submitted to CMS by an MA organization for payment
3 purposes must be supported by medical record documentation.” 79 Fed. Reg. 29926.
4 The United States objects to this Request as improper under Federal Rule of Civil
5 Procedure 36 and applicable case law to the extent it is compound in that it asks the
6 United States to admit multiple facts in one Request. The United States objects to
7 this Request to the extent it is duplicative of Request for Admission No. 217.

8 **Response:** Subject to and without waiving the foregoing objections, the United
9 States denies this Request.

10 **REQUEST FOR ADMISSION NO. 219:** Admit that CMS did not finalize the
11 Proposed Medical Record Review Rule that would have required Two-Way Looks in
12 part because of Actuarial Equivalence.

13 **Objection:** The United States incorporates its General Objections and Specific
14 Objections to the Definitions and Instructions as if stated herein, including but not
15 limited to, its specific objections to the definitions of “CMS” and “Actuarial
16 Equivalence.” The United States objects to this Request to the extent it calls for any
17 legal conclusion. The United States objects to this Request to the extent it seeks
18 disclosure of information that is protected from disclosure by an applicable privilege
19 or protection, including the attorney-client privilege, attorney work-product doctrine,
20 deliberative process privilege, and/or investigative files privilege. The United States
21 objects to this Request to the extent it calls for information that is already in
22 UnitedHealth’s possession, custody, or control, or is otherwise available to
23 UnitedHealth. The United States objects to this Request to the extent that
24 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
25 particularly in that it mischaracterizes CMS’ statements contained in the Response to
26 Public Comments Section of the May 23, 2014 Final Rule: “However, we emphasize
27 that our decision to not finalize this regulatory proposal does not change CMS’
28 existing contractual requirement that MA organizations must certify (based on best

1 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
2 the risk adjustment data they submit to CMS. Further, this decision does not change
3 the long- standing risk adjustment data requirement that a diagnosis submitted to
4 CMS by an MA organization for payment purposes must be supported by medical
5 record documentation.” 79 Fed. Reg. 29926. The United States objects to this
6 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
7 law to the extent it is compound in that it asks the United States to admit multiple
8 facts in one Request. The United States objects to this Request to the extent it is
9 duplicative of Request for Admission No. 220.

10 **Response:** Subject to and without waiving the foregoing objections, the United
11 States denies this Request.

12 **REQUEST FOR ADMISSION NO. 220:** Admit that CMS removed the portion of
13 the Proposed Medical Record Review Rule that would have required Two-Way
14 Looks from the Final Rule in part because of Actuarial Equivalence.

15 **Objection:** The United States incorporates its General Objections and Specific
16 Objections to the Definitions and Instructions as if stated herein, including but not
17 limited to, its specific objections to the definitions of “CMS” and “Actuarial
18 Equivalence.” The United States objects to this Request to the extent it calls for any
19 legal conclusion. The United States objects to this Request to the extent it seeks
20 disclosure of information that is protected from disclosure by an applicable privilege
21 or protection, including the attorney-client privilege, attorney work-product doctrine,
22 deliberative process privilege, and/or investigative files privilege. The United States
23 objects to this Request to the extent it calls for information that is already in
24 UnitedHealth’s possession, custody, or control, or is otherwise available to
25 UnitedHealth. The United States objects to this Request to the extent that
26 UnitedHealth is using this information to mischaracterize or misinterpret the facts,
27 particularly in that it mischaracterizes CMS’ statements contained in the Response to
28 Public Comments Section of the May 23, 2014 Final Rule: “However, we emphasize

1 that our decision to not finalize this regulatory proposal does not change CMS'
2 existing contractual requirement that MA organizations must certify (based on best
3 knowledge, information, and belief) the accuracy, completeness, and truthfulness of
4 the risk adjustment data they submit to CMS. Further, this decision does not change
5 the long- standing risk adjustment data requirement that a diagnosis submitted to
6 CMS by an MA organization for payment purposes must be supported by medical
7 record documentation.” 79 Fed. Reg. 29926. The United States objects to this
8 Request as improper under Federal Rule of Civil Procedure 36 and applicable case
9 law to the extent it is compound in that it asks the United States to admit multiple
10 facts in one Request. The United States objects to this Request to the extent it is
11 duplicative of Request for Admission No. 219.

12 **Response:** Subject to and without waiving the foregoing objections, the United
13 States denies this Request.

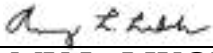
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16 Respectfully submitted,
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1 Dated: February 12, 2020

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PROOF OF SERVICE BY ELECTONIC MAIL

I am over the age of 18 and not a party to the action entitled U.S. ex rel. Poehling v. UnitedHealth Group, Inc., Claims Verification 16-8697 MWF (SSx). I am employed by the Department of Justice, Civil Division. My business address is 175 N Street NE, Room 10.1813, Washington, D.C. 20002.

On February 12, 2020, I served the foregoing UNITED STATES' RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S REQUESTS FOR ADMISSION TO THE GOVERNMENT (SET NO. THREE) on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: February 12, 2020.

Place of e-mailing: Washington, D.C.

Person(s) and/or Entity(s) to whom e-mailed:

See attached page

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 12, 2020, at Washington, D.C.



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21 FOR THE CENTRAL DISTRICT OF CALIFORNIA
22 WESTERN DIVISION

23 UNITED STATES OF AMERICA *ex*
24 *rel.* BENJAMIN POEHLING,

25 Plaintiffs,

26 v.

27 UNITEDHEALTH GROUP, INC., *et al.*,

28 Defendants.

No. CV 16-08697 FMO (SSx)

UNITED STATES' RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S FIRST SET OF
INTERROGATORIES TO THE
GOVERNMENT

1 **PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.**
2 **RESPONDING PARTY: UNITED STATES OF AMERICA**
3 **SET NUMBER: ONE**

4
5 **Preliminary Statement**

6 Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure (“Federal
7 Rules”) and Rule 33 of the Local Civil Rules of the United States District Court for
8 the Central District of California, the United States of America (“United States” or
9 “government”), through its undersigned counsel, provides these responses and
10 objections to Defendant UHC of California’s (“UnitedHealth” or “Defendant”) First
11 Set of Interrogatories, dated January 3, 2020. The objections and responses set forth
12 herein are based on information now known to the United States and its undersigned
13 attorneys, and will be revised, corrected, supplemented, amended, and clarified to the
14 extent required by Rule 26 as discovery proceeds.

15 **General Objections**

16 The following objections apply to each and every separately numbered
17 Interrogatory and are incorporated by reference to the extent applicable into the
18 objection to each Interrogatory.

19 1. The United States objects to the First Set of Interrogatories to the extent it is
20 vague, ambiguous, overbroad, unduly burdensome, or seeks to impose requirements
21 upon the United States beyond those called for or permitted by the Federal Rules of
22 Civil Procedure, the Local Civil Rules of the United States District Court for the
23 Central District of California, or any order of the Court. The United States responds
24 below pursuant to its obligations under the Federal Rules and the Local Civil Rules,
25 namely that the United States has taken and is continuing to undertake reasonable
26 efforts to identify information responsive to the Interrogatories.

27 2. The United States objects to the First Set of Interrogatories to the extent they
28 seek the disclosure of information concerning the United States’ investigation of this

1 matter as well as the United States' investigation in *United States of America ex rel.*
2 *Swoben v. SCAN Health Plan, et al.*, CV 09-5013 JFW (JEMx), 2017 U.S. Dist.
3 LEXIS 174308 (C.D. Cal. Oct. 5, 2017) ("*Swoben*"). This includes, but is not limited
4 to, the United States' investigative efforts, its assessments of facts and allegations, its
5 deliberative processes concerning actions taken regarding this matter and *Swoben*,
6 and other information generated before and after the commencement of both this
7 litigation and *Swoben*. The United States objects on the grounds that such
8 information is privileged, work-product protected, not relevant to claims or defenses,
9 and not proportional to the needs of the case.

10 3. The United States objects to the below First Set of Interrogatories to the extent
11 that a response requires disclosure of information protected from disclosure by an
12 applicable privilege or protection, including, but not limited to, the attorney-client
13 privilege, work product doctrine, deliberative process privilege, law enforcement
14 privilege, common interest privilege, or investigative files privilege, and protections
15 afforded by Fed. R. Civ. P. 26(b), or any other applicable privilege. The United States
16 will not respond in such a way as to disclose such protected information, but
17 inadvertent identification or disclosure of privileged information by the United States
18 shall not be a waiver of any applicable privilege. Under Federal Rule of Evidence
19 502, Federal Rule of Civil Procedure 26(b)(5)(B), other related sources of law, and
20 the Court's order regarding inadvertent disclosure of privileged information [Doc.
21 198], the government reserves any and all rights to claw back privileged information
22 it inadvertently discloses in response to the First Set of Interrogatories.

23 4. The United States submits these responses subject to, without intending to
24 waive, but expressly reserving the right to object to other discovery procedures
25 involving or relating to the subject matter of the information in responses to the First
26 Set of Interrogatories. The United States reserves the right to object on any ground, at
27 any time, to such other or supplemental requests as the Defendants may propound
28 involving or relating to the subject matter of the First Set of Interrogatories.

1 5. The United States reserves the right to supplement its responses to the First Set
2 of Interrogatories at any time, up to and including trial, as provided by the Federal
3 Rules.

4 6. The assertion of the same, similar, or additional specific objections to the First
5 Set of Interrogatories does not and should not be construed to waive or modify any of
6 the United States' general objections.

7 7. The United States objects to the First Set of Interrogatories to the extent they
8 require the United States to draw legal conclusions, comment on the merits of any
9 affirmative defenses, or otherwise seek to impose any requirements beyond those
10 established by the Federal Rules or the Local Rules.

11 8. The United States objects to the First Set of Interrogatories to the extent that
12 any it contains multiple subparts numbered as a single Interrogatory. By responding,
13 the United States in no way waives its right to object that UnitedHealth has exceeded
14 the maximum number of interrogatories permitted under the Federal Rules of Civil
15 Procedure.

16 **Specific Objections to the Definitions and Instructions**

17 The United States objects to the Definitions and Instructions to the extent they
18 (i) seek to impose burdens on the United States that are different from, inconsistent
19 with, or exceed those imposed by the Federal Rules of Civil Procedure and the Local
20 Civil Rules, (ii) are vague or ambiguous, and/or (iii) render the First Set of
21 Interrogatories overly broad, unduly burdensome, not proportionate to the needs of
22 the case, and not relevant. The United States further objects to the First Set of
23 Interrogatories to the extent they use terms not defined by UnitedHealth.

24 **Definition 10:** The United States objects to the definition of "Government"
25 (Definition 10) to the extent it includes any branch, agency, department, agent,
26 representative, contractor, attorney, consultant, or person acting on its behalf not
27 relevant to this action. This definition is plainly unreasonable, unduly burdensome,
28 and disproportionate to the needs of the case, in that it seeks to require the United

1 States to provide information not currently in the possession, custody, or control of
2 CMS, HHS Office of the Secretary and Immediate Office of the Secretary and HHS-
3 OIG. Subject to and without waiving these objections, the United States interprets
4 “Government” to mean CMS, HHS Office of the Secretary and Immediate Office of
5 the Secretary, and HHS-OIG. To the extent the United States interprets the use of
6 “Government” in a specific Interrogatory as directed at one, but not all, of the above
7 components, the United States will state its interpretation in its response.

8 **Definition 13:** The United States objects to the term “Person” (Definition 13) to the
9 extent it is defined to mean “the federal government and all departments and agencies
10 thereof, state governments, local governments, [and] other governmental agencies[.]”
11 This definition is plainly unreasonable, unduly burdensome, and disproportionate to
12 the needs of the case, in that it seeks to require the United States to provide
13 information not currently in the possession, custody, or control of CMS, HHS Office
14 of the Secretary and Immediate Office of the Secretary and HHS-OIG. Furthermore,
15 the United States objects to the extent each definition includes former CMS
16 contractors for whom the United States presently has no reasonable belief they
17 possess or control non-duplicative information relevant to any claim or defense in this
18 case.

19 **Definition 19:** The United States objects to the definition of “You” and “Your” to
20 the extent these terms are intended to encompass any agency, office, employee, agent,
21 representative, officer, or contractor of either the legislative or judicial branch, and
22 insofar as these terms are defined to include executive branch agencies and offices
23 not relevant to this action. This is plainly unreasonable, unduly burdensome, and
24 disproportionate to the needs of the case, in that it seeks to require the United States
25 to provide information not currently in the possession, custody, or control of CMS,
26 HHS Office of the Secretary and Immediate Office of the Secretary and HHS-OIG.
27 Subject to and without waiving these objections, the United States will interpret this
28 term to mean the Department of Justice, CMS, HHS Office of the Secretary and

1 Immediate Office of the Secretary, and HHS-OIG.

2 **Instruction 3:** The United States objects to Instruction 3 as vague and ambiguous.
3 The United States construes the Interrogatory to encompass the time period from
4 Date of Service Years 2008-2016.

5 **Instruction 5:** The United States objects to Instruction 5 to the extent it seeks to
6 impose burdens upon the United States beyond those called for or permitted by the
7 Federal Rules or the Local Rules for the Central District of California.

8 **Instruction 6:** The United States objects to Instruction 6 to the extent it seeks to
9 impose burdens upon the United States beyond those called for or permitted by the
10 Federal Rules or the Local Rules for the Central District of California.

11 **Instruction 7:** The United States objects to Instruction 7 to the extent it seeks to
12 impose burdens upon the United States beyond those called for or permitted by the
13 Federal Rules or the Local Rules for the Central District of California. The United
14 States will assert any applicable privileges and specify the material to which it applies
15 per Fed. R. Civ. P. 25(b)(5)(A) for all information responsive to a request to which
16 the United States has agreed to produce but which is withheld on the basis of a
17 privilege or protection.

18 **Specific Objections and Responses**

19 **INTERROGATORY NO. 1:** Identify for Date of Service Years 2008–2016
20 the Beneficiary (by name, HIC Number, and date of birth), Date of Service,
21 Diagnosis Code(s), CMS HCC(s) or RxHCC(s), and Provider (by individual
22 name, group name, address, NPI, Tax ID(s), and Provider ID), that corresponds
23 to each and every Diagnosis Code You allege UnitedHealth “knowingly and
24 improperly failed to delete . . . or otherwise return to the Medicare Program [as
25 an] overpayment.” United States’ Complaint ¶ 342, Dkt. 171.

26 **Objection:** The United States incorporates its General Objections and Specific
27 Objections to the Definitions and Instructions as if stated herein. The United States
28 further objects to this Interrogatory on the grounds that it is oppressive and unduly

1 burdensome in that it seeks information that is more readily available to or in the
2 possession, custody, or control of the UnitedHealth defendants concerning their own
3 Beneficiaries and Diagnoses Codes reported on behalf of their own Beneficiaries.
4 The United States further objects to this Interrogatory in that it prematurely seeks the
5 disclosure of expert analysis and opinion. The United States will provide its expert
6 analyses and opinions in accordance with the expert discovery schedule set forth in
7 this case. The United States further objects to this Interrogatory in that, with fact
8 discovery still ongoing, the United States has not yet identified “each and every
9 Diagnosis Code” that the United States alleges that UnitedHealth knowingly and
10 improperly failed to delete and that the interrogatory therefore prematurely seeks the
11 United States’ contentions about “each and every Diagnosis Code.” Further,
12 UnitedHealth has inhibited the United States’ ability to identify “each and every
13 Diagnosis Code” by improperly refusing to produce – for more than a year and a half
14 – complete chart review data for the relevant time period. Indeed, UnitedHealth only
15 recently produced chart review data for Date of Service Years 2015 and 2016 on or
16 about December 6, 2019. The United States further objects to the extent that the
17 Interrogatory asks for information that the United States does not have or cannot
18 determine because of the manner in which UnitedHealth recorded and maintained
19 data. The United States further objects to the extent that UnitedHealth’s use of an
20 ellipsis is misleading and confusing and renders the quotation nonsensical.

21 **Response:** Subject to and without waiving the foregoing objections, the United
22 States responds that although fact discovery is ongoing, and expert disclosures are not
23 due until December 18, 2020, and that the United States reserves the right to
24 supplement and/or amend this answer in full or in part as it learns new information
25 and as expert analysis progresses, the United States alleges that UnitedHealth
26 Defendants “knowingly and improperly failed to delete in the RAPS system the
27 invalid diagnoses that had been submitted to the Medicare Program for risk
28 adjustment payments which were made by the Medicare Program to them or

1 knowingly and improperly failed to otherwise return to the Medicare Program the
2 overpayments based on the invalid diagnoses” for each and every Diagnosis Code
3 that was known (as that term is defined by the False Claims Act) to be unsupported
4 by medical records and that affected the amount of payment received by
5 UnitedHealth from the Medicare Program. The information UnitedHealth seeks is
6 readily available to or in its possession, custody, or control, and can be derived from
7 documents that UnitedHealth has produced including, but not limited to:
8 MARA1795523; MARA1795803; MARA768242; MARA2100494-495;
9 MARA2100496-MARA2100500; MARA2100501-502; MARA2117122;
10 MARA2117127-128; MARA2117129-137; MARA2117312-539; MARA2152913-
11 MARA2152925; MARA2152926; MARA2152922; MARA2152927-
12 MARA2152934; MARA2156616- 618; MARA2156619-6787; MARA2157305-
13 MARA2157320; MARA2157332 - MARA2157345; MARA2157351-
14 MARA2160459; MARA2160460-MARA2160489; MARA2160490 –
15 MARA2160498; MARA2160502 - MARA2160535; MARA2160687-
16 MARA2160695; MARA2160704-MARA2160725; MARA2160726 -
17 MARA2160729; MARA2160732-MARA2160735; MARA2160730 -
18 MARA2160731; MARA2160736-MARA2160737; MARA2180340-
19 MARA2180341; MARA2180342- MARA2180343; MAPL000724235-
20 MAPL000724836; MAPL001370197-MAPL001370236; MAPL001570602 -
21 MAPL001570606; MAPL002077000 - MAPL002079216; MAPL003292331-
22 MAPL003292498; MAPL003667028-MAPL003667128; MAPL003958939-
23 MAPL003959010; MAPL005462834- MAPL005462902; and MAPL006427492-
24 MAPL006427602.

25 Further, the United States refers to MARA1298042, MARA2092181,
26 MARA2157036, MARA2160501, and MARA2117116, incorporates as if fully set
27 forth herein and identifies all Diagnosis Codes contained therein that affected the
28 amount of payment received by UnitedHealth from the Medicare Program.

1 At this time and based upon the incomplete information and subject to the right to
2 supplement and/or amend this answer in full or in part, the United States additionally
3 identifies and incorporates into its answer the attached chart of representative
4 examples of Diagnosis Codes that UnitedHealth “knowingly and improperly failed to
5 delete in the RAPS system” or “knowingly and improperly failed to otherwise return
6 to the Medicare Program the overpayments based on” such diagnoses. The provider
7 information in the attached chart has been reproduced as it appears in the data that
8 UnitedHealth produced in this case, including missing fields, dummy values, and
9 placeholders, and we have preserved the convention of using "~" to indicate a
10 database null. Further, although the Interrogatory asked for the Provider ID, there is
11 no field designated Provider_ID and we have responded with the Provider_Nbr. For
12 COSMOS Providers, we have included two sets of provider information: the provider
13 information that results from a direct lookup in the Provider table (2A), and the
14 provider information that results from a lookup in the SAS_All_Providers table you
15 provided to us, linking the LOB_Cd associated with the encounter's LOB_Key to the
16 Site_Cd field. For non-COSMOS Providers, the second set of columns has been left
17 blank.

18 The United States will supplement its response to this Interrogatory as
19 appropriate and subject to the expert discovery schedule set forth in this case.
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1 Respectfully submitted,
2 Dated: February 3, 2020 JOSEPH H. HUNT
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PROOF OF SERVICE BY ELECTRONIC MAIL

I am over the age of 18 and not a party to the action entitled U.S. *ex rel.* Poehling v. UnitedHealth Group, Inc., CV-16-8697 MWF (SSx). I am employed by the Department of Justice, Civil Division. My business address is 175 N Street NE, Room 10.224, Washington, D.C. 20002.

On February 3, 2020, I served the foregoing PLAINTIFF UNITED STATES' RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S FIRST SET OF INTERROGATORIES TO THE GOVERNMENT on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: February 3, 2020.

Place of e-mailing: Washington, D.C.

Person(s) and/or Entity(s) to whom e-mailed:

See attached page

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 3, 2020, at Washington, D.C.



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Beneficiary Information											Provider Table lookup (as provided)				SAS_All_Providers lookup using LOB_Cd as Site_Cd (for COSMOS providers)			
HICN	Last Name	First Name	DOB	Dx	HCC	RxHCC	HCC V22	DOS - From	DOS - Thru	Provider #	Provider Name	Address	NPI	Tax ID	Provider Name	Address	NPI	Tax ID
259369370A	DAILEY	WALTER	7/21/1930	20401	7	11		12/21/2010	12/21/2010	00010021292	~	~	~	0000000000	GONZALEZ, M.D., EVANGELIO TRENTON	690 DALLAS HWY STE 303, VILLA RICA, GA, 30180	1598739609	582453300
259369370A	DAILEY	WALTER	7/21/1930	436	96	97		12/21/2010	12/21/2010	00010021292	~	~	~	0000000000	GONZALEZ, M.D., EVANGELIO TRENTON	690 DALLAS HWY STE 303, VILLA RICA, GA, 30180	1598739609	582453300
462424512D	DUNCAN	LERA	12/8/1933	28800	45			1/15/2010	1/15/2010	0153180318	CHOWDHARY, SULTAN A	4201 MEDICAL CENTER DR #180, MCKINNEY, TX, 75069	1033114459	751312419				
245862242A	MOBLEY	BARBARA	2/1/1953	28800	45			7/20/2010	7/20/2010	00040003175	KIM, M.D., JUNG MIN	1044 BELMONT AVE, YOUNGSTOWN, OH, 44504	~	0340505560	CHAI, M.D., SEUNGJEAN	411 BILLINGSLEY RD STE 103, CHARLOTTE, NC, 28211	~	561886140
245862242A	MOBLEY	BARBARA	2/1/1953	2839	44	50		7/20/2010	7/20/2010	00040003175	KIM, M.D., JUNG MIN	1044 BELMONT AVE, YOUNGSTOWN, OH, 44504	~	0340505560	CHAI, M.D., SEUNGJEAN	411 BILLINGSLEY RD STE 103, CHARLOTTE, NC, 28211	~	561886140
255488111A	FLUELLEN	CHARLIE	8/23/1929	28809	45			8/25/2010	8/25/2010	00040069470	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713
255488111A	FLUELLEN	CHARLIE	8/23/1929	4139	83	89		11/17/2010	11/17/2010	00040069470	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713
255488111A	FLUELLEN	CHARLIE	8/23/1929	4414	105			7/22/2010	7/22/2010	00040069470	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713	PEACOCK, M.D., MICHAEL TODD	911 PLAZA AVE STE C, EASTMAN, GA, 31023	1487636742	582375713
513803046A	GROSS	DOROTHY	4/4/1954	2841	44	50		1/25/2010	1/25/2010	00360000101	SHAH, M.D., AMIT I.	4420 SUN N LAKE BLVD, SEBRING, FL, 33872	1407850449	0650826332	MATTAR, M.D., BASSAM I.	818 N EMPORIA ST STE 403, WICHITA, KS, 67214	1053372649	481181579
513803046A	GROSS	DOROTHY	4/4/1954	28803	45			1/25/2010	1/25/2010	00360000101	SHAH, M.D., AMIT I.	4420 SUN N LAKE BLVD, SEBRING, FL, 33872	1407850449	0650826332	MATTAR, M.D., BASSAM I.	818 N EMPORIA ST STE 403, WICHITA, KS, 67214	1053372649	481181579
256580343A	TIGNER	HERMAN	5/1/1941	20500	7			10/21/2010	10/21/2010	00330000635	FREITAG, M.D., ANNA	1351 WASHINGTON BLVD, STAMFORD, CT, 06902	1235113507	047629908	WELCH, M.D., NORMAN SPENCER	77 COLLIER RD NW STE 2080, ATLANTA, GA, 30309	~	581578080
256580343A	TIGNER	HERMAN	5/1/1941	20540	15	14		4/22/2010	4/22/2010	00330000635	FREITAG, M.D., ANNA	1351 WASHINGTON BLVD, STAMFORD, CT, 06902	1235113507	047629908	WELCH, M.D., NORMAN SPENCER	77 COLLIER RD NW STE 2080, ATLANTA, GA, 30309	~	581578080
257588470A	CALLAWAY	WILLIAM	3/6/1940	20500	7			10/4/2010	10/4/2010	00480000769	~	~	~	0582473891	JOSEPH, M.D., CARMEL	3630 J DEWEY GRAY CR, AUGUSTA, GA, 30909	1245286681	320344413
257588470A	CALLAWAY	WILLIAM	3/6/1940	4168	80	86		10/4/2010	10/4/2010	00480000769	~	~	~	0582473891	JOSEPH, M.D., CARMEL	3630 J DEWEY GRAY CR, AUGUSTA, GA, 30909	1245286681	320344413
341200050A	BRUHA	AUGUST	9/6/1928	2841	44	50		3/1/2010	3/1/2010	00360007921	CELANO, M.D., PAUL C.	6569 N CHARLES ST STE 205, BALTIMORE, MD, 21204	~	526049658	CELANO, M.D., PAUL C.	6569 N CHARLES ST STE 205, BALTIMORE, MD, 21204	~	526049658
341200050A	BRUHA	AUGUST	9/6/1928	2841	44	50		11/15/2010	11/15/2010	00360007921	CELANO, M.D., PAUL C.	6569 N CHARLES ST STE 205, BALTIMORE, MD, 21204	~	526049658	CELANO, M.D., PAUL C.	6569 N CHARLES ST STE 205, BALTIMORE, MD, 21204	~	526049658
497205501A	PLOUDER	JACK	3/23/1927	25072	15	14		2/24/2011	2/24/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
497205501A	PLOUDER	JACK	3/23/1927	25072	15	14		7/5/2011	7/5/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
497205501A	PLOUDER	JACK	3/23/1927	7854	104			7/5/2011	7/5/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
497205501A	PLOUDER	JACK	3/23/1927	4439	105	101		7/5/2011	7/5/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
497205501A	PLOUDER	JACK	3/23/1927	5852	131	125		7/5/2011	7/5/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
439270707A	KELLY	JEROME	2/21/1963	73340	37	38		5/9/2011	5/20/2011	00040000065	FERRI, M.D., FRED	1539 ATWOOD AVE STE 101, JOHNSTON, RI, 02919	1013903400	0050483739	LEE, M.D., CHOK KEUNG	1200 BINZ STE 875, HOUSTON, TX, 77004	1568416212	760106340
439270707A	KELLY	JEROME	2/21/1963	73342	37	38		2/23/2011	2/23/2011	00010002078	~	~	~	0391195501	UZOAGA, M.D., ENYIBUAKU RITA	9119 S GESSNER DR STE 305, HOUSTON, TX, 77074	1245246925	202374197
439270707A	KELLY	JEROME	2/21/1963	07054	27	25		7/1/2011	7/1/2011	00040000065	FERRI, M.D., FRED	1539 ATWOOD AVE STE 101, JOHNSTON, RI, 02919	1013903400	0050483739	LEE, M.D., CHOK KEUNG	1200 BINZ STE 875, HOUSTON, TX, 77004	1568416212	760106340
439270707A	KELLY	JEROME	2/21/1963	28800	45			5/9/2011	5/20/2011	00040000065	FERRI, M.D., FRED	1539 ATWOOD AVE STE 101, JOHNSTON, RI, 02919	1013903400	0050483739	LEE, M.D., CHOK KEUNG	1200 BINZ STE 875, HOUSTON, TX, 77004	1568416212	760106340
439270707A	KELLY	JEROME	2/21/1963	496	108	104		6/30/2011	6/30/2011	00040000065	FERRI, M.D., FRED	1539 ATWOOD AVE STE 101, JOHNSTON, RI, 02919	1013903400	0050483739	LEE, M.D., CHOK KEUNG	1200 BINZ STE 875, HOUSTON, TX, 77004	1568416212	760106340
439270707A	KELLY	JEROME	2/21/1963	4011	88			5/9/2011	5/20/2011	00040000065	FERRI, M.D., FRED	1539 ATWOOD AVE STE 101, JOHNSTON, RI, 02919	1013903400	0050483739	LEE, M.D., CHOK KEUNG	1200 BINZ STE 875, HOUSTON, TX, 77004	1568416212	760106340
439270707A	KELLY	JEROME	2/21/1963	4019	88			2/23/2011	2/23/2011	00010002078	~	~	~	0391195501	UZOAGA, M.D., ENYIBUAKU RITA	9119 S GESSNER DR STE 305, HOUSTON, TX, 77074	1245246925	202374197
448243317D	CHEATHAM	CLEMMIE	4/15/1930	20500	7			9/17/2011	9/18/2011	00040000367	TAN, M.D., AILEEN S.	4448 W LOOMIS RD STE 204, MILWAUKEE, WI, 53220	1720166234	0391696443	EZENWABACHILI, M.D., OBIAJULU C.	8300 BISSONNET ST STE 180, HOUSTON, TX, 77074	1518945674	760696321
495269943D	LAMPERT	JEAN	1/12/1935	73313	157	45		11/17/2011	11/17/2011	00040000227	ECKSTEIN, M.D., MICHAEL B.	3909 ORANGE PL STE 2400, BEACHWOOD, OH, 44122	1134265614	0341768928	NAUMOVICH, M.D., ANNA D.	5205 S GRAND BLVD, SAINT LOUIS, MO, 63111	1669542668	431483961
354467044A	RAMSAK	EDWARD	7/10/1952	2841	44	50		2/15/2011	2/15/2011	0195460699	PLUNKETT, LARRY	6311 E 14TH AVE, DENVER, CO, 80220	000000001427	841319830				
555187641D	MADRONAL	BELLA	3/16/1931	4139	83	89		6/2/2011	6/2/2011	E03300009073	STEPHEN BLOOMFIELD	5250 NEIL RD STE 207, RENO, NV, 89502	1518053743	263427764				
464889872A	HUBBARD	BETTY	5/21/1948	436	96	97		9/11/2012	9/11/2012	00040012076	M.D., ANIL GEORGE	2100 STANTONSBURG RD, GREENVILLE, NC, 27834	1154307684	0566000403	AJIM, M.D., ALICE A.	2101 CRAWFORD STE 210, HOUSTON, TX, 77002	~	412175620
464889872A	HUBBARD	BETTY	5/21/1948	27700	107	103		2/7/2012	2/7/2012	00040012076	M.D., ANIL GEORGE	2100 STANTONSBURG RD, GREENVILLE, NC, 27834	1154307684	0566000403	AJIM, M.D., ALICE A.	2101 CRAWFORD STE 210, HOUSTON, TX, 77002	~	412175620
132509123A	PENELLO JR	ARTHUR	6/11/1958	28260	44	50		8/9/2012	8/9/2012	00050085110	SHUMATE JR, M.D., JACK B.	100 DOCTORS DR STE B, PANAMA CITY, FL, 32405	1558366955	593562065	SHUMATE JR, M.D., JACK B.	100 DOCTORS DR STE B, PANAMA CITY, FL, 32405	1558366955	593562065
387849861A	DEQUAINE	MARK	11/1/1965	2849	44	50		6/1/2012	6/1/2012	00040007538	CARSON, M.D., JOHN TURNER	9686 CINCINNATI-COLUMBUS RD, WEST CHESTER, OH, 45241	1053409151	0295448596	LACEY, M.D., JAMES V.	101 SCHOOL CREEK TRL, LUXEMBURG, WI, 54217	1770571325	390817529
314340607A	GILLESPIE	ERNEST	7/28/1936	1980	7	11		2/20/2012	2/20/2012	00010038240	TAYLOR, M.D., MARSHA A.	5349 N 22ND ST STE 1, OZARK, MO, 65721	~	452926643	TAYLOR, M.D., MARSHA A.	5349 N 22ND ST STE 1, OZARK, MO, 65721	~	452926643
314340607A	GILLESPIE	ERNEST	7/28/1936	1889	10			2/20/2012	2/20/2012	00010038240	TAYLOR, M.D., MARSHA A.	5349 N 22ND ST STE 1, OZARK, MO, 65721	~	452926643	TAYLOR, M.D., MARSHA A.	5349 N 22ND ST STE 1, OZARK, MO, 65721	~	452926643
507365409A	STIKA	DOROTHY	9/22/1937	1963	7	11		1/24/2012	1/24/2012	00360006635	HEWITT, M.D., MAUREEN	440 E MARSHALL ST STE 201, WEST CHESTER, PA, 19380	1447312368	0232943766	SOORI, M.D., GAMINI S.	8303 DODGE ST STE 250, OMAHA, NE, 68114	1891775789	470754790
507365409A	STIKA	DOROTHY	9/22/1937	1745	10	10		1/24/2012	1/24/2012	00360006635	HEWITT, M.D., MAUREEN	440 E MARSHALL ST STE 201, WEST CHESTER, PA, 19380	1447312368	0232943766	SOORI, M.D., GAMINI S.	8303 DODGE ST STE 250, OMAHA, NE, 68114	1891775789	470754790
2565																		

VERIFICATION

I, Amanda Johnson, declare that I am the Director of the Division of Encounter Data and Risk Adjustment Operations, and I am authorized to make this Verification on behalf of the United States. I have read the UNITED STATES' RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S FIRST SET OF INTERROGATORIES TO THE GOVERNMENT dated February 3, 2020, and I personally know or have been informed of the contents thereof. The facts stated in the aforementioned responses are not all within my personal knowledge, but have been assembled by authorized employees and/or consultants of the United States, and I am informed by said employees and/or consultants that the facts stated therein are true at this time.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on May _12, 2020 at 7:05 am_.

Amanda Johnson
Director, Division of Encounter Data and Risk
Adjustment Operations
Centers for Medicare & Medicaid Services, Medicare
Plan and Payment Group

EXHIBIT D-11B

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19 UNITED STATES DISTRICT COURT
20 FOR THE CENTRAL DISTRICT OF CALIFORNIA
21 WESTERN DIVISION

22 UNITED STATES OF AMERICA *ex*
23 *rel.* BENJAMIN POEHLING,

24 Plaintiffs,

25 v.

26 UNITEDHEALTH GROUP, INC., *et al.*,

27 Defendants.
28

No. CV 16-08697 FMO

UNITED STATES' FIRST
SUPPLEMENTAL RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S FIRST SET OF
INTERROGATORIES TO THE
GOVERNMENT

PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.

RESPONDING PARTY: UNITED STATES OF AMERICA

SET NUMBER: ONE

Preliminary Statement

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure (“Federal Rules”) and Rule 33 of the Local Civil Rules of the United States District Court for the Central District of California, the United States of America (“United States” or “government”), through its undersigned counsel, hereby provides its first supplemental responses and objections to Defendant UHC of California’s (“UnitedHealth” or “Defendant”) First Set of Interrogatories, dated January 3, 2020. The objections and responses set forth herein are based on information now known to the United States and its undersigned attorneys, and will be revised, corrected, supplemented, amended, and clarified to the extent required by Rule 26 as discovery proceeds.

General Objections and Specific Objections to Definitions and Instructions

The United States incorporates by reference its General Objections and Specific Objections to Definitions and Instructions that are set forth in the United States’ Responses and Objections to Defendant UHC of California’s First Set of Interrogatories, dated February 3, 2020.

Specific Objections and Responses

INTERROGATORY NO. 1: Identify for Date of Service Years 2008–2016 the Beneficiary (by name, HIC Number, and date of birth), Date of Service, Diagnosis Code(s), CMS HCC(s) or RxHCC(s), and Provider (by individual name, group name, address, NPI, Tax ID(s), and Provider ID), that corresponds to each and every Diagnosis Code You allege UnitedHealth “knowingly and improperly failed to delete . . . or otherwise return to the Medicare Program [as an] overpayment.” United States’ Complaint ¶ 342, Dkt. 171.

1 **Response to Interrogatory No. 1:** The United States incorporates by reference each
2 of its General Objections and Specific Objections to the Definitions and Instructions
3 as if stated herein, and further incorporates by reference its specific objections to this
4 Interrogatory as set forth in United States' Responses and Objections to Defendant
5 UHC of California's First Set of Interrogatories, dated February 3, 2020.

6 Subject to and without waiving these objections, the United States also
7 incorporates its response to this Interrogatory as set forth in United States' Responses
8 and Objections to Defendant UHC of California's First Set of Interrogatories, dated
9 February 3, 2020, and further responds as follows. Although fact discovery is
10 ongoing, expert disclosures are not due until June 18, 2021, and the United States
11 reserves the right to supplement and/or amend this answer in full or in part as it learns
12 new information and as expert analysis progresses, the United States alleges that
13 UnitedHealth Defendants "knowingly and improperly failed to delete . . . the invalid
14 diagnoses that had been submitted to the Medicare Program for risk adjustment
15 payments which were made by the Medicare Program to them or knowingly and
16 improperly failed to otherwise return to the Medicare Program the overpayments
17 based on the invalid diagnoses" for each and every Diagnosis Code that was known
18 (as that term is defined by the False Claims Act) to be unsupported by medical
19 records and that affected the amount of payment received by UnitedHealth from the
20 Medicare Program.

21 At this time and subject to the United States' right to supplement and/or amend
22 this answer in full or in part, the United States additionally identifies and incorporates
23 into its answer the attached charts of Diagnosis Codes that UnitedHealth "knowingly
24 and improperly failed to delete" or "knowingly and improperly failed to otherwise
25 return to the Medicare Program the overpayments based on" such diagnoses for date
26 of service years (DOS) 2010-2013. The provider information in the attached charts
27 has been reproduced as it appears in the data that UnitedHealth produced in this case,
28 including missing fields, dummy values, and placeholders, and has preserved the

1 convention of using "~" to indicate a database null. Further, although the
2 Interrogatory asked for the Provider ID, there is no field designated Provider_ID and
3 the United States has responded with the Provider_Nbr. For COSMOS Providers, the
4 United States have included two sets of provider information: the provider
5 information that results from a direct lookup in the Provider table (2A), and the
6 provider information that results from a lookup in the SAS_All_Providers table
7 UnitedHealth provided to the United States, linking the LOB_Cd associated with the
8 encounter's LOB_Key to the Site_Cd field. For non-COSMOS Providers, the second
9 set of columns has been left blank.

10 The United States will supplement its response to this Interrogatory as
11 appropriate.
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2 Dated: August 17, 2020

Respectfully submitted,
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18 GREGORY A. MASON
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PROOF OF SERVICE BY ELECTRONIC MAIL

I am over the age of 18 and not a party to the action entitled U.S. *ex rel.* Poehling v. UnitedHealth Group, Inc., CV-16-8697 FMO. I am employed by the Department of Justice, Civil Division. My business address is 175 N Street NE, Room 10.224, Washington, D.C. 20002.

On August 17, 2020, I served the foregoing PLAINTIFF UNITED STATES' FIRST SUPPLEMENTAL RESPONSES AND OBJECTIONS TO DEFENDANT UHC OF CALIFORNIA'S FIRST SET OF INTERROGATORIES TO THE GOVERNMENT on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).

Date of e-mailing: August 17, 2020.

Place of e-mailing: Washington, D.C.

Person(s) and/or Entity(s) to whom e-mailed:

See attached page

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 17, 2020, at Washington, D.C.



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EXHIBIT D-12

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et al.*,

Defendants.

No. CV 16-08697 FMO

UNITED STATES' RESPONSES AND
OBJECTIONS TO DEFENDANT UHC
OF CALIFORNIA'S SECOND SET OF
INTERROGATORIES TO THE
GOVERNMENT

PROPOUNDING PARTY: UHC OF CALIFORNIA, INC.

RESPONDING PARTY: UNITED STATES OF AMERICA

SET NUMBER: THREE

Preliminary Statement

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure (“Federal Rules”) and Rule 33 of the Local Civil Rules of the United States District Court for the Central District of California, the United States of America (“United States” or “government”), through its undersigned counsel, hereby provides its responses and objections to Defendant UHC of California’s (“Defendant”) Third Set of Interrogatories, dated May 24, 2022. The objections and responses set forth herein are based on information now known to the United States and its undersigned attorneys, and will be revised, corrected, supplemented, amended, and clarified to the extent required by Rule 26 as discovery proceeds.

General Objections and Specific Objections to Definitions and Instructions

The following objections apply to each and every separately numbered Interrogatory and are incorporated by reference to the extent applicable into the objection to each Interrogatory.

1. UnitedHealth’s Interrogatories are inconsistent with the spirit and letter of the Federal Rules of Civil Procedure (“Federal Rules”), which explain that an interrogatory ought to narrow and sharpen issues for trial. *See* Fed. R. Civ. P. 33 Advisory Committee’s Note. UnitedHealth’s extensive Interrogatories do just the opposite by asking the United States to respond to vague and illogical mischaracterizations of its arguments, and seeking vast amounts of information without the objective to narrow and sharpen issues for trial. For example, the Interrogatories demand that the United States survey all “CMS and HHS-OIG Individuals” (as defined by UnitedHealth’s Third Set of Interrogatories, Definitions 8 and 22) to determine if anyone ever held a particular belief between 2008–2017.

1 2. The United States objects to the Third Set of Interrogatories to the extent
2 they are vague, ambiguous, overbroad, unduly burdensome, or seek to impose
3 requirements upon the United States beyond those called for or permitted by the
4 Federal Rules, the Local Civil Rules of the United States District Court for the
5 Central District of California (“Local Rules”), or any order of the Court. The United
6 States responds below pursuant to its obligations under the Federal Rules and the
7 Local Rules, namely that the United States has taken and is continuing to undertake
8 reasonable efforts to identify information responsive to the Interrogatories.

9 3. The United States objects to the Third Set of Interrogatories to the extent
10 that a response requires disclosure of information protected by an applicable privilege
11 or protection, including, but not limited to, the attorney-client privilege, work product
12 doctrine, deliberative process privilege, law enforcement privilege, common interest
13 privilege, or investigative files privilege, and protections afforded by Fed. R. Civ. P.
14 26(b), or any other applicable privilege. The United States will not respond in such a
15 way as to disclose such protected information, and inadvertent identification or
16 disclosure of privileged information by the United States shall not be a waiver of any
17 applicable privilege. Under Federal Rule of Evidence 502, Federal Rule of Civil
18 Procedure 26(b)(5)(B), other related sources of law, and the Court’s Revised
19 Protective Order Governing Non-Waiver of Privilege and Protected Material, Dkt.
20 412, the government reserves any and all rights to claw back privileged information it
21 inadvertently discloses in response to the Third Set of Interrogatories.

22 4. The United States submits these responses subject to, without intending
23 to waive, but expressly reserving the right to object to other discovery procedures
24 involving or relating to the subject matter of the information in responses to the Third
25 Set of Interrogatories. The United States reserves the right to object on any ground,
26 at any time, to such other or supplemental requests as the Defendants may propound
27 involving or relating to the subject matter of the Third Set of Interrogatories.
28

1 5. The United States reserves the right to supplement its responses to the
2 Third Set of Interrogatories at any time to the extent provided by the Federal Rules.

3 6. The assertion of the same, similar, or additional specific objections to the
4 Third Set of Interrogatories does not and should not be construed to waive or modify
5 any of the United States' general objections.

6 7. The United States objects to the Third Set of Interrogatories to the extent
7 they require the United States to draw legal conclusions, comment on the merits of
8 any affirmative defenses, or otherwise seek to impose any requirements beyond those
9 established by the Federal Rules or the Local Rules.

10 8. The United States objects to the Third Set of Interrogatories to the extent
11 that they contain multiple subparts numbered as a single Interrogatory. By
12 responding, the United States in no way waives its right to object that UnitedHealth
13 has exceeded the maximum number of interrogatories permitted under the Federal
14 Rules.

15 9. The United States objects to the Third Set of Interrogatories to the extent
16 they purport to require the United States to gather information in the possession or
17 custody of Government components beyond HHS-OIG and CMS on the grounds that
18 they are unduly burdensome and overbroad and that they seek information not
19 relevant to the claims or defenses in this action and disproportionate to the needs of
20 this case.

21 10. The United States objects to the Third Set of Interrogatories to the extent
22 they purport to require the United States to gather information in the possession or
23 custody of HHS-OIG where HHS-OIG is not the relevant agency for payment
24 purposes and therefore the Interrogatories are unduly burdensome, overbroad, and
25 seek information not relevant to the claims or defenses in this action and
26 disproportionate to the needs of this case.

27 11. To the extent the United States produces information or documents in
28 further response to these Interrogatories, it does not admit that the information or

documents are true, accurate, authentic, relevant, or admissible in this action. The United States reserves the right to challenge on evidentiary grounds any information or documents produced in response to these Interrogatories.

12. The fact that the United States has answered any part of all or any particular interrogatory is not intended to and shall not be construed to be a waiver by the United States of all or part of any objection to any interrogatory.

Specific Objections to the Definitions and Instructions

The United States objects to the Definitions and Instructions to the extent they (i) seek to impose burdens on the United States that are different from, are inconsistent with, or exceed those imposed by the Federal Rules and the Local Rules, (ii) are vague or ambiguous, and/or (iii) render the Third Set of Interrogatories overly broad, unduly burdensome, not proportionate to the needs of the case, and not relevant. The United States further objects to the Third Set of Interrogatories to the extent UnitedHealth has failed to define vague, ambiguous, and confusing terms.

Objections to Definition 1: The United States objects to the definition of “Believed” (Definition 1) in that “suppose” means something different than “hold something as an opinion” or “think,” and this definition encompassing two different meanings therefore renders UnitedHealth’s Third Set of Interrogatories confusing and self-contradictory. The United States will interpret “Believed” as to hold something as an opinion or to think.

Objections to Definition 5: The United States objects to the definition of “Chart Review” (Definition 5) as inconsistent with UnitedHealth’s chart review processes at issue in this litigation. The United States interprets “Chart Review” to mean UnitedHealth’s actual chart review process, in which certified coders were instructed to identify every risk-adjusting diagnosis code that had sufficient documentation support in a Chart.

Objections to Definitions 6, 20, and 21: The United States objects to the terms “CMS” (Definition 6), “Government” (Definition 20), and “HHS-OIG” (Definition

21) as overbroad and irrelevant to the extent they include current and former contractors or consultants. CMS and HHS-OIG speak through official pronouncements and do not speak through its contractors or consultants, making information provided by contractors and consultants overbroad and irrelevant for the purpose of responding to the Third Set of Interrogatories. The United States objects to the definition of “Government” (Definition 20) to the extent it includes any branch, agency, department, agent, representative, contractor, attorney, consultant, or person acting on its behalf not relevant to this action. This definition is plainly unreasonable, unduly burdensome, and disproportionate to the needs of the case, in that it seeks to require the United States to provide information not currently in the possession, custody, or control of CMS or HHS-OIG. Subject to and without waiving these objections, the United States interprets “Government” to mean CMS and HHS-OIG. To the extent the United States interprets the use of “Government” in a specific Interrogatory as directed only HHS-OIG or CMS (and not both), the United States will state its interpretation in its response. The United States further objects to the inclusion of “attorneys” in the definitions to the extent that the inclusion of “attorneys” requires the United States to gather information from attorneys within CMS’s Office of the General Counsel (“OGC”), the Office of Counsel for the Inspector General (“OCIG”), or the Department of Justice (“DOJ”). The United States is not searching for, collecting, or providing information or materials from any attorney within OGC, OCIG, or DOJ.

Objections to Definitions 7: The United States objects to the definition of “CMS-HCC Risk Adjustment Model” (Definition 7) as overly broad to the extent it includes iterations of the CMS-HCC Risk Adjustment Model (V12, V21, or V22) that were not used to calculate risk scores that were used determine payments to UnitedHealth. The United States interprets this definition to include only iterations of the CMS-HCC Risk Adjustment Model that were used to calculate risk scores that were used determine payments to UnitedHealth. The United States further objects to this

1 definition as overly broad to the extent it includes a timeframe that it is more
2 expansive that the timeframe for the damages sought in this matter. The United
3 States will interpret this definition to apply to iterations of the CMS-HCC Risk
4 Adjustment Model in use for 2008-2016 Date of Service Years/2009-2017 Contract
5 Years.

6 **Objections to Definitions 8 and 22:** The United States objects to the terms “CMS
7 Individual” (Definition 8) and “HHS-OIG Individual” (Definition 22) as irrelevant,
8 unduly burdensome, and beyond the scope of permissible discovery to the extent they
9 include all current or former contractors or current or former subcontractors, and
10 therefore demand that the United States obtain information from, or respond on
11 behalf of, persons or entities not reasonably accessible to the United States and over
12 whom the United States has no control. The United States further objects to the terms
13 “CMS Individual” and “HHS-OIG Individual” as overly broad and unduly
14 burdensome to the extent they include all current employees of each agency, which
15 includes thousands of people who are unlikely to have information relevant to these
16 interrogatories. The United States objects to the terms “CMS Individual” and “HHS-
17 OIG Individual” as overly broad and unduly burdensome to the extent they include
18 all former employees of each agency, and therefore purport to require the United
19 States to obtain information from, or to respond on behalf of, persons or entities not
20 reasonably accessible to the United States and over whom the United States has no
21 control. It is plainly unreasonable for the United States to survey each and every
22 current and former employee of CMS and/or HHS-OIG. The United States further
23 objects to the inclusion of “Person” in the definitions to the extent the inclusion of
24 “Person” includes attorneys and requires the United States to gather information from
25 attorneys within OGC, OCIG, or DOJ. The United States is not searching for,
26 collecting, or providing information or materials from any attorney within OGC,
27 OCIG, or DOJ.

28 **Objections to Definition 9:** The United States objects to the definition of “CMS

Contractor” as irrelevant, unduly burdensome, and beyond the scope of permissible discovery to the extent it includes all former contractors or former subcontractors, and therefore demands that the United States obtain information from, or respond on behalf of, persons or entities not reasonably accessible to the United States and over whom the United States has no control. The United States will not include former contractors or subcontractors in the definition of “CMS Contractor.”

Objections to Definitions 11 and 36: The United States objects to the definitions of “Concerning” (Definition 11) and “Relating to” and “regarding” (Definition 36) because the definitions render the Third Set of Interrogatories vague, ambiguous, confusing, overly broad, unduly burdensome, and disproportionate to the needs of the case. Indeed, these terms are defined to seek any piece of information that in some way—no matter how remote, indirect, or tangential—mentions or references matters set forth in the Interrogatory. The United States responds to the Third Set of Interrogatories by using these terms and the verbs constituting their definitions as limited by the constraining adverb “directly.”

Objections to Definition 12: The United States objects to the term “Corrected” (Definition 12) as vague because it is unclear where the referenced “remov[als]” and “changes” of Diagnosis Codes are made. The United States will interpret this to mean removals or change within the CMS databases from which data used to calibrate the CMS-HCC Risk Adjustment Model are pulled.

Objections to Definition 32: The United States objects to the definition of “Person” (Definition 32) to the extent it is defined to mean “the federal government and all departments and agencies thereof, state governments, local governments, [and] other governmental agencies[.]” This definition is plainly unreasonable, unduly burdensome, and disproportionate to the needs of the case, in that it seeks to require the United States to provide information not currently in the possession, custody, or control of CMS and HHS-OIG. Furthermore, the United States objects to the extent each definition includes former CMS contractors for whom the United States

1 presently has no reasonable belief they possess or control non-duplicative information
2 relevant to any claim or defense in this case.

3 **Objections to Definition 33:** The United States objects to the definition of
4 “Poehling Matter” as overly broad to the extent it includes *United States ex rel.*
5 *Swoben v. Secure Horizons*, CV-609-5013-JFW (JEM) (“Swoben”), which is a
6 separate litigation in which the Court declined to consolidate with this litigation, see
7 Statement of Decision Denying the United State of America’s Motion to Consolidate,
8 *United States ex rel. Swoben v. Secure Horizons*, CV-609-5013-JFW (JEM), Dkt.
9 295. The United State will not include the *Swoben* matter in this definition.

10 **Objections to Definition 42:** The United States objects to the definition of “You”
11 and “Your” to the extent these terms are intend to encompass any agency, office,
12 employee, agent, representative, officer, or contractor of either the legislative or
13 judicial branch, and insofar as these terms are defined to include executive branch
14 agencies and offices not relevant to this action. This is plainly unreasonable. Subject
15 to and without waiving these objections, the United States will interpret this term to
16 mean CMS and HHS-OIG. To the extent the United States interprets a specific
17 request as directed at only HHS-OIG or CMS (and not both), the United States will
18 state its interpretation in its response.

19 **Objections to Instructions**

20 **Objections to Instruction 3:** The United States objects to Instruction 3 as vague
21 and ambiguous. For the purposes of responding to these Interrogatories, the United
22 States will construe the relevant time period as January 1, 2004 through May 16,
23 2017, in accordance with the parties’ agreed-upon discovery timeframe. However,
24 with respect to Interrogatory 10, the United States will construe the relevant time
25 period as January 1, 2004 to June 30, 2019, in accordance with the parties’ agreed-
26 upon discovery timeframe pertaining to discovery relating to CMS’s proposed rule
27 *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare*
28 *Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for*

1 *the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care*
2 *Programs for Years 2020 and 2021* (“Proposed Rule”) and underlying FFS Adjuster
3 Study. See August 9, 2019 D. Schindler email to R. McAuliffe.

4 **Objections to Instruction 5:** The United States objects to Instruction 5 to the extent
5 it seeks to impose burdens upon the United States beyond those called for or
6 permitted by the Federal Rules or the Local Rules.

7 **Objections to Instruction 6:** The United States objects to Instruction 6 to the extent
8 it seeks to impose burdens upon the United States beyond those called for or
9 permitted by the Federal Rules or the Local Rules.

10 **Objections to Instruction 7:** The United States objects to Instruction 7 to the extent
11 it seeks to impose burdens upon the United States beyond those called for or
12 permitted by the Federal Rules or the Local Rules. The United States will assert any
13 applicable privileges and specify the material to which it applies per Fed. R. Civ. P.
14 26(b)(5)(A) for all information responsive to an Interrogatory to which the United
15 States has agreed to produce but which is withheld on the basis of a privilege or
16 protection.

17 **Objections to Instruction 8:** The United States objects to Instruction 8 to the extent
18 it requires the United States to identify “each” instance of duplicative, redundant, or
19 repetitive information.

20 **Specific Objections and Responses**

21 **INTERROGATORY NO. 10** Explain in detail the bases upon which You contend
22 that the Study Underlying CMS’s Proposed Rule is relevant to any claim, defense,
23 contention, or issue in this litigation.

24 **Objections:**

25 The United States incorporates by reference each of its General Objections and
26 Specific Objections to the Definitions and Instructions as if stated herein. The United
27 States objects to the phrase “explain in detail” as vague and ambiguous, and will
28 interpret the phrase to mean “explain.” The United States objects to the phrase “any

1 claim, defense, contention, or issue in this litigation” as vague and ambiguous, and
2 objects to the phrase insofar as it purports to include “contentions” or “issues” that
3 are not part of any claim or defense. The United States will interpret this phrase to be
4 “any claim or defense in this litigation.” The United States objects to this
5 Interrogatory insofar as it purports to require the United States to explain the
6 relevance of facts to UnitedHealth’s claims or defenses. The United States further
7 objects to this Interrogatory in that it requests that the United States explain how the
8 Study Underlying CMS’s Proposed Rule is relevant to UnitedHealth’s defenses or
9 contentions. Because UnitedHealth has not given the United States sufficient
10 information to understand what its defenses and contentions are, the United States is
11 unable to explain how the Study Underlying CMS’s Proposed Rule is relevant to
12 them, and reserves the right to rely on the Study Underlying CMS’s Proposed Rule in
13 any way as it learns additional information about UnitedHealth’s defenses and
14 contentions in this case. The United States objects to this Interrogatory to the extent
15 it misstates the United States’ contentions in this matter.

16 **Response to Interrogatory No. 10:** Subject to and without waiving the foregoing
17 objections, the United States hereby states that it does not contend that the Study
18 Underlying CMS’s Proposed Rule is relevant to the claims in this matter. It is the
19 United States’ position that the FFS Adjuster is not relevant to its claims in this case,
20 and therefore no FFS Adjuster study (including the Study Underlying CMS’s
21 Proposed Rule or any study that UnitedHealth might conduct) is relevant to the
22 United States’ claims in this case. However, if UnitedHealth contends that error rates
23 in FFS data are relevant to its defenses, the United States reserves the right to cite the
24 Study Underlying CMS’s Proposed Rule.

25 **INTERROGATORY NO. 11:** Identify all CMS Individuals and HHS-OIG
26 Individuals who You contend Believed or expressed in writing that the existence of
27 unsupported Diagnoses in CMS’s FFS Medicare data reduces the average value of the
28 Relative Factors. This Interrogatory should be construed to cover the time period

1 January 1, 2004 to June 30, 2019.

2 **Objections:**

3 The United States incorporates by reference each of its General Objections and
4 Specific Objections to the Definitions and Instructions as if stated herein. The United
5 States objects to this Interrogatory to the extent it requests information beyond May
6 16, 2017. The parties' agreed-upon discovery timeframe only extends to June 30,
7 2019 for discovery relating to CMS's Proposed Rule and underlying FFS Adjuster
8 Study. See August 9, 2019 D. Schindler email to R. McAuliffe. Further, the United
9 States objects to this Interrogatory to the extent that it is irrelevant because
10 Government agencies, including CMS and HHS-OIG, act through official policy and
11 regulations and not the beliefs or impressions of individual employees or contractors.
12 The United States objects to this Interrogatory to the extent it misstates the United
13 States' contentions in this matter. The United States does not contend that CMS
14 Individuals and HHS-OIG Individuals Believed or expressed in writing that the
15 existence of unsupported Diagnoses in CMS's FFS Medicare data reduces the
16 average value of the Relative Factors. The United States objects to this Interrogatory
17 as vague as to the meaning of "reduces the average value of the Relative Factors." It
18 is unclear if the Request is asking whether the average value of *every* Relative Factor
19 is reduced or if, on average, the value of the group of Relative Factors is reduced (*i.e.*,
20 some could go up and some could down in value but, on average, the value of the
21 group of Relative Factors is reduced). The United States interprets this Request as
22 seeking information regarding whether the average value of every Relative Factor is
23 reduced.

24 **Response to Interrogatory No. 11:** Subject to and without waiving the foregoing
25 objections, the United States hereby states that it does not contend that any CMS and
26 HHS-OIG Individual Believed or expressed in writing that the existence of
27 unsupported Diagnoses in CMS's FFS Medicare data reduces the average value of the
28 Relative Factors. Rather, it is the United States' position that UnitedHealth

1 contracted with CMS on an annual basis to receive payments under the CMS- HCC
2 Risk Adjustment Model in place at the time of the contract and did, in fact, receive
3 payments under those contracts from CMS that were calculated under the existing
4 CMS-HCC Risk Adjustment Model, making the existence of unsupported Diagnoses
5 in CMS's FFS Medicare data and any potential impact that they may have on
6 Relative Factors wholly irrelevant to this matter.

7 **INTERROGATORY NO. 12:** State in detail every material fact upon which You
8 base Your contention that MA Organizations "were obligated to 'look both ways'" or
9 to otherwise design their Chart Review program to also validate Diagnoses reported
10 by Providers that the MA Organizations submitted to CMS. United States' Am.
11 Compl. ¶ 122, Dkt. 171.

12 **Objections:**

13 The United States incorporates by reference each of its General Objections and
14 Specific Objections to the Definitions and Instructions as if stated herein. The United
15 States further objects to this Interrogatory to the extent that it seeks information
16 protected from disclosure by an applicable privilege or protection. The United States
17 objects to this Interrogatory as overly broad and unduly burdensome to the extent it
18 improperly requires the United States to "state in detail every material fact" of its
19 evidentiary case. *See Tubbs v. Sacramento Cty. Jail*, No. CIVS060280LKKGGHP,
20 2008 WL 863974, at *1 (E.D. Cal. Mar. 28, 2008) ("Each and every fact'
21 interrogatories pose problems for a responding party and a reviewing court. Parties
22 are not tasked with laying out every jot and tittle of their evidentiary case in response
23 to interrogatories."); *Lucero v. Valdez*, 240 F.R.D. 591, 594 (D.N.M. 2007)
24 ("Contention interrogatories should not require a party to provide the equivalent of a
25 narrative account of its case, including every evidentiary fact, details of testimony of
26 supporting witnesses, and the contents of supporting documents."); *Aldapa v. Fowler*
27 *Packing Co. Inc.*, 310 F.R.D. 583, 591 (E.D. Cal. 2015). The United States objects
28 that this Interrogatory is vague, confusing, and ambiguous because it distorts the

1 meaning of the United States' contention and theory of UnitedHealth's liability under
2 the False Claims Act by citing an incomplete fragment of a sentence from one
3 paragraph of the United States' Amended Complaint. This Interrogatory is vague,
4 ambiguous, confusing, and irrelevant to the extent it focuses on the design of an
5 MAO's chart review program rather than on UnitedHealth's Chart Review program
6 and UnitedHealth's failure to delete known invalid diagnosis codes. *See* MTD Order,
7 Dkt. 212 at 21 ("As the Government argues, the issue here is not the one-way Chart
8 Review generally, but the specific invalid diagnosis codes that Defendants submitted
9 and failed to delete despite information available to them."). This Interrogatory
10 misstates the United States' contention.

11 **Response to Interrogatory No. 12:** Subject to and without waiving the foregoing
12 objections, the United States does not contend in Paragraph 122 of its Complaint that
13 MA Organizations, as defined in this set of Interrogatories, were generally obligated
14 to "look both ways" or to otherwise design their Chart Review program to also
15 validate Diagnoses reported by Providers that the MA Organizations submitted to
16 CMS. Rather, as is clear in Paragraph 122, when read in its entirety, the United
17 States contends that UnitedHealth *did* design, and implemented, its Chart Review
18 program to identify all codes supported by Charts, but chose to submit to CMS new
19 diagnosis codes identified by its Chart Review program that would lead to additional
20 payments from CMS while failing to delete or otherwise retract diagnosis codes
21 previously submitted by UnitedHealth to CMS that its Chart Review program
22 revealed were not supported by medical record documentation. In addition to the
23 United States' factual allegations made in its Amended Complaint, the United States
24 further sets forth the following material facts that relate to its contention but do not
25 recite every "jot and tittle" of the United States' evidentiary case:

- 26 • Before submitting Diagnoses to CMS for payment, UnitedHealth signed
27 Electronic Data Interchange agreements on behalf of each of its MA
28 Organizations, agreeing that "it will be responsible for all Medicare risk

- 1 adjustment data submitted to CMS by itself, its employees, or its agents[;]”
- 2 “Based on best knowledge, information, and belief, that it will submit risk
- 3 adjustment data that are accurate, complete, and truthful[;]” and “That it will
- 4 research and correct risk adjustment data discrepancies.”
- 5 • Since at least 2008, UnitedHealth has entered into annual contracts with CMS
 - 6 where it agreed to “operate one or more coordinated care plans . . . in
 - 7 compliance with the requirements of this contract and applicable Federal
 - 8 statutes, regulations, and policies (e.g., policies as described in the Call Letter,
 - 9 Medicare Managed Care Manual, etc.).”
 - 10 • After entering into these contracts, UnitedHealth submitted Diagnoses to CMS.
 - 11 • Some of these Diagnoses originated from Providers, who submitted Diagnoses
 - 12 to UnitedHealth as part of a claim or beneficiary encounter (“Provider Claim or
 - 13 Encounter”). Those Diagnoses were later submitted by UnitedHealth to CMS
 - 14 for risk adjustment purposes.
 - 15 • Some of the Diagnoses UnitedHealth submitted to CMS originated from its
 - 16 Chart Review program. In its Chart Review program, UnitedHealth reviewed
 - 17 medical records and abstracted or identified Diagnosis Codes for the purpose
 - 18 of submitting additional Diagnosis Codes to CMS for risk adjustment
 - 19 payments. In its Chart Review Program, UnitedHealth instructed its Chart
 - 20 Review coders to look for all medical conditions purportedly documented in
 - 21 the records, record all Diagnosis Codes identifying those conditions, and report
 - 22 all of those Diagnosis Codes to UnitedHealth.
 - 23 • UnitedHealth coders were trained, qualified, and/or certified to accurately
 - 24 identify Diagnosis Codes supported by the medical record, in accordance with
 - 25 the Ninth or the Tenth Edition of the International Classification of Diseases
 - 26 (ICD) Clinical Modification Guidelines for Coding and Reporting (“ICD
 - 27 Guidelines”). UnitedHealth relied on its coders’ accuracy to submit to CMS
 - 28 Diagnosis Codes that were supported by the medical record but were not

1 previously submitted to UnitedHealth based on a Provider Claim or Encounter
2 and thus not previously submitted by UnitedHealth to CMS. UnitedHealth's
3 coders were required to meet quality and accuracy benchmarks—defined as
4 completeness in identifying all risk adjusting Diagnosis Codes that were
5 supported by the medical record in accordance with ICD Guidelines—when
6 reviewing and coding a medical record.

- 7 • UnitedHealth conducted additional medical record reviews, including through
8 quality assurance programs, recode projects, and claims verification of many of
9 the medical records that were included in its Chart Review Program.
- 10 • Many of the Diagnoses submitted by Providers to UnitedHealth (and,
11 ultimately, by UnitedHealth to CMS) were not identified in UnitedHealth's
12 Chart Review Program or other medical record reviews, even though the Chart
13 associated with the Diagnoses was reviewed in UnitedHealth's Chart Review
14 Program and also, in some instances, in the other medical record reviews
15 Programs. UnitedHealth did not delete or otherwise retract these unsupported
16 codes.
- 17 • Since at least 2004, employees of UnitedHealth attended trainings conducted
18 by CMS and/or CMS contractors, participated in CMS user group calls, and
19 engaged in email, in person, or telephonic communications with CMS
20 employees or contractors and were consistently told that Diagnoses must be
21 supported by Charts and if a Diagnoses that impacts a beneficiary risk score is
22 not supported by a Chart, the Diagnoses must be deleted or otherwise retracted
23 from CMS data systems.
- 24 • Since at least 2004, employees of UnitedHealth have also reviewed and relied
25 on written CMS guidance, including Chapter 7 of the Medicare Managed Care
26 Manual, CMS training materials, HPMS memoranda, and CMS Participant
27 Guides, which say that Diagnoses must be supported by Charts and Diagnoses
28 that are not supported by Charts must be deleted or otherwise retracted from

1 the CMS data systems.

- 2 • Each year since at least 2010, employees of UnitedHealth signed annual
3 attestations relating to Diagnoses submitted to CMS for, at least, 2008 Dates of
4 Service through 2016 Dates of Service. Through these attestations,
5 UnitedHealth requested “payment under the contract.” Specifically,
6 UnitedHealth “acknowledge[d] that the information described below directly
7 affects the calculation of CMS payments to the MA Organization or additional
8 benefit obligations of the MA Organization and that misrepresentation to CMS
9 about the accuracy of such information may result in Federal civil action and/or
10 criminal prosecution” and further certifying “[b]ased on best knowledge,
11 information, and belief . . . , all information submitted to CMS in this report is
12 accurate, complete, and truthful.”
- 13 • UnitedHealth, in fact, received payments from CMS pursuant to its contract
14 with CMS based on the Diagnoses it submitted to CMS.
- 15 • UnitedHealth had knowledge, as defined by 31 U.S.C. § 3729(b)(1)(A), that
16 Diagnoses it received from Providers and submitted to CMS were not
17 supported by Chart documentation, as determined by its Chart Review Program
18 and, in some instances, other medical record reviews, but it failed to delete
19 those Diagnoses and thereby retained payments from CMS to which it was not
20 entitled.

21 **INTERROGATORY NO. 13** Separately for each of the years 2008 to 2017,
22 Identify all CMS Individuals and HHS-OIG Individuals who You contend Believed
23 or expressed in writing that MA Organizations were required to design their Chart
24 Review program to also validate Diagnoses reported by Providers that the MA
25 Organizations submitted to CMS.

26 **Objections:**

27 The United States incorporates by reference each of its General Objections and
28 Specific Objections to the Definitions and Instructions as if stated herein. The United

1 States further objects on the ground that the Interrogatory is vague, confusing, and
2 unduly burdensome because it seeks a separate answer for each year for what an
3 individual “Believed” at the time and to the extent the Interrogatory requires the
4 United States to determine, year by year from 2008–2017, when a given Belief began
5 or ended. Further, the United States objects to this Interrogatory to the extent that it
6 is irrelevant because Government agencies, including CMS and HHS-OIG, act
7 through official policy and regulations and not the beliefs or impressions of
8 individual employees or contractors. The United States objects to this Interrogatory
9 to the extent it misstates the United States’ contentions in this matter. The
10 Interrogatory states that the United States contends that MA Organizations were
11 required to *design* their Chart Review program to also validate Diagnoses reported by
12 Providers that the MA Organizations submitted to CMS. The United States makes no
13 such contention. The United States does not contend that UnitedHealth had to design
14 its Chart Review program in any particular way—rather, the United States contends
15 that UnitedHealth *did* design its Chart Review program to identify all supported
16 codes, but chose to submit new diagnosis codes identified by its Chart Review
17 program that would lead to additional payments from CMS while failing to delete
18 diagnosis codes submitted by Providers that its Chart Review program revealed were
19 not supported by medical record documentation. Thus, the beliefs or written
20 statements by CMS employees about *whether* MA Organizations have to design their
21 Chart Review programs to also validate Diagnoses reported by Providers that the MA
22 Organizations submitted to CMS are irrelevant and any exercise to ascertain those
23 beliefs or otherwise identify applicable writings would be meaningless and will not
24 narrow and sharpen issues for trial. *See* Fed. R. Civ. P. 33 Advisory Committee’s
25 Note.

26 **Response to Interrogatory No. 13:** Subject to and without waiving the foregoing
27 objections, the United States does not contend that any CMS and HHS-OIG
28 Individual Believed or expressed in writing that MA Organizations were required to

1 design their Chart Review program in any particular way. However, the United
2 States does contend that the obligations of MA Organizations include, among other
3 things, that if an MA Organization identifies Diagnoses reported by Providers that the
4 MA Organization submitted to CMS that are not supported by medical record
5 documentation, the MA Organization must delete or otherwise retract those
6 unsupported diagnosis codes from CMS data systems.

7 **INTERROGATORY NO. 15** Describe in detail how You implemented each of
8 Your policies, processes, and procedures Relating to Your retention, preservation, or
9 destruction of Documents and Electronically Stored Information.

10 **Objections:**

11 The United States incorporates by reference each of its General Objections and
12 Specific Objections to the Definitions and Instructions as if stated herein. The United
13 States objects to this Interrogatory as vague because it is unclear what information is
14 sought. The United States interprets this Interrogatory to request information about
15 the general policies set up to establish the principles, responsibilities, and
16 requirements for managing CMS and HHS-OIG records. Further, the United States
17 does not interpret this Interrogatory to request information about the litigation hold in
18 place in the Poehling Matter because, if UnitedHealth were requesting information
19 about the litigation hold in the Poehling Matter, it would have done so, as it did in
20 Interrogatory 14. The United States further objects to this Interrogatory to the extent
21 that it seeks information protected from disclosure by an applicable privilege or
22 protection. The United States interprets this Interrogatory to exclude attorneys and is
23 not searching for, collecting, or providing information or materials from any attorney
24 within OGC, OCIG, or DOJ. The United States further objects to this Interrogatory
25 to the extent that the information sought is publicly available, and the burden of
26 deriving the answer to this Interrogatory is substantially the same for both parties.
27 The United States further objects to this Interrogatory to the extent that the
28 information sought is contained in documents already produced in this matter, and the

1 burden of deriving the answer to this Interrogatory is substantially the same for both
2 parties.

3 **Response to Interrogatory No. 15:** Subject to and without waiving the foregoing
4 objections, the United States hereby responds that the information sought by this
5 Interrogatory can be derived from the following publicly-available sources and
6 documents already produced in this matter, including the following policy and
7 training documents:

- 8 • HHS Policy for Records Management, last reviewed on May 2020, *available at*
9 [https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html)
10 [ocio-policy-for-records-management.html](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html);
- 11 • HHS Policy for Litigation Holds, dated November 29, 2016
12 (USBP009834298);
- 13 • HHS Policy for Records Management, dated November 25, 2015
14 (USBP000105908);
- 15 • HHS Policy for Records Management of Emails, dated May 15, 2008
16 (USBP000105921);
- 17 • HHS Records Management Procedures Manual, dated December 5, 2008
18 (USBP000105935);
- 19 • HHS Records Management Council (RMC) Charter, dated August 21, 2007
20 (USBP000105930);
- 21 • General Records Management Training (USBP000490288);
- 22 • Office of Personnel Management Operating Manual, The Guide to Personnel
23 Recordkeeping (USBP000490327);
- 24 • CMS Litigation Support Meeting Powerpoint, dated November 14, 2019
25 (USBP009834319);
- 26 • Procedures for Implementing Litigations Holds/Document Preservation in
27 Civil Litigation, Office of Strategic Operations and Regulatory Affairs, Centers
28 for Medicare & Medicaid Services, Last Updated – March 2013

1 (USBP009834304);

2 • OCIG ACRB Records Retention Guidance, dated March 17, 2020

3 (USBP009834292);

4 • OCIG Record Destruction Guidelines (USBP009834288).

5 The United States further responds that the information sought by this

6 Interrogatory can be derived from the following records schedules and related

7 documents already produced in this matter:

8 • Introduction to the General Records Schedules (USBP000490439);

9 • General Records Schedule 2.5: Employee Separation Records
10 (USBP000490244) and Crosswalk (USBP000490271);

11 • General Records Schedule 2.6: Employee Training Records
12 (USBP000490247); Crosswalk (USBP000490272); and Frequently Asked
13 Questions (USBP000490273);

14 • General Records Schedule 2.8: Employee Ethics Records
15 (USBP000490249);

16 • General Records Schedule 3.1: General Technology Management Records
17 (USBP000490255); Crosswalk (USBP000490279); and Frequently Asked
18 Questions (USBP000490280);

19 • General Records Schedule 5.4: Facility, Equipment, Vehicle, Property,
20 and Supply Records (USBP000490264);

21 • General Records Schedule 5.5: Mail, Printing, and Telecommunication
22 Service Management Records (USBP000490285);

23 • General Records Schedule Disposition Spreadsheet (USBP000490310);

24 • Office of the Inspector General Office of Audit Services Files Plan Rollup
25 (USBP000490311).

26 **INTERROGATORY NO. 16** Identify all Persons, including but not limited to CMS
27 Individuals and HHS-OIG Individuals, with responsibility for or involvement in
28 overseeing the implementation of policies Relating to Your retention, preservation, or

1 destruction of Documents and Electronically Stored Information.

2 **Objections:**

3 The United States incorporates by reference each of its General Objections and
4 Specific Objections to the Definitions and Instructions as if stated herein. The United
5 States objects to this Interrogatory as vague and overly broad because it is unclear
6 what is meant by “policies.” The United States will interpret “policies” to mean the
7 policies that are publicly available at: [https://www.hhs.gov/web/governance/digital-](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html)
8 [strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html). Further, the
9 United States does not interpret this Interrogatory to request information about the
10 litigation hold in place in the Poehling Matter because, if UnitedHealth were
11 requesting information about the litigation hold in the Poehling Matter, it would have
12 done so, as it did in Interrogatory 14. The United States further objects to this
13 Interrogatory as vague because it is unclear what constitutes “responsibility for or
14 Involvement in overseeing the implementation” and could, conceivably, extend to
15 each of the thousands of CMS and HHS-OIG employees as well as other individuals
16 tasked with maintaining or preserving records within the Executive Branch of the
17 United States government. The United States will interpret this Interrogatory to
18 pertain to the individuals with roles and responsibilities for implementing HHS
19 Policy for Records Management (“Records Management Policy”), last reviewed on
20 May 20 and available at [https://www.hhs.gov/web/governance/digital-strategy/it-](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html)
21 [policy-archive/hhs-ocio-policy-for-records-management.html](https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-records-management.html). The United States
22 further objects to this Interrogatory to the extent that it seeks information protected
23 from disclosure by an applicable privilege or protection. The United States interprets
24 this Interrogatory to exclude attorneys and is not searching for, collecting, or
25 providing information or materials from any attorney within OGC, OCIG, or DOJ.

26 **Response to Interrogatory No. 16:** Subject to and without waiving the foregoing
27 objections, the United States hereby states that Section 7 of the Records Management
28 Policy sets forth the roles and responsibilities of the HHS Secretary; the HHS

1 Secretary for Administration; the HHS Chief Information Office; the Agency Records
2 Management Officer; the Operating Divisions (“OpDiv”) Chief Information Officers;
3 the HHS Chief Information Security Officer; the OpDiv Chief Information Security
4 Officers; the OpDiv Records Management Officers; the OpDiv and Staff Divisions
5 (“StaffDiv”) Records Managers and Records Liaisons; the OpDiv and StaffDiv
6 Records Custodians; Managers and Supervisors; Contracting Officers and
7 Contracting Officer Representatives; HHS Employees, Contractors, Interns, and
8 Fellows; the Freedom of Information Act Official; the Office of the General Counsel;
9 the Office of the Inspector General; and IT Infrastructure and Operations and System
10 Managers with respect to records management.

11 **INTERROGATORY NO. 17** Identify for Date of Service Years 2004–2016, the
12 Number of Diagnoses Codes submitted in FFS Medicare that were audited in each
13 Date of Service Year through Medical Record Reviews by Medical Record Review
14 Contractors prior to calibrating or recalibrating the CMS-HCC Risk Adjustment
15 Model using Diagnoses Codes from that same Date of Service Year.

16 **Objections:**

17 The United States incorporates by reference each of its General Objections and
18 Specific Objections to the Definitions and Instructions as if stated herein. The United
19 States objects to this Interrogatory to the extent it calls for the United States to
20 prepare documents and/or perform data analysis that does not already exist. The
21 United States objects to this Interrogatory as irrelevant because, during each year of
22 the relevant time period, UnitedHealth’s MA Organizations entered into contracts
23 with CMS and agreed to receive payments based on the CMS-HCC Risk Adjustment
24 Model in place at the time. This is a case brought under the False Claims Act and it
25 does not involve any potential challenges by UnitedHealth to the CMS-HCC Risk
26 Adjustment Model payment system. Thus, any post-hoc analysis of the data used to
27 calibrate the model used for any such payments is irrelevant to the claims and
28 defenses in this matter and any substantive analysis by the United States in response

1 to this Interrogatory is not proportional to the needs of the case. The United States
2 objects to this Interrogatory as overly broad and not proportional to the needs of this
3 case to the extent that it seeks information relating to audits conducted for DOS years
4 irrelevant to the years for which damages are sought in this matter.

5 **Response to Interrogatory No. 17:** Subject to and without waiving the foregoing
6 objections, the United States hereby states that CMS regularly conducts audits of
7 claims submitted under Part A and Part B of the Medicare Program, some of which
8 included audits of diagnosis codes submitted with the claims data. To the extent
9 corrections were made to the claims, diagnosis codes, or costs and those changes
10 were applied in relevant databases in advance of the data pull for the data used in the
11 calibration or recalibration of the CMS-HCC Risk Adjustment Model, those
12 corrections were reflected in the data used in the calibration or recalibration of the
13 CMS-HCC Risk Adjustment Model. The United States has already produced
14 business records related to the Medical Record Reviews by Medical Record Review
15 Contractors of FFS Medicare, to the extent they existed, after a reasonable search
16 from which information responsive to this Interrogatory may be determined or
17 ascertained. The burden of determining or ascertaining the answer is substantially the
18 same for the United States as it is for UnitedHealth. The United States further states
19 that, after a reasonable inquiry, it has determined that CMS has not undertaken this
20 analysis, does not know the exact number of Diagnosis Codes responsive to this
21 Interrogatory, and, even using the data and business records CMS does possess
22 related to the Medical Record Reviews by Medical Record Review Contractors of
23 FFS Medicare (which were collected and produced to UnitedHealth), the United
24 States does not believe that it is possible to answer this Interrogatory.

25 **INTERROGATORY NO. 18** Identify for Date of Service Years 2004–2016, the
26 Number of Diagnoses Codes submitted in FFS Medicare that were Corrected in each
27 Date of Service Year through Medical Record Reviews by Medical Record Review
28 Contractors prior to calibrating or recalibrating the CMS-HCC Risk Adjustment

1 Model using Diagnoses Codes from that same Date of Service Year.

2 **Objections:**

3 The United States incorporates by reference each of its General Objections and
4 Specific Objections to the Definitions and Instructions as if stated herein. The United
5 States objects to this Interrogatory to the extent it calls for the United States to
6 prepare documents and/or perform data analysis that does not already exist. The
7 United States objects to this Interrogatory as irrelevant because, during each year of
8 the relevant time period, UnitedHealth's MA Organizations entered into contracts
9 with CMS and agreed to receive payments based on the CMS-HCC Risk Adjustment
10 Model in place at the time. This is a case brought under the False Claims Act and it
11 does not involve any potential challenges by UnitedHealth to the CMS-HCC Risk
12 Adjustment Model payment system. Thus, any post-hoc analysis of the data used to
13 calibrate the model used for any such payments is irrelevant to the claims and
14 defenses in this matter and any substantive analysis by the United States in response
15 to this Interrogatory is not proportional to the needs of the case. The United States
16 objects to this Interrogatory as overly broad and not proportional to the needs of this
17 case to the extent that it seeks information relating to audits conducted for DOS years
18 irrelevant to the years for which damages are sought in this matter.

19 **Response to Interrogatory No. 18:** Subject to and without waiving the foregoing
20 objections, the United States hereby states that CMS regularly conducts audits of
21 claims submitted under Part A and Part B of the Medicare Program, some of which
22 included audits of diagnosis codes submitted with the claims data. To the extent
23 corrections were made to the claims, diagnosis codes, or costs and those changes
24 were applied in relevant databases in advance of the data pull for the data used in the
25 calibration or recalibration of the CMS-HCC Risk Adjustment Model, those
26 corrections were reflected in the data used in the calibration or recalibration of the
27 CMS-HCC Risk Adjustment Model. The United States has already produced
28 business records related to the Medical Record Reviews by Medical Record Review

Contractors of FFS Medicare, to the extent they existed, after a reasonable search from which information responsive to this Interrogatory may be determined or ascertained. The burden of determining or ascertaining the answer is substantially the same for the United States as it is for UnitedHealth. The United States further states that, after a reasonable inquiry, it has determined that CMS has not undertaken this analysis, does not know the exact number of Diagnosis Codes responsive to this Interrogatory, and, even using the data and business records CMS does possess related to the Medical Record Reviews by Medical Record Review Contractors of FFS Medicare (which were collected and produced to UnitedHealth), the United States does not believe that it is possible to answer this Interrogatory.

Respectfully submitted,

Dated: June 23, 2022

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PROOF OF SERVICE BY ELECTRONIC MAIL

1. I am over the age of 18 and not a party to the action entitled U.S. *ex rel.* Poehling v. UnitedHealth Group, Inc., CV 16-8697 FMO (SSx). I am employed by the Department of Justice, Civil Division, Commercial Litigation Branch, Fraud Section. My business address is 175 N St. NE, Washington, District of Columbia 20002.
 2. On June 23, 2022, I served the foregoing PLAINTIFF UNITED STATES' SIXTH SET OF INTERROGATORIES TO DEFENDANTS on each person or entity named below by electronic mail, pursuant to written consent under Federal Rule of Civil Procedure 5(b)(2)(E).
 - Date of e-mailing: June 23, 2022.
 - Place of e-mailing: Washington, District of Columbia.
 - Person(s) and/or Entity(s) to whom e-mailed: See attached page
 3. I declare under penalty of perjury that the foregoing is true and correct.
- Executed on June 23, 2022, at Washington, District of Columbia.



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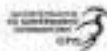
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EXHIBIT D-13 INTENTIONALLY BLANK

EXHIBIT D-14



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Federal Register / Vol. 73, No. 161 / Tuesday, August 19, 2008 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 413, 422, and 489

[CMS-1390-F; CMS-1531-IFC1; CMS-1531-IFC2; CMS-1385-F4]

RIN 0938-AP15; RIN 0938-AO35; RIN 0938-AO65

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems, and to implement certain provisions made by the Deficit Reduction Act of 2005, the Medicare Improvements and Extension Act, Division B, Title I of the Tax Relief and Health Care Act of 2006, the TMA, Abstinence Education, and QI Programs Extension Act of 2007, and the Medicare Improvements for Patients and Providers Act of 2008. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are generally applicable to discharges occurring on or after October 1, 2008. We also are setting forth the update to the rate-of-increase limits for certain hospitals and hospital units excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The updated rate-of-increase limits are effective for cost reporting periods beginning on or after October 1, 2008.

In addition to the changes for hospitals paid under the IPPS, this document contains revisions to the patient classifications and relative weights used under the long-term care

hospital prospective payment system (LTCH PPS). This document also contains policy changes relating to the requirements for furnishing hospital emergency services under the Emergency Medical Treatment and Labor Act of 1986 (EMTALA).

In this document, we are responding to public comments and finalizing the policies contained in two interim final rules relating to payments for Medicare graduate medical education to affiliated teaching hospitals in certain emergency situations.

We are revising the regulatory requirements relating to disclosure to patients of physician ownership or investment interests in hospitals and responding to public comments on a collection of information regarding financial relationships between hospitals and physicians. In addition, we are responding to public comments on proposals made in two separate rulemakings related to policies on physician self-referrals and finalizing these policies.

DATES: *Effective Dates:* This final rule is effective on October 1, 2008, with the following exceptions: Amendments to §§ 412.230, 412.232, and 412.234 are effective on September 2, 2008. Amendments to §§ 411.357(a)(5)(ii), (b)(4)(ii), (1)(3)(i) and (ii), and (p)(1)(i)(A) and (B) and the definition of entity in § 411.351 are effective on October 1, 2009.

Applicability Dates: The provisions of § 412.78 relating to payments to SCHs are applicable for cost reporting periods beginning on or after January 1, 2009. Our process for allowing certain hospitals to opt out of decisions made on behalf of hospitals (as discussed in section III.7. of this preamble) are applicable on August 19, 2008.

FOR FURTHER INFORMATION CONTACT: Gay Burton, (410) 786-4487, Operating Prospective Payment, MS-DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, and Postacute Care Transfer Issues.

Tzvi Hefter, (410) 786-4487, Capital Prospective Payment, Excluded Hospitals, Direct and Indirect Graduate Medical Education, MS-LTC-DRGs, EMTALA, Hospital Emergency Services, and Hospital-within-Hospital Issues.

Siddhartha Muzumdar, (410) 786-6673, Rural Community Hospital Demonstration Program Issues.

Sheila Blackstock, (410) 786-3502, Quality Data for Annual Payment Update Issues.

Thomas Valuck, (410) 786-7479, Hospital Value-Based Purchasing and Readmissions to Hospital Issues.

Rebecca Paul, (410) 786-0852, Collection of Managed Care Encounter Data Issues.

Jacqueline Proctor, (410) 786-8852, Disclosure of Physician Ownership in Hospitals and Financial Relationships between Hospitals and Physicians Issues.

Lisa Ohrin, (410) 786-4565, and Don Romano, (410) 786-1401, Physician Self-Referral Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web, (the Superintendent of Documents' home page address is <http://www.gpoaccess.gov/>), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required).

Acronyms

AARP American Association of Retired Persons
AAHKS American Association of Hip and Knee Surgeons
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
AF Atrial fibrillation
AHA American Hospital Association
AICD Automatic implantable cardioverter defibrillator
AHIMA American Health Information Management Association
AHIC American Health Information Community
AHRQ Agency for Healthcare Research and Quality
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
AOA American Osteopathic Association
APR DRG All Patient Refined Diagnosis Related Group System
ASU Ambulatory surgical center
ASITN American Society of Interventional and Therapeutic Neuroradiology
BBA Balanced Budget Act of 1997, Public Law 105-33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106-113
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106-554

Congress stipulated that hospitals paid based on the standardized amount should not receive additional payments based on the effect of documentation and coding changes that do not reflect real changes in case-mix. Similarly, we believe that hospitals paid based on the hospital-specific rate should not have the potential to realize increased payments due to documentation and coding improvements that do not reflect real increases in patients' severity of illness. While we continue to believe that section 1886(d)(3)(A)(vi) of the Act does not provide explicit authority for application of the documentation and coding adjustment to the hospital-specific rates, we believe that we have the authority to apply the documentation and coding adjustment to the hospital-specific rates using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. The special exceptions and adjustment authority authorizes us to provide "for such other exceptions and adjustments to [IPPS] payment amounts * * * as the Secretary deems appropriate." In light of this authority, for the FY 2010 rulemaking, we plan to examine our FY 2008 claims data for hospitals paid based on the hospital-specific rate. In the FY 2009 IPPS proposed rule, we stated that if we find evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing application of the documentation and coding adjustments to the FY 2010 hospital-specific rates under our authority in section 1886(d)(5)(I)(i) of the Act. As noted previously, the documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period are cumulative. For example, the -0.9 percent documentation and coding adjustment to the national standardized amount in FY 2009 is in addition to the -0.6 percent adjustment made in FY 2008, yielding a combined effect of -1.5 percent in FY 2009. Given the cumulative nature of the documentation and coding adjustments, if we were to propose to apply the documentation and coding adjustment to the FY 2010 hospital-specific rates, it may involve applying the FY 2008 and FY 2009 documentation and coding adjustments (-1.5 percent combined) plus the FY 2010 documentation and coding adjustment, discussed in the FY 2008 IPPS final rule with comment period, to the FY 2010 hospital-specific rates.

Comment: A number of commenters opposed application of the documentation and coding adjustment to the hospital-specific rates. MedPAC

supported application of a documentation and coding adjustment to the prospective payment rates and the hospital-specific rates for all IPPS hospitals that are paid based on their reported case-mix. Another commenter supported application of a documentation and coding adjustment to the hospital-specific rates if analysis of FY 2008 claims data supports a positive adjustment and recommended a transition be considered if the data support a negative adjustment.

Response: We appreciate the comments received. We did not propose to apply the documentation and coding adjustment to the hospital-specific rates for FY 2009. Instead, as we indicated in the proposed rule and reiterated above, we intend to consider whether such a proposal is warranted for FY 2010. To gather information to evaluate these considerations, we plan to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals paid based on the hospital-specific rate. If we find that application of the documentation and coding adjustment to the hospital-specific rates for FY 2010 is warranted, we would include a proposal in the FY 2010 IPPS proposed rule, which would be open for public comment at that time.

3. Application of the Documentation and Coding Adjustment to the Puerto Rico-Specific Standardized Amount

Puerto Rico hospitals are paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As noted previously, the documentation and coding adjustment we adopted in the FY 2008 IPPS final rule with comment period relied upon our authority under section 1886(d)(3)(A)(vi) of the Act, which provides the authority to adjust "the standardized amounts computed under this paragraph" to eliminate the effect of changes in coding or classification that do not reflect real changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to the national standardized amounts computed under section 1886(d)(3) of the Act, but does not apply to the Puerto Rico-specific standardized amount computed under section 1886(d)(9)(C) of the Act. In calculating the FY 2008 payment rates, we made an inadvertent error and applied the FY 2008 -0.6 percent documentation and coding adjustment to the Puerto Rico-specific standardized amount, relying on our authority under section 1886(d)(3)(A)(vi) of the Act. However, section 1886(d)(3)(A)(vi) of the Act authorizes application of a

documentation and coding adjustment to the national standardized amount and does not apply to the Puerto Rico-specific standardized amount. In this final rule, we are correcting this inadvertent error by removing the -0.6 percent documentation and coding adjustment from the FY 2008 Puerto Rico-specific rates. The revised FY 2008 Puerto Rico-specific operating standardized amounts are: \$1,471.10 for the labor share and \$901.84 for the nonlabor share for a hospital with a wage index greater than 1 and \$1,392.80 for the labor share and \$979.94 for the non-labor share for a hospital with a wage index less than or equal to 1. The revised FY 2008 Puerto Rico capital payment rate is \$202.89 (as discussed in section III.A.5.b. of the Addendum to this final rule). These revised rates are effective October 1, 2007, for FY 2008.

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the Puerto Rico-specific standardized amount, we believe that we have the authority to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount using our special exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Act. Similar to SCHs and MDHs that are paid based on the hospital-specific rate, discussed in section II.D.2. of this preamble, we believe that Puerto Rico hospitals that are paid based on the Puerto Rico-specific standardized amount should not have the potential to realize increased payments due to documentation and coding improvements that do not reflect real increases in patients' severity of illness. Consistent with the approach described for SCHs and MDHs in section II.D.2. of the preamble of this final rule, for the FY 2010 rulemaking, we plan to examine our FY 2008 claims data for hospitals in Puerto Rico. As we indicated in the FY 2009 proposed rule, if we find evidence of significant increases in case-mix for patients treated in these hospitals, we would consider proposing application of the documentation and coding adjustments to the FY 2010 Puerto Rico-specific standardized amount under our authority in section 1886(d)(5)(I)(i) of the Act. As noted previously, the documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period are cumulative. Given the cumulative nature of the documentation and coding adjustments, if we were to propose to apply the documentation and coding adjustment to the FY 2010 Puerto Rico-specific standardized amount, it may involve applying the FY 2008 and FY

2009 documentation and coding adjustments (–1.5 percent combined) plus the FY 2010 documentation and coding adjustment, discussed in the FY 2008 IPPS final rule with comment period, to the FY 2010 Puerto Rico-specific standardized amount.

Comment: Some commenters opposed application of the documentation and coding adjustment to the Puerto Rico-specific standardized amount. MedPAC supported application of a documentation and coding adjustment to the prospective payment rates and the hospital-specific rates for all IPPS hospitals that are paid based on their reported case-mix.

Response: We appreciate the comments. We did not propose to apply the documentation and coding adjustment to the Puerto Rico-specific standardized amount for FY 2009. Instead, as we indicated in the proposed rule, we intend to consider whether such a proposal is warranted for FY 2010. To gather information to evaluate these considerations, we plan to perform analyses on FY 2008 claims data to examine whether there has been a significant increase in case-mix for hospitals in Puerto Rico. If we find that application of the documentation and coding adjustment to the Puerto Rico-specific standardized amount for FY 2010 is warranted, we would include a proposal in the FY 2010 proposed rule, which would be open for public comment at that time.

4. Potential Additional Payment Adjustments in FYs 2010 Through 2012

Section 7 of Public Law 110–90 also provides for payment adjustments in FYs 2010 through 2012 based upon a retrospective evaluation of claims data from the implementation of the MS-DRG system. If, based on this retrospective evaluation, the Secretary finds that in FY 2008 and FY 2009, the actual amount of change in case-mix that does not reflect real change in underlying patient severity differs from the statutorily mandated documentation and coding adjustments implemented in those years, the law requires the Secretary to adjust payments for discharges occurring in FYs 2010 through 2012 to offset the estimated amount of increase or decrease in aggregate payments that occurred in FY 2008 and FY 2009 as a result of that difference, in addition to making an appropriate adjustment to the standardized amount under section 1006(d)(3)(A)(vi) of the Act.

In order to implement these requirements of section 7 of Public Law 110–90, we are planning a thorough retrospective evaluation of our claims

data. Results of this evaluation would be used by our actuaries to determine any necessary payment adjustments in FYs 2010 through 2012 to ensure the budget neutrality of the MS-DRG implementation for FY 2008 and FY 2009, as required by law. In the FY 2009 IPPS proposed rule, we described our preliminary analysis plans to provide the opportunity for public input.

In the proposed rule, we indicated that we intend to measure and corroborate the extent of the overall national average changes in case-mix for FY 2008 and FY 2009. We expect part of this overall national average change would be attributable to underlying changes in actual patient severity and part would be attributable to documentation and coding improvements under the MS-DRG system. In order to separate the two effects, we plan to isolate the effect of shifts in cases among base DRGs from the effect of shifts in the types of cases within base DRGs. The shifts among base DRGs are the result of changes in principal diagnoses while the shifts within base DRGs are the result of changes in secondary diagnoses. Because we expect most of the documentation and coding improvements under the MS-DRG system will occur in the secondary diagnoses, we believe that the shifts among base DRGs are less likely to be the result of the MS-DRG system and the shifts within base DRGs are more likely to be the result of the MS-DRG system. We also anticipate evaluating data to identify the specific MS-DRGs and diagnoses that contributed significantly to the improved documentation and coding payment effect and to quantify their impact. This step would entail analysis of the secondary diagnoses driving the shifts in severity within specific base DRGs.

In the proposed rule, we also stated that, while we believe that the data analysis plan described previously will produce an appropriate estimate of the extent of case-mix changes resulting from documentation and coding improvements, we may also decide, if feasible, to use historical data from our Hospital Payment Monitoring Program (HPMP) to corroborate the within-base DRG shift analysis. The HPMP is supported by the Medicare Clinical Data Abstraction Center (CDAC). From 1998 to 2007, the CDAC obtained medical records for a sample of discharges as part of our hospital monitoring activities. These data were collected on a random sample of between 30,000 to 50,000 hospital discharges per year. The historical CDAC data could be used to develop an upper bound estimate of the

trend in real case-mix growth (that is, real change in underlying patient severity) prior to implementation of the MS-DRGs.

In the FY 2009 IPPS proposed rule, we solicited public comments on the analysis plans described above, as well as suggestions on other possible approaches for conducting a retrospective analysis to identify the amount of case-mix changes that occurred in FY 2008 and FY 2009 that did not reflect real increases in patients' severity of illness.

Comment: A few commenters, including MedPAC, expressed support for the analytic approach described in the proposed rule. A number of other commenters expressed concerns about certain aspects of the approach and/or suggested alternate analyses or study designs. In addition, one commenter recommended that any determination or retrospective evaluation by the actuaries of the impact of the MS-DRGs on case-mix be open to public scrutiny prior to the implementation of final payment adjustments for FY 2010 through FY 2012.

Response: We thank the commenters for their comments. We will take all of the comments into consideration as we continue development of our analysis plans. Our analysis, findings, and any resulting proposals to adjust payments for discharges occurring in FYs 2010 through 2012 to offset the estimated amount of increase or decrease in aggregate payments that occurred in FY 2008 and FY 2009 will be discussed in future years' proposed rules, which will be open for public comment.

Comment: One commenter expressed concern about the impact that an adjustment to the FY 2010 through FY 2012 payment rates could have on small rural hospitals. The commenter stated that if CMS finds that there was an increase in aggregate payments in FY 2008 or FY 2009 that requires an offsetting adjustment to the FY 2010 through FY 2012 payment rates, CMS should consider a transition period before fully implementing such an adjustment.

Response: If our analysis suggests that an adjustment to the FY 2010 through FY 2012 payment rates is necessary, a proposal would be made in a future proposed rule and the public would have an opportunity to comment on the proposal at that time.

E. Refinement of the MS-DRG Relative Weight Calculation

1. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47188), we

continued to implement significant revisions to Medicare's inpatient hospital rates by basing relative weights on hospitals' estimated costs rather than on charges. We continued our 3-year transition from charge-based relative weights to cost-based relative weights. Beginning in FY 2007, we implemented relative weights based on cost report data instead of based on charge information. We had initially proposed to develop cost-based relative weights using the hospital-specific relative value cost center (HSRVcc) methodology as recommended by MedPAC. However, after considering concerns raised in the public comments, we modified MedPAC's methodology to exclude the hospital-specific relative weight feature. Instead, we developed national CCRs based on distinct hospital departments and engaged a contractor to evaluate the HSRVcc methodology for future consideration. To mitigate payment instability due to the adoption of cost-based relative weights, we decided to transition cost-based weights over 3 years by blending them with charge-based weights beginning in FY 2007. In FY 2008, we continued our transition by blending the relative weights with one-third charge-based weights and two-thirds cost-based weights.

Also, in FY 2008, we adopted severity-based MS-DRGs, which increased the number of DRGs from 538 to 745. Many commenters raised concerns as to how the transition from charge-based weights to cost-based weights would continue with the introduction of new MS-DRGs. We decided to implement a 2-year transition for the MS-DRGs to coincide with the remainder of the transition to cost-based relative weights. In FY 2008, 50 percent of the relative weight for each DRG was based on the CMS DRG relative weight and 50 percent was based on the MS-DRG relative weight. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for more detail on our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS-DRGs.

As we transitioned to cost-based relative weights, some commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high

cost items and overvalue low cost items if a single CCR is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to RTI to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. RTI issued an interim draft report in March 2007 which was posted on the CMS Web site with its findings on charge compression. In that report, RTI found that a number of factors contribute to charge compression and affect the accuracy of the relative weights. RTI found inconsistent matching of charges in the Medicare cost report and their corresponding charges in the MedPAR claims for certain cost centers. In addition, there was inconsistent reporting of costs and charges among hospitals. For example, some hospitals would report costs and charges for devices and medical supplies in the Medical Supplies Charged to Patients cost center, while other hospitals would report those costs and charges in their related ancillary departments such as Operating Room or Radiology. RTI also found evidence that certain revenue codes within the same cost center had significantly different markup rates. For example, within the Medicare Supplies Charged to Patients cost center, revenue codes for devices, implantables, and prosthetics had different markup rates than the other medical supplies in that cost center. RTI's findings demonstrated that charge compression exists in several CCRs, most notably in the Medical Supplies and Equipment CCR.

RTI offered short-term, medium-term, and long-term recommendations to mitigate the effects of charge compression. RTI's short-term recommendations included expanding the distinct hospital CCRs to 19 by disaggregating the "Emergency Room" and "Blood and Blood Products" from the Other Services cost center and by estimating regression-based CCRs to disaggregate Medical Supplies, Drugs, and Radiology cost centers. RTI recommended, for the medium-term, to expand the MedPAR file to include separate fields that disaggregate several existing charge departments. In addition, RTI recommended improving hospital cost reporting instructions so that hospitals can properly report costs in the appropriate cost centers. RTI's long-term recommendations included adding new cost centers to the Medicare cost report, such as adding a "Devices, Implants and Prosthetics" line under "Medical Supplies Charged to Patients"

and a "CT Scanning and MRI" subscripted line under "Radiology-Diagnostics".

Among RTI's short-term recommendations, for FY 2008, we expanded the number of distinct hospital department CCRs from 13 to 15 by disaggregating "Emergency Room" and "Blood and Blood Products" from the Other Services cost center as these lines already exist on the hospital cost report. Furthermore, in an effort to improve consistency between costs and their corresponding charges in the MedPAR file, we moved the costs for cases involving electroencephalography (EEG) from the Cardiology cost center to the Laboratory cost center group which corresponds with the EEG MedPAR claims categorized under the Laboratory charges. We also agreed with RTI's recommendations to revise the Medicare cost report and the MedPAR file as a long-term solution for charge compression. We stated that, in the upcoming year, we would consider additional lines to the cost report and additional revenue codes for the MedPAR file.

Despite receiving public comments in support of the regression-based CCRs as a means to immediately resolve the problem of charge compression, particularly within the Medical Supplies and Equipment CCR, we did not adopt RTI's short-term recommendation to create four additional regression-based CCRs for several reasons. We were concerned that RTI's analysis was limited to charges on hospital inpatient claims, while typically hospital cost report CCRs combine both inpatient and outpatient services. Further, because both the IPPS and OPSS rely on cost-based weights, we preferred to introduce any methodological adjustments to both payment systems at the same time. We have since expanded RTI's analysis of charge compression to incorporate outpatient services. RTI has been evaluating the cost estimation process for the OPSS cost-based weights, including a reassessment of the regression-based CCR models using both outpatient and inpatient charge data. Because the RTI report was not available until after the conclusion of our proposed rule development process, we were unable to include a summary of the report in the FY 2009 IPPS proposed rule. The IPPS-related chapters of RTI's interim report were posted on the CMS Web site on April 22, 2008, for a 60-day comment period, and we welcomed comments on the report. In this final rule, we are providing a summary of RTI's findings and the public comments

we received in section ILE.2. of the preamble of this final rule.

2. Summary of RTI's Report on Charge Compression

As stated earlier, subsequent to the release of the FY 2009 IPPS proposed rule, we posted on April 22, 2008, an interim report discussing RTI's research findings for the IPPS MS-DRG relative weights to be available during the public comment period on the FY 2009 IPPS proposed rule. This report can be found on RTI's Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-00291/PDF/Refining_Cost_to_Charge_Ratios_200804.pdf. The IPPS-specific chapters, which were separately displayed in the April 2008 interim report, as well as the more recent OPSS chapters, are included in the July 2008 RTI final report entitled, "Refining Cost-to-Charge Ratios for Calculating APC and DRG Relative Payment Weights," that became available at the time of the development of this final rule. The RTI final report can be found on RTI's Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-00291/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf.

RTI's final report distinguished between two types of research findings and recommendations: Those pertaining to the accounting or cost report data and those related to statistical regression analysis. Because the OPSS uses a hospital-specific CCR methodology, employs detailed cost report data, and estimates costs at the claim level, CMS asked RTI to closely evaluate the accounting component of the OPSS cost-based weight methodology. In reviewing the cost report data for nonstandard cost centers used in the crosswalk, RTI discovered some problems concerning the classification of nonstandard cost centers that impact both the IPPS and the OPSS. RTI reclassified nonstandard cost centers by reading providers' cost center labels. Standard cost centers are preprinted in the CMS-approved cost report software, while nonstandard cost centers are identified and updated periodically through analysis of frequently used labels. Under the IPPS, the line reassignments only slightly impact the 15 national aggregate CCRs used in the relative weight calculation. However, improved cost report data for CT Scanning, MRI, Nuclear Medicine, Therapeutic Radiology, and Cardiac Catheterization through line reassignments allowed for the reduction in aggregation bias by expanding the number of national CCRs available to separately capture these and other services. Importantly, RTI found that,

under the IPPS and the OPSS, this improvement to the cost reporting data reduces some of the sources of aggregation bias without having to use regression-based adjustments.

In general, with respect to the regression-based adjustments, RTI confirmed the findings of its March 2007 report that regression models are a valid approach for diagnosing potential aggregation bias within selected services for the IPPS and found that regression models are equally valid for setting payments under the OPSS. RTI also suggested that regression-based CCRs could provide a short-term correction until accounting data could be refined to support more accurate CCR estimates under both the IPPS and the OPSS. RTI again found aggregation bias in devices, drugs, and radiology and, using combined outpatient and inpatient claims, expanded the number of recommended regression-adjusted CCRs to create seven regression-adjusted CCRs for Devices, IV Solutions, Cardiac Catheterization, CT Scanning, MRI, Therapeutic Radiology, and Nuclear Medicine.

In almost all cases, RTI observed that potential distortions from aggregation bias and incorrect cost reporting in the OPSS relative weights were proportionally much greater than for MS-DRGs for both accounting-based and statistical adjustments because OPSS groups are small and generally price a single service. HCRIS line reassignments by themselves had little effect on most inpatient weights. However, just as the overall impacts on MS-DRGs were more moderate because MS-DRGs experienced offsetting effects in cost estimation among numerous revenue codes in an episode, a given hospital outpatient visit might include more than one service, leading to offsetting effects in cost estimation for services provided in the outpatient episode as a whole.

Notwithstanding likely offsetting effects at the provider-level, RTI asserted that, while some averaging is appropriate for a prospective payment system, extreme distortions in payments for individual services bias perceptions of service profitability and may lead hospitals to inappropriately set their charge structure. RTI noted that this may not be true for "core" hospital services, such as oncology, but has a greater impact in evolving areas with greater potential for provider-induced demand, such as specialized imaging services. RTI also noted that cost-based weights are only one component of a final prospective payment rate. There are other rate adjustments (wage index, IME, and DSH) to payments derived

from the revised cost-based weights and the cumulative effect of these components may not improve the ability of final payment to reflect resource cost. With regard to APCs and MS-DRGs that contain substantial device costs, RTI cautioned that other prospective payment system adjustments (wage index, IME, and DSH) largely offset the effects of charge compression among hospitals that receive these adjustments. RTI endorsed short-term regression-based adjustments, but also concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in hospital cost-based weights.

As a result of this research, RTI made 11 recommendations. The first set of recommendations is more applicable to the OPSS because it uses more granular HCRIS data and concentrates on short-term accounting changes to current cost report data. This set includes a recommendation that CMS immediately implement a review of HCRIS cost center assignments based on text searches of providers' line descriptions and reassign lines appropriately. The second set addresses short-term regression-based and other statistical adjustments. The third set focuses on clarifying existing cost report instructions to instruct providers to use all applicable standard cost centers, adding new standard cost centers (for Devices, CT Scans, MRIs, Cardiac Catheterization, and Infusion Drugs), and creating new charge category summaries in the MedPAR to match the new cost centers on the cost report. Specifically, the new MedPAR groups would be for Intermediate Care (revenue codes 0206 and 0214), Devices (revenue codes 0274, 0275, 0276 and 0278), IV Solutions (revenue code 0258), CT Scanning (revenue codes 035x), Nuclear Medicine (revenue codes 034x, possibly combined with 0404), and Therapeutic Radiology (revenue codes 033x). RTI also recommends educating hospitals through industry-led educational initiatives directed at methods for capital cost finding, specifically encouraging providers to use direct assignment of equipment depreciation and lease costs wherever possible, or at least to allocate moveable equipment depreciation based on the dollar value of assigned depreciation costs. Lastly, although not directly the focus of its study, RTI mentions the problem of nursing cost compression in the relative weights, and notes that cost compression within inpatient nursing services is a significant source of distortion in the various IPPS' relative

weights, possibly more so than any of the factors studied by RTI. RTI suggests that it may be best for hospitals to agree to expand charge coding conventions for inpatient nursing, which would foster increased use of patient-specific nursing incremental charge codes in addition to baseline unit-specific per-diem charges.

Comment: One commenter agreed with the enhancements made by RTI (in the portion of the RTI report that was made available to the public in the April 2008 report) to the model for disaggregating CCRs in the Medical Supplies cost center, but was "disappointed" that CMS did not post the complete report, including the impact of charge "decompression" on the APC weights under the OPSS, and urged CMS to release the full report as soon as possible to allow a comprehensive review of the findings applicable to both the IPPS and the OPSS.

Response: Because the final RTI report was not scheduled to be completed before July 2008, we were unable to make the complete report, including sections focusing on the OPSS, available to the public in April 2008. Because we wanted to give the public the benefit of a 60-day comment period on the IPPS sections of the RTI report that would generally coincide with the 60-day comment period on the FY 2009 IPPS proposed rule, we chose to make available in April 2008 those sections of the RTI report that specifically dealt with the IPPS MS-DRG relative weights. We note that on July 3, 2008, we included on the CMS Web site the link to the complete RTI report: http://www.rti.org/reports/cms/HHS-500-2005-00291/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf.

Comment: One commenter recommended that, for purposes of calculating the relative weights for FY 2009, CMS adopt RTI's recommendation to reassign cost center lines based on the provider's entered text description to correct errors in the assignment of costs and charges by hospitals in nonstandard cost centers on the cost report. The commenter also suggested that CMS adopt RTI's recommendation that, in the MedPAR file, intermediate care charges should be reclassified from the Intensive Care Unit cost center to the Routine cost center to correct a mismatch between where the intermediate care charges are assigned on the cost report (that is, in the Routine cost center) and where the charges are grouped in MedPAR (that is, with intensive care unit charges).

Response: The commenter's recommendations are important and are consistent with existing Medicare

policy. Currently, the MedPAR file incorrectly groups intermediate care charges with intensive care unit charges; intermediate care charges and costs are, in fact, to be included in the General Routine (that is, Adults and Pediatrics) cost center on the cost report, in accordance with section 2202.7.I.B. of the PRM-1. However, in its July 2008 report, RTI found that HCRIIS line reassignments by themselves had little effect on most inpatient weights (page 8). The impact of adopting these recommendations would likely be more pronounced if we were adopting regression-based CCRs for purposes of calculating the relative weights for FY 2009. However, because we are not using regression-based CCRs for FY 2009, we do not believe it is necessary to adopt the commenter's recommendations for the MS-DRG relative weights at this time, but will consider them for future rulemaking.

Comment: One commenter commended CMS for proposing to break out the existing line on the cost report for Medical Supplies Charged to Patients into two lines, one for costly devices and implants and the other for low-cost supplies, and for undertaking a comprehensive review of the cost report. However, the commenter observed that RTI's 2008 report demonstrates that additional lines are also needed to further break out drugs, radiology (CT scans and MRI scans) and cardiac catheterization because hospitals apply varying markups within these cost centers as well.

Response: We acknowledge, as RTI has found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the proposed rule, we proposed to focus on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS-DRG relative weights could result from correcting charge compression for devices and implants.

We note that in the CY 2009 OPSS/ASC proposed rule (73 FR 41490), we are proposing to break the single standard Drugs Charged to Patient cost center, Line 56, into two standard cost centers, Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients, to reduce the reallocation of pharmacy overhead cost from expensive to inexpensive drugs and biologicals. We use the term "pharmacy overhead" here to refer to overhead and related expenses such as pharmacy services and handling costs. This proposal is consistent with RTI's recommendation for creating a new cost center with a CCR that would be used to adjust

charges to costs for drugs requiring detail coding. In the CY 2009 OPSS/ASC proposed rule, we note that comments on the proposed changes to the cost report for drugs should address any impact on both the inpatient and outpatient payment systems because both systems rely upon the Medicare hospital cost report for cost estimation. Furthermore, in that proposed rule, we specifically invited public comment on the appropriateness of creating standard cost centers for Computed Tomography (CT) Scanning, Magnetic Resonance Imaging (MRI), and Cardiac Catheterization, rather than continuing the established nonstandard cost centers for these services (73 FR 41431).

3. Summary of RAND's Study of Alternative Relative Weight Methodologies

A second reason that we did not implement regression-based CCRs at the time of the FY 2008 IPPS final rule with comment period was our inability to investigate how regression-based CCRs would interact with the implementation of MS-DRGs. In the FY 2008 final rule with comment period (72 FR 47197), we stated that we engaged RAND as the contractor to evaluate the HSRV methodology in conjunction with regression-based CCRs and we would consider their analysis as we prepared for the FY 2009 IPPS rulemaking process. We stated that we would analyze how the relative weights would change if we were to adopt regression-based CCRs and an HSRV methodology using fully-phased in MS-DRGs. We stated that we would consider the results of the second phase of the RAND study as we prepared for the FY 2009 IPPS rulemaking process. We had intended to include a detailed discussion of RAND's study in the FY 2009 IPPS proposed rule. However, due to some delays in releasing identifiable data to the contractor under revised data security rules, the report on this second stage of RAND's analysis was not completed in time for the development of the proposed rule. Therefore, we continued to have the same concerns with respect to uncertainty about how regression-based CCRs would interact with the MS-DRGs or an HSRV methodology, and we did not propose to adopt the regression-based CCRs or an HSRV methodology in the FY 2009 IPPS proposed rule. Nevertheless, we welcomed public comments on our proposals not to adopt regression-based CCRs or an HSRV methodology at that time or in the future. The RAND report on regression-based CCRs and the HSRV methodology was finalized at the conclusion of our proposed rule

EXHIBIT D-15

75 FR 19678-01, 2010 WL 1483422(F.R.)

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 480

[CMS-4085-F]

RIN 0938-AP77

Medicare Program; Policy and Technical Changes to the Medicare
Advantage and the Medicare Prescription Drug Benefit Programs

Thursday, April 15, 2010

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

***19678 ACTION:** Final rule.

SUMMARY: This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy.

DATES: Effective Date: These regulations are effective on June 7, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted.

FOR FURTHER INFORMATION CONTACT:

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Sabrina Ahmed, (410) 786-7499, Part C issues.

Terry Lied, (410) 786-8973, Collection of information requirements and regulatory impact analysis issues.

Kristy Nishimoto, (410) 786-8517, Part C and D enrollment and appeals issues.

Jennifer Smith, (410) 786-2987, Part C and D compliance and sanction issues.

Frank Szefflinski, (303) 844-7119, Part C payment issues.

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3. Required Use of Standardized Model Materials Under Parts C and D (§ 422.2262 and § 423.2262)
4. Involuntary Disenrollment for Failure to Pay Plan Premiums Under Parts C and D (§ 422.74 and § 423.44)

Another commenter argued that CMS should not state that the transition period will be “as determined by CMS,” but rather specify how the transition period will be measured. The same commenter wrote that if CMS does finalize the proposed requirement, we should not apply it to any acquisition prior to issuance of the rule, as the organization would have already taken action based on transition-related guidance in the 2008 and 2009 call letters.

Response: As stated in the preamble to the proposed rule, based on our experience, we believe that our proposed timeline for transitions provides ample time for organizations and sponsors to ensure that benefit packages are sufficiently different and to notify enrollees of any changes. Because the transition period actually applies for *19740 the two contract years following the year of the acquisition or merger, that is, if a merger takes place in 2010, the MAO or sponsor would have until 2013 to offer meaningfully different plans, we believe this period is disruptive neither to plans nor to beneficiaries, and thus disagree with the commenter who asserted that a 3-year transition was needed to allow MA organizations and Part D plan sponsors to adapt their benefit structures and communicate to beneficiaries about the changes being made.

We clarify that only organizations or sponsors that merge or are acquired after the effective date of this final rule will be subject to the requirement at § 422.256(b)(4)(ii) and § 423.272(b)(3)(ii) that their offerings are meaningfully different after a 2-year transition period. In the case of plans offered by organizations or sponsors that merge or acquire other plans prior to the effective date of this regulation, the previously articulated 3-year transition period would apply.

3. Non-Renewing Low-Enrollment Plans (§ 422.506(b)(1)(iv), § 423.507(b)(1)(iii))

As part of our process to streamline and simplify the plan selection process for beneficiaries, and ensure that beneficiaries are only offered plans with long-term viability, we proposed in § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to include, as a specific ground for non-renewal of a contract, a finding that a Part C or Part D plan has failed to attract a significant number of enrollees over a sustained period of time. We justified this requirement on the grounds that, as a general matter, continuing such a low enrollment plan was not consistent with effective and efficient administration of the Medicare program for purposes of section 1857(c)(2)(B) of the Act (incorporated for Part D under section 1860D-12(b)(3)(B) of the Act), which provides authority to terminate a contract under such circumstances. In the preamble to the proposed rule, we acknowledged that there may be instances in which low enrollment over a sustained period of time is a function of the type of beneficiaries served, geographic location, or other circumstances, and that we would consider continuing to renew a low enrollment plan in such situations including, but not limited to, chronic care SNPs offering health care services especially tailored to this category of beneficiaries and not available elsewhere or employer group health plans offering benefits augmenting those of an MA plan to employees of a small business. We further stated that, if a case could be made that low enrollment is justified, and the absence of such a plan would significantly limit beneficiary health care options in a service area, consistent with effective and efficient administration of the Part C or Part D benefit, we would not non-renew that plan. Similarly, we also stated that the threshold for low enrollment could fluctuate, although we noted that we used a threshold of 100 enrollees for purposes of reducing the number of low enrollment plans for contract year 2010. Therefore, we did not propose to revise our regulations to specify a specific threshold. We solicited comments on this approach and whether we had provided sufficient clarity on how we would determine whether a low-enrollment plan would be non-renewed.

Comment: Several commenters supported the proposal to non-renew low enrollment plans, but recommended that the threshold and guidelines we would use to apply this requirement (including such factors as the number of plans in a market, plan enrollment, and the number of years of operation with low enrollment numbers) be clear and transparent, and that they be made available publicly early in the year preceding the contract year to which they will apply. One commenter wrote that CMS should convene a working group prior to enacting our proposed policy to non-renew low enrollment plans. Another commenter wrote that CMS should consider low enrollment to be in the 250 to 500 enrollee range rather than 100 enrollees (the number used in our efforts to reduce low-enrollment plans for contract year 2010, as detailed in the preamble to our proposed rule). Another recommended a low enrollment threshold of 1000 enrollees because it believes that plans serving fewer than 1000 people in a service area would be unable to offer negotiated savings, quality managed care, or popular plan features. A commenter asked CMS to clarify what is meant by “a small number of enrollees over a period of time.”

Response: We agree that guidelines concerning minimum enrollment thresholds and criteria should be published annually and as early as possible in the year preceding the contract year to which they will apply. While we disagree that we should specify thresholds in regulations, we intend to provide opportunities for the public to review and comment on our proposed thresholds and criteria for assessing low enrollment for the following contract year (for example, through our annual call letter). We recognize that we must be flexible in assessing minimum enrollment to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering (such as, a chronic care SNP), or recent establishment of the plan, may continue to operate and that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to provide for public input annually on our implementation guidance and will consider the suggestions for specific threshold amounts submitted by the commenters in that context, we do not believe the suggested “workgroup” to be necessary. With respect to the question of what constitutes “a small number of enrollees” over a period of time, the process described above may also be used to determine the number of enrollees that would trigger application of this regulation, as well as the period of time for which the small number would have to be sustained.

Comment: Another commenter recommended that CMS make clear that the length of time a plan has had low enrollment will be a primary factor in determining whether a plan is non-renewed, and that we should modify our regulations language to explicitly provide for “waivers” of the proposed requirement at § 422.506(b)(1)(iv) (§ 423.507(b)(1)(iii) for Part D plans) when special circumstances such as the type of beneficiaries served, geographic location, and absence of the plan would significantly limit beneficiary health care options in a service area.

Response: The length of time in which a plan has had low enrollment is only one of the factors that we will consider in determining whether it is consistent with effective and efficient administration of the Part C or Part D benefit. We will also consider the type of benefits being offered under the plan and the nature of the enrollment in the plan. As stated above, we recognize that we must be flexible in applying any minimum enrollment requirement to ensure that plans with legitimate reasons for low enrollments, such as lack of other health care plan options, specialized plan offering or recent establishment of the plan, may continue to operate. This flexibility will ensure that beneficiaries who might not otherwise have access to health care options offered by a low-enrollment plan will continue to have such access. Because we intend to apply this requirement in a flexible manner that considers the particular circumstances of each low enrollment plan, we do not ***19741** believe it is necessary to modify the proposed regulations at § 422.506(b)(1)(iv) and § 423.507(b)(1)(iii) to provide explicitly for “waivers” of this requirement.

Comment: A commenter recommended that non-renewed plans be permitted to passively enroll affected enrollees into another plan offered by the MA organization or Part D sponsor.

Response: With respect to the recommendation to provide for passive enrollment of beneficiaries in a non-renewed plan into another plan offered by that organization, we believe this is appropriate only in limited circumstances when a compelling case can be made that such passive enrollment is in beneficiaries' best interests. In making such determinations, we take into consideration criteria such as benefits, cost sharing, the provider network, and premiums to ensure a comparable plan offering. In all other cases, we believe it is most appropriate to leave enrollment decisions to beneficiaries, who will have an opportunity during the annual coordinated election period to select another MA plan or Part D plan offered by the MA organization or Part D sponsor offering the plan being terminated. If a plan is terminated or nonrenewed, the affected organization or sponsor must follow all beneficiary and CMS advance notification requirements as specified in §§ 422.506, 422.508, 422.510, and 422.512 (MA program regulations), §§ 423.507, 423.508, 423.509, and 423.510 (Part D program regulations) and related guidance for both programs. In addition, passive enrollment initiated by an organization or sponsor in the absence of CMS approval is not among the transactions permitted by us in our annual renewal/non-renewal guidance. Because of these requirements and policies, an MA organization or Part D sponsor wishing to enroll members from the terminating or non-renewing plan into another of their plans could not do this without prior CMS review and consent. If we were to determine that such a transaction was in beneficiaries' best interests, we would, as is our practice, facilitate and closely monitor the process. We note as well

that beneficiaries in terminated or non-renewed plans have guaranteed issue Medigap rights, access to information about other available health care options, and other information that will assist them in finding plans most suited to their needs.

Comment: Several commenters supported our proposal but asked that we make exceptions for SNPs. One commenter requesting the SNP exception wrote that “status as a SNP should be prima facie evidence that low enrollment is justified.” A few of these commenters specifically requested that such exceptions be codified in the final regulations text. One commenter requested an exception be made for employer group plans. One commenter requested an exception for MA-only plans, stating that enrollees who get their prescription drugs through some means other than an MA-PD should still have the option of remaining in an MA-only plan, and another commenter requested that “national” plans be exempted from these requirements.

Response: While we will consider exceptions on a case-by-case basis to any low-enrollment thresholds we establish, we do not believe it is necessary to exempt any specific plan type as a priority. As we stated in the preamble to the proposed rule, there may be reasons for exceptions based on plan type, geography, or special health conditions of enrollees served that warrant a waiver of the requirements. However, a specific plan type, for example, a SNP or employer group plan, will not automatically be exempt from the minimum enrollment standard for renewal due to plan type alone. While sustained low enrollment may well be justified in the case of certain SNPs serving individuals with a relatively rare condition, a SNP serving an individual with a more common disease such as diabetes, or serving dual eligibles, should be able to attract enrollees. Similarly, we do not believe there is justification for exempting MA-only plans or “national” plans from the requirements unless there are other reasons to exempt them (for example, lack of other health care plan options, the specialized nature of the plan, or the recent establishment of the plan).

4. Medicare Options Compare and Medicare Prescription Drug Plan Finder

In the proposed rule we asked for comments on ways to improve the web tools, Medicare Options Compare (MOC), and the Medicare Prescription Drug Plan Finder (MDPF). We summarize and respond to these comments below.

Comment: One commenter requested that CMS add a function to limit the information that can be seen in the MOC so that users of the tool can focus on information they need most.

Response: The 2011 contract year update will include functions that expand and collapse which will help users of the MOC better focus on specific information.

Comment: Another commenter asked that the MOC contain direct links to the plan(s) discussed, not just the organization's Web site as is now often the case.

Response: We are not making the suggested change at this time as we believe that MOC already includes sufficient information to contact plans.

Comment: Another commenter requested that the tool clearly indicate what is meant by an “enhanced plan,” even if this is just a general description in the tool of the typical features of an enhanced plan.

Response: We do not believe that revisions are necessary as information on enhanced plans is currently available in the glossary and at <http://www.medicare.gov/medicarereform/howtoread.asp>.

Comment: A commenter requested that CMS add back the search function in MPDPF notifying the user of the number of drugs covered by a particular plan. The same commenter requested that information be included about when a plan last updated its drug pricing information and that the tool includes information about coverage of drugs traditionally covered under Part B, for example, infused and injectable drugs for MA-PD plans.

Response: Currently the drugs an individual beneficiary takes may be entered and displayed to determine coverage, but the MPDPF does not permit display a list of all the drugs a plan covers as this would take a very long time for the tool to display. CMS reviews drug pricing on a regular basis and the data is updated monthly to reflect any changes. We believe the compare function best permits users to tailor their searches for the specific drugs in the specific forms that they need.

Comment: Another commenter wrote that the MOC is relatively thorough but inconsistent in that some plans in the tool do not include information about health care costs and that saved searches often yield different results when retrieved later. The commenter recommended that the tool be refined to allow the user to move easily back and forth between information for MA and Part D plans, that the conditions required for enrollment in a chronic care SNP be specified, and that the function concerning costs for tiers of drugs is “incredibly unfriendly and confusing.”

Response: We are considering how best to streamline and make the use of these comparative functions easier.

***19742 D. Changes To Improve Payment Rules and Processes**

This section addresses three payment issues under Part C. These provisions are outlined in Table 4.

Table 4^Improving Payment Rules and Processes

Provision	Part 417/422	Part 417/422	Part 423	Part 423
	Subpart	Section	Subpart	Section
Risk Adjustment Data Validation	Subpart F	§ 422.2	N/A	N/A.
Dispute and Appeals Process	Subpart G	§ 422.311		
Payments to Medicare Advantage Organizations- Actuarial Valuation	Subpart F	§ 422.254	N/A	N/A.
Determination of Acceptable Administrative Costs by HMO/CMP Cost Contract and Health Care Prepayment Plans (HCPPs)	Subpart O	§ 417.564	N/A	N/A.
Calculation of the Minimum Percentage Increase under Part C	Subpart G	§ 422.306	N/A	N/A.

1. Definitions Related to Risk Adjustment Data Validation Appeals (§ 422.2) and Addition of Medicare Advantage Organization Risk Adjustment Data Validation^Dispute and Appeal Procedures (§ 422.311)

In the October 22, 2009 proposed rule, we proposed regulations establishing an appeals process to be used by MA organizations to appeal the error calculation resulting from Risk Adjustment Data Validation (RADV) audits. As explained in the preamble of that proposed rule, under RADV audits and medical records are reviewed to determine whether they support diagnosis codes (known as Hierarchical Condition Codes, or HCCs) submitted to us under the MA risk adjustment methodology. Under this methodology, certain diagnosis codes are considered to signify higher costs for the enrollee, and therefore, we pay a higher amount to the MA organization for an enrollee to reflect these higher costs. If, in fact, a diagnosis code was not justified by the enrollee's medical condition, the higher payment amount associated with that diagnosis code would have been an overpayment. Under the RADV audit process we plan to recover the overpayments identified during the RADV audit. The appeals process we proposed in the October 22, 2009 proposed rule was intended to provide a mechanism for MA organizations to appeal the error calculation associated with the overpayments identified under RADV audits. We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process, but on the RADV audit process and underlying MA payment policy producing the overpayment

findings and our definitions proposed at § 422.2. Since neither the statute nor existing MA program regulations currently specify a process for appealing overpayments resulting from RADV audits, the appeals process we proposed was based on our authority to establish MA program standards by regulation at section 1856(b)(1) of the Act. Specifically, we proposed adding a new § 422.311 to part 422, subpart G, to specify RADV dispute and appeal rights for MA organizations. We proposed regulatory provisions allowing MA organizations that undergo RADV audit(s) to[^](1) submit physician and other practitioner signed attestations relating to physician and other outpatient medical records that had a missing signature, or credentials that resulted in a payment error finding; (2) dispute certain other types of medical record review-related findings through the use of a documentation dispute process; and (3) appeal our RADV payment error calculation. By availing themselves of these RADV dispute and appeal processes, we noted that MA organizations would be able to reduce their RADV payment error and thereby, reduce their overall estimated MA payment error. Therefore, we proposed the following provisions under part 422:

- To revise § 422.2 to add definitions of six terms that pertain to RADV activities, and thus to our proposals for implementing a RADV dispute and appeal processes.
- A new § 422.311 describing procedures that we would implement to afford MA organizations facing a potential overpayment determination resulting from RADV audits the opportunity to have certain potential RADV payment errors addressed in advance of RADV-audit-related payment error determinations, and to have other types of confirmed payment errors overturned. At § 422.311(a) and (b), we summarized the RADV audit procedures. Beginning with § 422.311(c), we proposed implementing a three-pronged RADV dispute and appeal procedure that MA organizations could employ to reduce their RADV payment error rate, including[^]
- Physician/practitioner attestation(s);
- Documentation dispute; and
- RADV payment error calculation appeal.

We noted that analysis of data originating from medical records submitted by MA organizations that have undergone RADV audit indicates that a substantial percentage of medical record-related payment error determinations are due to missing signatures or credentials on medical records. Medicare program rules dictate the necessity of physician signatures on medical records, and MA risk adjustment requirements dictate that risk adjustment diagnosis data be accepted only for health services that were provided by certain physician specialties. Therefore, RADV audit procedures require that, in addition to finding diagnosis information that would support the HCCs submitted by the MA organization for risk adjustment purposes, physician signatures, and appropriate credentials must be present on medical records. Medical records with missing signatures or credentials are scored as errors under RADV audit procedures. We estimated that if given the opportunity to do so, many physicians and other practitioners that provided the diagnosis information on RADV-reviewed medical records would in fact attest that they documented the information in these medical records, even though signatures and credentials were missing from those records. Moreover, the presence of a signature or credential attestation to accompany these medical records would in our opinion, provide justification for preventing both contract-level and national-level RADV payment errors ***19743** that would otherwise originate from medical record signature, or credential-related discrepancies.

Therefore, in proposed § 422.311(c)(1), we proposed to implement a process that would allow MA organizations to voluntarily submit CMS attestations (that is, attestations developed and pre-populated by CMS). These attestations would be signed by physicians/practitioners who would attest responsibility for providing and documenting the health services in the physician and outpatient medical record(s) that were submitted for RADV audit. We specified at proposed § 422.311(c)(1)(ii) and (iii) that MA organizations would be eligible to use attestations to address signature or credential-related discrepancies only from physician or outpatient medical records; attestations would not be allowed to address signature or credential-related discrepancies found on inpatient medical records. The proposed use of an attestation would not in any way supplant the medical record, nor would

it permit attesting physicians/practitioners to alter the existing medical record. Attestations would not be acceptable to address any issues outside of the RADV-audit process.

At proposed § 422.311(c)(1)(C)(iv), we indicated that we would prospectively notify MA organizations that if the “one best” medical record used to validate an audited HCC were missing a physician/practitioner signature or credential, the MA organization would be permitted to submit a CMS-RADV attestation along with the medical record, to fulfill the requirement that medical records contain physician/practitioner signatures and credentials.

We described the proposed process that we would jointly undertake to review attestations submitted for our review at proposed § 422.311(c)(1)(iv) and (v), noting the following:

- Only CMS-generated attestations that meet certain requirements described at § 422.311(c)(1) and (d) would be eligible for consideration. Failure to meet these requirements would result in us not reviewing or accepting submitted attestations.
- CMS attestations that have been altered or amended (for example, striking out prepopulated words and replacing them with hand-written replacement words) without instruction or written concurrence from us would not be accepted.
- Attestations would need to accompany the medical record at the same time that the medical record was submitted to us for RADV audit. MA organizations would not be permitted to submit attestations before or after submission of their RADV medical records.
- Attestations would need to originate from the physician/practitioner whose medical record accompanies and corresponds to the attestation. We would not accept attestations or medical records from any party other than the MA organization.
- Organizations would not be permitted to submit attestations during the documentation dispute or RADV reconsideration processes described at § 422.311(c)(2) and § 422.311(c)(3).

At proposed § 422.311(c)(1)(iv), we described the process that we would undertake to review attestations and notify appellant MA organizations of the results of these attestation reviews. Our attestation review determinations would be final and binding upon both parties and would not be eligible for further appeal.

We further proposed affording MA organizations the option of disputing other nonsignature or credential-types of RADV-related medical record diagnosis coding discrepancies via a proposed documentation dispute process that we described in new paragraph § 422.311(c)(2). Under our proposal, in order to be eligible for documentation dispute, MA organizations would need to submit their “one best” medical record in accordance with RADV medical record submission deadlines established by us during the RADV medical record request process.

At proposed § 422.311(c)(2)(a), we specified the types of RADV-related errors that would be eligible for the proposed documentation dispute process. The documentation dispute process would apply only to the errors that arise out of operational processing of medical records selected for RADV audits and submitted to us by established deadlines. In this context, errors that arise from operational processing mean errors that arise from the collection and processing of medical records for a RADV audit.

At § 422.311(c)(2)(ii), we proposed limitations that we would impose upon the documentation dispute process; namely that MA organizations would not be permitted to dispute any medical record coding discrepancies, nor would MA organizations be permitted to submit altogether new medical records in place of previously submitted medical records. Payment errors that resulted from missing medical records would not be eligible for documentation dispute. At proposed § 422.311(c)(2)(iii) and (iv), we indicated that we would prospectively notify MA organizations of RADV payment errors that would be eligible for documentation dispute, describe the documentation dispute process that we would undertake, along with the process that we would undertake to notify MA organizations of the results of documentation dispute reviews. As described at proposed §

422.311(c)(2)(v), our documentation dispute review determination would be final and binding upon both parties and would not otherwise be eligible for further administrative appeal.

Proposed § 422.311(c)(3) would establish an appeals process under which RADV payment error calculations would be subject to appeal. Unlike our proposed attestation process described at § 422.311(c)(1), and proposed documentation dispute process describe at § 422.311(c)(2), which would afford MA organizations the opportunity to dispute aspects of our medical record review process, the proposed RADV payment error calculation appeal process was specifically designed to afford MA organizations the opportunity to appeal our contract-level RADV payment error calculation. Under the proposed RADV payment error calculation appeal process, we proposed establishing a three-level appeal process whereby MA organizations may^

- Seek reconsideration;
- Appeal the reconsideration decision to an independent CMS Hearing Officer; and
- Appeal the decision of the independent CMS Hearing Officer to the CMS Administrator.

Given the complexity of RADV audits in general, and the calculation of RADV-related error rates in particular, we stated our belief that it was prudent to afford appellant MA organizations multiple-layers of RADV-related payment error appeal.

At proposed § 422.311(c)(3)(ii), we also specified that MA organizations would not, under the proposed RADV payment error calculation appeal process, be permitted to appeal medical record review errors, nor would MA organizations be permitted to seek formal appeal of physician or practitioner signature or credential-related review errors. We believed that medical record review-related issues would be addressed as a result of the rigorous medical record review process, and the attestation and documentation dispute processes described earlier in the proposed regulation. In accordance with our proposed regulation at § 422.311(c)(3)(i), the RADV payment error calculation appeals process would only apply to errors identified in the RADV payment error calculation. MA organizations would not be permitted to ***19744** utilize the payment error calculation appeal process as a method for submitting any medical records for consideration in the calculation of the payment error. In order to be eligible for RADV payment error calculation appeal, MA organizations would need to adhere to established RADV audit requirements, including the submission of medical records in the manner and by the deadlines specified by CMS.

Furthermore, we noted that MA organizations would not be permitted to appeal our RADV payment error calculation methodology. Our justification for excluding methodological appeals was two-fold. First, we said the methodology that we planned to employ to calculate RADV payment errors was methodologically sound and academically defensible. We stated that we intended to ensure that all MA organizations understand the RADV payment error calculation methodology by providing annual notice to all MA organizations of the methodology that will be employed for calculating Part C payment errors. MA organizations that object to CMS' RADV payment error calculation methodology would be given an opportunity to provide comment to us under ours annual notice of RADV audit methodology. Second, in addition to providing an annual notice of RADV audit methodology, we stated that we would provide an expanded explanation of methodology as part of each RDV audit report that we send to MA organizations that undergo RADV audit. Included in this expanded explanation of methodology would be RADV payment error calculation factors unique to each audited MA organization that would enable the MA organization to independently calculate its own RADV payment error.

At proposed § 422.311(c)(3)(iii) and (v), we specified that MA organizations would be notified of their RADV payment error calculation appeal rights at the time we issue a RADV audit report to that organization. MA organizations would have 30 calendar days from the date of this notice to submit a written request for reconsideration of its RADV payment error calculation. A request for reconsideration would need to specify the issues with which the MA organization disagrees, the reasons for the disagreements and explain why the organization believes the issues are eligible for reconsideration. The request for reconsideration would need to include additional documentary evidence that the MA organization considers material to the reconsideration, though

MA organizations would be prohibited from submitting medical record-related evidence such as new or previously submitted medical records or physician or practitioner attestations and from appealing any issues pertaining to the methodology applied in any part of the RADV audit. At proposed § 422.311(c)(3)(iv), we further specified that the MA organization would bear the burden of proof to demonstrate that our RADV payment error calculation was clearly incorrect.

We described our proposal regarding the conduct of a RADV payment error calculation reconsideration, the decision of the reconsideration official and the effect of the CMS reconsideration decision official at proposed § 422.311(c)(3)(e) and (f).

At proposed § 422.311(c)(3)(v) and (vi), we described the first level of RADV payment error calculation appeal, the request for reconsideration of our RADV payment error calculation. Under this process a CMS official or our contractor not otherwise involved in error-rate calculation activity would review our RADV payment error calculation and any written evidence submitted by the MA organization that pertains to CMS' RADV payment error calculation, recalculate the payment error utilizing our RADV payment error calculation methodology (as specified in our standard operating procedures), and render a determination whether the RADV payment error calculation was accurate. This CMS official or CMS contractor not otherwise involved in RADV error-rate calculation activity would recalculate and arrive at an independent RADV payment error. Whether the official or contractor agreed with our payment error calculation, or overturned the calculation and established a new RADV payment error, this party's RADV payment error calculation determination would be issued to a CMS reconsideration official. The CMS reconsideration official would review their analysis and make a determination whether to accept or reject the findings of the CMS official or CMS contractor that recalculated the RADV payment error. In instances when the CMS official or contractor recommended overturning CMS' RADV payment error calculation and the reviewing CMS reconsideration official agreed with the newly calculated RADV payment error, we would issue a reconsideration decision which informed the appealing MA organization in writing of its reconsideration decision, in effect, notifying the MA organization of its new RADV payment error. If the reconsideration official upheld the decision of the CMS official or contractor to sustain our initial RADV payment error calculation, the reconsideration official similarly would notify the appellant MA organization of its determination. In either instance, the decision of the reconsideration official would be final and binding, unless a request for hearing was filed by CMS or the appellant MA organization.

At proposed § 422.311(c)(4), we clarified that if CMS or an MA organization were dissatisfied with the decision of the CMS reconsideration official described at § 422.311(c)(3), CMS or the MA organization would be permitted to request a second-level RADV payment error calculation appeal, which is a hearing on the RADV payment error calculation determination. CMS or MA organization choosing to pursue a hearing would be required to file a request for hearing within 30 calendar days of the date the MA organization received the written RADV payment error calculation reconsideration decision, as described at proposed § 422.311(c)(3)(vi).

We noted that CMS or MA organizations requesting a hearing would need to do so in writing, including a copy of the CMS reconsideration official's decision to either uphold or overturn the initial RADV payment error calculation, and specify the findings or issues in that reconsideration decision that they disagreed with and why they disagreed with them. The hearing would be conducted by the CMS Office of Hearings and presided over by a CMS Hearing Officer who neither receives testimony nor accepts any new evidence that was not presented with the request for reconsideration of the RADV payment error calculation. The hearing would be held on the record, unless the parties requested, subject to the Hearing Officer's discretion, a live or telephonic hearing. The Hearing Officer would also be permitted to schedule a live or telephonic hearing upon their own motion. The CMS Hearing Officer would be limited to a review of the record that was used for the initial RADV payment error calculation and the reconsidered RADV payment error calculation.

Additionally, we noted that the Hearing Officer would have full power to make rules and establish procedures, consistent with the law, regulations, and CMS rulings. These powers would include the authority to take appropriate action in response to failure of an organization to comply with such procedures.

At proposed § 422.311(c)(4)(iv), we also indicated that the CMS Hearing Officer would review and decide ***19745** whether the reconsideration official's decision was correct and to notify CMS and the MA organization in writing of his/her decision, explaining the basis for the decision, which would be final and binding, unless the decision was reversed or modified by the CMS Administrator in accordance with § 422.311(c)(5).

We explained that the third level of RADV payment error calculation appeal that MA organizations can request would be discretionary review by the CMS Administrator. We described this proposed process at § 422.311(c)(5). At this level of appeal, CMS or the MA organization would be permitted to appeal the decision of the CMS Hearing Officer by requesting that the CMS Administrator review the CMS Hearing Officer's determination. Parties requesting CMS Administrator review would have to request the review within 30 calendar days of receipt of the CMS Hearing Officer's determination. If the Administrator agreed to review the case, the Administrator would review the Hearing Officer's decision as well as any other information included in the record of the Hearing Officer's decision and would determine whether to uphold, reverse, or modify the CMS Hearing Officer's decision. The Administrator's determination would be final and binding.

We also noted that, based on our experience with appeals of MA and Medicare Part D program contract determinations, we have determined that it would be necessary for us to establish a “compliance date” to use as a reference point in issuing a ruling regarding RADV audit findings. Therefore, we proposed at § 422.311(b)(2), to require that the compliance date for meeting Federal regulations requiring MA organizations to submit medical records for the validation of risk adjustment data (§ 422.310(e)) also be the due date when MA organizations (or their contractor(s)) selected for RADV audit would need to submit medical records to us. We stated we would inform an MA organization in writing regarding selection for RADV audit, including the due date for submission of medical records.

We invited and received a large number of comments from health plans, managed care industry trade associations, and other interested parties regarding not only the proposed appeals process described in proposed § 422.311^but also the RADV audit process and underlying Medicare Advantage payment policy. These comments have resulted in changes to our above-described proposals as discussed below.

While many comments that we received relate to the underlying RADV audit process and risk adjustment methodology and may not directly address the RADV appeals process specifically, we are responding to these comments, because they appear to be relevant to the RADV appeals process that we had proposed in our Notice of Proposed Rulemaking. Certain comments were outside the scope of our proposed rule and we have not included responses to those comments.

Comment: A comment alleged that it was premature for CMS to propose rules related to the RADV appeals process because the commenter stated that the Administrative Procedure Act (APA) required that the underlying RADV audit process giving rise to the overpayments that would be appealed under our proposed regulations be subjected to notice and comment rulemaking.

Response: We disagree and believe that the RADV audit process does not establish any substantive rules within the meaning of the APA or section 1871 of the Act, but rather is a means for ensuring that payments made to MA organizations comply with substantive rules governing MA payments that are set forth in the statute, and in regulations that have been subjected to notice and comment procedures. Regulations specifying that payment amounts are subject to audit (for example, § 422.504(d)(1)(i) have been subjected to notice and comment procedures, and provide ample notice of the fact that we have the right (and, indeed, the duty) to ensure that MA payment amounts are accurate. See also, § 422.310(e), which states that MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS, and that there may be penalties for submission of inaccurate data.

Indeed, we would point out that throughout the Medicare program, and government programs generally, audit policies and procedures intended to ensure or verify payment accuracy assist in the enforcement of rules, and are not themselves substantive rules subject to APA notice and comment procedures. Therefore, to the extent we are providing a RADV appeals process, we are

providing an opportunity that does not currently exist for MA organizations to appeal audit findings that they would otherwise not have been permitted to question.

Comment: Some commenters stated that CMS did not follow proper procedures and stated that procedures set forth in our proposed regulations, such as our “one best medical record” and other documentation requirements, established a substantive legal standard governing the payment to MA organizations, and therefore, they had to be included in the annual notice of changes to payment methods required under section 1853(b)(2) of the Act, which requires that MA organizations be afforded an opportunity to comment on changes in the methodology for determining MA payments.

Response: We disagree. The requirement in section 1853(b)(2) of the Act to provide an advance notice of methodological changes to MA organizations of proposed changes to the methodology and assumptions used to compute annual MA capitation rates pertains to the methodology for determining the proper amount of payment. All substantive changes to the risk adjustment methodology at issue in the RADV audit process have been described in the annual advance notice. The RADV audit process and appeals procedures proposed in the October 22, 2009 proposed rule do not make any substantive changes in the methodology for determining MA payment amounts. Rather, they are designed to ensure that this payment methodology has been applied correctly, and the MA organization has received the amount to which it was entitled under this methodology. The risk adjustment methodology provides that a specific amount be paid if an enrollee has a particular condition. The RADV audits and appeals process are designed to ensure that the enrollee in fact has that condition, and that the MA organization is thus entitled to the amount that has been paid for that condition. The fact that audits might determine that an MA organization was not, in fact, paid correctly, is not a change in methodology or assumptions related to how the payment amount is to be determined and therefore is not subject to the advance notice requirements under section 1853(b)(2) of the Act. Nonetheless, in our October 22, 2009 proposed rule, we proposed to provide notice of RADV audit methodology to the public, as well as a summary of RADV methodology issues for each audited MA organization at the time we issue our audit finding pursuant to an actual RADV audit. We offered to provide details of our RADV audit methodology in an attempt to provide additional transparency related to the process. We anticipate providing additional notice of RADV audit methodology to the public by publishing the methodology in some *19746 type of Medicare program document^most likely in a Medicare manual later this year (2010).

Comment: A commenter stated that CMS was not complying with requirements in section 1871(a)(2) of the Act, which states that “No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, * * * shall take effect unless it is promulgated by the Secretary by regulation* * *”

Response: As discussed previously, the RADV audit process, and the appeals procedures addressed in this rulemaking, do not “establish” or “change” any “substantive legal standard governing * * * payment.” To the contrary, they are designed to ensure that the substantive legal standards for payment set forth in the statute and regulations are correctly applied. The substantive rules governing the amount of payment to which the MA organization is entitled are unchanged as governed by statute and implementing regulations.

Comment: A commenter urged that CMS suspend RADV audits until such time as CMS subjects the rules to notice and comment rulemaking.

Response: As discussed previously, we do not believe subjecting the RADV audit process to rulemaking is required or appropriate, there would be no basis for suspending the audit process.

Comment: One commenter noted that when the risk adjustment system was initially established, the Secretary was required to submit a report to Congress in accordance with section 1853(a)(3)(A) of the Act that documented the proposed method of risk adjustment of MA payment rates, and that included an evaluation of the method by an outside, independent actuary of the actuarial soundness of the proposal. The commenter believed that such an evaluation was required in the case of the RADV audit process.

Response: We disagree that RADV audits impact the risk adjustment system in any manner. As indicated earlier, RADV audits are solely to verify that the risk adjustment methodology is being correctly applied.

We also received a large number of comments from MA organizations, managed care trade associations and a law firm regarding RADV methodological-related issues. While some comments were not relevant to the rules that CMS proposed regarding the RADV appeals process, there were a number of comments that we believe should be addressed, and as such, we do so as follows.

Comment: Many commenters recommended that CMS independently test and validate its RADV methodology before CMS implements it. The commenters indicated that CMS failed to provide any record of submitting its methodologies to an academic review and that if CMS has done so, we should have included such studies with the proposed rule so that interested parties could review and comment on any of these academic studies. The commenters recommended that CMS provide a process that permits thorough review and comment by plans of RADV audit methodology issues before undertaking further RADV audits. Several commenters further recommended that all methodological issues pertaining to RADV audits be appealable.

Response: Previously in this preamble we indicate that the process of independently reviewing medical records to validate risk adjustment data submitted by MA organizations for payment purposes has been established and operational for more than 10 years. Over the course of this timeframe, we have been advised on the RADV process by statisticians, senior analysts, expert medical record coders, physicians, managed care professionals, and other health care providers. From a medical record coding perspective, we have secured expert direction from Peer Review Organizations (PROs) (in the past) and Quality Improvement Organizations (QIOs) (currently) by incorporating them into the RADV team. From an analytic design and implementation perspective, we have in the past and continue to employ senior level expert analysts from different academic fields as independent contributors to the RADV operations team to review and validate the accuracy of the findings across the RADV process, including peer review of statistical sampling and payment error calculation methodologies. The independent expert analysis and review is similar to that conducted in an academic setting in that the participating parties are credentialed in a specific field of study, such as statistics, and possess substantial years of expertise conducting similar processes and analyses. The independent methodology review processes also involve the use of internal controls, and tests for consistency and accuracy. RADV procedures are subject to the evaluation requirements of the CMS Annual Financial Audit.

In addition, the RADV methodology that we employ in the process of reporting a component of the national Part C payment error is similar to the methodological approach that we employ in conducting contract-specific RADV audits and error calculations. This methodology has been reviewed and approved by officials at the HHS.

This notwithstanding, in considering the commenters' questions, where necessary, we will incorporate additional independent third party review for purposes of validating RADV error-calculation methodology. As indicated in our proposed rule and cited elsewhere in the preamble to this final rule, we intend to publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary. Finally, to ensure that audited organizations understand how their RADV error rate was calculated, as indicated in our proposed rule, we further intend to describe our RADV methodology in each audited organization's RADV audit report.

Given these efforts to ensure that the RADV process is transparent to audited MA organizations and the public, and that the methodology used under that process is reasonable, consistent, and accurate, we do not believe any further action is required.

Comment: Several commenters argued that CMS should include Medicare plan enrollees for whom no diagnosis code was submitted under the risk adjustment methodology as part of its RADV error testing samples. These commenters also recommended that CMS include “under-coding” findings in the audit error estimates in order to more accurately account for members' health status.

Response: Our RADV audit policy does account for both underpayments and overpayments. The RADV process addresses under-coding through the application of rules for crediting a sampled enrollee with additional HCCs that are identified incidentally, during medical record review. We emphasize that these “additional” diagnoses were not originally submitted for payment for enrollees selected in the sample, and yet we provide audited organizations credit through our RADV medical record review process.

However, we have not and do not expect to sample enrollees for whom no HCCs were submitted. This is because the RADV is an audit process that is intended to validate the HCCs that were submitted by MA organizations in order to determine whether the additional payment amounts associated with these *19747 diagnosis codes were properly made. Under our separate Risk Adjustment Data Submission Process, the data submission period for any given payment year is lengthy and extends beyond the actual payment year, providing a substantial amount of time for organizations to submit and/or correct enrollee HCC risk adjustment data for any given payment year^to reflect of enrollee health status. This is sufficient time for plans to submit data on all their enrollees, including those with no HCCs. The RADV audit process is not intended to serve as a de facto mechanism for extending the HCC data submission deadlines under which MA organizations operate.

We received a number of comments from MA organizations and a law firm regarding the financial impact of RADV audits. While these comments did not pertain directly to our proposed RADV appeals procedures, some comments nevertheless indirectly impact the RADV appeals rules. Therefore, we respond to several of these comments here.

Comment: Several commenters suggested that CMS's proposed methodology to calculate and apply error rates and payment adjustments across contract years after payments were made undermines the actuarially-based risk assumptions inherent in Plans' bid submissions.

Response: Regarding the assertion that RADV audits undermine the Part C bidding process, beginning with the introduction of the HCC risk adjustment model for CY 2004, we have published clear guidelines to be followed by MA organizations in the collection and support of diagnosis codes underlying risk scores for plan enrollees. In their preparation of a MA bid, certifying actuaries are expected to ensure that the underlying data are reasonable and appropriate for the circumstance, including the base year risk scores. If the ultimate risk scores for a plan's population are lower than initially forecast by the certifying actuary, then the plan is likely to experience lower than expected margin. Conversely, if the ultimate risk scores for a plan's population are higher than initially forecast by the certifying actuary, then the plan is likely to experience greater than expected margin. These results illustrate the nature of health plan capitation and the risk borne by MA organizations.

Comment: Commenters stated that the establishment of an audit methodology that involves retrospective contract-level payment adjustments creates the potential for unpredictable retroactive liability that MA organizations could not have considered in developing bids for affected prior years. Commenters suggested that CMS' sampling methodology undercuts the mandate in section 1854(b)(6)(B)(iv) of the Act that MA organizations' rates reflect the revenue needs of the organization. The commenters assert that MA organizations did not develop bid submissions for calendar years 2006 through 2009 with an expectation that CMS would implement contract-wide payment adjustments based on provider documentation issues outside of the MA organizations' control. As a result, if payments effectively are reduced retroactively as the result of RADV audits, the bid submissions (and resulting payments) arguably would not adequately reflect Plans' risks, and MA organizations may be forced to dip into their reserves to repay dollars that were not anticipated to be at risk.

Response: We disagree. If plan bids are developed based on faulty data, such as inappropriate claim costs or risk score data, there is a greater likelihood of error in the bid projection. There are many factors that influence the accuracy of bid projection, and data quality is just one such factor. There is no legal authority to change a bid amount after it has been accepted regardless if additional information suggests that the bid is too high or too low.

In general, it is our belief that health plans are confusing actuarial equivalence in payment amount^ which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve^ with differences in

the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnoses leading to such costs being incurred have a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employ to ensure accuracy under Medicare Part C actually further actuarial equivalence, rather than conflicting with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: Several commenters questioned whether CMS's RADV medical record review coders have the qualifications and experience necessary to code RADV-related medical records. Commenters specifically questioned whether RADV coders were equipped to code accurately in situations in which clinical training may be required in order to recognize all extractable ICD-9 codes. They inquired into the certification and coding experience qualifications for the RADV coders.

Response: The coders that CMS uses to review RADV medical records are fully qualified to code RADV-related medical records. All coders are professionally certified for example, Certified Professional Coder (CPC), Certified Coding Specialist (CCS), Registered Health Information Administrator, (RHIA) and Registered Health Information Technician (RHIT), and must have prior experience coding medical records. Coders have access to physician consultation as needed. Coders also have access to our Independent Coding Consultant^a coding expert with more than 10 years of professional coding experience, which we require to be RHIA, coding certified and to have at least 5 years of experience in RADV-specific coding.

Comment: Several commenters objected to what they contend is a burden that RADV audits impose upon the physicians and physician practices who must produce medical records necessary to conduct audits. These commenters recommended that CMS take into account the potential impacts of more aggressive program integrity efforts on the medical practices that provide care to MA plan enrollees. Outside of the proposed rule, we have also received letters arguing that the burden associated with RADV audits is not limited to the CMS' audits but also extends to internal audit activity undertaken by Medicare health plans that mimics the RADV audits that we undertake for Medicare payment validation. These commenters raised concerns that Medicare health plans were misrepresenting their internal audit activity as official CMS RADV audits.

Response: Section 422.310(e) requires that providers who voluntarily enter into contracts with MA organizations submit data to CMS contractors/IVCs for RADV audits. In an effort to minimize the burden associated with this activity, we have developed best practices that we encourage health plans to employ in their efforts to gather medical records from providers and hospitals. To the extent MA organizations employ these practices, it is our belief that the impact of RADV audits on providers can be minimized.

***19748** We also understand the increasing need for providers to be able to distinguish when they are being asked for medical records in association with an MA plan's own audit or in accordance with an official Medicare program RADV audit which is subject to legislative requirements. Therefore, we issue letters on our letterhead that MA organizations must use when requesting medical records from providers when the request is specifically related to an official CMS RADV audit. Providers may rely upon these letters as an indicator that a given medical record request is for CMS' RADV, and providers may request this authorizing letter before responding to requests by the MA plan.

We received a large number of comments from MA organizations, managed care trade associations and a law firm regarding the "one best medical record" policy that CMS proposed to apply to the RADV program. By way of explanation, the "one best medical record" policy specifies that for any one sampled beneficiary^with any one HCC^the MA organization is allowed to select and submit supporting medical record documentation of a face-to-face encounter for a physician or outpatient visit (one date of service) or an inpatient stay (range of dates from admit to discharge). The face-to-face encounter would have needed to occur at some point during the data collection year (from January 1st to December 31[FNst]).

Comment: Commenters contended that the one best medical record policy forces plans to omit relevant data that could be supported through documentation that CMS does not permit[^]such as prescription drug data and lab results.

Response: The RADV risk adjustment model is based upon FFS claims data from specific risk adjustment provider types, and not alternative data sources, such as, prescription drug data or lab results. Therefore, the RADV audit process is based upon supporting medical record documentation from provider data sources that are used to calibrate the model. As for the one best medical record policy, while MA organizations that voluntarily submit HCCs for Medicare payment are prospectively paid based on these unaudited and unvalidated HCCs submissions, we, upon the recommendation of MA organizations, agreed to allow any one medical record from across an entire data collection period to validate an HCC incorporated into the payment to the MA organization.

Comment: Some commenters contend that if CMS is going to rely on the one best medical record policy to the exclusion of other sources of information that might confirm an HCC, the RADV appeals process should allow for HCC medical record review findings to be appealed.

Response: To address these comments as described in § 422.311(c)(2) of this final rule, we have revised the process so that MA organizations may appeal medical record review determinations in accordance with the procedures specified in § 422.311(c)(2).

Comment: A number of commenters argued that the one best medical record policy is flawed in that it provides an insufficient basis for confirming an HCC for members with chronic diseases when a collection of several records, perhaps from various providers, considered in the aggregate might better verify a patient's condition.

Response: We disagree. In the case of a chronic disease such as congestive heart failure, all that is required is medical record documentation from one visit to a physician or a hospital, over the course of the data collection year, to validate the audited HCC.

Comment: We received several comments comparing the RADV audit and appeals process to varying program attributes of the Medicare FFS program. For example, some commenters argued that CMS' one best medical record rule conflicts with Medicare FFS standards since there is no one best medical record rule applied to Medicare payment error-rate testing for FFS providers.

Response: Payment error-testing under original Medicare is different than payment error testing under Medicare Part C. Under original Medicare, much of what comprises the error testing regimen is aimed at validating that a particular level of service was provided and therefore justifies a given level of Medicare payment. Under RADV, the payment error testing focuses on validating HCCs by examining medical records to determine whether they contain supporting diagnostic codes. This error testing is aimed at validating that a particular Medicare beneficiary indeed has the medical condition for which the MA organization has been paid for, and not whether a particular level of service (for example, level 1 office visit vs. level 2 office visits) was provided. Moreover, there is no evidence to support the notion that the Congress, in establishing the Part C payment process, ever intended the Part C payment process to mimic payment processes under Original Medicare. Indeed, they are fundamentally different.

Moreover, we believe that the one best medical record policy and the operational process associated with it are far less restrictive than Medicare FFS. MA organizations are not limited to the specified date(s) of service they reported to us with regard to selecting a medical record as supporting documentation for a specific HCC. We continue to believe that the one best medical record policy is appropriate for the Medicare Part C risk adjusted payment system which is distinct from a FFS payment system where payment is determined on a claim-by-claim basis. Under Part C, we only require that plans send one HCC for payment for an entire year; it therefore logically follows that we would only require one medical record to validate this HCC.

Comment: Some commenters stated that the one best medical record rule was inconsistent with the mandate that MA payment adjustments be actuarially equivalent to the FFS sector.

Response: It is our belief that health plans are confusing actuarial equivalence in payment amount[^] which demographic adjustments, risk adjustment methodology, and coding intensity adjustment are all designed to achieve[^]with differences in the way costs are documented. Because MA organizations are paid on a capitation basis, costs are not covered for a specific service provided. Rather, they are based on the actuarial value of such costs. The risk adjustment methodology uses diagnosis codes as a proxy for higher costs associated with a particular diagnosis. Because, under original Medicare, costs of specific services received are reimbursed, the diagnosis leading to such costs being incurred has a different relevance under original Medicare than they do under the Medicare Part C payment system. The risk adjustment methodology and RADV audit process that we employs to ensure accuracy under Medicare Part C we believe furthers actuarial equivalence, rather than conflicts with it. The differences between MA and original Medicare are simply attributable to differences in how payment is made. It is these differences that necessitate the actuarial equivalence standard in the first place.

Comment: A commenter noted that in Medicare Part A and B appeal contexts, supplemental information and testimony are considered, and given such weight as the fact finder determines is appropriate.

Response: Under our proposed appeals procedures that affords MA organizations the ability to appeal the Part C error calculation specified at § 422.311(c)(3), the CMS Hearing Officer ***19749** has the discretion to conduct the hearing in alternative ways beyond conducting the hearing on the record. For example, the Hearing Officer can choose to conduct the hearing by way of teleconference or in person. The CMS Hearing Officer also has the discretion to request supplemental information or to accept testimony, as he or she deems necessary. Also, under the medical record review appeal processes that we specify at § 422.311(c)(2), we afford MA organizations the ability to submit supplemental information[^]the attestation reviewed by the IVC[^] to validate the same HCC that the Initial Validation Contractor (IVC) initially determined to be in error.

Comment: Several commenters, focusing on the relationship between MA organizations and their providers, noted that errors in documentation are ultimately attributable to providers, not MA organizations. These commenters argued that, due to the nature of the MA program, while CMS makes a capitated payment to organizations that have relationships with providers, these providers may not have an incentive to document the HCCs which affect payment to the MA organization. The commenters also stated that contract-level payment adjustments penalize MA organizations, while it is providers who are responsible for maintaining adequate records. A commenter also suggested that we accept “other data” to supplement, or substitute, a medical record.

Response: Section 422.504(i)(1) clarifies for MA organizations that they are ultimately responsible for the risk adjustment information submitted to CMS. This section of the regulations states, “Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.” MA organizations are further directed in § 422.504(i)(2) that all their “first tier, downstream, and related entities are required to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect * * * medical records.” Therefore, while we acknowledge the comments, we maintain that it is the responsibility of MA organizations to ensure that they submit accurate risk adjustment information, and that the providers with whom they contract are aware that we have authority to audit medical records to verify this information.

We do not require MA organizations to submit HCCs for beneficiaries; MA organizations choose whether or not to do so. For risk adjustment diagnoses that are submitted, it is the responsibility of the MA organization to obtain appropriate documentation. If MA organizations are not confident in the information they obtain from their providers, they may wish to initiate education efforts, or include provisions in their contracts that ensure providers appropriately document diagnoses and provide medical record documentation to the plan upon request.

In regards to supplemental information, we have determined, and MA plans have been informed multiple times, that the appropriate format for obtaining risk adjustment information is a medical record. For validation purposes, plans are asked to submit the one best medical record documenting the HCC. We carefully determined the one best medical record policy, after

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 3 OF 14
EXHIBITS D-16 THROUGH D-25
PAGES 0635 THROUGH 0707**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024
Hearing Time: 10:00 a.m.
Courtroom: 6D

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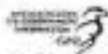
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EXHIBIT D-16



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Federal Register / Vol. 79, No. 7 / Friday, January 10, 2014 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 417, 422, 423, and 424

[CMS-4159-P]

RIN 0938-AR37

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: The proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also includes several provisions designed to improve payment accuracy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 7, 2014.

ADDRESSES: In commenting, please refer to file code CMS-4159-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4159-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4159-P, Mail Stop C4-26-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier)

your written comments ONLY to the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christopher McClintick, (410) 786-4682, Part C issues. Marie Manteuffel, (410) 786-3447, Part D issues. Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues. Whitney Johnson, (410) 786-0490, Part C and D payment issues. Clarisse Owens, (410) 786-0880, Part C and D compliance issues. Frank Whelan, (410) 786-1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication

of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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at § 423.360, we do not believe that it is necessary to reopen a payment reconciliation after that 5-year period, nor do we believe it is necessary to reopen a reconsidered payment determination. Therefore, we propose to amend § 423.346 (a) such that CMS will only reopen the initial payment determination and will not reopen a reconsidered payment determination.

As stated in our final rule entitled, "Medicare Program; Medicare Prescription Drug Benefit" published in the *Federal Register* on January 28, 2005 (70 FR 4194), CMS can initiate a reopening on its own or an organization could request a reopening, but such reopenings are at CMS' discretion. In determining whether to reopen, we will consider a number of issues, including, but not limited to, whether the contract has terminated and received a final settlement. We will not approve a request to reopen for a contract that has terminated and received a final settlement. In addition, when we perform a reopening on its own initiative, contracts that have been terminated and settled will not be included in the reopening.

b. Coverage Gap Discount Reconciliation Reopening

Under § 423.2320(b), CMS performs a Coverage Gap Discount Reconciliation in which CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Since the interim coverage gap payments are estimates (76 FR 63017, 63027 (October 11, 2011)), a cost-based reconciliation is performed to ensure that Part D sponsors are paid dollar for dollar for all manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. Manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for reconciliation continue to be invoiced to manufacturers within a maximum of 3 years of the date of dispensing, and manufacturers remit payments for invoiced coverage gap discount amounts to Part D sponsors.

We propose to establish a reopening provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that we established a reopening provision for the Part D payment reconciliation process described in our final rule, "Medicare Program; Medicare Prescription Drug Benefit" published on January 28, 2005 (70 FR 4194, 4316). In a Health Plan Management System (HPMS) memorandum dated April 30,

2010, we stated that the final reconciled discount program payments are subject to the reopening provision in § 423.346. We anticipate rarely needing to reopen the Coverage Gap Discount Reconciliation as a result of the invoicing process that continues to occur after the reconciliation process. However, we want to leave open the option to reopen if unforeseen events result in underpayments or overpayments to Part D sponsors. Therefore, we propose to amend § 423.346 to accommodate reopening a Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.346 by removing the phrase "or reconsidered" from paragraph (a), amending paragraph (a) to account for the proposed timing of the Part D reopening, removing paragraphs (a)(1) through (3) and (b)(1) through (3); adding a new paragraph (b) to accommodate a Coverage Gap Discount Reconciliation reopening; and revising paragraph (c) to eliminate the reference to "good cause."

4. Payment Appeals (§ 423.350)

Pursuant to § 423.2320 (b), we perform a Coverage Gap Discount Reconciliation in which we reconcile interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program. Current regulations do not describe the appeals process for a Coverage Gap Discount Reconciliation. We propose to establish an appeals provision for the Coverage Gap Discount Reconciliation for the same reasons and under the same authority that was used to establish the Part D payment reconciliation appeals process described in our final rule, "Medicare Program; Medicare Prescription Drug Benefit" published on January 28, 2005 (70 FR 4194, 4317). In an HPMS memorandum dated April 30, 2010, CMS stated that the final reconciled discount program payments are subject to the appeals provisions in § 423.350, and we now propose to revise § 423.350 to accommodate a Coverage Gap Discount Reconciliation appeals process.

Consistent with the Part D payment appeals process currently described at § 423.350, the proposed changes establish an appeals process whereby the final reconciliation of the interim Coverage Gap Discount Program payments may be subject to appeal. As stated in our final rule describing the Part D payment appeals process (70 FR 4317 (January 28, 2005)), the Part D payment appeals process only applies to perceived errors in the application of the payment methodology and the

payment information submitted by the Part D sponsor cannot be appealed through this process. In the January 28, 2005 final rule (70 FR 4317), Part D plans are expected to submit payment information correctly and within the established timelines. We codified at § 423.350(a)(2) that payment information submitted to CMS under § 423.322 and reconciled under § 423.343 is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations. We propose to amend § 423.350(a)(2) to include information that is submitted and reconciled under § 423.2320(b) is final and may not be appealed nor may the appeals process be used to submit new information after the submission of information necessary to determine retroactive adjustments and reconciliations.

Also consistent with the Part D payment appeals process, we propose that the request for a reconsideration of the Coverage Gap Discount Reconciliation must be filed within 15 days from the date of the final payment, which is the date of the final reconciled payment made under § 423.2320 (b). Therefore, we propose to amend § 423.350(b)(1) by adding a new paragraph (iv) to define the timeframe for filing a reconsideration of the Coverage Gap Discount Reconciliation.

Based on the preceding, we propose to revise § 423.350 by adding a new paragraph (a)(1)(v) to allow for an appeal of a reconciled coverage gap payment under § 423.2320 (b), by revising paragraph (a)(2) to indicate that the payment information submitted to CMS and reconciled under § 423.2320(b) is final and may not be appealed, and by adding a new paragraph (b)(1)(iv) to define the timeframe for appealing the final reconciled payment under § 423.2320(b).

5. Payment Processes for Part D Sponsors (§ 423.2320)

In our final rule entitled, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes" (77 FR 22071, 22086; April 12, 2012), CMS described the payment process for Part D sponsors under the Coverage Gap Discount Program. Under § 423.2320(a), CMS provides monthly interim Coverage Gap Discount Program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries. Part D

sponsors report the gap discount amounts to CMS, and through a contractor, CMS invoices the manufacturers on a quarterly basis for the applicable discount amounts. The manufacturers repay each Part D sponsor directly for the invoiced amounts under the Medicare Coverage Gap Discount Program Agreement (Agreement) described at § 423.2315. Under § 423.2320(h), CMS reconciles the interim payments with amounts invoiced to manufacturers.

In the event that a manufacturer fails to provide the applicable discounts in accordance with the Agreement, we must impose civil money penalties (CMPs) equal to the sum of the applicable discount the manufacturer would have paid under the Agreement and 25 percent of that amount. The CMP that is equal to the sum of the applicable discount the manufacturer would have paid under the agreement is used to pay the applicable discount that the manufacturer had failed to provide.

In our final rule describing the payment process for Part D sponsors under the Coverage Gap Discount Program, we did not contemplate a payment process in the event that a manufacturer becomes bankrupt and does not pay the Part D sponsors for quarterly invoiced amounts under the Agreement. Even though we will impose a CMP on a bankrupt manufacturer in an effort to collect the unpaid invoiced amounts, the bankruptcy settlements will likely result in the CMP being modified or reduced. In order to ensure that the Part D sponsors have the funds available to advance the gap discounts at the point-of-sale, as required under section 1860D-14A(c)(1)(A)(ii) of the Act, we now propose to amend § 423.2320 such that we will assume financial liability for the applicable discount by covering the costs of the quarterly invoices that go unpaid by a bankrupt manufacturer at the time of the Coverage Gap Discount Reconciliation described at § 423.2320(b). We would then file a proof of claim with the bankruptcy court to recover those costs from the bankrupt manufacturer.

The proposed policy that CMS assumes financial liability for the applicable discounts in the event of a manufacturer bankruptcy is consistent with CMS' payment processes for Part D sponsors under the Medicare Coverage Gap Discount Program. Under § 423.2320 (a), CMS provides interim payments to ensure that Part D sponsors have the funds available to advance the coverage gap discount to beneficiaries at point of sale. Under § 423.2320 (b), CMS reconciles the interim payments with the invoiced manufacturer discount

amounts in order make the PDP sponsor whole for the gap discount amount provided to the beneficiaries at point of sale. (For more information on these provisions, see October 11, 2011 final rule (76 FR 63017, 63027).) In order to remain consistent with the intent of the Coverage Gap Discount Reconciliation to make the Part D sponsor whole for the gap discounts amounts advanced at point of sale, CMS must provide payments to the Part D sponsor to cover the cost of the applicable discount in the event that the manufacturer cannot pay the quarterly invoices due to a bankruptcy. We propose to cover the costs of unpaid quarterly invoices only in the event that a manufacturer becomes bankrupt. We would not cover the cost of unpaid quarterly invoices for any other reasons because, in the event that a manufacturer fails to pay the quarterly invoices, we will impose CMPs that will cover the cost of the unpaid invoices. In the event that a manufacturer becomes bankrupt, we are concerned that the court will either modify or reduce the amount of the CMP, making the CMP process ineffective for covering the cost of the invoices and leaving the Part D sponsor in the position of having to cover the costs of the gap discount.

We propose to implement this policy by adjusting the Coverage Gap Discount Reconciliation to account for quarterly invoices that go unpaid as a result of a manufacturer becoming bankrupt. This adjustment will only occur for manufacturer discount amounts as they are reported on PDEs submitted by the submission deadline for the Part D reconciliation.

Based on the preceding, we propose to add a new paragraph (c) to § 423.2320 to describe a process for accounting for quarterly invoiced amounts that go unpaid by a bankrupt manufacturer.

6. Risk Adjustment Data Requirements (§ 422.310)

We propose to strengthen existing regulations related to the accuracy of risk adjustment data by amending § 422.310 on risk adjustment data validation. First, we propose to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under § 422.308(c)(1) and § 422.310(g)(2). (Paragraph § 422.308(c)(1) addresses adjustments to payments for health status, and paragraph § 422.310(g)(2) addresses deadlines for risk adjustment data submission, including the final risk

adjustment data submission deadline prior to CMS' calculation of the final risk factors for a payment year.) Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments. This proposed amendment furthers our goals of improving payment accuracy and reducing payment errors.

We also propose to amend § 422.310(g) regarding deadlines for submission of risk adjustment data. Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. We propose to revise the regulation to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment.

Finally, we propose to align this regulation with proposed § 422.326 by making two additional changes in paragraph (g). First, we propose the deletion of the January 31 deadline in subparagraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. This means that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, as discussed in section II.B.1.b. of this proposed rule. Second, we propose to add subparagraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

7. RADV Appeals

a. Background

We published Risk Adjustment Data Validation (RADV) appeals regulations in the April 15, 2010 *Federal Register*. These rules were proposed and finalized under CMS's authority to establish Medicare Advantage (MA) program standards by regulation at section 1856(b)(1) of the Act and are found at § 422.311 et seq.

As explained in the preamble of that final rule, Subpart G of the MA regulations at part 422 describes how

payment is made to MA organizations. These payment principles are based on sections 1853, 1854, and 1858 of the Act. Subpart G also sets forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates. Section 1853(a)(3) of the Act requires that we risk adjust our payments to MA organizations. Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status plus demographic characteristics of their enrolled beneficiaries and ensures that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees expected to incur lower health care costs and more for less healthy enrollees expected to incur higher health care costs). Accurate payments to MA organizations also help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, currently the Ninth Revision Clinical Modification guidelines (ICD-9-CM) to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes determine the risk scores, which in turn determine the risk adjusted reimbursement. As a result, physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD-9-CM coding guidelines (that is, coding diagnoses accurately and to the highest level of specificity).

MA enrollee Hierarchical Condition Categories (HCCs) are assigned based on risk adjustment diagnoses from FFS claims and from risk adjustment data submitted to us by MA organizations via the Risk Adjustment Payment System (RAPS). The CMS-HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee. The HCC data that MA organizations submit to CMS via the RAPS system is self-reported by the MA organization and does not go through a validation review before being incorporated into a given beneficiary's risk profile. Since there is an incentive for MA organizations to potentially over-report diagnoses so that they can increase their payment, the Agency audits plan-submitted diagnosis data a few years later to ensure they are

supported by medical record documentation.

Verifiable medical record documentation is the key to accurate payment and successful data validation. We annually select contracts for RADV audits. RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MA organizations for their enrollees and confirmed via medical record documentation. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year. We validate the HCC data submitted by MA organizations by reviewing hospital inpatient, hospital outpatient, and physician/practitioner provider medical records. The focus of this medical record review activity is on diagnoses related to the enrollee's HCC profile. Risk adjustment discrepancies are identified when the enrollee's HCCs used for payment (based upon MA organization-submitted data) differ from the HCCs assigned based on the medical record, under the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate.

Since finalizing these rules in 2010, we have conducted additional RADV audits and believe that some of the appeals provisions finalized in the 2010 RADV Appeals final rule should now be modified to prevent confusion, and to strengthen the RADV appeals process. We therefore, propose revisions to the RADV appeals regulations finalized in the April 15, 2010 Federal Register. These proposed revisions clarify program requirements and simplify the RADV appeals process. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

b. RADV Definitions

We propose to amend the RADV definitions at § 422.2 as follows:

- Removing the following definitions:
 - ++ "Initial Validation Contractus (IVC)" means the first level of medical record review under the RADV audit process.
 - ++ "RADV payment error calculation appeal process" means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.
 - ++ "The one best medical record for the purposes of Medicare Advantage Risk Adjustment

Validation (RADV)" means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

- Adding the following definition:
 - ++ "RADV appeal process" means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.
- Revising the following definitions:
 - ++ Risk adjustment data validation (RADV) audit means a payment audit of a Medicare Advantage (MA) organization administered by CMS or the Secretary that ensures the integrity and accuracy of risk adjustment payment data.
 - ++ "Attestation process" means a CMS-developed RADV process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues for eligible medical records. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

c. Publication of RADV Methodology

In the October 22, 2009 Notice of Proposed Rule Making (NPRM), and as reinforced in the April 15, 2010 Final Regulation, CMS indicated that we would, "publish its RADV methodology in some type of public document—most likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary". We also indicated that we would provide an annual notice of RADV audit methodology. Our last RADV-related notice of methodology was published in February, 2012. We will continue to publish a notice of the methodology employed, but will do so only if there is a change in the RADV methodology that would require publication. We note that these notices of RADV audit

methodology updated information provided on RADV audit methodology provided in the October 22, 2009 proposed rule and April 15, 2010 final rule.

In addition, we provided in the October 22, 2009 proposed rule preamble that we would provide an expanded explanation of methodology and payment error calculation factors as a part of each audit report of findings that we send to MA organizations that undergo RADV audit. Such explanation and factors have been and will continue to be part of the RADV audit report(s) that CMS provides health plans that have undergone RADV audits.

d. Proposal To Update RADV Appeals Terminology (§ 422.311)

Current RADV regulations utilize the following terms for the CMS-issued RADV audit report: Audit report post medical record review; RADV audit report; IVC-level RADV audit report; and RADV audit report of finding. This use of multiple terms to refer to what is the same audit report (the RADV audit report that CMS issues following conclusion of the medical record review portion of the audit) is potentially confusing. Therefore, we propose amending the RADV regulations throughout to adopt one common term to refer to RADV audit reports: "RADV Audit Report". By standardizing terminology throughout the RADV regulations, the proposed amendment provides clarity which may lead to increased efficiency. We welcome comment on this proposal.

As mentioned earlier in the description of RADV-related definitions that have changed, we have revised certain RADV-related definitions to accommodate changes to both the RADV audit process and the RADV appeals process. One definition that we have removed from the RADV regulations is Initial Validation Contractor, or IVC. The RADV medical record review process no longer utilizes "initial" and "secondary" validation contractors to conduct medical record review under RADV. Instead we now utilize medical record reviewers to code medical records undergoing RADV review. These reviewers may be employed by the same or different medical record review contractors. Therefore, the term "IVC" is no longer relevant to the RADV audit process. We therefore propose to remove this term from the RADV regulations at the following citations: § 422.311(c)(2)(i)(B) through (D); § 422.311(c)(2)(ii)(B); § 422.311(c)(2)(iii)(A), § 422.111(c)(2)(v), (vi), § 422.311(c)(3)(i)(A), and

§ 422.311(c)(3)(iii)(A) and (B). We invite comment on this proposal.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in Federal regulations at § 422.311 et seq.: Medical record review-determination appeals and RADV payment error calculation appeals. RADV medical record review-determination appeal requirements and procedures are discussed at § 422.311(b)(3) and § 422.311(c)(2). Medical record review determination appeal is a two-stage administrative appeal process: The first step is a hearing by a hearing officer, followed by a CMS Administrator-level review. This appeal procedure provides MA organizations with an opportunity to appeal RADV medical record review determinations that are made by coders reviewing the medical record documentation submitted by MA organizations undergoing RADV audit. The second type of RADV appeal, payment error calculation appeal, is discussed at § 422.311(c)(3). Payment error calculation appeal is a three-pronged appeal process: Reconsideration, followed by a hearing officer review, followed by CMS Administrator-level review. This appeal process was specifically designed to afford MA organizations the opportunity to appeal CMS's contract-level RADV payment error calculation.

We propose that the administrative appeals language described at § 422.311(b)(3) and § 422.311(c)(2) for RADV medical record review determination appeals and § 422.311(c)(3) for RADV payment error calculation appeals be replaced with new regulatory language proposed § 422.311(c)(1) et seq., that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We propose to combine the two RADV appeals processes into one combined RADV appeals process that is comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. A three-step administrative appeals process comprising reconsideration, hearing officer review, and Administrator-levels of review is a common administrative appeals model used elsewhere within the Medicare managed care program, such as in appealing contract award determinations and intermediate sanctions. The combined RADV appeal process that we are proposing at new § 422.311(c)(1) et seq., also has the

benefit of simplifying what is today a complex two-track appeal process into one process. While both CMS and the MA industry will benefit from simplifying this process, MA organizations also obtain an additional level of review under the combined approach since MA organizations will be afforded a reconsideration appeal step for medical record review determinations that is today—not part of the existing RADV appeal process. Shortening the existing two-track appeal process should also reduce the resources and level of effort needed from both MA organizations and CMS in participating in a RADV appeal proceeding. Under this proposal, MA organizations can simply request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. The specific details regarding this proposed process follow. We propose these changes based upon our experience with RADV appeals and because we hope to reduce the burden associated with undertaking RADV appeals on both MA organizations and CMS. The details of this proposed policy and procedure follows.

(1) Issues Eligible for RADV Appeal

Current regulations at § 422.311(c)(2) et seq., and § 422.311(c)(3) et seq., specify RADV-related medical record review and payment error calculation documents and issues eligible for the medical record review determination and payment error calculation appeal processes. We propose to amend the policies and procedures around issues eligible for RADV appeals at § 422.311(c)(2) and § 422.311(c)(3) by combining proposed policies and procedures for the existing two-pronged appeal approach into one set of policies and procedures for RADV appeals at the new § part 422.311(c)(2)(iv). At § 422.311(c)(2)(i), we propose that as a general rule, MA organizations may appeal RADV medical record review determinations and RADV payment error calculation, though in order to be eligible to pursue these appeals, we specify at proposed § 422.311(c)(2)(i)(A) and (B) that MA organizations must adhere to established RADV audit procedures and requirements and adhere to RADV appeals procedures and requirements. At § 422.311(c)(2)(ii) we propose that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. Furthermore, at proposed § 422.311(c)(2)(iii) we stipulate that the

EXHIBIT D-17

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Parts 417, 422, 423, and 424
(CMS-4159-F)****RIN 0938-AR37****Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.**SUMMARY:** The final rule will revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug

benefit program (Part D) regulations to implement statutory requirements; improve program efficiencies; and clarify program requirements. The final rule also includes several provisions designed to improve payment accuracy.

DATES: Effective Dates: These regulations are effective on July 22, 2014 except for the amendment in instruction 27 to § 423.100, the amendment in instruction 30 to § 423.501, and the amendment in instruction 34 to § 423.505, which are effective on January 1, 2018.**Applicability Dates:** In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.**FOR FURTHER INFORMATION CONTACT:**

Christopher McClintick, (410) 786-4682, Part C issues.

Marie Manteuffel, (410) 786-3447, Part D issues.

Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues.

Whitney Johnson, (410) 786-0490, Part C and D payment issues.

Joselyn Lassone, (410) 786-5116, Part C and D compliance issues.

Frank Whelan, (410) 786 1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. The applicability dates are discussed in the preamble for each of these items.**TABLE 1—APPLICABILITY DATE OF KEY PROVISIONS OTHER THAN 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE**

Preamble section	Section title	Applicability date
III.A.4	Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)).	01/01/2016
III.A.7	Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)	01/01/2015
III.A.20	Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(6)).	06/01/2015
III.A.24	Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460(b)(2)(i), 417.460(f)(1)(i)(A) through (C), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.44(d)(5)(ii) and (iv)).	01/01/2015

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(§§ 422.752, 423.752, 422.760 and 423.760)

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- b. Terminology Changes (§§ 422.510 and 423.509)
- c. Technical Change to Align Paragraph Headings (§ 422.510(b)(2))
- d. Terminology Change (§ 423.509(b)(2)(C)(ii))
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Regulations Text

Acronyms

ADS Automatic Dispensing System
 AEP Annual Enrollment Period
 AHFS American Hospital Formulary Service
 AHFS-DI American Hospital Formulary Service-Drug Information
 AHRQ Agency for Health Care Research and Quality

ALJ Administrative Law Judge
 ANOC Annual Notice of Change
 AO Accrediting Organization
 AOR Appointment of Representative
 BBA Balanced Budget Act of 1997 (Pub. L. 105-33)
 BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106-113)
 BIPA [Medicare, Medicaid, and SCHIP] Benefits Improvement Protection Act of 2000 (Pub. L. 106-554)
 BLA Biologics License Application
 CAHPS Consumer Assessment Health Providers Survey
 CAP Corrective Action Plan
 CCIP Chronic Care Improvement Program
 CC/MCC Complication/Comorbidity and Major Complication/Comorbidity
 CCS Certified Coding Specialist
 CDC Centers for Disease Control
 CHIP Children's Health Insurance Programs
 CMP Civil Money Penalty
 CMR Comprehensive Medical Review
 CMS Centers for Medicare & Medicaid Services
 CMS-HCC CMS Hierarchical Condition Category
 CTM Complaints Tracking Module
 COB Coordination of Benefits
 CORF Comprehensive Outpatient Rehabilitation Facility
 CPC Certified Professional Coder
 CY Calendar year
 DAB Departmental Appeals Board
 DEA Drug Enforcement Administration
 DIR Direct and Indirect Remuneration
 DME Durable Medical Equipment
 DMEPOS Durable Medical Equipment, Prosthetic, Orthotics, and Supplies
 D-SNPs Dual Eligible SNPs
 DOL U.S. Department of Labor
 DUA Data Use Agreement
 DUM Drug Utilization Management
 EAJR Expedited Access to Judicial Review
 EGWP Employer Group/Union-Sponsored Waiver Plan
 EOB Explanation of Benefits
 EOC Evidence of Coverage
 ESRD End-Stage Renal Disease
 FACA Federal Advisory Committee Act
 FDA Food and Drug Administration
 FEHBP Federal Employees Health Benefits Plan
 FFS Fee-For-Service
 FIDE Fully-Integrated Dual Eligible
 FIDE SNPs Fully-Integrated Dual Eligible Special Needs Plans
 FMV Fair Market Value
 FY Fiscal year
 GAO Government Accountability Office
 HAC Hospital-Acquired Conditions
 HCPP Health Care Prepayment Plans
 HEDIS HealthCare Effectiveness Data and Information Set
 HHS [U.S. Department of] Health and Human Services
 HIPAA Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191)
 HMO Health Maintenance Organization
 HOS Health Outcome Survey
 HPMS Health Plan Management System
 ICL Initial Coverage Limit
 ICR Information Collection Requirement

ID Identification
 IVC Initial Validation Contractor
 LCD Local Coverage Determination
 LEP Late Enrollment Penalty
 LIS Low Income Subsidy
 LPPO Local Preferred Provider Organization
 LTC Long Term Care
 MA Medicare Advantage
 MAAA Member of the American Academy of Actuaries
 MA-PD Medicare Advantage-Prescription Drug Plan
 MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)
 MOC Medicare Options Compare
 MOOP Maximum Out-of-Pocket
 MPDPF Medicare Prescription Drug Plan Finder
 MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173)
 MS-DRG Medicare Severity Diagnosis Related Group
 MSA Metropolitan Statistical Area
 MSAs Medical Savings Accounts
 MSP Medicare Secondary Payer
 MTM Medication Therapy Management
 MTMP Medication Therapy Management Program
 NAIC National Association of Insurance Commissioners
 NCD National Coverage Determination
 NCPDP National Council for Prescription Drug Programs
 NOQA National Committee for Quality Assurance
 NDA New Drug Application
 NDC National Drug Code
 NCC National Cuideline Clearinghouse
 NIH National Institutes of Health
 NOMNC Notice of Medicare Non-Coverage
 NPI National Provider Identifier
 NWS National Weather Service
 OIG Office of Inspector General
 OMB Office of Management and Budget
 OPM Office of Personnel Management
 OTC Over the Counter
 Part C Medicare Advantage
 Part D Medicare Prescription Drug Benefit Program
 PBM Pharmacy Benefit Manager
 PDE Prescription Drug Event
 PDP Prescription Drug Plan
 PFFS Private Fee For Service Plan
 POA Present on Admission (Indicator)
 POS Point-of-Sale
 PPO Preferred Provider Organization
 PPS Prospective Payment System
 P&T Pharmacy & Therapeutics
 QIC Qualified Independent Contractor
 QIO Quality Improvement Organization
 QRS Quality Review Study
 FACE Programs of All Inclusive Care for the Elderly
 RADV Risk Adjustment Data Validation
 RAPS Risk Adjustment Payment System
 RPPO Regional Preferred Provider Organization
 SCORM Shorthand Content Object Reference Model
 SEP Special Election Period
 SHIP State Health Insurance Assistance Programs
 SNF Skilled Nursing Facility

SNP Special Needs Plan
 SPAP State Pharmaceutical Assistance Programs
 SSA Social Security Administration
 SSI Supplemental Security Income
 T&C Terms and Conditions
 TPA Third Party Administrator
 TrOOP True Out-Of-Pocket
 UAC Usual and Customary
 UPIN Uniform Provider Identification Number
 USP U.S. Pharmacopoeia

I. Executive Summary

A. Purpose

The purpose of this final rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Affordable Care Act. This final rule is necessary to—(1) clarify various program participation requirements; (2) improve payment accuracy; and (3) make other clarifications and technical changes.

B. Summary of the Major Provisions

1. Modifying the Agent/Broker Requirements, Specifically Agent/Broker Compensation

The former regulatory compensation structure was comprised of a 6-year cycle that ended December 31, 2013. Under that structure, MA organizations and Part D sponsors provided an initial compensation payment to independent agents for new enrollees (Year 1), and paid a renewal rate (equal to 50 percent of the initial year compensation) for Years 2 through 6. MA organizations and Part D sponsors had the option to pay the 50 percent renewal rate for CY2014 (year 1). This compensation structure proved to be complicated to implement and monitor, and also created an incentive for agents to move beneficiaries as long as the fair market value (FMV) continued to increase each year. To resolve these issues, we proposed to revise the compensation structure. Under our proposal, MA organizations and Part D sponsors would continue to have the discretion to decide, on an annual basis, whether or not to use independent agents. Also, for new enrollments, MA organizations and Part D sponsors could determine what their initial rate would be, up to the CMS designated FMV amount. For renewals in Year 2 and subsequent years, with no end date, the MA organization or Part D sponsor could pay up to 35 percent of the current FMV amount for that year. We believed that revising the existing compensation

structure to allow MA organizations or Part D sponsors to pay up to 35 percent of the FMV for year 2 and subsequent years was appropriate based on a couple of factors. First, we believed that a 2-tiered payment system (that is, initial and renewal) would be significantly less complicated than a 3-tiered system (that is, initial, 50 percent renewal for years 2 through 6, and 25 percent residual for years 7 and subsequent years), and would reduce administrative burden and confusion for plan sponsors. Second, our analysis determined that 35 percent was the renewal compensation level at which the present value of overall payments under a 2-tiered system would be relatively equal to the present value of overall payments under a 3-tiered system (taking into account the estimated life expectancy for several beneficiary age cohorts). In addition to revising the agent and broker compensation structures, we proposed to amend the training and testing requirements as well as setting limits on referral fees (\$100) for agents and brokers.

We received more than 140 comments from agents, health plans, and trade associations opposing the 35 percent renewal rate, and instead suggesting that CMS maintain the 50 percent renewal rate. A number of commenters expressed concerns that the proposed reduction in compensation would represent a significant decrease from the current compensation limit, and a rate set at 50 percent of FMV would be in line with industry standard. They noted that the higher compensation amount would be particularly important for stand-alone prescription drug plans, as 35 percent would be insufficient to cover an agent's costs associated with the renewal transaction and could discourage agents from assisting in the annual evaluation of a Medicare beneficiary's options. Commenters also stated that, compared to current practice, the proposed 35 percent renewal rate is a reduction since a number of MA plans began offering a renewal rate of 50 percent for 10 years or more at the end of the 5-year cycle (2013). The majority of commenters also stated that agents play an important role in educating beneficiaries about Medicare and the proposed reduction in the renewal rate could reduce the level and quality of services provided to beneficiaries, thereby resulting in less information sharing and poorer plan choices by beneficiaries. Many commenters also stated that agents spend a significant amount of time in training, preparing, and educating beneficiaries and that the compensation

is already low relative to the hours spent. Some commenters also expressed concern that the lower compensation rate would discourage new agents from entering the MA market. Many agents stated they would have to stop selling MA products and instead sell other more profitable products. No plans strongly supported the 35 percent renewal rate. Therefore, we are modifying the compensation renewal rate from up to 35 percent to up to 50 percent. These changes will be applicable for enrollments effective January 2015. Because the proposed rate is similar to previous regulatory requirements, present CMS guidance, and industry practice, we believe this implementation timeframe is reasonable and appropriate. We are not finalizing the proposed changes to agent and broker training and testing at this time. We are finalizing limits on referral fees for agents as proposed.

2. Drug Categories or Classes of Clinical Concern

We are not finalizing any new criteria and will maintain the existing six protected classes.

3. Improving Payment Accuracy—Implementing Overpayment Provisions of Section 1128J(d) of the Social Security Act (§§ 422.326 and 423.360)

These proposed regulatory provisions codify the Affordable Care Act requirement establishing section 1128J(d) of the Act that MA organizations and Part D sponsors report and return identified Medicare overpayments.

We proposed to adopt the statutory definition of overpayment for both Part C and Part D, which means any funds that an MA organization or Part D sponsor has received or retained under Title XVIII of the Act to which the MA organization or Part D sponsor, after applicable reconciliation, is not entitled under such title. To reflect the unique structure of Part C and Part D payments to plan sponsors, we also propose to define two terms included in the statutory definition of overpayments: "funds" and "applicable reconciliation." We proposed to define funds as payments an MA organization or Part D sponsor has received that are based on data that these organizations submitted to CMS for payment purposes. For Part C we proposed that applicable reconciliation occurs on the annual final risk adjustment data submission deadline. For Part D, we proposed that applicable reconciliation occurs on the date that is the later of either the annual deadline for submitting prescription drug event

(PDE) data for the annual Part D payment reconciliations referred to in § 423.343(c) and (d) or the annual deadline for submitting DIR data.

In addition, we proposed to state in regulation that an MA organization or Part D sponsor has identified an overpayment if it has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment. An MA organization or Part D sponsor must report and return any identified overpayment it received no later than 60 days after the date on which it identified it received an overpayment. The MA organization or Part D sponsor must notify CMS, using a notification process determined by CMS, of the amount and reason for the overpayment. Finally, we proposed a look-back period with an exception for overpayments resulting from fraud, whereby MA organizations and Part D sponsors would be held accountable for reporting overpayments within the 6 most recent completed payment years for which the applicable reconciliation has been completed.

We received approximately 30 comments from organizations and individuals. Generally, commenters supported establishing separate applicable reconciliation dates for Part C and Part D. Many commenters questioned when the 60-day period for reporting and returning begins, and what activities constitute reporting and returning an overpayment to CMS, including questions about estimating an amount of overpayment. A number of commenters also requested to clarify the standards for "identifying" an overpayment, including questions about the meaning of reasonable diligence. Finally, a few commenters recommended that we impose the same limitation on the look-back period for all overpayments, even those relating to fraud.

We are finalizing the provisions at §§ 422.326 and 423.360, with the following modifications. First, we add at the end of paragraph § 422.326(d) the phrase "unless otherwise directed by CMS for the purpose of § 422.311." Also, to increase clarity we revise §§ 422.336(c) and 423.360(c) regarding identified overpayments. Finally, we strike the following sentence in the proposed paragraphs on the 6-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period."

4. Risk Adjustment Data Requirements

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of

risk adjustment data, including: (1) A requirement that medical record reviews, if used, be designed to determine the accuracy of diagnoses submitted under §§ 422.308(c)(1) and 422.310(g)(2); (2) a revision in the deadlines for submission of risk adjustment data; and (3) a limitation on the type and purpose of late data submissions. We also proposed a restructuring of subparagraph (g)(2) as

part of the revisions. We received approximately 25 comments from organizations and individuals regarding these proposals; many of the comments were concerned and critical of the proposals, highlighting vagueness and the potential for operational instability. For reasons discussed in more detail below in section III.B.2 of the preamble, we are not finalizing the proposed amendment regarding the scope of

medical reviews and we are not finalizing at this time the proposal to change the date for final risk adjustment data submission. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline.

C. Summary of Costs and Benefits

TABLE 2—SUMMARY OF COSTS AND BENEFITS

Provision description	Total costs	Transfers
Modifying the agent/broker requirements, specifically agent/broker compensation.	N/A	N/A
Improving Payment Accuracy	N/A	N/A
Eligibility of Enrollment for Incarcerated Individuals.		We estimate that this charge could save the MA program up to \$27 million in 2015, increasing to \$103 million in 2024 (total of \$650 million over this period), and could save the Part D program (includes the Part D portion of MA PD plans) up to \$46 million in 2015, increasing to \$153 million in 2024 (total of \$965 million over this period).

II. Background

A. General Overview and Regulatory History

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new “Part C” in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new “Part D” to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program, which it named the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the *Federal Register* on January 28, 2005 (70 FR 4568 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. For instance, in the September 18, 2008 and January 12, 2009 *Federal Register* (73 FR 54226 and 74 FR 1494, respectively), we issued Part C and D regulations to implement

provisions in the Medicare Improvement for Patients and Providers Act (MIPPA) (Pub. L. 110–275). We promulgated a separate interim final rule in January 16, 2009 (74 FR 2881) to address MIPPA provisions related to Part D plan formularies. In the final rule that appeared in the April 15, 2010 *Federal Register* (75 FR 19678), we made changes to the Part C and D regulations which strengthened various program participation and exit requirements; strengthened beneficiary protections; ensured that plan offerings to beneficiaries included meaningful differences; improved plan payment rules and processes; improved data collection for oversight and quality assessment; implemented new policies; and clarified existing program policy.

In a final rule that appeared in the April 15, 2011 *Federal Register* (76 FR 21432), we continued our process of implementing improvements in policy consistent with those included in the April 2010 final rule, and also implemented changes to the Part C and Part D programs made by recent legislative changes. The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010, as passed by the Senate on December 24, 2009, and the House on March 21, 2010. The Health Care and Education Reconciliation Act (Pub. L. 111–152), which was enacted on March 30, 2010, modified a number of Medicare provisions in Pub. L. 111–148 and added several new provisions. The Patient Protection and Affordable Care Act (Pub. L. 111–148) and the Health Care and Education Reconciliation Act (Pub. L. 111–152) are collectively

referred to as the Affordable Care Act. The Affordable Care Act included significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C and D programs largely focused on beneficiary protections, MA payments, and simplification of MA and Part D program processes. These provisions affected implementation of our policies regarding beneficiary cost-sharing, assessing bids for meaningful differences, and ensuring that cost-sharing structures in a plan are transparent to beneficiaries and not excessive. In the April 2011 final rule, we revised regulations on a variety of issues based on the Affordable Care Act and our experience in administering the MA and Part D programs. The rule covered areas such as marketing, including agent/broker training; payments to MA organizations based on quality ratings; standards for determining if organizations are fiscally sound; low income subsidy policy under the Part D program; payment rules for non-contract health care providers; extending current network adequacy standards to Medicare medical savings account (MSA) plans that employ a network of providers; establishing limits on out-of-pocket expenses for MA enrollees; and several revisions to the special needs plan requirements, including changes concerning SNP approvals.

In a final rule that appeared in the April 12, 2012 *Federal Register* (77 FR 22072 through 22175), we made several changes to the Part C and Part D

programs required by statute, including the Affordable Care Act, as well as made improvements to both programs through modifications reflecting experience we have obtained administering the Part C and Part D programs. Key provisions of that final rule implemented changes closing the Part D coverage gap, or "donut hole," for Medicare beneficiaries who do not already receive low-income subsidies from us by establishing the Medicare Coverage Gap Discount Program. We also included provisions providing new benefit flexibility for fully-integrated dual eligible special needs plans, clarifying coverage of durable medical equipment, and combatting possible fraudulent activity by requiring Part D sponsors to include an active and valid prescriber National Provider Identifier on prescription drug event records.

B. Issuance of a Notice of Proposed Rulemaking

In the proposed rule titled "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," which appeared in the January 10, 2014 *Federal Register* (79 FR 1918), we proposed to revise the

Medicare Advantage (MA) program (Part C) regulations and prescription drug benefit program (Part D) regulations to implement statutory requirements; strengthen beneficiary protections; exclude plans that perform poorly; improve program efficiencies; and clarify program requirements. The proposed rule also included several provisions designed to improve payment accuracy.

C. Public Comments Received in Response to the CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule

We received approximately 7,600 timely pieces of correspondence containing multiple comments on the CY 2014 proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule (for example, enrollment eligibility criteria for individuals not lawfully present in the United States) that we intend to address later and a few which we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed

rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

D. Provisions Not Finalized in This Final Rule

As noted previously, some of the provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Table 3 lists the provisions that were proposed but are not addressed at this time. We note that several provisions that were proposed are not being finalized in this rule and are effectively being withdrawn; those provisions are not listed in Table 3.

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME

Proposed rule section	Topic
Clarifying Various Program Participation Requirements	
III.A.2	Two-year Limitation on Submitting a New Bid in an Area Where an MA has been Required to Terminate a Low-enrollment MA Plan (§ 422.504(a)(19)).
III.A.6	Changes to Audit and Inspection Authority (§ 422.503(d)(2) and § 423.504(d)(2)).
III.A.9	Collections of Premiums and Cost Sharing (§ 423.294).
III.A.10	Enrollment Eligibility for Individuals Not Lawfully Present in the United States (§§ 417.2, 417.420, 417.422, 417.460, 422.1, 422.50, 422.74, 423.1, 423.30, and 423.44).
III.A.11	Part D Notice of Changes (§ 423.128(g)).
III.A.12	Separating the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC) (§ 422.111(a)(3) and § 423.128(a)(3)).
III.A.14	Exceptions to Drug Categories or Classes of Clinical Concern (§ 423.120(b)(2)(vi)).
III.A.15	Medication Therapy Management Program (MTMP) under Part D (§ 423.153(d)(1)(v)(A))—outreach strategies.
III.A.16	Business Continuity for MA Organizations and PDP Sponsors (§ 422.504(e) and § 423.505(p)).
III.A.21	Efficient Dispensing in Long Term Care Facilities and Other Changes (§ 423.154).
III.A.23	Medicare Coverage Gap Discount Program and Employer Group Waiver Plans (§ 423.2325).
III.A.26	Payments to PDP Plan Sponsors For Qualified Prescription Drug Coverage (§ 423.308) and Payments to Sponsors of Retiree Prescription Drug Plans (§ 423.882).
III.A.32	Transfer of TrOOP Between PDP Sponsors Due to Enrollment Changes during the Coverage Year (§ 423.464).
III.A.37	Expand Quality Improvement Program Regulations (§ 422.152).
III.A.38	Authorization of Expansion of Automatic or Passive Enrollment Non-Renewing Dual Eligible SNPs (D-SNPs) to another D-SNP to Support Alignment Procedures (§ 422.60).
Improving Payment Accuracy	
III.B.2	Determination of Payments (§ 423.329).
III.B.3	Reopening (§ 423.346).
III.B.4	Payment Appeals (§ 423.350).
III.B.5	Payment Processes for Part D Sponsors (§ 423.2320).
III.B.6	Risk adjustment data requirements—proposal regarding annual deadline for MAO submission of final risk adjustment data (§ 422.310(g)(2)(ii)).
Strengthening Beneficiary Protections	
III.C.1	Providing High Quality Health Care (§ 422.504(a)(3) and § 423.505(b)(27)).
III.C.2	MA-PD Coordination Requirements for Drugs Covered Under Parts A, B, and D (§ 422.112).

TABLE 3—PROVISIONS NOT FINALIZED AT THIS TIME—Continued

Proposed rule section	Topic
III.C.3	Good Cause Processes (§ 417.460, § 422.74 and § 423.44).
III.C.4	Definition of Organization Determination (§ 422.566).
III.C.5	MA Organizations May Extend Adjudication Timeframes for Organization Determinations and Reconsiderations (§ 422.568, § 422.572, § 422.590, § 422.618, and § 422.619).
Strengthening Our Ability to Distinguish Stronger Applicants for Part C and D Program Participation and to Remove Consistently Poor Performers	
III.D.1	Two-Year Prohibition When Organizations Terminate Their Contracts (§§ 422.502, 422.503, 422.506, 422.508, and 422.512).
III.D.2	Withdrawal of Stand-Alone Prescription Drug Plan Bid Prior to Contract Execution (§ 423.503).
III.D.3	Essential Operations Test Requirement for Part D (§§ 423.503(a) and (c), 423.504(b)(10), 423.505(b)(28), and 423.509).
III.D.4	Termination of the Contracts of Medicare Advantage Organizations Offering PDP for Failure for 3 Consecutive Years to Achieve 3 Stars on Both Part C and Part D Summary Star Ratings in the Same Contract Year (§ 422.510).
Implementing Other Technical Changes	
III.E.1	Requirements for Urgently Needed Services (§ 422.113).
III.E.2	Skilled Nursing Facility Stays (§§ 422.101 and 422.102).
III.E.3	Agent and Broker Training and Testing Requirements (§§ 422.2274 and 423.2274).
III.E.4	Deemed Approval of Marketing Materials (§ 422.2266 and § 423.2266).
III.E.5	Cross-Reference Change in the Part C Disclosure Requirements (§ 422.111).
III.E.6	Managing Disclosure and Recusal in P&T Conflicts of Interest: [Formulary] Development and Revision by a Pharmacy and Therapeutics Committee under PDP (§ 423.120(b)(1)).
III.E.8	Thirty-Six-Month Coordination of Benefits (COB) Limit (§ 423.466(b)).
III.E.9	Application and Calculation of Daily Cost-Sharing Rates (§ 423.153).
III.E.10	Technical Change to Align Regulatory Requirements for Delivery of the Standardized Pharmacy Notice (§ 423.562).
III.E.12	MA Organization Responsibilities in Disasters and Emergencies (§ 422.100).
III.E.14	Technical Changes to Align Part C and Part D Contract Determination Appeal Provisions (§§ 422.641 and 422.644).
III.E.15	Technical Changes to Align Parts C and D Appeal Provisions (§§ 422.660 and 423.650).
III.E.17	Technical Change to the Restrictions on use of Information under Part D (§ 423.322).

III. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

A. Clarifying Various Program Participation Requirements

1. Closing Cost Contract Plans to New Enrollment (§ 422.503(b)(4))

To ensure that our original intent is realized and to eliminate the potential for organizations to move enrollees from one of their plans to another based on financial or some other interest, we proposed to revise paragraph § 422.503(b)(4)(vi)(G)(5) so that an "entity seeking to contract as an MA organization must [n]ot accept, or share, a corporate parent organization with an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan."

In making the proposed revision to paragraph § 422.503(b), we also proposed to add the definition of "parent organization" to § 422.2 of the MA program definitions, specifying that, "Parent organization means a legal entity that owns one or more other subsidiary legal entities." Although the MA program regulations do not currently define the term "parent organization," our proposed definition is consistent with the way the term is

currently used in the context of the MA program, for example, when assessing an organization's business structure. We requested comments on whether a parent organization with less than a 100 percent interest in a subsidiary legal entity should trigger the prohibition we proposed with the amendment at § 422.503(b)(4).

During the public notice and comment process, a handful of commenters provided their input on our proposal. Some of the respondents included multiple comments. The comments and our responses follow.

Comment: A commenter supported the proposal, stating that it would prevent possible shifting of sicker enrollees to cost plans and should result in Medicare savings.

Response: We thank the commenter for the support.

Comment: A commenter stated that there is no evidence of complaints about the current situation and thus no change in current policy is necessary.

Response: The intention of our initial rule was to ensure that situations not arise in which an entity was able to move an enrollee from one of its plans to another plan in the same area based on financial or other reasons that may not be in the enrollee's best interest. The current regulations limit this possibility to some extent, but, without the

proposed changes, would leave open the possibility that legal entities controlled by a shared parent organization could move enrollees from one plan to another, based on something other than the enrollee's best interest.

Comment: A commenter stated that risk-adjusted payments for MA plans eliminate any incentive for an entity to move sicker enrollees from an MA plan to a cost plan.

Response: While risk adjusted payments do help to account for costs associated with sicker enrollees, it may still be advantageous for an organization to move an enrollee from an MA plan to a cost plan. Even with risk adjustment, there are other reasons an organization might want to move enrollees from one plan to another to include enrollment and other interests based on the organization's business model.

Comment: A commenter stated that, because cost plan cost-sharing and premiums must be equal to the actuarial value of Medicare fee-for-service cost-sharing, cost plan enrollees with high health care needs would have high relative costs resulting in higher premiums for the cost plan, thus removing any incentive for moving sicker enrollees from an entity's MA plan to the cost plan.

overpayment pending completion of the reopening.

Response: For both the Part C and Part D programs, the provisions regarding reporting and returning identified overpayments become effective the day after the date of applicable reconciliation. As we have stated, MA organizations and Part D sponsors are deemed to have returned the overpayment when they have submitted corrected data that is the source of the overpayment. We will recover the overpayment amount through routine processing. For Part D, that means that if an overpayment is discovered after the initial reconciliation but prior to the reopening described at § 423.346, a Part D sponsor may request a reopening and submit the corrected data to fulfill its obligation to return the overpayment. The overpayment will be reconciled through the routine reopening process.

Comment: A commenter stated that the onus on plans for the calculation of an overpayment amount creates a risk that CMS may be overpaid/underpaid in the monies returned.

Response: As explained in proposed rule (79 FR 1997), we will recover overpayments through the correction of erroneous data and established payment adjustment processes. Therefore, we believe that the risk the commenter mentions does not exist because CMS' systems will calculate the exact amount to be recovered.

Comment: A few commenters objected to the fact that the proposed rule does not address situations in which a sponsor has overpaid CMS, and requested that this regulation also set forth rules by which CMS handles an organization's overpayments to CMS.

Response: This final rule is intended to implement section 1128(d) of the Act, which pertains only to overpayments the government made to contracting MA organizations and Part D sponsors.

Comment: A commenter requested that MA organizations and Part D sponsors be able to submit auditable estimates of an overpayment in lieu of determining which data is in error and submitting corrected data, given the fact that the administrative costs of determining a specific set of data deletes is significant relative to the size of the issue. The commenter recommended that CMS permit plans to proactively suggest the use of such tools to resolve potential overpayments.

Response: The use of auditable estimates is intended only for a limited set of circumstances. This may occur, for example, when the Part D reopening occurs prior to the end of the look-back period or if an MA organization or Part

D sponsor had a thoroughly-documented catastrophic loss of stored data. Information about the nature of such a request would be detailed in forthcoming operational guidance. Therefore, we will not allow, on a routine basis, submission of auditable estimates in lieu of submission of corrected data. By recovering overpayments based on the corrected payment data, we will be more likely to ensure that the most accurate overpayment amounts are returned to the Medicare Trust Fund.

Comment: A commenter expressed concern that this final rule could impose a boundless duty to troll medical records in search of unknown vulnerabilities, and requested that CMS make clear that Part C and Part D plans are not obliged to proactively search for an overpayment without reason to believe that a specific overpayment exists.

Response: The focus of this final rule is on ensuring that MA and Part D organizations return an overpayment when it is identified. For many years organizations have been obliged to submit accurate, complete, and truthful payment-related data, as described at §§ 422.504(l) and 423.505(k). Further, CMS has required for many years that diagnoses that MA organizations submit for payment be supported by medical record documentation. Thus, we have always expected that MA organization or Part D sponsor implement, during the routine course of business, appropriate payment evaluation procedures in order to meet the requirement of certifying the data they submit to CMS for purposes of payment. Therefore, we do not believe that §§ 422.326 and 423.360 represent such a new requirement.

Comment: A commenter requested that CMS confirm that the data submission requirement under this section is based on enrollment data and risk adjustment scores, and thus does not apply to direct overpayments from providers.

Response: Once an overpayment is identified, the MA or Part D organization is responsible for correcting the data that caused the overpayment. This is data that is routinely submitted to CMS for payment purposes, such as, risk adjustment data.

Comment: A commenter requested that CMS clarify if changes in a beneficiary's low income subsidy (LIS) status could result in an overpayment under this provision.

Response: As we stated in the proposed rule, we believe that MA organizations and Part D sponsors cannot be held accountable for the accuracy of the data controlled and

submitted to CMS by other entities. (We emphasize here that the term "other entities" used to discuss these overpayment provisions does not include the following parties referenced in §§ 422.504(l) and 423.505(l): first tier, downstream, and related entities, contractors, or subcontractors to the MA organization or Part D sponsor.) It is the Social Security Administration and the states that notify CMS of individuals whom they have determined to be eligible for the Part D LIS. We in turn provide the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. Although, we will not consider an overpayment to have occurred strictly due to changes in a beneficiary's LIS status, Part D sponsors are required to adjust prescription drug event (PDE) data to accurately reflect the beneficiary's LIS status.

Comment: A commenter supported our proposal for when overpayments have been identified.

Response: We appreciate the commenter's support for our proposal.

Comment: A few commenters requested that CMS provide more clarity or an example of what is meant by "acts in reckless disregard or deliberate ignorance."

Response: We are revising our definition of an identified overpayment to state that an MA organization or Part D sponsor has identified an overpayment when it has determined, or should have determined through the exercise of reasonable diligence, that the MA organization or Part D sponsor has received an overpayment.

As to the circumstances that give rise to a duty to exercise reasonable diligence, we are not able to anticipate all factual scenarios in this rulemaking. MA organizations and Part D sponsors are responsible for ensuring that payment data they submit to CMS are accurate, truthful, and complete (based on best knowledge, information, and belief), and are expected to have effective and appropriate payment evaluation procedures and effective compliance programs as a way to avoid receiving or retaining overpayments. Thus, at a minimum, reasonable diligence would include proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments. However, conducting proactive compliance activities does not mean that the person has satisfied the reasonable diligence standard in all circumstances. In certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by

qualified individuals in response to credible information of a potential overpayment.

We note that in discussing the standard term "reasonable diligence" in the preamble, we are interpreting the obligation to "report and return the overpayment" which is contained in section 1128(d) of the Social Security Act. We are not seeking to interpret the terms "knowing" and "knowingly", which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Comment: Some commenters thought that we had an overly broad interpretation of the statute and that there was no statutory basis for CMS to interpret the term "identified" in section 6402 of the Affordable Care Act to include "reckless disregard or deliberate ignorance of the existence of the overpayment." A commenter stated that the term "knowing" is not actually used in the overpayment standard set forth in section 6402(d) of the Affordable Care Act, so the mere existence of an errant reference to the False Claims Act definition of "knowing" does not give CMS sufficient basis to apply the expansive False Claims Act knowledge standard to the definition of "identified" under section 6402. This commenter noted that in an earlier version of the Affordable Care Act, H.R. 3962, used the False Claims Act knowledge standard in the section on reporting and returning of overpayments. The commenter also stated that the final version of the Affordable Care Act enacted by the Congress used the term "identified," and not the word "knowledge." This commenter believed that the Congress's explicit rejection of the False Claims Act knowledge standard, and use of the term "identified" in the final legislative language weighs against incorporating the False Claims Act knowledge standard into the regulatory provision.

Response: We disagree with the commenters' arguments. While we acknowledge that the terms "knowing" and "knowingly" are defined but not otherwise used in section 1128(d), we believe that the Congress intended for section 1128(d) to apply broadly. If the requirement to report and return overpayments applied only to situations where the MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated. Thus, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: Several commenters recommended that CMS remove the language relating to "reasonable diligence" from the proposed regulation. These commenters believed that an identified overpayment should be limited to actual knowledge of an overpayment.

Response: For the reasons discussed previously, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

Comment: A few commenters were concerned that by adding a reasonable diligence requirement, CMS appears to be suggesting that a much lower level of sponsor behavior—a failure to act reasonably—could trigger potential False Claims Act liability. One commenter stated that the phrase "reasonable diligence" is not a recognized or defined standard and is overly vague as to the obligations of plans to follow through on information received regarding a potential overpayment. The commenters have serious concerns about the implication of such a standard.

Response: We understand the commenters' concerns. However, we do not believe that it is inappropriate to expect that MA organizations and Part D sponsors act reasonably. We note that it is the statute that establishes liability under the False Claims Act for failure to report and return identified overpayments, pursuant to section 1128(d)(3).

c. Look-Back Period for Reporting and Returning Overpayments

We proposed at §§ 422.326(e) and 423.360(e) to codify a look-back period for MA organizations and Part D sponsors. MA organizations and Part D sponsors would be required to report and return any overpayment that they identify within the 6 most recent completed payment years. The statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. CMS proposed 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years also is consistent with the CMP provisions, and maintenance of records requirements under the contracts. We also proposed that overpayments resulting from fraud would not be subject to this limitation of a look-back period.

We received the following comments on the look-back period, and our responses follow.

Comment: We received a few comments recommending that we shorten the 6-year look-back period. A commenter noted that permitting greater finality in overpayment reporting and recovery will decrease administrative costs and free up resources to focus on benefits. This commenter also stated that an organization would have to retain a significant amount of documentation to fully support and justify payments, more than what they would retain under CMS's 10-year record retention requirement. Several commenters recommended that the look-back period be 3 years to align with the RAC look-back period. A commenter noted that the 3-year period would also be consistent with the federal government's treatment of government contractors that are subject to the Federal Acquisition Regulation. A couple of commenters recommended that we implement a 4-year look-back period to align with the 4-year period that Medicare Administrative Contractors can reopen Medicare fee-for-service payment determinations.

Response: We disagree with the commenters' recommendations to shorten the look-back period. We note that section 1128(d) of the Act has no time limit to the obligation to report and return overpayments received by a provider or supplier. However, as we stated in the preamble to our proposed rule and again in this preamble to our final rule, we proposed 6 years as the look-back period because we believe this best balances government's interest in having overpayments returned with entities' interest in finality. Six years is consistent with the CMP provisions, and maintenance of records requirements under the contracts. It is also consistent with the False Claims Act in that the statute of limitations related to the False Claims Act is 6 years from the date of the violation or 3 years from the date the relevant government official learns of the situation, but in no case more than 10 years from the date of the violation. We believe that our final rule does not create additional recordkeeping burden or cost. Under § 422.504(d) and § 423.505(d), MA organizations and Part D sponsors are required to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices related to costs, financial statements, cash flow, etc.

Comment: A commenter requested that CMS clarify the parameters of the 6-year look-back provision.

Response: As we stated in the preamble to the proposed rule and this

final rule and again in §§ 422.326(e) and 423.360(e), MA organizations and Part D sponsors are required to report and return any overpayment that they identify within the 6 most recent completed payment years. That would mean, for example, after the initial reconciliation that takes place for Part D payments (that is, the determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) for contract year 2015 (which will take place at the end of 2016), Part D sponsors are obligated to report and return overpayments under § 423.360 for contract years 2010 through 2015.

Comment: A few commenters recommended that CMS impose the same limitation on the look-back period for all overpayments, even those relating to fraud. A commenter noted that under the statutory scheme set forth in section 6402 of the Affordable Care Act, the existence of an overpayment does not depend on, or otherwise reflect, the existence of fraud. Commenters also requested clarification from CMS whether MA organizations and Part D sponsors that become aware of an overpayment prior to the look-back period have an obligation to investigate and determine whether that overpayment resulted from fraud. These commenters were concerned that MA organizations and Part D sponsors would have to investigate potential overpayments indefinitely, no matter how far in the past they may have occurred, because these organizations would have to determine whether there was any fraud in connection with the potential overpayment in order to determine whether a reporting obligation exists.

Response: Upon further review, we agree with the commenters' suggestion that CMS impose the same limitation on the look-back period for all overpayments. Six years is consistent with the more commonly applicable FCA statute of limitations as well as the statute of limitations under section 1128A of the Act. Therefore, we have elected to establish a 6-year look-back period regardless of the nature of the overpayment, and we have amended the regulation text at §§ 422.326(e) and 423.360(e) accordingly. We note that the government may have other avenues for pursuing the return of overpayments due to false and fraudulent claims outside of these provisions.

Finally, we note that an MA organization's and Part D sponsor's

obligation to investigate and identify false and fraudulent claims is outside the scope of this final rule.

After consideration of the public comments received on the overpayment provisions, we are finalizing as proposed the following provisions: §§ 422.1, 422.300, 422.504(l), 423.1, and 423.505(k). We are finalizing the provisions at § 422.326, with the following modifications. First, we add at the end of paragraph (d) the phrase "unless otherwise directed by CMS for the purpose of § 422.311." Second, we strike the following sentences in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by an MA organization is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d) above."

Finally, we are finalizing the provisions at § 423.360 with the following modifications. We strike the following sentence in the proposed paragraph on the six-year look-back period: "Overpayments resulting from fraud are not subject to this limitation of the lookback period." To increase clarity we also revise paragraph (c) regarding identified overpayments. We also are making a technical correction by redesignating proposed paragraph (d)(3) on enforcement as paragraph (e), and redesignating proposed paragraph (e) on the six-year look-back period as paragraph (f), and revising new paragraph (e) on enforcement to say "Any overpayment retained by a Part D sponsor is an obligation under 31 U.S.C. 3729(b)(3) if not reported and returned in accordance with paragraph (d)."

2. Risk Adjustment Data Requirements (§ 422.310)

We proposed several amendments to § 422.310 to strengthen existing regulations related to the accuracy of risk adjustment data. We proposed to renumber existing paragraph § 422.310(e) as paragraph (e)(2) and add new paragraph (e)(1), which would require that any medical record reviews conducted by an MA organization must be designed to determine the accuracy of diagnoses submitted under

§§ 422.308(c)(1) and 422.310(g)(2). Under our proposal, medical record reviews conducted by an MA organization could not be designed *only* to identify diagnoses that would trigger additional payments by CMS to the MA organization; medical record review methodologies would have to be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.

We also proposed to amend § 422.310(g) regarding deadlines for submission of risk adjustment data; our proposal was to restructure and revise subparagraph (g)(2) and add subparagraph (g)(3). Our current procedures generally permit submission of risk adjustment data after the final risk adjustment submission deadline only to correct overpayments. Thus, we proposed, at § 422.310(g)(2)(ii) to explicitly permit late submissions only to correct overpayments but not to submit diagnoses for additional payment so that the regulation text would be consistent with our procedures.

Finally, we proposed to make two additional changes in paragraph (g). First, we proposed the deletion of the January 31 deadline in paragraph (2) and replacing it with the statement that CMS will announce the deadline by which final risk adjustment data must be submitted to CMS or its contractor. We noted that the risk adjustment data submission deadline would also function as the Part C applicable reconciliation date for purposes of proposed § 422.326 on overpayment rules, also discussed in this final rule. Second, we proposed adding paragraph (3) to § 422.310(g). Proposed paragraph (3) cites § 422.326 as the source of rules for submission of corrected risk adjustment data after the final risk adjustment data submission deadline, that is, after applicable reconciliation as defined at § 422.326(a).

In response to the January 10, 2014 proposed rule, we received approximately 25 pieces of correspondence from organizations and individuals regarding these proposals. We received the following public comments and our responses follow.

Comment: Many commenters expressed concern about the vagueness and overly broad statement of CMS' proposal to amend § 422.310(e) to require that medical record reviews conducted by MA organizations be designed to determine the accuracy of diagnoses they submitted to CMS. Some commenters thought this implied a requirement to verify every diagnosis

submitted by every provider, while others thought this implied a restriction on the ability of plans to identify what medical records to review. Other commenters believed the proposed amendment limited plans' ability to review medical records for operational purposes other than risk-adjusted payment, such as focusing on only a portion of a medical record for a subset of beneficiaries in order to enhance HEDIS scores, conduct contract compliance reviews, and validate claims processing and billing.

Finally, a few commenters argued that CMS should offset the payment impact of diagnoses an MA organization submitted to CMS that were later found through medical record reviews to not be supported by medical record documentation by adjusting the amount of CMS' overpayment to the MA organization for the level of error in equivalent diagnoses in FFS claims data. Specifically, the commenters argued that CMS should give MA organizations a credit for erroneous diagnoses they submitted from their providers' claims up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program. The commenters also argued that there is no reason to require that both MA and FFS diagnosis data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Response: We thank the commenters for their input. We are not finalizing the proposed amendment to § 410.322(e).

However, we emphasize that our decision to not finalize this regulatory proposal does not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allows sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern

that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: We are not finalizing this proposal at this time.

Comment: Many commenters disagreed with CMS' proposal under § 410.322(g)(2) that, after the final risk adjustment data submission deadline, CMS would permit submission of data to correct overpayments but not permit late submission of diagnosis data that would result in additional payment, asserting that this asymmetrical approach does not promote CMS' stated goal of improving payment accuracy. The commenters maintained that an MA organization should be allowed to submit additional diagnoses after the final risk adjustment data submission deadline to correct not only an overpayment to the MA organization, but also an underpayment. A commenter recommended that, after the final deadline, MA organizations should be able to submit paired deletions-additions of diagnoses as long as the result is not an increased payment to the organization but a smaller reduction in payment than would otherwise occur if only the deletion were submitted; for example, an MA organization may want to delete the diagnosis code for diabetes with acute complications and replace it with the code for diabetes without complications so that it loses only some of the payment. Finally, a commenter requested that CMS allow exceptions to the general rule that no new diagnoses may be submitted after the final risk adjustment data submission deadline for special circumstances such as system failures, file formatting issues, and other technical problems.

Response: For a given payment year (which is a calendar year), CMS applies diagnoses from the previous year (the data collection year) to calculate beneficiary risk scores used to risk-adjust payments to MA organizations in the payment year. MA organizations must finalize any corrections and new submissions of diagnosis data for a data collection year by January 31 of the year after the payment year. That is, we allow 13 months after the end of the diagnosis year for MA organizations to identify errors in data they have submitted (that is, deleting diagnoses from CMS' systems) and to identify and

submit additional diagnoses that were not submitted during the diagnosis year. We believe that is a very reasonable period of time to finalize risk adjustment data for a diagnosis year.

These risk adjustment processes have been in place for many years, and we believe it is the responsibility of MA organizations to have internal audit processes in place allowing them to finalize their risk adjustment data for a payment year by the conclusion of this 13-month period. Therefore, we are finalizing, as proposed, the provision codified at § 422.310(g)(2)(i) that, after the final deadline, an MA organization may submit risk adjustment data to correct overpayments but not to add payments.

Comment: A commenter supported CMS' proposal to limit post-deadline modifications to deletions of incorrect diagnoses but requested that CMS offer one additional opportunity to eliminate unsupported diagnosis codes in advance of a RADV audit.

Response: When we are preparing to initiate a RADV audit cycle, all MA organizations are notified that they should eliminate unsupported diagnoses from CMS' systems by a date specified in the notice. Subsequently, we inform the contracts that have been selected for RADV.

In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e). Also, we are not finalizing at this time our proposal at § 422.310(g)(2)(ii) to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline. We did not receive any comments on subparagraph (g)(3) and are finalizing it as proposed.

3. RADV Appeals

a. Background

We published final Risk Adjustment Data Validation (RADV) appeals regulations in the April 15 2010 *Federal Register* (75 FR 19677). These rules were proposed and finalized under our authority to establish Medicare Advantage (MA) program standards at section 1856(b)(1) of the Act and are found at § 422.311 et seq. Since finalizing these rules in 2010, we conducted additional RADV audits and determined that some of the appeals

provisions finalized in the 2010 RADV Appeals final rule should be modified to strengthen and streamline the RADV appeals process and to prevent confusion. Therefore, we proposed revisions to the RADV appeals regulations on January 10, 2014. These proposed RADV provisions will apply to any RADV determinations issued on or after the effective date of this regulation.

We proposed changing certain RADV definitions at § 422.2. Specifically, we proposed removing the definition Initial Validation Contractor (IVC); removing the definition of RADV payment error calculation appeal process; and removing the definition of "One Best Medical Record for the purposes of Medicare Advantage Risk Adjustment Data Validation (RADV)". In addition, we proposed adding one new definition by specifically defining the RADV appeals process. We also proposed revising the definitions of "Risk Adjustment Data Validation (RADV)" and "attestation process" within the RADV appeals context. Furthermore, we proposed amending RADV definitions at § 422.2 to specify that the Secretary, along with CMS, could conduct RADV audits.

At § 422.311, we proposed to update select RADV appeals terminology. We proposed amending the RADV regulations by adopting one common term to refer to RADV audit reports: "RADV Audit Report". As mentioned earlier, we proposed removing from the RADV regulations the term—"Initial Validation Contractor, or IVC," since RADV medical record review process no longer utilizes "initial" and "secondary" validation contractors to conduct medical record review under RADV. Instead, we now utilize medical record reviewers to code medical records who may be employed by the same or different medical record review contractors.

At § 422.311(c)(1), we proposed to simplify the RADV appeals process by combining the two existing RADV appeal procedures—one for medical record review and one for payment error calculation—into one set of requirements and one process comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. Combining these existing RADV medical record review determination and payment error calculation appeals policies and processes improves the overall appeals process by simplifying the overall RADV appeals process and reducing burden on all parties involved in the RADV appeals process. We also believed that doing so improves overall

RADV appeals procedures by providing clarity that leads to greater efficiencies in adjudicating RADV appeals. Within this overall framework, we also proposed defining issues that would be eligible for RADV appeal at § 422.311(c)(2) and issues that would not be eligible for RADV appeals under this combined-appeal process at § 422.311(c)(3). We further proposed defining the manner and timing of a request for RADV appeal at § 422.311(c)(2)(iii), a reconsideration process at § 422.311(c)(6), a hearing process at § 422.311(c)(7)(iv), and an Administrator-level review at § 422.311(c)(8).

At § 422.311(a), we proposed that the Secretary, along with CMS, be permitted to conduct RADV audits beginning with the effective date of this regulation. Because of the absence of a clearly-defined burden of proof standard for RADV medical record review determination appeals, at § 422.311(c)(4) we proposed adoption of a burden of proof standard for all RADV determinations—be they payment error calculation or RADV medical record review determinations—whereby the burden would be on MA organizations to prove, based on a preponderance of the evidence, that CMS's determination(s) was (were) erroneous. At § 422.311(b)(2) we proposed changing the compliance date for meeting RADV audit requirements for the validation of risk adjustment data to the due date when MA organizations selected for RADV audit must submit medical records to the Secretary—and not only CMS.

We received comments from health plans, managed care industry trade associations, providers, provider trade associations and other interested parties. These comments have resulted in changes to the previously described proposals, as discussed later in this section. Some of the comments we received did not apply to the proposed RADV appeals processes. However, because some of these comments apply to underlying RADV audit process, we are responding to certain comments because they appear to be relevant to the RADV appeals process. Other comments were clearly outside the scope of our proposed rule, so we have not included responses to those comments.

b. RADV Definitions

We proposed to amend the RADV definitions at § 422.2 as follows:

- Removing the following definitions:
 - ++ "Initial Validation Contractor (IVC)" means the first level of medical record review under the RADV audit process.

- ++ "RADV payment error calculation appeal process" means an administrative process that enables MA organizations that have undergone RADV audit to appeal the CMS calculation of an MA organization's RADV payment error.

- ++ "The one best medical record for the purposes of Medicare Advantage Risk Adjustment Validation (RADV)" means the clinical documentation for a single encounter for care (that is, a physician office visit, an inpatient hospital stay, or an outpatient hospital visit) that occurred for one patient during the data collection period. The single encounter for care must be based on a face-to-face encounter with a provider deemed acceptable for risk adjustment and documentation of this encounter must be reflected in the medical record.

- Adding the following definition:

- ++ "RADV appeal process" means an administrative process that enables MA organizations that have undergone RADV audit to appeal the Secretary's medical record review determinations and the Secretary's calculation of an MA organization's RADV payment error.

- Revising the following definitions:

- ++ Risk adjustment data validation (RADV) audit means a payment audit of a Medicare Advantage (MA) organization administered by CMS or the Secretary that ensures the integrity and accuracy of risk adjustment payment data.

- ++ "Attestation process" means a CMS-developed RADV process that enables MA organizations undergoing RADV audit to submit CMS-generated attestations for eligible medical records with missing or illegible signatures or credentials. The purpose of the CMS-generated attestations is to cure signature and credential issues for eligible medical records. CMS-generated attestations do not provide an opportunity for a provider or supplier to replace a medical record or for a provider or supplier to attest that a beneficiary has the medical condition.

We received no comments specifically recommending modifications to the proposed definitions as stated, though we did receive comments regarding the policy behind some of these definition changes. The policy comments will be addressed later in this rule, though we are finalizing the specific definitions without modification.

c. Publication of RADV Methodology

In the October 22, 2009 proposed rule, and as reinforced in the April 15, 2010 final rule, we indicated that we would, "publish its RADV methodology in some type of public document—most

likely, a Medicare Manual, so that the public can review and provide comment as it deems necessary". We also indicated that we would provide an annual notice of RADV audit methodology. Our last RADV-related notice of methodology was published in February 2012. We will continue to publish a notice of the methodology employed, but will do so only if there is a change in the RADV methodology that would require publication. We note that these notices of RADV audit methodology updated information provided on RADV audit methodology provided in the October 22, 2009 proposed rule and April 15, 2010 final rule.

In addition, we provided in the October 22, 2009 proposed rule preamble that we would provide an expanded explanation of methodology and payment error calculation factors as a part of each audit report of findings that we send to MA organizations that undergo RADV audit. Such explanation and factors have been and will continue to be part of the RADV audit report(s) that CMS provides health plans that have undergone RADV audits.

d. Proposal To Update RADV Appeals Terminology (§ 422.311)

Current RADV regulations utilize the following terms for the CMS-issued RADV audit report: Audit report post medical record review; RADV audit report; IVC-level RADV audit report; and RADV audit report of finding. This use of multiple terms to refer to what is the same audit report (the RADV audit report that CMS issues following conclusion of the medical record review portion of the audit) is potentially confusing. Therefore, we proposed amending the RADV regulations throughout to adopt one common term to refer to RADV audit reports: "RADV Audit Report". By standardizing terminology throughout the RADV regulations, the proposed amendment provides clarity which may lead to increased efficiency.

As mentioned earlier in the description of RADV-related definitions that have changed, we have revised certain RADV-related definitions to accommodate changes to both the RADV audit process and the RADV appeals process. One definition that we have removed from the RADV regulations is Initial Validation Contractor, or IVC. The RADV medical record review process no longer utilizes "initial" and "secondary" validation contractors to conduct medical record review under RADV. Instead we now utilize medical record reviewers to code medical records undergoing RADV review.

These reviewers may be employed by the same or different medical record review contractors. Therefore, the term "IVC" is no longer relevant to the RADV audit process. As a result, we proposed to remove this term from the RADV regulations at the following citations: § 422.311(c)(2)(i)(B) through (D); § 422.311(c)(2)(ii)(B); § 422.311(c)(2)(iii)(A), § 422.311(c)(2)(v), (vi), § 422.311(c)(3)(ii)(A), and § 422.311(c)(3)(iii)(A) and (B). We invited comment on this proposal.

Comment: A commenter requested that CMS verify that the medical record review error determination standard, which presently requires multiple review determinations by independent coders to confirm a CMS-HCC coding error, remains in effect and is not altered by this proposed rule.

Response: While we did not propose RADV coding changes, we believe the question merits a response. We believe that our proposal to remove the definition of "Initial Validation Contractor" (IVC) may have led some to believe that we were abandoning RADV audit processes that require multiple levels of independent medical record review (coding) by independent reviewers before we will confirm a CMS-HCC coding error. This standard has not changed, notwithstanding the removal of the term IVC from the RADV appeals rules. We continue to utilize medical record reviewers to code medical records undergoing RADV review, though these reviewers may now be employed by the same or different medical record review contractors. The principle of independent review and multiple confirmations of an identified CMS-HCC remain in effect.

e. Proposal To Simplify the RADV Appeals Process

Currently, there are two types of RADV-related appeals processes described in our regulations at § 422.311: Medical record review-determination appeals and RADV payment error calculation appeals. RADV medical record review-determination appeal requirements and procedures are discussed at § 422.311(b)(3) and § 422.311(c)(2). Medical record review determination appeal is a two-stage administrative appeal process—the first step is a hearing by a hearing officer, followed by a CMS Administrator—level review. This appeal procedure provides MA organizations with an opportunity to appeal RADV medical record review determinations that are made by coders reviewing the medical record documentation submitted by MA

organizations undergoing RADV audit. The second type of RADV appeal, payment error calculation appeal, is discussed at § 422.311(c)(3). Payment error calculation appeal is a three-pronged appeal process: reconsideration, followed by a hearing officer review, followed by CMS Administrator—level review. This appeal process was specifically designed to afford MA organizations the opportunity to appeal CMS's contract-level RADV payment error calculation.

We proposed that the administrative appeals language described at § 422.311(b)(3) and § 422.311(c)(2) for RADV medical record review determination appeals and § 422.311(c)(3) for RADV payment error calculation appeals be replaced with new regulatory language proposed § 422.311(c)(1), that combines the two existing RADV appeal policies and procedures into one set of requirements and one process. We proposed to combine the two RADV appeals processes into one combined RADV appeals process that is comprised of three administrative steps: Reconsideration, hearing officer review, and CMS Administrator-level review. A three-step administrative appeals process comprising reconsideration, hearing officer review, and Administrator-levels of review is a common administrative appeals model used elsewhere within the Medicare managed care program, such as in appealing contract award determinations and intermediate sanctions. The combined RADV appeal process that we proposed at new § 422.311(c)(1), also has the benefit of simplifying what is today a complex two-track appeal process into one process. While both CMS and the MA industry will benefit from simplifying this process, MA organizations also obtain an additional level of review under the combined approach since MA organizations will be afforded a reconsideration appeal step for medical record review determinations that is today—not part of the existing RADV appeal process. Shortening the existing two-track appeal process should also reduce the resources and level of effort needed from both MA organizations and CMS in participating in a RADV appeal proceeding. Under this proposal, MA organizations can simply request to appeal their RADV audit findings one time and specify whether they want to appeal either their medical record review determination(s), payment error calculation, or both. The specific details regarding this proposed process follow. We proposed these changes based upon

our experience with RADV appeals and because we hope to reduce the burden associated with undertaking RADV appeals on both MA organizations and CMS. The details of the proposed policy and procedure follow.

(1) Issues Eligible for RADV Appeal

Current regulations at §§ 422.311(c)(2) et seq., and 422.311(c)(3) et seq., specify RADV-related medical record review and payment error calculation documents and issues eligible for the medical record review determination and payment error calculation appeal processes. We proposed to amend the policies and procedures around issues eligible for RADV appeals at § 422.311(c)(2) and § 422.311(c)(3) by combining proposed policies and procedures for the existing two-pronged appeal approach into one set of policies and procedures for RADV appeals at the new § 422.311(c)(2)(iv). At § 422.311(c)(2)(i), we proposed that as a general rule, MA organizations may appeal RADV medical record review determinations and RADV payment error calculation, though in order to be eligible to pursue these appeals, we specify at proposed § 422.311(c)(2)(i)(A) and (B) that MA organizations must adhere to established RADV audit procedures and requirements and adhere to RADV appeals procedures and requirements. At § 422.311(c)(2)(ii) we proposed that failure to follow RADV audit procedures and requirements and RADV appeals procedures and requirements will render the MA organization's request for RADV appeal invalid. Furthermore, at proposed § 422.311(c)(2)(iii) we stipulate that the MA organization's written request for medical record review determination appeal must specify the audited HCC(s) that have been identified pursuant to RADV audit as being in error, and further specify that MA organizations must provide a justification in support of the audited HCC(s) that the MA organization elects to appeal. At § 422.311(c)(2)(i)(iv) we proposed that for each audited HCC, MA organizations may appeal one medical record that has undergone RADV medical record review and that if an attestation was submitted to cure a signature or credential issue, that attestation may likewise be included in the HCC appeal. For example, if an MA organization submitted a medical record that did not contain a signature and/or credential—and the MA organization submitted an attestation to cure the error that CMS subsequently failed to accept—the MA organization could choose to appeal CMS's determination to not accept the submitted attestation. We reiterate that

the purpose of CMS-generated attestations is to cure signature and credential errors associated with an eligible submitted medical record and not to provide an opportunity for a provider or supplier to attest that a beneficiary has a certain medical condition. Evidence for the existence of the medical condition is found in a medical record.

We proposed to modify our language at § 422.311(c)(2)(i)(v) to clarify existing RADV appeals provisions which stipulate that MA organizations must adhere to the "one best medical record" policy. Under changes to the RADV audit methodology announced by CMS in February 2012, we now allow MA organizations to submit more than one medical record (that is, more than the "one best medical record") during the RADV audit process to validate an audited CMS-HCC. However, for purposes of appealing a CMS medical record review determination, we will not permit organizations to appeal multiple medical records but will instead—require that MA organizations identify a record from amongst those records submitted, and to submit that record for appeal. For each audited HCC, MA organizations may appeal only one medical record that has undergone RADV review. This policy was published in the February 2012 White Paper and is not included in this final rule.

At § 422.311(c)(2)(vi) we proposed that a written request for RADV payment error calculation appeal must clearly specify the MA organization's own RADV payment error calculation and must also specify where the payment error calculation was erroneous.

(2) Issues Not Eligible for RADV Appeals

At § 422.311(c)(3) we proposed documents and issues that are ineligible for RADV appeals. Consistent with the overall approach of combining into one RADV appeals process what was heretofore two separate RADV appeals processes—by way of this new proposed section, we propose to amend existing regulations at § 422.311(c)(3). At new § 422.311(c)(3), we proposed that MA organizations' request for appeal may not include HCCs, medical records or other documents beyond the audited HCC, selected medical record and any accompanying attestation that the MA organization chooses to appeal. We specify at § 422.311(c)(3)(ii) that the MA organizations may not appeal CMS's medical record review determination methodology or CMS's payment error calculation methodology. This is a

clarification to existing RADV regulations at § 422.311(c)(3)(D) which specifies that MA organizations may not appeal CMS's payment error calculation methodology. At § 422.311(c)(3)(iii) we specify that MA organizations may not appeal RADV medical record review-related errors when appealing RADV error-calculation issues since medical record review determination issues must be resolved before we can calculate RADV payment errors. And at § 422.311(c)(3)(iv) we specify that RADV errors that result from an MA organization's failure to submit a medical record are not eligible for appeal.

(3) Manner and Timing of a Request for RADV Appeal

We proposed to replace existing RADV regulations at § 422.311(c)(2)(iii) et seq., and § 422.311(c)(3)(iii) et seq., regarding the manner and timing of a request for RADV appeals. Again, at § 422.311(c)(5), we proposed to combine the formerly two separate sets of requirements and procedures into one RADV appeals process addressing the request for RADV appeal. At § 422.311(c)(5)(i) we proposed that at the time the Secretary issues her RADV audit report, the Secretary notifies audited MA organizations that they may appeal RADV HCC errors that are eligible for medical record review determination appeal and may appeal the Secretary's RADV payment error calculation. At § 422.311(c)(5)(ii) we specify that MA organizations have 30 days from the date of CMS's issuance of the RADV audit report to file a written request with CMS for RADV appeal. This request for RADV appeal must specify whether the MA organization requests medical record review determination appeal, whether the MA organization requests RADV payment error calculation appeal, or whether the MA organization requests both medical record review determination appeal and RADV payment error calculation appeal—and in each instance—the issues with which the MA organization disagrees, and the reasons for the disagreements. See proposed regulations at § 422.311(c)(6).

In proposed § 422.311(c)(5)(ii), we specify that while MA organizations may now elect to appeal either medical record review determination, payment error calculation, or both—they must notify CMS which issues they will appeal at the same time. This new provision replaces existing RADV appeals requirements regarding notification at § 422.311(c)(2)(iii) and § 422.311(c)(3)(iii)(C).

EXHIBIT D-18



TABLE 1 TO PARAGRAPH (a)(1)—Continued

Commodity	Parts per million
Coffee, green beans	0.03
Fennel, Florence, fresh leaves and stalk	20
Kohlrabi	4
Leaf petiole vegetable subgroup 22B	20
Leafy greens subgroup 4-16A	40
Papaya	1.5
Peppermint, dried leaves	0.8
Peppermint, fresh leaves	0.6
Spearmint, dried leaves	0.8
Spearmint, fresh leaves	0.6
Spice group 26	70
Vegetable, Brassica, head and stem, group 5-16	4
Vegetable, legume, bean, edible podded, subgroup 6-22A	4
Vegetable, legume, bean, succulent shelled, subgroup 6-22C	0.2
Vegetable, legume, pea, edible podded, subgroup 6-22B	4
Vegetable, legume, pea, succulent shelled, subgroup 6-22D	0.2
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E	0.7

¹ There are no U.S. registrations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS-4185-F2]

RIN 0938-AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule announces certain policies to improve program

integrity and payment accuracy in the Medicare Advantage (MA) program. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level MA Risk Adjustment Data Validation (RADV) program. Specifically, this final rule codifies in regulation that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018 and will not extrapolate RADV audit findings for PYs 2011 through 2017. We are also finalizing a policy whereby CMS will not apply an adjustment factor (known as a Fee-For-Service (FFS) Adjuster) in RADV audits. We are also codifying in regulation the requirement that MA organizations (MAOs) remit improper payments identified during RADV audits in a manner specified by CMS.

DATES: This final rule is effective on April 3, 2023.

FOR FURTHER INFORMATION CONTACT: Joseph Strazzire, 410-786-2775 or David Gardner, 410-786-7791.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

Contract-level Risk Adjustment Data Validation (RADV) audits are our main corrective action for overpayments made to Medicare Advantage organizations (MAOs) when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. The purpose of this final rule is to outline our audit methodology and related policies for the contract-level RADV program. Specifically, this final rule codifies in regulation our approach to the use of extrapolation, our decision to not apply an FFS Adjuster in RADV audits, and the payment years in which these policies will apply.

We are finalizing that, as part of the RADV audit methodology, CMS will extrapolate RADV audit findings. We are not adopting any specific sampling or extrapolated audit methodology, but will rely on any statistically valid method for sampling and extrapolation that is determined to be well-suited to a particular audit. Rather than applying extrapolation beginning for payment year (PY) 2011 audits as we proposed,

we are finalizing a policy whereby we will not extrapolate RADV audit findings for PYs 2011 through 2017 and will begin extrapolation with the PY 2018 RADV audit. As a result, CMS will only collect the non-extrapolated overpayments identified in the CMS RADV audits and Department of Health and Human Services Office of Inspector General (HHS-OIG) audits between PY 2011 and PY 2017, and will begin collection of extrapolated overpayment findings for any CMS and OIG audits conducted in PY 2018 and any subsequent payment year. We believe that this is an appropriate policy because it recognizes our fiduciary duty to protect taxpayer dollars from overpayments, and preserves our ability to collect on potentially significant amounts of overpayments made to plans beginning in PY 2018 using an extrapolation methodology. This final rule will also allow CMS to focus on conducting future RADV audits as soon as practicable after an MAO payment year concludes, which was the topic of significant public comment to the proposed rule. Lastly, we have determined that it is in the best interest of all parties to ensure that the contract-level RADV appeals process, which is also outlined in regulation, is able to successfully process all RADV appeals. By not using an extrapolation methodology prior to PY 2018, we expect to better control the total number of active appeals that are submitted in the first few years following finalization of this rule, which will alleviate burden on MAOs and CMS.

We are also finalizing a policy whereby CMS will not apply an FFS Adjuster in RADV audits because we have determined that an FFS Adjuster is not appropriate. As described at great length in this final rule, we have decided not to apply an FFS Adjuster in RADV audits because: (1) we believe, consistent with the D.C. Circuit's decision in *UnitedHealthcare Insurance Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. August 13, 2021, reissued November 1, 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140)), that the actuarial equivalence provision of the statute applies only to how CMS risk adjusts the payments it makes to MAOs and not to the obligation of MAOs to return improper payments (for example, payments for unsupported diagnosis codes); and (2) it would not be reasonable to read the Social Security Act (the Act) as requiring a reduction in payments to MAOs by a statutorily-set minimum adjustment in the coding pattern adjustment, while at the same

time prohibiting CMS from enforcing longstanding documentation requirements by requiring an offset to the recovery amounts calculated for CMS audits.

We are also codifying in regulation the requirement that MAOs remit improper payments identified during RADV audits in a manner specified by CMS. After the effective date of this final regulation, on a rolling basis (over a period of months, which will be communicated to MAOs by CMS), we will begin issuing the enrollee-level audit findings from the CMS RADV audits that have been completed, as well as recovering the enrollee-level improper payments identified in HHS-OIG audits.

Nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 869 (D.C. Cir. 2021) ("Neither Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer."). Nor does this rule change the longstanding obligation of an insurer to refund payments to CMS if it learns through any means that a diagnosis lacks support in the beneficiary's medical record. *Id.*

II. Background

A. General Overview of Risk Adjustment Payments in the MA Program

The Balanced Budget Act of 1997 (BBA), Public Law (Pub. L.) 105-33, established a new Part C of the Medicare program, known then as the Medicare+Choice (M+C) program, which became effective in January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for Medicare beneficiaries. These health plans provide all Medicare Part A and Part B (also known as "Original Medicare," or "Medicare FFS") benefits, and most offer additional benefits beyond those covered under the Medicare FFS program. The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), enacted in December 2003. The MMA updated and improved the choice of plans for beneficiaries under Part C and changed the way benefits are established and payments are made. As of August 2022, over 29 million individuals receive their

Medicare benefits through MA, which represents nearly half of the total Medicare beneficiary population.¹

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MAOs. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MAOs based on the health status and demographic characteristics of their enrolled beneficiaries, and that MAOs are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MAOs also ensures we are safeguarding Federal taxpayer dollars.

The current risk adjustment model employed to adjust MAO payments is known as the CMS Hierarchical Condition Category (CMS-HCC) model. This model functions by categorizing International Classification of Disease, Clinical Modification (ICD-CM)² diagnosis codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. There are approximately 9,875 diagnoses mapped to 86 HCCs in the CMS-HCC Risk Adjustment Model for 2022.³ MA enrollee HCCs are assigned based on data submitted to CMS by MAOs. The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee and the greater payment that is received by the MAO.

The CMS-HCC model was first used for payment in 2004 and has been recalibrated numerous times since then. When CMS recalibrates the CMS-HCC risk adjustment model, it uses data from Medicare FFS claims, using diagnoses in one year to predict the following year's expenditures. Claims data from beneficiaries enrolled in the Medicare FFS program are used to calibrate the CMS-HCC model, which produces a set of coefficients (also known as risk

¹ CMS, *CMS Fast Facts*, August 2022 Edition, pg.1, <https://data.cms.gov/sites/default/files/2023-08/4f0176a6-d534-47c1-b447-b074f014079a/CMSFastFactsAug2022.pdf>.

² The ICD-CM is a modification of the ICD, authorized by the World Health Organization, used as a source for diagnosis codes in the United States. The ICD-CM has been adopted by the Secretary as the standard medical data code set. See 45 CFR 161.1002.

³ Source: 2022 Midyear Final ICD-10 Mappings at <https://www.cms.gov/fileszip/2022-midyear-final-icd-10-mappings.zip>.

factors) that represent the marginal (additional) cost of each medical condition and demographic factor reported for a given beneficiary. (For additional information, see the Medicare Managed Care Manual, Ch. 7, section 70.1.4.) Each beneficiary's risk coefficients are added together to form a risk score for that beneficiary that is used to adjust the insurer's base payment rate for that beneficiary.

The diagnosis data that MAOs submit to CMS do not undergo a validation review by CMS before being relied on by CMS to calculate each enrollee's risk score and make payments. Because there is an incentive for MAOs to potentially over-code diagnoses to increase their payments, that is, to code diagnoses not properly substantiated by medical record documentation, CMS conducts post-payment audits of MAO-submitted diagnosis data from a selection of MAOs for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. These audits are called contract-level Risk Adjustment Data Validation (RADV) program audits. While RADV audits are intended to identify improper risk adjustment payments, they are not specifically designed to detect fraud,⁶ nor are they intended to identify all improper diagnosis submissions made by MAOs for risk adjustment payment.⁶

B. Purpose and Description of Contract-Level RADV Audits

The improper payment measurements conducted each year by CMS that are included in the HHS Agency Financial Report, as well as audits conducted by

the HHS-OIG, have demonstrated that the MA program is at high risk of improper payments. In fiscal year (FY) 2021 (based on calendar year 2019 payments), we calculated that CMS made over \$15 billion in Part C overpayments, a figure representing nearly 7 percent of total Part C payments.⁷ The HHS-OIG has also released several reports over the past few years that demonstrate a high risk of improper payments in the MA program,⁸ and for several years has identified the MA program as one of the top management and performance challenges facing HHS due to the high amount of improper payments.⁹ The Medicare program, including MA, has also been identified by the Government Accountability Office (GAO) as a high-risk program due to the risk of substantial improper payments.¹⁰

RADV audits are our main corrective action for overpayments made to MAOs when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. We select MAOs for RADV audits using a risk-based approach that focuses on HCCs that are more likely to be in error as identified by prior RADV audits, Part

C Improper Payment Measurements, and OIG findings, and other vulnerability analyses. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year and after CMS recalculates the risk factors for affected individuals to determine if payment adjustments are necessary, as described at 42 CFR 422.310(g).¹¹ RADV audits are intended to confirm the presence of risk adjustment conditions (that is, diagnoses that map to HCCs) as reported by MAOs in medical record documentation. RADV audits confirm the presence of the diagnoses related to the enrollee's HCC profile through the review of certain categories of medical records submitted by the MAOs for the purpose of a RADV audit; specifically, inpatient hospital, hospital outpatient facility, and physician/practitioner (excluding suppliers of durable medical equipment, prosthetics, orthotics, and supplies) medical records. Risk adjustment discrepancies are identified when an enrollee's HCCs used for payment, which are based on MAO self-reported data, differ from the HCCs assigned based on the medical record review performed by CMS through the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be used to calculate a total payment error estimate, for the larger universe of enrollees within an MAO contract from which a sample is drawn, within specified confidence intervals using statistical extrapolation.

C. History of the Contract-Level RADV Program

RADV audits have existed in various forms and approaches for over 20 years. RADV audits began for payment year (PY) 1999, when the amount of payment made to MAOs on a risk-adjusted basis was small (10 percent). During the audit period from PY 1999 until PY 2003, our RADV activity had an educational focus and was primarily intended to provide information that could be used by MAOs to improve the accuracy of the risk adjustment data submitted to CMS for payment. Payment adjustments (recoveries) were limited to enrollee-level adjustments for those enrollees sampled in the audits and were not extrapolated to the overall error of the

⁶ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/m180607.pdf>.

⁷ For example, the Department of Justice is responsible for pursuing potential violations of the False Claims Act, which includes certain elements of knowledge.

⁸ CMS contract-level RADV audits focus on specific MAO contracts to determine and recover improper payments. The HHS-OIG also undertakes audits of MAOs, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS-OIG audits, including the extrapolated amounts calculated by the OIG. CMS also oversees the Part C Improper Payment Measurement, previously referred to as "national RADV," to determine a program-wide improper payment rate as required by the Payment Integrity Information Act of 2019 (Pub. L. 116-117). In addition to risk adjustment oversight conducted by CMS, HHS also oversees HHS-RADV, which was created by the Affordable Care Act to strengthen the integrity of the Affordable Care Act Marketplace by validating the accuracy of data submitted by issuers that is used to calculate the amount of funds transferred to issuers based on the actuarial risks of the individuals they enroll. Neither the Part C Improper Payment Measurement nor the HHS-RADV programs are subject to the provisions of this final rule.

⁹ HHS, FY 2021 HHS Agency Financial Report, pg. 211, <https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf>. CMS made over \$23 billion in total Part C improper payments. The improper payment measurement for the MA program in FY 2021 included both overpayments (\$11 billion) and underpayments (\$8 billion).

¹⁰ For example, see reports: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. For example, see reports: Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, May 21, 2021, <https://oig.hhs.gov/oas/reports/region7/71901187.asp>; Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H3672) Submitted to CMS, February 24, 2021, <https://oig.hhs.gov/oas/reports/region3/21801628.asp>; Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contract H3916) Submitted to CMS, September 29, 2022, <https://oig.hhs.gov/oas/reports/region3/31900001.asp>; Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Criteron Health Plan, Inc., (Contract H4481) Submitted to CMS, July 18, 2022, <https://oig.hhs.gov/oas/reports/region2/22001009.asp>; Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS, February 3, 2022, <https://oig.hhs.gov/oas/reports/region7/71701189.asp>; Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1030) Submitted to CMS, April 19, 2021, <https://oig.hhs.gov/oas/reports/region7/71601165.asp>.

¹¹ For example, see OIG, 2021 Top Management and Performance Challenges Facing HHS, pg. 13, <https://oig.hhs.gov/reports-and-publications/top-challenges/2021/2021-tmc.pdf>.

¹² GAO, Medicare Program & Improper Payments, <https://www.gao.gov/highrisk/medicare-program-improper-payments>.

¹³ See the May 23, 2014 final rule titled "Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule" (79 FR 29843, at 29926) for a more detailed discussion of the timing and execution of the RADV audit and appeals process.

contract. As a result, for the few MA plans we audited, payment recovery amounts were small.

Risk adjustment payments using the CMS-HCC risk adjustment model began for the first time in PY 2004. Because of various risk adjustment payment methodology changes required in the BBA and the Benefits Improvement and Protection Act of 2009 (BIPA) (Pub. L. 111-154), we provided a payment "phase-in" under the new risk adjustment methodologies from 2000 to 2007, when MAOs' payments were 100 percent risk-adjusted under the current methodology.¹² Under the new methodology that began in PY 2004, MAOs were required to submit diagnoses from multiple sites of care, which increased the administrative data burden on MAOs. Because of this burden and the associated phase-in of the new methodology, CMS considered PYs 2004 through 2006 as pilot years for the purpose of the RADV program and did not seek to recover improper payments for those payment years based on the audit results.

Improper payment recovery resumed for PY 2007, when we conducted two sets of RADV audits: (1) Pilot 2007, which involved 5 MA contracts; and (2) Targeted 2007, which involved 32 MA contracts. CMS began with the Pilot 2007 audit to test the methodology and make any needed changes before conducting the Targeted 2007 audit. CMS selected MA contracts after measuring the weighted average change in disease scores (risk scores) over the preceding 3-year period and grouping MAO contracts as high, medium, or low relative to other MA contracts that were eligible for a RADV audit. Through these two sets of audits, we recouped \$13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the audits and not extrapolated to the overall contract error. After CMS' findings were reported to each MAO, any MAO that disagreed with CMS' determinations could challenge them through an administrative dispute and appeals process that was established by regulation (75 FR 19678). This dispute and appeals process, as subsequently amended (75 FR 32858 and 79 FR 29844), remains in effect and allows for the appeal of the medical record review determination and/or the payment error calculation through a three-level administrative review process, as

outlined in 42 CFR 422.311. To date, CMS has not recovered based on RADV audit findings for audit years after PY 2007, as described more fully in this section of this rule.

1. Development of an Audit Methodology (PYs 2007 Through 2010)

After the RADV audits were conducted for PY 2007, CMS paused RADV audits for PYs 2008, 2009, and 2010. CMS used those years to continue refining the methodology for the RADV audits, including the consideration of statistical methods to calculate extrapolated improper payments based on the individual errors identified. The use of extrapolation would enable us to make contract-level payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we published an informal proposal on the CMS website that outlined our intended RADV methodology for: (1) selecting a statistically valid sample of enrollees from each audited MA contract; and (2) calculating a contract-level payment adjustment by extrapolating the results of that sample. We invited public comment on this proposed methodology.

2. Informal Proposal Comments and the FFS Adjuster

In response to the December 2010 informal proposal, some MAOs suggested that CMS cannot lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at the published rates. These MAOs argued that there is a difference in auditing standards between Medicare FFS and MA diagnosis data because, in contrast to the MAO-submitted diagnoses data, Medicare FFS data is "unaudited" by CMS. This difference purportedly exists because most FFS payments are made on the basis of the item or service provided and not the beneficiary's diagnosis or diagnoses. For example, an office visit is paid based on whether the evaluation and management service billed met Medicare coverage and payment rules, not based on what diagnoses are listed on the claim or in the medical record. As a result, they argued, the Medicare FFS data used to calculate MAO payments will understate the cost of treating various conditions and, because erroneous diagnoses in the FFS claims data are used to calibrate the MA payment model, CMS must either adjust payment rates (by raising them) or adjust documentation standards (by loosening

them) to resolve the alleged incompatibility between the payment rates and documentation standards. This proposed adjustment to the MAO payment rates and/or documentation standard is referred to as an "FFS Adjuster."

To understand the MAOs' argument about why an FFS Adjuster is needed, some background is important. These MAOs ground their arguments in section 1853(a)(1)(C)(i) of the Act, which requires the Secretary to adjust payments to MAOs for demographic and health-related risk factors so as to ensure "actuarial equivalence." As described previously, the Act requires that we calculate risk-adjusted payments to MAOs to ensure that MAOs are paid appropriately based on the enrollees' health status and demographic characteristics. The current risk adjustment model does this by calculating plan enrollees' risk scores and, in turn, using them to adjust the MAOs' base payment rates, which are the rates for the average beneficiary.

This system of risk adjustment rests on two important principles. First, MAOs' payments are calculated using the CMS-HCC risk adjustment model, which is published each time it is updated (see section 1853(b) of the Act).¹³ Second, an MAO may only report a diagnosis when that diagnosis is properly supported by the beneficiary's medical records. As we noted in our April 15, 2022 Health Plan Management System (HPMS) memorandum, *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*, MAOs must submit data that conforms to all relevant national standards, including the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Guidelines for Coding and Reporting requirement that diagnoses be documented in patients' medical records. (See 42 CFR 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3).) The diagnosis codes and other risk adjustment information that MAOs submit directly affect the calculation of CMS payments to the MAO. A diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 869, 877 (D.C. Cir. 2021). Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency policy

¹² CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates*, 4-5 (March 28, 2003), <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf>.

¹³ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents>.

documents, including the Medicare Managed Care Manual.¹⁴ In their annual contracts with CMS, MAOs agree to operate in accordance with applicable Federal statutes, regulations, and policies, including policies described in the Medicare Managed Care Manual. MAOs are also required to submit a sample of medical records for the validation of this risk adjustment data, as required by CMS (see 42 CFR 422.310(e)).

3. The 2012 Methodology

The feedback received from industry in response to the informal proposal in 2010 was considered by CMS, and on February 24, 2012, we issued on our website¹⁵ what we described as a final methodology for RADV contract-level payment error calculation, to begin with PY 2011 RADV audits (referred to herein as the "2012 methodology"). That methodology described sampling techniques and a statistical calculation to extrapolate from the sample selected, as well as the use of an FFS Adjuster.¹⁶ (Although the use of an FFS Adjuster beginning with PY 2011 RADV audits was included in the 2012 methodology, CMS has not issued final RADV audit results for PY 2011 audits or any subsequent year, and therefore, an FFS Adjuster has not been applied to any RADV audits issued by CMS to date.)

Sampling Technique: Under the 2012 methodology, up to 201 enrollees from each audited MA contract would be selected according to certain criteria. These criteria included, but were not limited to, the enrollee's: (1) continuous enrollment in the MA contract for the entire data collection year and January of the payment year; (2) lack of end-stage renal disease (ESRD) or hospice status for the entire data collection year and January of the payment year; (3) enrollment in Medicare Part B coverage for the entire data collection year; and (4) assignment of at least one CMS-HCC based on diagnoses submitted by the MAO for risk-adjustment payment. The RADV-eligible enrollees would then be ranked by risk score and divided into three equal strata (low risk score, average risk score, and high risk score), with an equal number of enrollees randomly selected from each stratum

(for example, 67 enrollees per stratum in the case of an audit of 201 enrollees).

Payment Error Calculation: After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and also was not in ESRD or hospice status) during the payment year. A payment error amount for each stratum would be calculated, which could include both RADV-identified overpayments and underpayments, and an overall payment error estimate for the audited contract would be derived, along with a 99 percent confidence interval around the payment error estimate.

FFS Adjuster: As part of the 2012 methodology, we also stated that we would apply an FFS Adjuster before finalizing audit recovery. The 2012 methodology stated that the actual value of the FFS Adjuster would be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

CMS subsequently conducted an extensive study regarding the impact of such errors in Medicare FFS claims data for the purpose of determining the appropriate value of an FFS Adjuster. This study found that, in fact, errors in Medicare FFS claims data did not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model and, therefore, did not have any systematic effect on the payments made to MAOs. On October 26, 2018, we published an Executive Summary and Technical Appendix of our FFS Adjuster study findings on the CMS website, which are available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html>. Additional information on this study can also be found in the November 2018 proposed rule.

4. The 2018 RADV Proposed Rule

In the 2018 proposed rule, to enhance transparency and provide ample notice to MAOs, we proposed to codify in regulation our methodological approach to RADV audits that would apply to all of the payment year audits that have not yet been finalized. These methodologies would apply to PY 2011 and subsequent years and include our proposals to use extrapolation and not apply an FFS Adjuster to our RADV audit findings.

5. Subsequent Federal Register Notices (2018, 2019, 2021, and 2022)

Since publication of the 2018 proposed rule, we have published

several related notices to further enhance transparency and encourage robust public comment:

- On December 27, 2018, we announced in the *Federal Register* (83 FR 56681) an extension of the comment period for the proposed RADV provisions until April 30, 2019, as well as a plan to release data underlying the October 26, 2018, FFS Adjuster Study.¹⁷
- On March 6, 2019, we issued a notice in the *Federal Register* (84 FR 8069) announcing the release of additional data underlying the FFS Adjuster Study, both on the CMS website and to those organizations who established data use agreements (DUAs) with the CMS Office of Enterprise Data Analytics (OEDA).¹⁸
- On April 25, 2019, we posted updates to existing documentation related to the study data, as well as additional data on the CMS website.¹⁹
- On April 30, 2019, we issued a notice in the *Federal Register* (84 FR 18215) granting an additional extension of the comment period for the proposed RADV provisions until August 28, 2019. We also announced that we would be releasing additional data underlying the FFS Adjuster study, including data containing Protected Health Information (PHI), to all parties who entered an applicable DUA with CMS and paid the required fee.²⁰
- On June 28, 2019, we issued a notice in the *Federal Register* (84 FR 30983)²¹ that we replicated the FFS Adjuster Study and published a summary of that replication as an addendum to the study on the CMS website.²² The purpose of this replication was to allow us to test our initial results and release a more complete set of underlying data. (Certain intermediate data elements, not saved as part of the implementation of the initial study, were preserved and published in the addendum.) The

¹⁷ <https://www.federalregister.gov/documents/2018/12/27/2018-28070/medicare-and-medicaid-programs-risk-adjustment-data-validation>.

¹⁸ <https://www.federalregister.gov/documents/2019/03/06/2019-04052/medicare-program-release-of-data-underlying-risk-adjustment-data-validation-provisions>.

¹⁹ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/NPDM-4185-Provisional-Data-Release-CPI-FFSA-Coefficients.xlsx>.

²⁰ <https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limited-datasets/>.

²¹ <https://www.federalregister.gov/documents/2019/06/28/2019-13091/medicare-and-medicaid-programs-risk-adjustment-data-validation>.

²² <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html>.

¹⁴ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOIMs-Items/CMS0219328>.

¹⁵ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-part-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf>.

¹⁶ *Id.* at 4-6.

results of the replication were broadly consistent with the initial implementation of the study. In addition, the addendum contained further discussion of the study's assumptions and methodology. We also released the programming language used to implement the replication of the study, and a description of the technical requirements for use of that programming language.

• In the October 21, 2021 *Federal Register* (86 FR 58245), we issued a notice that provided a 1-year extension of the timeline for publication of the final rule.²³

As part of this extension, we explained our determination that we were unable to meet the 3-year timeline for publication.²⁴ Based on extensive public comments received on the 2018 proposed rule and subsequent FFS Adjuster study and related data, along with delays resulting from the agency's focus on the COVID-19 public health emergency, we determined that additional time was needed to address the complex policy and operational issues that were raised. As such, we

extended the timeline to publish the final rule from November 1, 2021 to November 1, 2022.

• In the November 1, 2022 *Federal Register* (87 FR 85723), we issued a notice that provided a 3-month extension of the timeline for publication of the final rule.²⁵ We explained that we were unable to meet the November 1, 2022, timeline for publication of the previously referenced RADV-audit related provisions. We explained that we continued to have ongoing delays resulting from the agency's focus on the COVID-19 public health emergency, and we determined that additional time continued to be needed to address the complex policy and operational issues that were raised. As such, we extended the timeline to publish the final rule from November 1, 2022, to February 1, 2023.

We received approximately 154 timely pieces of correspondence in response to the 2018 proposed rule and the subsequent notices and data releases. Summaries of the public comments that respond to the RADV provisions, and our responses to those public comments, are set forth in the discussion that follows. Additional public comments outside of the scope of the RADV proposed provisions were not considered and are not addressed in this final rule.

III. Provisions of the RADV Final Rule

A. Extrapolation of RADV Audit Findings

1. Use of Extrapolation in the Medicare Program

Extrapolation, or the act of estimating a value (such as an overpayment amount for a Medicare provider) based on a statistically valid sample of units (such as Medicare claims), has historically been a standard part of auditing practice at CMS. There is significant guidance, including case law and best practices from HHS and other Federal agencies, stating that extrapolation may be utilized as a valid part of calculating improper payments. In particular, courts have held that sampling and extrapolation are a valid method of calculating improper Medicare payments, so long as statistically valid methods are used. See *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005) (noting that "sampling of similar claims and extrapolation from the sample is a recognized method of proof" for the

United States in an affirmative case seeking recovery under a common-law theory). See also *Ratanasen v. California Dep't of Health Serv.*, 11 F.3d 1467, 1469–71 (9th Cir. 1993) (collecting cases in which sampling and extrapolation have been approved in the Medicaid context, and "join[ing] other circuits in approving the use of sampling and extrapolation as part of audits in connection with Medicare and other similar programs"); *Chaves Cnty. Home Health Serv. v. Sullivan*, 931 F.2d 914, 917–23 (D.C. Cir. 1991). The authority to use sampling and extrapolation in Medicare audits is grounded in our statutory and regulatory authority to audit providers and recoup improper payments. See *Chaves*, 931 F.2d at 919 (interpreting the Medicare statute to allow for a "sample adjudication procedure" followed by extrapolation from that sample, which "is reasonable given the logistical imperatives recognized by courts in other comparable circumstances").

Sampling and extrapolation have been used to calculate improper payments in Medicare FFS (Part A and Part B) for decades. CMS formally approved of this technique in 1986 (HCFA Ruling 86–1), but Medicare Administrative Contractors (MACs), which are responsible for determining medical necessity and paying Medicare FFS claims, have been using it "at least since 1972." *Chaves*, 931 F.2d at 921; see *id.* at 913 (explaining that "sample adjudication has been used in previous instances involving post-payment review of 'coverage determinations' under Part A," and that HCFA Ruling 86–1 "simply reiterated [the agency's] belief that it had the latitude to employ sample audits on post-payment review to efficiently recoup overpayments for non-covered services"). In 1991, the United States Court of Appeals for the District of Columbia Circuit, in *Chaves*, upheld the use of this audit methodology against arguments that the Medicare statute required individualized review of claims submitted by providers (*id.* at 922).

The MMA imposed limits on the use of sampling and extrapolation in Medicare payment decisions in the context of Part A and Part B, when a settlement to resolve improper payments is not reached. Since 2003, Medicare Part A and Part B extrapolation under section 1893(f)(3) of the Act has been limited to instances in which the Secretary determines either that "there is a sustained or high level of payment error" or that "documented educational intervention has failed to correct the payment error." No similar limitation applies to the MA program,

²³ <https://www.federalregister.gov/documents/2021/10/21/2021-22908/medicare-and-medicare-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

²⁴ Section 1871(a)(3)(A) of the Act requires the Secretary to "establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation." Section 1871(a)(3)(B) of the Act provides that "[e]ach timeline . . . shall not be longer than 3 years except under exceptional circumstances." The Secretary therefore may not "establish" a "regular timeline" for the finalization of a proposal or interim final rule that exceeds three years, absent exceptional circumstances. Section 1871(a)(3)(B) of the Act authorizes the Secretary to "vary such timeline"—that is, to alter the "regular timeline" initially "established" for finalization—by publishing a timely notice in the *Federal Register* with "a brief explanation of the justification for such variation." As we have said, "[i]f the Secretary may extend the initial targeted publication date of the final regulation, if the Secretary provides public notice including a brief explanation of the justification for the variation no later than the regulation's previously established proposed publication date." 69 FR 78443.

Under the plain text of the Act, no "exceptional circumstances" are required for the Secretary to extend the initial targeted publication date of the final regulation, but only "a brief explanation of the justification" for doing so. The Secretary has often extended such timelines without any reference to "exceptional circumstances." (See 66 FR 50363; 85 FR 55385; 85 FR 52940; 85 FR 7; 79 FR 62356; 74 FR 8867; 72 FR 16794; 72 FR 18710.) But the Secretary has also said that the Act "permits an extension of a published timeline under exceptional circumstances," 69 FR 78442, and has invoked "exceptional circumstances" in extending such timelines, including in the notices published in this rulemaking. For the reasons explained in this notice, the Act has never required exceptional circumstances for such extensions—though exceptional circumstances have often been present, as they were here, when such timelines have been extended.

²⁵ <https://www.federalregister.gov/documents/2022/11/01/2022-23563/medicare-and-medicare-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

As previously discussed, sampling and extrapolation is a generally accepted audit technique in the Medicare context, and the Act does not apply any limits to the use of extrapolation in the MA program. Therefore, we believe that CMS has the authority to implement this audit methodology in RADV audits for any case in which a RADV audit identifies improper risk-adjusted payments. We also believe that this is a reasonable approach to our RADV audits, given the sustained and high level of risk adjustment payment error, as previously described.

2. Summary of Proposed Rule

In the 2018 proposed rule, CMS proposed to extrapolate contract-level RADV audit findings using statistically valid random sampling techniques. CMS proposed to extrapolate findings in PY 2011 and all subsequent payment years, but specifically sought comment on how to treat the audits for PYs 2011, 2012, and 2013. In the proposed rule, we explained that we had conducted RADV audits for PYs 2011–2013 according to the sampling and extrapolation methodology described in the 2012 methodology but that these audits were not yet finalized because we had not yet issued the audit findings to the MAOs.²⁶ For PYs 2011 through 2013, we estimated that audited MA contracts received \$650 million in improper payments.

In the 2018 proposed rule, we stated that, given the amount of improper payments identified under the MA program, interest in determining an accurate recovery amount for each audited MA plan, and importance of protecting the overall integrity of the program, we believed that it was in the public interest for CMS to apply the RADV payment error methodology(ies) adopted through this rulemaking to PY 2011 and all subsequent years. We stated that CMS would be acting in compliance with the improper payment obligations under the Act (most recently updated as part of the Payment Integrity Information Act of 2019 (PIIA)), as well as our fiduciary responsibility to recover funds due to the Medicare Trust Funds. We also noted that our February 2012 publication put MAOs on notice that CMS expected to calculate a contract-level payment error for PY 2011 and subsequent payment years by extrapolating from its review of a statistically valid sample of enrollees, and that MAOs have never been entitled to receive or retain payments associated

with HCCs that cannot be validated by medical records.

We also proposed that MAOs would be required to remit extrapolated recovery amounts from RADV audit findings through CMS' payment system, the Medicare Advantage and Prescription Drug system (MARx), as offsets to MA plans' monthly capitation payments. In the event that the recovery amount exceeds the payment in one month, we proposed that the recovery would be spread across adjustments for multiple months until the full amount is recovered. We also proposed that CMS might likewise require MAOs to remit such recovery amounts based upon audit findings by the HHS-OIG.

We explained in the 2018 proposed rule that CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions. However, we explained that, in the interest of transparency, we were choosing to inform MAOs about our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate, through rulemaking.

In addition to codifying in regulation our existing authority to use extrapolation techniques in the RADV context, we also used the 2018 proposed rule as a means to gather public feedback on sampling methodologies that could be employed for purposes of extrapolation. We explained that, in addition to the contract-level approach described in the 2012 RADV Methodology, we have identified other potential methodologies for sampling and extrapolation that are based on a particular sub-cohort or sub-cohorts in a given payment year. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported.

TABLE 1—DIABETES HCCs

HCC category description	HCC
Diabetes with acute complications ...	17
Diabetes with chronic complications	18
Diabetes without complication	19

After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees in the sub-cohort or sub-cohorts. After reviewing these enrollees' medical records that are submitted by the MAO, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for all enrollees in the sub-cohort or sub-cohorts in that payment year.

We noted in the 2018 proposed rule that using a sub-cohort methodology, such as one focused on enrollees with high-risk HCCs, could allow us to use a much smaller sample size to calculate a statistically valid extrapolated improper payment amount. This is possible because, when selecting a sample from a smaller population (that is, a sub-cohort of enrollees), one can still achieve an acceptable level of statistical confidence with that smaller sample size. This sub-cohort-based audit methodology would also allow us to spread our audit resources across a wider range of MA contracts and focus on cohorts of enrollees that raise programmatic concerns, while also reducing operational burden on both CMS and the MAOs due to the reduced sample size needed to calculate improper payments.

In the 2018 proposed rule, we invited comment on both the contract-level audit methodology published in February 2012 and our proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also sought comment on whether there are particular situations in which one methodology may be preferable to the other. We emphasized that neither proposed methodology was meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology. We also stated that, if we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would announce any future changes to that methodology (or those methodologies) through the Health Plan Management System (HPMS).

In addition, we stated that we may begin to conduct RADV audits for PYs 2014 and 2015 before finalizing the policies in the proposed rule, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup improper payments identified. We also sought comment on whether the use of sampling and extrapolation for certain payment years would require the exercise of our statutory authority to engage in retroactive rulemaking, as set out in section 1871(e)(1)(A) of the Act, which authorizes retroactive application of rules where "failure to apply the change would be contrary to the public interest."

We also discussed proposed changes to our RADV dispute and appeals regulations in 42 CFR 422.311 to conform with the finalized RADV provisions. Specifically, consistent with

²⁶ See 83 FR 55038.

our other proposed policies, we proposed to amend § 422.311 by adding language to clarify that recovery of improper payments from MAOs will be conducted according to the Secretary's payment error extrapolation and recovery methodologies, and that CMS will apply extrapolation to RADV audits beginning with PY 2011. We also requested comment on whether to explicitly expand the MAOs' RADV appeal rights, such as by permitting appeal of the RADV payment error calculation methodology used in a RADV audit, similar to practices in Medicare FFS. A summary of the comments received and our responses follow.

3. Summary of Public Comments

Comment: Several commenters supported CMS' proposal to use extrapolation in RADV audits, as well as our proposal to begin extrapolation for PY 2011 audits. Commenters indicated that this is the most effective way to address improper payments in MA.

Response: We thank commenters for their support. While we plan to finalize our proposal to apply extrapolation to RADV audits, we are making a change to the years in which to apply extrapolation to achieve what we believe is an appropriate final policy that still takes into consideration our obligation to address potentially significant improper payments in the MA program. Extrapolation will now begin with the PY 2018 RADV audits rather than PY 2011, as proposed. This change, as further described in this section of this rule, is being made due to our fiduciary duty to protect taxpayer dollars from overpayments, certain operational considerations, and public comments on the timeliness of RADV audits.

Comment: Several commenters opposed the use of extrapolation in RADV audits. Some commenters questioned whether we had the statutory authority to use sampling and extrapolation in RADV audits. These commenters suggested that, because section 1893(f)(3) of the Act grants CMS the authority to use sampling and extrapolation in certain circumstances when conducting audits in Medicare Part A and Part B, CMS cannot use those techniques in Part C audits without an equivalent grant of statutory authority.

Several commenters challenged the statistical and methodological validity of both the contract-level sampling and extrapolation techniques described in the 2012 methodology, as well as an approach based on sub-cohorts of enrollees. A commenter stated that it is more difficult for plans to determine

results from extrapolation in MA than in Medicare FFS because RADV audits can include the review of multiple medical records to validate one diagnosis from various providers with "disparate methods of documentation."

Some comments focused on the application of extrapolation beginning in PY 2011. Several commenters asserted that increased liabilities of MAOs from retroactive application of an extrapolated payment error recovery would deter future participation by MAOs in the MA program and reduce benefits to beneficiaries. Several commenters expressed concern that extrapolation for past payment years will destabilize physician care. Specifically, the concern is that providers participating in risk-sharing contracts with MAOs that have not yet completed a final settlement may be at risk for losses. The same commenters believe that recovering improper payments when the audit methodology has been revised several times is inequitable to the MAOs.

Response: We appreciate these comments and considered them when finalizing the timing and content of these extrapolation policies. As discussed previously, CMS has the authority to use sampling and extrapolation in its RADV audits. Federal courts have held that sampling and extrapolation are a valid method of calculating improper Medicare payments, so long as statistically valid methods are used. The MMA added section 1893(f)(3) of the Act, which specifically applies to Medicare Part A and Part B and limits the use of extrapolation to determine overpayment amounts for recoupment under certain circumstances. This provision did not confer new authority to use extrapolation, but limited our preexisting audit authority in Medicare Part A and Part B. No similar limitation has been applied to audits in Medicare Part C. However, CMS will continue to focus its RADV efforts on MAOs identified as being at higher risk of improper payments.

In the implementation of this authority to use sampling and extrapolation in RADV, CMS will employ statistical methods to determine statistically valid sample sizes, accurately identify payment error, and extrapolate to the universe of enrollees from which the sample is selected. These statistically valid methods may include applying one or more RADV audit methodologies for any given RADV audit. In addition, while CMS views extrapolation as a statistically valid methodology for RADV audits, the agency may, at times, use its discretion

to not utilize extrapolation in a particular instance. For example, there may be unforeseen circumstances in which the statistical validity of the sample is disturbed (such as the need to exclude a large number of cases from the sample due to the loss of medical records in a natural disaster) and extrapolation is no longer possible, despite the initial intent to do so. There may be other limited instances in which CMS seeks to collect overpayments associated only with enrollees in a given sample, or wishes to perform only a probe sample of RADV reviews without the use of a statistically valid sample and yet will seek to recover any identified, non-extrapolated overpayments. The OIG may also independently decide not to extrapolate for reasons outside the control of CMS, and CMS will still recover those overpayments in accordance with the provisions in this final rule. To account for this, we are finalizing § 422.311(a)(2) to read "CMS *may* (emphasis added) apply extrapolation to audits for payment year 2018 and subsequent payment years," rather than "CMS will apply extrapolation . . ." as proposed. This language is not intended to signal that it would be a frequent occurrence to not extrapolate in PY 2018 and future audits; rather, extrapolation is expected to be the standard practice for RADV audits beginning in PY 2018.

As previously stated, we believe that it is in the best interest of the Federal Government and our efforts to protect taxpayer dollars to extrapolate in our RADV audits, given the substantial amount of improper payments in MA and the fact that RADV is CMS' main corrective action used to address the submission of inaccurate diagnosis data. However, we also have decided not to extrapolate for PY 2011 through 2017 audits, as originally proposed, due to certain operational considerations and public comments on the timeliness of RADV audits. The reasoning for this decision is discussed in greater detail later in this final rule.

In addition, we do not agree with the comment that RADV audits include the review of multiple medical records with "disparate methods of documentation." We reemphasize that the policies we are finalizing in this rule do not impose new documentation requirements on providers. The core component of a RADV audit is ensuring that all diagnoses reported to CMS are properly supported by medical record documentation. CMS' existing regulatory documentation standards, 42 CFR 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3), including the RADV-specific authority to validate risk

adjustment data through the review of a sample of medical records at § 422.310(e), remain unchanged under this final rule and are described in current agency policy documents, including the Medicare Managed Care Manual (with which MAOs agree, in their MA contracts, to comply). MAOs are also already required to ensure that contracted providers meet MA documentation requirements.

We respectfully disagree with commenters' assertions that liabilities will increase. We are not imposing additional liabilities, penalties or retroactive application of new requirements or policy. We only seek to recover improper payments received by MACs for HCCs that are not substantiated by enrollees' medical records. We continue to rely on existing program methods to establish auditing practices that encourage proper payment recovery consistent with established audit practices. We recognize that MAOs enter into agreements with providers, including those with a risk-sharing component, and we encourage all parties to those agreements to take steps to mitigate the submission of diagnosis codes that are not properly supported in the medical record.

We emphasize that nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. Nor does this rule change the longstanding obligation of an insurer to refund payments to CMS if it learns that a diagnosis lacks support in the beneficiary's medical record.

Comment: Many comments were received on the proposed extrapolation methodologies, mainly focused on our proposed sub-cohort approach. Some commenters requested clarity on the sub-cohort methodology, while others expressed support for this methodology with various suggestions to improve it. Commenters questioned whether the proposed sub-cohort methodology will replace the existing contract-level methodology, which utilizes a general, non-targeted sampling methodology, and how CMS will determine which HCC groups will be used in the identification of sub-cohorts. A commenter requested that CMS confirm whether RADV will consist of a single audit methodology or whether MAOs will be subject to multiple audit methodologies.

Some commenters believe that applying a sub-cohort extrapolation methodology of enrollees would produce inaccurate results in RADV

audits because of differences between plans with regard to size and risk characteristics. For example, several commenters argued that plans with a higher than average risk score are at increased risk for RADV audit because high-risk enrollees are more likely to have more HCCs. Other commenters believe that a small sample size, which CMS sees as a benefit of a sub-cohort methodology, will result in inaccuracies. Others commented that an extrapolation methodology based on sub-cohorts of enrollees would violate the statutory mandate of "actuarial equivalence" between payments made under MA and Medicare FFS because it would generate recoveries based on random outcomes without regard to specific characteristics of MA plans' diagnostic mix, enrollment size, and risk scores. A commenter requested that, if CMS adopts a sub-cohort extrapolation methodology, it uses a pilot period first before implementing the program on a large scale and extrapolating results.

Other comments spoke to extrapolation methods more generally, including the appropriate confidence interval, potential for plans of certain sizes to be unduly chosen for RADV audits, and perceived inability to assess potential liability for RADV audits already performed if CMS abandons the extrapolation methodology set forth in the 2012 methodology.

Other comments on our proposed extrapolation methodologies were focused on the impact of underpayments. A commenter objected to the RADV audit sampling methodology, arguing that it results in a purported payment recovery bias against MAOs. The commenter believes the results of the RADV audit sample are "asymmetric," thus incorrectly representing the improper payment rate. More specifically, the commenter asserted that "[t]hrough there is no upper limit for how high the payment recovery amount can be, there is no balancing negative recovery amount." In other words, the commenter objected that MAOs cannot receive a payment from CMS based on a RADV audit if, overall, the risk scores should have been higher because, for instance, there were more supported diagnoses that had not been submitted (that is more under-coding) than unsupported diagnoses that had been submitted (that is over-coding). Other commenters shared these concerns, as well as voiced concern that RADV audit samples do not account for the reported bias that exists for enrollees who have no diagnosis codes submitted during the year but have existing documentation to support a diagnosis

that could have been submitted. The same commenters perceive the audit methodology as being random and indiscriminate, believing that the results will incorrectly estimate the risk profile of enrollees.

A commenter requested information related to the sampling methodology used to select enrollees for the PY 2014 RADV audit. Specifically, the commenter requested details on the development of the regression model used to predict payment error and on the sampling criteria from which the RADV audit currently extrapolates. This commenter also contended that the PY 2014 methodology appears to maximize the probability of selecting individuals with coding errors.

Response: As previously explained, extrapolation is an established auditing practice and remains a valid method for addressing audit recoveries. In this final rule, we are clarifying the scope of our authority to strengthen the integrity of the MA program by identifying improper payments. Our initiatives are designed to ensure fair and accurate recovery efforts by focusing on the areas at highest risk of improper payments. We will use statistically valid methodologies to extrapolate improper payment findings to the universe of enrollees from which a sample is selected. These statistically valid methodologies may include applying one or more RADV audit methodologies for any given RADV audit. As previously discussed, we may also determine that extrapolation will not be applied in certain limited instances. We emphasize that, in this final rule, we are not adopting either the contract-level sampling and extrapolation technique described in the 2012 methodology or a specific extrapolated audit methodology based on sub-cohorts of enrollees. Instead, for future RADV audits, CMS will rely on any statistically valid method for sampling and extrapolation that it determines to be well-suited to a particular audit. We described the sub-cohort methodology in the 2018 proposed rule to provide the industry with transparency on potential audit methodologies. In addition, while not required, CMS will continue to disclose our extrapolation methodology to MAOs through HPMS memos or other appropriate means, providing MAOs with the information sufficient to understand the means by which CMS extrapolated the improper payment determination.

Any sampling and extrapolation methodologies adopted by CMS for RADV audits will be focused on MAO contracts and enrollees' HCCs that, through statistical modeling and/or data

analytics, are identified as being at highest risk for improper payments. This is an appropriate approach to any Federal MA audit that seeks to recoup taxpayer dollars that have been inappropriately paid to MAOs for diagnoses that are not supported in the medical record. This approach was also recommended by the GAO in a 2016 report titled "Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments."²⁷ The GAO recommended that CMS "modify [its] selection of contracts for contract-level RADV audits to focus on those contracts most likely to have high rates of improper payments by taking actions such as the following: selecting more contracts with the highest coding intensity scores; excluding contracts with low coding intensity scores; selecting contracts with high rates of unsupported diagnoses in prior contract-level RADV audits; if a contract with a high rate of unsupported diagnoses is no longer in operation, selecting a contract under the same MAO that includes the service area of the prior contract; and selecting some contracts with high enrollment that also have either high rates of unsupported diagnoses in prior contract-level RADV audits or high coding intensity scores."²⁸

We also note that the purpose of RADV audits is to validate that diagnoses submitted by MAOs for risk-adjusted payment are properly supported by medical record documentation. See 42 CFR 422.310(e). RADV audits are the main corrective action used to address the submission of inaccurate diagnosis data. Occasionally, upon review of these medical records, CMS will uncover "additional" diagnoses supported by the medical records that were not submitted for payment by MAOs during the data collection period for enrollees selected in the sample. Under current contract-level RADV policy, when CMS uncovers these additional diagnoses that map to CMS-HCCs during medical record review of audited CMS-HCC(s), these newly-discovered diagnosis codes are used to recalculate risk scores in certain circumstances, which may result in an updated (reduced) improper payment calculation.

MAOs are required by CMS regulations (§§ 422.503 and 422.504) and MAO contracts to establish compliance programs and processes to ensure accurate diagnosis coding and

the submission of accurate diagnosis data. These processes should enable MAOs to identify not only instances where diagnoses submitted for risk-adjustment payment are not supported by the medical record, but also diagnoses that may not have been submitted to CMS. MAOs can submit additional diagnoses for risk-adjusted payment up until the final risk adjustment data submission deadlines described at § 422.310(g)(2)(ii). As with overpayment recoveries under the Affordable Care Act and CMS's Overpayment Rule, the purpose of RADV audits is not to reopen submission deadlines and for CMS to make additional payments.²⁹ RADV audits identify overpayments after the final risk adjustment data submission deadline.

Comment: Some comments were focused on the scope and number of plans selected for RADV audit. A commenter objected to an increase in the number of plans selected for the RADV audits. Another commenter requested an explanation of how sample sizes will be determined for Program of All-Inclusive Care for the Elderly (PACE) organizations, most of which have fewer than 500 enrollees.

Response: As previously described, any extrapolation methodology adopted by CMS for RADV audits will be focused on MAO contracts that, through statistical modeling and/or data analytics, are identified as being at highest risk for improper payments. Examples of MAO contracts that may be deemed higher risk for the purposes of RADV audit selection are discussed later in this section. This is also the best approach to ensure that MAOs that do not show indications of being at high risk of improper payments are not exposed to audit burden to the exclusion of higher-risk plans. In addition, as noted previously, such an approach was recommended by the GAO in its April 2016 report.³⁰ CMS does not currently subject PACE organizations to RADV audits and CMS' selection methodology for each year will

describe any adjustments made for PACE or other low enrollment contracts.

Comment: Several commenters noted that implementing these proposed policies would lead to more audit burden for providers because of an increase in documentation standards for treating providers. For example, commenters believe that this is a "more stringent audit expectation" that will increase administrative burden at a time in which there is already a physician shortage, thereby impacting patients. Another commenter contended that our extrapolation methodology should reflect that certain HCCs are more difficult to substantiate in medical record documentation than others.

Response: RADV audits will not impose new documentation requirements on health care providers and, therefore, we believe there will be no additional audit impact on providers that contract with MAOs to provide services to MA plan enrollees. As previously stated, nothing in this rule changes the longstanding principle that a diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MAO. In addition, there is a longstanding requirement under § 422.310(e), in place since the beginning of the MA program, that "[MAOs] and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS," which is unaffected by this final rule. This requirement is consistent with longstanding requirements applicable to Medicare Part A and Part B providers that they furnish sufficient information to support payment. 42 U.S.C. 1395(g) (Effective July 7, 2004) ("[No] . . . payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider . . ."); *Clinic Res. Mgmt. v. Burwell*, 2015 WL 3932857, at *2 (S.D. Tex. June 26, 2015) ("The provider is responsible for maintaining and submitting adequate information to substantiate medical necessity and entitlement to payment.");³¹

²⁷ Under section 1853(a)(3) of the Act, the Secretary must require MAOs to submit data regarding inpatient hospital services and other services, as well as other information as the Secretary deems necessary to calculate MA risk adjustment payments. This authority has been implemented at § 422.310, which requires MAOs to submit "data necessary to characterize the context and purposes of such item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner." § 422.310(b). MAOs must submit data that conforms to CMS' requirements for data equivalent to Medicare FFS

²⁷ GAO, at 26, <https://www.gao.gov/assets/gao-16/78.pdf> (April 2016).

²⁸ *Id.*

²⁹ Section 6402 of the Affordable Care Act (Pub. L. 111-148) established section 1126(d) of the Act. Under the Part C and D Overpayment Rule (79 FR 29844), which implemented section 6402 of the Affordable Care Act, MAOs are required to correct overpayments by self-reporting and returning payments associated with MAO diagnosis codes not supported by medical record documentation. Although MAOs are required to correct identified overpayments after the final risk adjustment data submission deadline in order for CMS to conduct audits and recover the overpayments, MAOs are not permitted to submit additional diagnoses for payment after the submission deadline.

³⁰ GAO, at 26, <https://www.gao.gov/assets/gao-16/76.pdf> (April 2016).

Comment: A commenter contested CMS' proposal to recover contract-level payment adjustments through a lump-sum reduction in the plans' monthly payments through MARx. The commenter noted that, for example, CMS currently makes retroactive, beneficiary-specific adjustments related to miscellaneous corrections to beneficiaries' status (such as eligibility, State and county of residence, date of death, etc.) outside of the RADV process. The commenter requested that CMS seek only beneficiary-level recoveries through RADV audits so as not to overlap with these non-RADV recoveries.

Response: While we appreciate the commenter's consideration of the other areas in which CMS may make adjustments to MA payments, we do not believe that current and proposed RADV efforts overlap with non-RADV adjustments. RADV audits only validate diagnoses associated with a beneficiary's medical record documentation, not a beneficiary's demographic characteristics. If an HCC cannot be validated with medical records, MAOs are not entitled to the risk-adjustment payment associated with that HCC.

Comment: Several commenters opposed the application of our extrapolation methodology to past payment years claiming that, pursuant to section 1853(b)(2) of the Act, this would be considered a retroactive application of policy and CMS must disclose our RADV audit methodology changes prior to any payment year RADV audit. Some commenters also asserted that the application of this rule to past payment years would alter the actuarial soundness of payments previously received by MA contracts, as existing contracts relied on the RADV audit methodology we announced in the 2012 RADV Methodology. Other commenters also characterized this approach as contrary to the Supreme Court's holding in *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 204 L. Ed. 2d 139 (2019), which emphasized that a substantive legal standard must go through a notice-and-comment process.

Response: First, as a fundamental concept, this policy does not impose any new requirements on MAOs that

could be construed as retroactive. The 2012 RADV Methodology did not create a different "documentation standard" for MA plans than the standard that applies to traditional Medicare providers, nor did we state that an FPS Adjuster should set a permissible rate for the submission of erroneous codes. There is only one documentation standard for diagnosis coding, as discussed previously: proper medical record documentation is required for any reported diagnosis code to be valid. That is the consistent policy throughout the Medicare program (see previous discussion).

The RADV auditing methodology has not fundamentally changed the longstanding requirement that a diagnosis submitted to CMS by an MAO for payment must be properly supported by medical record documentation. See *UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867, 869, 877 (D.C. Cir. August 13, 2021, reissued November 1, 2021), cert. denied, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140). Rather, it only enforces the well-established regulatory requirement that MA diagnoses be validated under that longstanding documentation standard. (For additional information, see § 422.310(e); 83 FR 55037 (and authorities cited therein).)

We also noted in the 2018 proposed rule that we may begin to conduct RADV audits for additional payment years (specifically, 2014 and 2015) before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified.

Even if this methodology was determined to be a retroactive application of policy, a position with which we do not agree, it is still necessary to comply with statutory requirements and is in the public interest for CMS to apply extrapolation to past payment years, and, therefore, is authorized under the Act. CMS has the authority, in accordance with section 1871(e)(1)(A) of the Act, to apply retroactive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability to items and services furnished before the effective date of the change, if the Secretary determines that "such retroactive application is necessary to comply with statutory requirements or failure to apply the change would be contrary to the public interest." We believe that recovering extrapolated improper amounts is necessary to comply with statutory requirements and advances the public interest by protecting the overall integrity of the MA program. We have

a statutory mandate under the FICA to reduce improper payments and a fiduciary responsibility to recover funds due and owed to the Medicare Trust Funds.

As previously discussed, HHS and the GAO have identified a significant volume of improper payments in the MA program,⁴² and RADV audits are the main way CMS ensures payment accuracy to MAOs. As further discussed in the Regulatory Impact Analysis section of this final rule, CMS estimates extrapolated improper payment recoveries of approximately \$479 million per audit year beginning with the PY 2018 audit. We also believe that there will be an additional sentinel effect of RADV audits on the improper payment rate as MAOs improve their processes to report only those diagnoses that meet CMS requirements for risk adjustment payment.

In addition, as discussed previously, RADV audits will not impose new documentation requirements on health care providers. The core component of a RADV audit is ensuring that all diagnoses are properly supported by medical records. We only seek to recover improper payments received by MAOs for HCCs that are not substantiated by enrollees' medical records. MAOs have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records. Therefore, applying the rule under the public interest exception in section 1871(e)(1)(A) of the Act would not upset any settled or reasonable reliance interests. This all serves the public interest by reducing the improper allocation of taxpayer dollars that can otherwise be used for other purposes within the Federal Government, including solvency of the Medicare Trust Funds. Thus, applying the rule retroactively is necessary to comply with statutory requirements and in the public interest within the meaning of section 1871(e)(1)(A) of the Act.

Comment: Several comments provided input on the potential promulgation of rules permitting administrative appeals of RADV audit methodology. A commenter opined that such procedures were unnecessary because stakeholders had an opportunity to participate in the development of our methodology through the notice-and-comment

⁴² For example, the FY 2021 HHS Agency Financial Report, pg. 211, <https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf>, states that Part C Improper Payment Measurement (IPM) estimated approximately \$15 billion in overpayments for calendar year 2019 risk-adjusted payments to MAOs.

data, when appropriate, and to all relevant national standards. The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Guidelines for Coding and Reporting is the existing national standard. (See § 422.310(d)(1); 45 CFR 182.1902(c)(2) and (c)(3)). This is consistent with obligations imposed on hospitals and providers in Medicare Parts A and B, who are required to furnish proper documentation and comply with the ICD Guidelines. See, for example, 42 U.S.C. 1395g and 1395n.

EXHIBIT D-19 INTENTIONALLY BLANK

EXHIBIT D-20 INTENTIONALLY BLANK

EXHIBIT D-21

Message

From: Nelson, Steve E., steve.nelson@unum.com,
Sent: 6/26/2015 11:41:35 AM
To: cheri.rice@unumchicago.com
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the date to which the certifications relate.
- The certifications use the phrase best knowledge, information, and belief, which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson

Chief Executive Officer

UnitedHealthcare Medicare & Retirement

EXHIBIT D-22

*Privileged and Confidential
Attorney Work Product
Attorney/Client Communication
April 29, 2014*

CMS MEETING NOTES

Meeting Date

- April 29, 2014
- Approximate start time was 12:45 eastern time

Attendees

- CMS: Sean Cavanaugh, Cynthia Tudor, Cheri Rice, Dan [Farmer], Julie Grover
- UnitedHealth Group (UHG): Dan Schumacher, Steve Nelson, Karen Erickson, Thad Johnson

Location

- UHG attendees: HHS offices in Washington DC
- CMS attendees: CMS offices in Baltimore, MD

Topic

- Medical records review requirements; Notice of Proposed Rulemaking (NPR or "proposed rule") issued in January 2014; 2012 annual risk adjustment data certification

Meeting Summary

- CMS and UHG representatives began the meeting by introducing themselves. UHG representatives explained the reason for requesting the meeting and asked whether the CMS attendees had seen the email to Marilyn Tavenner sent by Larry Renfro on April 27 requesting the meeting (see exhibit A hereto). CMS attendees acknowledged that they had read the email and inquired as to UHG's specific ask.
- UHG representatives explained their understanding that CMS' proposed rule relates to future periods and wanted to confirm any potential impact to 2012 dates of service in light of the annual risk adjustment data certification for 2012 dates of service due on April 30.
- CMS had a number of clarifying questions relating to UHG's current processes as they relate to medical records review
- UHG representatives provided a general overview of UHG's claim verification process and explained that UHC had already submitted a number of deletes for 2012 dates of services as a result of that process. (Later in the meeting, UHG representatives informed CMS that the number of new and unique diagnosis code deletes already submitted was approximately 13,000.) UHG representatives also indicated that, in light of the proposed rule and other discussions with CMS, UHC had suspended its claims verification process pending a decision by the Company of whether it was appropriate to submit additional deletes to CMS that have been identified through the Company's claims verification process; and also whether the Company should continue with, make changes to, or stop, its current process to identify any additional potential deletes relating to 2012 dates of service.
- Cheri Rice of CMS indicated that until the proposed rule relating to medical records review was finalized, MA plans do not have any proactive responsibility to confirm whether diagnoses submitted by physicians are correct. She also said, however, that if a plan has knowledge that specific codes submitted through medical claims are not supported by medical charts appropriate deletes should be submitted. She summarized this by saying that if a plan has knowledge of an overpayment it should submit appropriate deletes.

- There was then a more detailed discussion of UHG's claim verification process, including the last step of the process being a review by an external expert. Cheri Rice asked for a quantification of the number of codes at various steps in the process. UHG's representatives informed CMS of the number of new and unique codes that had previously been submitted for deletion for 2012 dates of services (approximately 13,000); the number of new and unique codes for which all steps of the claims verification process had been completed, including external review, but which had not been submitted as deletes due to the Company suspending its claims verification process in light of (1) CMS' proposed rule, (2) prior conversations with CMS and (3) the inherent FFS error rate (approximately 8,000); and the number of codes that the Company estimated might be deleted if the Company were to continue its claims verification process to conclusion, including external review, for all codes that were still under review in the claims verification process (i.e., codes for which the claims verification process had not been completed) (approximately 40,000). Cheri Rice requested clarification of the last group and was informed that these codes were at various stages of the process including not having been through external review.
- Cheri Rice then asked some follow-up questions on the general state of the submission of deletes relating to 2012 dates of service based on a call other CMS employees had with OptumInsight the week of April 21, and whether our inquiry was related to the deletes discussed on that call. UHG representatives explained that the prior call related to a number of other deletes that were still in the process of being completed, including finalization of the Q/A process relating to chart review and completion of the Company's process for obtaining attestations for medical charts that may not have included signatures. UHG further explained in response to CMS questions that the Q/A process for chart review was separate from the claims verification process and was a quality control procedure for codes added as a part of chart review. As part of this discussion, CMS representatives reiterated that, under CMS regulations, MA plans were not required to design their chart review programs for overall accuracy until the proposed rule is finalized. Sean Cavanaugh stated that, under current rules, if UHG doesn't know codes are inaccurate the Company would not have to delete them. He went on to state that if UHC does not know until the end of its claims verification process that a code is incorrect then there is no requirement to delete the code until the effective date of CMS' final rule. Cheri Rice added that there is a false claims act requirement that plans not knowingly keep overpayments so if you do not know that there is an overpayment you do not need to delete a code.
- UHC representatives then informed CMS that, due to the new electronic certification methodology and the resultant inability to footnote the certification as UHG had done previously, UHG would be submitting a letter from Steve Nelson explaining UHG's understandings regarding the certification. CMS representatives indicated they were working with other plans on similar concerns.
- UHG inquired whether CMS could provide any guidance into assumptions the Company should make about chart review requirements in preparing its bids for 2015. After conferring among themselves, CMS representatives acknowledged the issues created by the proposed rule, but stated they could not provide any guidance into assumptions UHG should make in preparing its 2015 bids.
- UHG representatives thanked CMS attendees for their time and the meeting concluded.

EXHIBIT D-23

Paul, Rebecca (CMS/CM)

From: Rice, Cheri M (CMS/CM)
Sent: Tuesday, June 7, 2016 11:22 AM
To: Kreisel, Johanna (OS/OGC)
Cc: Paul, Rebecca (CMS/CM); Harlow, Jennifer A. (CMS/CM); Reed, Asante, Monica (CMS/CM); Chaudhuri, Iina (CMS/CM); Simons, Kellie M. (CMS/CM); Tudor, Cynthia G. (CMS/CM)
Subject: FW: 2014 CMS RAF Attestation

Redacted

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Tuesday, June 7, 2016 10:21 AM
To: Rice, Cheri M. (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Subject: 2014 CMS RAF Attestation

Cheri,

As we have done the past several years, we are reaching out to you to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you in the past, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing regarding our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our prior discussion and understanding regarding the certifications.

- As with our past certifications, the 2014 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices
- The certifications only cover risk adjustment data for 2014 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are continuously engaged in the ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2014 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule two years ago that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to

determine the necessity of risk adjustment diagnoses. As we discussed in that time, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes. Based on our conversations with CMS six years ago, CMS's withdrawal of the proposed rule, and CMS's announced plans to use a ICD Adjuster to address diagnoses not supported by a medical record in the context of RVDV, we ended this process and informed you of that decision at the time. That decision remains operative for 2014 days of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through a claim are unsupported by the medical record. We do have a quality assurance process that delete codes initially identified during claim review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. And again, we appreciate your time and attention on this matter.

Nancy Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT D-24

29

TUESDAY

APRIL, 2014 • 119th Day, 246 Days Left • 16th Week

APPOINTMENTS & SCHEDULED EVENTS

DIARY AND WORK RECORD

Steve Nelson
Don Thurnaker
John C. PO
U. H. C. + Media
Thurnaker
United

8 0800
9 0900
10 1000
11 1100
12 1200
1 1300
2 1400
3 1500
4 1600
5 1700
6 1800
7 1900
8 2000

No pending
to confirm
accuracy of dx
Claims ver
deleted 13k
from 2012
8k - completed
steps - will
delete
Universe in process
41k
various
stages
not finished.

2012 - client
review, "stoppy"
to sign attestations

TO BE DONE TODAY (ACTION LIST)

Obligations to stop
stop review on
tell us about
what they find.
"Addition" - evaluate
accuracy
stop work.

EXPENSE & REIMBURSEMENT RECORD

Imps

EXHIBIT D-25

**FILED UNDER SEAL IN ITS
ENTIRETY**

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 4 OF 14
EXHIBITS D-26 THROUGH D-34
PAGES 0708 THROUGH 0757**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024
Hearing Time: 10:00 a.m.
Courtroom: 6D

**REDACTED VERSION OF DOCUMENT PROPOSED TO BE
FILED UNDER SEAL**

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EXHIBIT D-26

Message

Sent: 8/22/2016 1:54:59 AM
To: Nelson, Steve H [steve_nelson@uhc.com]
BCC: Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Jennifer.harlow.cms20728073]; Chaudhuri, Ilina (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Ilina.Chaudhuri.CMS]; Reed-Asante, Monica (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Monica.Reed.CMS]; Paul, Rebecca (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=rebecca.paul.cms55708697]; Simons, Kellie M. (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Kellie.Gombeski.CMS]; Kreisel, Johanna (OS/OGC) [/O=HHS EES/OU=EXtErnal (FYDIBOHF25SPDLT)/cn=Recipients/cn=b191e47b8d7d42b8a6a6460de4a4eabb]; Burke, Sherry Lynn (HHS/OGC) [/O=HHS EES/OU=EXtErnal (FYDIBOHF25SPDLT)/cn=Recipients/cn=65433f2bbb034833b76096f08ab6184f]
Subject: RE: 2014 CMS RAF Attestation

Steve,

With this email, we are acknowledging receipt of your email dated 6/7/16. However, neither the receipt of your email nor any acknowledgment of such receipt should be interpreted as acquiescence by the Government to any purported modification to the Attestations of Risk Adjustment Data submitted by United or to any of the arrangements described in or statements made in your email, or as a release of any of United's present or future liability to the Government. As you know, both regulation and the MA organizations' contracts with CMS prescribe the specific language of this Attestation, and the MA organizations' execution and submission of the Attestation as specified is a condition of payment by the Medicare Program.

With respect to your fifth point, as we noted last year in response to a similar email from you, there are laws and contractual provisions that impose standards, requirements and responsibilities on MA organizations in connection with federal payments, including risk adjustment payments, they receive from the Medicare Program. We cannot provide legal advice to United about whether its current or proposed courses of action are compliant with such laws and obligations, but we do wish to remind you that MA organizations are required to implement effective compliance programs that prevent, detect and correct non-compliance with CMS program requirements, to exercise reasonable diligence in identifying overpayments, and to report and return such overpayments to the Medicare Program within 60 days. MA organizations cannot delegate these legal obligations to others.

Cheri Rice
Director, Medicare Plan Payment Group
Centers for Medicare and Medicaid Services

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Tuesday, June 7, 2016 10:21 AM
To: Rice, Cheri M. (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Subject: 2014 CMS RAF Attestation

Cheri,

As we have done the past several years, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you in the past, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing regarding our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our prior discussion and understanding regarding the certifications.

- As with our past certifications, the 2014 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2014 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are continuously engaged in the ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2014 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule two years ago that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed at that time, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS two years ago, CMS's withdrawal of the proposed rule, and CMS's announced plans to use a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision at the time. That decision remains operative for 2014 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT D-27

Message

From: Rice, Cheri M. (CMS/CM) [/O=HHS EES/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CHERI.RICE.CMS59728027]
Sent: 7/30/2015 9:56:36 PM
To: steve_nelson@uhc.com
Subject: RE: 2013 CMS RAF Attestation

Steve,

With this email, we are acknowledging receipt of your email dated 6/26/15. However, neither the receipt of your email nor any acknowledgment of such receipt should be interpreted as acquiescence by the Government to any purported modification to the Attestations of Risk Adjustment Data submitted by United or to any of the arrangements described in or statements made in your email, or as a release of any of United's present or future liability to the Government. As you know, both regulation and the MA organizations' contracts with CMS prescribe the specific language of this Attestation, and the MA organizations' execution and submission of the Attestation as specified is a condition of payment by the Medicare Program.

With respect to your fifth point, as we noted last year in response to a similar email from you, there are laws and contractual provisions that impose standards, requirements and responsibilities on MA organizations in connection with federal payments, including risk adjustment payments, they receive from the Medicare Program. We cannot provide legal advice to United about whether its current or proposed courses of action are compliant with such laws and obligations, but we do wish to remind you that MA organizations are required to implement effective compliance programs that prevent, detect and correct non-compliance with CMS program requirements, to exercise reasonable diligence in identifying overpayments, and to report and return such overpayments to the Medicare Program within 60 days. MA organizations cannot delegate these legal obligations to others.

Cheri Rice
Director, Medicare Plan Payment Group
Centers for Medicare and Medicaid Services

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Friday, June 26, 2015 12:42 PM
To: Rice, Cheri M. (CMS/CM)
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

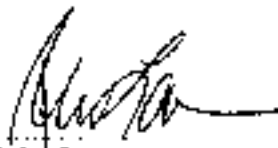
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EXHIBIT D-28

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contracts between the Centers for Medicare & Medicaid Services (CMS) and the UnitedHealth Group affiliate listed in Attachment 1, hereafter referred to as the MA Organization, governing the operation of the Medicare Advantage and Medicare Advantage- Prescription Drug plans listed in Attachment 1, the MA Organization hereby requests payment under the contract and, in doing so, makes the following attestation concerning CMS payments to the MA Organization * The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2009 to December 31, 2009 all risk adjustment data for 2009 dates of service available to the MA Organization as of December 31, 2009, with respect to the MA and MA-PD plans listed in Attachment 1. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in such report and not subsequently deleted prior to the date hereof is accurate, complete, and truthful.


NAME: John Larsen
TITLE: Chief Financial Officer,
Public & Senior Markets Group
On behalf of the UnitedHealth Group
entities listed in Attachment 1

3/26/10
DATE

* This Certification is based on facts reasonably available or made available to the MA Organization as of the date of this Certification and is not to be construed as a representation by the entities listed in Attachment 1, their affiliates, officers, representatives, or agents that the data to which the Certification relate may not require subsequent modification should additional information become available. Best knowledge, information, and belief means based on normal business practices. In addition, the scope of this Certification does not include risk adjustment data related to "long-term institutionalized" or "community," which the MA Organization is not required to report to or otherwise verify for CMS. Such designations are made by CMS based on a CMS data source and are subject to reconciliation by CMS in accordance with Section 91.1.2 of Chapter 7 of the Medicare Managed Care Manual. As previously communicated to CMS, we believe these designations are materially inaccurate. However, we acknowledge CMS' position that such designations are generally accurate.

Attachment 1
Page 1 of 2

<u>Contract</u>	<u>Contracting Party</u>
H0151	United HealthCare of Alabama, Inc.
H0251	United HealthCare Plan of the River Valley, Inc.
H0303	PacificCare of Arizona, Inc.
H0316	United HealthCare of Arizona Inc.
H0321	Arizona Physicians IPA, Inc.
H0401	United HealthCare of Arkansas, Inc.
H0408	United HealthCare Insurance Company
H0418	United HealthCare Insurance Company
H0543	PacificCare of California
H0609	PacificCare of Colorado, Inc.
H0620	United HealthCare Insurance Company
H0624	United HealthCare Insurance Company
H0710	United HealthCare Insurance Company
H0752	Oxford Health Plans (CT), Inc.
H1080	United HealthCare of Florida, Inc.
H1108	United HealthCare Insurance Company
H1111	United Healthcare of Georgia, Inc.
H1286	United HealthCare Insurance Company
H1303	United HealthCare Insurance Company
H1509	United HealthCare Insurance Company
H1717	United HealthCare Insurance Company
H1944	United HealthCare Insurance Company
H2001	United HealthCare Insurance Company
H2003	United HealthCare Insurance Company
H2011	United HealthCare Insurance Company
H2182	United HealthCare Insurance Company
H2226	United HealthCare Insurance Company
H2228	United HealthCare Insurance Company
H2406	United HealthCare Insurance Company
H2654	United HealthCare of the Midwest, Inc.
H2802	United HealthCare of the Midlands, Inc.
H2803	United HealthCare Insurance Company
H2905	Sierra Health and Life Insurance Company, Inc.
H2931	Health Plan Of Nevada, Inc.
H2961	Health Plan of Nevada, Inc.
H3107	Oxford Health Plans (NJ), Inc.
H3113	Oxford Health Plans (NJ), Inc.
H3164	AmeriChoice Of New Jersey, Inc.
H3209	United HealthCare Insurance Company
H3307	Oxford Health Plans (NY) Inc.
H3379	United HealthCare of New York, Inc.
H3387	United HealthCare of New York, Inc.
H3456	United HealthCare of North Carolina, Inc.

Attachment 1

Page 2 of 2

<u>Contract</u>	<u>Contracting Party</u>
H3659	United HealthCare of Ohio, Inc.
H3749	Pacificare of Oklahoma, Inc.
H3805	Pacificare of Oregon, Inc.
H3812	United HealthCare Insurance Company
H3887	United HealthCare Insurance Company
H3912	United HealthCare Insurance Company
H3971	United HealthCare Insurance Company
H4102	United HealthCare of New England, Inc.
H4106	United HealthCare Insurance Company
H4406	United HealthCare of Tennessee, Inc.
H4449	Sierra Health and Life Insurance Company, Inc.
H4514	Evercare of Texas, LLC
H4456	United HealthCare Plan of the River Valley, Inc.
H4522	United HealthCare Insurance Company
H4590	Pacificare of Texas, Inc.
H4604	United HealthCare of Utah
H4720	United HealthCare Insurance Company of New York
H4837	United HealthCare of Wisconsin
H4971	United HealthCare Insurance Company
H5005	Pacificare of Washington, Inc.
H5008	United HealthCare Insurance Company
H5253	United HealthCare of Wisconsin, Inc.
H5417	United HealthCare Insurance Company
H5424	United HealthCare Insurance Company
H5435	Pacificare Life & Health Insurance Company
H5440	United HealthCare Insurance Company
H5507	United HealthCare Insurance Company
H5516	United HealthCare Insurance Company
H5532	United HealthCare Insurance Company
H5678	United HealthCare Insurance Company
H5697	United HealthCare Insurance Company
H5749	United HealthCare Insurance Company
H5754	United HealthCare Insurance Company
H5918	United HealthCare Insurance Company
H6228	United HealthCare Insurance Company
H6793	United HealthCare Insurance Company
H6952	Great Lakes Health Plan, Inc.
H7187	United HealthCare Insurance Company
H7949	Pacificare Of Nevada, Inc.
H8748	United HealthCare Insurance Company
H9011	United HealthCare of Florida Inc.
H9149	United HealthCare Insurance Company
R3175	United HealthCare Insurance Company

Attachment 3
Page 3 of 3

<u>Contract</u>	<u>Contracting Party</u>
R5287	United HealthCare Insurance Company
R5342	United HealthCare Insurance Company of New York
R5674	Siema Health and Life Insurance Company, Inc.
R7444	United HealthCare Insurance Company

EXHIBIT D-29



HPMS
Health Plan Management System

Health Plan Management System

[Home](#)

Risk Adjustment Certification Reports - Payment Year 2017 (Dates of Service 2016)

Confirmation #: 409

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION, MEDICARE MEDICAID PLAN OR PACE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and UNITEDHEALTHCARE INSURANCE COMPANY (H0624), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2016, to December 31, 2016, all risk adjustment data (*inpatient hospital, outpatient hospital, and physician*) available to the MA Organization, Medicare Medicaid Plan or PACE Organization as of the applicable deadline(s), with respect to the above-stated MA, MMP, and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

TIMOTHY NOEL on behalf of

UNITEDHEALTHCARE INSURANCE COMPANY (H0624)

10/12/2018

Close

EXHIBIT D-30



Risk Adjustment Certification Reports - Payment Year 2016 (Dates of Service 2015)

Confirmation #: 401

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION, MEDICARE MEDICAID PLAN OR PACE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and UNITEDHEALTHCARE INSURANCE COMPANY (H0319), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2015, to December 31, 2015, all risk adjustment data (*inpatient hospital, outpatient hospital, and physician*) available to the MA Organization, Medicare Medicaid Plan or PACE Organization as of the applicable deadline(s), with respect to the above-stated MA, MMP, and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

TIMOTHY NOEL on behalf of

UNITEDHEALTHCARE INSURANCE COMPANY (H0319)

10/12/2018

Close

EXHIBIT D-31



Risk Adjustment Certification Reports - Payment Year 2015 (Dates of Service 2014)

Confirmation #: 909

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION, MEDICARE MEDICAID PLAN OR PACE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and UNITEDHEALTHCARE INSURANCE COMPANY (R7444), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2014, to December 31, 2014, all risk adjustment data (*inpatient hospital, outpatient hospital, and physician*) available to the MA Organization, Medicare Medicaid Plan or PACE Organization as of the applicable deadline(s), with respect to the above-stated MA, MMP, and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

BRIAN THOMPSON on behalf of

UNITEDHEALTHCARE INSURANCE COMPANY (R7444)

6/7/2016

Close

EXHIBIT D-32



Risk Adjustment Certification Reports - Payment Year 2014 (Dates of Service 2013)

Confirmation #: 1150

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and UNITEDHEALTHCARE INSURANCE COMPANY (R7444), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2013, to December 31, 2013, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of January 31, 2015, with respect to the above-stated MA and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

BRIAN THOMPSON on behalf of

UNITEDHEALTHCARE INSURANCE COMPANY (R7444)

6/26/2015

Close

EXHIBIT D-33

From: Thompson, Brian R (CEO UHC M&R) [brian_r_thompson@uhc.com]
Sent: Friday, October 12, 2018 6:34 45 PM
To: Rice, Cheri M. (CMS:CM)
CC: Korinko, Anna L; Harlow, Jennifer A. (CMS:CM)
Subject: PY2016 and PY2017 RAF Attestations

Cheri,

As we have done the past several years, we are reaching out to you to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you in the past, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing regarding our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our prior discussion and understanding regarding the certifications.

- As with our past certifications, the 2016 and 2017 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may modify the data to which the certifications relate.
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2015 and 2016 dates of service that were submitted to CMS and not subsequently deleted before the date of the certifications.
- As we have mentioned to you previously, we are continuously engaged in the ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2015 and 2016 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule in 2014 that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During the conversations between United and CMS before the proposed rule was withdrawn, CMS confirmed to United that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As was discussed at that time, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on the conversations with CMS in 2014, CMS's withdrawal of the proposed rule, and CMS's announced plans to use a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision at the time.
- As you know, United subsequently filed suit under the Administrative Procedures Act (APA) against the Department alleging that the final overpayment rule adopted by CMS in 2014 violates the Medicare Act because it purports to require MA plans to delete unsupported diagnosis codes even though CMS does not delete similar diagnosis codes from the data used to calibrate risk adjustment payments. In September 2018, the District Court granted United's motion for summary judgment.
- In 2017, the Department of Justice filed Complaints in Intervention in two False Claims Act (FCA) cases indicating that it has a broader view of the significance of this certification. The allegations in these complaints related to this certification have now been dismissed.
- Our decision to discontinue our prior process remains operative for 2015 and 2016 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.
- Notwithstanding the Justice Department's allegations regarding the requirements related to risk adjustment data and the meaning of our certification, we are not certifying that we have validated

diagnostic codes submitted through claims so that we have deleted such codes based on our review of medical records during chart review.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Brian Thompson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT D-34

**FILED UNDER SEAL IN ITS
ENTIRETY**

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 5 OF 14
EXHIBITS D-35 THROUGH D-44
PAGES 0758 THROUGH 1019**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT D-35

Message

From: Bonfante, Maricruz (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MARICRUZ.BOFANTE.CMS]
Sent: 9/27/2013 5:29:02 PM
To: Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=jennifer.harlow.cms20728073]; Chaudhuri, Ilina (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Ilina.Chaudhuri.CMS]; Scott, John A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=john.scott.cms63365671]
CC: Johnson, Whitney S. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=whitney.may.cms61855760]; Smith, Jonathan (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Jonathan.Smith3.CMS]; Pulley, Tobi A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Tobi.Pulley.CMS]; Johnson, Amanda S. (CMS/CPC) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=amanda.ryan.cms69944978]; Paul, Rebecca (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=rebecca.paul.cms55708697]; Franzel, Ashley S. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=ashley.franzel.cms02591694]; Gover, Julie (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Julie.Gover2.CMS]; Hornsby, Anne M. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=anne.hornsby.cms49724712]
Subject: RE: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

Jennifer:

Yes and No. I pulled some cases which use the phrase "reasonable diligence", but only one seemed to provide a standard for it. The cases were primarily ERISA and RICO cases.

A more commonly used term of art would be "due diligence" or "reasonable care". Anne and I started trying to piece something together, but I would have to agree that if we want to stay consistent with the CPI reg – we should hold on trying to create a standard on our end – especially if we want to lessen plan burden and also not create an affirmative obligation to "identify".

Maricruz J. Bonfante
Center for Medicare (CM)
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410.786.5086 | 410.786.6730

From: Harlow, Jennifer A. (CMS/CM)
Sent: Friday, September 27, 2013 1:23 PM
To: Chaudhuri, Ilina (CMS/CM); Scott, John A. (CMS/CM)
Cc: Johnson, Whitney S. (CMS/CM); Smith, Jonathan (CMS/CM); Pulley, Tobi A. (CMS/CM); Johnson, Amanda S. (CMS/CPC); Paul, Rebecca (CMS/CM); Franzel, Ashley S. (CMS/CM); Gover, Julie (CMS/CM); Bonfante, Maricruz (CMS/CM); Hornsby, Anne M. (CMS/CM)
Subject: RE: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

Is "reasonable diligence" a term of art that is commonly used in legal forums?

Redacted

From: Chaudhuri, Ilina (CMS/CM)
Sent: Friday, September 27, 2013 12:05 PM
To: Scott, John A. (CMS/CM)
Cc: Johnson, Whitney S. (CMS/CM); Smith, Jonathan (CMS/CM); Pulley, Tobi A. (CMS/CM); Johnson, Amanda S. (CMS/CPC); Paul, Rebecca (CMS/CM); Franzel, Ashley S. (CMS/CM); Gover, Julie (CMS/CM); Bonfante, Maricruz (CMS/CM); Hornsby, Anne M. (CMS/CM); Harlow, Jennifer A. (CMS/CM)

0759

CONFIDENTIAL

USBP066819447

Subject: Re: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

I like that - deliberately choosing not to define the term, consistent with CPI.

On Sep 27, 2013, at 11:41 AM, "Scott, John A. (CMS/CM)" <John.Scott@cms.hhs.gov> wrote:

Got it. Maybe that's all we need to say then:

We are developing these overpayment regulations in a manner consistent with the overpayment regulations developed by CPI, including CPI's use of "due diligence." Because CPI did not define due diligence in its regulations, we deliberately chose not to define it in our proposed regulations either.

Redacted

Just a thought.

From: Johnson, Whitney S. (CMS/CM)

Sent: Friday, September 27, 2013 10:04 AM

To: Scott, John A. (CMS/CM); Smith, Jonathan (CMS/CM); Pulley, Tobi A. (CMS/CM); Johnson, Amanda S. (CMS/CPC); Paul, Rebecca (CMS/CM); Chaudhuri, Iliana (CMS/CM); Franzel, Ashley S. (CMS/CM)

Cc: Gover, Julie (CMS/CM); Bonfante, Maricruz (CMS/CM); Hornsby, Anne M. (CMS/CM); Harlow, Jennifer A. (CMS/CM)

Subject: Re: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

Redacted

final (I checked with them). We took this term from CPI and need to be consistent as possible. OMB is asking this question.

From: Scott, John A. (CMS/CM)

Sent: Friday, September 27, 2013 09:38 AM

To: Johnson, Whitney S. (CMS/CM); Smith, Jonathan (CMS/CM); Pulley, Tobi A. (CMS/CM); Johnson, Amanda S. (CMS/CPC); Paul, Rebecca (CMS/CM); Chaudhuri, Iliana (CMS/CM); Franzel, Ashley S. (CMS/CM)

Cc: Gover, Julie (CMS/CM); Bonfante, Maricruz (CMS/CM); Hornsby, Anne M. (CMS/CM); Harlow, Jennifer A. (CMS/CM)

Subject: RE: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

I don't think our response answers the question about defining reasonable diligence. We say a plan must use reasonable diligence to determine whether an overpayment exists, but we aren't saying what

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exercise reasonable diligence to do that is up them. In other words, reasonable diligence in this context may be the amount of diligence the plan deems reasonable to identify an overpayment.

Redacted

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USBP066819448

From: Johnson, Whitney S. (CMS/CM)
Sent: Thursday, September 26, 2013 2:05 PM
To: Smith, Jonathan (CMS/CM); Pulley, Tobi A. (CMS/CM); Scott, John A. (CMS/CM); Johnson, Amanda S. (CMS/CPC); Paul, Rebecca (CMS/CM); Chaudhuri, Ilina (CMS/CM); Franzel, Ashley S. (CMS/CM)
Cc: Gover, Julie (CMS/CM); Bonfante, Maricruz (CMS/CM); Hornsby, Anne M. (CMS/CM); Harlow, Jennifer A. (CMS/CM)
Subject: OMB Responses (Overpayment and Part D technical changes in CMS-4159-P) - For your review - due by noon tomorrow

Hello,

Below are draft responses to OMB questions we have received (so far...). Please send me any major edits/comments by noon tomorrow. Thanks!

Whitney

Redacted

Any person who 'knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government' may be found liable under the False Claims Act. (See 31 U.S.C. 3729 et seq.). Additionally, any person who knows of an overpayment [as defined in section 1128J(d)(4) of the Act] and does not report and return the overpayment in accordance with such section' may be found liable under the Civil Monetary Penalties Law (section 1128A(a)(10) of the Act) and accordingly could be excluded from participation in Federal health care programs.

A102: Reasonable Diligence: Is this defined somewhere?

As indicated in preamble, it is to determine whether an overpayment exists. Without such a proposal, some providers and suppliers might avoid performing activities to determine whether an overpayment exists.

A103: "CMS will recover the returned overpayment through routine processing according to the systems schedule established in the annual operations budget": Please provide more information on the timing of these processes.

For Parts C and D, some reconciliations are routine and some are at CMS discretion. For Part C, final reconciliations occur each year around August (risk adjustment). For Part D, final reconciliations occur around October for the previous payment year. Reopening of the reconciliation for a payment year generally occurs several years later and for Part D we are proposing once within five years after the initial final reconciliation. Running reconciliation is resource-intensive.

A104: "However, in light of the overpayment provision.....we do not believe that it is necessary to reopen a payment reconciliation after that five year period, nor do we believe it is necessary to reopen a reconsidered payment determination": Please confirm that even in the case of fraud reopening a payment reconciliation is still subject to the 5 year limitation.

That is correct. Even in the case of fraud, the reopening payment reconciliation is still subject to the 5 year limitation. If an overpayment (even an overpayment resulting from fraud) is discovered after a payment year has closed, the overpayment will be reported and returned to CMS via the overpayment process described at proposed § 423.360.

A105: "we now propose to amend 423.2320 such that.....CMS will then attempt to recover those costs from the bankrupt manufacturer by filing a proof of claim with the bankruptcy court": Are there estimated costs with this policy?

Given our experience, we do not anticipate many manufacturers failing to pay quarterly invoices as a result of bankruptcy. The more typical scenario we see is that a manufacturer, or its assets, becomes acquired by another company prior to the manufacturer declaring bankruptcy. Since 2011, only one manufacturer has declared bankruptcy, and it is too early to determine whether or not there could be costs, or the extent of those costs, based on that case.

A016: "In the event that a manufacturer becomes bankrupt, CMS is concerned that the court will either discharge or reduce the amount of the CMP....": In absence of CMS covering these costs, would these losses show up in reconciliation?

CMS reconciles based on the amounts invoiced to the manufacturers, not the amounts actually paid by the manufacturers. Therefore, if a manufacturer fails to pay a quarterly invoice, that unpaid invoiced amount will not be reflected in reconciliation.

A107: "Medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments": How will this be enforced?

We expect that RADV audits will help in evaluating whether a MA organization is effectively fulfilling this requirement.

EXHIBIT D-36



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For Medicare Advantage Organizations
Participant Guide**

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INTRODUCTION

INTRODUCTION

Purpose (Slide 2)

The purpose of this training is to provide participants who are new to risk adjustment the support necessary to understand risk adjustment. This information will enable new participants to collect and submit risk adjustment data in accordance with Centers for Medicare & Medicaid Services (CMS) requirements.

About This Training

This training is organized into nine modules:

- 1. Risk Adjustment Methodology**
Provides an understanding of CMS' Risk Adjustment models and payment methodologies.
- 2. Risk Adjustment Process Overview**
Identifies the systems and timeline for the risk adjustment data collection, submission, editing, and reporting processes.
- 3. Data Collection**
Describes the acceptable sources of risk adjustment data and data collection formats.
- 4. Data Submission**
Describes the acceptable formats for submitting risk adjustment data.
- 5. Edits**
Identifies data integrity logic and error codes, error resolution, and suggestions for avoiding errors.
- 6. Diagnosis Codes & Risk Adjustment**
Provides important medical record documentation and coding guidelines related to risk adjustment.
- 7. Data Validation**
Identifies the data validation approach under the CMS' Risk Adjustment models, including responding to CMS medical record requests.
- 8. Reports**
Describes risk adjustment reports, and defines their uses in monitoring data collection and submission processes.
- 9. Verifying Risk Scores**
Describes the process for calculating the risk score and its impact on risk adjusted payment.

ICON KEY

Example



Reminder



Resource





2007 Risk Adjustment Data Training For Medicare Advantage Organizations Participant Guide

INTRODUCTION

This participant guide is designed as the foundation of the training program. The presentation slides complement the participant guide and both will be used extensively throughout this training. The participant binder includes the participant guide, presentation slides, a resource guide, and job aids. Collectively, these tools enhance the learning experience. Sections of the binder are described in Table A.

TABLE A – TRAINING TOOLS

SECTION	DESCRIPTION
Participant Guide	- Detailed description of relevant risk adjustment information - Case studies - Exercises - Answer keys
Slides	- Organized by module - Printed two slides per page
Resource Guide	- List of common acronyms - Risk adjustment instructions - Contact information - Other source documents

Future Use of This Participant Guide

The participant guide, slides, and resource guide are designed for use when participants return to their organizations. Additional copies of the training materials are available at www.csscooperations.com. CMS revises training materials, when required. An appropriate label will appear in the footer of the replacement pages affected by the revisions. Organizations are encouraged to register at www.csscooperations.com to receive notification for these revisions.

Audience

This training program is designed for individuals new to the risk adjustment process. The primary audiences for this training are:

- Staff of new Medicare Advantage (MA) and Medicare Advantage – Prescription Drug (MA-PD) organizations, Regional and Employer Group Health plans, demonstration projects, Program of All-Inclusive Care for the Elderly (PACE) organizations, and specialty plans.
- Existing staff unable to attend previous training sessions.
- New staff at the existing organizations mentioned above.
- Third party submitters contracted to submit data on behalf of MA Risk Adjustment organizations.

The organizations listed in Table B will be used throughout this training.



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TABLE B – ORGANIZATION DESCRIPTION

NAME	DESCRIPTIONS
MA Organizations	Organizations, including Health Maintenance Organizations with or without Prescription Drug Programs, Employer Group Health and Medical Savings Account organizations, private fee-for-service organizations, preferred provider organizations, and provider sponsored organizations that receive capitated payments to provide comprehensive medical services to Medicare beneficiaries.
PACE	Program of All-Inclusive Care for the Elderly (PACE) that serves a community of frail and elderly individuals who are eligible for nursing home placement based on State Medicaid criteria.
MSHO/ MnDHO	Minnesota Senior Health Options (MSHO) and Minnesota Disability Health Options (MnDHO) are managed care products in a ten-county area in Minnesota, including the Twin Cities. They integrate Medicare and Medicaid financing of acute and long-term care service delivery for dually eligible and Medicaid eligible physically disabled adults and elderly. MnDHO is approved for Carver, Scott, Washington, Hennepin, Ramsey, Dakota, and Anoka counties.
S/HMO	Social Health Maintenance Organizations (SHMO) offer seniors an expanded care benefits package that may include prescription drugs and community-based services, which enables them to maintain independence and avoid nursing home placement.
WPP	Wisconsin Partnership Program (WPP) is a comprehensive program for Medicaid and Medicare beneficiaries who are elderly or disabled and meet the State's nursing home criteria. WPP integrates health and long-term support services, and includes home and community-based waiver services (HCBS), physician services, and all other medical care.
SCO	The MassHealth Senior Care Option (SCO) is a dual eligible demonstration that CMS and the Division of Medical Assistance for the Commonwealth of Massachusetts developed. The contractors provide care through managed care organizations to beneficiaries who enroll voluntarily. SCOs serve community-well, community-frail and institutionalized beneficiaries age 65 and older. SCOs are required to contract with State Aging Services Access Point providers as part of the SCO care management team, which deliver home and community-based services as part of an integrated model of care.
Capitated Demonstration Projects	Capitated demonstration projects use alternative capitated financing to allow the provider to offer comprehensive medical service.



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Learning Objectives (Slide 5)

At the completion of this training, participants will be able to:

- Identify Risk Adjustment and payment methodologies.
- Describe the requirements for data collection.
- Determine the process for submitting data to CMS.
- Interpret the editing rules and steps in the error resolution process.
- Name and interpret the reports available for risk adjustment monitoring.
- Demonstrate how to verify risk scores.

The roles and contact information for important resources are provided in Table C.

TABLE C – RISK ADJUSTMENT PROCESS POINTS OF CONTACT

ORGANIZATION	ROLE	CONTACT INFORMATION
CMS Center for Beneficiary Choices	Develops and implements the risk adjustment payment methodology for the MMA program. Monitors plans to improve the quality of data.	Sean Creighton sean.creighton@cms.hhs.gov Henri Thomas henry.thomas@cms.hhs.gov Louis Johnson Louis.johnson@cms.hhs.gov Lateefah Hughes Lateefah.hughes@cms.hhs.gov
CMS Regional Offices	Provide assistance to Risk Adjustment organizations and beneficiaries regarding various issues related to the Medicare program.	Contact your plan manager.
Palmetto Government Benefits Administration (Palmetto GBA)	Manages the Front-End Risk Adjustment System (FERAS) and the Customer Service and Support Center (CSSC).	www.csscooperations.com
Leading Through Change, Inc. (LTC, Inc.)	Training Contractor responsible for risk adjustment training initiatives, including regional training programs and User Group meetings.	RARegistration@medicaretraining.net



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RISK ADJUSTMENT METHODOLOGY

MODULE 1 – RISK ADJUSTMENT METHODOLOGY

Purpose (Slide 2)

To provide information on risk adjusted data submission and payment under the risk payment models. The goal of risk adjustment is to pay applicable Parts C and D organizations accurately and fairly by adjusting payment for enrollees based on demographics and health status. Changes to risk adjustment under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) are also provided in this module.

Learning Objectives (Slide 3)

At the completion of this module, participants will be able to:

- Define the purpose of risk adjustment.
- Identify the components of risk adjusted payments.
- Describe the Part C community model.
- Describe how to calculate the frailty adjuster.
- Describe Part C Community and Long-term institutional models.
- Describe how to calculate a risk factor.
- Recognize the components of the Part C End-Stage Renal Disease (ESRD) model.
- Describe the Part D Prescription Drug Risk Adjustment model.
- Identify the new enrollee factors.

ICON KEY

Definition



Example



Reminder



Resource



1.1 Risk Adjustment History (Slides 4-9)

The following is a list of key dates that have occurred during the process of implementing a risk adjustment payment methodology.

- Balanced Budget Act of 1997 (BBA) (42 CFR 422).
 - Created the Medicare+Choice (M+C) program.
 - Mandated risk adjustment payment methodology to increase payment accuracy.
 - Mandated the implementation of a frailty adjuster for the Program for All-Inclusive Care for the Elderly (PACE) organizations.
- August 1998
 - Hospital inpatient encounter data collection began.



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RISK ADJUSTMENT METHODOLOGY

- January 2000 – Principal Inpatient Diagnostic Cost Group (PIP-DCG) Payment Model implemented.
 - Gradual phase-in of risk adjustment based on principal inpatient diagnosis and demographic factors (age, sex, Medicaid status, original reason for Medicare entitlement).
 - Implemented at 10 percent PIP-DCG and 90 percent demographic.
 - The PIP-DCG model is based on hospital inpatient diagnoses only.
- Benefits Improvement and Protection Act of 2000 (BIPA) (December).
 - Established the current implementation schedule to achieve 100 percent risk adjusted payment in 2007.
 - Mandated the incorporation of ambulatory data.
- May 2001 – Secretary of the Department of Health and Human Services suspended collection of ambulatory data to seek burden reduction for M+C organizations.
- January 2002 – CMS announced new risk adjustment data processing system—RAPS (Risk Adjustment Processing System).
- March 2002 – Draft CMS-HCC Payment Model selected.
 - New risk adjustment model needed to accommodate other types of data (hospital outpatient and physician)
 - Included approximately 70 condition groups with reduced number of diagnostic codes.
 - Proposed for implementation in calendar year 2004.
- February 3, 2003 – CMS presented a draft CMS-HCC model discussed at national public meeting and addressed the elimination of the data lag for payment.
- March 28, 2003 – Advanced Notice of Methodological Changes (i.e., 45-Day notice) published the proposed CMS-HCC model, ESRD model, frailty adjuster, and elimination of the data lag.
- May 12, 2003 – Published final M+C rates for 2004 payment.
 - Announced final CMS-HCC model, including the institutional and community models.
 - Provided risk adjustment new enrollee factors.
 - Delayed implementation of ESRD model for M+C until 2005.
 - Described process for elimination of the data lag.



See 2004 45-Day Notice at

<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf> and May 12, 2003 Announcement of Rates for 2004 at:

<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2004.pdf>

- December 8, 2003 – Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Enacted (P.L. 108-173).
 - Created MA program to replace M+C program.
 - Retained many M+C provisions.
 - Created Medicare drug benefit to begin in 2006.
 - Established bidding methodology for MA organizations and drug plans in 2006.



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RISK ADJUSTMENT METHODOLOGY

- January 16, 2004-New ratebook for 2004 published.
 - Revised ratebook took into account changes from MMA—adding 4th prong to the "highest of" methodology for 2004 and modifying the minimum percentage increase rate for 2004 and beyond.
-  See January 16, 2004 cover letter regarding revised MA rates at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2004b.pdf>
- March 26, 2004-Advanced Notice of Methodological Changes for 2005 (i.e., 45-Day notice) published.
 - Proposed revised MA payment methodology—based on MMA, ratebook transitions to "highest of 2."
 - Proposes ESRD model for implementation in 2005.
-  See 2005 45-Day Notice for additional details at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2005.pdf>
- May 2004-Announcement of draft diagnoses collected for drug risk adjustment model for payment beginning in 2006 and additional codes for CMS-HCC risk adjustment models.
- May 10, 2004-Announcement of rates for 2005.
 - Announced MA county capitation rates.
 - Announced final ESRD CMS-HCC risk adjustment model.
- February 18, 2005-Advanced Notice of Methodological Changes for 2006 (i.e., 45-Day notice) published.
 - Proposed changes in the MA capitation rate methodology and risk adjustment methodology under Part C.
 - Proposed the health status risk adjustment methodology for Part D [Draft Prescription Drug (RxHCC) Model].
 - Proposed payment methodologies for the direct, low income, and reinsurance subsidies, and risk sharing.
-  See 2006 45-Day Notice for additional details at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2006.pdf>
-  April 4, 2005-Announcement of rates for 2006.
 - Announced final Part D risk adjustment model.
 - Rolled back proposed changes to MA risk adjustment model outlined in February 18, 2005 Advance Notice.
 - April 8, 2005-Updated regional rates.
 - April 13, 2005-Updated ratebook.
-  See Final 2006 Notice for additional details at:
<http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2006.pdf>
- April 7, 2005- Risk Adjustment models and ICD-9/HCC crosswalks posted at
http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp



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RISK ADJUSTMENT METHODOLOGY



April 3, 2006—Announcement of 2007 Payments posted at
<http://www.cms.hhs.gov/MedicareAdvltgSpecRateStats/Downloads/Announcement2007.pdf>.

- Announced recalibrated version of the CMS-HCC model for 2007
- Announced updated normalization factor for CMS-HCC models



April 2, 2007—Announcement of 2008 Payments posted at
<http://www.cms.hhs.gov/MedicareAdvltgSpecRateStats/Downloads/Announcement2008.pdf>.

- Announced recalibrated versions of ESRD models for 2008
- Announced normalization factor for Part D risk adjustment model
- Announced updated normalization factor for Part C CMS-HCC and functioning graft models
- Announced normalization factor for ESRD dialysis and transplant models
- Announced recalibrated frailty model
- Announced new frailty payment implementation for PACE and certain demonstration organizations

1.2 Calculating Payments

1.2.1 Payments for 2004 and 2005

Traditionally, payments to MA organizations were based solely on demographic information. Risk adjustment provides more accurate payments for MA organizations. Payments are higher for less healthy enrollees and lower for more healthy enrollees. For 2004 and 2005, MA risk payment calculations involved two steps:

1. Derive the county risk rate, and
2. Multiply by the individual risk factor.

CMS derived county risk rates for Part A and Part B by multiplying the unadjusted Part A and Part B county rates (used for demographic payments) by a rescaling factor, based on the CMS-HCC risk factor of the FFS enrollees in that county. This county risk rate was then multiplied by the individual's CMS-HCC risk factor to determine the appropriate payment amount. The MA organization demographic and CMS-HCC payment rates for 2004 through 2007 and beyond are as follows:

- For 2004, MA organizations were paid using 70 percent of the demographic payments and 30 percent of the CMS-HCC payments.
- For 2005, MA organizations were paid using 50 percent of the demographic payments and 50 percent of the CMS-HCC payments.
- For 2006, MA organizations were paid using 25 percent of the demographic payments and 75 percent of the CMS-HCC payment.
- For 2007 and beyond, MA organizations are paid using 100 percent of the CMS-HCC payment.

Prior to the passage of the MMA, the 2004 MA (then M+C) rates for each county were defined as the maximum of three possible categories: the blended capitation rate, minimum "floor" amount, or minimum two percent increase rate. With the enactment of the MMA in December 2003, the original 2004 payment methodology changed and required CMS to issue revised capitation rates for CY 2004.



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The MMA mandated that a fourth rate type, 100 percent of projected fee-for-service Medicare costs (with adjustments to exclude direct medical education and include a VA/DOD adjustment) be added to the payment methodology. With the addition of this 4th prong to the MA payment methodology, the formula reconnects the link between managed care payment rates and fee-for-service spending at the county level. For 2004 only (a transition year under the MMA rate-setting rules), the county capitation rate was this highest of four rates: blended rate, floor amount, minimum increase rate, and FFS rate.

In addition, from 2004 onward, the MMA modifies the methodology for calculating the minimum percentage increase. The previous year's rate is increased by the larger of:

- 2 percent
- or
- the Medicare growth percentage, - with no adjustments to this growth trend for over/under projections for years before 2004.

For 2005 and subsequent years, the MA capitation rate for a county is the minimum percentage increase rate, except for years when CMS re-tabulates ("rebases") the FFS rates. In rebasing years, the county capitation rate is the higher of the minimum percentage increase rate or the FFS rate.

1.2.2 MA Capitation Rates for 2006 through 2008

CY 2006 was the first year that MAOs were paid based on the MMA bid-based methodology. Thus, the capitation rates are no longer the same as payment rates. Capitation rates are used to establish benchmarks, and payment rates are plan-specific per capita monthly bids (adjusted).

For 2006, the final estimate of the increase in the National Per Capita Medicare Advantage Growth Percentage for aged beneficiaries was 4.8 percent, which is greater than 2 percent. Therefore, 4.8 percent was used as the minimum update percentage in calculating the 2006 rates. For 2006, all capitation rates are the 2005 rate increased by 4.8 percent. Per the MMA, CMS is not required to rebase the county fee-for-service rate every year and did not do so for 2006. In addition, for 2006, MA organizations were paid using 25 percent of the demographic payments and 75 percent of the CMS-HCC risk payments.

For 2007, the final estimate of the National Per Capita Medicare Advantage Growth Percentage was 7.1 percent. Because fee-for-service rates were rebased (to reflect more recent county growth trends in fee-for-service expenditures), counties where the FFS rate is greater than the minimum percentage increase rate received the FFS rate. For 2007, 6 percent of the counties received the FFS rates. For 2007 and beyond, payments to MA organizations will be at 100 percent of the CMS-HCC risk rate.

For 2008, the final estimate of the National Per Capita MA Growth Percentage is 5.7%. This final estimate includes 4.3 percent for the 2008 underlying trend change and 1.3 percent due to corrections to prior years' estimates, as required by law. CMS did not re-tabulate the FFS rates for 2008, so all MA capitation rates are minimum percentage increase rates.

1.2.3 Risk Ratebook

For payments years through 2006, a rescaling factor has been used to convert the demographic capitation rates to the risk adjusted capitation rates for each county. This is referred to as a restandardizing



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RISK ADJUSTMENT METHODOLOGY

the ratebook. The rescaling factor is defined as the county rate properly standardized to the new risk adjustment factors divided by the demographic county rate. In addition to restandardizing the ratebook, a budget neutrality factor is applied to make risk adjustment budget neutral. (see below for more information)

Section 5301 of the Deficit Reduction Act (DRA) changes the way CMS develops its capitation rates, beginning in 2007. The DRA established a single risk ratebook for monthly capitation rates, because the statutory transition for MA plans from payment based on the demographic rates and demographic adjustment factors to payment based on risk adjustment rates and risk adjustment factors were completed in 2006. Effective 2007, MA capitation rates are risk rates. Capitation risk rates are used to determine the plan benchmarks for virtually all MA plans and MAOs set their bids in relation to their benchmarks.

The DRA defines the risk rates as the base ratebook, so CMS will now publish two sets of rates – risk and demographic rates. CMS will continue to publish the demographic rates because they are used in budget neutrality (BN) factor calculations. Also, the demographic rates will be used in 2007 to determine payments to certain demonstrations and PACE organizations, which lag one year in the transition blend so that 25 percent of their payments will be based on demographic rates.

In addition, the FFS normalization factor, which was applied in the rate book prior to 2007, is instead applied to the risk scores starting in 2007. The result of these two approaches is mathematically the same.

Table 1A shows the risk adjustment models and updates implemented for payments beginning with 2004. Note that all models are implemented with their associated new enrollee models.

TABLE 1A – RISK ADJUSTMENT MODEL IMPLEMENTATION FOR PAYMENT (Slides 12 & 37)

PAYMENT YEAR	RISK ADJUSTMENT MODEL IMPLEMENTED FOR PAYMENT	CALIBRATION YEARS	NORMALIZATION FACTOR
2004-2006	CMS-HCC Community & Institutional	1999-2000	1.05
2005-2007	ESRD Functioning Graft	1999-2000	1.05
	ESRD Dialysis and Transplant	1999-2000	N/A
2006-current	RxHCC	2002-2006	N/A
2007-current	Recalibrated CMS-HCC Community & Institutional	2002-2003	1.029
2008	Recalibrated ESRD Functioning Graft	2002-2003	1.04
	Recalibrated ESRD Dialysis and Transplant	2002-2003	1.010
	Recalibrated CMS-HCC Community and Institutional	2002-2003	1.04*
	RxHCC	2002-2006	1.065**

*The 2008 normalization factor for the CMS-HCC community and institutional models was updated from 2007 to include one additional year of FFS data. Note that the 2007 recalibrated model did not change for 2008 payments.

**The 2008 normalization factor for the RxHCC model will be first implemented in 2008. Note that the 2006 model did not change for 2008 payments.



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RISK ADJUSTMENT METHODOLOGY

1.2.3.1 Adjustment for Budget Neutrality

While risk adjustment (without the implementation of budget neutrality) would reduce aggregate payments to the MA program, budget neutrality redistributes these payments as a constant percentage to organizations affected by risk adjustment (including MA organizations, PACE, and certain demonstrations). In other words, under budget neutrality, savings that would have accrued to the Medicare Trust Fund due to the application of risk adjustment are instead redistributed among MA organizations. The budget neutrality factor is calculated as the difference between payments under 100 percent of the risk adjustment method (i.e., under the CMS-HCC model) versus payment under 100 percent of the demographic only method.

The following sections discuss recent changes in the application of budget neutrality policy.

1.2.3.2 Change in the Budget Neutrality Calculation to Account for Different Payment Methodologies for Local MA Plans Versus Regional MA Plans

Because of the difference in payment methods for local MA plans versus regional MA plans beginning in 2006, CMS will modify the budget neutrality calculation. Budget neutrality is calculated as the difference between aggregate MA payments at the local MA benchmark rate that would have been made using the demographic method for 100 percent of payments and the aggregate payments that would be made using 100 percent of risk adjusted payments. Budget neutrality will be applied to both local and regional MA plans. For regional plans, this means that the budget neutrality factor will be applied to the statutory component of the benchmark.

1.2.3.3 Phase Out of Budget Neutrality

The DRA mandates the phase-out schedule for the BN factor from 2007 through 2010. The phase out schedule is shown in Table 1B. Under the budget neutrality methodology, in 2006, 100 percent of the difference between payment under the demographic method and payment under risk adjustment was added back to the risk payment rates via a rescaling factor. However, due to the payment blend for 2006 this will result in 75 percent of the budget neutrality amount being added back to the blended benchmark. For 2007, 55 percent of the BN factor was applied to every risk rate. The percentage applied will decrease each year until 2011, when it is 0 percent (see Table 1B).

TABLE 1B – PHASE-OUT SCHEDULE FOR BUDGET NEUTRAL RISK ADJUSTMENT PAYMENTS

YEAR	BUDGET NEUTRALITY PERCENTAGE
2006	100% ^{1/}
2007	55%
2008	40%
2009	25%
2010	5%
2011	0%

^{1/} 100 percent of the difference between payment under the demographic method and the payment under the risk adjusted method will be added to the risk adjusted payment rates. However, due to the payment blend for 2006 of 25 percent demographic and 75 percent risk adjustment the net effect is a 75 budget neutrality adjustment.



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RISK ADJUSTMENT METHODOLOGY

1.2.4 Payment Blends

The schedule for implementing risk adjusted payments based on the CMS-HCC model and the blended transitional approach is shown below. In 2004, the CMS-HCC model was implemented at a 30 percent risk adjusted payment, with the remaining 70 percent represented by the demographic payment. The portion of risk adjusted payment will increase to 50 percent in 2005, to 75 percent in 2006, and finally to 100 percent in 2007. There was not blended payment transition for the Part C ESRD and Part D models. Payments under these models were implemented at 100 percent risk adjustment from the beginning. The CMS-HCC implementation schedule is shown in Table 1C. The Part C blended payment transition schedule for PACE and certain demonstration organizations is on a one year lag from the payment transition for MA organizations. Table 1D shows that CMS-HCC implementation schedule for specialty organizations.

**TABLE 1C – RISK ADJUSTMENT IMPLEMENTATION SCHEDULE FOR MA ORGANIZATIONS
AND FOR MA-PDS AND PDPS FOR DRUG BENEFIT**

PAYMENT YEAR	CMS-HCC MODEL -COMMUNITY -INSTITUTIONAL	ESRD CMS-HCC MODEL	DRUG BENEFIT MODEL
2004	70% Demographic 30% CMS-HCC Model	N/A	N/A
2005	50% Demographic 50% CMS-HCC Model	100%	N/A
2006	25% Demographic 75% CMS-HCC Model	100%	100%
2007	100% CMS-HCC Model	100%	100%

TABLE 1D – PAYMENT BLEND SCHEDULE FOR SPECIALTY ORGANIZATIONS

TYPE OF HEALTH PLAN	PART C TRANSITION BLEND*				
	2004	2005	2006	2007	2008
PACE	90/10%	70/30%	50/50%	25/75%	100%
WPP	90/10%	70/30%	50/50%	25/75%	100%
MSHO and MnDHO	90/10%	70/30%	50/50%	25/75%	100%
S/HMOs	90/10%	70/30%	50/50%	25/75%	100%
SCO	90/10%	70/30%	50/50%	25/75%	100%

*Represents percentage of original demographic payment methodology (specific to each plan type) versus CMS-HCC risk adjusted portion of payment. ESRD and Part D risk adjustment were implemented at 100 percent risk.



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1.2.5 Fee-for-Service Normalization Adjustment (Slide 37)

The purpose of the fee-for-service normalization adjustment is so that CMS payments are based on a population with an average risk score of 1.0. Because average predicted FFS expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years. Through 2006, CMS adjusted the restandardized ratebook to the appropriate denominator for the payment year. The denominator represented the national average predicted fee-for-service expenditures per beneficiary in that year. Every year there are shifts in the Medicare population. Specifically, fee-for-service coding across all sites of service, coding has not yet stabilized as much as inpatient hospital coding. Therefore, it has been necessary to apply a fee-for-service normalization factor to adjust for changes in coding patterns.

The DRA required CMS to apply the fee-for-service normalization factor to the risk scores. For 2007 the Part C normalization factor for the recalibrated CMS-HCC model is 1.029, and 1.05 for the ESRD functioning graft models. The functioning graft normalization factor remained unchanged from the previous year since the ESRD models were not recalibrated for 2007. There was no normalization factor applied to the dialysis and transplant risk scores for 2007. For 2008, the normalization factor is 1.04 for the CMS-HCC and ESRD functioning graft risk scores. The Part D normalization factor is 1.065.

CMS will implement a four-year normalization phase-in of the Part C - ESRD dialysis and transplant risk scores. For 2008 (Y1) through 2011 (Y4), CMS will calculate a yearly normalization factor. The calculated normalization factor for each year will be adjusted using the specified phase-in percentage for that year. The risk scores will then be divided by the resulting adjusted normalization factor for that year. For example, in 2008 (Y1), dialysis and transplant risk scores will be divided by 25% of the calculated 2008 normalization factor. The normalization factor calculated for 2008 is .039 (or 3.9%). This factor will be multiplied by 25% to get the adjusted normalization factor. Therefore, the ESRD dialysis and transplant risk score normalization formula is $[\text{risk score} / (1 + (\text{the adjusted factor}))]$, which is 1.010 (i.e., $1 + (.039 * 25\%)$) (See Table 1E).

Beneficiary risk scores are divided by a normalization factor. The fee-for-service normalized risk scores will appear on the MMRs. If plans calculate their own raw risk scores using the CMS-provided software, they will need to divide these raw risk scores by the respective normalization factors to obtain the risk scores used for payment.

**TABLE 1E – DIALYSIS AND TRANSPLANT RISK SCORE NORMALIZATION
PHASE-IN SCHEDULE**

YEAR	ADJUSTED NORMALIZATION FACTOR PHASE-IN PERCENTAGE
2008 (Y1)	$1 + (.039 * 25\%)$
2009 (Y2)	$1 + (\text{Calculated Normalization Factor} * 50\%)$
2010 (Y3)	$1 + (\text{Calculated Normalization Factor} * 75\%)$
2011 (Y4) (forward)	$1 + (\text{Calculated Normalization Factor} * 100\%)$



For a complete explanation of the derivation of the demographic and risk adjusted ratebook, see the following: <http://www.cms.hhs.gov/manuals/Downloads/mc85c07.pdf>



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1.2.6 Payments for 2006 and Beyond

1.2.6.1 Bidding Background

Beginning in 2006, CMS' payments for plan enrollees are based on the plan bid relative to the plan benchmark. An MA organization's combined bid for its service area, for both local and regional organizations (or service area segment, in the case of a local organization), will have three parts:

- An amount for the provision of Medicare Parts A and B medical benefits. (This is the standardized A/B bid, and does not include beneficiary cost-sharing.)
- An amount for basic coverage of Medicare prescription drug benefits (if any).
- An amount for the provision of supplemental medical and prescription drug benefits (if any).

Benchmarks. For both local and regional MA plans, the plan A/B benchmark, when compared against the plan A/B bid, determines whether a plan will have savings and rebates to offer additional benefits, or whether the MA organization will have to charge a basic premium for the plan's coverage of Part A and B benefits.

For local plans, the plan A/B benchmark is determined according to formulas established in the MMA. For a single-county plan (or segment), the plan A/B benchmark is the capitation rate for that county, adjusted to reflect the plan's projected risk profile to allow comparison to the plan A/B bid.

For local plans serving more than one county, the plan A/B benchmark is the enrollment-weighted average of all the county capitation rates in the plan's service area (or segment), adjusted by the projected risk profile of the plan. (In determining the enrollment-weighted average, the weights are based on the plan's projected enrollment in each county of its service area.)

The standardized benchmark for each MA region is a blend of two components: a statutory component consisting of the weighted average of the county capitation rates across the region; and, a competitive component consisting of the weighted average of all of the standardized A/B bids for regional plans in the region. The weighting for the statutory component is based on MA eligible individuals in the region. "MA eligibles" refers to all Medicare beneficiaries in the FFS and MA programs. The weighting for the competitive component (which includes each regional plan's bid) is based on the projected enrollment of the regional plans competing in the region. The blend of the two components will reflect the market share of traditional Medicare (for the statutory component) and the market share of all MA organizations (for the competitive component) in the Medicare population nationally.

1.2.7 Intra-Service Area Rate (ISAR) Adjusted County Payment Rates

In 2006 and beyond, payments to MA organizations must be adjusted to account for variations in MA local payment rates among the different MA local areas included in the MA plan's service area. For each MA plan, CMS will apply an ISAR adjustment based on the variation among MA capitation rates in the counties of a MA plan's service area. The ISAR is used to convert the plan's service-area bid into plan-specific county rates.



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The ISAR factor is calculated as the ratio of a county rate to the weighted average of all county rates for the service area, using plan projected county enrollment as the weights. For example, a plan with a service area of three counties (X, Y, and Z) could have ISAR factors of 0.98 for county X, 1.12 for county Y, and 0.9 for county Z. The weighted average of all the plan's county ISAR factors for that plan's service area must equal 1.0. Thus, for each county in the plan's service area, there will be a plan-specific county rate derived from the bid and the ISAR factor.

1.2.8 Plan Payments

Plan payments Part C benefits are based on the relationship of the plan's bid with the plan benchmark.

(a) If the plan bid is less than the plan benchmark, monthly payment from CMS for an enrollee is:

$$\text{ISAR-adjusted county rate} \times \text{enrollee risk factor} + \text{rebate}$$

(b) If the plan bid is equal to the plan benchmark, monthly payment from CMS for an enrollee is:

$$\text{ISAR-adjusted county rate} \times \text{enrollee risk factor}$$

There is no rebate and no basic beneficiary premium.

(c) If the plan bid is greater than the plan benchmark, monthly payment from CMS for an individual is:

$$\text{ISAR-adjusted county rate} \times \text{enrollee risk factor} + \text{government premium adjustment.}$$

There is no rebate and the enrollee pays a basic premium. The combined payment from CMS and the enrollee will on average equal the organization's bid (based on enrollment assumed in the bid submission).

For enrollees who are out of the service area, the base payment will be the 1.0 bid (with individual-level risk adjustment for demographic and health status factors). (Note that for plans with bids above benchmarks, the base payment for out-of-area enrollees is the benchmark because the beneficiary premium is subtracted from CMS' payment.) The rebate amount is not geographically or otherwise adjusted. It is a fixed amount determined through comparison of the plan A/B bid to the plan A/B benchmark based on the plan's projected enrollment.



Example: Plan with a Rebate

- Mr. Jones' plan:
 - Standardized ("1.0") A/B bid = \$600
 - Rebate = \$54
 - His plan's county ISAR factor = .98
 - His risk factor = 1.2
- ISAR-adjusted payment rate for Mr. Jones' county for his plan: $(\$600 \times .98) = \588
- Monthly Part C payment for Mr. Jones for his plan: $(\$588 \times 1.2) + 54 = \759.60

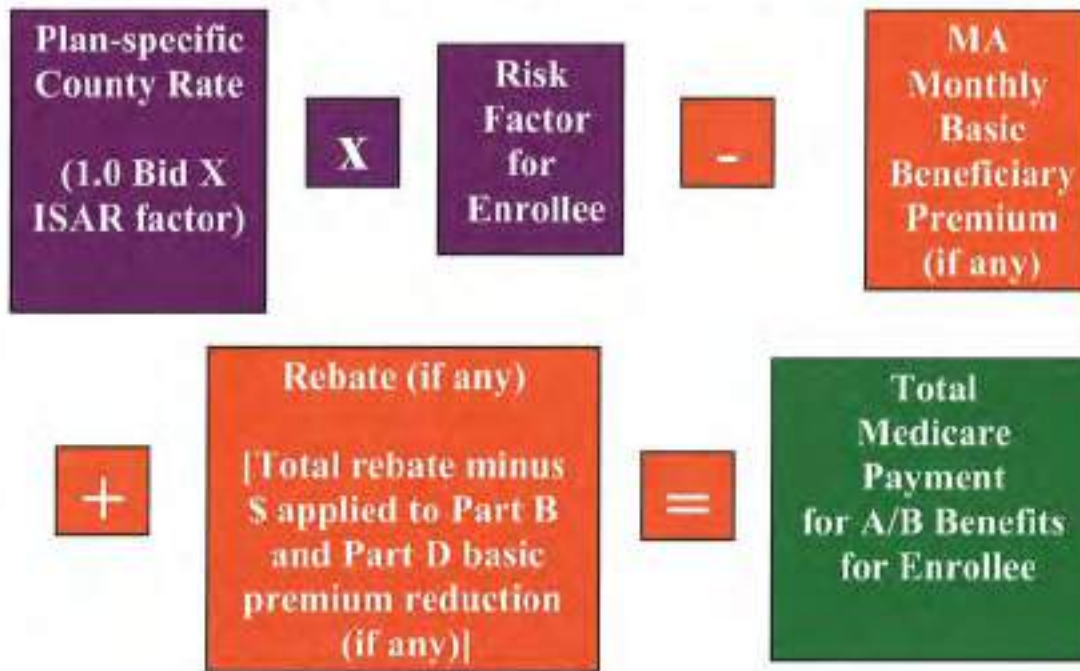


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Figure 1A illustrates the calculation of Risk Adjusted Payment for Plans.

Figure 1A – Calculation of Risk Adjusted Payment for Plans



1.3 Risk Adjustment Payment Models for Payment (Slide 13)

In 2003, after public comment, the CMS-HCC model was finalized as the risk adjustment payment model. The goal was to select a clinically sound risk adjustment model that improved payment accuracy while minimizing the administrative burden on MA organizations.

The model is a revision of the Hierarchical Condition Category model, originally developed by Health Economics Research, Inc. The CMS-HCC model functions by categorizing *International Classification of Diseases, 9th Edition, Clinical Modification* (ICD-9-CM) codes into separate groups of clinically related codes, (e.g., diabetes, cancer, ischemic heart disease, infections, etc.) that have similar cost implications.

In order to improve payment further, CMS has developed separate models for different populations who have different cost patterns than the general Medicare population. There are four CMS-HCC models used to calculate risk scores for MA plans: a community model, a long-term institutional model, an ESRD model, and a new enrollee model. The new enrollee model is different than the other models in that it is not disease based.

CMS implemented the Prescription Drug (Rx-HCC) model in 2006 for payment under Part D. The RxHCC model is also a disease based model similar to the CMS-HCC model. However, it varies in that there is a base model and there are separate multipliers for the long term institutionalized (LTI) and low income



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beneficiaries which are applied to payment outside the model. The RxHCC model is described in detail towards the end of this module.

CMS has updated all of its Part C models and the frailty adjustment model, which is used for Non-ESRD ≥ 55 community residents. The result of the model recalibrations also yields updated normalization factors. Application of the normalization factors is described later in this module.

In 2007, CMS implemented updated versions of the CMS-HCC community and institutional risk adjustment models. Fee-for-service (FFS) claims data for the years 2002 and 2003 were used in the recalibrated model. Diagnosis data for 2002 predict 2003 expenditures. As these data are more current than the 1999 and 2000 data used for the original CMS-HCC model, the updated models reflect newer treatment and coding patterns in Medicare FFS.

For 2008, CMS recalibrated the original Part C ESRD models, and refined the frailty adjustment factors that are applied to the Part C community model risk scores. Similar to the community and institutional recalibration efforts, the ESRD models were recalibrated using 2002 and 2003 FFS claims data for ESRD enrollees. The frailty factors are used to calculate frailty scores applied to the payments to PACE organizations and certain demonstration plans. For PACE plans, CMS will transition from using the frailty factors used in 2007 to the revised frailty factors over five years. CMS will apply the current frailty adjustment factors to MA demonstration organization's payments on a phased-out schedule (described in the frailty section).

CMS' suite of payment models share common conceptual framework in general; however, the purpose for each is distinct to the expenditure patterns for specific Medicare populations.

Table 1F describes the characteristics of the Part C (CMS-HCC) and Part D (RxHCC) models.

TABLE 1F – CHARACTERISTICS OF THE RISK ADJUSTMENT MODELS

CHARACTERISTIC	DESCRIPTION
SIMILAR MODEL CHARACTERISTICS (PART C AND PART D)	
Selected Significant Disease (SSD) Model	- Serious manifestations of a condition are considered rather than all levels of severity of a condition. - Models are additive. - Include most body systems and conditions.
Prospective Model	Uses diagnostic information from a base year to predict total costs for the following year.
Site Neutral	Models do not distinguish payment based on a site of care.
Diagnostic Sources	Models recognize diagnoses from hospital inpatient, hospital outpatient, and physician settings.
Multiple Chronic Diseases Considered	- Risk adjusted payment is based on assignment of diagnoses to disease groups, also known as HCCs. - Model is most heavily influenced by Medicare costs associated with chronic diseases.
Disease Interactions and Hierarchies Included	- Interactions allow for additive factors based on chronic conditions and disabled status to increase payment accuracy. - Hierarchies allow for payment based on the most serious conditions when less serious conditions also exist.
Demographic Variables	- Models include four demographic factors: age, sex, disabled status, and original reason for entitlement. - These factors are typically measured as of the data collection period.



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TABLE 1F – CHARACTERISTICS OF THE RISK ADJUSTMENT MODELS (CONTINUED)

CHARACTERISTIC	DESCRIPTION
PART C SPECIFIC CHARACTERISTICS	
Frailty Adjuster	Frailty add-on is used for PACE and certain demonstration plans with a frail elderly population in the community.
Medicaid Eligibility	- Medicaid status for full risk enrollees is prospective and always determined based on the data collection period. - Medicaid status for new enrollees is concurrent and based on Medicaid status during the payment year (during final payment).
Community-Based and Long-Term Institutionalized Enrollees Distinguished	- Long-term institutionalized is defined as enrollees with 90 days or greater of residence in a nursing home. - Institutional model is not based on institutional factor demographic-only model. - Separate models account for higher treatment costs of similarly-ill community residents. - Community and institutional models both include 70 disease groups.
ESRD CMS-HCC Model	- Model addresses disparate treatment costs structures related to ESRD enrollee status. - The model includes specific payments for individuals with dialysis, transplant, and functioning graft. - The ESRD model includes 67 disease groups.
PART D SPECIFIC CHARACTERISTICS	
LTI Multiplier	- Long term institutional (LTI) factor – gets assigned to the risk scores of beneficiaries with 90 days of residence or greater in a nursing home. - LTI status is determined based on the data collection period.
LIS Multiplier	- Two low income status (LIS) factors (full subsidy, and partial subsidy) – one or the other gets assigned to the risk score for enrollees based on their Part D determined LIS status. - LIS status is determined during the payment year.

1.3.1 Components of the Risk Score in the CMS-HCC Model

CMS uses diagnoses from Medicare fee-for-service and/or from RAPS for determining the HCCs for each enrollee. Medicare fee-for-service data are utilized for risk adjusted payment when an enrollee joins an MA organization (or PACE/demonstration) after opting out of traditional Medicare fee-for-service coverage. That is, if an enrollee new to an MA organization enrolls in January of a calendar year, then CMS will use up to 12-months of prior fee-for-service data within the data collection period (both Part A and Part B) to obtain diagnostic data. Where data for a person have been submitted via RAPS, those data are also used in calculating the risk score for a person.

The risk score used in calculating payments under the CMS-HCC model includes demographics as part of the risk model as well as different disease groups or HCCs. The model allows for the recognition of coexisting diseases when calculating payment by recognizing multiple chronic conditions listed for the beneficiary. Interactions (i.e., combinations) are used to account for expected costs that are higher because, for example, multiple coexisting diseases cause additional complications. Hierarchies are imposed to provide payments only for the most severe manifestation of a certain disease.

1.3.1.1 Demographic Factors (Slide 15)

The risk score uses five demographic factors in calculating the risk score under the CMS-HCC model, including age, sex, Medicaid status, disability, and original reason for Medicare entitlement (i.e., disability).



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Age and Sex: Based upon the enrollee's age and sex, risk adjusted demographic factors are assigned for the calculation of the enrollee's risk factor.

Under the CMS-HCC model, CMS bases payments for the entire payment year upon the age an enrollee attains as of February 1st of each year with one exception, when an enrollee ages in to Medicare. (i.e., Beneficiaries are treated as age 65 for risk adjustment purposes when they attained 65 years of age in the payment year and the reason for entitlement is age.)

Disabled Status: The disabled factors for enrollees under 65 years old are labeled as "disabled" and those over 65 years old are labeled as "aged." Under the CMS-HCC model, additional payments are made for Medicaid eligible disabled individuals.

Original Reason for Medicare Entitlement (OREC): The factors labeled "originally disabled" apply to enrollees that are 65 years old or over who were originally entitled for Medicare due to disability. Under the CMS-HCC model, additional payments are made for OREC individuals with Medicaid based on age and sex,

Medicaid Status: The Medicaid factor applies to enrollees who are entitled to Medicaid under Title XIX of the Social Security Act. A Medicaid factor is applied based on the "aged", "disabled", or "originally disabled" status of the Medicaid enrollee.

1.3.1.2 Disease Groups/HCCs (Slide 16)

Disease groups contain major diseases and are broadly organized into body systems. For risk adjustment purposes, CMS refers to disease groups as HCCs. The HCC assigned to a disease is determined by the ICD-9-CM diagnosis codes submitted during a data collection period. Only selected diagnosis codes are included in the CMS-HCC model. There are 70 distinct disease groups for payment for community and long-term institutionalized residents. The ESRD model has approximately 67 disease groups, depending on the subpart of the model.

Example 1

DISEASE GROUP/HCC	DESCRIPTION
HCC92	Specified Heart Arrhythmia
HCC158	Hip Fracture/Dislocation

1.3.1.3 Disease Hierarchies (Slide 17)

Finally, the CMS-HCC model incorporates disease hierarchies. These hierarchies are used to provide payments for only the most severe manifestation of a disease, even when diagnoses for less severe manifestations of a disease are also present in the beneficiary during the data collection year. For example, an individual with diabetes that progresses over a year from having no complications (HCC19) to having acute complications (HCC17) would trigger the payments for HCC17 but not for HCC19. (Note that payments for HCC17 are higher than for HCC19.)



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Example 4

Cancer

CMS-HCC DISEASE HIERARCHIES			
If the Disease Group is Listed in This Column...		...Then Drop the Associated Disease Group(s) Listed in This Column	
HCC	Disease Group Label	HCC	Disease Group Label
9	Lymphatic, head & neck, brain & other major cancers	10	Breast, prostate, colorectal & other cancers & tumors

1.3.1.4 Disease Interactions

Certain combinations of coexisting diagnoses for an individual can increase their medical costs. The CMS-HCC model recognizes these higher costs through incorporating payments for disease interactions.

There are six disease interactions in the community model and five in the institutional model. Examples of the disease interactions include a two-way combination of diabetes mellitus (DM) and congestive heart failure (CHF) or a three-way combination of chronic obstructive pulmonary disease (COPD), cerebrovascular disease (CVD), and coronary artery disease (CAD).

In calculating this part of the risk score for an individual, the individual score for each HCC is added and then the disease interaction score is added. In the example below, the risk adjusted payment would include an additional factor when an enrollee has both diabetes mellitus and congestive heart failure.



Example 2

Two-disease Interaction for Community-Based Enrollee

Factor 1: Diabetes Mellitus (DM), HCC15 = 0.608

Factor 2: Congestive Heart Failure (CHF), HCC80 = 0.395

Factor 3: Interaction: DM*CHF = 0.204

Risk Score = (demographics) + 0.608 + 0.395 + 0.204

In this case, the enrollee receives an additional interaction instead of only two factors for HCC15 and HCC80.

1.3.1.5 Disabled/Disease Interactions

Another type of interaction accounted for in the CMS-HCC model involves certain diseases and the disabled status for an enrollee. There are five disabled/disease interactions in the community model and four in the institutional model.

Below is an example of an individual who is disabled and has been diagnosed with rheumatoid arthritis and an opportunistic infection.



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Example 3

Disabled/Disease Interaction for Community-Based Enrollee

Factor 1: Rheumatoid Arthritis, HCC38 = 0.363

Factor 2: Opportunistic Infection, HCC5 = 0.410

Factor 2: Disabled * Opportunistic Infection = 0.941

Risk Score = (demographics) + 0.363 + 0.410 + 0.941

1.3.2 New Enrollee Factors

For purposes of risk adjustment, new enrollees are defined as newly eligible disabled or age-in beneficiaries (including "ever-disabled" age-in beneficiaries) with less than 12 months of Medicare Part B entitlement during the data collection year. Note that payments based on Medicaid eligibility will be made retroactively for all new enrollees, once enrollment can be established and verified.

As indicated in Table 1G, beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less than 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees.

Previously, beneficiaries with 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A-only" enrollees) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some demonstrations that "Part A only" enrollees are always considered to be new enrollees, CMS has created an option for determining payments for this category of enrollees. Effective for 2006 payments, organizations may elect to have CMS determine payments for all "Part A-only" enrollees using either new enrollee factors or full risk adjustment factors. The organization's decision will be applied to **all** "Part A-only" enrollees in the plan. Plans may not elect to move some eligible "Part A-only" enrollees into risk adjustment, while retaining others as new enrollees.

This option elected by the organization will remain turned "on" until CMS is notified otherwise prior to August 31st of any successive year. CMS will apply this option during reconciliation for a payment year only (that is, it will not be applied prospectively). Plans interested in this option must contact: Henry Thomas at Henry.Thomas@cms.hhs.gov by 8/31/2007 to elect this option.



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TABLE 1G – WHICH RISK ADJUSTMENT FACTORS APPLY TO PAYMENT*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare**	
	0 - 11 months	≥ 12 months
0 - 11 months	new enrollee factors	Plan's option: new enrollee or full risk adjustment factors
≥ 12 months	full risk adjustment factors	full risk adjustment factors

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled to benefits under Part A and enrolled in Part B.

** During data collection period (previous calendar year).

During the payment year, a new enrollee factor will also be assigned to any beneficiary whose risk score is not available. In this case, the beneficiary's correct risk score will be determined during the next reconciliation.



The new enrollee factors for Part C are available at:

<http://www.cms.hhs.gov/MedicareAdvgtgSpecRateStats/Downloads/Announcement2008.pdf>

1.3.3 Community and Long-Term Institutional Model Distinctions

The CMS risk adjustment approach for Part C uses separate models for non-ESRD community and long-term institutional residents. Separate models were necessary because there are significant cost differences between the traditional community-based MA beneficiary population and the long-term institutionalized beneficiary population with the same disease profile. An adjustment for place of residence improves the payment accuracy of risk adjustment.

A long-term institutionalized MA enrollee is defined as someone who resides in an institution for more than 90 days as identified using the Minimum Data Set (MDS). The costs of the short term institutionalized (less than 90 days) are recognized in the community model.

Table 1H lists the considerations for community and long-term institutionalized populations.



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TABLE 1H – COMMUNITY VERSUS LONG-TERM INSTITUTIONALIZED POPULATIONS

CMS-HCC MODEL CONSIDERATIONS FOR COMMUNITY AND LONG-TERM INSTITUTIONALIZED POPULATIONS	
Community-Based	Long-Term Institutionalized
• Disease-related incremental payments for the community population are generally higher. • Community-based payment includes costs for the short term institutionalized (i.e., less than 90 days in an institution). • Community-based population payment would over predict costs for long-term institutionalized population, even with the same health status. • Currently, most MA organizations have a small proportion of long-term institutionalized enrollees (less than 10 organizations have more than 5% long-term institutionalized enrollees). • For 2004 and 2005, CMS paid all enrollees in most MA organizations as community based. Beginning in 2006, CMS will make prospective payments based on the beneficiaries' statuses (i.e., community or institutional). • The final reconciliation for a payment year will incorporate the correct institutional status for each enrollee for each month.	• Age and sex payment factors are generally higher for the long-term institutionalized population. • Many of the costs of the long-term institutionalized population are not paid for by Medicare. • Institutional model merges a number of disease groups to assure stable coefficients for this population. • Long-term institutional status will be recognized in the payment year. • MDS collected from nursing homes will be used to identify long-term institutionalized enrollees. • The presence of a 90-day assessment and current residence in an institution = long-term institutionalized enrollee. • No additional reporting by MA organizations is required. • Enrollees remain in long-term institutionalized status until discharged to the community for more than 14 days.

As described above in Table 1H, institutional status will be determined from information included in the MDS that is reported by Medicare certified nursing homes. Under the CMS-HCC model, MA organizations **will not report** the institutional status of their enrollees.



Example 5

Below is an example of the different HCC factors for community versus long-term institutional enrollees.

DISEASE GROUP	DESCRIPTION	COMMUNITY FACTOR	INSTITUTIONAL FACTOR
HCC1	HIV/AIDS	0.933	0.735
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.648	0.568



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Table 1I reflects the distribution of Medicare beneficiaries in the January 2005 cohort institutionalized longer than 90 days as of April 2004.

**TABLE 1I – DISTRIBUTION OF LONG-TERM INSTITUTIONALIZED BENEFICIARIES
ACROSS ORGANIZATION TYPES - 2005**

Organization Type	Total Number Beneficiaries	Number Beneficiaries Institutional	Percent of Beneficiaries Institutional	Number of Plans	Number Of Plans >5% of Beneficiaries Institutional
1876 Cost	337,869	5,435	1.61%	32	3
Dual Eligible and Other Demonstrations	7,427	2,387	32.14%	12	5
HCPP	97,210	2,512	2.58%	15	0
PACE	10,150	531	5.23%	32	19
Medicare Advantage	4,848,817	50,158	1.03%	199	12
S/HMO	133,763	840	0.63%	4	0
Total	5,435,236	61,863	1.14%	294	39

Key

Dual Eligible and Other Demonstrations: include Wisconsin Partnership Program (WPP), Minnesota Senior Care Options (MSHO) and Disability Health Options (MnDHO), Massachusetts Senior Options (SCO)

S/HMO: Social Health Maintenance Organizations

1.3.4 Frailty Adjuster (Slides 19-20)

The frailty adjuster is included as part of risk adjusted payments for A and B services to PACE and certain demonstration organizations. The purpose of the frailty adjuster is to predict Medicare expenditures that are unexplained by the risk adjustment methodology alone. The CMS-HCC model uses diagnoses to adjust the payments to MA organizations. This model was calibrated based on the general Medicare population that has an average level of functional impairment. The frailty model further adjusts payment based on whether an organization's enrollees are more or less frail than the average.

Under frailty adjustment, the relative frailty of an organization is measured in terms of the number of functional limitations as represented by the Activities of Daily Living (ADL) scale. There are six ADLs: 1) bathing and showering; 2) dressing; 3) eating; 4) getting in or out of bed or chairs; 5) walking; and 6) using the toilet. A sample of individuals in each organization is surveyed to determine the relative frailty of the organization. Frailty adjustment lowers risk scores for individuals with 0 ADLs and increases risk scores for all of the categories of ADLs.



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1.3.4.1 Why is There a Frailty Adjuster?

- The Balanced Budget Act of 1997 (BBA) mandated that Medicare capitated payments to PACE organizations be based on MA payment rates, adjusted to account for the comparative frailty of PACE enrollees.
- The CMS-HCC model does not explain all of the variation in expenditures for the frail, community-based population. The frailty adjuster is used to project the Medicare expenditures of community populations age 55 and over that are unexplained by risk adjustment.

1.3.4.2 Which Organizations Are Currently Being Paid Under Frailty Adjustment?

Table 1J lists the types of health plans being paid under frailty adjustment.

TABLE 1J – PLANS RECEIVING FRAILITY ADJUSTMENT

TYPE OF HEALTH PLAN	FRAILITY ADJUSTER IS PART OF RISK ADJUSTED PAYMENT
MA	NO
PACE	YES
Wisconsin Partnership Program (WPP)	YES
Minnesota Senior Care Options (MSHO) and Disability Health Options (MnDHO)	YES
Social Health Maintenance Organizations (S/HMOs)	YES
Massachusetts Senior Options (SCO)	YES

1.3.4.3 How Does the Frailty Adjuster Work Under the CMS-HCC Model?

The frailty adjustment factors were designed to explain (or predict) the Medicare expenditures that are unexplained by risk adjustment for groups with similar functional impairments. Therefore, frailty adjustment was designed to be applied in conjunction with the CMS-HCC model. Since the CMS-HCC model adequately predicts the Medicare expenditures of the long-term institutionalized and the under-55 disabled population, frailty adjustment is only applied to non-ESRD community residents who are 55 and over.

CMS calculates an organization-level frailty score based on the difficulties in activities of daily living (ADLs) that are reported by enrollees. The organization-level frailty score is then added to the risk score for each 55 and over community resident.

1.3.4.4 Frailty Model Development (Slide 22)

The current frailty factors were calibrated using ADL limitation information from the Medicare Current Beneficiary Survey (MCBS) -- which is a face-to-face survey. Annual frailty factors were calculated using the Health Outcomes Survey – Modified (HOS-M) -- which is an anonymous mail-in survey with telephone follow-up.



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For 2008 payments, CMS has changed its source for calibrating the frailty model from the MCBS to the FFS CAHPS data. The change has the advantage of using two surveys with similar methodologies for calibrating the model and for calculating annual frailty scores — both the HOS-M and FFS CAHPS collect ADL information via mail surveys with telephone follow-up. CMS added questions regarding ADLs to the FFS CAHPS surveys collected between March 2003 and February 2004, used claims data for the beneficiaries in the sample, and recalibrated the frailty factors with these data.

The revised frailty factors are also generally lower because:

1. Through mail versus face-to-face survey, beneficiaries more accurately report their functional impairments. Researchers have recognized that written surveys capture more accurate accounts of personal reporting than surveys that are conducted face-to-face. The changes in reporting of ADL limitations resulted in more accurate accounting of the residual expenditures from the CMS-HCC model; and
2. The decrease in home health payments mandated by BBA—as frailty is highly correlated with home health expenditures in a community setting. CMS will continue to use the current frailty methodology to transition frailty payment for PACE organizations and phase-out frailty payments for certain demonstration organization. This implementation schedule is provided in Section 1.3.4.5.

The CAHPS frailty calibration sample is much larger than the MCBS sample. These data have helped to better determine the relationship between frailty and costs given Medicaid and non-Medicaid status in the general Medicare population. For this reason, CMS is able to reliably estimate separate frailty factors for Medicaid and non-Medicaid frail Medicare beneficiaries—because the Medicaid and non-Medicaid frail populations show differences in the relationships between unexplained expenditures (in the CMS-HCC model) and functional impairments. Table 1K provides the Current and Revised Frailty Factors by ADL distribution.

CMS has considered the impact of applying a program wide frailty adjuster and the effect of this on the current bidding methodology. CMS decided that the frailty adjuster will not be applied across all MA organizations. Methodologically, a program-wide adjustment does not improve payment accuracy for two reasons:

1. The HOS data used currently to determine frailty scores for payment is sampled only at the contract level, and therefore, does not allow for accurate calculation of frailty scores at the plan benefit package (PBP) level—thus, contract level frailty scores would lead to inconsistent payments across plans and beneficiaries; and
2. MA organizations would need to project frailty scores in their bids. Due to the changing nature of the marketplace and the different enrollment profiles of plans from year to year, this creates a risk that the level of frailty assumed by a plan in its bid would not reflect its actual score in the payment year.

TABLE 1K – CURRENT AND REVISED FRAILTY FACTORS

ADL LIMITATIONS	CURRENT FACTOR	REVISED MODEL FACTORS	
		NON-MEDICAID	MEDICAID
0	-0.141	-.089	-.183
1-2	+0.171	+0.110	+0.024
3-4	+0.344	+0.200	+0.132
5-6	+1.088	+0.377	+0.188



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1.3.4.5 Frailty Payment Implementation

In 2008, CMS will begin transitioning PACE organization payments to 100 percent of the revised frailty factors over a 5-year period through 2012. In each year, the monthly PACE organizations payment would be based on the A/B risk score plus the established frailty transition amount. CMS will also begin a four year phase-out of frailty payments using the current methodology through 2011 for the dual demonstration organizations-- Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP), and Massachusetts Senior Care Options (SCO). Table 1L shows the frailty payment implementation schedule for PACE and demonstration organizations. The percentage (%) represents the percent of the contract-level frailty factor (current and/or revised) that will be added to the monthly A/B risk scores for payment.

TABLE 1L – FRAILITY PAYMENT IMPLEMENTATION SCHEDULE FOR PACE AND DUAL DEMONSTRATION ORGANIZATIONS

TYPE OF CONTRACT	2008 FRAILITY PAYMENT SCHEDULE	2009 FRAILITY PAYMENT SCHEDULE	2010 FRAILITY PAYMENT SCHEDULE	2011 FRAILITY PAYMENT SCHEDULE	2012 FRAILITY PAYMENT SCHEDULE
% current frailty factor / % revised frailty factor					
PACE	90 / 10	70 / 30	50 / 50	25 / 75	0 / 100
Wisconsin Partnership Program (WPP)	75 / 0	50 / 0	25 / 0	0 / 0	
Minnesota Senior Care Options (MSHO) and Disability Health Options (MnDHO)	75 / 0	50 / 0	25 / 0	0 / 0	
Social Health Maintenance Organizations (S/HMOs)	75 / 0	50 / 0	25 / 0	0 / 0	
Massachusetts Senior Options (SCO)	75 / 0	50 / 0	25 / 0	0 / 0	

The range of frailty scores varies considerably among the organizations to which frailty adjustment applies (i.e., "frailty" plans). Table 1M shows a range of frailty scores by type of organizations for the current frailty methodology conducted using the MCBS and the new frailty calibration methodology using the FFS CAHPS data.



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TABLE 1M – RANGE OF FRAILTY SCORE BY TYPE OF ORGANIZATION

ORGANIZATION TYPE	CURRENT MODEL FRAILTY SCORE (MCBS DATA)	RECALIBRATED—MEDICAID/ NON-MEDICAID FRAILTY SCORE (FFS CAHPS DATA)
PACE	0.375 – 0.791	0.064-0.226
S/HMOs	0.057 – 0.122	0.008-0.039
WPP	0.371 – 0.574	0.091-0.162
MnDo	0.583	0.143
MSHO	0.176 – 0.263	-0.017-0.009
SCO	0.166 – 0.414	-0.033-0.053

1.3.4.6 ADL Information Collection and Frailty Adjuster Development

CMS will continue to calculate annual contract-level frailty scores using results from the HOS-M survey. The revised frailty adjuster that will be used for PACE organization payments will include eight factors (instead of four factors under the current model): Medicaid eligible ADL limitations 0, 1-2, 3-4, and 5-6; and Non-Medicaid ADL limitations 0, 1-2, 3-4, and 5-6. The weighted factors will be summed to get the contract-level frailty score for payment. Demonstration organizations stated in Section 1.3.4.4 will continue to receive frailty payments based on the single frailty factor that is calculated using the current methodology (i.e., MCBS).

1.3.4.7 Calculating the Frailty Score for Payment

The organization-level frailty score is calculated as the weighted average frailty factor across all 55 and over community survey respondents for that organization.

The first step is to determine the number of ADLs with which each respondent has difficulty or is unable to do. Then the number of respondents in each ADL category (0 ADLs, 1 to 2 ADLs, 3 to 4 ADLs and 5 to 6 ADLs) is counted. These counts are multiplied by the corresponding frailty factor for each ADL category. The resulting products are then summed for each organization. This sum is divided by the number of 55 and over community respondents, yielding a weighted average factor (or frailty score) for each organization. The same frailty score is used for all 55 and over respondents and non-respondents of a plan who reside in the community.

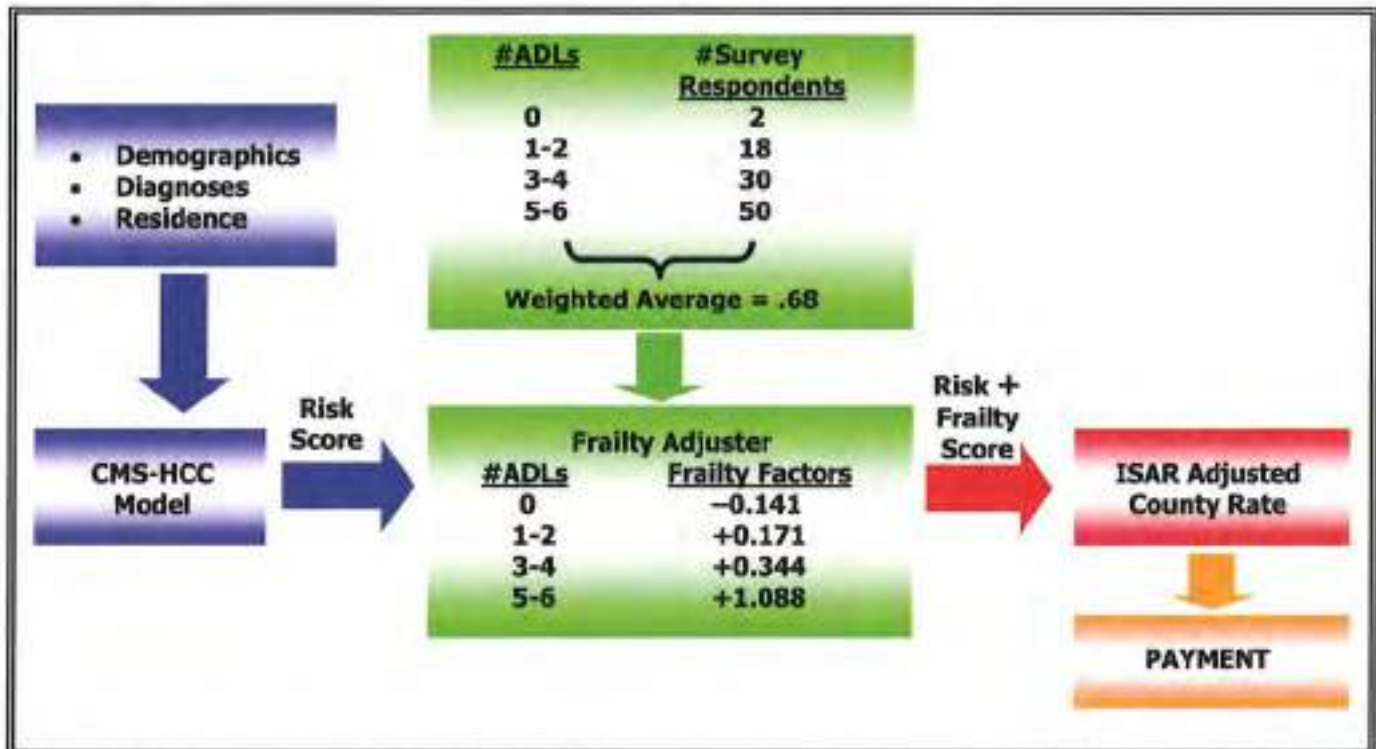
This frailty score is added to the risk score of each 55 and over community enrollee in the organization (including new enrollees), resulting in a risk+frailty score for each individual. Payments to these plans are the product of this combined score and the risk adjusted county rate. Figure 1B illustrates this calculation and includes the ADL-based frailty factors.



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Figure 1B – Frailty Adjustment Calculation



Note: For new PACE organizations not yet participating in the survey, their frailty score is the weighted average factor across all community respondents of all PACE organizations.

1.3.5 Payment Methodology for ESRD Enrollees (Slides 25-27)

In order to further improve payment accuracy, CMS implemented the ESRD risk adjustment model. Effective January 2005, MA enrollees with ESRD were incorporated into diagnosis-based risk adjustment using a different version of the CMS-HCC model. This ESRD models were re-estimated for payments beginning in 2007 and ESRD risk score normalization of dialysis and transplant risk scores will be implemented in 2008. Section 605 of BIPA required CMS to adjust its approach to computing ESRD payment rates to reflect the method used in the ESRD S/HMO demonstration then in place. The three parts of the ESRD CMS-HCC model are:

Dialysis Status—A risk adjustment model that is calibrated for people on dialysis, so the payment weights are unique to these beneficiaries. The State ratebook used for dialysis payments was rebased with more recent data.

Transplant Status—Kidney or Kidney/Pancreas – CMS calculates the payment amount by calculating the cost of services during the month of the transplant and for the two succeeding months. CMS makes different payments for those who have a kidney transplant and for those who have a pancreas transplant simultaneous with the kidney transplant. However, because the initial data system used for payment will not be able to distinguish individuals with a double transplant in a timely manner, all transplants will initially be paid at the kidney transplant rate. The rarer double transplant will be taken into account in



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reconciliation. CMS also differentiates payments for months close to the transplant period from those further out.

Functioning Graft Status—A modified version of the CMS-HCC model for people who have functioning kidney grafts, i.e., that they have received a kidney transplant or kidney/pancreas transplant at least three months ago and did not return to dialysis status since the transplant. The model has an additional term to recognize the extra costs of immunosuppressive drugs and higher intensity of care for this group.

CMS developed this three-part model in response to the findings on expenditure patterns for ESRD beneficiaries. Dialysis patients have high ongoing costs, while transplant patients incur a very high one-time cost. Functioning graft patients are much more similar to the general population than they are to dialysis patients except for the cost of immunosuppressive drugs. Using the same payment weights for all three groups would lead to over- or underpayments to MA organizations.

CMS updated the state ratebook used to make payments for enrollees in dialysis and transplant status. CMS will phase-in the revised State rates by blending payments based on the current ratebook and the ratebook using the dialysis-only trend. Over a 4-year period, CMS will apply the payment blend according to the schedule described below in Table 1N.

TABLE 1N – NEW ESRD DIALYSIS AND TRANSPLANT PAYMENT TRANSITION

YEAR	CURRENT RATEBOOK PERCENTAGE	REVISED RATEBOOK PERCENTAGE
2008	75%	25%
2009	50%	50%
2010	25%	75%
2011	0	100%

1.3.5.1 Risk Adjustment Model for Dialysis Patients

The dialysis model has the same HCC categories used for the CMS-HCC model. The exception is that the HCCs representing dialysis status and kidney failure are excluded (HCC130 to HCC131). This means that the ESRD model has only 68 HCC categories. The model is calibrated only on dialysis patients, so the disease weights used for payment recognize disease and expenditure patterns are unique to this population.

The data used for calibrating the ESRD models were 2002 (diagnostic) and 2003 (program payment) data on fee-for-service ESRD beneficiaries. For example, expenditures for a fee-for-service beneficiary on dialysis from January through August 2003 who received a transplant in September 2003 are included in the dialysis group for eight months, but then are excluded. From September through November 2003, this beneficiary's costs are included in the transplant data to determine estimated average transplant costs. As of December 2003, this beneficiary is included in the functioning graft model.



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1.3.5.2 Transplant Model

To accommodate the high one-time cost of a transplant, CMS will make payments over three months to cover the costs for this transplant and payments for the immediate subsequent services. CMS calibrated the payments by using fee-for-service hospital stay payments for the transplant, and physician and other services rendered for the hospital stay and the two months after discharge. The national average was converted to a relative factor by dividing by the national average payment for dialysis patients. For example, the factor for month 1 is calculated as: \$32,558 (average transplant costs in month 1) divided by \$5,039 (mean monthly dialysis costs, i.e., \$60,471/12). The relative factors for transplant reflect the costs in each month; therefore, the 1st month has a substantially higher factor (6.45) than months 2 and 3 (1.01). The transplant factor is applied to the dialysis state ratebook to provide a transplant payment. Payment will be made in practice by determining the month of transplant and paying the amount over the three-month period starting with the transplant month.

1.3.5.3 Functioning Graft Model

The model for functioning graft enrollees is based on the model for the general population, except that HCCs for kidney transplant status, dialysis status, and renal failure are excluded. For their members with functioning grafts, as for dialysis members, MA organizations will be paid in 2008 based on the diseases reported from all risk adjustment sources in the prior year. However, functioning graft status is recognized in the payment year. In the adapted general population model, almost all of the HCC disease coefficients have been held to their general population values. A few HCCs have been removed and extra terms have been added specific to being in functioning graft status.

The values for the add-on terms have been estimated with data specific to this population and recognize the Medicare coverage of immunosuppressive drugs and the added intensity of services required by this population. They are identified as "graft factors" in the functioning graft model. The graft factors include two sets of coefficients. One set is used between the fourth and the end of the ninth month after a transplant and the second set is used for tenth month and all months thereafter. The functioning graft payment automatically begins the month after the third transplant payment unless the ESRD Network reports that the member has returned to dialysis or had to have another transplant. Anytime a functioning graft patient returns to dialysis, payment is made using the dialysis model.

1.3.5.4 Model Comparison of Coefficients (Slide 28)

The ESRD dialysis model has a higher base factor (age/sex) and lower factors associated with diagnoses than does the CMS-HCC model. This is because Medicare costs for ESRD beneficiaries are much higher than they are for the average Medicare beneficiary, but they are relatively uniform. This means that the Medicare costs for ESRD beneficiaries do not vary as much as the Medicare costs for Medicare beneficiaries in general. Hence, diseases do not explain as much of the cost variation among ESRD beneficiaries and therefore, these costs are retained in the age/sex coefficient in the ESRD dialysis model.

1.3.5.5 New Enrollee Factor

The dialysis and functioning graft models have new enrollee factors for enrollees whose risk scores are not available. New enrollees with transplants receive the normal transplant model factors.



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1.3.5.6 Reporting of ESRD Status

In implementing the new ESRD risk adjustment method, CMS will utilize the existing systems for identification of enrollees receiving dialysis services. Currently, MA enrollees are assigned ESRD status as a result of a physician certifying their ESRD status on CMS Form 2728, the End-Stage Renal Disease Medical Evidence Report. The ESRD facility sends Form 2728 to the Renal Network, which then transmits the status to CMS systems where various databases are updated to record the ESRD status. Payments for dialysis are triggered by this system.

1.3.6 Medicare Part D

Medicare Part D Drug Benefit. In Title I, in addition to the creation of the MA program in Title II of the MMA, Congress added a voluntary prescription drug benefit to Medicare (known as Part D) to be made available for all Medicare beneficiaries through either the MA program or the prescription drug plans. To that end, MA organizations will be required to provide at least one MA plan that provides a "required drug coverage" in each of its service areas. MA plans that offer drug coverage are called MA prescription drug plans (MA-PDs). Beneficiaries receiving health care benefits through fee-for-service Medicare will have the option of accessing prescription drug coverage through sponsors of prescription drug plans (PDPs). Unlike PDPs which can offer supplemental drug coverage only when they offer a standard package in an area, MA-PDs can offer plans with supplemental coverage that qualify as "required prescription drug coverage." Similar to the MA program, CMS established regions (34) through which PDP sponsors will offer Part D drug coverage. To the extent practicable, CMS designed the PDP regions to overlap with the MA regions. Payments to PDP plans for eligible low-income Medicare beneficiaries will be subsidized at different levels depending upon the income and asset of the enrollee.

The MMA requires organizations intending to offer MA plans with original Medicare Parts A and B benefits and/or Part D benefits to submit bids in early June of each year for their basic, supplemental and/or Part D benefit packages. Each bid must reflect a plan's actual revenue requirements to provide the benefits offered in the proposed benefit packages. Benchmarks will be created for local and/or regional plans for bid-benchmark comparisons. Monthly capitated payments will be made based on each plan's bid risk adjusted for health status minus the beneficiary premium amount. The MMA mandates MA organizations and PDPs to provide basic prescription drug coverage as one of their benefit plans.

1.3.6.1 Part D Risk Adjustment Model (Slides 29-30)

The Part D model is similar to the CMS-HCC risk adjustment model. The model includes 113 coefficients: 84 disease groups, 24 age-sex adjustments, 3 interactions between age and disease, and 2 sex-age-originally disabled status interactions. The model was developed assuming an unlimited drug benefit, and was then adjusted for the plan's liability under the Medicare standard Part D benefit.

CMS announced the final Part D risk adjustment on April 4, 2005. The model is published at:
http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp

The Part D risk adjustment model shares most of the characteristics of the CMS-HCC model. That is, the model is: prospective, additive, hierarchical, and contains demographic new enrollee model.



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The key differences are:

- The Part D model is designed to predict plan liability for prescription drugs under the Medicare drug benefit rather than Medicare Part A/B costs.
- Different diseases predict drug costs than Part A/B costs.
- Incremental costs of low-income (LI) and long term institutional (LTI) beneficiaries are multipliers to the base RxHCC model score.

As in the CMS-HCC model, some of the disease groups fall into hierarchies. Drug regimens may intensify and more drugs added in cases where a disease has a higher severity. In such an instance, the highest cost category of the related diseases is triggered and the lower cost category does not increase the Part D risk score.

Like the CMS-HCC model, the Part D model uses the presence of particular demographic characteristics and diagnoses to predict costs in the following year for an individual. The model clusters a set of ICD-9-CM diagnoses within groups that are similar clinically and in terms of their expected costs. The groupings used to predict drug spending are variants of the groups used to predict Part A and B spending, and the data sources for diagnoses are the same as those used in Part C. Disease groups and draft coefficients for the Part D risk adjustment can be found on the CMS web site at:

http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp

In development of the model, drug spending in dollars is used as the dependent variable of a regression model that estimates the marginal or incremental spending related to each of the explanatory variables (demographics and conditions) in the model. The model is ultimately expressed not in dollars, but as relative factors. The incremental dollars associated with each variable in the model are divided by the mean predicted dollars to produce a "relative costliness" or risk factor. Summing the risk factors for an individual yields a total risk adjustment factor that, when multiplied by a base rate, yields an individualized capitation rate.

Recent research has found that the variation in drug expenditures that can be explained is primarily driven by chronic conditions persisting from year to year. The research suggests many of the diagnoses used by CMS for the CMS-HCC model could be used in the Part D risk adjustment model in addition to new diagnosis codes collected. For example, the findings indicated that certain chronic conditions such as congestive heart failure and schizophrenia (CMS-HCC model diagnoses) are good predictors of drug expenditures. However, this research also shows that hypertension and glaucoma, not currently in the model, are also key predictors of drug expenditures. Hence, such findings lead to the conclusion that additional diagnoses, beyond those in the current CMS-HCC model, need to be collected to properly develop a drug risk adjustment model. It is equally true that some conditions currently included in the CMS-HCC model are predictive of Medicare Part A and B medical costs, but not predictive of Part D costs. As such, these diseases could decrease drug expenditures.

Using a similar methodology to that used for the development of the CMS-HCC risk adjustment model, CMS created a list of diagnoses for the drug risk adjuster and, in April 2005, announced the final list of conditions for inclusion in the drug risk adjustment model. Some of the diagnoses overlap with the current CMS-HCC model and others do not. In particular, there are 1,540 ICD-9 codes unique to the CMS-HCC model, 1,940 ICD-9 codes unique to the Part D risk adjustment model, and 1,622 ICD-9 codes



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included in both models. Collection of the diagnoses for the CMS drug risk adjustment model from current MA organizations began in July 2004 and will begin payment in January 2006.

Beneficiaries with less than 12 months of Part B enrollment prior to the payment year and who do not have a complete diagnostic record in the Medicare files will be classified as new enrollees. These individuals will receive the new enrollee factor for the RxHCC model.

1.3.6.2 Low Income and Long Term Institutionalization Multipliers (Slides 31-32)

Base Part D risk factors are incremented by either a LI or a LTI multiplier to account for the additional costs of beneficiaries in these categories. See Table 10 for the definition of LI multipliers for the Part D benefit.

TABLE 10 – DEFINITION OF THE LOW INCOME MULTIPLIERS FOR PART D BENEFIT

	GROUP 1	GROUP 1	GROUP 2	GROUP 2
Income test	Medicaid Dual <100% FPL	<135% FPL	<135% FPL	135-150% FPL
Asset test	<2× SSI	<3× SSI	>3× SSI & <\$10,000 single \$20,000 couple	<\$10,000 single \$20,000 couple
Deductible	\$0	\$0	\$50	\$50
Copay for generic drugs up to catastrophic threshold	\$1	\$2	—	—
Copay for brand-name drugs up to catastrophic threshold	\$3	\$5	—	—
Coinsurance up to catastrophic threshold	—	—	15%	15%
Coinsurance above catastrophic threshold	0%	0%	0%	0%
Copay for generic drugs above catastrophic threshold	\$0	\$0	\$2	\$2
Copay for brand-name drugs above catastrophic threshold	\$0	\$0	\$5	\$5
Premium subsidy	100%	100%	100%	Sliding scale

The LI multiplier is estimated to be 1.08 for Group 1 LI individuals (as defined above) and 1.05 for Group 2 individuals (as defined above). This multiplier is defined on a concurrent basis. (For example, if an individual were not defined as LI for January 2007 but was determined to be a Group 1 beneficiary for February 2007, the plan would receive the LI multiplier for February (and beyond) but not for January.)

An enhancement was also computed for the predicted spending by persons institutionalized in nursing facilities for more than 90 days. Spending for this group is expected to be higher because prices for the specific packages of drugs they receive are somewhat higher than the same drugs in the community.



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(An analysis of drug data done by IMS Health shows that the price differences in the claims were small, particularly for brand name drugs that dominate the spending.) There are also effects related to compliance in acquiring and taking drugs in the institutional environment. On the other side, often patients take fewer drugs because of more careful monitoring of interactions.

An analysis was done for the spending by the institutionalized by first using the base model to predict for this population and then comparing the actual spending and liability to the predicted. For the case of spending, there was a significant positive effect for the aged and the disabled who are in institutions. The effect for the disabled is greater than for the aged. It was also observed that average spending for both groups was in the 100 percent coinsurance range. The disabled mean was quite close to the catastrophic limit. The implications of additional demand being, to a large extent, in the range in which plans do not have incremental liability means that the effect on plan liability is much smaller than the effect on spending. The final payment adjustments for the institutionalized are smaller for the aged than for the disabled and smaller perhaps than some people expect because the final measure is plan liability rather than spending.

Figure 1C illustrates the calculation of the Part D Direct Subsidy.

Figure 1C – Calculation of Part D Direct Subsidy





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1.4 Parts C and D Final Submission of Risk Adjustment Data (Reconciliation)

Reconciliation is used to complete the implementation of payments, with CMS calculating final risk adjustment factors and beneficiary status based on complete data. CMS continues to allow a period (approximately 13 months after the data collection year) for submitting final RAPS data for the appropriate data collection period. Data not received or submitted by the initial submission deadline for a data collection period can be submitted by the final submission deadline (reconciliation). In addition to incorporating new RAPS and fee-for-service diagnoses, reconciliation takes into account necessary adjustments to institutional status and demographic data for enrollees.

Note: CMS reconciles risk-adjusted payments for a calendar year only one time. When submitting risk adjustment data for reconciliation, plans may submit as well as correct data that was previously submitted.

1.4.1 Parts C and D Risk Adjustment Schedule & Elimination of the Payment Lag

Risk adjusted payments were originally implemented with a 6-month payment lag from the end of the collection period to the start of revised payments, based on the data collected.



Example: 6

Data Collection Period: July 1, 2006 through June 30, 2007

Data Collection End Date: June 30, 2007

CY2007: First payment made based on this collection period = January 1, 2008

As you can see, payments began 6 months after the end of the data collection period.

Note: The purpose of eliminating the lag between the end of the data collection period and the payment based on that year's data is to use the most recent data for more accurate payment.

Data Collection Period: January 1, 2007 through December 31, 2007

Data Collection End Date: December 31, 2007

CY2007: Updated payment made based on the non-lagged data collection period = July, 2008

- CMS calculates a preliminary risk factor based on lagged data. For 2008, it will be based on data from July 2006 through June 2007. Payments from January 2008 through June 2008 will be based on this factor.
- In July 2008 CMS will use a risk factor based on non-lagged data (i.e., from calendar year 2007) for calculating payments. That factor will be used for the remainder of the year.
- By eliminating the lag, the collection period will change from July 1 through June 30 to January 1 through December 31 (or a calendar year).



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1.5 Updating Diagnosis Codes in the Parts C and D Risk Adjustment Models

CMS updates the risk adjustment models to reflect the annual updates to the ICD-9 diagnostic code set. After clinical review, new ICD-9 diagnosis codes are added to the appropriate diagnostic categories and included in the CMS-HCC model. A comprehensive listing of the ICD-9 codes that MA organizations are required to submit for all risk adjustment models can be found at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage. This list will be updated annually to take into account new codes that are required for risk adjustment.



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

MODULE 2 – RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

Purpose

The success of Medicare Advantage (MA) risk adjustment is dependent upon organizations understanding the process of collecting and submitting accurate risk adjustment data. The purpose of this module is to provide participants with important terms, key resources, and schedule information that will provide the foundation for this training.

Learning Objectives

At the completion of this module, participants will be able to:

- Define common risk adjustment terminology.
- Demonstrate knowledge in interpreting key components of the risk adjustment process.
- Interpret the risk adjustment schedule.
- Identify the Centers for Medicare & Medicaid Services (CMS) outreach efforts available to organizations.

ICON KEY

Example

Reminder

Resource



2.1 Common Risk Adjustment Terms (Slide 6)

Table 2A provides descriptions of common risk adjustment terminology.

TABLE 2A – RISK ADJUSTMENT COMMON TERMS

TERM	DESCRIPTION
FERAS	Risk adjustment submitters send data to Palmetto through the Front-End Risk Adjustment System .
RAPS	Risk adjustment data are processed by the Risk Adjustment Processing System .
RAS	The Risk Adjustment System calculates the risk score.
MARx	The Medicare Advantage Prescription Drug System calculates the risk payment.
Common UI	The Common UI maintains Medicare beneficiary eligibility data.
HPMS	The Health Plan Management System is a CMS MA information system that contains health plan-level data.
Relevant Diagnosis	ICD-9-CM diagnosis code in the CMS-Hierarchical Condition Category (HCC) model.



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2 Risk Adjustment Process Overview

Hospital inpatient, hospital outpatient, and physician risk adjustment data must be submitted at least quarterly. Risk adjustment data are processed through RAPS.

2.2.1 Risk Adjustment Data Requirements (Slide 7)

- The data required under the risk adjustment process include:
 - Health Insurance Claim (HIC) number.
 - Diagnosis code.
 - Service from date.
 - Service through date.
 - Provider type (hospital inpatient, hospital outpatient, physician).
- MA organizations must submit data at least quarterly to CMS.
- Each quarterly submission should represent approximately one-fourth of the data that the MA organization will submit during a data collection year. MA organizations will be monitored to ensure compliance.
- All beneficiary ICD-9-CM diagnosis codes relevant for the CMS-HCC risk adjustment model must be reported at least once per enrollee in the data collection period.

2.2.2 Risk Adjustment Data Collection (Slide 8)

- MA organizations may choose to collect data from providers in a variety of formats:
 - Standard fee-for-service claim or encounter formats
 - Uniform Billing Form (UB-04)
 - HCFA 1500
 - National Standard Format (NSF) v3.01
 - American National Standards Institute (ANSI) X12 837 v30.51 or v40.10. Health Insurance Portability and Accountability Act (HIPAA) mandated transactions must use v40.10.
 - Superbill
 - RAPS format
 - HIC number
 - Provider type
 - Diagnosis code
 - Service from date
 - Service through date



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2.3 Risk Adjustment Data Submission (Slide 9)

- MA organizations must submit data to CMS through FERAS (Palmetto GBA) utilizing the following formats:
 - RAPS format (all types of data)
 - Direct Data Entry Screen (all types of data)

Figure 2A illustrates the risk adjustment dataflow.



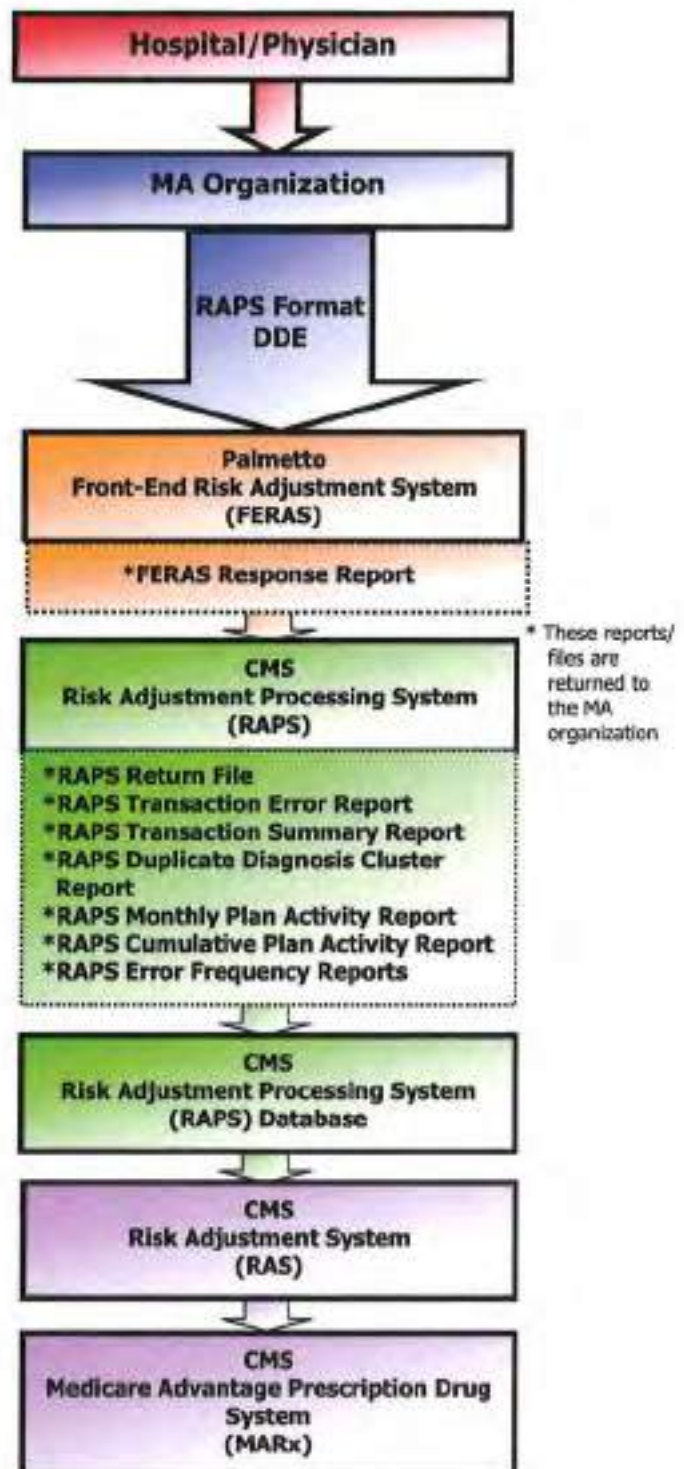
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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2.4 Risk Adjustment Dataflow (Slide 10)

- Hospital/physician submits data to MA organization via:
 - Full or abbreviated UB-04, HCFA 1500, NSF v3.01, ANSI x837 v30.51 or v40.10, Superbill or RAPS format.
- The MA organization submits these data at least quarterly to Palmetto GBA.
- The MA organization submits the data via Direct Data Entry or in the RAPS format.
- The data are sent to FERAS for processing where the file-level data, batch-level data, and first and last detail records are checked.
- If any data are rejected, then data are reported on the FERAS Response Report.
- After passing the FERAS checks, the file is submitted to RAPS where detail editing is performed.
- The RAPS Return File is returned daily and shows all records approved and where errors occurred.
- The RAPS Transaction Error Report displays records on which errors occurred.
- The RAPS Transaction Summary Report is sent to the MA organization daily and identifies data that have been finalized in RAPS database.
- The Duplicate Diagnosis Cluster Report identifies diagnosis clusters submitted with information that duplicates a stored cluster.
- The RAPS Monthly Plan Activity Report and Cumulative Plan Activity Report provides a summary of all diagnoses stored for a given time period.
- Distributed monthly and quarterly, the Error Frequency Report provides an overview of all errors associated with files submitted in test and production.
- RAPS database stores all finalized diagnosis clusters.
- RAS calculates the Risk Adjuster Factors by executing the CMS-HCC model.
- MARx is used in the calculation of payments and determination of plan payments. MARx replaced Medicare Managed Care System (MMCS) on November 15, 2005.

Figure 2A – Risk Adjustment Dataflow





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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2.5 Important Information About Risk Adjustment Processing

- MA organizations transmit data to FERAS at Palmetto GBA.
- FERAS performs format and face validity checks on the file- and batch- level as well as formatting verification on the first and last detail record (CCC) in the file.
- If the data fail the front-end checks, the complete file is rejected at the front end.
- The FERAS Response Report identifies whether the file is accepted or rejected up front.
- Once the file has passed front-end checks, it moves to RAPS. All validity edits on detail-level data are performed in this system.
- Processing time from beginning to end should take approximately 1 to 2 days.
- After the file has processed through RAPS, the MA organization will receive a RAPS Return File and RAPS Transaction Error Report identifying any errors.
- All ICD-9-CM diagnoses that pass validity edits are stored in the RAPS database.
- The MA organization will also receive a RAPS Transaction Summary Report reflecting all finalized data sent to the RAPS database along with all rejected data.
- The MA organization also receives two monthly risk adjustment management reports: 1) the RAPS Monthly Plan Activity Report and 2) the RAPS Cumulative Plan Activity Report.
- All data are converted to the RAPS format and returned in the RAPS Return File.
- Interim hospital inpatient bills (112, 113, and 114 bill types) must not be submitted. If a MA organization receives interim bills, the organization should submit the hospital inpatient diagnoses on receipt of the final bill (114). This means the appropriate *discharge* diagnoses will be submitted for risk adjustment, rather than the *admitting* diagnoses.



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2.3 Submission Schedule (Slide 11)

The elimination of the payment lag changes the submission schedule. This requires MA organizations to meet three submission deadlines—the first Friday in September, the first Friday in March of each year, and a reconciliation (final submission) deadline of January 31. The schedule is illustrated in Table 2B.

TABLE 2B – SUBMISSION TIMETABLE

CY	DATES OF SERVICE	INITIAL SUBMISSION DEADLINE	FIRST PAYMENT DATE	FINAL SUBMISSION DEADLINE
2007	July 1, 2005 through June 30, 2006	September 1, 2006	January 1, 2007	NA
2007	January 1, 2006 through December 31, 2006	March 2, 2007	July 1, 2007	January 31, 2008
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	NA
2008	January 1, 2007 through December 31, 2007	March 7, 2008	July 1, 2008	January 31, 2009
2009	July 1, 2007 through June 30, 2008	September 5, 2008	January 1, 2009	NA
2009	January 1, 2008 through December 31, 2008	March 6, 2009	July 1, 2009	January 31, 2010



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.4 Training and Support (Slide 12)

To ensure that participating organizations have the necessary tools and information to be successful with the risk adjustment process, CMS has planned the following outreach efforts, as described in Table 2C.

TABLE 2C – TRAINING AND SUPPORT

INITIATIVE	DESCRIPTION
Customer Service & Support Center (CSSC)	This toll free help line (1-877-534-2772) is available Monday – Friday, 9:00 a.m. to 7:00 p.m. Eastern Time (ET) (with the exception of corporate observed holidays) to provide assistance. The support center provides ongoing assistance. The FERAS system is available to submit risk adjustment data 24 hours a day, 7 days a week regardless of holidays. The only exception is from 5:00 PM EST - 10:00 PM EST on Sunday when systems and equipment undergo routine maintenance.
<u>www.csscooperations.com</u>	The CSSC website, <u>www.csscooperations.com</u> is the gateway to RAPS. Visitors to the site can access information about RAPS/FERAS, including opportunities to register for service, enroll to submit risk adjustment data, and obtain comprehensive information about data entry and report layouts. In addition, the site provides valuable links to CMS instructions and other official resources. Monthly User Group and other training information are regularly posted. Finally, the site provides up-to-date system status alerts and answers to frequently asked questions (FAQs) about risk adjustment. To register for email updates, go to <u>www.csscooperations.com</u>, click on Risk Adjustment Processing System (RAPS), and then click on "Register for Medicare Advantage". Afterwards, click on "new registrations only" and complete the registration form.
User Groups	Conducted once each month from 1:30 – 2:30 p.m. ET. The purpose of the User Group meeting is to share information among participants, distribute new information, and identify issues for future resolution. Meeting notes and Q&As are provided. To register online for User Groups, go to <u>www.medicaretraining.net</u>.
Onsite Consultation	On-site consultation visits provide MA organizations with the opportunity to gain valuable information about risk adjustment data submission and data validation processes. These consultations generally occur between April and May. Each visit includes a review of the MA organization's system.
Monthly and Regional Training Program	The program provides practical training for new and current users.
<u>www.medicaretraining.net</u>	The website, <u>www.medicaretraining.net</u> is the website for risk adjustment training and User Group information. The website includes information about trainings and user groups, training dates, locations, online registration, and training FAQs.



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MODULE 3 – DATA COLLECTION

Purpose (Slide 2)

For the purpose of risk adjustment, Medicare Advantage (MA) organizations must collect data from hospital inpatient facilities, hospital outpatient facilities, and physicians. The collection of data from the appropriate risk adjustment sources and formats is critical for accurate risk adjusted payment. This module is designed to offer participants an opportunity to apply data collection principles in accordance with Centers for Medicare & Medicaid Services (CMS) requirements.

Learning Objectives (Slide 3)

At the completion of this module, participants will be able to:

- Identify the data elements required for risk adjustment.
- List the three sources of risk adjustment data.
- Describe the data collection formats.
- Discuss factors to consider when determining the method for collection of diagnostic data.
- Apply Health Insurance Portability and Accountability Act (HIPAA) transaction standards for purposes of risk adjustment data collection.

ICON KEY

Example
Reminder
Resource



3.1 Required Risk Adjustment Data Elements (Slide 5)

MA organizations must collect certain data elements from the sources (providers/physicians) of risk adjustment data described in this module. The minimum data elements that must be collected are:

- Health Insurance Claim (HIC) Number
- ICD-9-CM Diagnosis Codes
- Service From Date
- Service Through Date
- Provider Type

3.1.1 HIC Number (Slides 6-7)

A HIC number is a Medicare beneficiary's identification number. Both CMS and the Railroad Retirement Board (RRB) issue Medicare HIC numbers. The format of a HIC number issued by CMS is a Social Security number followed by an alpha or alphanumeric Beneficiary Identification Code (BIC). RRB numbers issued before 1964 are 6-digit numbers preceded by an alpha prefix. After 1964, the RRB began using Social Security numbers as Medicare beneficiary identification numbers preceded by an alpha prefix. Table 3A shows the characteristics for each HIC type.



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TABLE 3A – STRUCTURE OF HIC NUMBERS

HIC TYPE	CHARACTERISTICS
CMS	9-Digit Social Security number - alpha suffix "A" beneficiary "B" spouse "C" children "D" divorced spouse, widow, widower - alpha-numeric suffix - indicates number of children (e.g., "C1" first child)
RRB pre-1964	- alpha prefix 6-digit random numbers
RRB post-1964	- alpha prefix 9-digit Social Security number

Note: MA organizations are not required to collect HIC numbers from physicians and providers, but must identify beneficiaries using the HIC number when submitting data to CMS.

3.1.2 ICD-9-CM Diagnosis Code (Slide 8)

International Classification of Diseases-9th Edition-Clinical Modification (ICD-9-CM) codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. ICD-9-CM codes do not describe the service performed, just the patient's medical condition. Diagnosis codes drive the risk scores, which drive the risk adjusted reimbursement from CMS to MA organizations.

3.1.3 Service From and Through Dates (Slide 9)

The dates of service define when a beneficiary received medical treatment from a physician or medical facility. For outpatient and physician services, the From Date and Through Date may be identical. For inpatient services, these dates are different from each other, and reflect the dates of admission to and discharge from a facility.



Date span is the number of days between the From Date and Through Date for a reported diagnosis. For risk adjustment, the date span is important to determine if the reported diagnosis cluster falls within the data reporting period.

3.1.4 Provider Type (Slide 10)

For the purpose of risk adjustment, MA organizations must collect data from the following provider types:

- Hospital inpatient facilities
- Hospital outpatient facilities
- Physicians

These are the three principal sources of data. MA organizations are responsible for determining provider type based on the source of the data.



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3.2 Data Sources

MA organizations are responsible for ensuring that the data they collect comes from acceptable sources. These sources are hospital inpatient facilities, hospital outpatient facilities, and physicians.

3.2.1 Hospital Inpatient (Slide 11)

A hospital inpatient service is one provided by a hospital during which a patient is admitted to the facility for at least one overnight stay.

Inpatient hospital data should be differentiated based on whether it is received from within or outside of the MA organization's provider network. Effective May 1, 2007, a network hospital should have a National Provider Identifier (NPI) number as a hospital inpatient facility. Table 3B identifies covered and non-covered facilities with regard to risk adjustment data collection.

TABLE 3B – HOSPITAL INPATIENT

PROVIDER TYPE	COVERED FACILITIES	NON-COVERED FACILITIES*
Hospital Inpatient	• Short-term (general and specialty) Hospitals • Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria) • Long-term Hospitals • Rehabilitation Hospitals • Children's Hospitals • Psychiatric Hospitals • Medical Assistance Facilities/ Critical Access Hospitals	• Skilled Nursing Facilities (SNFs) • Hospital Inpatient Swing Bed Components • Intermediate Care Facilities • Respite Care • Hospice

* These are examples of non-covered facilities and not a comprehensive list.



When submitting hospital inpatient data, MA organizations must make a distinction between the principal diagnosis and other diagnoses. The details of submitting data will be covered in the Data Submission module.

3.2.2 Hospital Outpatient (Slide 12)

Hospital outpatient services are therapeutic and rehabilitative services provided for sick or injured persons who do not require inpatient hospitalization or institutionalization.

Data must be collected from hospital outpatient departments. As with hospital inpatient facilities, the MA organization must determine which facility is Medicare certified, network, or non-network. Table 3C identifies covered and non-covered hospital outpatient facilities.



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TABLE 3C – HOSPITAL OUTPATIENT

PROVIDER TYPE	COVERED FACILITIES	NON-COVERED FACILITIES*
Hospital Outpatient	• Short-term (general and specialty) Hospitals • Medical Assistance Facilities/ Critical Access Hospitals • Community Mental Health Centers 1** • Federally Qualified Health Centers 2/ Religious Non-Medical Health Care Institutions (formerly Christian Science Sanatoria) ** • Long-term Hospitals • Rehabilitation Hospitals • Children's Hospitals • Psychiatric Hospitals • Rural Health Clinic (Free-standing and Provider-Based) 3**	• Free-standing Ambulatory Surgical Centers (ASCs) • Home Health Care • Free-standing Renal Dialysis Facilities
	NON-COVERED SERVICES	
	• Laboratory Services • Ambulance • Durable Medical Equipment • Prosthetics	• Orthotics • Supplies • Radiology Services

* These are examples of non-covered facilities and are not to be considered a comprehensive list.

** Facilities use a composite bill that covers both the physician and the facility component of the services, and services rendered in these facilities do not result in an independent physician claim.

1. Community Mental Health Centers (CMHCs) provide outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically ill, and residents of the CMHC's mental health services area who have been discharged from inpatient treatment at an inpatient facility.
2. Federally Qualified Health Centers (FQHCs) are facilities located in a medically underserved area that provide Medicare beneficiaries with preventive primary medical care under the general direction of a physician.
3. Rural Health Clinics (RHCs) are Medicare certified facilities that are located in a rural, medically underserved area that provide ambulatory primary medical care under the general direction of a physician.

**3.2.2.1 Determining Whether Facilities Are Acceptable for Risk Adjustment
(Slide 13)**

MA organizations are responsible for ensuring data collected and submitted are acceptable for the risk adjustment process. In the past, the provider number has been used to assist in this. However, CMS is in the process of implementing a new provider identifier, the National Provider Identification (NPI) number. As will be discussed below, the CMS will continue to allow the use of the legacy provider number along with the new NPI for a transition time. However, the NPI does not have intelligence, so a new code called the "taxonomy code" was developed to help identify types of providers. Both the legacy provider number and the taxonomy code can be used in determining the appropriateness of the covered hospital entities for the purposes of risk adjustment data collection. Table 3D illustrates the steps MA organizations may use to identify the provider numbers or taxonomy codes for facilities.



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TABLE 3D – DETERMINING COVERED HOSPITAL ENTITY PROVIDER NUMBERS

SITUATION	ISSUE	ACTION
Situation 1	The provider number or taxonomy code is identified.	Determine if the number is in an acceptable range for risk adjustment. If in the acceptable range, submit the data.
Situation 2	An in-network provider submitted a claim but did not include the provider number or taxonomy code.	Obtain the provider number or taxonomy code and determine if the number is in an acceptable range for risk adjustment. If in the acceptable range, submit the data. NOTE: All network providers are required to have certified Medicare provider numbers or taxonomy codes; therefore, do not submit risk adjustment data for this provider until these numbers are obtained.
Situation 3	An out-of-network provider submits a claim without a provider number.	Try to obtain a provider number or taxonomy code, if possible. If not available, check the list of Veterans Administration and Department of Defense (VA/DoD) listings published on csscooperations.com . If the provider is listed there, submit the data. If the provider is not on the VA/DoD list, the organization may need to contact CMS to determine if the provider is acceptable for risk adjustment. NOTE: All network providers are required to have certified Medicare provider numbers or taxonomy codes; therefore, do not submit risk adjustment data for this provider until these numbers are obtained.

3.2.2.2 National Provider Identifier

CMS has recently issued contingency guidance for National Provider Identifier implementation. This contingency guidance provides that, for a period of 12 months after the NPI Rule compliance date of May 23, 2007, CMS will not impose civil money penalties on covered entities that deploy contingency plans, including (in order to ensure the smooth flow of payments) continuing to use and accept legacy identifiers on HIPAA transactions, if they have made reasonable and diligent efforts to become compliant and, in the case of health plans (that are not small health plans), in order to facilitate the compliance of their trading partners.

MA organizations should verify that diagnoses are collected from Medicare certified hospitals/facilities and that data from all Medicare certified network hospital/facilities include the associated Medicare provider identifiers (NPI and taxonomy code; and in the interim the legacy provider number). They should also verify that the Medicare certified hospitals/facilities providing the data are from acceptable facilities and



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services. As stated above, plans may use either the legacy Medicare provider numbers or the taxonomy code to determine if facilities and services are acceptable for risk adjustment.

MA organizations may wish to create a system for checking if the data are from acceptable facilities and for acceptable services. They may check the legacy provider number against the provider number ranges or check the taxonomy code against the taxonomy code ranges, both of which identify what type of service has been rendered.

If using the provider number, please note that it has six characters. The first two characters are numerals and represent the state/territory as illustrated in Table 3E.

TABLE 3E – PROVIDER NUMBER STATE ASSIGNMENTS

STATE	CODE	STATE	CODE	STATE	CODE
Alabama	01	Kentucky	18	Oklahoma	37
Alaska	02	Louisiana	19	Oregon	38
American Samoa	64	Maine	20	Palau	N/A
Arizona	03	Maryland	21	Pennsylvania	39
Arkansas	04	Massachusetts	22	Puerto Rico	40
California	05	Michigan	23	Rhode Island	41
Colorado	06	Minnesota	24	South Carolina	42
Connecticut	07	Mississippi	25	South Dakota	43
Delaware	08	Missouri	26	Tennessee	44
District of Columbia	09	Montana	27	Texas	45
Florida	10	Nebraska	28	Utah	46
Georgia	11	Nevada	29	Vermont	47
Guam	65	New Hampshire	30	Virgin Islands	48
Hawaii	12	New Jersey	31	Virginia	49
Idaho	13	New Mexico	32	Washington	50
Illinois	14	New York	33	West Virginia	51
Indiana	15	North Carolina	34	Wisconsin	52
Iowa	16	North Dakota	35	Wyoming	53
Kansas	17	Ohio	36		



States and territories are included in the list of Medicare provider numbers.

The third character may be a numeral or a letter. Provider numbers with a **U, W, Y, Z, 5** or **6** in the third character indicate that the service was provided in a swing bed component of a hospital or a skilled nursing facility, which, are not covered entities. The last three characters are numerals unique to the facility.

If using the taxonomy code, the bill type will be needed to identify if the service was provided in non-covered entity such as a swing bed component of a hospital or a skilled nursing facility.



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As an additional check, refer to Tables 3F and 3G, which provide the only acceptable ranges for hospital facilities. The tables reflect the range of provider numbers for risk adjustment covered hospital entities. Risk Adjustment data are not acceptable when received from facilities with numbers outside the ranges.



Skilled nursing facilities, home health care and hospital inpatient swing bed components are not covered entities for risk adjustment data.

TABLE 3F – HOSPITAL INPATIENT COVERED ENTITIES

TYPE OF HOSPITAL INPATIENT FACILITY	PROVIDER NUMBER RANGE	TAXONOMY CODE/TYPE OF BILL(TOB)
Short-term (General and Specialty) Hospital	XX0001-XX0899 XXS001-XXS899 XXT001-XXT899	282N00000X 273R00000X 273Y00000X
Medical Assistance Facilities/Critical Access Hospitals	XX1225-XX1399	282NC0060X
Religious Non-Medical Health Care Institutions	XX1990-XX1999	TOB 4XX
Long-term Hospitals	XX2000-XX2299	282E00000X
Rehabilitation Hospitals	XX3025-XX3099	283X00000X
Children's Hospitals	XX3300-XX3399	282NC2000X
Psychiatric Hospitals	XX4000-XX4499	283Q00000X

TABLE 3G – HOSPITAL OUTPATIENT COVERED ENTITIES

TYPE OF HOSPITAL OUTPATIENT FACILITY	PROVIDER NUMBER RANGE	TAXONOMY CODE/TYPE OF BILL (TOB)
Short-term (General and Specialty) Hospital	XX0001-XX0899 XXS001-XXS899 XXT001-XXT899	282N00000X 273R00000X 273Y00000X
Medical Assistance Facilities/Critical Access Hospitals	XX1225-XX1399	282NC0060X
Community Mental Health Centers	XX1400-XX1499 XX4600-XX4799 XX4900-XX4999	TOB 76X
Federally Qualified Health Centers/Religious Non-Medical Health Care Institutions	XX1800-XX1999	TOB 73X for FQHC TOB 4XX for RNHCI
Long-term Hospitals	XX2000-XX2299	282E00000X
Rehabilitation Hospitals	XX3025-XX3099	283X00000X
Children's Hospitals	XX3300-XX3399	282NC2000X
Rural Health Clinics, Freestanding and Provider-Based	XX3400-XX3499 XX3800-XX3999 XX8500-XX8999	TOB 71X
Psychiatric Hospitals	XX4000-XX4499	283Q00000X



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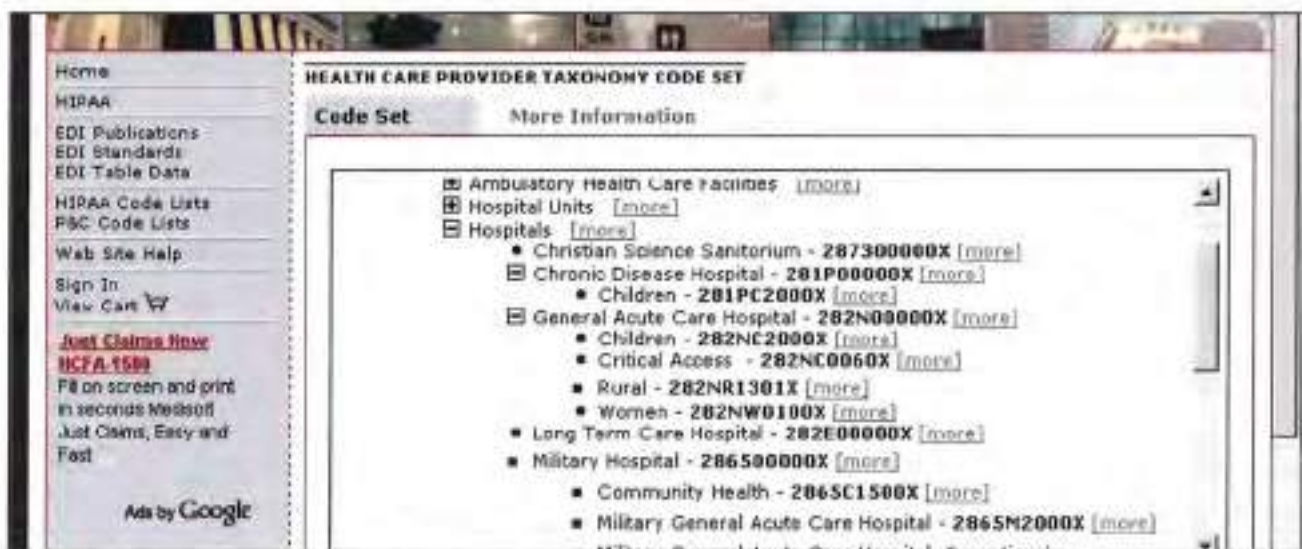
The implementation of the NPI did not change the valid Hospital Inpatient and Outpatient facilities for submission of risk adjustment data nor eliminate the process for receiving and verifying information from Medicare health care providers that are in network. Institutional providers that currently bill Medicare using more than one legacy identifier in order to identify subparts of their facility are required to submit a taxonomy code on all of the claims they submit to Medicare.

The following web site serves as a reference to types of facilities and taxonomy codes.

<http://www.wpc-edi.com/codes/taxonomy>

Figure 3A is a screen shot of the wpc-edi.com website which serves as a reference tool to determine types of facilities and taxonomy codes.

Figure 3A – WPC-EDE.COM



The following website serves as a reference for hospital provider numbers:

<http://www.ahd.com/freesearch.php3>

Figure 3B is a screenshot of the search page on the American Hospital Directory website. This web-based search database allows MA organizations the opportunity to access Medicare provider number by entering key words, city, state, zip code, or area code. When using the search tool, users need to be aware of the following:

- The most effective search option is to select the state where the provider is located.
- When entering the hospital name, users should be aware that the official name of the hospital may be different than what is included in the database.
- Avoid entering abbreviations.



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Figure 3B – American Hospital Directory



See Resource Guide for more information about Medicare provider numbers.

3.2.3 Physician Data (Slide 14)

The collection of physician data relevant for risk adjustment is associated with the physician's specialty. That is, all ICD-9-CM diagnoses that are in the risk adjustment model and rendered as a result of a physician visit must be collected by the MA organization. This includes data collected from non-network as well as network physicians.

Only those physician specialties and other clinical specialists identified in Table 3H are acceptable for risk adjustment.



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TABLE 3H – ACCEPTABLE PHYSICIAN SPECIALTIES

CODE	SPECIALTY	CODE	SPECIALTY	CODE	SPECIALTY
01	General Practice	29	Pulmonary Disease	70*	Multispecialty Clinic or Group Practice
02	General Surgery	33*	Thoracic Surgery	72*	Pain Management
03	Allergy/Immunology	34	Urology	76*	Peripheral Vascular Disease
04	Otolaryngology	35	Chiropractic	77	Vascular Surgery
05	Anesthesiology	36	Nuclear Medicine	78	Cardiac Surgery
06	Cardiology	37	Pediatric Medicine	79	Addiction Medicine
07	Dermatology	38	Geriatric Medicine	80	Licensed Clinical Social Worker
08	Family Practice	39	Nephrology	81	Critical Care (Intensivists)
10*	Gastroenterology	40	Hand Surgery	82	Hematology
11	Internal Medicine	41	Optometry (specifically means optometrist)	83	Hematology/Oncology
12	Osteopathic Manipulative Therapy	42	Certified Nurse Midwife	84	Preventive Medicine
13	Neurology	43	Certified Registered Nurse Anesthetist	85	Maxillofacial Surgery
14	Neurosurgery	44	Infectious Disease	86	Neuropsychiatry
16*	Obstetrics/Gynecology	46*	Endocrinology	89*	Certified Clinical Nurse Specialist
18*	Ophthalmology	48*	Podiatry	90	Medical Oncology
19	Oral Surgery (Dentists only)	50*	Nurse Practitioner	91	Surgical Oncology
20	Orthopedic Surgery	62*	Psychologist	92	Radiation Oncology
22*	Pathology	64*	Audiologist	93	Emergency Medicine
24*	Plastic and Reconstructive Surgery	65	Physical Therapist	94	Interventional Radiology
25	Physical Medicine and Rehabilitation	66	Rheumatology	97*	Physician Assistant
26	Psychiatry	67	Occupational Therapist	98	Gynecologist/Oncologist
28*	Colorectal Surgery	68	Clinical Psychologist	99	Unknown Physician Specialty

* Indicates that a number has been skipped.



Qualified physician data for risk adjustment requires a face-to-face visit with the exception of pathology services (professional component only).



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3.2.4 Alternative Data Sources

Alternative data sources (ADS) include diagnostic data from sources other than hospital inpatient, hospital outpatient, and physician services. MA organizations may use ADS as a **check** to ensure that all required diagnoses have been submitted to CMS for risk adjustment purposes, such as pharmacy records and information provided to national or state cancer registries. The MA organization may not, however, use ADS as substitutes for diagnoses from a hospital/physician. As in all diagnoses submitted, there must be medical record documentation to support the diagnosis as having been documented as a result of a hospital inpatient stay, a hospital outpatient visit, or a physician visit during the data collection period.

For example, a prescription for an ACE inhibitor, alone, is not considered sufficient for the sole data source of "clinical evidence" of congestive heart failure (CHF); instead, the medical record needs to document an appropriate clinician's diagnosis of CHF during the data collection period (e.g., where an "appropriate clinician" is a physician/nurse practitioner/physician assistant). A laboratory test showing one reading of high blood sugar is not considered sufficient "clinical evidence" of diabetes—the medical record needs to document a clinician's diagnosis of diabetes during the data collection period.

3.2.5 Excluded Providers

Medicare will not pay for items or services rendered to beneficiaries and recipients by an excluded provider or by entities owned or managed by an excluded provider. Providers are excluded for the following reasons: a program related crime, patient abuse or neglect, health care fraud in any health care program, and convictions relating to controlled substances.

 The HHS monthly exclusion notification can be found at <http://oig.hhs.gov/fraud/exclusions.html>.

3.3 Data Collection Formats and Considerations

There are several formats that MA organizations can accept when collecting data from medical providers. Table 3I lists the formats by provider type.

3.3.1 Data Collection Formats (Slide 16)

For facility services, the standard billing format is UB-04 (Uniform Billing Form –2004 version). The HCFA 1500 form is the standard format for physician services.

TABLE 3I – DATA COLLECTION FORMATS

HOSPITAL INPATIENT/HOSPITAL OUTPATIENT	• UB-04 • ANSI X12 837 4010 • RAPS Format
PHYSICIAN	• HCFA 1500 • NSF 3.01 • ANSI X12 837 4010 • RAPS Format • Superbill



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3.3.2 Collection Format Features

MA organizations need to carefully consider decisions regarding data collection tools, as they may impact the volume and accuracy of data received from physicians and providers. When examining the data collection options, the organization's management should consider the features of each of the approved data collection tools. Table 3J describes key features of each data collection tools.

TABLE 3J – COLLECTION FORMAT FEATURES

FORMAT	FEATURE					
	PHYSICIAN SERVICES	HOSPITAL INPATIENT/ OUTPATIENT SERVICES	MINIMUM DATA SET	FULL CLAIMS DATA	PAPER FORMAT	ELECTRONIC
HCFA 1500*	•			•	•	
UB-04*		•		•	•	
NSF*	•			•	•	•
ANSI X12 837	•	•		•		•
Superbill	•		•		•	
RAPS Format	•	•	•			•

*These data collection formats are not HIPAA compliant transactions. However, if your plan is HIPAA compliant and your trading partners are not HIPAA compliant, CMS is allowing receipt of non-HIPAA formats until such time as your trading partners are prepared to submit the HIPAA transaction sets.

The data collection options provided by CMS offer the MA organization the ability to determine which format works best for each of the plan's providers. A variety of collection formats may be used for different providers. If an organization plans to use multiple collection formats, consideration should be given to the complexity and costs associated with supporting these formats (e.g., systems, processes, staffing, etc.).

3.3.3 Collecting Data from Physicians Using a Superbill

The superbill is a data collection option for risk adjustment. The superbill is a common physician office claim form that lists standard ICD-9-CM codes, CPT (Current Procedural Terminology) codes, and beneficiary information. Typically, physicians use the superbill to record clinical information with the appropriate codes to aid in preparing claims or encounter data for submission. MA organizations may develop superbills for use by their capitated physicians for capturing diagnostic information for risk adjustment.



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If the MA organization currently utilizes a superbill that works well for its data collection needs, then it is not necessary to create a new format for risk adjustment data collection. Additionally, if a physician group has a superbill that will capture all relevant risk adjustment diagnoses, it is not necessary for the MA organization to replace that superbill with one that is specific to risk adjustment requirements.



Examples

Examples of Superbills

Two examples of superbills are provided in Figures 3C and 3D. The first example is a typical fee-for-service superbill for an internist. This superbill contains both ICD-9-CM diagnosis codes and CPT procedure codes. For illustrative purposes, the relevant risk adjustment diagnoses have been bolded.

The second example illustrates what the same superbill might look like if used specifically for collection of risk adjustment data. The ICD-9-CM code list provided by CMS is used to develop the list of common internist ICD-9-CM diagnoses codes on the superbill. These are codes that are relevant diagnoses for the risk adjustment model, related conditions that are not specific to risk adjustment, as well as other common internists' diagnoses. A space was left for the internist to enter diagnoses that are not on the list. Note that there are no CPT procedure codes on the superbill because they are not required for risk adjustment.

DATA COLLECTION

JOHN E. DOE, M.D. <i>Internal Medicine</i> Board Certified		PATIENT NAME		INSURANCE	
123 Main Street Anytown, IL 99999 Office (555) 555-5555 Billing (555) 555-5550 TAX I.D. #12345678		OFFICE 847	PATIENT NUMBER	ADMIT DATE	DIAGNOSIS
DR.#	ACCIDENT TYPE ☐ Work Comp ☐ Auto ☐ Other	DATE OF ACCIDENT ____/____/____		1)	2)
				3)	4)

OFFICE SERVICE			
New	Mod	Fee	Est. Mod Fee Dk
Level 1	99201	— 48 —	99211 — 27 —
Level 2	99202	— 82 —	99212 — 48 —
Level 3	99203	— 121 —	99213 — 67 —
Level 4	99204	— 176 —	99214 — 105 —
Level 5	99205	— 222 —	99215 — 155 —

PHYSICALS			
Near	Mod	Fee	Est. Mod Fee Dk
2-17yrs	99334	— 188 —	99334 — 133 —
18-39yrs	99385	— 182 —	99385 — 140 —
40-64yrs	99386	— 189 —	99386 — 147 —
>65yrs	99387	— 203 —	99387 — 154 —

INITIAL HOSPITAL CARE	
Level 1	99221 — 95 —
Level 2	99222 — 156 —
Level 3	99223 — 213 —

DAILY HOSPITAL CARE	
Level 1	99231 — — —
From _____ To _____ @ \$55	
Level 2	99232 — — —
From _____ To _____ @ \$57	
Level 3	99233 — — —
From _____ To _____ @ \$67	
Discharge	99236 — 92 —
Discharge-over 30	99238 — 174 —

G HOME CARE	
Partial Detailed	99302 — 13 —
Partial Comprehensive	99303 — 6 —
Follow Up Level 1	99311 — — —
Follow Up Level 2	99312 — 71 —
Follow Up Level 3	99313 — 99 —
Discharge-30 minutes or less	99315 — — —
Discharge-over 30 minutes	99316 — — —

PROCEDURES	
Venipuncture	96915 — 17 —
Ear Irrigation	96916 — 44 —
ECG With Interpretation & Report	93000 — 39 —
ECG Only	93005 — 25 —
ID Abcass	10960 — 119 —
ID	86580 — 12 —
Stool WBC	80770 — 6 —
Analysis with Micro	81800 — 9 —
Analysis without Micro	81802 — 7 —

IMMUNIZATIONS & INJECTIONS	
B-12	J3420 — 3 —
Hepatitis A, Adult	90632 — 70 —
Hepatitis B, Adult	90746 — 70 —
Hepatitis B, adolescent	90744 — 60 —
Influenza-Whole	90550 — 15 —
MMR	90707 — 57 —
Pneumovax	90732 — 40 —
Tetanus	90703 — 26 —
Other _____	
Other _____	

VACCINES	
☐ MCR PAP SMOAR	962_25 EMU
962_25 Pap \$50	
962_25 PSM Exam \$60	
V15.80 High Risk Dx	
V76.2 Routine Dx	
☐ FLU SHOT	90659 Flu Shot
90471 Admin	
V04.8 Flu Vaccine Dx	
☐ MCR FLU SHOT	



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FIGURE 3D – SAMPLE RISK ADJUSTMENT SUPERBILL

JOHN E. DOE, M.D. <i>Internal Medicine</i> <i>Board Certified</i> 123 Main Street Anytown, IL 99999 Office (555) 555-5555 Billing (555) 555-5550 TAX I.D. #12345678	<table style="width: 100%; border: none;"> <tr> <td style="width: 30%; border-bottom: 1px solid black; text-align: center;">PATIENT NAME</td> <td style="width: 70%; border-bottom: 1px solid black; text-align: center;">INSURANCE</td> </tr> </table>		PATIENT NAME	INSURANCE
PATIENT NAME	INSURANCE			
DR# _____	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;"> ACCIDENT TYPE ☐ Work Comp ☐ Auto ☐ Other </td> <td style="width: 50%; border-bottom: 1px solid black; text-align: center;"> DATE OF ACCIDENT ____/____/____ </td> </tr> </table>		ACCIDENT TYPE ☐ Work Comp ☐ Auto ☐ Other	DATE OF ACCIDENT ____/____/____
ACCIDENT TYPE ☐ Work Comp ☐ Auto ☐ Other	DATE OF ACCIDENT ____/____/____			

DIAGNOSIS CODES: ICD-9-CM

427.3	A. Fib/flutter
427.9	Amythmia
285.9	Anemia,NOS
284	Aplastic; Anemia
413	Angina
300.00	Anxiety
716.90	Arthritis, NOS
714	Arthritis, Rheumatoid
427.9	Amythmia,NOS
429.2	ASCVD
429.2	ASCVD
493.2	hmo COP
174	ast C male
511.72	ast p
590	ndus, NOS
566.0	nchitis, acute
591	nchitis, chroni
562.9	ritis, NOS
786.50	Chest pain
428	CHF
574.20	Cholelithiasis, NOS
153	Colon CA
496	COPD
436	CVA
276.5	Dehydration
294.8	Dementia
311	Depression
296	Depression, major
692.9	Dermatitis
250	Diabetes
250.9	Diabetes, Brittle
250.3	Diabetic Coma
250.1	Diabetic Keto
250.4	Diabetic Nephrosis
250.6	Diabetic Neuropathy
250.0	Diabetes,NIDDM
250.7	Diabetic PVD
250.5	Diabetic Retinopathy
562.11	Diverticulitis
453.8	DVT
610.1	Fibrocystic Breast
729.1	Fibromyalgia
558.9	Gastroenteritis
530.81	GERD
578.9	GI bleeding
240.9	Gout
274.9	Gout
242.0	Graves' Disease

573.3	Hepatitis,NOS
070.1	Hepatitis A
070.30	Hepatitis B
070.51	Hepatitis C, Acute
070.54	Hepatitis C, Chronic
401.9	Hypertension
242.90	Hyperthyroidism
276.8	Hypokalemia
276.0	Hyponatremia
244.9	Hypothyroidism
487.1	Influenza
564.1	Irrit. Bowel Syn
56.30	Labyrinthitis
710	Lupus
263	Malnutrition
595.2	Medicine Side Effect
410	MI
424.0	Mitral Valve
5.9	Neuropathy
110.0	Onychomycosis
715.60	Osteoarthritis
733.00	Osteoporosis
427.0	PAT
427.1	PVT
427.2	Parox Tachycardia
462	Pharyngitis
486	Pneumonia
48	Pneumonia, specified
185	Prostate Cancer
600.00	Prostate Hypertrophy
415.19	Pulmonary Embolism
592.0	Renal Lithiasis
477.9	Rhinitis, Allergic
473.9	Sinusitis
079.89	Systemic Viral Infec
451.9	Thrombophlebitis
193	Thyroid Cancer
241.0	Thyroid Nodule
245.9	Thyroiditis
533.9	Ulcer, Peptic
53	Ulcer, perforated
411	Unstable Angina
465.9	URI
599.0	UTI

Other: _____

Next Visit

Total: \$ _____

Amt Pd \$ _____

12 ☐ Check # _____

44 ☐ Co-Pay Not Collected

Physician Signature _____ Date _____

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REPRODUCTION



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3.3.4 Factors Affecting Data Collection Method (Slide 17)

The risk adjustment model requires that MA organizations collect a subset of data from their providers/physicians. While CMS requires that only the minimum data are collected for risk adjustment, MA organizations should also consider their business needs.

- The organization may decide to collect full claims data for a variety of reasons:
 - The organization has fee-for-service contracts and pays providers and physicians based on the specific service provided to patients.
 - The organization is earning or maintaining National Committee for Quality Assurance (NCQA) accreditation and is therefore required to collect Health Employers Data Information Set (HEDIS) data used to evaluate the plan's performance in areas of customer service, access to care, and claims processing.
 - The organization has established an internal process for credentialing purposes that requires evidence of compliance with regulatory and other standards of practice such as Joint Commission on Accreditation of Health Care Organizations (JCAHO) or American College of Surgeons. The JCAHO certification requires extensive onsite review to evaluate the health organization's performance in areas that impact healthcare.
- The organization may decide to collect the minimum data set for a variety of reasons:
 - The organization has capitated payment arrangement with physicians and providers, and pays a fixed amount for services provided.
 - The organization's physicians are paid employees of the managed care plan.

3.3.4.1 Contractual Relationships and Implications for Data Collection (Slide 18)

There are several types of contractual payment relationships that MA organizations have with network physicians. These relationships include: fee-for-service, capitated, staff model, and mixed services. These contractual relationships affect how MA organizations collect data from physicians. Table 3K describes the contractual payment relationships.

TABLE 3K – CONTRACTUAL PAYMENT RELATIONSHIPS

FEE-FOR-SERVICE	In a fee-for-service contract, the physician is paid based on the specific services provided to each patient.
CAPITATED	The physician is paid a fixed amount per patient per month, regardless of the types of services provided.
STAFF MODEL	Physicians are paid employees of the managed care plan. Physicians generally provide services in a clinic setting.
MIXED SERVICES MODEL	In a mixed services model environment, managed care organizations use a combination of contractual arrangements.



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3.4 Health Information Portability and Accountability Act (HIPAA) (Slide 19)

Effective October 16, 2003, when HIPAA transaction standards became mandatory, all *electronic* claims/encounters sent from providers/physicians to MA organizations (health plans) constitute a HIPAA-covered transaction. Any MA organization that receives an electronic claim/encounter from a provider/physician must use the ANSI X12 837 v.40.10 format. This means that after the MA organization receives electronic data in HIPAA format, it cannot request that the physician resubmit the identical information (same patient, same diagnosis) in a different format (e.g., HCFA 1500) for purposes of risk adjustment data collection.

However, if needing to clarify original information or to obtain additional information, MA organizations may use an abbreviated data collection instrument for the sole purpose of collecting supplemental diagnostic information.

UB-92 and NSF are the old data collection formats and are not HIPAA compliant transactions. However, if your plan is HIPAA compliant and your trading partners are not HIPAA compliant, CMS is allowing receipt of the non-HIPAA formats until such time as your trading partners are prepared to submit the HIPAA transaction sets. This allowance is not an extension of the mandatory date of HIPAA (October 2003), and all organizations must be able to accept the HIPAA transactions. This extension simply allows plans to continue electronic commerce while their trading partners work toward compliance.



If the transaction is from a provider to an MA organization (i.e., data collection) **and** the transaction is a claim or an encounter, **then** data must be used for risk adjustment **and** the same data cannot be requested in a different format from the provider.

3.5 Provider Communication and Risk Adjustment

Communicating risk adjustment requirements to physicians and providers can help to improve the quality and quantity of the data submitted by MA organizations. It can also help physicians and providers understand the importance of accurate coding and medical record documentation, and their role in data validation. This section describes key messages to include in provider communications, characteristics of effective communication with physicians and providers, and communication methods to consider when sending messages about risk adjustment.

3.5.1 Key Messages

Physicians and providers receive many messages from MA and other managed care organizations. It is easy for a message about risk adjustment to get lost in the stream of communications sent to physicians and providers. To help ensure that messages about risk adjustment get the attention of the provider community, it is important that organizations routinely include basic information about risk adjustment in a variety of provider communications. The key messages to reinforce are:

- **What is the purpose of risk adjustment?**

Risk adjustment strengthens the Medicare program by ensuring that accurate payments are made to MA organizations based on the health status of their enrolled beneficiaries. Accurate payments to MA organizations help ensure that providers are paid appropriately for the services they provide to MA beneficiaries. Finally, risk adjustment provides MA organizations with incentives to enroll and treat less healthy individuals.



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- **Why is risk adjustment important to physicians and providers?**

The risk adjustment model relies on the ICD-9-CM diagnosis codes to prospectively reimburse MA organizations based on the health status of their enrolled beneficiaries. Physicians and providers must focus attention on complete and accurate diagnosis reporting according to the official ICD-9-CM coding guidelines.

- **What are the responsibilities of physicians and providers?**

Physicians must report the ICD-9-CM diagnosis codes to the highest level of specificity and report these codes accurately. This requires accurate and complete medical record documentation. They are required to alert the MA organization of any erroneous data submitted and to follow the MA organization's procedures for correcting erroneous data. Finally, they must report claims and encounter information in a timely manner, generally within 30 days of the date of service (or discharge for hospital inpatient facilities).



Organizations may also want to include information about the correct data collection formats available to them, as well as any information revealed through analysis of data collection trends uncovered through monitoring of the risk adjustment process.

3.5.2 Characteristics of Effective Communication

Physicians and providers tend to respond more positively to communications from MA organizations when the messages are considered reliable, accurate, timely, and helps them make their organization or practice more efficient. For this reason, it may be helpful to consider the following characteristics when developing provider communications:

- **Authoritative**

Make the "look and feel" of provider communications conservative, official, and factual. Be certain all information is accurate. Grammar, spelling, and punctuation must be perfect, or the errors will undercut the reader's level of confidence in the message.

- **Current**

Ensure that risk adjustment information is the most recent available. Update provider handbooks, websites, job aids, and training materials routinely so all information is current. Physicians and providers will not spend time reading information they know is outdated.

- **Timely**

Provide information to providers when they need to know it. For example, if MA organizations need physicians and providers to send their diagnostic data via a specific format by a certain date, send that message to them with enough lead-time to allow them to prepare for and meet the deadline for the change.

- **Consistent**

Send consistent messages about risk adjustment. MA organizations can contact the Customer Service and Support Center (CSSC) anytime to confirm that information they are about to send out to providers is correct. Physicians and providers appreciate receiving the right information the first time and every time.



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- **Practical, relevant and well organized**

Delete "background noise" from your physician and provider messages. That is, identify the primary message you want to send and provide the key information necessary to make the point. That is, focus the message. Identify any specific actions that are required in clear, easy-to-read language.

- **Accessible**

Create materials for physicians and providers that are easy to access. Information that physicians and providers can locate quickly helps to ensure compliance with risk adjustment requirements, whether that information is available on the Internet, or in a paper document.

3.5.3 Communication Methods

Many MA organizations indicate that communicating to physicians and providers through a single medium, like a newsletter, is not effective. A multimodal approach is more successful at reaching the provider community because it reaches a broader audience and reinforces the message in a number of different formats.

When deciding the methods to communicate with physicians and providers, consider the following steps:

- **Identify the methods that tend to work best for the organization.** Many MA organizations indicate that the organization's provider Web page and newsletters reach audiences, but small and large group training sessions are most successful for causing a change in action.
- **Determine the goal of the message.** If the message's intent is to raise awareness about a topic, then broad-based communication methods may be appropriate. However, if the message is intended to change the way physicians and providers do something, then group meetings, followed up by emails, and provider handbook and contract updates may be excellent options.
- **Consider the physician's and provider's response.** If the message is likely to provoke a negative reaction from the provider community, then meetings with them can be helpful in addressing and clarifying issues, and discussing possible solutions to problems.

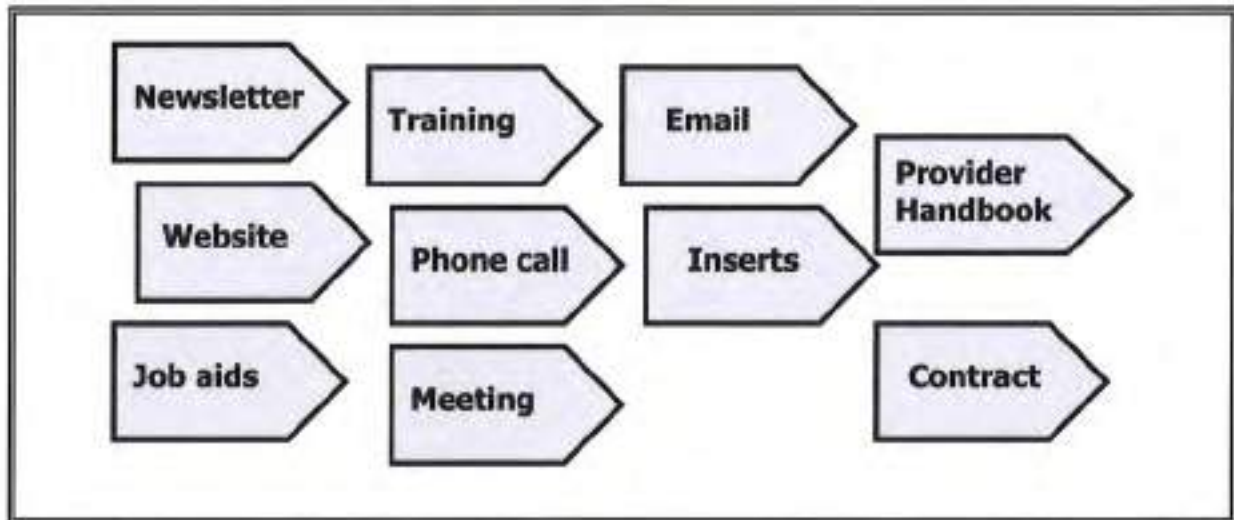
There are a number of methods MA organizations may use to communicate risk adjustment messages to the provider community. These are illustrated in Figure 3E. Understand that, once your organization establishes a communication channel, physicians and providers will rely on that channel to receive information. Any new channels MA organizations use may not be as effective as established ones.



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Figure 3E – Communication Methods





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DATA SUBMISSION

MODULE 4 – DATA SUBMISSION

Purpose (Slide 2)

Medicare Advantage (MA) organizations must submit accurate diagnostic data when submitting risk adjustment data. This module describes the file layout for risk adjustment process submissions.

Learning Objectives (Slides 3-4)

At the completion of this module, participants will be able to:

- Understand the submission process requirements, connectivity options, and Risk Adjustment Processing System (RAPS) file layout.
- Identify the data elements required to submit risk adjustment data.
- Locate and describe the diagnosis clusters in the RAPS format.
- Understand the Direct Data Entry (DDE) process.
- Describe the filtering process.
- Describe the diagnoses deletion process.

ICON KEY	
Example	
Reminder	
Resource	

4.1 Submission Process Requirements (Slide 6)

New MA organizations must complete an Electronic Data Interchange (EDI) Agreement with the Centers for Medicare & Medicaid Services (CMS) and submit that Agreement to the Customer Service and Support Center (CSSC) prior to submitting risk adjustment data. The EDI Agreement is a contract between the MA organization and CMS attesting to the accuracy of the data submitted. An officer (e.g., CEO) that represents the MA organization must sign this document. New Plans must submit the EDI Agreement within 1 month of the HPMS effective date.

MA organizations must make special arrangements to use a third party submitter. If the submitter is an entity other than an MA organization, the submitter must complete the Submitter ID Application Form, and the MA organization must complete the EDI Agreement. MA organizations must complete, sign, and return the EDI Agreement for each plan number submitting data. CMS holds the MA organization accountable for the content of submissions regardless of who submits the data.

New MA organizations must submit test data within 3 months of the HPMS effective date and a production file must be submitted within 4 months of the effective date.

If a new contract number is required, the MA organization must submit a new EDI agreement. If the submitter's system successfully submitted test data previously, CMS does not require additional testing.



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MA organizations must submit during each calendar quarter, at a minimum, approximately one-fourth of their total risk adjustment data submission for the collection period. More frequent submissions are recommended and benefit MA organizations, in identifying data collection and submission issues early.

4.2 Connectivity Options (Slide 7)

Connectivity refers to the electronic connection between the MA organization and CMS. MA organizations use the electronic connection to submit risk adjustment to CMS and receive information in return. Table 4A describes the three connectivity options.

TABLE 4A – CONNECTIVITY OPTIONS

Connect:Direct	Formerly Network Data Mover (NDM). Mainframe-to-mainframe connection. Next day receipt of FERAS response.
FTP File Transfer Protocol	Modem-to-modem (dial-up) or lease line connection. Requires password and phone line. Same day receipt of FERAS response.
Gentran	Two connectivity options: -Secure File Transfer Protocol (SFTP); standards based protocol via a vender. -Secure Hyper Text Transfer Protocol (HTTPS), secure web interface.

Small plans with less than or equal to 100,000 members may submit data using the Gentran Mailbox. For technical support questions regarding Gentran mailbox, users may contact the Customer Support for Medicare Modernization (CSMM) by calling (800) 927-8069, emailing mmahelp@cms.hhs.gov, or viewing the website at <http://www.cms.hhs.gov/mmahelp>.

4.3 Relevant Diagnosis (Slide 8)

MA organizations must submit each relevant diagnosis at least once during a reporting period for each enrolled beneficiary.



For payments beginning on January 1, 2008, the initial submission deadline is September 7, 2007 for the reporting period July 1, 2006 through June 30, 2007. For payments beginning on July 1, 2008, March 7, 2008 is the initial submission deadline for reporting data with dates of service January 1, 2007 through December 31, 2007. **Refer to the Risk Adjustment Process Overview module, Table 2B.**

A relevant (model) diagnosis must meet the following criteria:

- The diagnosis is included in the CMS-Hierarchical Condition Category (CMS-HCC), Prescription Drug (RxHCC) or End Stage Renal Disease (ESRD) risk adjustment models.
- The diagnosis must be received from one of the three provider types (hospital inpatient, hospital outpatient, and physician) covered by the risk adjustment requirements.



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- The diagnosis must be collected according to the risk adjustment data collection instructions.

MA organizations may elect to submit a diagnosis more than once during a data collection period for any given beneficiary, as long as that recorded diagnosis was from a face-to-face visit with one of the three provider types covered under risk adjustment. MA organizations may submit any diagnoses received from the three covered provider types, including diagnoses that are not in the CMS-HCC risk adjustment model. Diagnoses that are in the model but that were not collected from one of the three provider types cannot be submitted as risk adjustment data.

4.4 Submission Formats (Slide 9)

Effective October 1, 2007, MA organizations must submit data electronically using one of two formats:

- RAPS format (all provider types)
- DDE screen (all provider types)

4.5 Submission File Layout Logic (Slide 10)

Submissions are organized into three levels of data:

- File-level information—identifies the submitter
- Batch-level information—identifies the MA organization
- Detail-level information—identifies the beneficiary

Figure 4A illustrates a summary of the RAPS file structure.



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Figure 4A – RAPS File Structure Summary

RT AAA – FILE HEADER (Submitter Info)

Always the first record on the file, and must be followed by Record Type (RT) BBB.

- Record ID
- Submitter ID
- File ID
- Transaction Date
- Production/Test Indicator
- Filler

RT BBB – BATCH HEADER (MA Organization Info)

Must follow RT AAA or RT YYY and must be followed by RT CCC.

- Record ID
- Sequence Number
- Plan Number
- Filler

RT CCC – DETAIL RECORD (Beneficiary Info)

Must follow RT BBB or RT CCC and may be followed by another RT CCC.

- Record ID
- Sequence Number
- Sequence Number Error
- Patient Control Number (optional)
- HIC Number
- HIC Error Code
- Patient Date of Birth (optional)
- Date of Birth Error Code
- Diagnosis Cluster (10 Occurrences)
 - ▶ Provider Type
 - ▶ From Date
 - ▶ Through Date
 - ▶ Delete Indicator
 - ▶ Diagnosis Code
 - ▶ Diagnosis Code – Filler
 - ▶ Diagnosis Cluster – Error 1
 - ▶ Diagnosis Cluster – Error 2
- Corrected HIC Number
- Filler

RT YYY – BATCH TRAILER

Must follow RT CCC and may be followed by another RT BBB or RT ZZZ.

- Record ID
- Sequence Number
- Plan Number
- CCC Record Total
- Filler

RT ZZZ – FILE TRAILER

Must follow RT YYY, and must be the last record on the file.

- Record ID
- Submitter ID
- File ID
- BBB Record Total
- Filler

DETAIL LEVEL

BATCH LEVEL

FILE LEVEL



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4.6 Diagnosis Cluster

The diagnosis cluster contains the core information used to calculate a risk adjustment factor. The following components are included in the cluster:

- Provider Type
- From Date
- Through Date
- Diagnosis Code

A maximum of 10 diagnosis clusters are allowed per CCC record. Each cluster must include the items identified above. If any of these attributes are submitted more than once for the same HIC number, a duplicate diagnosis cluster error will occur.

4.7 Provider Type

MA organizations must submit risk adjustment data for hospital inpatient, hospital outpatient, and physician services. MA organizations may submit all provider types in the same CCC record. The provider type must be coded accurately. There is one provider type per diagnosis cluster. Table 4B shows the provider types and their codes.

Type of Bill (TOB), which is coded on the UB-04 during the collection of hospital data, may be used to assist in translating the correct provider type. Table 4B also shows the TOB and provider type correlation.

TABLE 4B – PROVIDER TYPES

PROVIDER TYPE	CODE	TYPE OF BILL
Principal Hospital Inpatient (principal diagnosis)	01	111 or 112
Hospital Inpatient Other (other diagnosis)	02	111 or 112
Hospital Outpatient	10	131, 132, 141 or 142
Physician	20	N/A



Interim bills (112, 113, & 114 bill types) are not accepted. If an MA organization receives interim bills, do not submit the hospital inpatient diagnoses until the receipt of the final interim bill (114).

4.8 From and Through Dates

- CCYYMMDD is the correct submission format for the "From and Through" dates of service.
- The "Through Date" defines the data used in the data collection year for risk adjustment purposes.



June 30, 2006 is submitted as 20060630.

Table 4C shows the "From" and "Through Dates" for each provider type.



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TABLE 4C – FROM AND THROUGH DATES

PROVIDER TYPE	FROM DATE	THROUGH DATE
Hospital Inpatient	Admission Date	Must have a through date and must be the discharge date
Hospital Outpatient	Exact date of patient visit or the first date service began for a series of services	Exact date of patient visit or the last date of service for a series of services
Physician		



When a submitter submits a "From Date" that does not include a "Through Date" for physician or hospital outpatient services, RAPS automatically copies the "From Date" into the "Through Date" field.

4.9 Diagnosis Code

- Each relevant (model) diagnosis code must be submitted at least once during a reporting period.
- The decimal is implied in the format.

4.10 RAPS Format

Table 4D describes each field of the RAPS file layout.

- The shaded fields in the table represent where the RAPS Return File provides new information after data processes through RAPS.
- There are two diagnosis cluster error fields because MA organizations can receive up to two errors on any diagnosis cluster.



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TABLE 4D – RAPS FILE LAYOUT

RAPS RECORD AAA – FILE HEADER				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
1	1-3	Required	Record ID	File-level information that identifies the submitter. This field should always be populated with "AAA."
2	4-9	Required	Submitter ID	Identifies the submitter and should be populated with the six-digit alphanumeric SH# assigned by CSSC.
3	10-19	Required	File ID	10-digit alphanumeric character identifying the specific file submitted. This file name may not be repeated within a 12-month period.
4	20-27	Required	Transaction Date	Specifies the date that the file was submitted to Palmetto and formatted as CCYYMMDD.
5	28-31	Required	Production Test Indicator	Must be populated with "PROD" or "TEST." Submission test data proceeds through the entire process.
6	32-512	Spaces	Filler	Must be populated with 481 spaces. The "Filler" field allows for additional fields in the future.

RAPS RECORD BBB – BATCH HEADER				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
1	1-3	Required	Record ID	Batch-level information that identifies the MA organization is populated with "BBB."
2	4-10	Required	Sequence Number	This field identifies the batch submitted. The first batch in a file must begin with 0000001. All successive batch sequence numbers in the file must be incremented by one. This is a numeric field.
3	11-15	Required	Plan Number	Identifies the MA organization and should be populated with the five-digit alphanumeric contract assigned by CMS. (H#, R#, etc.)
4	16-512	Spaces	Filler	Must be populated with 497 spaces. The "Filler" field allows for additional fields in the future.



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TABLE 4D – RAPS FILE LAYOUT (CONTINUED)

RAPS RECORD CCC – DETAIL LEVEL				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
1	1-3	Required	Record ID	Detail-level information that identifies the beneficiary information. This field should always be populated with "CCC."
2	4-10	Required	Sequence Number	This field identifies the detail record submitted. The first detail record in a batch must begin with 0000001. All successive detail sequence numbers in the batch must be incremented by one. This is a numeric field. Limited to 1,000,000 per day.
3	11-13	RAPS RETURN	Sequence Number Error Code	This field must be submitted with spaces. Upon return, this field is populated with an error code if RAPS finds an error in the sequence number, or will remain blank if no errors were detected in the sequence number.
4	14-53	Optional	Patient Control Number	This optional field may be used by the MA organization to identify the claim submitted. The field allows up to 40 alphanumeric characters.
5	54-78	Required	HIC	The Health Insurance Claim number for the beneficiary. This is a 25-digit alphanumeric field. Enter spaces, not zeros, in unused spaces.
6	79-81	RAPS RETURN	HIC Error Code	This should be submitted with spaces. Upon return, this field is populated with an error code if RAPS finds an error in the HIC number, or remains blank if no errors were detected in the HIC number.
7	82-89	Optional	Patient DOB	This optional field may be populated with the patient's date of birth and is used to verify that the correct beneficiary identification was submitted. If the field is populated, it must be formatted as CCYYMMDD, and CMS edits this field against the information on file at the MBD. If no DOB is submitted, fill with spaces.
8	90-92	RAPS RETURN	DOB Error Code	This field must be submitted with spaces. Upon return, this field is populated with an error code if RAPS finds an error with DOB, or remains blank if no errors were detected in the DOB.



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TABLE 4D – RAPS FILE LAYOUT (CONTINUED)

RAPS RECORD CCC – DETAIL LEVEL (CONTINUED)				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
9	93-412	DIAGNOSIS-CLUSTER (10 occurrences)		The following 8 fields (9.0-9.7) may be repeated 10 times in the same "CCC" record with one diagnosis per cluster. Each diagnosis cluster must contain 32 characters or spaces. Plans must not skip clusters when submitting active diagnosis codes. If there are less than 10 diagnosis clusters the remaining clusters are space filled. If there are more than 10 diagnoses, a new "CCC" record must be established.
9.0		Required	Provider Type	This 2-digit alphanumeric field identifies the site of service provided (01,02,10,20).
9.1		Required	From Date	For hospital inpatient this describes the admission date. For physician and hospital outpatient this describes the date of service. Must be formatted as CCYYMMDD.
9.2		Required	Through Date	For hospital inpatient this describes the discharge date. For physician and hospital outpatient this may be left blank and the system will fill with the "From Date." Must be formatted as CCYYMMDD.
9.3		Conditional	Delete Indicator	This field allows the MA organization to delete a diagnosis, for correction purposes, that has been stored in the RAPS database. Enter a "D" or space.
9.4		Required	Diagnosis Code	This field is populated with the three-to five-digit ICD-9-CM diagnosis code. The decimal is implied and should not be included (e.g., 42732).
9.5		SPACE	Diagnosis Code Filler	This field is designed to allow space for future ICD-10-CM codes and any other growth in the diagnosis cluster. This field must be populated with spaces.
9.6		RAPS RETURN	Diagnosis Cluster Error 1	This field must be submitted with spaces. Upon return, this field is populated with one error code if RAPS finds an error in the diagnosis cluster, or remains blank if no errors were detected in the diagnosis cluster.
9.7		RAPS RETURN	Diagnosis Cluster Error 2	This field must be submitted with spaces. Upon return, this field is populated with one error code if RAPS finds an error in the diagnosis cluster, or remains blank if no errors were detected in the diagnosis cluster.
19	413-437	RAPS RETURN	Corrected HIC number	This field must be submitted with spaces. If the MA organization has submitted an outdated HIC, upon return, this field is populated with the most current HIC number and the "HIC Error" field contains an information error code.
20	438-512	Spaces	Filler	Must be populated with 75 spaces. The "Filler" field allows for additional fields in the future.



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TABLE 4D – RAPS FILE LAYOUT (CONTINUED)

RAPS RECORD YYY – BATCH TRAILER				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
1	1-3	Required	Record ID	Batch trailer information should be populated with "YYY."
2	4-10	Required	Sequence Number	A 7-digit numeric character identifying the batch submitted. Must match the "BBB" record.
3	11-15	Required	"H" Number	"H" number assigned by CMS to identify the MA organization. Must match the "H" number in the corresponding "BBB" record (i.e., the "BBB" record with the same sequence number).
4	16-22	Required	CCC Record Total	This field should total the number of CCC records in the batch. This field is numeric and should be filled with leading zeroes (e.g., 0000001). Limited to 1,000,000 per day.
5	23-512	Spaces	Filler	Must be populated with 490 spaces. The "Filler" field allows for additional fields in the future.

RAPS RECORD ZZZ – FILE TRAILER				
FIELD NO	POSITION	SUBMISSION STATUS	FIELD NAME	EXPLANATION
1	1-3	Required	Record ID	File Trailer Information should be populated with "ZZZ."
2	4-9	Required	Submitter ID	Identifies the submitter and must match the 6-digit alphanumeric SH# in the AAA records.
3	10-19	Required	File ID	10-digit alphanumeric character identifying the specific file submitted. Must match the File ID in the "AAA" record.
4	20-26	Required	BBB Record Total	This field should total the number of batches in the file. This field is numeric and should be filled with leading zeros (e.g., 0000001).
5	27-512	Required	Filler	Must be populated with 486 spaces. The "Filler" field allows for additional fields in the future.



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4.11 Filtering Risk Adjustment Data (Slides 13-14)

MA organizations are required to filter risk adjustment data to ensure that they submit data from only appropriate data sources (e.g., hospital inpatient, hospital outpatient, and physician provider types). A filtering process is used to identify the correct provider types in claims and encounter data. CMS further recommends the following filtering guidelines:

- Hospital inpatient data require admission and discharge dates of service from appropriate facilities. **Refer to the Data Collection module** for examples of covered facilities.
- Physician data require face-to-face visits with a professional listed on the CMS specialty list. **Refer to the Data Collection module** for the list of acceptable physician data sources.
- Hospital outpatient data require the most demanding or accurate filtering. Data requirements include diagnoses from appropriate facilities and covered services contained on the CMS covered outpatient listings. **Refer to the Data Collection module** for examples of covered facilities and non-covered services/facilities.

The following over-filtering and under-filtering examples may be useful:

- a) Hospital Inpatient:
 - Over-filtering - Failing to submit data from specialized facilities (e.g., Rehabilitation and Psychiatric Hospitals).
 - Under-filtering - Submitting data from interim bills or from non-covered institutional stays (e.g., nursing facility data).
- b) Hospital Outpatient:
 - Over-filtering - Failing to submit data from specialized facilities, particularly those that do not appear on the inpatient provider list (e.g., Rural Health Clinics, Federally Qualified Health Centers) excluding bills with both covered and non-covered procedure codes.
 - Under-filtering - Submitting data from non-covered facilities or submitting non-covered services from covered facilities (e.g., laboratory only or radiology only claims).
- c) Physicians:
 - Over-filtering - Failing to capture data from non-physician practitioners that appear on the physician specialty list (e.g., nurse practitioners, physician assistants, etc.).
 - Under-filtering - Submitting all paid claims from the claims database, including laboratory, Durable Medical Equipment (DME), ambulance, etc.



For those plans that use CPT codes to screen diagnosis codes submitted to CMS, please note that the CPT range for radiology is 7000 through 79999. The following CPT codes indicate diagnostic radiology and diagnoses on claims and should not be submitted to CMS in risk adjustment data: 70010 through 76999 and 78000 through 78999.

4.12 Modifying Risk Adjustment Data (Slide 15)

RAPS allows for the correction of risk adjustment data submitted to CMS. This correction process is based on the concept that the incorrect cluster must be deleted from the system before the correct cluster information is added. For this reason, data correction is at least a two-step process.



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4.13 Deleting Diagnosis Clusters (Slide 16)

Each diagnosis cluster ("Diagnosis Code," "From Date," "Through Date," and "Provider Type") is stored separately as a unique cluster associated with a beneficiary's HIC number. If a diagnosis was submitted in error and needs to be corrected, the original diagnosis cluster must be resubmitted with a delete indicator in the appropriate field. **Delete transactions may only be submitted using the RAPS format or the DDE function.** When a delete record is received, CMS maintains the original diagnosis cluster on file and adds a delete indicator to it and the date of the deletion.

4.14 Reasons to Delete a Diagnosis Cluster (Slide 17)

There are three reasons MA organizations may delete a diagnosis cluster:

- Diagnosis cluster submitted erroneously (e.g., data from an interim bill was submitted for hospital inpatient).
- Incorrect HIC number used for submission of a beneficiary's diagnostic information.
- An error in a diagnosis cluster field (i.e., "Provider Type," "Dates of Service," "Diagnosis Code").

MA organizations submit deletions within a file, batch, or record containing previously submitted risk adjustment data.

4.15 Steps for Deleting a Diagnosis Cluster (Slides 18-20)



Before deleting an error, verify that the diagnosis cluster appears on the RAPS Return File. Only diagnosis clusters accepted by RAPS and stored in the RAPS database may be deleted.

There are two methods for deleting diagnosis clusters:

Method 1 for Deleting Clusters

1. Submit RAPS format using normal submission process with appropriate HIC number included.
2. Enter information in the diagnosis cluster fields (9.0, 9.1, 9.2, 9.4, 9.5) exactly as it appeared in the original submission.
3. In field 9.3 enter a "D" for delete.
4. Enter the appropriate information in all other records to ensure the submission file is complete.
5. Transmit the file to FERAS. (See www.cssoperations.com for details.)

Method 2 for Deleting Clusters

1. Create a file using the DDE screens available through FERAS at Palmetto (detailed information about the DDE process is located in Section 4.20).
2. Enter information exactly as it appeared in the original submission.
3. In the DDE "CCC" record screen, hit the down arrow key and select "D."
4. Proceed with entering all appropriate information.
5. Upload the file created in DDE to FERAS at Palmetto.



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4.16 MA Organization Responsibilities Regarding Deletions (Slide 21)

- MA organizations must submit delete records when an erroneous diagnosis cluster has been accepted by RAPS and stored in the RAPS database.
- If a diagnosis cluster is deleted for the purpose of correcting data, the MA organization is responsible for submitting the correct diagnosis cluster. Conversely, if the MA organization submits corrected data, the MA organization must submit the appropriate deletion record. That is, if the correct diagnosis cluster is submitted, the erroneous diagnosis cluster cannot be ignored.
- If a correction applies to the same beneficiary as the deletion, the correction may be included in the same "CCC" record as the deletion. (Do not exceed 10 diagnosis clusters per "CCC" record.)
- If only one of several clusters within the CCC record requires modification, do not resubmit all other associated clusters. If clusters are resubmitted exactly the same without the delete indicator, the plans will generate a duplicate cluster error.
- If the corrected diagnosis cluster belongs to a different beneficiary than the deleted diagnosis cluster, the correct diagnosis cluster may be submitted in the same file as the deletion.



MA organizations should not delete a diagnosis code or record repeatedly on the same day and on the same record. MA organizations should implement a process to ensure that only one instance of a specific diagnosis cluster (either add or delete) is submitted on a given day.

4.17 Direct Data Entry (Slide 22)

MA organizations have the option of manually entering diagnostic information via the DDE application offered by Palmetto. DDE instructions are illustrated in the screen shots below. DDE is available in FERAS at Palmetto via the Medicare Data Communications Network (MDCN).

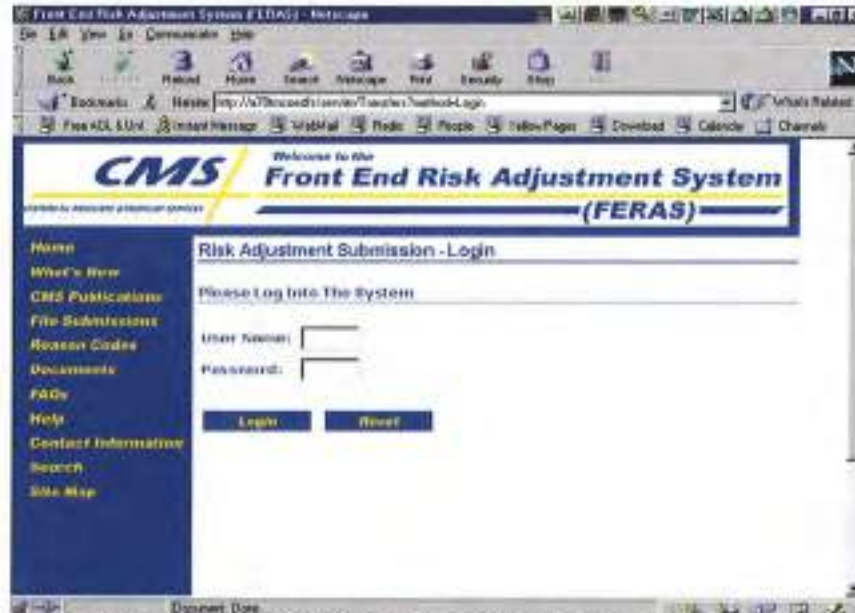
- DDE entries allow for deletion of records for corrections even if another submission format was used.
- The DDE screens, as shown in Figures 4B through 4G, automatically prevent the placement of incorrect data characters (e.g., alpha characters will not be accepted in the "From" or "Through Date" fields).
- After the user has entered all relevant data, the user will click on the "Create File" button in FERAS. This will create a file on the user's local PC.
- After the file is created on the local PC, the user must upload the file to FERAS in order to complete the process.
- Files created in DDE and uploaded to FERAS will receive a FERAS Response Report, which may be downloaded from the MA organization's electronic mailbox.



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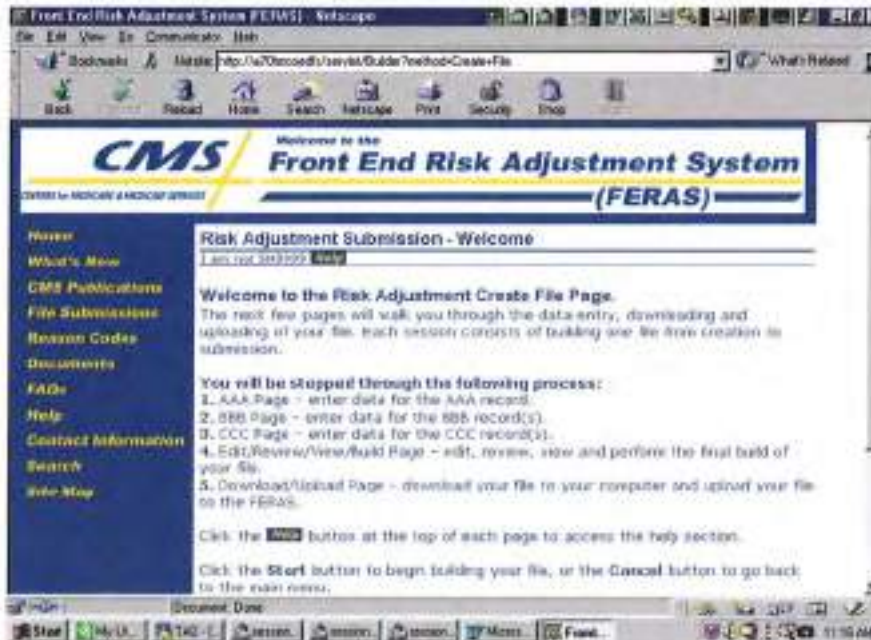
DATA SUBMISSION

Figure 4B – DDE 1



LOGIN PAGE – Submitters are assigned a User Name and Password to access the DDE application.

Figure 4C – DDE 2



WELCOME PAGE – Submitters are provided instructions on the use of the DDE.



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Figure 4D – DDE 3

Front End Risk Adjustment System (FERAS) - Netscape

Home

What's New

CMS Publications

File Submissions

Reason Codes

Documents

FAQs

Help

Contact Information

Search

Site Map

Welcome to the
Front End Risk Adjustment System
(FERAS)

Risk Adjustment Submission - Record AAA Information

Record ID: AAA

Submitter Number: 000000

File ID: 1234567890

Transfer Date: 20030409

PROD/TEST Indicator: TEST

Go To AAA Cancel Reset

The file-level information is entered and must begin with RT AAA.

Figure 4E – DDE 4

Front End Risk Adjustment System (FERAS) - Netscape

Home

What's New

CMS Publications

File Submissions

Reason Codes

Documents

FAQs

Help

Contact Information

Search

Site Map

Welcome to the
Front End Risk Adjustment System
(FERAS)

Risk Adjustment Submission - Record BBB Information

Record ID: BBB

Sequence Number: 000000

Plan Number: 000000

Go To BBB Cancel Reset

The batch-level information is entered and must begin with RT BBB.



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Figure 4F – DDE 5

Front End Risk Adjustment System (FERAS) - Netscape

Record ID: CCC Sequence Number: 0000001

Patient Control Number: 9976543210

HEC Number: 1134567890 DOD: 10020621

Diagnosis Cluster	Provider Type	From Date (YYYYMMDD)	Thru Date (YYYYMMDD)	Delete Ind	Diagnosis Code
1.	01	20010101	20020101		25001
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Buttons: Submit, Cancel, Make CCC, Cancel, Reset

The CCC Record allows up to 10 diagnostic clusters.

Figure 4G – DDE 6

Front End Risk Adjustment System (FERAS) - Netscape

Risk Adjustment Submission - File Submitted

Your file has been submitted to the FERAS.

File Statistics:

AAA Records	0000001
BBB Records	0000001
CCC Records	0000001
YYY Records	0000001
XXX Records	0000001
File Size	2510 Bytes

Your response file will be available shortly.

Check for your response using either the [Download](#) or [View](#) Page.

Buttons: Upload File, Download File, View File, Delete File, Create File

The file has been uploaded to FERAS.



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MODULE 5 – EDITS

Purpose (Slide 2)

The risk adjustment process includes an editing stage to ensure the accuracy of the data prior to storing the data for risk adjustment calculation. When Medicare Advantage (MA) organizations understand common errors and steps to prevent such errors, the efficiency of the risk adjustment process is increased. This module introduces participants to the Front-End Risk Adjustment System (FERAS) and the Centers for Medicare & Medicaid Services (CMS) Risk Adjustment Processing System (RAPS) data logic and editing processes. It provides information to assist MA organizations in minimizing data errors and taking appropriate steps in correcting errors that occur.

Learning Objectives (Slide 3)

At the completion of this module, participants will be able to:

- Interpret the FERAS and the RAPS data integrity logic and error codes.
- Describe the FERAS and RAPS editing processes.
- Recognize common FERAS and RAPS errors and determine action required to avoid or correct them.

ICON KEY	
Example	
Reminder	
Resource	

5.1 Data Flow (Slide 4)

After MA organizations submit data to Palmetto, FERAS performs format and integrity checks on the file and batch levels, as well as on the first and last detail (CCC) record. After the data pass the checks, they are sent to RAPS for complete editing of all detail records before they are stored in the RAPS database.

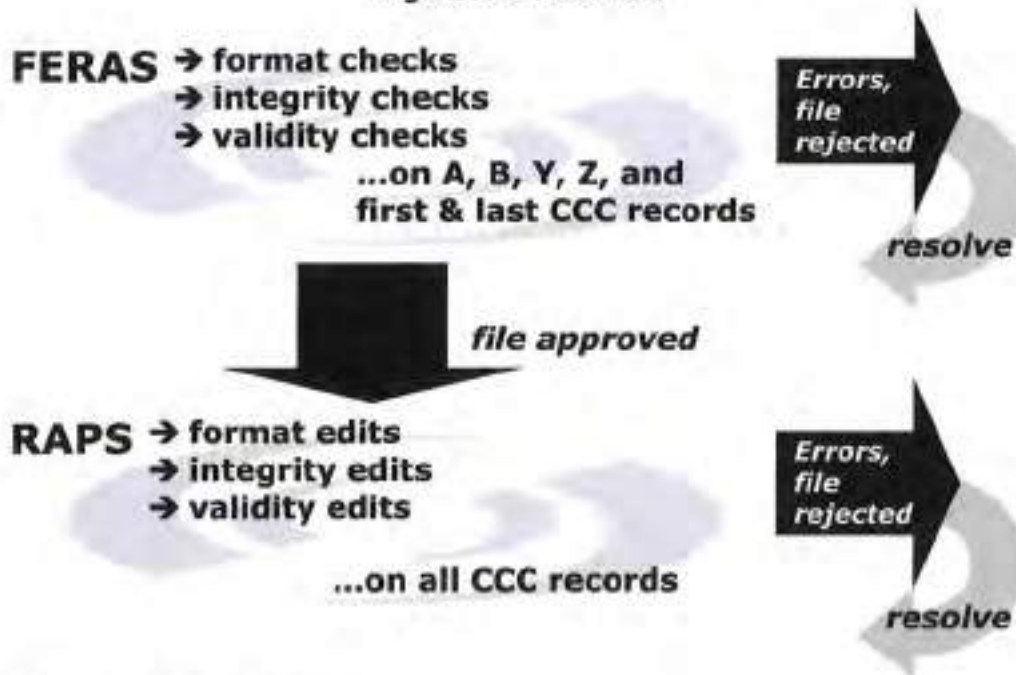
Files submitted in Test and Production are processed through FERAS and RAPS, and all edits are performed. Test files, however, are not stored in the RAPS database. The flow of data for edit processing is illustrated in Figure 5A.



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Figure 5A – Data Flow



5.1.1 FERAS System (Slide 5)

MA organizations submit data to FERAS, which performs the format and integrity checks.

- FERAS performs format and integrity checks on file- and batch-level data.
- FERAS checks the first and last detail records in each batch.
- FERAS accepts or rejects the entire file.
- FERAS ensures that all accepted transactions contain the following correct data:
 - AAA and ZZZ record.
 - At least one BBB record for each YYY record.
 - Following each BBB record, at least one CCC record with at least one diagnosis cluster populated.
 - Valid submitter ID and plan numbers.
 - Valid record and file totals.
 - The first and last CCC record will be edited to ensure that the submitted data are in the correct location on the record (i.e., spaces are where they should be located).
 - Record Type CCC must be present in the first field.
 - The first sequence number must equal 0000001.
 - The last sequence number must equal the total CCC record count in the YYY record.
 - The "HIC (Health Insurance Claim) Error Code" and "Diagnosis Code – Filler" fields contain spaces. Do not fill fields with zeros.

If all checks pass, the transaction processing continues in RAPS. If any of the data fail, the complete file is rejected.



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Example: 1

Scenario: The MA organization submitted a file and entered "AA1" in record type AAA, field 1.

Results: FERAS will reject the entire file with error message 100. The field must always be populated with "AAA".

Generally, FERAS errors occur during the initial establishment of the system and risk adjustment process in MA organizations. After data are processed, automated formats are programmed, and FERAS errors occur less frequently.

5.1.2 FERAS Error Code Logic (Slide 7)

When a FERAS check fails, an associated error code is created. Table 5A describes the error code logic. If any errors occur in FERAS, the complete file is rejected and returned to the submitter after all checks are completed.

TABLE 5A – FERAS ERROR CODE LOGIC

SERIES	EXPLANATION
100	File-level errors on the AAA or ZZZ records.
200	Batch-level errors on the BBB or YYY records.
300-400	Check performed on first and last CCC records.

- The 100- and 200- series error codes are assigned based on the level of checks that are performed, as well as the location of the edit.
- The entire file is returned to the submitter.

5.1.3 FERAS Error Code Ranges (Slide 8)

Error code ranges are explained in Table 5B.



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TABLE 5B - ERROR CODE RANGES

SERIES	EXPLANATION
100	Indicates that the system could not determine the record type; all editing stopped at that point.
101-109	Indicates a failure of a face-validity edit on the AAA record (file-level header). The last digit indicates the specific field in which the error was found. For example, the 101-error code refers to an error found in field 1 on the AAA record.
111-125	Indicates a failure of a cross-reference edit between a field on the AAA (file-level header) record and a look-up table, a field on another record, or a value calculated from another record. The last digit will indicate the specific AAA field against which the cross-check was performed. For example, the 112-error code indicates that the submitter ID in field 2 did not appear on a look-up table of valid submitter IDs.
151-159	Indicates a failure of a face-validity edit on the ZZZ record (file-level trailer). The last digit indicates the specific field in which the error was found. For example, the 151-error code refers to an error found in field 1 on the ZZZ record.
161-175	Indicates a failure of a cross-reference edit between a field on the ZZZ (file-level trailer) record and a look-up table, a field on another record, or a value calculated from another record. The last digit will indicate the specific ZZZ field against which the cross-check was performed. For example, the 162-error code indicates that the submitter ID, field 2 in ZZZ record, does not match the submitter ID on the AAA record.
201-209	Indicates a failure of a face-validity edit on the BBB (batch-level header) record. The last digit indicates the specific field in which the error was found. For example, the 201-error code refers to an error found in field 1 on the BBB record.
211-225	Indicates a failure of a cross-reference edit between a field on the BBB (batch-level header) record and a look-up table, a field on another record, or a value calculated from another record. The last digit will indicate the specific BBB field against which the cross-check was performed. For example, the 213-error code indicates that the submitter ID, field 3 in BBB record, is not authorized to submit for the plan ID.
251-259	Indicates a failure of a face-validity edit on the YYY (batch-level trailer) record. The last digit indicates the specific field in which the error was found. For example, the 251-error code refers to an error found in field 1 in the YYY record.
261- 275	Indicates a failure of a cross-reference edit between a field on the YYY (batch-level header) record and a look-up table, a field on another record, or a value calculated from another record. The last digit will indicate the specific YYY field against which the cross-check was performed. For example, the 262-error code indicates that the sequence number in the YYY record field 2 does not match the sequence number in field 2.
301-489	Indicates a format problem with the first or last CCC record. The problem is either with the face validity of the data in specific fields or the presence of data in fields that are required to be blank. In either circumstance, the basic CCC record format is assumed to be in error and the entire file is rejected.



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Note: FERAS checks the validity and format of an individual field before performing checks between fields. For example, the system first checks that there is a valid submitter ID on the AAA record before it checks that the submitter ID reported in the YYY record is identical. FERAS file-level, batch-level, and detail-level error codes are described in Table 5C.

TABLE 5C – FERAS ERROR CODES

FILE-LEVEL ERROR CODES

ERROR CODE	RECORD ID	ERROR DESCRIPTION
100	AAA	INVALID RECORD TYPE
101	AAA	AAA RECORD MISSING FROM TRANSACTION
102	AAA	MISSING / INVALID SUBMITTER-ID ON AAA RECORD
103	AAA	MISSING FILE-ID ON AAA RECORD
104	AAA	MISSING / INVALID TRANSACTION DATE ON AAA RECORD
105	AAA	MISSING / INVALID PROD-TEST-INDICATOR ON AAA RECORD
112	AAA	SUBMITTER ID NOT ON FILE
113	AAA	FILE NAME DUPLICATES ANOTHER FILE ACCEPTED WITHIN LAST 12 MONTHS
114	AAA	TRANSACTION DATE IS GREATER THAN CURRENT DATE
151	ZZZ	ZZZ RECORD MISSING FROM TRANSACTION
152	ZZZ	MISSING / INVALID SUBMITTER-ID ON ZZZ RECORD
153	ZZZ	MISSING / INVALID FILE-ID ON ZZZ RECORD
154	ZZZ	MISSING / INVALID BBB-RECORD-TOTAL
162	ZZZ	ZZZ SUBMITTER-ID DOES NOT MATCH SUBMITTER-ID ON AAA RECORD
163	ZZZ	FILE ID DOES NOT MATCH FILE ID ON AAA RECORD
164	ZZZ	ZZZ VALUE IS NOT EQUAL TO THE NUMBER OF BBB RECORDS

BATCH-LEVEL ERROR CODES

ERROR CODE	RECORD ID	ERROR DESCRIPTION
201	BBB	BBB RECORD MISSING FROM TRANSACTION
202	BBB	MISSING / INVALID SEQUENCE NUMBER ON BBB RECORD
203	BBB	MISSING / INVALID PLAN NUMBER ON BBB RECORD
212	BBB	SEQUENCE NUMBER ON BBB RECORD IS OUT OF SEQUENCE
213	BBB	SUBMITTER ID NOT AUTHORIZED TO SUBMIT FOR THIS PLAN ID
251	YYY	YYY RECORD MISSING FROM TRANSACTION
252	YYY	MISSING / INVALID SEQUENCE NUMBER ON YYY RECORD
253	YYY	MISSING / INVALID PLAN NUMBER ON YYY RECORD
254	YYY	MISSING / INVALID CCC-RECORD-TOTAL
262	YYY	LAST YYY SEQUENCE NUMBER IS NOT EQUAL TO NUMBER OF YYY RECORDS
263	YYY	PLAN NUMBER DOES NOT MATCH PLAN NUMBER IN BBB RECORD
264	YYY	YYY VALUE IS NOT EQUAL TO THE NUMBER OF CCC RECORDS
272	YYY	SEQUENCE NUMBER ON YYY RECORD IS OUT OF SEQUENCE



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TABLE 5C – FERAS ERROR CODES (CONTINUED)
DETAIL-LEVEL ERROR CODES

ERROR CODE	RECORD ID	ERROR DESCRIPTION
301	CCC	CCC RECORD MISSING FROM TRANSACTION
302	CCC	MISSING / INVALID SEQ-NO ON CCC RECORD
303	CCC	SEQUENCE-ERROR-CODE FILLER NOT EQUAL TO SPACES
304	CCC	HIC-ERROR-CODE FILLER NOT EQUAL TO SPACES
305	CCC	DOB-ERROR-CODE FILLER NOT EQUAL TO SPACES
306	CCC	DIAGNOSIS CODE-FILLER NOT EQUAL TO SPACES
307	CCC	DIAGNOSIS-CLUSTER-ERROR-1 NOT EQUAL TO SPACES
308	CCC	DIAGNOSIS-CLUSTER-ERROR-2 NOT EQUAL TO SPACES
309	CCC	SEQUENCE-NUMBER ON CCC RECORD IS OUT OF SEQUENCE
310	CCC	MISSING / INVALID HIC-NO ON CCC RECORD
311	CCC	AT LEAST ONE DIAGNOSIS CLUSTER REQUIRED ON TRANSACTION
313	CCC	DELETE-INDICATOR MUST BE BLANK OR EQUAL TO "D"
314	CCC	INVALID DIAGNOSIS CODE FORMAT ON CCC RECORD
315	CCC	CORRECTED HIC NOT EQUAL TO SPACES
350	CCC	INVALID PATIENT-DOB ON CCC RECORD
400	CCC	MISSING / INVALID PROVIDER-TYPE ON CCC RECORD
401	CCC	INVALID FROM-DATE ON CCC RECORD
402	CCC	INVALID THRU-DATE ON CCC RECORD



Example: 2

Scenario: The MA organization submitted a file with a 2.0 in the "Diagnosis Code – Filler" field on the first CCC record.

Results: FERAS would reject the complete file due to data being placed in the "Diagnosis Code – Filler" field of the diagnosis cluster; it must be populated with spaces. FERAS would identify this error, since it occurred in the first CCC record.



FERAS errors rarely occur after MA organizations program file layouts and adequately test the formats before submission to CMS.

5.1.4 RAPS Edits (Slide 10)

After data pass the FERAS checks, the file is sent via Connect: Direct to the CMS data center for RAPS processing.

- As a precautionary measure, RAPS performs balancing checks to ensure that the complete file was received from Palmetto prior to editing data.



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- The RAPS system performs editing on the CCC transactions.
- The data elements edited include HIC Number, Provider Type, Diagnosis Code, From Date, and Through Date.
- If Date of Birth is submitted, RAPS performs an edit on that field.

5.1.5 RAPS Editing Rules

The RAPS editing process takes place in four logical stages.

Stage 1- Field Validity and Integrity Edits (Slide 11)

RAPS performs format and integrity checks on all CCC-level fields as a first level of editing. If there are data in the "HIC Error Code" or "Diagnosis Code - Filler" fields, the entire detail record is rejected with no further editing performed. If a record fails this stage of editing, it is assumed that the data are corrupt.

The dates also are checked at this stage. If the dates within a diagnosis cluster are not valid dates, then RAPS stops the editing process for that diagnosis cluster because all other data edits within a diagnosis cluster depend upon the validity of the dates.

Stage 2 - Field-to-Field Edits (Slide 12)

After RAPS checks format and integrity of the fields, the field-to-field editing takes place.

- RAPS ensures that the from date is equal or prior to the through date.
- RAPS also checks all diagnosis clusters for hospital outpatient and physician provider types to ensure compliance with the 31-day span rule.
- RAPS checks all data to make certain that MA organizations submit the reconciliation data properly. See Submission Timetable in Module 2 (Risk Adjustment Process Overview) for dates of service included in each data submission period.

Stage 3 - Eligibility Edits (Slides 13)

The next stage of editing cross-checks the appropriate fields against the common tables in MBD and MARx. MA organizations may access MBD through the common user interface, Medicare Advantage & Part D Inquiry System. For risk adjustment purposes, these common tables are the authoritative source of beneficiary information, and supports managed care enrollments to MA organizations.

In this editing stage, the HIC number, date of birth, and Medicare entitlement are checked. For example, in Stage 1 editing, the system ensured that a valid HIC number was present in field 5 of the CCC record. In Stage 3 editing, the system makes certain that the HIC number exists on the common tables.

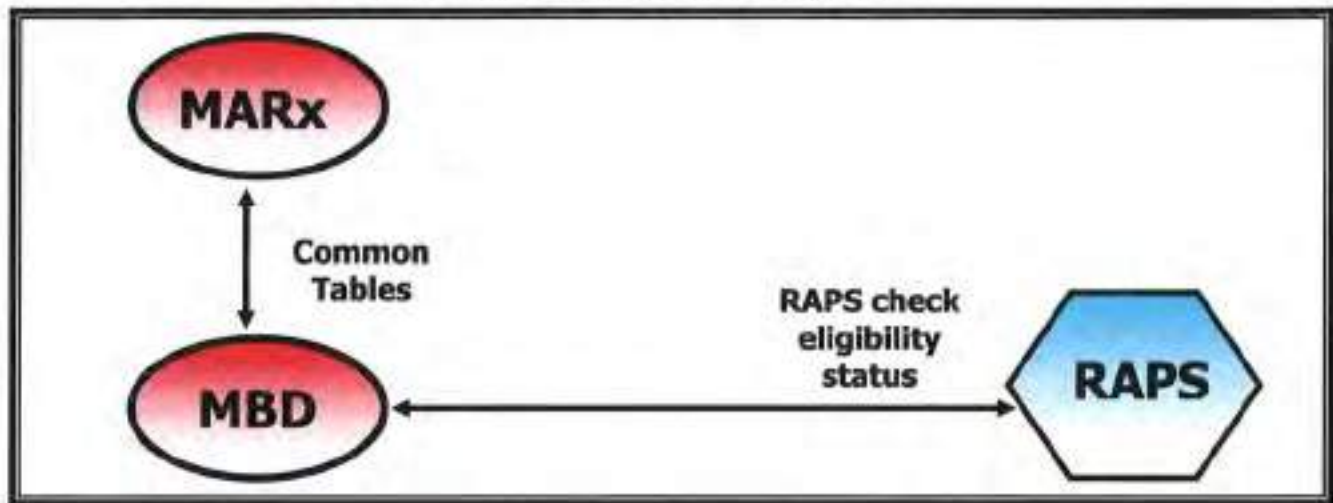


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Figure 5B illustrates the flow of data between MARx and MBD and RAPS.

Figure 5B –Flow of Data for Eligibility Checks



The HIC number is a common way to begin researching data in the common tables.

- The common tables store historical data on file, so if a beneficiary's HIC number changed, the common tables will cross-reference the old and new numbers.
- Railroad Retirement Board (RRB) beneficiary numbers are cross-referenced automatically. This allows users to research demographic and eligibility information for beneficiaries with RRB and HIC numbers.

Stage 4 – Diagnosis Code Edits (Slide 14)

After RAPS edits the integrity of the individual fields and validates the HIC number and eligibility, it edits the diagnosis code against the Diagnosis Lookup Table in RAPS. In this stage, the system first ensures that each diagnosis code is valid. Then the system checks each diagnosis code against service dates and gender. If any of these edits fail, the diagnosis cluster is not stored in the RAPS database. The edits at this stage also include an edit to check if the diagnosis code is in the risk adjustment model. If the diagnosis code is not in the model, an information error is returned. The diagnosis cluster is stored if an information-only error is returned, and no further action by the MA organization is required.

Explanations of error codes and their consequences, RAPS error codes, informational edits, and duplicate diagnosis cluster edit are presented in Tables 5D, 5E, 5F, and 5G, respectively.



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TABLE 5D – EXPLANATION OF ERROR AND CONSEQUENCES

SERIES	EXPLANATION OF ERROR AND CONSEQUENCES
300-349	Record-level error. The record was bypassed and all editing was discontinued. No diagnosis clusters from this record were stored.
350-399	Record-level error. All possible edits were performed, but no diagnosis clusters from this record were stored.
400-489	Diagnosis cluster error. All possible diagnosis edits were performed, but the diagnosis cluster is not stored.
490-499	Diagnosis delete error; diagnosis was not deleted.
500-599	Informational message, all edits were performed; diagnosis cluster was stored unless some other error is noted.

TABLE 5E – RAPS ERROR CODES

ERROR CODE	RECORD ID	ERROR DESCRIPTION
301	CCC	CCC RECORD MISSING FROM TRANSACTION
302	CCC	MISSING / INVALID SEQUENCE-NUMBER ON CCC RECORD
303	CCC	SEQUENCE-ERROR-CODE FILLER NOT EQUAL TO SPACES
304	CCC	HIC-ERROR-CODE FILLER NOT EQUAL TO SPACES
305	CCC	DOB-ERROR-CODE FILLER NOT EQUAL TO SPACES
306	CCC	DIAGNOSIS CODE FILLER NOT EQUAL TO SPACES
307	CCC	DIAGNOSIS-CLUSTER-ERROR-1 NOT EQUAL TO SPACES
308	CCC	DIAGNOSIS-CLUSTER-ERROR-2 NOT EQUAL TO SPACES
309	CCC	SEQUENCE-NUMBER ON CCC RECORD IS OUT OF SEQUENCE
310	CCC	MISSING / INVALID HIC-NUMBER ON CCC RECORD
311	CCC	AT LEAST ONE DIAGNOSIS CLUSTER REQUIRED ON TRANSACTION
313	CCC	DELETE-INDICATOR MUST EQUAL SPACE OR "D" FOR DELETE
314	CCC	INVALID DIAGNOSIS CODE FORMAT ON CCC RECORD
315	CCC	CORRECTED HIC NOT EQUAL TO SPACES
350	CCC	INVALID PATIENT-DOB ON CCC RECORD
353	CCC	HIC NUMBER DOES NOT EXIST ON MBD
354	CCC	PATIENT DOB DOES NOT MATCH WITH MBD DOB



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TABLE 5E – RAPS ERROR CODES (CONTINUED)

ERROR CODE	RECORD ID	ERROR DESCRIPTION
400	CCC	MISSING / INVALID PROVIDER-TYPE CODE ON CCC RECORD
401	CCC	INVALID SERVICE FROM-DATE ON CCC RECORD
402	CCC	INVALID SERVICE THROUGH-DATE ON CCC RECORD
403	CCC	SERVICE THROUGH-DATE MUST BE GREATER THAN 12/31/2004
404	CCC	SERVICE FROM-DATE MUST BE LESS THAN OR EQUAL TO THROUGH-DATE
405	CCC	DOB IS GREATER THAN SERVICE FROM-DATE
406	CCC	SERVICE FROM-DATE IS NOT WITHIN MEDICARE ENTITLEMENT PERIOD
407	CCC	SERVICE THROUGH-DATE IS NOT WITHIN MEDICARE ENTITLEMENT PERIOD
408	CCC	SERVICE FROM-DATE IS NOT WITHIN MA ORG ENROLLMENT PERIOD
409	CCC	SERVICE THROUGH-DATE IS NOT WITHIN MA ORG ENROLLMENT PERIOD
410	CCC	BENEFICIARY IS NOT ENROLLED IN PLAN ON OR AFTER SERVICE FROM-DATE
411	CCC	SERVICE THROUGH-DATE IS GREATER THAN DATE OF DEATH
412	CCC	SERVICE FROM-DATE GREATER THAN TRANSACTION DATE
413	CCC	SERVICE THROUGH-DATE GREATER THAN TRANSACTION DATE
450	CCC	DIAGNOSIS DOES NOT EXIST FOR THIS SERVICE THROUGH-DATE
451	CCC	SERVICE THROUGH-DATE IS GREATER THAN DIAGNOSIS END DATE
453	CCC	DIAGNOSIS CODE IS NOT APPROPRIATE FOR PATIENT SEX
454	CCC	DIAGNOSIS IS VALID, BUT IS NOT SUFFICIENTLY SPECIFIC FOR RISK ADJUSTMENT GROUPING
455	CCC	DIAGNOSIS CLUSTER NOT EDITED DUE TO RECORD FORMAT ERROR
460	CCC	SERVICE FROM- AND THROUGH-DATE SPAN IS GREATER THAN 31 DAYS
490	CCC	COULD NOT DELETE, DIAGNOSIS CLUSTER NOT IN RAPS DATABASE BENEFICIARY RECORD
491	CCC	DELETE ERROR, DIAGNOSIS CLUSTER PREVIOUSLY DELETED
492	CCC	DELETE ERROR, DIAGNOSIS CLUSTER WAS NOT DELETED. A DIAGNOSIS CLUSTER WITH THE SAME ATTRIBUTES WAS ALREADY DELETED FROM THE RAPS DATABASE ON THIS DATE

TABLE 5F – INFORMATIONAL EDITS

ERROR CODE	RECORD ID	ERROR DESCRIPTION
500	CCC	BENEFICIARY HIC NUMBER HAS CHANGED ACCORDING TO CMS RECORDS; USE CORRECT HIC NUMBER FOR FUTURE SUBMISSIONS
501	CCC	VALID DIAGNOSIS BUT NOT A RELEVANT DIAGNOSIS FOR RISK ADJUSTMENT DURING THIS SERVICE PERIOD



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TABLE 5G – DUPLICATE DIAGNOSIS CLUSTER EDIT

ERROR CODE	RECORD ID	ERROR DESCRIPTION
502	CCC	DIAGNOSIS CLUSTER WAS ACCEPTED BUT NOT STORED. A DIAGNOSIS CLUSTER WITH THE SAME ATTRIBUTES IS ALREADY STORED IN THE RAPS DATABASE



Example: 3

Scenario: The Low Rest Insurance Company submitted a risk adjustment transaction for Susan Doe who was admitted into the hospital. The principal diagnosis submitted was 601.0 for acute prostatitis.

Results: The error code 453 would occur. The system checked that the diagnosis field was complete. Next, the system verified that the HIC number was entered. RAPS then verified that the HIC number was on the common tables and the beneficiary was eligible. The diagnosis was determined to be a valid diagnosis. However, the diagnosis was not valid for the sex. This diagnosis cluster was rejected and not stored in the RAPS database.

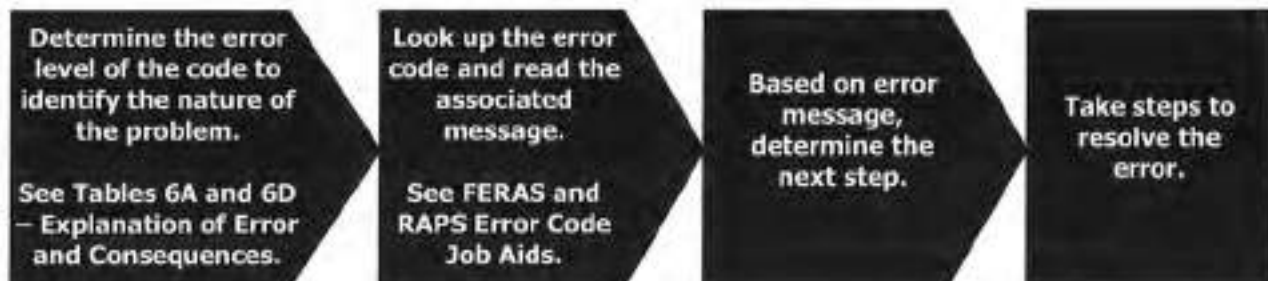
5.2 Resolving Error Codes

CMS began accepting risk adjustment data in FERAS and processing data through RAPS in October 2002. While the error rate is less than one percent, there are several errors that represent the majority of the common errors seen.

5.2.1 Resolution Steps (Slide 17)

It is the MA organization's responsibility to resolve errors that CMS identifies. Described below in Figure 5C are the basic steps required to resolve errors. If inaccurate data are the cause of the error, the organization must submit a new record with corrected information to resolve the error.

Figure 5C – Resolution Steps





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System problems may occur when MA organizations submit and delete the same diagnosis cluster several times on the same day. The error code 492 will occur if the organization tries to delete the same cluster more than once.



Example: 4

Scenario: John Smart at BaseCare Health Plan deleted a diagnosis cluster. Later the same day, he mistakenly added the same cluster using Direct Data Entry (DDE). Realizing his mistake, John immediately attempted to delete this cluster using DDE.

Results: The error code 492 occurs, indicating that (1) the diagnosis cluster was not successfully deleted and (2) that the cluster is already stored as a delete and another delete is not necessary.

Effective January 3, 2006, new error code 455 was added to the RAPS Error Codes list. The message reads "Diagnosis cluster not edited due to record format error." The diagnosis cluster is not stored. A plan will receive this error if the plan leaves a cluster blank within a CCC record, and then populates the next cluster. Error code 455 clusters may occur with, or after, the first blank diagnosis cluster. Blank clusters will not receive a 455 error.

When a submitter receives a 455-error code, "Diagnosis Cluster Not Edited Due to Record Format Error", the following steps should be taken:

- Since this is a 400-level error code message, the submitter will refer to the diagnosis cluster.
- The error code series 400-489 indicates that all possible diagnosis edits were performed but the diagnosis cluster is not stored.
- The submitter should ensure that the CCC record contains valid clusters, left justified in the record, followed by blank clusters.
- Resubmit following correction.

Note: A 455 error will not occur with error codes 302 through 315. These error codes indicate the CCC record is not valid.



Example: 5

Scenario: Horizon Valley Health Plan submitted eight diagnosis clusters. However, the fifth diagnosis cluster was a blank cluster.

Results: Error code 455 occurs. All of the diagnosis clusters following the blank cluster received the error code 455. All possible diagnosis edits were performed, but the diagnosis clusters were not stored.



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5.2.2 Informational Error Messages

RAPS generates informational messages that do not stop processing of data, i.e., no immediate action is necessary. However, these messages, illustrated in Table 5H, provide MA organizations with information to improve future submissions.

TABLE 5H – INFORMATIONAL MESSAGE CODES

ERROR CODE	RECORD ID	ERROR DESCRIPTION	PROCESS IMPROVEMENT
500	CCC	BENEFICIARY HIC NUMBER HAS CHANGED ACCORDING TO CMS RECORDS; USE CORRECT HIC NUMBER FOR FUTURE SUBMISSIONS.	USE UPDATED HIC NUMBER ON ALL FUTURE SUBMISSIONS FOR THIS BENEFICIARY.
501	CCC	VALID DIAGNOSIS BUT NOT A RELEVANT DIAGNOSIS FOR RISK ADJUSTMENT DURING THIS SERVICE PERIOD.	DETERMINE IF FILTERING SHOULD BE INCORPORATED INTO SUBMISSION PROCESS TO REDUCE NUMBER OF 501 MESSAGES.

5.2.3 Duplicate Diagnosis Cluster Error and 5 Percent Benchmark

CMS has put a 5 percent benchmark requirement in place for 502 errors, "Diagnosis cluster was accepted but not stored. A diagnosis cluster with the same attributes is already stored in the RAPS database," CMS monitors plans with error rates that exceed the benchmark. CMS defines a duplicate submission as a diagnosis cluster with the same attributes (provider type, from date, through date, diagnosis code, and HIC number) that are already stored in the RAPS database.

Each duplicate cluster that receives a 502-error code counts toward the 5 percent benchmark. For example, if a record included 10 diagnosis clusters and each one was a duplicate of another cluster, there would be 10 502-error codes and all 10 would count towards the 5 percent benchmark.

CMS will look at the overall metrics per file, as this is the easiest way to measure the benchmark. CMS will look at files on a weekly basis to determine volume and the number of duplicates the plan receives to determine if a compliance letter needs to be sent.

If the submitter is a third party and the file contains records for multiple plans, the review will occur at the plan level within the file. Table 5I provides examples of how CMS reviews plan submissions against the benchmark.



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TABLE 5I – 502 BENCHMARK COMPARISON EXAMPLES

EXAMPLE NUMBER	EXAMPLE DESCRIPTION
1	If a plan submitted one file in a given week with two records and they were duplicates, the plan would have a 100% duplicate rate, but with only two records.
2	Afterwards, the plan submitted additional files that had 10,000 records and a 2% duplicate rate. In this case, CMS would not send this plan a compliance letter.
3	If, on the other hand, a plan submitted a file with 2 million records and 1 million of them were duplicates, CMS would send a compliance letter.

Submitters should consider establishing an automated system or a process that checks previously submitted files for accepted diagnosis clusters in order to minimize or eliminate the resubmission of duplicate diagnosis clusters.

While this is an informational error and does not require action in terms of correcting an error, it is critical that plans self-monitor their submissions so that they do not exceed the 5 percent benchmark requirement on 502 errors. Table 5J provides tips to ensure plans are compliant with the guidance on the 5 percent benchmark for duplicate diagnosis cluster errors.

**TABLE 5J – TIPS FOR ENSURING COMPLIANCE WITH THE 5 PERCENT BENCHMARK
FOR DUPLICATE DIAGNOSIS CLUSTER ERROR GUIDANCE**

TIP	DESCRIPTION
Tip 1: Identify a Duplicate Diagnosis Cluster	CMS defines a Duplicate Diagnosis Cluster as one that shares all of the same attributes (HIC Number, Provider Type, From and Through Dates and Diagnosis) as one previously submitted and stored in the RAPS database.
Tip 2: Review Your Reports	Review your current and previous RAPS Return Files to determine which clusters were stored. If the cluster was stored, do not resubmit.
Tip 3: Understand Error Resolution	If you are resolving an error, you do not necessarily need to resubmit all clusters included in the record. If you are resolving a 300-level error, this indicates that none of the diagnosis clusters were stored because there was a record level error. If this is the case, you will need to resubmit all clusters associated with the record. This would not create a duplicate diagnosis because none of the records were previously stored. If you are resolving a 400-level error, this indicates that a specific diagnosis cluster was not stored. You should only resubmit the specific cluster that resulted in the 400-level error message. <i>Do not</i> resubmit all clusters within the record. If there were ten clusters within the record, but you received a 400-level error message on only two of the clusters, you should only resubmit the two clusters where the error occurred.
Tip 4: Understanding Modifying Data	In the case of self-identified errors, those not reported as an error on the RAPS reports, you should be careful to only resubmit the diagnosis clusters that require a modification. If you submit a record with eight clusters, but the following week you realize that the date of service was incorrect in one of the clusters, you would submit that specific cluster with a "D" in the delete indicator field, and submit a new cluster with the correct date. Resubmitting all of the remaining seven clusters would create seven duplicates.



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Use the tips above to assist your plan in reducing or eliminating the submission of duplicate diagnosis clusters to avoid implications that may result in suspension of data submission privileges and ultimately impact your payments.



Example: 6

Scenario: Blue Health Plan submitted a CCC record with five diagnosis clusters in which the third diagnosis cluster has an invalid HIC number. Blue Health Plan also submitted a CCC record with seven diagnosis clusters in which the sixth diagnosis cluster received an error indicating the diagnosis was not appropriate for the patient sex.

Results:

The CCC record with the five diagnosis clusters received a record level error, error code 310 on the third cluster. This means that the diagnosis clusters were not stored for this CCC record and all the diagnosis clusters in this record should be resubmitted.

The CCC record with the seven diagnosis clusters received a cluster level error, error code 453 on the sixth cluster. The only cluster not accepted and stored from this CCC record is the sixth cluster. Therefore, the only cluster that should be resubmitted by Blue Health Plan is the sixth cluster, the one that received the error. Resubmitting the other diagnosis clusters that were accepted and stored would result in the Blue Health Plan receiving error code 502 for submitting duplicate diagnosis clusters. This would count against the plan's 5% benchmark.

5.2.4 Common Errors (Slide 22)

In an effort to prevent common errors, the next section describes the errors and steps that MA organizations may take to minimize their occurrence.

5.2.4.1 File Name Duplicates Another File Accepted Within Last 12 Months

To identify the unique file that has been accepted, CMS requires that all files include a 10-digit alphanumeric file ID. This file ID is required when submitting test or production data. Once a file ID has been submitted and accepted in test or production, the same file ID may not be submitted on any other files within 12 months.

In addition, if a file ID was accepted in encounter data processing prior to October 2003, the file ID should not be used for Risk Adjustment processing within 12 months. FERAS performs an edit of the entire 10-digit file number, therefore submitters should make certain that those digits are unique.



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Example: 7

SenCare Health Plan submitted an encounter data hospital inpatient production file in August 2002 and an encounter data physician test file in August 2002. The plan cannot submit both files with the same file ID within 12 consecutive months (between August 2002 and August 2003).

Prevention

Submitters should consider establishing an automated system to assign a file sequence number during the establishment of the data file.

Correction

When a submitter receives a 113-error code, "File name duplicates another file accepted within the last 12 months", the following steps should be taken:

- Since this is a 100-level error code message, the submitter will refer to the AAA record.
- The error code 113, describes the field within the AAA record that must be corrected.
- The submitter must enter a valid 10-digit file ID in AAA 3.
- The file must be resubmitted following correction.



Since this file was rejected by FERAS, it will not be processed in RAPS until the data are corrected.

5.2.4.2 Delete Error, Diagnosis Cluster Previously Deleted

When a plan submits a delete and RAPS accepts it, the cluster is not physically deleted from the RAPS database. The RAPS database stores a "D" in the delete indicator and enters a delete date to indicate when the diagnosis was deleted. If a plan tries to delete the exact same diagnosis cluster at a later time, the system will generate a 491-error code, informing the plan that the cluster was already deleted.

Prevention

This issue normally occurs when plans delete all clusters from a previously submitted file, and the original file included duplicate diagnosis clusters. One way to prevent the errors is to check for duplicate diagnosis clusters prior to submitting the file with the deletes on it.

Correction

There is no corrective action necessary because the 491-error code indicates that the cluster has already been deleted.



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5.2.4.3 Diagnosis Cluster Not Successfully Deleted. Another Diagnosis Cluster With the Same Attributes Was Already Deleted From the RAPS Database On This Date

When plans submit delete records, the "D" indicator and the delete date become part of the unique database key for the diagnosis cluster. Diagnosis clusters must have one unique attribute in the database key in order to be stored. The 492-error code occurs when a plan deletes, adds, and then attempts to delete the exact same cluster during a single processing day. The delete will successfully process, as will the following add transaction. The add transaction will create a new record for this diagnosis cluster. The second delete cannot process, since accepting the second delete will cause the creation of a duplicate record in the RAPS database. This error is different from the 491 in that the last record on file will be the add record; that is, the diagnosis cluster has not been successfully deleted.

Prevention

Again, this error normally occurs when plans submit large files of correction records. Plans should check when deleting records that they are not adding the exact same cluster in the same file, or on different files on the same day. If a plan detects multiple submissions of the same diagnosis cluster, the plan should determine the final status of the cluster, deleted or active, and take appropriate action.

Correction

When a submitter receives a 492-error code, "Diagnosis Cluster Not Successfully Deleted", the following steps should be taken:

- Since this is a 400-level error code message, the submitter will refer to the CCC record.
- The error code series 490-499 indicates that it is a deletion problem.
- The submitter must determine if the diagnosis cluster should be deleted or active as a final action.
- If the cluster should be active, no further action is required.
- If the diagnosis is supposed to be deleted, the plan must submit one delete record. Since any future submissions will have a different delete date than any other clusters on file, a single delete record will successfully process.

5.2.4.4 Service From Date Is Not Within MA Organization Enrollment

MA organizations can reduce the numbers of errors that are returned due to invalid eligibility by accessing the common user interface to determine eligibility and other demographic information stored on the common tables. Implementing the following procedures can reduce time spent on resolving errors.

- Develop a monthly validation protocol verifying eligibility of MA organization enrollees.
- Program internal information systems that cross check the common tables before submitting data to FERAS.



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The Beneficiary Eligibility and Beneficiary Detail screens in the common user interface provide information that supports the MA risk adjustment requirements. The information includes:

- Date of birth.
- HIC Number.
- Medicare effective date.
- Medicare termination date.

Note: MA organizations can manually research each beneficiary online or electronically research beneficiaries in batches using the Batch Eligibility Query Request File.

The beneficiary receiving services under the MA program must be enrolled in Medicare during the service period. The dates of service reported in the diagnosis clusters must be within the enrollment dates that are posted on the common tables. RAPS cross-references the common tables to verify that the beneficiary was covered during the identified from and through dates of service. Prior to March 2003, MA organizations received the 408- and 409-error codes to reflect data inconsistencies between various CMS systems.



The 408-error code occurs with all data. The 409-error code occurs only with hospital outpatient and physician data.

Prevention

Submitters should check the from and through dates of service against internal enrollment records. Remember that for hospital outpatient and physician data, both the from and through dates must be within MA enrollment periods. For hospital inpatient data, only the from dates must be within MA enrollment periods. Performing these pre-edits will minimize the number of errors received regarding enrollment information.

Correction

When a submitter receives a 408-error code "Service from date is not within MA organization enrollment period", or a 409-error code "Service through date is not within MA organization enrollment period", the following steps should be taken:

- Since this is a 400-level error code message, the submitter will refer to the diagnosis cluster.
- The submitter must ensure that the correct service from date was entered in CCC 9.1.
- The submitter must ensure that the correct service through date was entered in CCC 9.2.
- The submitter should check these dates against the plan enrollment dates in the common tables.
- If the submitter determines that there are discrepancies in the data in CMS systems, contact CSSC.
- If the CSSC determines that the common tables require updated plan enrollment data, resubmit the data after CSSC corrects the data.



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Since this is not a format or integrity edit, this error will not be detected in FERAS; therefore, DDE users may encounter this error. When this is detected in RAPS, the problem must be corrected in order to store any diagnosis clusters associated with this record.

5.2.4.5 Beneficiary Is Not Enrolled In Plan On or After Service From Date

Beneficiaries must be enrolled in the plan on or after the date of the service provided.

Prevention

Using information from the monthly membership report and internal enrollment files, submitters should be knowledgeable regarding the enrollment and eligibility of their beneficiaries. Establishing a systematic beneficiary enrollment tracking system will reduce the number of errors associated with this edit.



The 408- and 409-error code messages indicate that the service occurred while the beneficiary was not participating in *any* MA program. The 410-error code message indicates that the service occurred while the beneficiary was not enrolled in *your* organization.

Correction

When a submitter receives a 410-error code "Beneficiary is not enrolled in plan on or after service from date", the following steps should be taken:

- Since this is a 400-level error code message, the submitter will refer to the diagnosis cluster.
- The submitter must ensure that the correct service from date was entered in CCC 9.1.
- The submitter should check the service from date against the plan enrollment dates to confirm that the beneficiary was enrolled in this plan on or after the from date.
- If the submitter determines that there are discrepancies in the data in CMS systems, contact CSSC.
- If CSSC determines that the common tables require updated plan enrollment data, resubmit after CSSC corrects the data.



Since this is not a format or integrity edit, this error will not be detected in FERAS; therefore, DDE users may encounter this error. When this is detected in RAPS, the problem must be corrected in order to store any diagnosis clusters associated with this record.



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DIAGNOSIS CODES & RISK ADJUSTMENT

MODULE 6 – DIAGNOSIS CODES & RISK ADJUSTMENT

Purpose

It is neither the intention of this module nor the purpose of this training to provide diagnostic coding training. However, this module does provide Risk Adjustment organizations with an introduction to diagnosis coding and stresses the importance of accurate diagnosis documentation and coding for risk adjustment. The module first explains the structure and layout of the official Centers for Medicare & Medicaid Services (CMS) diagnosis coding set-- the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The module also discusses the diagnosis coding guidelines that apply to the ICD-9-CM, and how following these guidelines ensures accurate risk adjustment. The module demonstrates how verification of compliance with coding guidelines depends upon accurate documentation in the medical record. Finally, the module provides information to assist MA organizations in communicating with their physicians regarding proper documentation and diagnosis coding.

Learning Objectives

At the completion of this module, participants will be able to:

- Identify the background, key terms, and organization of ICD-9-CM.
- Describe the coding update process, recent and proposed changes impacting risk adjustment, and the status of ICD-10-CM.
- Apply official coding guidelines to common Medicare diagnoses and understand the impact on associated Hierarchical Condition Category (HCC) assignment.
- Define and identify V codes and E codes in the HCC model.
- Describe the importance of ICD-9-CM and medical record documentation to risk adjustment.
- Identify resources available for additional training and policy formation regarding documentation and coding.

ICON KEY

Example



Reminder



Resource



6.1 Introduction

Medicare uses ICD-9-CM as the official diagnosis code set for all lines of business including determination of risk adjustment factors. MA organizations must:

- Implement procedures to ensure that diagnoses are coming from physician, hospital inpatient, or hospital outpatient provider types.
- Submit all relevant ICD-9-CM diagnosis codes for each beneficiary.
- Submit unique diagnoses at least once during the risk adjustment data reporting period.



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DIAGNOSIS CODES & RISK ADJUSTMENT

The source medical record documentation that supports each coded diagnosis must be obtainable and demonstrate adherence to official coding guidelines.



Relevant diagnoses are defined as those diagnoses collected from one of the three provider types that are used in the Risk Adjustment models (i.e., CMS-HCC, ESRD and RxHCC models).

This module emphasizes physician documentation and reporting of diagnosis codes. Historically, physician reimbursement in fee-for-service is primarily based on procedures or services rather than diagnoses, and physicians are very familiar with documentation guidelines for procedures and services. Physicians generally are not as familiar with diagnosis codes and their associated documentation guidelines as they are with procedure coding rules. The Risk Adjustment models depend upon accurate diagnosis coding, which means that physicians must fully understand and comply with documentation and coding guidelines for reporting diagnoses.

6.1.1 Benefit to the MA Organization and Physician

Benefits to the MA organization and physician are illustrated in Table 6A.

TABLE 6A – BENEFITS TO MA ORGANIZATIONS AND PHYSICIANS

A basic understanding of ICD-9-CM process and guidelines assists MA organizations in:
• Interpreting and designing management reports. • Determining possible causes of ICD-9-CM errors. • Communicating diagnosis-related collection issues to the provider staff. • Developing and maintaining information systems that meet the clinical data collection needs of the organization. • Understanding clinical issues important to beneficiaries. • Planning for future MA organization services.
Medical record documentation and coding impact several issues important to the physician and MA organization including:
• Accurate reimbursement. – ICD-9-CM codes are the basis of the Risk Adjustment models. – Accurate diagnosis codes are a result of clear, consistent, and complete documentation. – CMS may verify the accuracy of the diagnoses submitted relative to the medical record documentation. • Communication among all members of the health care team. • Evaluation of the care provided. • Research and education. • Practice patterns.

6.2 Structure and Terminology of ICD-9-CM

ICD-9-CM diagnosis codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. They do not describe the service performed, just the patient's medical condition. For any classification system to be reliable, the application of the codes must be consistent across users.



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DIAGNOSIS CODES & RISK ADJUSTMENT

Therefore, CMS, the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), and the National Center for Health Statistics (NCHS) together have developed official coding guidelines. These guidelines are available on: www.cdc.gov/nchs/data/icd9/icdguide.pdf. The diagnosis portion of ICD-9-CM consists of two volumes: the Disease Tabular and the Disease Index.

- **The Disease Tabular (Numeric)** is also known as Volume I of ICD-9-CM. It is a numeric listing of codes organized primarily by body system. The Disease Tabular provides much more detail than the Alphabetic Index on conditions included and excluded in the code selected. Another code in the same category may represent the diagnostic description better than the one indicated in the Disease Index.
- **The Disease Index (Alphabetic)** is also known as Volume II of ICD-9-CM. It is an index of all diseases and injuries categorized in ICD-9-CM. When a code is listed after the description, it means the reader should look up that code in the Disease Tabular section to determine if that is the most specific code to describe the diagnosis. The index is organized by main terms and subterms that further describes or specifies the main term. In general, the main term is the condition, disease, symptom, or eponym (i.e., disease named after a person), not the organ or body system involved.

6.2.1 Special Notes and Abbreviations

Throughout ICD-9-CM, there are notes and cross references to assist the coder in arriving at the most accurate code according to official coding guidelines. Examples include:

Excludes notes: Informs the coder which diagnosis codes are not included in the code selected.

Use Additional Code note: Informs the coder that more than one code is needed to fully describe the condition and gives examples of common associated conditions.

Not otherwise specified (NOS): Basically means "unspecified." The documentation does not provide additional information to assign a more specific code in the particular category. In many (but not all) code categories, the fourth digit "9" signifies an unspecified code.

Not elsewhere classified (NEC) also is present in ICD-9-CM. It is used when the medical record documents a condition to a level of specificity not identified by a specific ICD-9-CM code. In some cases the fifth digit "8" represents an NEC code.

6.2.2 Supplemental Classifications and Tables

Included in Volumes I and II are supplemental classifications and special tables that provide additional guidance in determining the most accurate code.

- **V codes** are a section of ICD-9-CM diagnosis codes that represent factors that influence health status or describe contact with health services. They are used to describe those circumstances or reasons for encounter other than for disease or injury. Selected V codes are included in the Risk Adjustment models and are described later in this module.



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- **E codes** are a supplemental classification included in ICD-9-CM and are used for reporting external causes of injuries and poisonings. The Risk Adjustment models include codes E950-E959, describing suicide or self-inflicted injuries.
- **Neoplasm Table** located in the Alphabetic Index (see *Neoplasm*) lists all cancer codes by site and nature of the disease (e.g. malignant primary or secondary, benign, or unspecified behavior).
- **Table of Drugs and Chemicals** is located at the end of the Alphabetic Index. It lists drug classifications; as well as specific names of drugs; identifies the code for poisoning by that drug; and the associated E code to specify if the poisoning was accidental, an adverse effect (therapeutic use), suicide attempt, assault, or undetermined.

6.3 ICD-9-CM Updates

To assist users of ICD-9-CM in interpreting and clarifying the guidelines, as well as publishing updated codes and applications, the AHA Central Office on ICD-9-CM publishes quarterly official code advice in *Coding Clinic for ICD-9-CM*. The *Coding Clinic for ICD-9-CM* is the approved resource to update and clarify the use of ICD-9-CM. The small volumes (typically about 20 pages) include clarifications of previous advice and guidelines, or new information on a specific diagnosis coding practice by means of articles and a question and answer section.

The ICD-9-CM diagnosis code listing is updated on October 1 and April 1 (beginning April 2005). The ICD-9-CM Coordination and Maintenance Committee holds a public forum for requested updates and publishes a transcript of their recommendations on the CMS website and in the *Federal Register*. Revisions discussed at the April and December meetings generally become effective in October the following year. A complete listing and description of annual updates are available in *Coding Clinic for ICD-9-CM* during the fourth quarter of each year. More information on the process for updating ICD-9 codes may be found at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp.



Note: There were no new ICD-9 codes implemented in April 2006. The next update to ICD-9-CM will be in October 2006. The annual ICD-9-CM diagnosis codes update may result in updates to the list of diagnosis codes used in the Risk Adjustment models. CMS posts a list of new codes in the CMS-HCC model annually, prior to the codes taking effect on October 1 and April 1.



The ICD-9-CM coding guidelines are not updated as frequently as the list of diagnosis codes. The most recent official guideline revision is published in *Coding Clinic for ICD-9-CM*, December 2005.

6.3.1 Diagnosis Codes Phase-in Schedule

As described in Table 6B below, starting with 2008 payment, the list of acceptable ICD-9-CM codes for the CMS-HCC, ESRD and RxHCC risk adjustment models for risk adjustment for any given payment year will comprise the list of published NCHS/CMS codes that are valid for the payment year.



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TABLE 6B – RISK ADJUSTMENT PHASE IN SCHEDULE FOR NEW LISTS OF DIAGNOSIS CODES

Year of Payment	Date Collection Period	Description/Source of Codes
2007	1/06 – 12/06	The list of codes is published on our website at: http://www.cms.hhs.gov/MedicareAdvgtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage , which lists acceptable codes by years.
2008	1/07 – 12/07	The list of codes is published on our website at: http://www.cms.hhs.gov/MedicareAdvgtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2007, 2008
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2008, 2009
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2009, 2010

6.3.2 International Classification of Diseases 10th Revision, Clinical Modification (ICD-10-CM)

ICD-10-CM is the clinical modification of ICD-10, which was adopted by the World Health Organization in July 2000. In 1994, the NCHS began a comprehensive evaluation of ICD-10-CM to determine if it is a significant improvement over ICD-9-CM and should be implemented in the United States. The new system was tested and results were favorable. In November 2003, the National Committee on Vital and Health Statistics recommended that the Secretary of the Department of Health and Human Services (HHS) approve ICD-10-CM for all lines of business. The Secretary of HHS is currently studying this recommendation. To implement this new coding system as part of the Health Insurance Portability and Accountability Act (HIPAA), the Secretary will publish a notice of proposed rule-making, and request public comment on the new policy.

6.4 Coding Guidelines Impacting the CMS-HCC Model

Standard ICD-9-CM coding practices support the CMS-HCC model. In all cases, the documentation must support the code selected and substantiate that the proper coding guidelines were followed. Data validation ensures that both are appropriate. Upcoding or changing diagnoses to obtain higher reimbursement without supporting source documents is fraudulent. However, thoroughly reviewing documentation and coding practices through internal auditing procedures ensure that data have been reported correctly and that appropriate reimbursement is received. This benefits both the MA organization and physician/provider. Several guidelines that impact physician documentation and reporting of diagnosis data are listed in the following sections.

6.4.1 Co-Existing and Related Conditions

The instructions for risk adjustment implementation refer to the official coding guidelines for ICD-9-CM, published at www.cdc.gov/nchs/icd9.htm and in the *Coding Clinic*. Physicians should “code all documented conditions that co-exist at the time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19 not in HCC model) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment.”



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Co-existing conditions include chronic, ongoing conditions such as diabetes (250.XX, HCCs 15-19), congestive heart failure (428.0, HCC 80), atrial fibrillation (427.31, HCC 92), chronic obstructive and pulmonary disease (496, HCC 108). These diseases are generally managed by ongoing medication and have the potential for acute exacerbations if not treated properly, particularly if the patient is experiencing other acute conditions. It is likely that these diagnoses would be part of a general overview of the patient's health when treating co-existing conditions for all but the most minor of medical encounters.

Co-existing conditions also include ongoing conditions such as multiple sclerosis (340, HCC 72), hemiplegia (342.9X, HCC 100), rheumatoid arthritis (714.0, HCC 38) and Parkinson's disease (332.0, HCC 73). Although they may not impact every minor healthcare episode, it is likely that patients having these conditions would have their general health status evaluated within a data reporting period, and these diagnoses would be documented and reportable at that time.



MA organizations must submit each relevant diagnosis at least once during a risk adjustment reporting period. Therefore, these co-existing conditions should be documented by one of the allowable provider types at least once within the data reporting period.

Another type of co-existing conditions is symptoms. Symptoms that are integral to an underlying condition should not be coded.



Example: 1

Initial myocardial infarction (410.91, HCC 81) is a specific condition that, when coded, would eliminate the need to code symptoms of that condition. For example, unstable angina (411.1, HCC 82) or angina pectoris (413.9, HCC 83) are symptoms of initial myocardial infarction and various other cardiovascular conditions and would not typically be coded in addition to the underlying problem.

6.4.1.1 Combination Codes

Often ICD-9-CM combines two or more conditions into one code when both conditions occur together or when one is a manifestation of the other. When a combination code fully describes the encounter, the combination code is reported, not the separate component codes. However, when ICD-9-CM instructions include "Code also" notes, follow the directions to fully describe the encounter.



Example: 2

Hypertension (401.9) is not in the risk adjustment model; however it may be associated with other conditions resulting in combination codes that are in the model. The documentation must specifically and directly connect the conditions using terms such as "due to" or "associated with" hypertension. The mere listing of the diseases in the same paragraph or diagnosis list does not assume the connection. For example "congestive heart failure *due to* hypertension" is coded 402.91 (hypertensive heart disease with CHF, HCC 80). Other examples include hypertensive renal disease with renal failure (403.91, HCC 131) and hypertensive heart and renal disease with heart failure and renal failure (404.93, HCC 131 & 80).



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Code also combinations

Some codes have suggestions of related codes that might further explain the exact nature of the condition. While these codes are not required to be present, in many cases a second code is appropriate and should be utilized.



Example: 3

Some diabetes codes carry "Code also" instructions that impact directly on the Risk Adjustment models.

- If a patient has diabetic retinopathy (250.50, HCC 18), the tabular section requires a code for also the manifestation (if known). The ICD-9-CM offers several different manifestations, such as blindness (369.00-369.9, not in the CMS-HCC model) or proliferative diabetic retinopathy (362.02, HCC 119). Here, coding the correct manifestation is essential to correct HCC assignment.
- Diabetic ulcers are one of the conditions covered under diabetes with other specified manifestations (250.80, HCC 16). If ulcers are the specific manifestation, the guidelines say to code also the site of the ulcer, such as lower extremity (707.10, HCC 149). If the specific manifestation is diabetic bone changes (731.8), that code is not in the CMS-HCC model, but should be coded as instructed in the tabular section. Again, coding the correct specific manifestation ensures appropriate HCC assignment.

6.4.2 Unconfirmed Diagnoses

Physicians and hospital outpatient departments shall not code diagnoses documented as "probable," "suspected," "questionable," "rule out," or "working." Rather, the condition(s) shall be coded to the highest degree of certainty known for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit. CMS recognizes that this is an area where the physician-reported diagnosis and hospital inpatient diagnosis for the same encounter may disagree, particularly since hospital inpatient rules allow for coding of suspected conditions as if they were confirmed.

It also is understood that the physician record is not a static document. Positive test results and notations regarding contact with the patient for a revised plan of treatment often are added to the record several days after the patient encounter. When these addenda are made, corrections or additions to the diagnoses reported to MA organizations may be recommended, particularly if the HCC assignment is impacted.



Example: 4

A physician removes a mole during an office visit and sends the specimen for pathology. The diagnoses documented are "suspicious skin lesion" (709.9, not in model) and "rule out melanoma." At this point, the diagnosis 709.9 may be submitted, but the diagnosis of melanoma may not. The pathology report is returned several days later and confirms malignant melanoma (172.9, HCC 10). The physician reviews the findings, initials the report, and documents in the record the results and notification to the patient. Since the removal of the mole was done during the office visit, the new code (172.9, melanoma) should be submitted with that date of service.



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6.4.3 Clinical Specificity in Documentation

Clinical specificity involves having a diagnosis fully documented in the source medical record instead of routinely defaulting to a general term for the diagnosis. It is important to understand medical terminology in order to identify terms in the medical record that may be a more specific description of a general term. Communication with the physician is key to improving documentation skills that allow for more specific coding. The following examples are guidelines and specific conditions selected from various chapters of ICD-9-CM (e.g., Circulatory, Respiratory, Neoplasm, etc.) that are representative of documentation and coding decisions that impact HCCs.

The first three examples involve situations in which a physician may use the most common code for all forms of a disease and conditions. Remember, this practice has had no impact in the past on physician reimbursement. With the Risk Adjustment models, physicians must be careful to code the correct forms and manifestations of diseases and conditions.



Example: 5

Anemia (285.9) is the most commonly coded form of anemia in physician offices. However, there are many types of anemia. Some are in the models and some are not. If the term "neutropenia" is used to describe the anemia, it must be coded to the more specific diagnosis code 288.0 (agranulocytosis), which groups to HCC 45. "Refractory" anemia is coded 238.7 (HCC 44). It is important that physicians code these types of anemia accurately.



Example: 6

Pneumonia (486) unspecified is not in the model. If the organism responsible for the pneumonia (HCC 111-112) is known or if the physician documents that the patient aspirated prior to developing pneumonia (507.0 HCC 111), the more specific code should be reported.



Example: 7

Mental disorders in the HCC models require particular attention to specific wording in documentation and coding. Episodic mood disorders (296.XX, HCC 55) are mental diseases that include mood disturbances such as major depression (296.2X-296.3X). Physicians are encouraged to carefully document the characteristics of the mood disturbance (e.g., mania, depression, single episode, recurrent episode, circular) and use specific mental disorder terminology in the final diagnosis. The coder is cautioned to exactly code only the narrative provided by the physician in the final diagnosis and not make any further assumptions based on the patient work-up. For example, in coding depression, careful use of the ICD-9-CM index directs the coder to the correct type documented. If the physician does not document specific descriptor terms such as "major" or "recurrent", then code 311 (depression, not otherwise specified, not in the model) is used.

Use of "history of." In ICD-9-CM, "history of" means the patient no longer has the condition and the diagnosis often indexes to a V code not in the HCC models. A physician can make errors in one of two ways with respect to these codes. One error is to code a past condition as active. The opposite error is to code as "history of" a condition when that condition is still active. Both of these errors can impact risk adjustment.



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Example: 8

The diagnosis statement "history of hip fracture" is not coded as a current hip fracture (820.8, HCC 158), but with a V code for orthopedic aftercare (V54.XX) or history of injury (V15.5), if appropriate. Neither "history of" code is in the HCC models. If a patient has a current acute condition, then the "history of" wording should not be used to describe the recent occurrence.



Example: 9

The physician may actually intend to communicate that a condition is ongoing, but note the "history of" a condition. An example of this is "history of Hepatitis C" (V12.09 personal history of other infectious disease). Hepatitis C generally presents as a chronic condition (070.54, HCC 27) that is rarely fully eradicated. While assigning V12.09 is not necessarily an example of incorrect coding, it may indicate that the physician office is not coding correctly. Again, communication and clear documentation are essential to make the appropriate determination.

Correct use of associated terms. Some conditions are described by more than one term depending on the clinical presentation and medical terminology practices of the physician. Coders must be careful not to assign a diagnosis to conditions that are not specified by the physician and cannot be validated by the medical record.



Example: 10

Cancer coding requires detailed specificity. Several different HCCs exist for cancer, and assigning the appropriate HCC requires closely following the cancer coding guidelines. The HCC varies depending on whether the cancer is a primary site or a secondary site. Coding guidelines state that if the malignant status is not specified, then code to the primary site, except for the following: bone, brain, diaphragm, heart, liver, lymph nodes, mediastinum, meninges, peritoneum, pleura, retro peritoneum, and spinal cord. Applying this rule assures that the correct HCC for secondary malignant neoplasm is assigned rather than an HCC for primary malignant neoplasms. [For example, bone cancer (primary) (170.9, HCC 9) vs. bone cancer (secondary) (198.5, HCC 7). Since the cancer is not specified as primary or secondary, and bone is one of the sites listed above, the correct HCC is 7.]



Cancer codes are part of a multi-category HCC hierarchy. It is not unusual for a patient to have more than one type of cancer. However, only the most severe and costly form of cancer is recognized in the HCC models. Even if the type of cancer included in HCC 7 is of a different site or origin than any other cancer the patient has and is included in HCCs 8, 9, and 10, the HCC models drop it.



Complete Neoplasm guidelines are included in the Resource Guide.

6.4.4 Coding to the Highest Specificity-Fourth and Fifth Digits

ICD-9-CM codes have three, four, or five digits. Diagnoses should be reported to the highest level of code available for that category. In selected cases, the fifth digit may impact whether the code is in the models, but at a different HCC level, which may impact reimbursement.



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Example: 11

Myocardial infarction (MI) (heart attack, 410.XX) is unspecified or subsequent episode fifth digits 0 and 2 are in HCC 82. All initial care for a new MI (from physician office to emergency room to hospital) should have the fifth digit of "1" and group to HCC 81.



Example: 12

Diabetes (250.XX) codes group into HCCs 15, 16, 17, 18, or 19 depending on the fourth digit applied. The fourth digit designates manifestations or complications of diabetes such as neurological conditions, eye disorders, or diabetic ulcers.



At a minimum, the submitted ICD-9-CM codes must be sufficiently specific to allow appropriate grouping of the diagnoses in the risk adjustment model. CMS encourages MA organizations to use the full level of specificity in submitting data to provide the most accurate coding and grouping of codes in the model.

6.4.5 V Codes

Health status situations that should be described by V codes are common in physician documentation. Those that impact risk adjustment include HIV status, transplant status, artificial opening status or maintenance, dialysis status or encounter, and amputation status. These V codes are used in several HCCs.

6.4.6 E Codes

The HCC models include codes E950-E959 describing suicide or self inflicted injuries (HCC 55, Major Depressive Disorders). The injury or poisoning diagnosis codes that would be reported with these E codes are not included as relevant diagnoses. Therefore, it is important that the physician documents and codes the appropriate external cause of all self-inflicted injuries and poisonings so the MA organization can report them as relevant diagnoses.



The complete list of V codes and E codes in the model is provided in the Resource Guide.

6.5 Supporting Documentation Summary

Accurate coding begins with complete documentation. Characteristics of effective documentation include quality documentation as a team effort that may require some intervention by the MA organization. Table 6C lists documentation considerations.



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TABLE 6C – DOCUMENTATION CONSIDERATIONS

Documentation Guidelines • Reported diagnoses must be supported with medical record documentation. • Medical records and codes are subject to CMS validation. • Characteristics of acceptable documentation include: – Clear. – Concise. – Consistent. – Complete. – Legible.
Physician Documentation and Communication Tips • Document and report co-existing diagnoses. • Communicate issues regarding inadequate documentation. • Adhere to proper methods for appending (late entries) or correcting inaccurate data entries. – Lab/Radiology results. – Strike through, initial, and date. Do not obliterate. • Use only standard abbreviations. • Identify patient and date on each page of the record.
SOAP Notes • SOAP note format assists both the physician and record reviewer/coder in identifying key documentation elements. SOAP stands for: – Subjective: How the patients describe their problem or illness. – Objective: Data obtained from examinations, lab results, vital signs, etc. – Assessment: Listing of the patient's current condition and status of all chronic conditions. How the objective data relate to the patient's acute problem. – Plan: Next steps in diagnosing problem further, prescriptions, consultation referrals, patient education, and recommended time to return for followup.

6.6 Provider and Staff Training

Remaining current on medical record documentation and coding guidelines is important to ensure accurate risk adjustment payment. Table 6D provides examples of resources available for medical record documentation and coding guidelines.



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TABLE 6D – DOCUMENTATION AND CODING RESOURCES

TRAINING SOURCES	DESCRIPTION
Official Coding Guidelines on CDC Website Available at www.cdc.gov/nchs/icd9.htm	The Official ICD-9-CM Coding Guidelines are available as an Adobe .pdf file, or as a CD-ROM. The CDC site has the .pdf file for download, as well as information to order the CD-ROM from the Government Printing Office.
Coding Clinic for ICD-9-CM Available through AHA.	Published quarterly by the AHA. It is the official publication for ICD-9-CM coding guidelines and advice as designated by the AHA, AHIMA, CMS, and the NCHS.
American Health Information Management Association (AHIMA) www.ahima.org	AHIMA is a professional association for health information management professionals. Members make information accessible to healthcare providers and work in the healthcare industry and in the public sector by managing, analyzing, and using data that are critical to patient care. The AHIMA Catalog online offers tools for coders such as audio seminars, books, and continuing education courses.
American Academy of Professional Coders (AAPC) www.aapc.com	AAPC provides education and certification for professional medical coders. Certifications focus on physician practice (CPC) and hospital outpatient facility (CPC-H) coding. Students learn Current Procedural Terminology (CPT) Codes, diagnosis codes (ICD-9-CM), and Healthcare Common Procedure Coding System (HCPCS) while focusing on HIPAA, Office of Inspector General (OIG), and Medicare compliance.
American Medical Association (AMA) www.ama-assn.org	AMA is an advocate of physician and patient rights. Coders may access the AMA Press Online Catalog to find current resources on medical record documentation and the medical record review process.
American Hospital Association (AHA) www.aha.org	AHA is a national organization that serves and represents hospitals, healthcare networks, and their patients. The AHA Online Store offers coders online reference materials including ICD-9-CM, HCPCS, and testing and certification for HIPAA.
Local Colleges Check local community and 4-year colleges for courses.	These provide online courses in clinical coding and guidelines.



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RISK ADJUSTMENT DATA VALIDATION

MODULE 7 – RISK ADJUSTMENT DATA VALIDATION

Purpose (Slide 2)

To provide participants with an understanding of the risk adjustment data validation process.

Objectives (Slide 3)

- Identify
 - The purpose and goals of risk adjustment data validation
 - The stages of risk adjustment data validation
 - Risk adjustment data discrepancies
- Understand
 - The components of a medical record request
 - Requirements for acceptable medical record documentation
 - Payment adjustments and appeals
- Provide
 - Recommendations and lessons learned.

ICON KEY

Example



Reminder



Resource



7.1 Risk Adjustment Data Validation

7.1.1 Purpose of Risk Adjustment Data Validation (Slide 4)

Data validation occurs after risk adjustment data are collected and submitted, and payments are made to the Medicare Advantage (MA) organizations. CMS uses medical record review to validate the accuracy of risk adjustment diagnoses submitted by MA organizations for payment. Future data validation activities may include other data monitoring activities.

Risk adjustment data validation is the process of verifying that diagnosis codes submitted for payment by the MA organization are supported by medical record documentation for an enrollee.

Purpose: To ensure risk adjusted payment integrity and accuracy



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7.1.2 Objectives of Risk Adjustment Data Validation (Slide 5)

The primary objectives of risk adjustment data validation are to:

- Identify:
 - Confirmed risk adjustment discrepancies
 - Contracts in need of technical assistance to improve the quality of risk adjustment data
- Measure:
 - Accuracy of risk adjustment data
 - Impact of discrepancies on payment
- Improve/Inform:
 - Quality of risk adjustment data
 - The CMS-Hierarchical Condition Category (HCC) model.

7.1.3 Good Documentation = Accurate Payment (Slide 6)

Good documentation begins at the time of the patient's face-to-face encounter with the physician. The physician documents the clinical findings in the medical record. The medical record is used to determine ICD-9-CM codes. The pertinent information from the patient encounter is submitted to the MA organization for payment.

7.1.4 Guidelines for Risk Adjustment Data Validation (Slide 7)

The guidelines for risk adjustment data validation reflect the purpose and goals described above. Beginning with the CY2004 payments, validation activities incorporated the review of hospital inpatient, hospital outpatient, and physician medical records. This process reflects the implementation of the CMS-HCC model that began with CY2004 payment. Beginning with CY2006 payments, validation activities incorporated RxHCC data. This process reflects the implementation of the CMS RxHCC model that began with CY2006 payment.

Guiding Principle: The risk adjustment diagnosis must be based on clinical medical record documentation from a face-to-face encounter, coded according to the *ICD-9-CM Guidelines for Coding and Reporting*, assigned based on dates of service within the data collection period, and submitted to the MA organization from an appropriate risk adjustment provider type and an appropriate risk adjustment physician data source.

In addition to the Guiding Principle, risk adjustment data validation guidelines include the following:

- The medical record documentation must support an assigned HCC.
- Beneficiary HCCs and risk adjustment records are selected based on risk adjustment diagnoses (ICD-9 codes), provider type, and the Health Insurance Claim (HIC) number that are submitted to the Risk Adjustment Processing System (RAPS).



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- Given the flexibility of the Guiding Principle, contracts must select **"one best medical record"** to support each beneficiary HCC identified for validation. This means the contract decides whether to submit a hospital inpatient, hospital outpatient, or physician medical record when more than one option is available.
- Since CMS does not collect provider identifiers for risk adjustment, MA organizations must be able to track and locate supporting medical record documentation.
- Once a MA organization selects the "one best medical record," the organization must identify the date of service to be reviewed to facilitate the medical record review process. The coders that are hired to review the medical records on behalf of CMS will not search beyond the date of service identified by the MA organization for the review.
- Payment adjustments are based on confirmed risk adjustment discrepancies.
- An appeals process is in place to address disagreement with a confirmed risk adjustment discrepancy.

7.1.5 Medical Record Documentation (Slide 8)

As stated in the *1997 Documentation Guidelines for Evaluation and Management Services*, "Medical record documentation is required to record pertinent facts, findings, and observations about an individual's health history, including past and present illnesses, examinations, tests, treatments, and outcomes."

7.1.6 Overview of Risk Adjustment Data Validation (Slides 9-10)

Risk adjustment data validation is the process of verifying that diagnosis codes submitted by the MA organization for payment are supported by medical record documentation for an enrollee. It involves the review of hospital inpatient, hospital outpatient, and physician medical records. Since contracts must select the "one best medical record" to validate the HCC from hospital inpatient, hospital outpatient, and physician medical records, the approach is flexible. Additionally, the data validation approach is based on the CMS risk adjustment models:

- CMS-HCC—CY 2004 and beyond for Part C
- CMS RxHCC—CY 2006 and beyond for Part D.

Hereafter for purposes of this module only, the term "HCC" refers to both CMS-HCCs and RxHCCs.

CMS contracts with two independent review contractors to conduct medical record reviews. The initial validation contractor (IVC) conducts facilitates the process and conducts the initial review of medical records. The second validation contractor (SVC) receives the discrepant medical records from the IVC, confirms risk adjustment discrepancies that are identified by the IVC, and implements the appeals process. Both IVC and SVC use certified coders to abstract diagnosis codes and validation provider type, physician data source, and date(s) of service.



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7.1.7 Risk Adjustment Discrepancies (Slide 11)

Risk adjustment discrepancies are identified when the HCC assigned based on risk adjustment data submitted by the MA organization differs from the HCC assigned after validation. Risk adjustment discrepancies affect the beneficiary risk score because of the change in HCC.

7.1.8 Data Validation Activities (Current and Future) (Slide 12)

CMS has several data validation activities on which it is or will be working. They are as follows:

- CY 2004
 - July 12, 2007: Disseminated plan-specific findings to MA organizations in the targeted sample.
 - August 29, 2007: Conducted teleconference to communicate the CY 2004 pre-reconciled medical record review national results.
 - Mid-October 2007: Anticipate mailing pre-reconciled findings to MA organizations with enrollees selected for the national sample.
- CY 2005
 - Quality checking the IVC and SVC results.
 - Anticipate releasing findings in the late fall.
- CY 2006
 - Selected contracts notified in May 2007.
- CY 2007
 - CMS to sample after final data submission deadline (January 31, 2008).

7.1.9 Risk Adjustment Data Validation Process (Slide 13)

Risk adjustment data validation occurs every year. Figure 7A illustrates the overall data validation process. This process involves the coordination of multiple entities such as CMS, MA organizations, and CMS contractors. The data validation process begins with selecting MA organizations, then beneficiaries and their respective HCCs. This occurs after the risk adjustment data submission deadline for calendar year payment. The stages of the risk adjustment data validation process are briefly described below:

- ➔ **STAGE 1 Contract Selection:** CMS designs a sampling plan to select MA organizations for risk adjustment data validation. Once the MA organizations are selected, individual beneficiaries and their HCCs are selected on the basis of the sample framework. The sample is based on payment year risk adjustment data. Every MA organization has a chance of being selected for validation.
- ➔ **STAGE 2 Medical Record Request Process:** Stage 2 is defined by three distinct segments: 1) medical record request; 2) medical record submission (contract response); and 3) medical record receipt. After the sample has been drawn, medical records are requested from the selected MA organizations. All correspondence with MA organizations related to Stage 1 is facilitated by the IVC.
- ➔ **STAGE 3 Medical Record Review:** After medical records are received by the IVC, certified ICD-9 coders review the medical records to validate the selected beneficiary HCC(s). During this stage, data discrepancies are identified. Data discrepancies occur when beneficiary medical record documentation does not match the risk adjustment data submitted for payment. A data discrepancy that results in an HCC assignment change is known as a risk adjustment



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discrepancy. All identified risk adjustment discrepancies undergo a second, independent medical record review to confirm the discrepancy. The second medical record review is conducted by the SVC. This activity is transparent to MA organizations. There is no correspondence between the SVC and contracts during this stage.

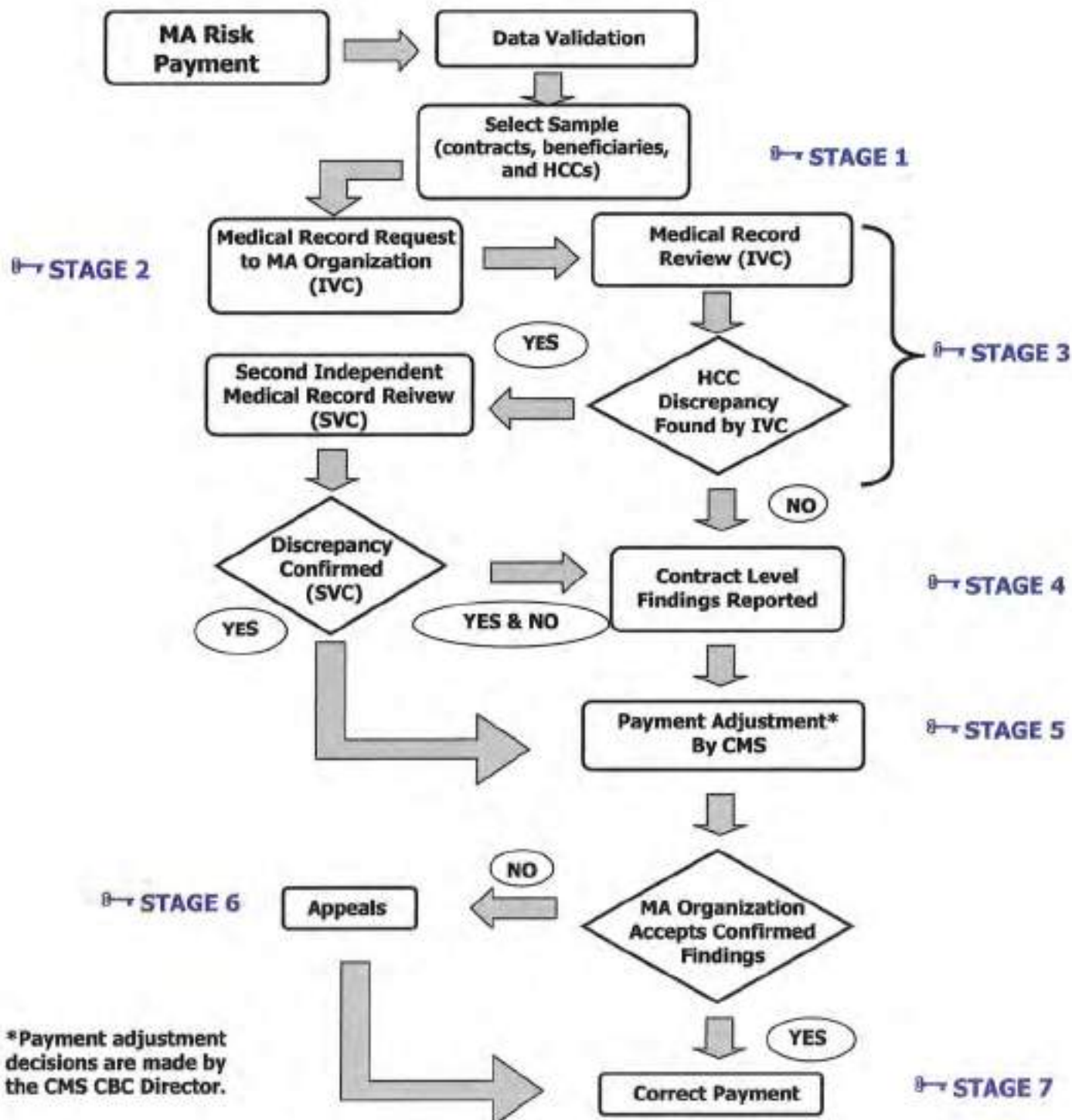
- ➔ **STAGE 4** **Contract-Level Findings:** At this point in the data validation process, CMS communicates contract-level findings from Stage 3 to the selected MA organizations. Data discrepancies determined by medical record review are described. Additional feedback such as national and contract-level response rates and discrepancy rates are provided. Contract patterns, systemic problems, and contracts in need of additional technical assistance may also be identified during this stage.
- ➔ **STAGE 5** **Payment Adjustment:** The CMS CBC Director makes all decisions with regard to payment adjustment based on validation findings. A payment adjustment is based on a confirmed risk adjustment discrepancy. If the CMS CBC Director decides to make the adjustment, then the change in the risk adjustment payment is applied. Payment adjustments are typically reflected in the Monthly Membership Report (MMR).
- ➔ **STAGE 6** **Appeals:** After payment adjustments are made, MA organizations have the option of appealing the change. In the event that a contract chooses to appeal, then the organization has 60 days from the date of the payment adjustment to respond. This process is fully described in the *Appeals* section of this module.
- ➔ **STAGE 7** **Correct Payment:** The conclusion of the appeals process determines the correct risk adjusted payment for an MA organization. The original payment adjustment decision may stand (unchanged) or be reversed. All appeal decisions are final.



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Figure 7A – Data Validation Process





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7.2 Components of the Risk Adjustment Data Validation Process

The key components of the data validation process include: 1) sampling; 2) the medical record request process and the receipt of medical record documentation by the IVC; and 3) the medical record review.

7.2.1 Contract Selection **STAGE 1** (Slide 14)

Sampling

Sampling for data validation is conducted on an annual basis. Sampling involves the selection of contracts, beneficiaries, and the beneficiary HCC(s). The sample is drawn from risk adjustment data submitted for the payment year (data collection period, January 1 through December 31). The sampling approach includes both random and targeted components. Some contracts may be selected randomly, while others may be targeted.

Under the CMS-HCC model, CMS expects to select a national sample for each payment year. The purpose of the national sample is to derive national net payment error and risk adjustment discrepancy estimates for the payment year. In addition to the national random sample, some targeted sampling will be employed. The targeting criteria may include:

- Patterns in the risk adjustment data that are suggestive of potential problems.
 - A contract may be targeted for data validation because the risk adjustment data for that contract showed a disproportionately high number of HCCs.
- Past performance from previous data validation years.
 - A contract may be selected for medical record review as a result of a high error rates from prior validation activities.

In addition, CMS may sample based on random selection of specific contract types(s). The medical records reviewed for a beneficiary could reflect either the entire HCC profile (all HCCs) or a subset of one or more HCCs. Every MA organization has equal opportunity of being selected.

7.2.2 Medical Record Request Process **STAGE 2** (Slides 15)

During Stage 2 CMS works with the IVC to implement the process for requesting and receiving medical records from MA organizations. Stage 2 is defined by three distinct segments: 1) medical record request; 2) medical record submission (contract response); and 3) medical record receipt.



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7.2.2.1 Medical Record Request - Initial Contact Letter (Slide 16)

On behalf of CMS, the IVC sends an initial contact letter to the Medicare compliance officer for each MA organization selected for validation. The purpose of the initial contact letter is to: 1) inform the compliance officer that the organization was selected for data validation; and 2) request a primary point of contact (either the compliance officer or a designee) to be responsible for facilitating the medical record request process for the organization.

7.2.2.2 Medical Record Request - Beneficiary List (Slide 16)

A list of contract-specific selected beneficiaries for each selected MA organization is sent to the confirmed primary contact person for the MA organization. The beneficiary list is generated based on risk adjustment data submitted for the enrollee sample. The list may be provided to MA organizations either in advance of or in conjunction with the medical record request instructions package. The purpose of the list is to provide MA organizations with ample opportunity to easily identify the selected enrollees in their systems, and establish contact with the specific provider(s) of services for those enrollees. As previously mentioned, CMS does not require or store provider identification numbers as part of risk adjustment data. Therefore, the MA organization must use data systems that can:

- Track and locate the requested medical records.
- Link a specific diagnosis to a specific provider.

The beneficiary list is provided in an electronic spreadsheet format, which displays:

- MA organization's name,
- Current Contract ID (H-number), and
- Previous Contract ID (H-number)—this information is furnished if the contract ID used during the data collection period differs from the current contract ID.

For each selected enrollee the following information is included in the beneficiary list:

- Coversheet ID number (A masked ID tracking number that can be found on the bottom left of each HCC coversheet)
- Enrollee Last Name
- Enrollee First Name
- Enrollee Date of Birth
- Enrollee HIC Number
- Validation HCC
- ICD-9-CM code(s) related to the validation HCC—you must submit a medical record to support the enrollee HCC.

Note that the beneficiary list will contain a line for each enrollee's unique HCC. This means that if an enrollee has multiple different HCCs, each line for the enrollee will comprise a unique HCC and all associated risk adjustment diagnoses that were submitted by your organization for that HCC. Therefore, a complete enrollee HCC profile could comprise multiple lines on the beneficiary list. Table 7A displays a sample beneficiary list. The information shown on the line with each beneficiary HCC reflects all ICD-9 codes submitted by the MA organizations for that HCC.



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Example 1

For beneficiary Joe K. Smith – HCCs 38, 80 and 16 will be validated. For HCC 38, the MA organization may rely on one of the five ICD-9 codes associated with that HCC to identify the date of service and provider, and **"one best medical record"** for review. The organization could also opt to identify a provider that rendered a diagnosis that is not on the list, but will map to HCC 38. Contracts should take advantage of whichever approach yields the most efficient results.

TABLE 7A – BENEFICIARY LIST

MA Organization Name – Health Plan for People with Medicare											
Current Contract ID: H1111											
Previous Contract ID: H0000											
Coversheet ID #	LAST NAME	FIRST NAME	MI	DOB	HIC	HCC	ICD-9 CODE	ICD-9 CODE	ICD-9 CODE	ICD-9 CODE	ICD-9 CODE
H1111-10005-HCC38	Smith	Joe	K	09/02/1925	183838279A	HCC 38	7101	446	4460	4465	71430
H1111-10005-HCC80						HCC 80	40201	40491	416		
H1111-10005-HCC16						HCC 16	2506	25062	2508	25080	
H1111-10006-HCC16	Johnson	James		8/16/1937	987699890A	HCC 16	2506	2508			
H1111-10007-HCC2	Mumford	Anne	A	03/15/1933	986023456A	HCC 2	0382	0389			
H1111-10007-HCC79						HCC 79	42741	51883			

7.2.2.3 Medical Record Request - Comprehensive Instructions and Coversheets (Slide 16)

A comprehensive instructions package is sent to MA organizations to facilitate the request for submitting medical records. This package will at a minimum include the following:

- Detailed instructions for requesting records from providers and submitting to the IVC;
- Guidance and best practices to further assist organizations with the request process;
- A list of the beneficiaries (as previously described) and their HCCs;
- CMS letters addressed to providers describing the overall risk adjustment data validation approach;
- HIPAA fact sheet to discuss HIPAA privacy;
- CMS sample request letters to providers; and
- Coversheets for each enrollee HCC.

The organizations must request records from hospital inpatient, hospital outpatient, or physician providers. When requesting medical records from your providers, be sure to attach the HIPAA fact sheet and include your MA organization contact information. This will facilitate the provider's contacting you in the event the provider has questions with regard to the medical record request.



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When requesting medical records from providers, the organization must make every effort to limit disclosure of beneficiary health information to the minimum necessary as it pertains to the specific diagnosis (es) as rendered by the provider. This means that if the organization finds a date of service for which one provider rendered a diagnosis then the organization should only request from that provider medical record documentation for the respective diagnosis.

7.2.3 Medical Record Submission (Slide 17)

MA organizations must submit medical records and all corresponding coversheets for each enrollee HCC to the IVC. In responding to the medical record request, MA organizations must select the "one best medical record" to support the enrollee HCC.

7.2.3.1 Medical Record Submission and Coversheets (Slide 17)

Under the CMS-HCC model, beneficiaries could have more than one HCC. Therefore, one coversheet will be generated and provided for every HCC being validated for each selected beneficiary. Each coversheet shows every risk adjustment diagnosis that was submitted to RAPS and generated the same HCC. Attachment A provides a sample beneficiary HCC coversheet with directions for completion.

Note that if one enrollee has two different HCCs, the contract will receive two separate HCC coversheets for that enrollee. In addition, one medical record could be used to support multiple HCCs. If you identify a medical record that supports more than one HCC selected for validation, then complete each HCC coversheet, and attach them to that the one medical record.

The coversheet is where the concept of the "one best medical record" is applied. The coversheet will at a minimum provide enrollee demographic information, stored risk adjustment data (HCC and ICD-9 codes). The MA organization must select and submit the best medical record and indicate on the coversheet the provider type and date(s) of service to be reviewed for the HCC. The date(s) of service could include a range of consecutive dates if the record is from a hospital inpatient provider or one date if the record is from a hospital outpatient or physician provider.



All coversheets must be returned regardless of whether a medical record is submitted to support the HCC. MA organizations must complete the coversheets to identify the information being submitted. Complete medical record coversheets are essential to timely medical record review.



If an MA organization is unable to submit the required medical record(s) to support the enrollee HCC(s), it must complete the coversheet as per the instructions package prior to submitting the coversheet to the IVC. This will inform the IVC that no medical record could be obtained to support the HCC.

CMS reimburses MA organizations for each medical record submitted per beneficiary HCC; however, only one medical record per beneficiary HCC will be accepted for reimbursement. If one record supports more than one beneficiary HCC, then the contract will receive reimbursement for one record. Reimbursement checks are sent by the IVC after completion of data validation activities.



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Guidance for Submitting Medical Records to the IVC

1. Do not submit medical records for date(s) of service that occurred outside of the data collection period.
2. If you select an inpatient discharge to substantiate the HCC(s), submit the entire inpatient medical record. Do not just submit parts of the record that may state the diagnosis as inpatient coding guidelines may differ from those for outpatient settings depending on the diagnosis.
3. Several organizations choose to submit medical record documentation that reflects only the physician face-to-face portion of an inpatient record when the entire inpatient record is not available. When this is the case complete the coversheet to reflect a "physician" provider type and the date of service in the medical record for which the physician visit occurred during the inpatient stay. Only submit the medical record page(s) for the selected physician face-to-face.

If the entire inpatient medical record is available, the contract should opt to submit the entire record and complete the coversheet as appropriate to reflect the date range for the stay. It is likely that this approach would not limit the amount of diagnoses to be abstracted for the stay.

4. In order to prevent medical record information from inadvertently being attached to the wrong coversheet(s), be sure that all coversheets are stapled to the record whenever possible. We understand that this may be difficult to do with large inpatient medical records. If necessary, consider the use of rubber bands to attach coversheets with the records. Do not submit loose documentation or documentation with only paper clips.
5. If you are submitting for multiple organizations (i.e., those with different "H" numbers), separate the records for the different organizations.
6. Unless instructed by the IVC, submit only one coversheet per enrollee HCC. Only one coversheet—the first—will be accepted. If you are unsure whether a record substantiates an HCC, you must determine whether to submit it or wait for another record.
7. Do not clip together medical records for multiple different enrollees.
8. When in doubt about the clinical documentation in a medical record and you have no viable substitute, send the medical record even if you do not believe the record supports the HCC. We may find that the record does support the HCC and/or could contain clinical information that result in risk adjustment ICD-9 codes that were not previously submitted CMS.
9. **SUBMIT ALL MEDICAL RECORDS AND COVERSHEETS BY THE OFFICIAL DEADLINE.** In the event that you are unable to submit a medical record(s), you must complete as per the instructions package and return the coversheets to the IVC.



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7.2.4 Medical Record Receipt by the IVC and Reimbursement (Slide 18)

Once medical records are selected by the MA organization, the organization must submit them to the IVC for data validation. Upon receipt, the IVC will log medical records into a chart-tracking database on the basis of the barcode on each medical record coversheet. This method identifies the date the medical record was received for a given HCC. To protect patient confidentiality, all records are stored in a secure, designated area accessible only to those having direct responsibility for risk adjustment data validation activities.

When the coversheet and medical record are received by the IVC, the following intake process is initiated:

- Administrative check—confirms beneficiary demographic information, including name, HIC number, and service date within or outside of the collection period.
- Clinical check—determines whether the:
 - Record is from an appropriate provider type.
 - Pertinent components needed for coding are included in the record.
 - Record is dated and signed.

Based on the administrative and clinical checks, the IVC may elect to contact (telephone call or email message) the MA organization to request clarification or additional information. This step is provided as a service to the organization and normally is performed only if the records are received in a timely manner.

After intake, the medical record (with coversheet) is assigned to a category. The possible categories include:

- Identified as "okay" for review;
- Problem; or
- Missing medical record.

Throughout the data validation process, CMS and its contractors will make a reasonable effort to alert MA organizations of medical record documentation issues and allow contracts the opportunity to correct problems.

7.2.4.1 Medical Record Documentation **STAGE 3** **(Slide 19)**

Proper medical record documentation is the key to accurate payment and successful data validation. The accurate assignment of ICD-9-CM diagnosis codes is based on thorough medical record documentation. Therefore, risk adjusted payment accuracy also relies on medical record documentation. Remember, a beneficiary HCC is assigned based on a diagnosis cluster that has been submitted to RAPS.

Below are some general guidelines for medical record documentation, based on the sources of the documentation.



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**7.2.4.2 General Guidelines for Hospital Inpatient Medical Record Documentation
(Slide 20)**

Hospital inpatient medical records are generally considered to be the most reliable source of diagnostic coding because hospitals employ certified professional coders.

Coding

According to the *ICD-9-CM Official Guidelines for Coding and Reporting*, for hospital inpatient stays a medical record reviewer should code the principal diagnosis and:

...all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded.

The required medical record documentation should include, but is not limited to, the following:

- Face sheet
- History and physical exam
- Physician orders
- Progress notes
- Operative and pathology reports
- Consultation reports
- Diagnostic (radiology, cardiology, etc.) testing reports
- Discharge summary.

7.2.4.3 General Guidelines for Hospital Outpatient and Physician Medical Record Documentation (Slide 20)

Hospital outpatient and physician office medical records should include, but are not limited to, the following:

- Face sheet
- History and physical exam
- Physician orders
- Progress notes
- Diagnostic reports (to support documentation)
- Consultation reports



Submit all relevant medical record components needed to validate the date of service, beneficiary, the HCC, and ICD-9 code selected. When you submit medical record documentation to support only the physician face-to-face that occurred during an inpatient stay, the same medical components are needed; however, the medical record documentation will be reviewed in accordance with *Diagnostic Coding and Reporting Guidelines for Outpatient Services*.



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Only services

EXHIBIT D-37 INTENTIONALLY BLANK

EXHIBIT D-38

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the views of the Department of Justice. Further, they should not be considered as an
endorsement by EOUSA of any policy, program, or service.*

If, however, the prosecutor believes that the court could potentially exclude or limit the RA's testimony because it borders on expert testimony, the prosecutor should alternatively notice the witness as a potential expert witness and follow the requirements of Rule 702 of the Federal Rules of Evidence. It is important for prosecutors to determine how judges in their district have typically treated RA summary testimony. In some districts, judges treat the RAs as summary expert witness and expect prosecutors to comply with the requirements for experts under Rule 702.

5. Employees of the defendant's business

If the defendant prepared her fraudulent tax returns through a business that had employees, those employees can also be valuable witnesses at trial. Employees who did not participate in preparing false tax returns could testify about the general operations of the business and how legitimate tax returns were prepared, including how tax information was obtained from clients and incorporated into tax returns. They could also testify about any training and instructions the defendant gave them about how to prepare tax returns. Employees who had a role in the preparation of false tax returns could also testify about any instructions the defendant gave them about falsifying items on those tax returns.

6. IRS Special Agent

Although calling the case agent to testify is often discouraged, as it potentially puts the entire investigation on trial and certainly makes discovery disclosure obligations more burdensome, there are certain occasions when you would want to call the IRS Special Agent who investigated the case to testify. For example, in circumstances where the Special Agent has interviewed the defendant, who has made certain favorable admissions that the prosecutor believes should be introduced at trial. If there is a second Special Agent at the interview, it would be preferable to call the non-case agent to testify instead, so long as they are able to testify concerning those statements made by the defendant.

C. Rule 404(b) evidence

In almost every fraudulent return preparer prosecution, there will be evidence of false tax returns prepared by the defendant that cannot be

excluded from sequestration. Fed. R. Evid. 615. When a witness's testimony relates only to a summary of evidence, even the rationale for the sequestration of the witness is absent. *See United States v. Charles*, 456 F.3d 249, 258 (1st Cir. 2006); *see also United States v. Strauss*, 473 F.2d 1262, 1263 (3d Cir. 1973) (purpose of excluding witnesses is "to prevent the shaping of testimony by witnesses to match that given by other witnesses") (internal citations omitted).

included in the indictment because they fall outside of the statute of limitations. The prosecutor should consider whether to offer this as “other act” evidence under Rule 404(b) of the Federal Rules of Evidence.

Rule 404(b) provides that while “evidence of any crime, wrong, or act is not admissible to prove a person’s character in order to show that on a particular occasion the person acted in accordance with the character,” evidence of any crime, wrong, or act “may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident.”³⁰

In fraudulent return preparer prosecutions, the evidence of other, similarly false tax returns prepared by the defendant is typically offered to prove the defendant’s intent. In a case charged under 26 U.S.C. § 7206(1) or 7206(2) the government must prove that the defendant acted willfully, that is, that the defendant intentionally violated a known legal duty.³¹ Willfulness is rarely proved directly in any case, much less a tax case, but often is proved by circumstantial evidence of a defendant’s conduct.³² Evidence of other, similarly false tax returns prepared by the defendant is highly probative of the defendant’s intent.

The prosecutor should be cautious, however, in how much evidence to attempt to admit through Rule 404(b). While there is no bright line rule, it is prudent to make sure that the uncharged conduct is proportionate to the charged conduct. Otherwise, an objection under Rule 403 of the Federal Rules of Evidence of unfair prejudice may be sustained.³³

D. Common defenses

While, on occasion, a defendant will claim not to have prepared the false tax returns at issue in a fraudulent return preparer trial, a more typical defense is that the defendant did not act willfully because she did not know what she was doing was wrong. This commonly takes one of

³⁰ Fed. R. Evid. 404(b).

³¹ Willfulness has the same meaning in fraudulent return preparer cases as it has for other criminal tax violations: “the word ‘willfully’ in these statutes generally connotes a voluntary, intentional violation of a known legal duty.” *United States v. Bishop*, 412 U.S. 346, 360 (1973); *see also* *Cheek v. United States*, 498 U.S. 192, 200 (1991); *United States v. Ervasti*, 201 F.3d 1029, 1041 (8th Cir. 2000).

³² *See generally* *Huddleston v. United States*, 485 U.S. 681, 685 (1988) (“Extrinsic acts evidence may be critical to the establishment of the truth as to a disputed issue, especially when that issue involves the actor’s state of mind and the only means of ascertaining that mental state is by drawing inferences from conduct.”).

³³ Under Rule 403, a court may find that the probative value of an excessive number of uncharged returns is not “substantially outweighed by the danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.” Fed. R. Evid. 403.

two forms: (1) the defendant did not know she reported false information on the tax returns (“blame the clients”); or (2) the defendant did not know she reported items incorrectly on the tax returns (“blame the tax law”). If the prosecutor has properly prepared the case, neither of these defenses is likely to be successful.

A “blame the clients” defense gains little traction where client-witnesses testify unequivocally that they did not provide the false information to the defendant, and where the tax returns of multiple client witnesses all contain the same, or similar falsities. This testimony is even stronger when it is corroborated by prior or subsequent tax returns of the client witnesses that were not prepared by the defendant, and that did not include similar falsities. This evidence supports the argument that the false items on the tax returns had to have come from the defendant.

A “blame the law” defense can be trickier to rebut. Often, an appeal to the jurors’ common sense is the best approach. A defendant’s scheme may be so egregious (for example, reporting wholly fake Schedule C businesses for clients) that an argument that the defendant did not know it was wrong lacks all credibility.

To support either defense, a defendant may seek to admit evidence of uncharged, non-fraudulent tax returns to support a willfulness defense. As a general rule, evidence of non-criminal conduct is irrelevant, and the fact that a defendant prepared other, accurate tax returns has no bearing on whether the tax returns charged in the indictment are false.³⁴ Accordingly, if applicable, the prosecutor should consider moving *in limine* to exclude any such evidence before trial.

E. Jury instructions

In addition to any applicable Circuit pattern jury instructions, the prosecutor can find model jury instructions for fraudulent return preparer cases in the Tax Division’s Criminal Tax Manual. Several instructions warrant particular consideration. First, a unanimity instruction can be important in a fraudulent return preparer case. That is, where a particular count in the indictment alleges that a tax return is false in more than one way, the prosecutor should consider an instruction that the jury need not find that *all* items alleged as false in the count are false, but the jury must unanimously agree on what item alleged as false is false.³⁵

³⁴ See, e.g., *United States v. Daulton*, 266 F.App’x. 381, 386 (6th Cir. 2008) (“[e]vidence of noncriminal conduct to negate the inference of criminal conduct is generally irrelevant”); *United States v. Ellisor*, 522 F.3d 1255, 1270 (11th Cir. 2008) (evidence of good conduct is not admissible to negate criminal intent); *United States v. Scarpa*, 897 F.2d 63, 70 (2d Cir. 1990).

³⁵ See, e.g., *United States v. Helmsley*, 941 F.2d 71, 93 (2d Cir. 1991).

Second, given that in some fraudulent return preparation cases the defendant's clients were knowing and willing participants in the fraud, an instruction that the culpability of the client is irrelevant to the culpability of the preparer should be used. The defense is likely to attempt to blame the clients for the falsities on their tax returns, but it is not a defense that the client also knew that the return was false.

IV. Sentencing

The defendant has been convicted at trial, and it is now time for sentencing. There are several issues the prosecutor should be prepared to address at sentencing.

A. Tax loss

1. Two-level enhancement for return preparers

First, the prosecutor should always argue that a two-level increase in the defendant's offense level is appropriate because the defendant "was in the business of preparing or assisting in the preparation of tax returns."³⁶

2. Aggravating Role Enhancement

Second, the prosecutor should consider whether the facts of the return preparer case merit an aggravating role enhancement. Aggravating role enhancements apply if the defendant was an organizer, leader, manager, or supervisor in the criminal activity and range from a two-level increase to a four-level increase.³⁷ The enhancement may be appropriate in cases where the return preparer's employees were knowingly filing false returns. It may also be appropriate if the false return scheme involved other participants responsible for creating false documents to support the fraudulently filed tax returns.

3. Relevant conduct

Third, the prosecutor should seek to include as many uncharged, but false, tax returns in the applicable tax loss calculations as possible.

In determining the base offense level for sentencing, a court must include all relevant conduct.³⁸ The U.S. Sentencing Guidelines specify that relevant conduct includes "all acts and omissions . . . that were part of the same course of conduct or common scheme or plan as the offense of conviction," but only for "offenses of a character for which § 3D1.2(d)

³⁶ U.S.S.G. § 2T1.4(b)(1)(B).

³⁷ U.S.S.G. § 3B1.1.

³⁸ U.S.S.G. § 1B1.3(a).

would require grouping of multiple counts”—which includes tax offenses sentenced under Part T of Chapter Two of the Guidelines.³⁹ The commentary to section 2T1.1 further explains that “all conduct violating the tax laws should be considered as part of the same course of conduct or common scheme or plan unless the evidence demonstrates that the conduct is clearly unrelated.”⁴⁰ Thus, other fraudulently prepared tax returns, because they are part of the same course of conduct or common scheme or plan as the offense of conviction, should be accounted for as relevant conduct in calculating tax loss.⁴¹

Relevant conduct is important in fraudulent return preparer prosecutions because the counts charged in the indictment rarely capture the full extent of the defendant’s crimes. Thus, the prosecutor should argue that the proper tax loss includes all other known false tax returns prepared by the defendant. Any tax returns that can be shown, by a preponderance of the evidence, to be false should be treated as relevant conduct, including other false tax returns prepared for the clients who testified at trial and false returns prepared on behalf of clients whose returns were not included in the indictment. It is proper to include tax returns that were confirmed to be false during IRS interviews with taxpayers, even if there was no opportunity for the defendant to cross-examine the taxpayers.⁴² The relevant conduct can include tax loss from years barred by the statute of limitations, and it can also include acquitted conduct.⁴³

Given that much of this type of evidence is unlikely to have been admitted at trial, it will need to be introduced at sentencing. Typically, an IRS RA can testify about these additional tax loss figures and the methodology used to calculate them.

4. Extrapolation

Relevant conduct can also be established through an extrapolation method. “To extrapolate means ‘to estimate the values of . . . a function or series . . . outside a range in which some of its values are known, on

³⁹ *Id.*; U.S.S.G. § 3D1.2(d) (providing that “[o]ffenses covered by” (inter alia) “§§2T1.1, 2T1.4, 2T1.6, 2T1.7, 2T1.9, 2T2.1, [and] 2T3.1” “are to be grouped under this subsection”).

⁴⁰ U.S.S.G. § 2T1.1, n.2.

⁴¹ *See, e.g.,* *United States v. Hendrickson*, 822 F.3d 812, 829–30 (6th Cir. 2016) (court properly included tax loss from fraudulent refunds in failure to file case).

⁴² *United States v. Goosby*, 523 F.3d 632, 639 (6th Cir. 2008).

⁴³ *See, e.g.,* *United States v. Ziskind*, 491 F.3d 10, 16–17 (1st Cir. 2007); *United States v. Watts*, 519 U.S. 148, 157 (1997) (per curiam) (guidelines range may rest on uncharged conduct or conduct underlying acquitted charges, if court finds conduct proven by a preponderance of evidence).

the assumption that the trends followed inside the range continue outside it.⁴⁴ In a fraudulent return preparer case, that means taking a random sample of tax returns that are “representative of the larger group of” returns, calculating the tax loss within that sample, and then using that figure to estimate the total tax loss.⁴⁵

For an extrapolation to be unbiased, the sample returns must be randomly chosen.⁴⁶ The sample returns must be chosen from the entire universe of the defendant’s returns, not those already flagged by the IRS as suspicious. A sample used for extrapolation must also consist of enough returns to allow the estimate of the total tax loss to be made with reasonable confidence—typically, that means the sample must be at least thirty returns.⁴⁷ Practically speaking, a successful extrapolation may require a lot of legwork, especially on behalf of the case agent, who will need to interview taxpayers or obtain other evidence (such as IRS audit files) that establish which of the sample returns are false. Extrapolation can be time-consuming and complicated. A prosecutor who would like to undertake it should consult with the Tax Division to obtain guidance and assistance.

B. Restitution

Restitution is an important component of sentencing in criminal tax cases. Restitution is limited to the actual loss caused by the counts of conviction, unless the defendant agrees to pay a higher restitution amount.⁴⁸ As a result, the restitution calculations will often differ from the total tax loss calculations. As previously discussed, restitution can only be ordered as a separate part of the defendant’s sentence if the defendant agrees to pay restitution in a plea agreement. When negotiating a plea agreement, the Tax Division directs prosecutors to include the sample restitution language in the Criminal Tax Manual. If there isn’t a plea agreement, or the plea agreement does not include an agreement to restitution, then the court may only order restitution as a condition of supervised release or probation.⁴⁹ It is important that prosecutors alert the court to the appropriate manner of ordering restitution to ensure a clean record.

⁴⁴ *United States v. Mehta*, 594 F.3d 277, 283 (4th Cir. 2010) (internal citation omitted).

⁴⁵ *Id.*

⁴⁶ *See United States v. Jenkins*, 786 F.App’x 852, 860 (11th Cir. 2019).

⁴⁷ *See United States v. Johnson*, 185 F.3d 765, 769 (7th Cir. 1999).

⁴⁸ U.S. DEP’T OF JUST., CRIMINAL TAX MANUAL, 44.03[1].

⁴⁹ U.S. DEP’T OF JUST., CRIMINAL TAX MANUAL, 44.00; CTM 44.10[1].

EXHIBIT D-39

February 22, 2008

NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2009 for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the MA capitation rate methodology and risk adjustment methodology applied under Part C of the Act for CY 2009. Preliminary estimates of the national per capita MA growth percentage and other MA payment methodology changes for CY 2009 are also discussed. For 2009, CMS will announce the MA capitation rates on the first Monday in April 2008, in accordance with the timetable established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita MA growth percentage component of the minimum percentage increase, which is a key factor in determining the MA capitation rates. Attachment II sets forth the changes in payment methodology for CY 2009 for original Medicare benefits. Attachment III sets forth the changes in payment methodology for CY 2009 for Part D benefits. Attachment IV presents the preliminary CMS-HCC risk adjustment factors, and Attachment V presents the annual adjustments for 2009 to the Medicare Part D benefit parameters for the defined standard benefit.

Any changes to employer/union-only group waiver plan payment for 2009 will be issued in future guidance.

Comments or questions may be submitted electronically to the following address: AdvanceNotice2009@cms.hhs.gov. Comments or questions also may be mailed to:

Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
S3-16-16
Baltimore, Maryland 21244

In order to receive consideration prior to the April 7, 2008 release of the Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies, comments must be received by 6:00 PM EST on Friday, March 7, 2008.

/ s /

Abby L. Block

Director

Center for Beneficiary Choices

/ s /

Paul Spitalnic, A.S.A., M.A.A.A.

Director

Parts C & D Actuarial Group

Office of the Actuary

Attachments

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Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year 2009

Section 1853(c)(1) of the Social Security Act (the Act) provides that, for years when CMS is “rebasing” the amount representing the actuarial value of 100 percent of costs under original fee-for-service (FFS) Medicare, MA capitation rates will be based on the greater of 100 percent of FFS costs or an increase which is the greater of two percent or the national per capita MA growth percentage, with no adjustment to this percentage for over- or under-estimates for years before 2004. CMS is rebasing the FFS rates for 2009. See section J, Attachment II for a discussion of the proposed methodology for adjusting the FFS rates to reflect DOD and VA costs, per Section 1853(c)(1)(D)(iii) of the Act.

The current estimate of the change in the national per capita MA growth percentage for aged and disabled enrollees combined in CY 2009 is 4.8 percent. This estimate reflects an underlying trend change for CY 2009 in per capita costs of 3.4 percent and adjustments to the estimates for CY 2008, CY 2007, CY 2006, CY 2005, and CY 2004 aged and disabled MA growth percentages of 2.4 percent, -0.9 percent, 0.1 percent, -0.3 percent, and 0.2 percent, respectively. Our new estimates for these years are lower than the estimates actually used in calculating the CY 2008 capitation rate book for CYs 2005 and 2007 and higher for CYs 2004, 2006, and 2008 than was published April 2, 2007, and are required by Section 1853(c)(6)(C) of the Act.

The following table summarizes the estimates for the change in the national per capita MA growth percentage.

Table I-1. National Per Capita MA Growth Percentage

	Aged	Disabled	ESRD	Aged+Disabled
2009 Trend Change	3.4%	3.4%	1.6%	3.4%
Revision to CY 2008 Estimate	1.8%	5.7%	2.9%	2.4%
Revision to CY 2007 Estimate	-1.1%	0.2%	-3.2%	-0.9%
Revision to CY 2006 Estimate	0.3%	-1.3%	-5.1%	0.1%
Revision to CY 2005 Estimate	-0.2%	-1.2%	-1.8%	-0.3%
Revision to CY 2004 Estimate	0.2%	0.2%	-0.2%	0.2%
Total Change	4.5%	7.0%	-5.9%	4.8%

Notes: (1) The total percentage change is multiplicative, not additive and may not exactly match due to rounding.

(2) Starting in 2008, the trend change for ESRD reflects an estimate of the trend for dialysis-only beneficiaries.

These estimates are preliminary and could change before the final rates are announced on April 7, 2008 in the Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies. Further details on the derivation of the national per capita MA growth percentage will also be presented in the Announcement.

Attachment II. Changes in the Payment Methodology for Original Medicare Benefits for CY 2009

Section A. Recalibration of CMS-HCC Model

In 2009, CMS will implement an updated version of the aged-disabled CMS-HCC risk adjustment model, including community, institutional, and new enrollee segments of the model. Fee-for-service (FFS) claims data for the years 2004 and 2005 are used in the recalibration of the model. Disease groupings are the same as in past models; however, the factors are different.

When CMS recalibrates the CMS-HCC risk adjustment model with more recent data, an updated coefficient is calculated for each diagnosis group and demographic characteristic in the model (e.g., age, sex), which represents the marginal (additional) cost of that diagnosis group or demographic characteristic in predicting FFS per capita costs. These coefficients are then converted to relative cost factors by dividing each by the per capita cost predicted for a specific year. For the CY 2009 recalibration, CMS used predicted per capita costs for 2007. The relative factors are used to calculate risk scores for individual beneficiaries, which will average 1.0 in the denominator year.

The current CMS-HCC model is calibrated on 2002 and 2003 data, and recalibrating the model on more current data results in more appropriate relative weights for each HCC because they reflect more recent coding and expenditure patterns in FFS Medicare. In addition, recalibrating with more recent data adjusts the model for increases in predicted FFS expenditures between calibration years. Recalibration of the CMS-HCC model can result in changes in relative risk scores for individual beneficiaries and for average plan risk scores, depending on individual beneficiaries' combinations of diagnoses.

One change that was made to the model was to remove the constraints on two HCCs: Metastatic Cancer (HCC 7) and Severe Cancers (HCC 8). In the version of the model currently in use, the coefficients of HCC 7 (Metastatic Cancer) and HCC 8 (Severe Cancers) were constrained to be equal. In the past, these HCCs were constrained because there were concerns regarding the completeness of the coding for Metastatic Cancer, specifically that secondary (metastatic) cancers were sometimes incorrectly coded as primary cancers.

With the constraint removed, the estimated incremental cost of Metastatic Cancer (HCC 7) is now higher than that for Severe Cancers (HCC 8). CMS determined that there was significant clinical and expected treatment cost difference between metastatic and localized cancer (e.g., chemotherapy for metastatic cancer). Although current coding may be imperfect, there are specific diagnostic tests and indications for metastatic versus localized cancers, and allowing a payment differential will provide incentives for accurate coding. More importantly, a higher incremental payment for beneficiaries with metastatic cancer will provide for more accurate payment to Medicare Advantage plans that enroll such beneficiaries.

In Attachment IV of this Notice, we provide the relative cost factors for each HCC for each segment of the aged-disabled model.

Section B. Frailty Adjustment**B1. Frailty Adjustment Factors**

CMS has recalibrated the frailty factors for CY 2009. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by the CMS-HCC risk adjustment model. Whenever CMS recalibrates the CMS-HCC risk adjustment model, the amount of unexplained Medicare expenditures can change. Thus, it is necessary to simultaneously recalibrate the frailty factors. Table II-1 presents the preliminary recalibrated frailty factors for CY 2009.

Table II-1. Preliminary Recalibrated Frailty Factors for CY 2009

ADL	2008 Factors (Non-Medicaid)	2009 Recalibrated Factors (Non-Medicaid)	2008 Factors (Medicaid)	2009 Recalibrated Factors (Medicaid)
0	-0.089	-0.093	-0.183	-0.180
1-2	+0.110	+0.112	+0.024	+0.035
3-4	+0.200	+0.201	+0.132	+0.155
5-6	+0.377	+0.381	+0.188	+0.200

CMS is not proposing to change the way we calculate the contract-level frailty score; we will use the results from each contract's 2008 HOS survey to calculate each contract-level frailty score for CY 2009.

B2. Frailty Adjustment Transition for PACE organizations

Frailty adjustment factors will be applied to payment to PACE organizations using the transition schedule published in the 2008 Announcement (published April 2, 2007). PACE frailty scores for payment year 2009 will be calculated at a blend of 70% of the frailty factors in use prior to 2008 and 30% of the recalibrated frailty factors implemented in 2009. The full transition schedule is as follows:

- In 2008 (year 1): 90% of the pre-2008 frailty factors and 10% of the 2008 frailty factors.
- In 2009 (year 2): 70% of the pre-2008 frailty factors and 30% of the 2009 frailty factors.
- In 2010 (year 3): 50% of the pre-2008 frailty factors and 50% of the most recently calibrated frailty factors.
- In 2011 (year 4): 25% of the pre-2008 frailty factors and 75% of the most recently calibrated frailty factors.
- In 2012 (year 5): 100% of the most recently calibrated frailty factors.

B3. Frailty Adjustment Transition for Certain Demonstrations

Frailty adjustment factors will be applied to payment to the following MA plan types using the phase-out schedule published in the 2008 Announcement (published April 2, 2007): Social Health Maintenance Organizations (S/HMOs), Minnesota Senior Health Options (MSHO)/Minnesota Disability Health Options (MnDHO), Wisconsin Partnership Program (WPP) and Massachusetts Senior Care Options (SCO) plans.

The full phase out schedule is as follows:

- In 2008 (year 1): 75% of the pre-2008 frailty factors
- In 2009 (year 2) 50% of the pre-2008 frailty factors
- In 2010 (year 3) 25% of the pre-2008 frailty factors
- In 2011, 0% of the pre-2008 frailty factors

Section C. Normalization Factors

When we calibrate a risk adjustment model and normalize the risk scores to 1.0, we produce a fixed set of dollar expenditures and coefficients appropriate to the population and data for that calibration year. When the model with fixed coefficients is used to predict expenditures for other years, predictions for prior years are lower and predictions for succeeding years are higher than for the calibration year. Because average predicted fee-for-service (FFS) expenditures increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years.

The normalization factor is derived by first using the model to predict risk scores for the FFS population over a number of years. Next, we trend the risk scores to determine the annual percent change in the risk score. This amount is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor.

Starting in 2009, CMS will use a standard of five years of data in the normalization trend. Each year, CMS will drop the earliest year and add a new year of risk scores to the trend data to create the five-year dataset. By using a standard number of years, CMS intends to calculate risk score trends based on recent trends in coding, while maintaining stability in the year-to-year trends used. For the CY 2009 recalibration, trends calculated for the aged-disabled CMS-HCC, ESRD Dialysis, and the RxHCC models are developed on risk scores calculated for 2003-2007.

Below are the preliminary normalization factors for each model. The final normalization factors will be included in the April 7, 2008 Announcement.

C1. Normalization Factor for the CMS-HCC Model

The preliminary 2009 normalization factor for the aged-disabled model is 1.030. The 2009 factor will adjust for two years of FFS risk score growth, i.e., from the denominator year of 2007 to the payment year of 2009. This 2009 normalization factor of 1.030 is lower than the 2008 factor of 1.04 because the 2008 factor adjusted for three years of FFS risk score growth (2005-2008).

C2. Normalization Factor for the ESRD Dialysis Model

The preliminary 2009 normalization factor for the ESRD dialysis model is 1.019. The 2009 factor will adjust for six years of risk score growth, i.e., from the denominator year of 2003 to the payment year of 2009, and will be applied at a phased-in percentage of 50%. (As discussed in last year's Advance Notice, the ESRD Dialysis normalization factor is being applied on the same transition schedule as is the transition of the ESRD State ratebook; see Section G2.)

C3. Normalization Factor for the RxHCC Model

The preliminary 2009 normalization factor for the RxHCC model is 1.085. This normalization factor reflects a trend calculated on five years of risk score data (2003-2007). We calculated the RxHCC normalization factor by taking the actual 2007 average Part D risk score for all potential Part D plan enrollees and the annual trend applied for the two years between the calculation of actual average Part D risk score and the payment year (2007-2009).

C4. Normalization Factor for Functioning Graft Enrollees' Risk Scores

CMS applies the normalization factor for the aged-disabled CMS-HCC model to Functioning Graft enrollees' risk scores because all but one of the coefficients for the Functioning Graft model are constrained to equal the coefficients of the CMS-HCC model, and because CMS pays for Functioning Graft enrollees using the county ratebook. However, because CMS recalibrates the functioning graft coefficients along with the dialysis model, the functioning graft coefficients still have a denominator of 2005 (instead of the 2007 denominator that the CMS-HCC community and institutional coefficients will have in 2009). For that reason, CMS will add an additional year to the 2008 CMS-HCC normalization factor; the preliminary 2009 normalization factor to be applied to the 2009 risk scores of enrollees in functioning graft status is 1.058.

Section D. Budget Neutrality

From 2003 through 2006, CMS implemented risk adjusted payments in a budget neutral manner by applying to the risk rates 100 percent of the Budget Neutrality (BN) factor, which is calculated as the estimated difference between payments to MA organizations at 100 percent of the demographic rates and payments at 100 percent of the risk rates. As previously announced by CMS on February 17, 2006 in the Advance Notice for 2007, and as summarized below, the phase-out of budget-neutral risk adjusted payments began in 2007 and will be completed by 2011, when plans will receive no budget neutrality payment adjustment. For 2009, 25 percent of the BN factor will be applied to the risk rates.

Since CMS cannot calculate the BN factor until the final capitation rates are determined, the factor will be announced in the April 7, 2008 Rate Announcement.

Phase-out Schedule for Budget Neutral Risk Adjusted Payments:

The percentage of the budget neutrality factor that is applied to the risk rates is:

- 2007: 55%
- 2008: 40%
- 2009: 25%
- 2010: 5%
- 2011: 0%

Section E. Adjustment for MA Coding Intensity

Background

As promulgated by the Deficit Reduction Act (DRA), Section 1853(k)(2)(B)(iv)(III) requires CMS to reflect in its risk adjustment for Part C payment “differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences.” The DRA further instructs that results of the analysis will be “incorporated into the risk scores only for 2008, 2009, and 2010.” In order to comply with this section of the DRA, CMS has studied the changes in MA and FFS risk scores, the differences between those changes, and the coding patterns behind these changes.

From our research for the 2008 payment year, CMS found that MA risk scores increased approximately twice as much as FFS risk scores did for our study population between 2004 and 2006. There are a number of key reasons why risk scores in the MA and FFS sectors may rise at different rates. The composition of enrollment in each sector can have an effect on the change in the average risk score. Initially, some MA plans may have had difficulty gathering and reporting diagnosis codes as completely as FFS, so part of the differential risk score growth could be due to “catching up” to FFS. MA plans may be finding and diagnosing disease at a higher rate than FFS providers. Or, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS.

Our preliminary research on coding patterns, which was conducted prior to the release of the 2008 Rate Announcement, was unable to clarify enough about the coding pattern differences that result in MA and FFS risk score differences. Therefore, we did not make an adjustment for coding patterns differences in payment year 2008. We stated that we would continue to study this issue, with particular focus on the plans that have experienced significant increases in risk scores, in an effort to determine what the appropriate adjustment might be for 2009 and 2010.

CMS has continued its analysis of the coding patterns that result in differences in the MA and FFS risk scores. The findings below are based on diagnoses reported for payment years 2004-2006. CMS will update these figures by adding the (currently unavailable) 2007 risk scores to the analysis, prior to the publication of the Announcement on April 7, 2008.

Study Results

Composition effects: In order to analyze the gross difference between the change in FFS and MA risk scores, we examined the change in risk scores for three categories of enrollees: stayers, leavers, and joiners. **Stayers** were those enrollees who remained in the same sector (either FFS or MA) over the study period, **leavers** were those who left either the MA or FFS sector, either to go to the other sector or who died, and **joiners** were those who came into FFS or MA, either from the other sector or who were newly eligible to Medicare. We found that indeed some of the difference in the change in risk scores between MA and FFS was due to composition effects. Specifically, we found that:

- A significant portion of the beneficiaries who join MA are beneficiaries who are switching from FFS. In FFS, the vast majority of beneficiaries who join are newly-eligible to Medicare. The risk scores of beneficiaries who are newly eligible to Medicare

tend to be very low and these low risk scores depress FFS risk score growth relative to MA.

- Of the leavers, decedents (who have high risk scores) are a slightly larger fraction of FFS beneficiaries than of MA enrollees and, thus, the exit of high-risk score decedents restrains the year-to-year growth of average FFS risk scores by slightly more than it does MA scores.

Because most new enrollees in FFS are newly-eligible to Medicare and FFS is losing higher risk beneficiaries, overall average MA risk scores are pushed up at a faster rate than risk scores in FFS. Over the two-year period, approximately 50% of the difference between the MA and FFS sectors in the growth of risk scores is due to enrollment patterns and approximately 50% is due to the more rapid growth in risk scores for beneficiaries who stay in the same sector in consecutive years.

Focus on “stayers.” Focusing on the stayers allows us to examine differences in risk score changes that are not due to the changing composition of the enrolled population. In our analyses of the impact of coding patterns on stayers’ risk scores, we did the following:

- We focused on two cohorts of stayers: those who were stayers in 2004-2005, and those who were stayers in 2005-2006. We weren’t able to add the 2006-2007 cohort to the analysis prior to the release of the Advance Notice, but will do so before the release of the Announcement in April 2008.
- For each cohort, we defined MA stayers as those enrollees who were in the same contract in the July of each cohort year, as well as in each data collection year. For example, for the 2004-2005 stayer cohort, we include enrollees who were in the same contract in July 2004 and July 2005, and in all of 2003 and 2004. This criterion resulted in the exclusion of enrollees who would have been new enrollees in the data collection years, as well as those enrollees who switched contracts.
- We found that the overall risk scores of MA stayers increased by 0.032 more than those of FFS stayers over the two-year study period. As discussed below, we then broke down the change in aggregate risk scores into the changes in the disease component of the CMS-HCC risk score (the “disease score”) versus the demographic component.

Focus on the disease score of stayers: The disease score is the HCC component of the risk score that plans (and FFS providers) affect by their reporting of diagnosis codes. Among stayers, we found that MA disease scores increased more quickly than FFS disease scores and that change in the disease component of the risk score accounted for approximately 90% of the difference in the change in MA versus FFS risk scores.

We found that, on average, disease scores for stayers in MA plans increased 20% faster than stayers in FFS over the two years in the study period. Specifically, FFS disease scores for stayers increased by 0.145 over the two-year period between 2004 and 2006, while the average disease score among beneficiaries who remained enrolled in a single MA contract for at least two data collection years increased by 0.174 over the same time period for a two-year difference of 0.029.

Dynamics behind changes in disease scores: CMS also analyzed the reasons why the change in MA and FFS disease scores differed among stayers. A significant portion of the difference in

disease score changes is attributable to the reporting of 26 HCCs (of the 70 HCCs in the model) that fall into one of seven hierarchies: diabetes (5 HCCs), cardiovascular disease (4 HCCs), coronary artery disease (3 HCCs), cancer (4 HCCs), quadriplegia and other central nervous system disease (4 HCCs), liver disease (3 HCCs), and dialysis/renal disease (3 HCCs).

Approximately one-third of the difference in disease score change is due to increases in severity within these hierarchies, particularly within the diabetes hierarchy. The remaining difference results primarily from greater retention of reported diagnosis codes within certain hierarchies from one year to the next, especially the coronary artery disease, liver, diabetes, and renal hierarchies.

Variation among contracts: CMS research has also revealed a large amount of variation among MA contracts in the disease score change among stayers, and in the dynamics behind contracts' changing disease scores. As described above, on average, disease scores for MA stayers increased by 0.174 over the 2004-2006 study period, or 0.029 greater than the average increase of 0.145 for FFS stayers. We found that approximately 40% of the contracts in our study – those operating continuously during the 2004, 2005, and 2006 payment years – had changes in stayer disease scores that were less than the changes in FFS stayers' disease scores. Looking at enrollees, we found that 25% of the MA stayers in our analysis were enrolled in contracts where the difference between the two-year increase in stayers' disease scores and the FFS increase was at least twice the industry average.

Catch-up to FFS levels of coding: Although CMS cannot definitely determine whether “catch up” to FFS coding occurred or not, CMS recognizes that plans may have experienced some catch up, particularly during initial years of operation. In order to take any such catch up into account in our adjustment, we are proposing to:

- Adjust for MA coding only in 2009 and later (not adjust for previous year's coding patterns differences).
- Make an adjustment for contracts that have existed since at least 2005.
- Adjust risk scores for enrollees in contracts that have significant coding pattern differences from FFS.
- We are proposing to weight the impact of coding differences on disease scores in more recent years (when plans would have caught up to FFS) differently than coding patterns differences in earlier years.

More complete coding: We do not assume that the coding pattern differences that we found in our study are the result of improper coding. As discussed above, CMS understands that MA plans have made efforts to identify enrollees' conditions and may be coding more completely than FFS. However, because MA coding patterns differ from FFS coding patterns, the normalization factor (which is calculated based on FFS coding) does not currently adjust for these different coding patterns.

Impact of health status on risk score changes: As noted above, it is possible that beneficiaries enrolled in MA plans may be getting sicker faster than beneficiaries in FFS and this could be driving faster risk score growth for MA enrollees. Given the care coordination and disease management activities of MA plans, however, we do not find it reasonable to assume that MA stayers' underlying health status is getting worse at a faster rate than stayers in FFS. CMS analysis has found that MA mortality rates during the study period do not explain rising risk

scores; when applying expected mortality rates to the MA population, risk scores are expected to decrease, not increase. (In our analysis, we adjusted mortality rates for age, sex, county, Medicaid status, and institutional status.)

Calculation and Application of a Coding Intensity Measure

While our research supports the finding that MA plans have coding patterns that differ from FFS, we only have a few years to observe the differences in MA and FFS coding patterns. Therefore, for 2009 we propose to apply an MA coding adjustment factor as follows:

- Apply an adjustment to the risk scores of enrollees in those contracts for which the difference between the change in stayers' disease scores and the change in the FFS stayers' disease scores is two or more times the industry average; this threshold is approximately the same as a threshold at the plans enrolling the 25% of MA stayers with the largest change in disease score. We considered a few other options for applying an adjustment:
 - We considered applying an adjustment to those contracts above two standard deviations above the mean difference in disease score change, but the variation among plans is so great that such a threshold would eliminate most contracts.
 - We considered applying an adjustment on a contract-by-contract basis, but decided instead to apply a relatively high threshold in order to focus on the contracts that have experienced the largest changes in their stayers' disease scores, relative to FFS stayers' disease scores.

CMS is requesting comments on the criteria for determining the threshold used to determine those contracts' payment to which we would apply an adjustment factor.

- Exclude those contracts that were not in existence until after 2005 (came into existence in 2006 or later). Contracts that existed in 2005 and earlier have at least two years of experience reporting to CMS stayers' diagnosis codes that have been used to calculate risk scores.
- Exclude contracts with under an average of 1,000 enrollees during 2005-2006. CMS considers these contracts too small to provide enough data to make reliable estimates of their coding patterns.

CMS proposes to calculate the 2009 MA coding adjustment as follows:

1. *Calculate the average annual difference between the increase in MA and FFS stayers' disease scores.* The average annual change in stayers' disease scores for a contract is calculated as the change in average disease score, averaged over as many cohorts of stayers that a contract has, e.g., CMS would calculate the annual average change in disease score for contracts that have been in existence since 2003 or earlier as the average of the change in disease score for the 2004-2005, 2005-2006, and the 2006-2007 stayer cohorts. We would then subtract the FFS annual average change in stayers' disease score to obtain the differential increase in stayers' disease scores. Changes in disease scores would be adjusted for age and survivor status.

2. *Calculate this average annual difference in the change in stayers' disease scores within that group of contracts that would fall above the threshold for applying the adjustment.* For example, we would calculate the annual average difference between MA and FFS stayers' disease score increase based only on MA data from those contracts where the difference between the change in stayers' disease scores and the change in FFS stayers' disease scores was two or more times the industry average. We would calculate the average disease score change for the set of contracts by weighting each contract's disease score change by the number of beneficiaries in each contract. We would then subtract the FFS disease score change from this weighted average. Based on the two years of data that were included in our analysis to date, the difference in the change in stayers' disease score for the contracts in this group and the FFS average is 0.050.
3. *Adjust the annual average difference in disease score change for the average percent of MA plan enrollees in the payment year who were enrolled in the same plan in the data collection year.* CMS currently estimates that this percentage of enrollees is approximately 75%, but will finalize the percentage after we add 2007 risk score data to our analysis. Based on our current estimate of 75% for the proportion of MA enrollees who are stayers, the adjustment for the contracts with the top 25% of MA enrollees with the largest difference between their change in disease score and the FFS change in disease score would be 0.0375. CMS (1) will update this calculation with 2007 data, (2) proposes to convert the adjustment amount into a percent change to risk scores in the Announcement, and (3) will consider whether to apply a straight average across the year-to-year differences, or whether to give more weight the disease score change differences in the most recent years. CMS requests comment on how we calculate the adjustment factor.

The average change in MA stayers' disease score, the change in MA stayers' disease scores for the top group of contracts, the FFS average change in disease score, the difference between MA and FFS, and the proportion of stayers we project to be enrolled in MA contracts in 2009, along with other calculations, will be updated in the Announcement.

Section F. Medicare as Secondary Payer (MSP) Adjustment Factor for Aged & Disabled Enrollees

MA capitation rates are calculated as if Medicare were always the primary payer; adjustments to the rates for situations in which Medicare is secondary are made as part of actual payment. The MSP adjuster applied to aged and disabled beneficiaries is calculated as the ratio of the actual Medicare spending for all MSP months for all MSP beneficiaries to the predicted Medicare spending for all MSP months for all MSP beneficiaries. Actual spending was calculated using the 2005 claims from the same analytic files used to recalibrate the CMS-HCC model. The predicted amount was calculated using the newly recalibrated CMS-HCC model. MSP status, which was determined using the working aged/working disabled status data in 2005, was used both for determining whom to exclude from the recalibration and for determining which beneficiaries to include in the MSP adjuster calculation.

CMS has recalculated the MSP adjuster for working aged and working disabled beneficiaries. The current adjuster of 0.215 will be revised to 0.174 in the 2009 payment year. There are two reasons for the change in the adjuster. First, CMS has refined the methodology used to calculate the adjuster. Previously, we prorated each beneficiary's MSP months using their total Medicare-paid costs during all months when beneficiary was enrolled. The new methodology includes costs only from those months in which beneficiaries have MSP status. Second, the average number of actual dollars calculated in the MSP months has decreased.

We are not proposing to change the formula for calculating the contract-level working aged/working disabled factor that is applied to each contract's total monthly payment for non-hospice/non-ESRD enrollees. We would simply change the value of the adjuster in that formula from 0.215 to 0.174.

Section G. ESRD Bidding and Payment

Pursuant to Section 1853(a)(1)(H) of the Act, CMS has the authority to determine whether to apply the competitive bidding methodology to ESRD enrollees, and must establish "separate rates of payment" with respect to ESRD beneficiaries.

G1. ESRD Bidding Policy

For 2009, CMS will continue the policy of excluding costs for ESRD enrollees in the plan A/B bid. The MA Bidding Instructions for CY 2009 will provide guidance on the option of adjusting A/B mandatory supplemental premiums to reflect the costs or savings for ESRD enrollees in the basic and supplemental benefits.

G2. Transition to New ESRD Payment

As announced in last year's Advance Notice, CMS continues the phase-in of the revised State capitation rates used to determine payments for enrollees in dialysis and transplant status. For payment year 2009, CMS will pay for ESRD dialysis and transplant enrollees using a blend of 50% of the old State ratebook (in use through 2007) and 50% of the revised State ratebook (implemented in 2008). The revised ESRD State ratebook reflects the dialysis-only trend. During the transition period, we will continue to trend forward the old and the revised State rates using the same dialysis-only growth trend. CMS is not rebasing the ESRD Dialysis State rates for 2009.

The full transition schedule is as follows. CMS payments for ESRD dialysis and transplant beneficiaries enrolled in MA plans will be:

- In 2008 (year 1): a blend of 75% old ratebook-based payments and 25% revised ratebook-based payments.
- In 2009 (year 2): a blend of 50% old ratebook-based payment and 50% revised ratebook-based payments.
- In 2010 (year 3): a blend of 25% old ratebook-based payments and 75% revised ratebook-based payments.
- In 2011: 100% of the revised ratebook.

In States where the revised dialysis rates are higher than the pre-2008 State rates, we will apply the revised ESRD State rates.

G3. ESRD Functioning Graft Payments

CMS pays for Functioning Graft enrollees with risk scores calculated using the aged-disabled CMS-HCC model coefficients, with the exception of the coefficient for HCC174 (Major Organ Transplant), which is not constrained, and the Graft factors, which are additive to the functioning graft risk scores. However, because CMS recalibrates the functioning graft coefficients along with the dialysis model, for 2009 CMS will continue to use the functioning graft coefficients published in the April 7, 2007 Advance Notice for 2008, when the ESRD dialysis model was last recalibrated. See Section C4 for a discussion of the normalization factors to be used with the functioning graft risk scores.

Section H. Regional Plan Stabilization Fund

Section 221 of the MMA added Section 1858(e) to the Act to create a new MA Regional Plan Stabilization Fund. The purpose of the fund is to provide financial incentives to MA organizations to offer MA regional PPO plans in each MA region, and to retain MA regional PPO plans in regions with relatively low MA market penetration.

Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 – enacted December 18, 2007 – delayed Stabilization Fund payments until January 1, 2013.

Section I. Continuation of Clinical Trial Policy

In 2009, we will continue the policy of paying on a fee-for-service basis for clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials.

Section J. Adjustment to FFS Capitation Rates for VA-DOD Costs

Per Section 1853(c)(1)(D)(iii) of the Act, CMS proposes to adjust to the extent appropriate the 2009 FFS rates to reflect CMS' "estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs."

The Office of the Actuary (OACT) proposes to compare the risk-adjusted Medicare reimbursements of dual-eligible individuals — those entitled to benefits under this title and entitled to benefits from the Department of Defense (e.g., DoD TRICARE for Life, DoD US Family Health Plan) or the Department of Veterans Affairs (VA) — with individuals entitled only under this title. In cases where groupings of dual-eligible individuals (who would possibly have services provided in VA or DoD facilities not reimbursed by Medicare) have risk-adjusted Medicare reimbursements significantly different from other Medicare-eligible individuals, we propose to adjust the MA FFS rates by excluding these individuals from the calculation. This

exclusion implicitly assumes that these individuals, if they had received all their services from Medicare-covered providers, would have the same risk-adjusted Medicare reimbursements as the remaining individuals.

MA FFS rates could be higher or lower under this adjustment. This is because the MA FFS rates are risk-adjusted rates. We note that under the current payment methodology we are missing two pieces of information on beneficiaries receiving health services through the VA or DoD:

1. The amounts Medicare would have reimbursed if these individuals had received their services from Medicare-covered providers rather than from VA/DoD providers.
2. Diagnostic information identified in VA/DoD-provided services but not identified in Medicare-covered services. Lack of diagnostic information could potentially understate individuals' risk scores.

Since the MA FFS rates are calculated using risk-adjusted reimbursements, there could be cases where the risk scores are understated to a greater extent than reimbursements leading to a reduction in the MA FFS rates in some counties.

In light of the foregoing, further information and analysis is required before making a final decision on the appropriateness of adjustments.

Section K. Operational Policies

K1. Reporting of Medicaid Status for Part C Payment

In CY 2009, CMS will complete the transition to using the MMA Medicare/Medicaid Dual Eligible monthly submission file (MMA State files) as the main source of Medicaid status for Part C plan payments. At the same time, CMS will end the use of the Third Party files as a source of Medicaid status. CMS anticipates that this change in Medicaid status source will improve – and increase – the identification of dual-eligible MA enrollees. As discussed in the 2008 Announcement (published April 2, 2007), CMS has found that the MMA State files identify approximately one million more dual eligibles than both the Third Party files and plan-reported data. (Please note that the changes discussed here only affect how we assign Medicaid status for Part C risk adjustment purposes, and that we are not changing how we identify deemed individuals for purposes of Part D payment.)

Plan Reporting. For any Medicaid period open on or after January 1, 2008, organizations may no longer submit batch “01” transactions to CMS. Instead, to request changes to Medicaid status, organizations must submit retroactive “01” transactions to IntegriGuard, as indicated in Table II-2.

Table II-2. Data sources for the assignment of Medicaid status

	Payment year 2007	Payment year 2008	Payment year 2009
New enrollees	1. Third Party Buy-In file 2. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard	1. MMA State files 2. Plan-reported • Retroactive "01s" through IntegriGuard
Full risk enrollees		1. MMA State files 2. Third Party Buy-In file 3. Plan-reported Medicaid • Batch "01" transactions • Retroactive "01s" through IntegriGuard	

Notes: Full risk enrollees. CMS considers full risk Medicare beneficiaries as dually-eligible if they were eligible for title XIX during any month in the year prior to the payment year. Full risk Medicare beneficiaries have 12 months of Part B in the year prior to the payment year.

New enrollees. CMS assigns Medicaid status for new enrollees on a concurrent basis, i.e., if a newly-enrolled Medicare beneficiary is eligible for title XIX during any month during the payment year, they are considered Medicaid for that year.

K2. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

As discussed in the 2008 Announcement (released April 2, 2007), CMS is implementing the use of a standard set of valid codes to determine which plan-submitted diagnosis codes are acceptable for use in CMS's Risk Adjustment Processing System (RAPS). The goal is for RAPS to accept and store only those diagnoses codes that are valid. RAPS has historically accepted and stored old ICD-9 codes that had been superseded by more recent National Center for Health Statistics (NCHS) codes, i.e., invalid codes, without sending error messages to the plans. Having a standard set of valid codes for each year will make it more efficient for CMS and plans to manage risk adjustment processing, editing, and error reporting.

Starting with payment year 2009, RAPS will only accept valid ICD-9-CM codes for two fiscal years -- the fiscal year that begins prior to the payment year and the fiscal year that begins during the payment year -- for the CMS-HCC, ESRD, and RxHCC risk adjustment models. For example, for diagnoses codes to be used in 2009 final payment, i.e., for diagnoses from service dates between January 1, 2008 and December 31, 2008, RAPS will only accept codes that are valid for Fiscal Year 2008 and Fiscal Year 2009. (Please note that for the initial risk score run for payment year 2009, CMS will use valid diagnosis codes from FY 2007 and FY 2008 -- services dates between July 1, 2007 and June 30, 2008.)

Refer to Table II-3 for the implementation schedule of the new rules regarding the acceptance of diagnosis codes. Please note that Table II-3 of this Notice supersedes the table published in the April 2, 2007 Rate Announcement for 2008.

CMS is in the process of updating the "future diagnoses file" to eliminate invalid codes from that list. However, whether submitting diagnosis codes from the list of current model diagnoses or the list of future diagnoses, plans should resubmit an updated valid diagnosis code whenever they receive a RAPS error code specifying that a submitted diagnosis code is invalid. Both lists of current diagnosis codes and future diagnosis codes can be found in a zipped file on the CMS Web site at

http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage. Please refer to the HPMS memo released November 26, 2007 for a discussion of this policy and of the related RAPS error codes.

Table II-3. Acceptable diagnoses codes

Year of Payment	Date of Service	Source of codes
2007	1/06 – 12/06	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2008	1/07 – 12/07	The list of codes published on our website at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage (which lists acceptable codes by year)
2009	1/08 – 12/08	Valid diagnoses in Fiscal Years 2008, 2009
2010	1/09 – 12/09	Valid diagnoses in Fiscal Years 2009, 2010
2011	1/10 – 12/10	Valid diagnoses in Fiscal Years 2010, 2011

Attachment III. Changes in the Payment Methodology for Medicare Part D for CY 2009

Section A. Benefit Design

A1. Medicare Part D Benefit Parameters: Annual Adjustments for Defined Standard Benefit in 2009

In accordance with section 1860D-2(b) of the Social Security Act (the Act), CMS must update the statutory parameters for the defined standard Part D prescription drug benefit each year. These parameters include the annual deductible, initial coverage limit, annual out-of-pocket threshold, and minimum copayments for costs above the annual out-of-pocket threshold. As required by statute, the parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in Part D drug expenses, and the defined standard Part D benefit continues to cover a constant share of Part D drug expenses from year to year. The Part D benefit parameters are updated using two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary or the "annual percentage increase", and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

As required by statute, the first indexing method, the "annual percentage increase," is used to update the following Part D benefit parameters:

- (i) the deductible, initial coverage limit, and out-of-pocket threshold for the defined standard benefit;
- (ii) minimum copayments for costs above the annual out-of-pocket threshold;
- (iii) maximum copayments below the out-of-pocket threshold for certain low-income full subsidy eligible enrollees;
- (iv) the deductible for partial low-income subsidy (LIS) eligible enrollees; and
- (v) maximum copayments above the out-of-pocket threshold for partial LIS eligible enrollees.

The benefit parameters listed above will be increased by 7.54% for 2009 as summarized by Table III-1 below. This increase reflects the 2008 annual percentage trend of 5.97% as well as a multiplicative update of 1.48% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase.

Per 42 CFR 423.886(b)(3), the cost threshold and cost limit for qualified retiree prescription drug plans are updated after 2006 in the same manner as the deductible and out-of-pocket threshold for the defined standard benefit. Thus, the "annual percentage increase" will be used to update these parameters as well. The cost threshold and cost limit for qualified retiree prescription drug plans will be increased by 7.54% from their 2008 values.

The statute requires CMS to use the second indexing method, the annual percentage increase in the CPI, to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These maximum copayments will be increased by 3.18% for 2009 as summarized in Table III-1 below.

This increase reflects the 2008 annual percentage trend in CPI of 2.60%, as well as a multiplicative update of 0.57% for prior year revisions. Please see Attachment V for additional information on the calculation of the annual percentage increase in the CPI.

Table III-1. Updated Part D Benefit Parameters for Defined Standard Benefit, Low-Income Subsidy, and Retiree Drug Subsidy

Annual Percentage Increases			
	Annual percentage trend for 2008	Prior year revisions	Annual percentage increase for 2008
Applied to all parameters but (1)	5.97%	1.48%	7.54%
CPI (all items, U.S. city average): Applied to (1)	2.60%	0.57%	3.18%
Part D Benefit Parameters		2008	2009
Standard Benefit Design Parameters			
Deductible		\$275	\$295
Initial Coverage Limit		\$2,510	\$2,700
Out-of-Pocket Threshold		\$4,050	\$4,350
Total Covered Part D Drug Spend at OOP Threshold (2)		\$5,726.25	\$6,153.75
Minimum Cost-sharing in Catastrophic Coverage Portion of Benefit			
Generic/Preferred Multi-Source Drug		\$2.25	\$2.40
Other		\$5.60	\$6.00
Part D Full Benefit Dual Eligible Parameters			
Copayments for Institutionalized Beneficiaries		\$0.00	\$0.00
Maximum Copayments for Non-Institutionalized Beneficiaries			
Up to or at 100% FPL			
Up to Out-of-Pocket Threshold (1)			
Generic/Preferred Multi-Source Drug (3)		\$1.05	\$1.10
Other (3)		\$3.10	\$3.20
Above Out-of-Pocket Threshold		\$0.00	\$0.00
Over 100% FPL			
Up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug		\$2.25	\$2.40
Other		\$5.60	\$6.00
Above Out-of-Pocket Threshold		\$0.00	\$0.00
Part D Non-Full Benefit Dual Eligible Full Subsidy Parameters			
Resources ≤ \$6,290 (individuals) or ≤ \$9,440 (couples) (4)			
Maximum Copayments up to Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug		\$2.25	\$2.40
Other		\$5.60	\$6.00
Maximum Copayments above Out-of-Pocket Threshold		\$0.00	\$0.00
Resources bet \$6,290-\$10,490 (ind) or \$9,440-\$20,970 (couples) (4)			
Deductible (3)		\$56.00	\$60.00
Coinsurance up to Out-of-Pocket Threshold		15%	15%
Maximum Copayments above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug		\$2.25	\$2.40
Other		\$5.60	\$6.00
Part D Non-Full Benefit Dual Eligible Partial Subsidy Parameters			
Deductible (3)		\$56.00	\$60.00
Coinsurance up to Out-of-Pocket Threshold		15%	15%
Maximum Copayments above Out-of-Pocket Threshold			
Generic/Preferred Multi-Source Drug		\$2.25	\$2.40
Other		\$5.60	\$6.00
Retiree Drug Subsidy Amounts			
Cost Threshold		\$275	\$295
Cost Limit		\$5,600	\$6,000

(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) Amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement.

(3) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2008 values of \$55.91, \$1.04, and \$3.13 respectively.

(4) The actual amount of resources allowable will be updated for contract year 2009.

Office of the Actuary
Centers for Medicare and Medicaid Services
February 22, 2007

A2. Reporting Drug Costs When Contracting with a Pharmacy Benefit Manager (PBM)

In the 2008 Part D Payment Notification issued on April 2, 2007, we stated our intent to issue a Notice of Proposed Rulemaking proposing that the pass through amount (the amount received by the pharmacy or other dispensing provider) be the only acceptable price for determining beneficiary cost-sharing and reporting drug costs to CMS in 2009 and beyond. This Notice of Proposed Rulemaking was released in the Federal Register on May 25, 2007. CMS has reviewed the comments received and expects to issue the final rule in Spring 2008. This will allow sufficient time for Part D sponsors to prepare their 2009 Part D bids in accordance with the policies established in the final rule.

Section B. Bidding**B1. Calculation of the National Average Monthly Bid Amount**

CMS will complete the transition to an enrollment-weighted average for the calculation of the national average monthly bid amount in 2009. Section 1860D-13(a)(4)(B) of the Act directs CMS to calculate the national average monthly bid amount each year as a weighted average of the standardized bid amounts for each prescription drug plan (PDP) and Medicare Advantage Prescription Drug Plan (MA-PD) described in section 1851(a)(2)(A)(i) of the Act starting in 2007. When calculating the national average monthly bid amount for contract year 2006, CMS assigned equal weighting to PDP sponsors, under section 1860D-13(a)(4)(B)(ii), because CMS did not have prior enrollment for these Part D plans. MA-PD plans were assigned a weight based on their prior MA enrollments and new MA-PD plans were assigned zero weight.

In 2007, CMS implemented the Medicare Part D demonstration entitled, "Medicare Demonstration to Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans," and began a transition from the 2006 method of calculating the national average monthly bid amount to the weighted average method based on actual plan enrollments. Under this demonstration, the national average monthly bid amounts for contract years 2007 and 2008 were calculated as a composite of (i) a weighted average calculated using the 2006 weighting methodology and (ii) a weighted average calculated based on actual plan enrollments. In 2007, 80% of the national average monthly bid amount was based on the 2006 averaging methodology and 20% was based on the enrollment-weighted average. In 2008, 40% of the national average monthly bid amount is based on the 2006 averaging methodology and 60% is based on the enrollment-weighted average. Please find the weighting methodologies for contract years 2006-2009 below.

Table III-2. Weighting Blends for the National Average Monthly Bid Amount

Contract Year	2006 Weighting	Enrollment Weighting
2006	100%	0%
2007	80%	20%
2008	40%	60%
2009	0%	100%

CMS will complete the transition to the weighted average method based on actual plan enrollments in 2009. Thus for contract year 2009, 100% of the national average monthly bid amount will be based on the enrollment-weighted average. The "Medicare Demonstration to

Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans" will not be extended for contract year 2009. The 2009 national average monthly bid amount and the reference month for the plan enrollment used to determine the enrollment-weighted average will be provided in future guidance after the June bid submission deadline.

B2. Calculation of the Low-Income Benchmark Premium Amount

The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) directs CMS to use a weighted average to calculate the regional low-income benchmark premium amount used in the determination of the low-income premium subsidy amount. In determining the 2006 low-income benchmark premium amounts, PDPs were weighted equally, MA-PD plans were assigned a weight based on prior enrollment as of March 31, 2005, and new MA-PD plans were assigned a zero weight. In 2007, under the "Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries," CMS calculated the regional low-income benchmark premium amounts using the same weighting methodology applied in 2006, i.e., all PDP bids were weighted equally, and MA-PD bids received weights based on plan enrollments in the reference month (June 2006).

For contract year 2008, CMS implemented a transition to the statutorily required weighting such that the regional low-income benchmark premiums would experience a smaller decrease. CMS calculated the 2008 regional benchmarks using a composite of the 2006 weighting approach (simple average) and the statutory weighting formula (weighted average).

- The first component, the simple average, was the same as the 2006 weighting methodology for the regional low-income benchmark premium amount. The PDP organization premium amounts for basic prescription drug coverage in each region would be weighted equally and the MA-PD plan premiums, after the application of Part A/B rebates, would be weighted based upon prior enrollment.
- The second component was a weighted average of the premium amounts for each PDP and MA-PD with a weighting based on each plan's prior enrollment as a percentage of all beneficiaries enrolled in those plans.

In 2008, 50% of the regional low-income benchmark amount was based on the first component, the simple average, and 50% was based on the second component, the enrollment weighted average.

CMS proposes to calculate the 2009 regional benchmarks using a composite of the 2006 weighting approach (simple average) and the statutory weighting formula (weighted average) again. However, in 2009, 25% of the regional low-income benchmark amount will be based on the first component, the simple average, and 75% will be based on the second component, the enrollment weighted average. This proposal would continue the transition to the statutorily required weighting that was started in 2008, such that the regional low-income benchmark premiums would experience a smooth glide path to the statutory weighting approach.

Under the demonstration in 2007 and 2008, CMS also implemented a policy whereby Part D plans were required to charge full-subsidy eligible beneficiaries a monthly beneficiary premium equal to the low-income premium subsidy amount, if the plan's premium exceeded the low-

income premium subsidy amount by a certain "de minimis" amount. We do not propose to extend the "de minimis" component of this demonstration to 2009. On January 8, 2008, CMS published a proposed rule titled "Option for Prescription Drug Plans to Lower Their Premiums for Low-Income Subsidy Beneficiaries." It is our intent that the policy in the final version of this rule will replace the current "de minimis" policy.

B3. Coordination of Benefits (COB) User Fees

CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. CMS may review and update this user fee annually to reflect the costs associated with COB activities. For contract year 2008, the Part D COB user fee was \$1.36 per enrollee per year. Upon review of the anticipated costs of COB activities in 2009, the Part D COB user fee will increase to \$2.52 per enrollee per year for contract year 2009. This COB user fee will be collected at a rate of \$0.28 per enrollee per month from January to September (for an annual rate of \$0.21 per enrollee per month) for a total user fee of \$2.52 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2009 bids.

B4. Budget Neutrality Offsets for Reinsurance Payment Demonstration Plans in 2009

The budget neutrality offsets applied to the capitated reinsurance payments for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans will remain at \$10.00 per member per year for contract year 2009. The Part D Reinsurance Payment Demonstration is a budget neutral alternative payment approach that provides an incentive for Part D sponsors to offer supplemental drug coverage to Medicare beneficiaries. Under this demonstration, Medicare pays participating Part D plans a capitated reinsurance payment that is actuarially equivalent to the federal reinsurance payments that they would otherwise receive when a beneficiary reaches the catastrophic phase of the Part D benefit (\$4,050 in True Out-of-pocket costs for 2008).

This demonstration must be budget neutral as stated in the Instructions for Part D Payment Demonstration released on May 10, 2005 such that the expected Medicare costs under the demonstration are no more than the expected costs to the Medicare program in the absence of the demonstration. In order to ensure budget neutrality, the capitated reinsurance payments for all plans offered under the Part D Reinsurance Payment Demonstration were offset by \$10.00 per member per year in 2008.

As stated in the Federal Register Notice published on February 25, 2005 (70 FR 9360), in order to ensure budget neutrality for this payment demonstration, CMS may increase these offsets each year in order to reflect an increase in the expected costs of the demonstration. The capitated reinsurance payments for 2009 must continue to be offset by \$10.00 per member per year to ensure that the Part D Reinsurance Payment Demonstration remains budget neutral. When developing the 2009 bids for flexible capitated, fixed capitated, and Medicare Advantage rebate option plans, Part D sponsors should reflect this offset amount in the direct administrative expense line item of the Bid Pricing Tool (BPT).

Section C. Risk Adjustment

C1. Normalization Factor for the RxHCC Model

Please see Section C, item C3 in Attachment II, Changes in the Payment Methodology for Original Medicare Benefits for CY 2009.

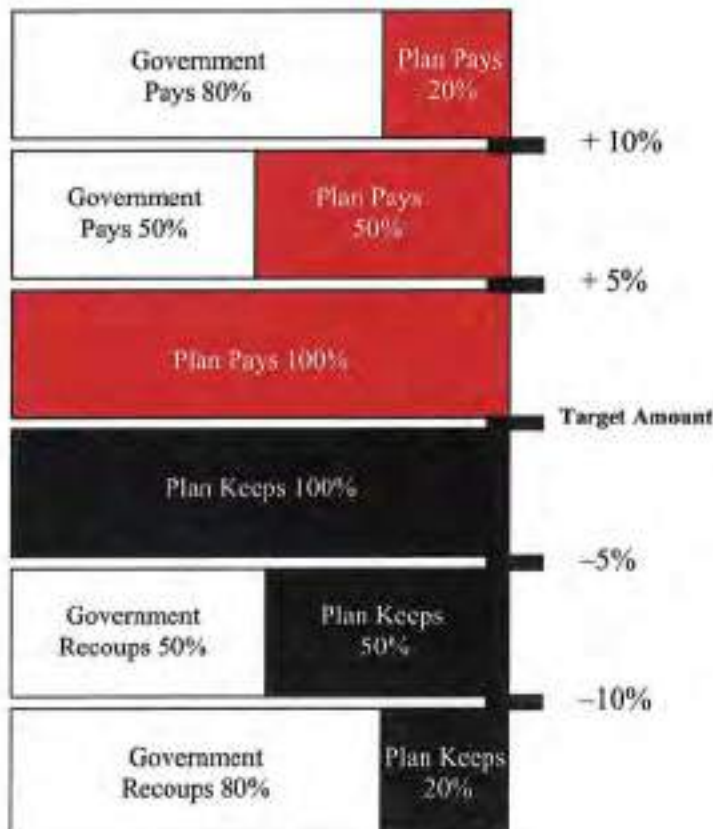
C2. Standard Set of ICD-9 Diagnosis Codes for Risk Adjustment

Please See Section K, item K2 in Attachment II, Changes in the Payment Methodology for Original Medicare Benefits for CY 2009.

Section D. Payment Reconciliation

Pursuant to section 1860D-15(e) of the Act and the regulations at 42 CFR 423.336, the risk percentages and payment adjustments for Part D risk sharing are unchanged from contract year 2008. The risk percentages for the first and second thresholds remain at 5% and 10% of the target amount respectively for 2009. The payment adjustments for the first and second corridors are 50% and 80% respectively. Please see Figure 1 below which illustrates the risk corridors for 2008-2011.

Figure 1. Part D Risk Corridors for 2008-2011



Attachment IV. Preliminary CMS-HCC Risk Adjustment Factors**Exhibit IV-1. Preliminary 2009 Community and Institutional Factors for the CMS-HCC Model**

Variable	Disease Group	Community Factors	Institutional Factors
Female			
0-34 Years		0.187	1.026
35-44 Years		0.206	0.884
45-54 Years		0.275	0.888
55-59 Years		0.333	0.943
60-64 Years		0.411	0.943
65-69 Years		0.299	0.971
70-74 Years		0.368	0.931
75-79 Years		0.457	0.835
80-84 Years		0.544	0.775
85-89 Years		0.637	0.704
90-94 Years		0.761	0.614
95 Years or Over		0.771	0.457
Male			
0-34 Years		0.120	1.030
35-44 Years		0.164	0.871
45-54 Years		0.217	0.871
55-59 Years		0.249	0.978
60-64 Years		0.389	1.015
65-69 Years		0.328	1.221
70-74 Years		0.413	1.154
75-79 Years		0.517	1.143
80-84 Years		0.597	1.087
85-89 Years		0.692	1.001
90-94 Years		0.834	0.932
95 Years or Over		0.980	0.743
Medicaid and Originally Disabled Interactions with Age and Sex			
Medicaid Female Aged		0.179	0.091
Medicaid Female Disabled		0.131	0.091
Medicaid Male Aged		0.166	0.091
Medicaid Male Disabled		0.077	0.091
Originally Disabled Female		0.204	0.023
Originally Disabled Male		0.168	0.023
Disease Coefficients			
	Description Label		
HCC1	HIV/AIDS	0.945	0.967
HCC2	Septicemia/Shock	0.759	0.764
HCC5	Opportunistic Infections	0.300	0.288
HCC7	Metastatic Cancer and Acute Leukemia	2.276	0.824
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	1.053	0.470

Variable	Disease Group	Community Factors	Institutional Factors
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	0.794	0.368
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	0.208	0.182
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation ¹	0.508	0.459
HCC16	Diabetes with Neurologic or Other Specified Manifestation ¹	0.408	0.459
HCC17	Diabetes with Acute Complications ¹	0.339	0.459
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation ¹	0.259	0.459
HCC19	Diabetes without Complication ¹	0.162	0.248
HCC21	Protein-Calorie Malnutrition	0.856	0.374
HCC25	End-Stage Liver Disease	0.978	0.654
HCC26	Cirrhosis of Liver	0.406	0.384
HCC27	Chronic Hepatitis	0.406	0.384
HCC31	Intestinal Obstruction/Perforation	0.311	0.345
HCC32	Pancreatic Disease	0.403	0.309
HCC33	Inflammatory Bowel Disease	0.241	0.205
HCC37	Bone/Joint/Muscle Infections/Necrosis	0.535	0.497
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	0.346	0.215
HCC44	Severe Hematological Disorders	1.015	0.493
HCC45	Disorders of Immunity	0.912	0.427
HCC51	Drug/Alcohol Psychosis ³	0.274	0.000
HCC52	Drug/Alcohol Dependence ³	0.274	0.000
HCC54	Schizophrenia	0.524	0.351
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	0.353	0.293
HCC67	Quadriplegia, Other Extensive Paralysis	1.011	0.434
HCC68	Paraplegia	0.993	0.434
HCC69	Spinal Cord Disorders/Injuries	0.558	0.225
HCC70	Muscular Dystrophy ¹	0.395	0.000
HCC71	Polyneuropathy	0.327	0.225
HCC72	Multiple Sclerosis	0.599	0.145
HCC73	Parkinson's and Huntington's Diseases	0.592	0.092
HCC74	Seizure Disorders and Convulsions	0.267	0.177
HCC75	Coma, Brain Compression/Anoxic Damage ³	0.415	0.000
HCC77	Respirator Dependence/Tracheostomy Status	1.867	1.559
HCC78	Respiratory Arrest	1.082	1.235
HCC79	Cardio-Respiratory Failure and Shock	0.578	0.445
HCC80	Congestive Heart Failure	0.410	0.228
HCC81	Acute Myocardial Infarction	0.359	0.424
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	0.284	0.424
HCC83	Angina Pectoris/Old Myocardial Infarction	0.244	0.290
HCC92	Specified Heart Arrhythmias	0.293	0.207
HCC95	Cerebral Hemorrhage	0.324	0.179
HCC96	Ischemic or Unspecified Stroke	0.265	0.179
HCC100	Hemiplegia/Hemiparesis	0.437	0.039
HCC101	Cerebral Palsy and Other Paralytic Syndromes ¹	0.180	0.000
HCC104	Vascular Disease with Complications	0.610	0.482
HCC105	Vascular Disease	0.316	0.165

Variable	Disease Group	Community Factors	Institutional Factors
HCC107	Cystic Fibrosis	0.399	0.631
HCC108	Chronic Obstructive Pulmonary Disease	0.399	0.359
HCC111	Aspiration and Specified Bacterial Pneumonias	0.703	0.573
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.249	0.181
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.252	0.497
HCC130	Dialysis Status	1.349	1.718
HCC131	Renal Failure	0.368	0.388
HCC132	Nephritis	0.125	0.253
HCC148	Decubitus Ulcer of Skin	1.153	0.485
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.449	0.241
HCC150	Extensive Third-Degree Burns ³	1.416	0.000
HCC154	Severe Head Injury ¹	0.415	0.000
HCC155	Major Head Injury ¹	0.106	0.000
HCC157	Vertebral Fractures without Spinal Cord Injury	0.443	0.161
HCC158	Hip Fracture/Dislocation ³	0.429	0.000
HCC161	Traumatic Amputation	0.678	0.260
HCC164	Major Complications of Medical Care and Trauma	0.296	0.309
HCC174	Major Organ Transplant Status	0.705	0.920
HCC176	Artificial Openings for Feeding or Elimination	0.662	0.841
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.678	0.260
Disabled/Disease Interactions			
D_HCC5	Disabled Opportunistic Infections	0.623	1.016
D_HCC44	Disabled Severe Hematological Disorders	1.036	0.362
D_HCC51	Disabled Drug/Alcohol Psychosis	0.729	0.299
D_HCC52	Disabled Drug/Alcohol Dependence	0.310	0.299
D_HCC107	Disabled Cystic Fibrosis ³	1.097	-
Disease Interactions			
INT1	DM CHF ²	0.154	0.125
INT2	DM CVD	0.102	0.028
INT3	CHF COPD	0.219	0.194
INT4	COPD CVD CAD	0.173	0.071
INT5	RF CHF ^{2,3}	0.231	-
INT6	RF CHF DM ²	0.477	0.358

NOTES:

¹ Includes Type I or Type II Diabetes Mellitus.

² Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not "credited" with the two-way interactions. All other interaction terms are additive.

³ HCC or disease interaction excluded from institutional model because estimated coefficient less than 0 or t-statistic less than 1.0.

The 2007 denominator of \$7,463.14 used to calculate both the community and institutional factors is the national predicted average annual cost under the model.

DM is diabetes mellitus (HCCs 15-19).

CHF is congestive heart failure (HCC 80).

COPD is chronic obstructive pulmonary disease (HCC 108).
CVD is cerebrovascular disease (HCCs 95, 96, 100, and 101).
CAD is coronary artery disease (HCCs 81-83).
RF is renal failure (HCC 131).

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.

SOURCE: RTI International analysis of 2004/2005 Medicare 100% institutional sample.

Exhibit IV-2. Preliminary Disease Hierarchies for the CMS-HCC Model

Hierarchical Condition Category (HCC)	If the Disease Group is Listed in This Column...	...Then Drop the Associated Disease Group(s) Listed in This Column
	Disease Group Label	
5	Opportunistic Infections	112
7	Metastatic Cancer and Acute Leukemia	8, 9, 10
8	Lung, Upper Digestive Tract, and Other Severe Cancers	9, 10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations or Peripheral Circulatory Manifestation	16, 17, 18, 19
16	Diabetes with Neurologic or Other Specified Manifestation	17, 18, 19
17	Diabetes with Acute Complications	18, 19
18	Diabetes with Ophthalmologic or Unspecified Manifestations	19
25	End-Stage Liver Disease	26, 27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67	Quadriplegia/Other Extensive Paralysis	68, 69, 100, 101, 157
68	Paraplegia	69, 100, 101, 157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78, 79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82, 83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105, 149
107	Cystic Fibrosis	108
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131, 132
131	Renal Failure	132
148	Decubitus Ulcer of Skin	149
154	Severe Head Injury	75, 155
161	Traumatic Amputation	177

How Payments are Made with a Disease Hierarchy – EXAMPLE: If a beneficiary triggers HCCs 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then HCC 149 will be dropped. In other words, payment will always be associated with the HCC in column 1 if a HCC in column 3 also occurs during the same collection period. Therefore, the MA organization's payment will be based on HCC 148 rather than HCC 149.

Exhibit IV-3. Preliminary 2009 CMS-HCC Model for New Enrollees

	Non-Medicaid & Non-Originally Disabled	Medicaid & Non-Originally Disabled	Non-Medicaid & Originally Disabled	Medicaid & Originally Disabled
Female				
0-34 Years	0.496	0.807	0.000	0.000
35-44 Years	0.652	0.963	0.000	0.000
45-54 Years	0.841	1.152	0.000	0.000
55-59 Years	0.969	1.280	0.000	0.000
60-64 Years	1.094	1.404	0.000	0.000
65 Years	0.497	0.958	1.096	1.557
66 Years	0.554	0.987	1.153	1.587
67 Years	0.595	1.028	1.194	1.628
68 Years	0.619	1.052	1.218	1.651
69 Years	0.652	1.085	1.251	1.684
70-74 Years	0.759	1.208	1.320	1.769
75-79 Years	0.955	1.357	1.430	1.832
80-84 Years	1.118	1.520	1.593	1.995
85-89 Years	1.255	1.657	1.730	2.132
90-94 Years	1.358	1.760	1.834	2.236
95 Years or Over	1.232	1.634	1.707	2.109
Male				
0-34 Years	0.344	0.675	0.000	0.000
35-44 Years	0.583	0.914	0.000	0.000
45-54 Years	0.729	1.060	0.000	0.000
55-59 Years	0.827	1.158	0.000	0.000
60-64 Years	1.033	1.365	0.000	0.000
65 Years	0.550	1.022	1.116	1.587
66 Years	0.586	1.058	1.117	1.589
67 Years	0.664	1.136	1.195	1.667
68 Years	0.664	1.136	1.195	1.667
69 Years	0.723	1.195	1.254	1.726
70-74 Years	0.855	1.322	1.392	1.859
75-79 Years	1.113	1.484	1.521	1.893
80-84 Years	1.299	1.670	1.707	2.078
85-89 Years	1.468	1.839	1.876	2.247
90-94 Years	1.630	2.001	2.038	2.409
95 Years or Over	1.638	2.009	2.046	2.417

NOTES:

The 2007 denominator of \$7,463.14 used to calculate the new enrollee factors is the national predicted average annual cost under the model.

Three sets of interaction coefficients were constrained to be equal (Male, Age 67 & Male, Age 68; Medicaid, Male, Age 65 & Medicaid, Male, Ages 66 to 69; Originally Disabled, Female, Age 65 & Originally Disabled, Female, Ages 66 to 69). These constraints are necessary so that predicted expenditures, and risk scores for all demographic groups, vary in a reasonable way, as shown in the table of mutually exclusive demographic groups.

SOURCE: RTI International analysis of 2004/2005 Medicare 5% sample.

**Attachment V. Medicare Part D Benefit Parameters for the Defined Standard Benefit:
Annual Adjustments for 2009**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs CMS to update the statutory parameters for the defined standard Part D drug benefit each year. These parameters include the standard deductible, initial coverage limit, and catastrophic coverage threshold, and minimum copayments for costs above the annual out-of-pocket threshold. In addition, CMS is statutorily required to update the parameters for the low income subsidy benefit and the cost threshold and cost limit for qualified retiree prescription drug plans eligible for the Retiree Drug Subsidy. Included in this notice are (i) the methodologies for updating these parameters, (ii) the updated parameter amounts for the Part D defined standard benefit and low-income subsidy benefit for 2009, and (iii) the updated cost threshold and cost limit for qualified retiree prescription drug plans.

As required by statute, the parameters for the defined standard benefit formula are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries. Accordingly, the actuarial value of the drug benefit increases along with any increase in drug expenses, and the defined standard Part D benefit continues to cover a constant share of drug expenses from year to year.

All of the Part D benefit parameters are updated using one of two indexing methods specified by statute: (i) the annual percentage increase in average expenditures for Part D drugs per eligible beneficiary, and (ii) the annual percentage increase in the Consumer Price Index (CPI) (all items, U.S. city average).

I. Annual Percentage Increase in Average Expenditures for Part D Drugs Per Eligible Beneficiary

Section 1860D-2(b)(6) of the Social Security Act defines the “annual percentage increase” as “the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.” The following parameters are updated using the “annual percentage increase”:

Deductible: From \$275 in 2008 and rounded to the nearest multiple of \$5.

Initial Coverage Limit: From \$2,510 in 2008 and rounded to the nearest multiple of \$10.

Out-of-Pocket Threshold: From \$4,050 in 2008 and rounded to the nearest multiple of \$50.

Minimum Cost-Sharing in the Catastrophic Coverage Portion of the Benefit: From \$2.25 per generic or preferred drug that is a multi-source drug, and \$5.60 for all other drugs in 2008, and rounded to the nearest multiple of \$0.05.

Maximum Copayments below the Out-of-Pocket Threshold for certain Low Income Full Subsidy Eligible Enrollees: From \$2.25 per generic or preferred drug that is a multi-source drug, and \$5.60 for all other drugs in 2008, and rounded to the nearest multiple of \$0.05.

Deductible for Low Income (Partial) Subsidy Eligible Enrollees: From \$56¹ in 2008 and rounded to the nearest \$1.

Maximum Copayments above the Out-of-Pocket Threshold for Low Income (Partial) Subsidy Eligible Enrollees: From \$2.25 per generic or preferred drug that is a multi-source drug, and \$5.60 for all other drugs in 2008, and rounded to the nearest multiple of \$0.05.

II. Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

Section 1860D-14(a)(4) of the Social Security Act specifies that the annual percentage increase in the CPI, All Urban Consumers (all items, U.S. city average) as of September of the previous year is used to update the maximum copayments below the out-of-pocket threshold for full benefit dual eligible enrollees with incomes that do not exceed 100% of the Federal poverty line. These copayments are increased from \$1.05 per generic or preferred drug that is a multi-source drug, and \$3.10 for all other drugs in 2008², and rounded to the nearest multiple of \$0.05 and \$0.10, respectively.

III. Calculation Methodology

Annual Percentage Increase

For the 2007 and 2008 contract years, the annual percentage increases, as defined in section 1860D-2(b)(6) of the Social Security Act, were based on the National Health Expenditure (NHE) prescription drug per capita estimates because sufficient Part D program data was not available. For the 2009 contract year benefit parameters, Part D program data is used to calculate the annual percentage trend as follows:

$$\frac{\text{August 2007} - \text{July 2008}}{\text{August 2006} - \text{July 2007}} = \frac{\$2,659.37}{\$2,509.48} = 1.0597$$

In the formula, the average per capita cost for August 2006 – July 2007 (\$2,509.48) is calculated from actual Part D prescription drug event (PDE) data and the average per capita cost for August 2007 – July 2008 (\$2,659.37) is calculated based on actual Part D PDE data incurred from August – December, 2007 and projected through July, 2008.

¹ Consistent with the statutory requirements of 1860D-14(a)(4)(B) of the Social Security Act, the update for the deductible for low income (partial) subsidy eligible enrollees is applied to the unrounded 2008 value of \$55.91.

² Consistent with the statutory requirements of 1860D-14(a)(4)(A) of the Social Security Act, the copayments are increased from the unrounded 2008 values of \$1.04 per generic or preferred drug that is a multi-source drug, and \$3.13 for all other drugs.

The 2009 benefit parameters reflect the 2008 annual percentage trend as well as a revision to the prior estimates for the 2006 and 2007 annual percentage increases. Based on the updated NHE prescription drug per capita costs, the 2007 and 2008 increases are now estimated to be 6.45% and 6.59%, respectively. Accordingly, the 2009 benefit parameters reflect a multiplicative update of 1.47% ($1.0645/1.0529 * 1.0659/1.0619 - 1$) for prior year revisions. In summary, the 2008 parameters outlined in section I are updated by 7.54% for 2009 as summarized by Table V-1.

Table V-1. Annual Percentage Increase

Annual percentage trend for July 2008	5.97%
Prior year revisions	1.48%
Annual percentage increase for 2008	7.54%

Note: Percentages are multiplicative, not additive.

Values are carried to additional decimal places and may not agree to the rounded values presented above.

Annual Percentage Increase in Consumer Price Index, All Urban Consumers (all items, U.S. city average)

The annual percentage increase in the CPI as of September of the previous year referenced in section 1860D-14(a)(4)(A)(ii) is interpreted to mean that, for contract year 2009, the September 2008 CPI should be used in the calculation of the index. To ensure that plan sponsors and CMS have sufficient time to incorporate the cost-sharing requirements into benefit, marketing material and systems development, the methodology to calculate this update includes an estimate of the September 2008 CPI based on the projected amount included in the President's FY2009 Budget. The September 2007 value is from the Bureau of Labor Statistics. The annual percentage trend in CPI for contract year 2009 is calculated as follows:

$$\frac{\text{Projected September 2008 CPI}}{\text{Actual September 2007 CPI}} \text{ or } \frac{213.9}{208.5} = 1.026$$

(Source: President's FY2009 Budget and Bureau of Labor Statistics, Department of Labor)

The 2009 benefit parameters reflect the 2008 annual percentage trend in the CPI, as well as a revision to the prior estimate for the 2007 annual percentage increase. The 2008 parameter update reflected an annual percentage trend in CPI of 2.17%. Based on the actual reported CPI for September 2007, the September 2007 CPI increase is now estimated to be 2.76%. Thus, the 2009 update reflects a multiplicative 0.57% ($1.0276/1.0217 - 1$) correction for prior year revisions. In summary, the cost sharing items outlined in section II are updated by 3.18% for 2009 as summarized by Table V-2.

Table V-2. Cumulative Annual Percentage Increase in CPI

Annual percentage trend for September 2008	2.60%
Prior year revisions	0.57%
Annual percentage increase for 2008	3.18%

Note: Percentages are multiplicative, not additive.
 Values are carried to additional decimal places and may not agree to the rounded values presented above.

IV. Part D Payment Demonstration Adjustment

The fixed capitated option of the Part D Payment Demonstration includes a catastrophic benefit that begins at the total drug expense corresponding to the out-of-pocket threshold in the Defined Standard Benefit. For 2009, this amount is increased from \$5,726.50 in 2008 to \$6,153.75. Specifically, this is the minimum amount of total covered Part D drug expenditures that will have occurred when the beneficiary reaches the out-of-pocket threshold of \$4,350 in 2009 in the defined standard benefit. This expense level is determined arithmetically as a function of the 2009 out-of-pocket threshold (as opposed to being indexed directly).

V. Retiree Drug Subsidy Amounts

As outlined in §423.886(b)(3) of the regulations implementing the Part D benefit, the cost threshold and cost limit for qualified retiree prescription drug plans that end in years after 2006 are adjusted in the same manner as the annual Part D deductible and out-of-pocket threshold are adjusted under §423.104(d)(1)(ii) and (d)(5)(iii)(B), respectively. Specifically, they are adjusted by the "annual percentage increase" as defined previously in this document and the cost threshold is rounded the nearest multiple of \$5 and the cost limit is rounded to the nearest multiple of \$50. The cost threshold and cost limit are defined as \$265 and \$5,350, respectively, for plans that end in 2007, and, as \$275 and \$5,600, respectively, for plans that end in 2008. For 2009, the cost threshold is increased to \$295, and the cost limit is increased to \$6,000.

EXHIBIT D-40



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

☐ PICA										☐ PICA									
1. MEDICARE ☐ (Medicare) MEDICAID ☐ (Medicaid) TRICARE ☐ (TRICARE) CHAMPVA ☐ (Champion) GROUP HEALTH PLAN ☐ (Group) FICA BACKLASH ☐ (FICA) OTHER ☐ (Other)										1a. INSURED'S I.D. NUMBER (For Program in Item 1)									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)										3. PATIENT'S BIRTH DATE MM DD YY SEX ☐ M ☐ F									
5. PATIENT'S ADDRESS (No. Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)										4. INSURED'S NAME (Last Name, First Name, Middle Initial)									
6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐										7. INSURED'S ADDRESS (No. Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)									
8. RESERVED FOR NUCC USE										9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)									
10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) ☐ YES ☐ NO b. AUTO ACCIDENT? ☐ YES ☐ NO c. OTHER ADJACENT? ☐ YES ☐ NO										11. IS THERE ANOTHER HEALTH BENEFIT PLAN? ☐ YES ☐ NO If yes, complete items 2, 3a, and 3d.									
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED:										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.) SIGNED:									
14. DATE OF CURRENT ILLNESS MM DD YY FREQUENCY (Last time) MM DD YY										15. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY									
17. NAME OF REFERRING PHYSICIAN (Last Name, First Name, Middle Initial)										16. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY									
19. ADDITIONAL CLAIM INFORMATION (Signature)										20. OUTSIDE LAB? ☐ YES ☐ NO \$ CHARGES									
21. PRIOR AUTHORIZATION NUMBER										22. SUBMISSION CODE ORIGINAL REF. NO.									
24. A. DATES OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. PROCEDURE, SERVICE, OR SUPPLY (Explain Unusual Circumstances) CPT/HCPCD D. MODIFIER E. DIAGNOSIS ICD-9 F. \$ CHARGES G. CODE OR UNIT H. ICD-9 QUAL I. RENDERING PROVIDER ID #										25. FEDERAL TAX I.D. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT ☐ YES ☐ NO 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Revid for NUCC Use									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED: DATE:										32. SERVICE FACILITY LOCATION INFORMATION									
33. BILLING PROVIDER INFO & PRI #										34. BILLING PROVIDER INFO & PRI #									

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PECA

PRISA

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

EXHIBIT D-41

February 24, 2012

**Notice of Final Payment Error Calculation Methodology for
Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits**

Introduction

On December 21, 2010 the Centers for Medicare and Medicaid Services (CMS) posted on its website the "Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment". CMS invited public comment on the proposed methodology, with such comments to be submitted in writing by Friday, January 21, 2011.

CMS carefully reviewed the more than 500 comments received on the draft methodology. This Notice responds to the analytic concerns raised relating to extrapolation and payment recovery and presents the final methodology for the RADV payment error calculation.

Following the background section, this Notice provides a general walkthrough of the RADV payment error calculation methodology in two sections: (A) sampling; and (B) payment error calculation.

This methodology will be applied to the next round of RADV contract-level audits, which will be conducted on payment year 2011. Payment year 2011 is the first year for which payment recovery based on extrapolated estimates will be conducted for Medicare Advantage (MA). Note that sampling for RADV audits will occur after the close of final reconciliation for the payment year being audited.

CMS' RADV audit initiative is the Agency's primary strategy to address the national payment error rate for the MA program, which is currently estimated to be 11 percent for FY 2011. In addition to recovery of overpayments through RADV audits, CMS also expects that these contract-level audits will have a sentinel effect on the quality of risk adjustment data submitted for payment by MA organizations.

Background

Section 1853(a)(3) of the Social Security Act requires that CMS risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes submitted by MA organizations are used to determine beneficiary risk scores, which in turn determine the risk-adjusted reimbursement.

RADV audits determine whether the diagnosis codes submitted by MA organizations can be validated by supporting medical record documentation. This medical record documentation must meet certain criteria and standards specified in RADV materials that CMS provides to audited contracts. Diagnoses that cannot be validated contribute to a payment error rate. This document describes the sampling

methodology that CMS will use for RADV audits and the methodology for calculating the payment error for each audited Medicare Advantage contract.

A. Sampling

To conduct these audits, CMS selects a set of MA contracts for each RADV audit cycle. Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment.

Sampling Frame

First, CMS identifies all beneficiaries under each MA contract who are "RADV-eligible" because they meet the following criteria:

1. Enrolled in an MA contract (H-number, E-number, or R-number) in January of the payment year— based on CMS' monthly member enrollment files;
2. Continuously enrolled in the same MA contract (as identified in step (1) above) from January of the data collection year through January of the payment year;
3. Non-End Stage Renal Disease (non-ESRD) status from January of the data collection year through January of the payment year;
4. Non-hospice status from January of the data collection year through January of the payment year;
5. Enrolled in Medicare Part B coverage for all 12 months during the data collection year (i.e., defined as full risk enrollees for risk adjusted payment); and
6. Had at least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection year that led to at least one CMS-Hierarchical Condition Category (HCC) assignment for the payment year.

Sample Size and Strata

Next, CMS selects a sample of beneficiaries from each contract's cohort of RADV-eligible enrollees. Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the RADV-eligible enrollees in each contract will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum.

CMS will select up to 201 enrollees for medical record review from each contract selected for a contract-level audit. For smaller contracts, i.e., those with fewer than 1,000 RADV-eligible enrollees, CMS will individually adjust their sample sizes by using the finite population correction factor. The sample sizes for these smaller contracts will be 201 or fewer enrollees.

To achieve a sample size of 201 enrollees per contract, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample, i.e., N_h/n_h , where h represents the corresponding stratum.

For example, if a contract has 3,000 RADV-eligible enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be randomly selected from each group. The weight for each sampled enrollee will equal 14.925 (i.e., $1,000/67$).

For small contracts with fewer than 1,000 RADV-eligible enrollees, the same enrollee-based stratification process will be applied; however, a proportionally smaller number of enrollees will be randomly sampled from each group or stratum.

The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population it represents.

Once enrollees have been selected, the MA contract will be required to submit medical records to support all CMS-HCCs represented in the sampled beneficiaries' risk scores for the payment year.

Effective with the CY 2011 RADV audit, CMS will allow audited MA contracts to submit multiple medical records for each CMS-HCC being validated. All diagnoses will be abstracted from the first medical record that validates the CMS-HCC under review. The one best medical record policy will continue to apply to the RADV audit dispute and appeal processes outlined in 42 CFR §422.311. CMS will provide more detailed information in the RADV audit procedures that will be distributed to audited MA contracts.

B. Payment Error Calculation

Enrollee-level Payment Error Calculation

CMS will calculate each contract's payment error based on the validation results. For each sampled enrollee, the RADV-corrected risk score and corrected payment will be calculated based on the CMSHCCs that are supported by RADV medical record review findings for the enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the RADV-corrected payment (per member per month). The payment error for each enrollee will be either positive (representing a net overpayment), or negative (representing a net underpayment). An annual payment error amount will be calculated for each sampled enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year.

Payment Error Extrapolation Calculation

To derive the payment error estimate for each MA contract, the annual payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed for each stratum [h] during the sampling phase as N_h/n_h , where N represents the number of enrollees in the RADV-eligible population and n is the number of enrollees sampled). The weighted enrollee annual payment error will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract (the "point estimate"). A 99 percent confidence interval (CI) will then be calculated for the estimated payment error for each audited MA contract.

The following formulas illustrate computation of a 99 percent CI around the payment error estimate for one contract, assuming a sample size of 201, with 67 enrollees selected from each of three strata groupings.

The lower bound of the 99 percent CI is computed as the estimated payment error for the contract (PE) minus (2.575 multiplied by the standard error), or $(PE - (2.575 * SE))$. The standard error (SE) can be calculated as follows:

1. Derive the variance, v_h , (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (h).
2. Calculate the variance of the estimated total (V_T) payment error, where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1st, 2nd, 3rd) stratum:

$$= \sum_h \frac{N_h^2}{67} V_T V_h$$

3. The standard error is $SE_T = \sqrt{V_T}$

Payment Recovery Amount and the Fee-For-Service Adjuster

If the CI for the point estimate includes zero or is below zero, the contract will have the payment recovery amount constrained to zero.

If the CI for the point estimate is above zero, the payment recovery amount for the contract will be determined as follows. First, a preliminary payment recovery amount will be set at the lower bound of the 99 percent CI for the contract's point estimate. Second, to determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard

used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

EXHIBIT D-42

Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model

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This article describes the CMS hierarchical condition categories (HCC) model implemented in 2004 to adjust Medicare capitation payments to private health care plans for the health expenditure risk of their enrollees. We explain the model's principles, elements, organization, calibration, and performance. Modifications to reduce plan data reporting burden and adaptations for disabled, institutionalized, newly enrolled, and secondary-payer subpopulations are discussed.

INTRODUCTION

Medicare is one of the world's largest health insurance programs, with annual expenditures exceeding \$200 billion. It provides health insurance to nearly 40 million beneficiaries entitled by elderly age, disability, or ESRD. Approximately 11 percent of Medicare beneficiaries are enrolled in private managed care health care plans, with the rest in the traditional FFS program. The 1997 BBA modified the Medicare managed care (MMC) and other capitated programs, collectively called

M+C.¹ Medicare pays private plans participating in M+C a monthly capitation rate to provide health care services to enrolled beneficiaries.

Historically, capitation payments to MMC plans were linked to FFS expenditures by geographic area, with payments set at 95 percent of an enrollee's county's adjusted average per capita cost (AAPCC). The AAPCC actuarial rate cells were defined by: age, sex, Medicaid enrollment (indicating poverty), institutional status (for nursing home residents), and working aged status (for beneficiaries with employer-based insurance where Medicare is a secondary payer). Separate county factors were calculated for the aged and non-aged disabled (under 65 years), and at the State-level only (due to small numbers), for ESRD-entitled beneficiaries.

The AAPCC payment methodology explains only about 1-percent of the variation in expenditures for Medicare beneficiaries, and does not pay more for sicker people. Thus, research showed that the managed care program was increasing total Medicare Program expenditures, because its enrollees were healthier than FFS enrollees, and the AAPCC did not account for this favorable selection (Brown et al., 1993; Riley et al., 1996; Mello et al.,

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¹ The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) renames the M+C program Medicare Advantage. However, since this renaming does not officially take place until 2006, we continue to use M+C.

2003). Also, more money was not directed to plans enrolling sicker beneficiaries, or to plans specializing in treating high-cost populations, such as beneficiaries with particular chronic diseases or high levels of functional impairment.

The M+C program fundamentally changed the MMC payment method, including a mandate for health-based Medicare capitation payments by 2000. To support this mandate, the BBA required managed care organizations (MCOs) to report inpatient encounter data (i.e., records for each inpatient admission of a plan's enrollees noting, among other things, the beneficiaries' diagnoses) beginning in 1998. In 2000 CMS, which administers the Medicare Program, implemented the PIP-DCG model as a health-based payment adjuster (Pope et al., 2000a). This model estimates beneficiary health status (expected cost next year) from AAPCC-like demographics and the worst principal inpatient diagnosis (principal reason for inpatient stay) associated with any hospital admission. PIP-DCG-based payments were introduced gradually, with only 10 percent of total Medicare capitation payments adjusted by PIP-DCG factors in 2000. The other 90 percent of payments were still adjusted using a purely demographic (AAPCC-like) model.

The PIP-DCG model was intended as a transition, a feasible way to implement risk adjustment based on the readily available, already audited inpatient diagnostic data. Relying on inpatient diagnoses is the PIP-DCG model's major shortcoming, since only illnesses that result in hospital admissions are counted; MCOs that reduce admissions (e.g., through good ambulatory care) can end up with apparently healthier patients and lower payments. Congress's BIPA (2000) addressed the PIP-DCG limitations by requiring the use of ambulatory diagnoses in Medicare risk-

adjustment, to be phased in from 2004 to 2007 at 30, 50, 75, and 100 percent of total payments. CMS began collecting encounter data from MCOs for the physician office and hospital outpatient settings (i.e., records of each enrollee visit to these providers with dates, procedures performed, diagnoses, etc.) in October 2000 and April 2001, respectively. However, following complaints from MCOs about the burden of reporting encounter data, CMS suspended data collection in May 2001, ultimately adopting a drastically streamlined data reporting strategy (discussed later).

CMS evaluated several risk-adjustment models that use both ambulatory and inpatient diagnoses, including ACGs (Weiner et al., 1996), the chronic disease and disability payment system (CDPS) (Kronick et al., 2000), clinical risk groups (CRGs) (Hughes et al., 2004), the clinically detailed risk information system for cost (CD-RISC) (Kapur et al., 2003), and DCG/HCCs (Pope et al., 2000b). CMS chose the DCG/HCC model for Medicare risk-adjustment, largely on the basis of transparency, ease of modification, and good clinical coherence. The DCG/HCC model, part of the same DCG family of models as the PIP-DCG, was developed with CMS funding by researchers at RTI International² and Boston University, with clinical input from physicians at Harvard Medical School.³

Prior to implementing Medicare risk-adjustment in 2004, the DCG/HCC model developers and CMS staff adapted the original model for consistency with CMS' simplified data collection, and for customized fit for Medicare subpopulations. The resulting CMS-HCC model reflects these

² The early development of the DCG/HCC model was done by Health Economics Research, Inc. while under contract to CMS. However, RTI International acquired Health Economics Research, Inc. in 2002.

³ The original version of the DCG/HCC model is described in Ellis et al. (1996). The DCG/HCC model has been refined as described in Pope et al., 1998 and 2000b.

Medicare-specific adaptations of the DCG/HCC model and provides a comprehensive framework for Medicare risk-adjustment.

This article describes the DCG/HCC and CMS-HCC models. The next section describes the DCG/HCC model, including the principles and elements of its diagnostic classification system and how its performance compares to earlier models. We then describe the modifications to accommodate the simplified data that lead to the CMS-HCC model. The final section describes the CMS-HCC model adaptations for subpopulations.

DCG/HCC MODEL PRINCIPLES

Diagnostic Classification System

The following ten principles guided the creation of the diagnostic classification system.

Principle 1—Diagnostic categories should be clinically meaningful. Each diagnostic category is a set of ICD-9-CM codes (Centers for Disease Control and Prevention, 2004). These codes should all relate to a reasonably well-specified disease or medical condition that defines the category. Conditions must be sufficiently clinically specific to minimize opportunities for gaming or discretionary coding. Clinical meaningfulness improves the face validity of the classification system to clinicians, its interpretability, and its utility for disease management and quality monitoring.

Principle 2—Diagnostic categories should predict medical expenditures. Diagnoses in the same HCC should be reasonably homogeneous with respect to their effect on both current (this year's) and future (next year's) costs. (In this article we present prospective models predicting future costs.)

Principle 3—Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures. Diagnostic categories used in establishing payments should have adequate sample sizes in available data sets. Given the extreme skewness of medical expenditure data, the data cannot reliably determine the expected cost of extremely rare diagnostic categories.

Principle 4—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, while the effects of unrelated disease processes accumulate. Because each new medical problem adds to an individual's total disease burden, unrelated disease processes should increase predicted costs of care. However, the most severe manifestation of a given disease process principally defines its impact on costs. Therefore, related conditions should be treated hierarchically, with more severe manifestations of a condition dominating (and zeroing out the effect of) less serious ones.

Principle 5—The diagnostic classification should encourage specific coding. Vague diagnostic codes should be grouped with less severe and lower-paying diagnostic categories to provide incentives for more specific diagnostic coding.

Principle 6—The diagnostic classification should not reward coding proliferation. The classification should not measure greater disease burden simply because more ICD-9-CM codes are present. Hence, neither the number of times that a particular code appears, nor the presence of additional, closely related codes that indicate the same condition should increase predicted costs.

Principle 7—Providers should not be penalized for recording additional diagnoses (monotonicity). This principle has

two consequences for modeling: (1) no condition category should carry a negative payment weight, and (2) a condition that is higher-ranked in a disease hierarchy (causing lower-rank diagnoses to be ignored) should have at least as large a payment weight as lower-ranked conditions in the same hierarchy.

Principle 8—The classification system should be internally consistent (transitive). If diagnostic category A is higher-ranked than category B in a disease hierarchy, and category B is higher-ranked than category C, then category A should be higher-ranked than category C. Transitivity improves the internal consistency of the classification system, and ensures that the assignment of diagnostic categories is independent of the order in which hierarchical exclusion rules are applied.

Principle 9—The diagnostic classification should assign all ICD-9-CM codes (exhaustive classification). Since each diagnostic code potentially contains relevant clinical information, the classification should categorize all ICD-9-CM codes.

Principle 10—Discretionary diagnostic categories should be excluded from payment models. Diagnoses that are particularly subject to intentional or unintentional discretionary coding variation or inappropriate coding by health plans/providers, or that are not clinically or empirically credible as cost predictors, should not increase cost predictions. Excluding these diagnoses reduces the sensitivity of the model to coding variation, coding proliferation, gaming, and upcoding.

In designing the diagnostic classification, principles 7 (monotonicity), 8 (transitivity), and 9 (exhaustive classification) were followed absolutely. For example, if the expenditure weights for our models did not originally satisfy monotonicity, we imposed constraints to create models that did. Judgment was used to make tradeoffs

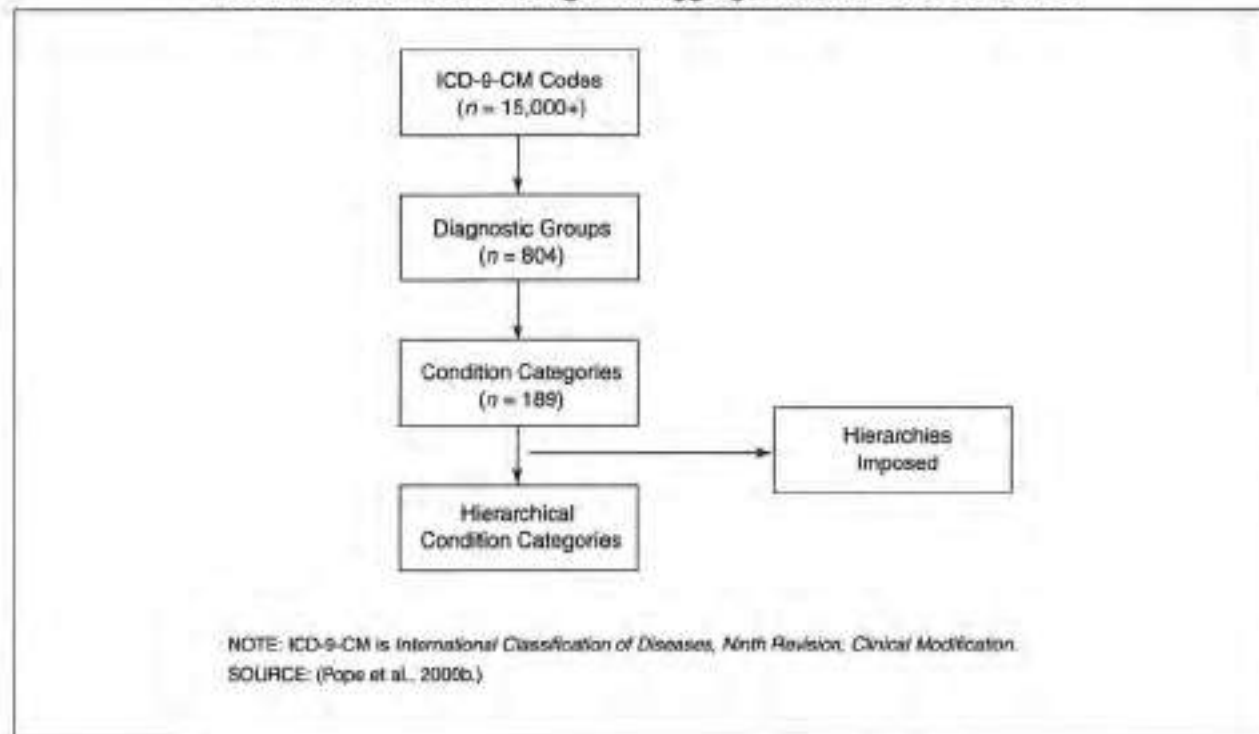
among other principles. For example, clinical meaningfulness (principle 1) is often best served by creating a very large number of detailed clinical groupings. But a large number of groupings conflicts with adequate sample sizes for each category (principle 3). Another tradeoff is encouraging specific coding (principle 5) versus predictive power (principle 2). In current coding practice, non-specific codes are common. If these codes are excluded from the classification system, substantial predictive power is sacrificed. Similarly, excluding discretionary codes (principle 10) can also lower predictive power (principle 2). We approached the inherent tradeoffs involved in designing a classification system using empirical evidence on frequencies and predictive power, clinical judgment on relatedness, specificity, and severity of diagnoses, and the judgment of the authors on incentives and likely provider responses to the classification system. The DCG/HCC models balance these competing goals to achieve a feasible health-based payment system.

Elements and Organization

As shown in Figure 1, the HCC diagnostic classification system first classifies each of over 15,000 ICD-9-CM codes into 804 diagnostic groups, or DxGroups. Each ICD-9-CM code maps to exactly one DxGroup, which represents a well-specified medical condition, such as DxGroup 28.01 Acute Liver Disease. DxGroups are further aggregated into 189 Condition Categories, or CCs.⁴ CCs describe a broader set of similar diseases, generally organized into body systems, somewhat like ICD-9-CM major diagnostic categories.

⁴ Most CCs are assigned entirely with ICD-9-CM codes. But CCs 185-189 are assigned by beneficiary utilization of selected types of DME, such as wheelchairs. CC 173, Major Organ Transplant, is defined by procedure codes only. CC 129, ESRD is defined by Medicare entitlement status. None of these CCs are included in the CMS-HCC model.

Figure 1
Hierarchical Condition Categories Aggregations of ICD-9-CM Codes



Although they are not as homogeneous as DxGroups, CCs are both clinically- and cost-similar. An example is CC 28 Acute Liver Failure/Disease that includes DxGroups 28.01 and 28.02 Viral Hepatitis, Acute or Unspecified, with Hepatic Coma.

Hierarchies are imposed among related CCs, so that a person is only coded for the most severe manifestation among related diseases. For example (Figure 2), ICD-9-CM Ischemic Heart Disease codes are organized in the Coronary Artery Disease hierarchy, consisting of 4 CCs arranged in descending order of clinical severity and cost, from CC 81 Acute Myocardial Infarction to CC 84 Coronary Atherosclerosis/Other Chronic Ischemic Heart Disease. A person with an ICD-9-CM code in CC 81 is excluded from being coded in CCs 82, 83, or 84 even if codes that group into those categories were also present. Similarly, a person with ICD-9-CM codes that group into both CC 82 Unstable Angina and Other Acute Ischemic Heart

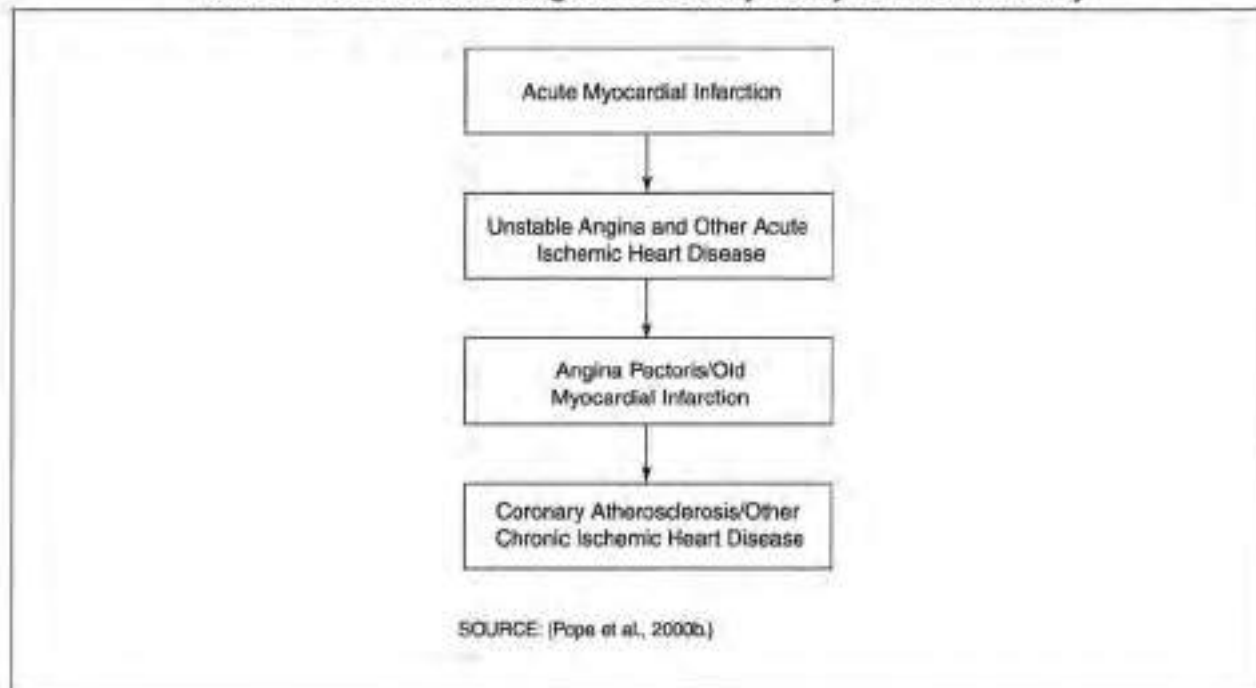
Disease, and CC 83 Angina Pectoris/Old Myocardial Infarction is coded for CC 82, but not CC 83. After imposing hierarchies, CCs become Hierarchical Condition Categories, or HCCs.⁵

Although HCCs reflect hierarchies among related disease categories, for unrelated diseases, HCCs accumulate. For example, a male with heart disease, stroke, and cancer has (at least) three separate HCCs coded, and his predicted cost will reflect increments for all three problems. The HCC model is more than simply additive because some disease combinations interact. For example, the presence of both Diabetes and Congestive Heart Failure (CHF) could increase predicted cost by more (or less) than the sum of the separate increments for people who have diabetes or CHF alone.

We tested 35 two- and three-way interactions among six common and high-cost chronic diseases defined by HCCs or

⁵The full list of hierarchies used in the CMS-HCC model is available on request from the authors.

Figure 2
Hierarchical Condition Categories Coronary Artery Disease Hierarchy



groups of HCCs: diabetes, cerebrovascular disease, vascular disease, or chronic obstructive pulmonary disease (COPD), CHF, and coronary artery disease (Pope et al., 2000b), as well as three interactions of several of these conditions with renal failure.⁶ Simple additivity yields most of the explanatory power, in the sense that adding all 38 interactions barely increased the base DCG/HCC model's R^2 (from 11.10 to 11.13 percent). However, six interactions were substantial in magnitude, statistically significant, and clinically plausible. Hence, to improve clinical face validity and predictive accuracy for important subgroups of beneficiaries, we include them in the DCG/HCC model. For example, the simultaneous presence of CHF and COPD leads to higher expected costs than would be calculated by adding the separate increments for CHF and COPD alone.

⁶ In later work unpublished work, we also examined all two-way interactions of cancer with the other six diagnoses, but did not find any significant effects.

Because a single beneficiary may be coded for none, one, or more than one DxGroup or HCC, the DCG/HCC model can individually price tens of thousands of distinct clinical profiles using fewer than 200 parameters. The model's structure thus provides, and predicts from, a detailed comprehensive clinical profile for each individual.

HCCs are assigned using hospital and physician diagnoses from any of five sources: (1) principal hospital inpatient; (2) secondary hospital inpatient; (3) hospital outpatient; (4) physician; and (5) clinically-trained non-physician (e.g., psychologist, podiatrist). The DCG/HCC model does not distinguish among sources; in particular, it places no premium on diagnoses from inpatient care. Using Medicare 5-percent sample FFS data, we investigated adding diagnoses from other sources (Pope et al., 2000b). Adding diagnoses from home health providers raised the explanatory power of the base model from

11.15 to 11.65 percent. Further adding diagnoses from DME suppliers raised the explanatory power from 11.65 to 11.85 percent. All other sources of diagnoses either add no predictive power (SNF, ASC, or hospice) or detract from predictive power (clinical laboratory and radiology/imaging clinics). Diagnoses assigned by home health and DME providers are likely to be less reliable than those assigned by physicians or other providers with greater clinical training. Diagnoses from laboratory and imaging tests are also problematic given the significant proportion of rule-out diagnoses. In implementing the CMS-HCC model, potential gains in predictive power from using additional sources were balanced against the costs of collecting and auditing these data; the decision was to only ask MCOs to collect diagnoses from the five baseline sources previously listed.

Consistent with principle 10, we excluded discretionary diagnostic categories (HCCs) from the preliminary prospective payment model. We excluded diagnoses that were vague/non-specific (e.g., symptoms), discretionary in medical treatment or coding (e.g., osteoarthritis), not medically significant (e.g., muscle strain), or transitory or definitively treated (e.g., appendicitis). We also excluded HCCs that did not (empirically) add to costs, and finally, the five HCCs that were defined by the presence of procedures or use of DME, because, as much as possible, we wanted payments to follow what medical problems were present as opposed to what services were offered.⁷ Altogether, we excluded 88 of the 189 HCCs, leaving 101 HCCs in the preliminary prospective payment model. As discussed further, additional HCCs were excluded from the final, 70-category CMS-HCC model.

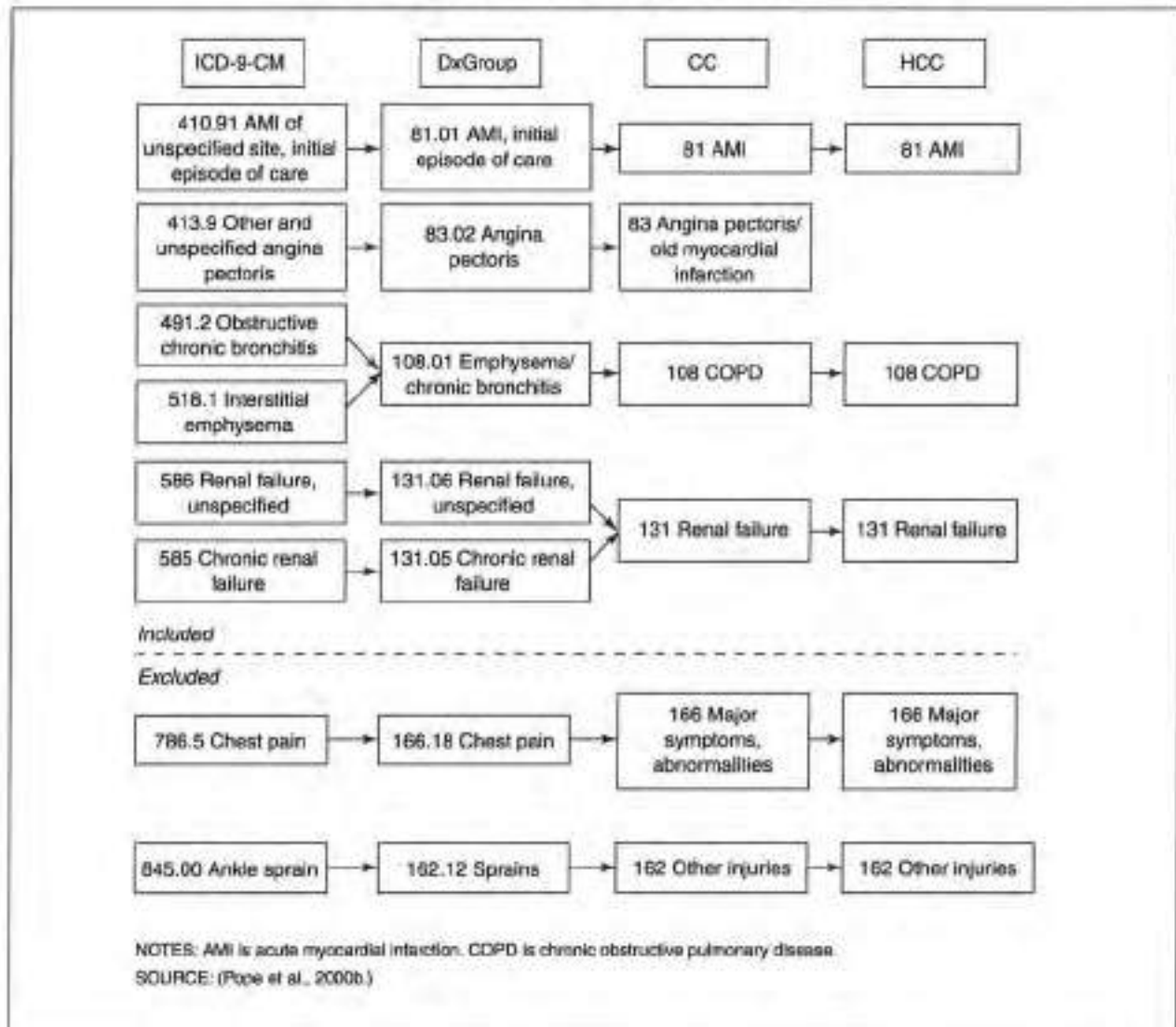
⁷ The DME HCCs were developed to predict costs associated with functional impairment not captured by diagnoses. Although they did improve prediction for the functionally impaired, substantial under-prediction remained (Pope et al., 2000b; Kantter and Pope, 2001).

The DCG/HCC model also relies on demographics. Demographic adjusters included in the model are 24 mutually exclusive age/sex cells (e.g., female, age 65-69), an indicator for at least 1-month of Medicaid enrollment in the base year (a poverty indicator), and an indicator of originally disabled status. The age cells distinguish beneficiaries currently entitled to Medicare by age (65 or over) versus disability (under 65); a separate, explicit aged versus disabled entitlement status indicator would be redundant. The originally disabled indicator distinguishes beneficiaries who are currently age 65 or over, but were first entitled to Medicare before age 65 by disability. The age/sex, Medicaid, and originally disabled categories add to each other and to the HCC diagnostic categories.⁸ The demographic variables are the same as have been used in the PIP-DCG model, and are discussed at greater length elsewhere (Pope et al., 2000a).

Figure 3 displays a hypothetical clinical vignette of a female age 79, eligible for Medicaid and diagnosed with acute myocardial infarction (AMI), angina pectoris, COPD, renal failure, chest pain, and an ankle sprain. Note that although this female receives CCs for both AMI and angina, she receives no HCC for angina because AMI is a more severe manifestation of coronary artery disease. Also note that while payment includes additive increments for females age 75-79 (demographic categories not shown in Figure 3), Medicaid, AMI, COPD, and renal failure, the HCCs for major symptoms and other injuries are excluded from the payment calculation. Chest pain is a symptom associated with a variety of medical conditions ranging from minor to serious, and sprains are transitory, with minimal implications for next year's cost.

⁸ We did not systematically investigate interactions of age and sex with HCCs (diagnoses). This is a subject for future research.

Figure 3
Clinical Vignette for Hierarchical Condition Categories Classification 79 Year Old Female with AMI, Angina Pectoris, COPD, and Renal Failure



PERFORMANCE OF DCG/HCC AND PIP-DCG MODELS

The predictive accuracy of risk-adjustment models is typically judged by the R^2 statistic (percentage of variation explained) to measure predictive accuracy for individuals and predictive ratios (ratios of mean predicted to mean actual expenditures for subgroups of beneficiaries) to measure predictive accuracy for groups. The R^2 of age/sex, PIP-DCG, and DCG/HCC models as measured on 1996-1997 Medicare's 5-

percent sample FFS data are: age/sex, 1.0 percent; PIP-DCG, 6.2 percent; and DCG/HCC, 11.2 percent.

Adding PIP-DCG to demographic predictors (age/sex) increases predictive power sixfold. Adding secondary inpatient and ambulatory diagnoses (hospital outpatient and physician), and arraying them in a multi-condition cumulative model (DCG/HCC) nearly doubles the power again. Besides the R^2 , another interesting summary statistic is the percentage of payments based on demographic variables: 100

Table 1
Predictive Ratios¹ for Alternative Risk-Adjustment Models

Category	Model		
	Age/Sex	PIP-DCG	DCG/HCC
Quintiles of Expenditures			
First (Lowest)	2.66	2.09	1.23
Second	1.93	1.54	1.23
Third	1.37	1.10	1.14
Fourth	0.95	0.84	1.02
Fifth (Highest)	0.44	0.75	0.86
Top 5 Percent	0.28	0.61	0.77
Top 1 Percent	0.17	0.47	0.69
Hospitalizations			
None	1.33	1.07	1.03
1	0.63	1.02	1.02
2	0.44	0.91	0.98
3 or More	0.26	0.69	0.82
Diagnoses²			
Heart Failure	0.47	0.74	0.97
Heart Attack	0.45	0.78	0.98
COPD	0.59	0.79	0.99
Hip Fracture	0.56	0.83	0.99
Depression	0.54	0.77	0.92
Colorectal Cancer	0.60	0.78	0.98
Cerebral Hemorrhage	0.44	0.73	1.04

¹ Mean predicted cost divided by mean actual cost.

² From either inpatient or ambulatory setting.

NOTES: Expenditures, hospitalizations, and diagnoses are measured in the base year. COPD is chronic obstructive pulmonary disease.

SOURCE: (Pope et al., 2000b.)

percent in a demographic model, 81 percent in the PIP-DCG model, but only 43 percent in the DCG/HCC model (Pope et al., 2001). With over one-half of payments determined by diagnoses, the DCG/HCC model moves decisively away from the AAPCC demographic-based payment system.

Table 1 shows predictive ratios for selected groups of Medicare beneficiaries. Ratios close to 1.0 indicate accurate prediction of costs; less than 1.0, under prediction; and, more than 1.0, over prediction. The PIP-DCG model improves substantially on age/sex, and in almost all cases, the DCG/HCC model improves significantly on the PIP-DCG model. This is true even for hospitalizations, where the PIP-DCG model distinguishes between those hospitalized or not, while the DCG/HCC model makes no distinction by source of diagnosis.⁹ Despite the DCG/HCC model's

⁹The DCG/HCC model captures multiple conditions that might be diagnosed in multiple inpatient stays, whereas the PIP-DCG model captures only the single principal inpatient diagnosis most predictive of future costs if multiple inpatient stays occur.

impressive gains over the age/sex and PIP-DCG models, it still under-predicts for the most expensive and most often hospitalized beneficiaries.

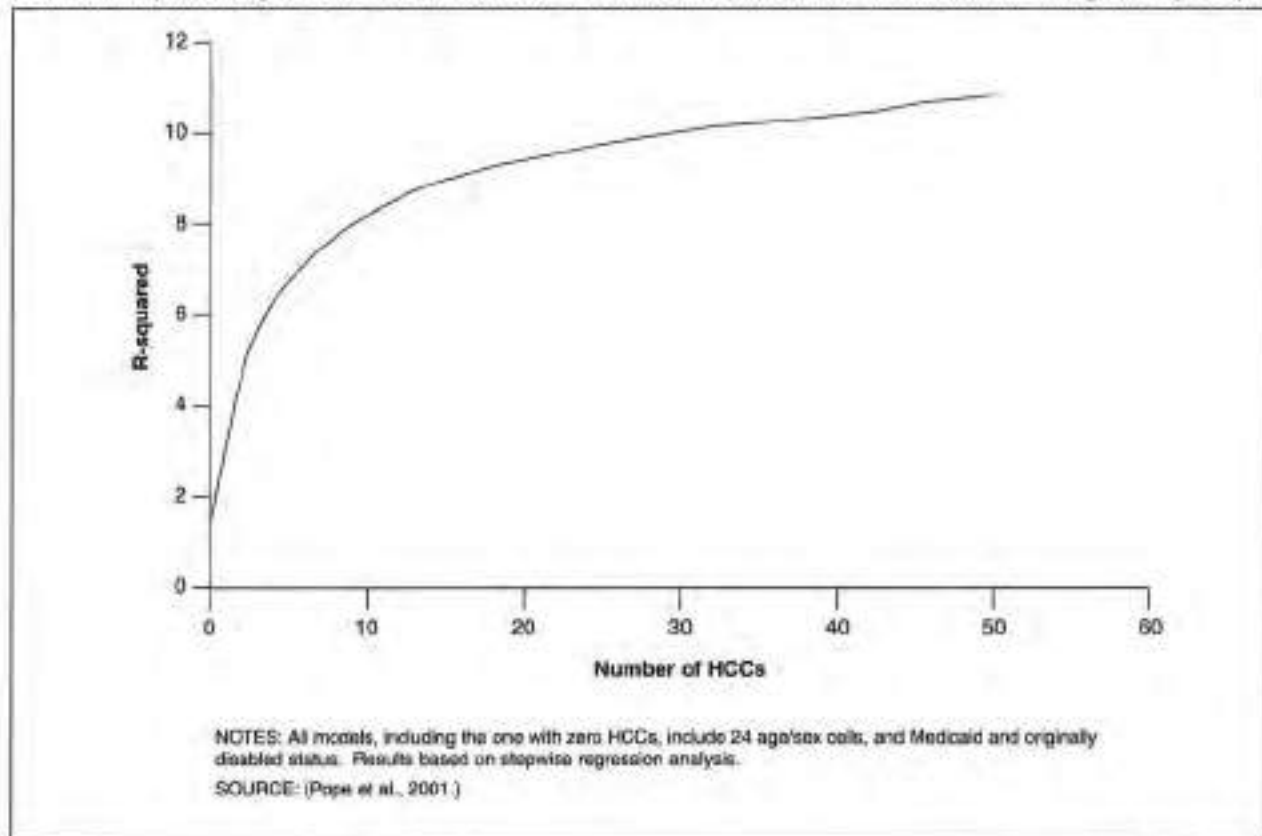
CMS-HCC MODEL

This section describes how the DCG/HCC model was modified before implementation as the M+C risk adjuster for capitation payments in 2004. We will refer to the modified model as CMS-HCC.

DCG/HCC Model Modification to Simplify Data Collection

When several MCOs withdrew from the M+C program around the year 2000, CMS sought to improve plan retention. Since some MCOs had complained of the burden of collecting encounter data for risk-adjustment, CMS sought to develop risk adjustment models that predict well and rely on ambulatory data, but with reduced data col-

Figure 4
Model Explanatory Power as a Function of Number of Hierarchical Condition Categories (HCC)



lection requirements. One measure of the data collection burden imposed by a model is its number of diagnostic categories.¹⁰

We investigated the relationship between number of diagnostic categories used in the DCG/HCC model and its predictive power (Pope et al., 2001). Figure 4 plots the relationship between number of diagnostic categories and model explanatory power measured by R^2 . Diagnostic categories (HCCs) were entered into the model in descending order of their incremental explanatory power using stepwise regression. The base model (with zero HCCs) includes 26 demographic variables, the 24 age/sex cells, and Medicaid and originally disabled status. Its R^2 is 1.69 percent.

¹⁰The relationship between number of diagnostic categories and data collection burden is controversial. Some MCOs seemed to feel that it would be less burdensome to report all diagnoses, which CMS allows.

The incremental contribution to predictive power declines rapidly with the number of diagnostic categories added to the model. The first diagnostic category entered by the stepwise regression is CHF, which more than doubles the demographic model R^2 to 4.11 percent. The second condition category entered is COPD, raising the R^2 to 4.94 percent. This is an incremental gain of 0.83 percentage points, substantial, but much less than the increment of 2.42 percentage points due to CHF. With 5 HCCs included, 61 percent of the maximum explanatory power of the full (101 HCC) model is attained; with 10 HCCs, 74 percent of the maximum is achieved; with 20, 85 percent, and with 30, 90 percent. The incremental R^2 from adding a diagnostic category is 0.48 percentage points at 5 HCCs; 0.26 percentage points at 10 HCCs; 0.08 percentage points at 20 HCCs; and 0.05 percentage points at 30 HCCs.

This analysis shows that a parsimonious risk-adjustment model with a substantially reduced number of diagnostic categories is almost as predictive as a full model. But parsimony has a cost. In limiting the number of conditions that affect payment, many serious, high-cost diagnoses—especially rare ones—will be ignored. MCOs enrolling beneficiaries with excluded diagnoses will be disadvantaged, and beneficiaries with such conditions may not be well served by MCOs.

CMS considered these results, and consulted with clinicians, on the tradeoff between number of diagnostic categories and predictive power, and also other criteria for diagnostic categories to include in risk adjustment, such as well-defined diagnostic criteria and clinical coherence and homogeneity. It was important that the HCC hierarchies not be disrupted by deletion of higher-ranked HCCs while lower-ranked HCCs were retained. After this process, CMS selected 70 HCCs to include in the CMS-HCC model. The choices reflect a balance among the competing considerations of reducing data collection burden, maximizing predictive power, including rare, high-cost conditions, and selecting only well-defined and clinically coherent conditions. Generally, the higher-cost, more severe conditions at the top of the HCC disease hierarchies were retained, while some lower-cost, more frequent and more discretionary conditions at the bottom of the hierarchies were pruned. For example, in the coronary artery disease hierarchy, AMI (heart attack), other acute IHD (e.g., unstable angina), and angina pectoris/old myocardial infarction were retained, but chronic IHD (e.g., coronary atherosclerosis) was excluded.

After the CMS-HCC model was finalized, a list of approximately 3,000 of the more than 15,000 ICD-9-CM diagnosis codes was identified that are sufficient to define the

model's 70 HCCs. In addition, because the CMS-HCC model does not give extra credit for multiple reports of the same diagnosis, MCOs need only report a single encounter during the relevant year of data collection that establishes the diagnosis. The information required for the single encounter is: (1) beneficiary identification number, (2) date (to establish that the diagnosis was made during the relevant reporting period), (3) setting (to establish that the diagnosis was made in one of the allowed hospital or physician settings), and (4) ICD-9-CM diagnosis code. In short, MCOs are required to report only the minimum.

Concern about the quality of diagnostic reporting is the greatest in physician offices, where diagnoses have not heretofore affected payment, and recording of diagnoses is less rigorously practiced than in hospitals. The auditing standard that CMS has promulgated for reporting of physician office diagnoses is that a physician has established the diagnosis in the medical record, and that medical coders have recorded it in accordance with ICD-9-CM rules. CMS will conduct coding audits, but not clinical audits. That is, CMS will require MCOs to demonstrate that a diagnosis is present in the medical record on the specified date and has been coded according to ICD-9-CM. CMS will not require clinical verification of these diagnoses, such as diagnostic test results.

CMS-HCC Model Calibration

We calibrated the CMS-HCC model to 1999-2000 Medicare 5-percent sample FFS data for beneficiaries entitled by age or disability (beneficiaries entitled by ESRD were excluded). The model is prospective, meaning that diagnoses collected in a base year (1999) are used to predict expenditures in the following year (2000). An

important operational change from the PIP-DCG model is that the data lag will be eliminated, making the application of the model consistent with its calibration. With the PIP-DCG model, the data collection period for a payment year ended 6 months before the start of the year, i.e., on June 30 of the previous year, so that final capitation rates could be published by January 1 of the payment year. With the CMS-HCC model, provisional rates will be established by January 1 based on 6-month lagged data, and final rates will be available by June 30 of the payment year based on the previous calendar year's diagnoses. A reconciliation process will adjust the first 6 months of payments to the final rates, if necessary.

A standard set of sample restrictions was employed to ensure a population of beneficiaries with complete 12-month base year diagnostic profiles and complete payment year Medicare expenditures from the FFS claims for aged and disabled beneficiaries (Pope et al., 2000b). Decedents are included in the payment year for their eligible period. Complete FFS claims are not available for months of M+C enrollment or when Medicare is a secondary payer, and M+C plans are not responsible for hospice care, so these months were excluded from our sample. The final sample size is 1,337,887 beneficiaries.

We summed all Medicare payments for a beneficiary for months in 2000 satisfying our sample restrictions, excluding (1) deductibles and copayments paid by the beneficiary; (2) hospice payments; and (3) indirect medical education payments. Hospice and indirect medical education payments are excluded because they were not included in M+C capitation rates, but were paid directly to hospices and teaching hospitals utilized by M+C enrollees. Payments were annualized by dividing them by the fraction of months in 2000 that

satisfy our sample restrictions; all analyses are weighted by this eligibility fraction. In general, annualization and weighting ensures that monthly payments are correctly estimated for all beneficiaries, including those who died (Ellis et al., 1996).¹¹

The model was calibrated using weighted least squares multiple regression. The CMS-HCC regression model estimated for the combined aged and disabled Medicare population is shown in Table 2.

The elements of the model are:

- Age/sex cells (24).
- Medicaid interacted with sex and age/disabled entitlement status.
- Originally disabled status interacted with sex.
- HCC diagnostic categories (70).
- Interactions of diagnostic categories with entitlement by disability (5).
- Disease interactions (6).

The R^2 for this model is 9.8 percent. Several coefficients are constrained because the unconstrained coefficients violate the principle that higher-ranked conditions in a hierarchy should have higher predicted costs, or for other reasons.¹²

As an example of expenditure prediction, consider our hypothetical scenario in Figure 3 of a female age 79 eligible for Medicaid diagnosed with AMI, angina pectoris, COPD, renal failure, chest pain, and an ankle sprain. The female receives the following incremental cost predictions: female, 75 to 79, \$2,562; aged, female, Medicaid, \$616; AMI (HCC 81), \$1,885; angina pectoris, \$0; COPD (HCC 108), \$1,936; renal failure (HCC 131), \$2,908;

¹¹ In our calibration, we did not make any geographic adjustments to Medicare payments. In past work, we have found that deflating payments by a geographic input price index had little effect on estimated risk-adjustment model parameters.

¹² Clinical consultants to CMS suggested that metastatic cancer is not consistently correctly coded, so HCCs 7 and 8 were constrained to have equal coefficients. HCCs 81 and 82 were constrained to have equal coefficients because the ICD-9-CM diagnostic detail CMS collects from health plans is not sufficient to distinguish them.

Table 2
Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC)
Combined, Community, and Institutional Models

	Combined		Models Community		Institutional			
Number of Observations	1,337,887		1,291,308		65,593			
R ²	0.0977		0.0976		0.0596			
Adjusted R ²	0.0977		0.0976		0.0589			
Dependent Variable Mean	5,352		5,213		8,937			
Root Mean Square Error	13,407		13,337		15,954			
Model Parameters	105		105		50			
Variable	Parameter Estimate	t-ratio	Parameter Estimate	t-ratio	Parameter Estimate	t-ratio		
Female								
0-34 Years	678	3.81	598	3.38	5,457	11.72		
35-44 Years	1,110	8.82	1,012	8.03	5,457	11.72		
45-54 Years	1,177	11.20	1,096	10.40	5,457	11.72		
55-59 Years	1,463	11.87	1,360	11.00	5,457	11.72		
60-64 Years	1,996	17.26	1,924	16.56	5,457	11.72		
65-69 Years	1,646	42.11	1,572	40.15	5,970	11.73		
70-74 Years	2,061	60.25	1,970	57.42	6,049	17.09		
75-79 Years	2,562	71.59	2,475	68.56	5,089	19.63		
80-84 Years	2,998	71.39	2,936	68.34	4,813	22.51		
85-89 Years	3,360	63.45	3,408	61.01	4,515	23.28		
90-94 Years	3,683	46.81	4,077	46.25	4,048	19.08		
95 Years or Over	3,128	23.27	4,130	25.32	2,980	10.34		
Male								
0-34 Years	405	2.72	346	2.32	5,664	13.77		
35-44 Years	701	6.63	617	5.81	5,664	13.77		
45-54 Years	1,059	12.15	973	11.14	5,664	13.77		
55-59 Years	1,460	13.42	1,386	12.68	5,664	13.77		
60-64 Years	1,824	17.90	1,755	17.13	5,664	13.77		
65-69 Years	1,827	41.47	1,774	40.28	7,435	13.24		
70-74 Years	2,380	59.66	2,323	58.17	6,350	14.34		
75-79 Years	3,031	69.04	2,960	67.13	6,210	16.45		
80-84 Years	3,454	62.03	3,372	59.83	6,201	17.67		
85-89 Years	4,129	52.24	4,050	49.80	6,366	17.40		
90-94 Years	4,505	32.20	4,620	31.08	5,378	11.29		
95 Years or Over	4,753	15.83	5,307	15.89	4,287	5.34		
Medicaid and Originally Disabled								
Interactions with Age and Sex								
Medicaid-Female-Disabled	1,141	11.31	1,133	11.18	—	—		
Medicaid-Female-Aged	616	12.91	940	18.18	—	—		
Medicaid-Male-Disabled	632	6.80	592	6.31	—	—		
Medicaid-Male-Aged	788	10.33	944	11.62	—	—		
Originally Disabled-Female	1,231	17.34	1,213	16.44	—	—		
Originally Disabled-Male	809	11.66	757	10.73	—	—		
Disease Coefficients Label								
HCC1	HIV/AIDS	3,587	13.16	3,514	12.88	6,893	5.42	C1
HCC2	Septicemia/Shock	4,385	34.74	4,583	32.92	4,854	13.89	
HCC5	Opportunistic Infections	3,643	10.43	3,346	9.29	6,893	5.42	C1
HCC7	Metastatic Cancer and Acute Leukemia	7,438	81.16	7,510	81.00	2,771	4.54	
HCC8	Lung, Upper Digestive Tract, and Other Severe Cancers	7,438	81.16	7,510	81.00	2,771	4.54	
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	3,540	35.91	3,539	35.51	2,319	3.50	
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,209	26.35	1,194	25.79	1,330	4.01	

Refer to NOTES at end of table.

Table 2—Continued
Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC)
Combined, Community, and Institutional Models

Variable	Label	Models					
		Combined		Community		Institutional	
		Parameter Estimate	t-ratio	Parameter Estimate	t-ratio	Parameter Estimate	t-ratio
Disease Coefficients							
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	3,827	37.71	3,921	36.90	3,137	10.49
HCC16	Diabetes with Neurologic or Other Specified Manifestation	2,931	30.09	2,833	28.43	3,137	10.49
HCC17	Diabetes with Acute Complications	2,056	7.84	2,008	7.41	3,137	10.49
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	1,839	18.35	1,760	17.32	3,137	10.49
HCC19	Diabetes without Complication	1,055	26.10	1,024	25.02	1,308	5.32
HCC21	Protein-Calorie Malnutrition	3,818	27.52	4,727	29.77	2,193	6.49
HCC25	End-Stage Liver Disease	4,486	14.01	4,616	14.92	1,375	5.09
HCC26	Cirrhosis of Liver	2,727	11.93	2,645	11.37	1,375	5.09
HCC27	Chronic Hepatitis	1,839	6.73	1,841	6.71	1,375	5.09
HCC31	Intestinal Obstruction/Perforation	1,997	21.69	2,094	21.62	1,375	5.09
HCC32	Pancreatic Disease	2,336	17.30	2,281	16.61	1,375	5.09
HCC33	Inflammatory Bowel Disease	1,574	10.25	1,575	10.16	1,375	5.09
HCC37	Bone/Joint/Muscle Infections/Necrosis	2,629	19.68	2,546	18.41	2,539	4.42
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	1,683	27.72	1,653	26.93	1,463	3.61
HCC44	Severe Hematological Disorders	5,055	30.80	5,188	30.69	2,299	4.08
HCC45	Disorders of Immunity	4,224	26.77	4,260	26.64	2,299	4.08
HCC51	Drug/Alcohol Psychosis	1,571	6.57	1,810	8.99	1,131	6.06
HCC52	Drug/Alcohol Dependence	1,477	6.15	1,361	5.44	1,131	6.06
HCC54	Schizophrenia	2,592	26.75	2,786	27.04	1,131	6.06
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,024	30.00	2,209	30.85	1,131	6.06
HCC67	Quadriplegia, Other Extensive Paralysis	5,665	27.45	6,059	27.20	504	3.94
HCC68	Paraplegia	5,665	27.45	6,059	27.20	504	3.94
HCC69	Spinal Cord Disorders/Injuries	2,484	17.77	2,526	17.45	504	3.94
HCC70	Muscular Dystrophy	2,239	3.82	1,981	3.27	504	3.94
HCC71	Polyneuropathy	1,480	19.74	1,377	18.06	504	3.94
HCC72	Multiple Sclerosis	2,329	11.44	2,654	12.19	504	3.94
HCC73	Parkinson's and Huntington's Diseases	1,954	19.69	2,436	22.04	504	3.94
HCC74	Seizure Disorders and Convulsions	1,334	17.25	1,361	16.68	504	3.94
HCC75	Coma, Brain Compression/Anoxic Damage	2,396	7.88	2,912	8.62	504	3.94
HCC77	Respirator Dependence/Tracheostomy Status	10,417	29.54	10,783	28.46	7,259	8.19
HCC78	Respiratory Arrest	7,543	20.23	7,327	18.79	7,259	8.19
HCC79	Cardio-Respiratory Failure and Shock	3,451	42.70	3,550	42.39	1,481	4.31
HCC80	Congestive Heart Failure	2,055	38.48	2,141	38.54	903	4.16
HCC81	Acute Myocardial Infarction	1,885	31.23	1,785	29.13	1,476	5.75
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	1,885	31.23	1,785	29.13	1,476	5.75
HCC83	Angina Pectoris/Old Myocardial Infarction	1,246	22.82	1,205	21.76	1,476	5.75

Refer to NOTES at end of table.

Table 2—Continued
Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC)
Combined, Community, and Institutional Models

Variable		Models					
		Combined		Community		Institutional	
		Parameter Estimate	t-ratio	Parameter Estimate	t-ratio	Parameter Estimate	t-ratio
Disease Coefficients							
HCC92	Specified Heart Arrhythmias	1,362	31.73	1,363	30.95	961	4.62
HCC95	Cerebral Hemorrhage	1,901	10.05	2,011	9.88	774	4.01
HCC96	Ischemic or Unspecified Stroke	1,498	20.90	1,569	20.34	774	4.01
HCC100	Hemiplegia/Hemiparesis	1,678	13.96	2,241	16.61	504	3.04
HCC101	Cerebral Palsy and Other Paralytic Syndromes	767	3.34	840	3.42	504	3.94
HCC104	Vascular Disease with Complications	3,432	36.22	3,473	35.49	2,612	6.30
HCC105	Vascular Disease	1,682	39.94	1,832	41.72	583	3.72
HCC107	Cystic Fibrosis	1,936	45.73	1,929	44.87	1,180	4.69
HCC108	Chronic Obstructive Pulmonary Disease	1,936	45.73	1,929	44.87	1,180	4.69
HCC111	Aspiration and Specified Bacterial Pneumonias	3,010	20.47	3,556	21.53	2,377	6.82
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	1,151	6.55	1,034	5.68	2,377	6.82
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	1,975	13.36	1,791	11.96	5,102	5.46
HCC130	Dialysis Status	15,926	26.97	15,778	25.96	15,959	5.82
HCC131	Renal Failure	2,908	23.20	2,954	22.73	2,162	6.26
HCC132	Nephritis	1,541	6.95	1,401	6.23	2,152	6.26
HCC148	Decubitus Ulcer of Skin	3,888	32.32	5,285	37.28	1,628	5.98
HCC149	Chronic Ulcer of Skin, Except Decubitus	2,381	26.76	2,485	26.65	1,346	3.98
HCC150	Extensive Third-Degree Burns	4,427	2.36	4,935	2.54	1,274	3.37
HCC154	Severe Head Injury	2,396	7.88	2,912	8.62	1,274	3.37
HCC155	Major Head Injury	1,211	8.43	1,239	8.08	1,274	3.37
HCC157	Vertebral Fractures w/o Spinal Cord Injury	2,462	20.64	2,514	20.23	504	3.94
HCC158	Hip Fracture/Dislocation	1,301	13.37	2,010	18.51	0	—
HCC161	Traumatic Amputation	3,965	17.86	4,322	17.92	1,274	3.37
HCC164	Major Complications of Medical Care and Trauma	1,438	18.25	1,346	16.60	1,347	3.66
HCC174	Major Organ Transplant Status	3,790	8.55	3,702	8.37	4,523	11.13
HCC176	Artificial Openings for Feeding or Elimination	3,810	23.84	4,054	22.39	4,523	11.13
HCC177	Amputation Status, Lower Limb/Amputation Complications	3,965	17.86	4,322	17.92	1,274	3.37
Disabled/Disease Interactions							
D-HCC5	Disabled Opportunistic Infections	3,965	5.49	4,047	5.52	—	—
D-HCC44	Disabled Severe Hematological Disorders	4,649	9.98	4,580	9.72	—	—
D-HCC51	Disabled Drug/Alcohol Psychosis	2,830	7.12	2,808	6.32	—	—
D-HCC52	Disabled Drug/Alcohol Dependence	2,160	6.90	2,122	6.61	—	—
D-HCC107	Disabled Cystic Fibrosis	9,691	6.70	9,547	6.63	—	—

Refer to NOTES at end of table.

Table 2—Continued
Centers for Medicare & Medicaid Services-Hierarchical Condition Categories (CMS-HCC)
Combined, Community, and Institutional Models

Variable		Models					
		Combined		Community		Institutional	
		Parameter Estimate	t-ratio	Parameter Estimate	t-ratio	Parameter Estimate	t-ratio
Disease Interactions							
INT1	DM-CHF1	1,265	14.62	1,296	14.46	1,064	2.91
INT2	DM-CVD	490	4.05	639	4.89	—	—
INT3	CHF-COPD	1,261	14.82	1,238	14.06	1,906	4.95
INT4	COPD-CVD-CAD	316	1.49	406	1.82	—	—
INT5	RF-CHF1	857	3.94	1,202	5.24	—	—
INT6	RF-CHF-DM1	4,185	18.48	4,433	18.71	—	—

NOTES: Beneficiaries with the three-way interaction RF-CHF-DM are excluded from the two-way interactions DM-CHF and RF-CHF. DM is diabetes mellitus (HCCs 15-19). CHF is congestive heart failure (HCC 80). COPD is chronic obstructive pulmonary disease (HCC 108). CVD is cerebrovascular disease (HCCs 95-96, 100-101). CAD is coronary artery disease (HCCs 81-83). RF is renal failure (HCC 131). * means coefficients of HCCs are constrained to be equal. C1, C2, and C3 denote non-contiguous constraints.

SOURCE: Pope, G.C. and Kautter, J., RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

chest pain, \$0; and ankle sprain, \$0¹³ (Table 2). Her total cost prediction is the sum of these increments, or \$9,907.

Calibration of DCG/HCC models on several years of data reveals increasingly thorough diagnostic coding. For example, if 1999 diagnoses are used to predict expenditures with a model calibrated on 1996/1997 data, mean expenditures will be over predicted. If more complete coding over time is not accounted for, MCOs will be overpaid by the use of current diagnoses with a model calibrated on historical data. CMS makes a slight downward adjustment in HCC-predicted expenditures to account for this.

CMS-HCC Models for Subpopulations

Medicare beneficiaries differ along characteristics that are important for risk adjustment. First, they may be entitled to Medicare in one of three ways: age, disability, or ESRD. Second, some beneficiaries reside in institutions rather than in the community. Third, some enrollees are new to

Medicare and do not have complete diagnostic data. Fourth, Medicare is a secondary payer for some beneficiaries. To account for the different cost and diagnostic patterns of these disparate subgroups of beneficiaries, the CMS-HCC model was adapted for Medicare subpopulations. This section describes models for subpopulations.¹⁴

Beneficiaries Entitled by Disability

Approximately 12 percent of Medicare beneficiaries are entitled to Medicare because they are under age 65 and have a medical condition that prevents them from working (the disabled). Models calibrated on the full Medicare population (excluding ESRD eligibles), mostly reflect cost patterns among the elderly, the other 88 percent of the population. The implications of some diagnoses might differ between the elderly and disabled. For example, a diagnosis that is disabling may be more severe, and the cost of treating a disease may vary by age. We considered allowing differences in incremental expenditure weights for some diagnoses (HCCs) for the disabled (Pope et al., 1998; 2000b).

¹³ The female receives no incremental cost prediction for angina pectoris because AMI is higher-ranked in the coronary artery disease hierarchy and excludes angina. No incremental prediction is made for chest pain and ankle sprain because these diagnoses are not included in the CMS-HCC model.

¹⁴ Risk-adjustment models for ESRD-entitled and functionally-limited beneficiaries are not described in this article.

Using Medicare's 5-percent sample FFS data (1996-1997), we estimated the DCG/HCC model separately on aged and disabled subsamples. We evaluated differences in age versus disabled parameter estimates according to their statistical significance, magnitude, clinical plausibility, and frequency of occurrence in the disabled population (Pope et al., 2000b). Based on these considerations, we chose nine diagnostic categories to receive incremental payments when they occur among disabled beneficiaries. Five of these categories remained significantly different for the disabled when the CMS-HCC model was re-estimated on 1999-2000 data: opportunistic infections, severe hematological disorders (e.g., hemophilia, sickle cell anemia), drug/alcohol psychosis, drug/alcohol dependence, and cystic fibrosis. Incremental annual payments for these conditions among the disabled (in addition to base payments for the elderly) are substantial, ranging from \$2,160 to \$9,691.

Other than for these five conditions, disease risk-adjustment weights are the same for the aged and disabled populations. The CMS-HCC model is estimated on a combined sample of aged and disabled beneficiaries, with disabled interactions for these five diagnostic categories. The combined aged/disabled model is shown in Table 2.

Community and Institutional Residents

Using the newly available Medicare MDS, we identified long-term nursing home residents in the current (i.e., payment) year. Long-term nursing home residence was defined as continuously residing in a nursing home for at least 90 days, as indicated by a 90-day clinical assessment reported by the nursing facility through the MDS. In our prospective risk-adjustment modeling sample of 1,337,887

beneficiaries, 65,593 beneficiaries, or 5 percent, had at least 1 month of long-term nursing facility residence in 2000.¹⁵

Table 3 compares sample sizes and mean expenditures by demographic categories for community and institutional residents, and shows predictive ratios from the CMS-HCC model calibrated on the combined community/institutional sample (Table 2). Nearly one-half (49 percent) of long-term nursing facility residents are age 85 or over. Facility residents are only 2 percent of the combined community plus institutional population for females age 70 to 74, but fully 37 percent of the combined population for females age 95 or over.

Overall, institutional residents are 71 percent more expensive than community residents, \$8,937 in mean annualized expenditures compared to \$5,213. The age profiles of expenditures are quite different. Among community residents, mean expenditures rise steadily with age in the under 65 disabled population and then again in the elderly population, except for a slight decline for the oldest females. In contrast, among the institutionalized, mean expenditures are fairly constant across all ages until they decline significantly among the oldest old. For all age/sex cells except the oldest old, mean expenditures for the institutionalized are substantially higher than for community-dwelling beneficiaries.

However, although not shown in Table 3, among beneficiaries diagnosed with particular HCCs, mean expenditures for the institutionalized are often similar to those of community residents. For example, among all beneficiaries with CHF (HCC 80), expenditures for the institutionalized are \$11,719, which is \$255 less than for community residents. More generally, when classifying people by the presence of

¹⁵ Beneficiaries with both community and long-term institutional months in the same year are included in both samples, weighted by the fraction of their total months alive in the year in each status.

Table 3
Descriptive Statistics for Community and Institutionalized Residents

Variable	Community			Institutional		
	Observations	Mean Annualized Expenditures	Predictive Ratio ¹	Observations	Mean Annualized Expenditures	Predictive Ratio ¹
Overall	1,291,308	5,213	0.99	65,593	8,937	1.12
Demographics						
Female						
0-34 Years	7,007	3,623	1.00	49	6,251	0.99
35-44 Years	15,566	4,332	1.00	199	9,395	0.94
45-54 Years	22,077	4,692	1.00	473	8,869	1.07
55-59 Years	14,023	5,254	1.00	343	10,168	0.91
60-64 Years	15,793	5,993	1.00	501	9,906	1.04
65-69 Years	129,970	3,714	1.00	1,380	10,961	0.99
70-74 Years	171,775	4,372	1.00	3,098	10,901	0.97
75-79 Years	157,586	5,260	1.00	6,260	9,458	1.08
80-84 Years	111,303	6,101	0.99	8,801	8,797	1.13
85-89 Years	66,301	6,882	0.97	12,294	8,054	1.19
90-94 Years	26,852	7,606	0.92	9,535	7,146	1.29
95 Years or Over	8,074	7,338	0.83	4,729	5,734	1.42
Male						
0-34 Years	10,272	2,868	1.00	106	10,622	0.95
35-44 Years	22,913	3,666	1.00	384	9,596	0.92
45-54 Years	29,377	3,968	1.00	606	10,186	0.91
55-59 Years	16,391	4,651	1.00	438	10,340	0.96
60-64 Years	18,581	5,214	1.00	588	10,486	1.00
65-69 Years	105,856	4,018	1.00	1,132	12,432	0.88
70-74 Years	128,874	5,014	1.00	1,921	11,501	0.99
75-79 Years	106,402	6,207	1.00	2,642	11,411	1.04
80-84 Years	64,263	7,083	1.00	3,404	11,049	1.06
85-89 Years	30,765	8,144	0.99	3,116	10,754	1.08
90-94 Years	9,343	8,731	0.97	1,783	9,489	1.20
95 Years or Over	1,944	9,062	0.92	611	8,096	1.37
Medicaid	196,604	6,523	0.97	33,074	8,895	1.17
Originally-Disabled	81,894	7,614	0.99	7,415	10,606	1.11

¹ Ratio of mean expenditures predicted by the Centers for Medicare & Medicaid Services - Hierarchical Condition Categories (CMS-HCC) model for combined community/institutional samples to mean actual expenditures.

SOURCE: Pope, G.C. and Kautter, J., RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

a single diagnosis, expenditures for the institutionalized may be higher, lower, or about the same.

Thus, the main reason that people in facilities cost more is that they have more medical problems, a distinction that is fully accounted for by the HCCs. In fact, the predictive ratios from the combined CMS-HCC model for community and institutional beneficiaries are, respectively, 0.99 and 1.12 (Table 3). This means that the combined model, on average, under predicts expenditures for community residents by 1 percent, and over predicts expenditures for

long-term nursing home residents by 12 percent. Lower expenditures among facility residents adjusting for disease burden could result from substituting non-Medicare for Medicare-reimbursed services; since most nursing home service are not reimbursed by Medicare. Also, greater monitoring of nursing home than community residents may identify and prevent problems leading to hospitalization. The under-prediction for community residents and over-prediction for facility residents is most severe for the oldest age groups, most likely due to decisions to limit

aggressive care for very old residents in nursing homes. The over-prediction of the costs of the institutionalized, together with their different cost patterns by age and diagnosis, led us to consider differentiating the CMS-HCC model for community and institutional populations.

Within a multiple regression model estimation framework, we investigated alternative approaches to allowing differences in the model between community and institutional residents, ultimately choosing to estimate separate models. This properly calibrates the prediction of each group's costs, while allowing all demographic and disease coefficients to differ between community and institutional populations.

In addition to the combined model, Table 2 shows the CMS-HCC community and institutional models. Not surprisingly, the community model R^2 and most of the demographic and disease coefficients are very similar to the combined model, because community residents comprise 95 percent of the combined sample. A few coefficients show greater differences. The community coefficients for the oldest age cells are significantly larger than the combined model coefficients because the lower-cost very old institutionalized have been removed from these cells. The community coefficients for the aged enrolled in Medicaid are also significantly higher, as are several HCC coefficients.

The institutional model R^2 is considerably lower than the community model. But some of the community model's predictive power comes from distinguishing beneficiaries who are healthy (no diagnoses) versus sick (with diagnoses), while the institutional model is explaining cost variations among a population comprised entirely of impaired individuals. Diagnoses help explain why someone might be institutionalized (i.e., distinguish healthy from sick), but are not as powerful in explaining

expenditure differences among the institutionalized. Disease (HCC) coefficients tend to be smaller in the institutional model than in the community model (Table 2). Diagnoses are less predictive of incremental costs among the more uniformly expensive institutional population than they are among the community population.

We constrained certain groups of demographic and diagnostic coefficients in the institutional model to be equal (Table 2), because the small available sample of institutionalized beneficiaries resulted in their low prevalence in some diagnostic categories (HCCs) and made it difficult to obtain stable estimates of each separate parameter. For the same reason, we included no disabled interaction terms, and only two of the disease interaction terms in the institutional model. Also, HCC 158 Hip Fracture/Dislocation was excluded because its coefficient was negative.

The age/sex coefficients for the institutionalized are much higher than for community residents except for the oldest ages. This implies that institutionalized beneficiaries are predicted to be expensive regardless of their diagnostic profile (e.g., even lacking any of the diagnoses included in the CMS-HCC model), whereas community residents are predicted to be expensive only if diagnosed with at least one of the serious diseases included in the CMS-HCC model. This makes sense since institutionalization itself is a marker of poor health, aside from diagnostic profile, but the institutionalized age/sex coefficients decline for the oldest ages, and fall below the community coefficients. Medical treatment may be less aggressive for old, frail beneficiaries who are institutionalized.

Among the institutional population, the coefficient for Medicaid was negative and the coefficients for originally disabled was statistically insignificant. These variables

were excluded from the institutional model. Beneficiaries often qualify for Medicaid after spending down their personal assets to pay for a lengthy nursing home stay. Thus, Medicaid may be a proxy for beneficiaries in the later portion of their stays, when they are less expensive than in the earlier, post-acute phase of their nursing home tenure.

New Medicare Enrollees

The CMS-HCC model requires a complete 12-month base year diagnostic profile to predict the next year's expenditures. Beneficiaries without 12 months base year Medicare enrollment, but at least 1 month of prediction year enrollment, are defined as new enrollees. About two-thirds of new enrollees are age 65.¹⁶ New enrollees may be under age 65 if they become eligible for Medicare by disability; they may be over age 65 if they delay Medicare enrollment or are not originally enrolled in both Parts A and B.¹⁷ We developed a demographic model to predict expenditures for new enrollees who lack the data needed to apply the CMS-HCC model.

Table 4 presents frequencies and mean annualized expenditures from the 5-percent FFS sample data for new enrollees and continuing enrollees. Continuing enrollees are defined as beneficiaries having 12 months of Parts A and B Medicare enrollment in the base year and at least 1 month in the prediction year. For female and male new enrollees age 65, mean annualized expenditures are \$2,729 and \$2,900, respectively, less than one-half of costs of

continuing enrollees (\$6,952 for female and \$6,055 for male). For almost all new enrollees age 65, the original reason for Medicare entitlement is age.¹⁸ In contrast, continuing enrollees age 65 were originally entitled to Medicare by disability, and hence are much more expensive. For other ages, mean expenditures of new and continuing enrollees are much more similar. To achieve sufficient sample sizes in all age ranges to calibrate the new enrollees model, we merged the new and continuing enrollees samples, which resulted in a sample size of 1,495,225 with mean expenditures of \$5,184. For age 65, actual new enrollees dominate the combined sample, and the cost weight reflects their (low) relative costs. Continuing enrollees age 65 are included in the sample to calibrate the originally disabled coefficient for age 65. For other than age 65, the sample is dominated by continuing enrollees, but their costs appear to proxy actual new enrollee costs reasonably well for younger or older ages.

Beneficiaries for Whom Medicare is a Secondary Payer

Working aged beneficiaries are Medicare beneficiaries, age 65 or over, with private group health insurance coverage from their or their spouse's employer. By law, Medicare is a secondary payer for these beneficiaries. The primary private health plan must pay for medical expenses to the extent of its defined benefits. Only if Medicare covers services not covered by the private plan, or has more generous coverage (e.g., lower deductibles or copayments) for Medicare-covered services, is Medicare responsible for payment, and then only to the extent of the difference in

¹⁶ To simplify the new enrollees model, we recoded new enrollees age 64 on February 1 with an original reason for Medicare entitlement of aged to age 65. Thus, the age 65 cell in the new enrollees model combines new enrollees ages 64 and 65 on February 1 of the prediction year whose original reason for entitlement is aged.

¹⁷ For example, a beneficiary might be entitled to Part A (hospital insurance) by age at age 65 or over, but might not pay Part B (physician insurance) premium until an older age.

¹⁸ Some age 65 new enrollees might have originally been entitled to Medicare by disability when under age 65, but then have rejoined the work force and lost their Medicare eligibility, only to re-enroll at age 65.

Table 4
Descriptive Statistics for New and Continuing Medicare Enrollees¹

Age/Sex Category	New Enrollees ²		Continuing Enrollees ³	
	Observations	Mean Annualized Expenditures	Observations	Mean Annualized Expenditures
Female				
0-34 Years	2,540	3,532	7,037	3,653
35-44 Years	3,885	4,341	15,717	4,385
45-54 Years	5,891	4,814	22,431	4,767
55-59 Years	4,029	4,903	14,277	5,354
60-64 Years	3,310	5,706	16,159	6,094
65 Years	58,946	2,729	3,336	6,952
66 Years	1,448	3,319	29,534	3,401
67 Years	845	3,349	31,560	3,684
68 Years	531	3,116	32,578	3,740
69 Years	504	3,808	33,893	3,905
70-74 Years	1,311	4,672	173,829	4,461
75-79 Years	471	5,063	161,843	5,387
80-84 Years	200	6,043	118,144	6,276
85-89 Years	95	8,111	75,186	7,035
90-94 Years	46	5,931	34,135	7,500
95 Years or Over	15	6,457	11,886	6,795
Male				
0-34 Years	3,434	3,089	10,342	2,934
35-44 Years	4,281	3,690	23,172	3,748
45-54 Years	5,820	4,099	29,814	4,074
55-59 Years	4,120	4,603	16,677	4,772
60-64 Years	4,196	4,775	18,986	5,346
65 Years	46,262	2,900	3,940	6,055
66 Years	1,546	3,205	24,472	3,644
67 Years	872	2,976	25,279	3,933
68 Years	570	3,501	25,915	4,145
69 Years	490	3,638	27,009	4,285
70-74 Years	1,223	5,700	130,148	5,087
75-79 Years	429	6,476	108,214	6,307
80-84 Years	144	5,916	68,505	7,231
85-89 Years	63	8,028	32,848	8,326
90-94 Years	19	13,027	10,601	8,827
95 Years or Over	2	3,221	2,420	8,967

¹ Aged and disabled beneficiaries. Excludes working aged and ESRD beneficiaries.

² Enrollees with less than 12 months of base year eligibility.

³ Enrollees with 12 months of base year eligibility.

SOURCE: Pope, G.C. and Kautter, J. RTI International, Ellis, R.P. and Ash, A.S., Boston University, Ayanian, J.Z., Harvard Medical School and Brigham and Women's Hospital, Iezzoni, L.I., Harvard Medical School and Beth Israel Deaconess Medical Center, Ingber, M.J., Levy, J.M., and Robst, J., Centers for Medicare & Medicaid Services, Analysis of 1999-2000 Medicare 5% Standard Analytic File (SAF).

coverage. Medicare expenditures for working aged beneficiaries are lower for this reason, as well as because working may be a proxy for better health.¹⁹ Estimation of a separate model for the working aged is not feasible with the sample sizes available from the Medicare's 5-percent FFS sample. A simple adjustment to CMS-HCC model predictions is a multiplier that scales cost predictions to be lower for these beneficiaries.

¹⁹ Throughout this section, we use the terms working and working aged to include both those who are actually working, and the spouses of those who are working.

We defined the working aged as beneficiaries otherwise satisfying the requirements of our 1999-2000 aged/disabled prospective modeling sample who had at least 1 month of working aged status in the prediction year (2000). There are 19,057 beneficiaries in our working aged sample, or about 1.4 percent as many individuals as in our aged/disabled sample. The mean annualized expenditures of the working aged are \$966, less than one-fifth as much as for the aged/disabled community sample (\$5,213). The CMS-HCC community

model over-predicts mean working aged expenditures by a factor of 3.66. Essentially, we define the working aged multiplier as the ratio of mean actual to mean predicted expenditures for the working aged sample, where expenditures are predicted by the CMS-HCC community model. With an adjustment for beneficiaries who have a mixture of working aged and non-working-aged months in the payment year, the working aged multiplier is 0.215.

CONCLUSIONS

CMS' adaptation of the DCG/HCC model makes substantially more accurate predictions of medical costs for M+C enrollees than has previously been possible. Its use is intended to redirect money away from MCOs that cherry-pick the healthy, while providing the MCOs that care for the sickest patients the resources to do so. The ultimate purpose of the CMS-HCC payment model is to promote fair payments to MCOs that reward efficiency and encourage excellent care for the chronically ill. The CMS-HCC model will continue to evolve. Additional diagnoses may be needed to predict drug expenditures incurred under the drug benefit enacted by MMA (2003). The model may need to be recalibrated to reflect new treatment patterns and disease prevalence. Diagnosis-based risk adjustment may need to be coordinated with disease management programs and incentives for quality of care.

The model has evolved over two decades of research,²⁰ with careful attention to clinical credibility, real-world incentives and feasibility tradeoffs. Continuous feedback between government technical staff and policymakers at CMS on the one hand, and

research organization and academic researchers on the other, has shaped the CMS-HCC model. Much of the recent research reported in this article has related to adapting the model for Medicare sub-populations. The use of a single modeling framework—the CMS-HCC model—provides unity and organization to the subgroup models with the unique features specific to certain types of beneficiaries. Comprehensive risk adjustment, based on ambulatory as well as inpatient diagnoses, is just beginning to be implemented. Thus, it is too early to tell whether it will achieve its goals. As risk adjustment continues to be incorporated in Medicare payments to MCOs, it will be important to evaluate its impact on these organizations and the beneficiaries they serve, especially organizations that care for the chronically ill and their enrollees. This will tell us a great deal about the feasibility and consequences of matching health care resources to needs.

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Measuring Diagnoses: ICD Code Accuracy

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Objective. To examine potential sources of errors at each step of the described inpatient International Classification of Diseases (ICD) coding process.

Data Sources/Study Setting. The use of disease codes from the ICD has expanded from classifying morbidity and mortality information for statistical purposes to diverse sets of applications in research, health care policy, and health care finance. By describing a brief history of ICD coding, detailing the process for assigning codes, identifying where errors can be introduced into the process, and reviewing methods for examining code accuracy, we help code users more systematically evaluate code accuracy for their particular applications.

Study Design/Methods. We summarize the inpatient ICD diagnostic coding process from patient admission to diagnostic code assignment. We examine potential sources of errors at each step and offer code users a tool for systematically evaluating code accuracy.

Principle Findings. Main error sources along the “patient trajectory” include amount and quality of information at admission, communication among patients and providers, the clinician’s knowledge and experience with the illness, and the clinician’s attention to detail. Main error sources along the “paper trail” include variance in the electronic and written records, coder training and experience, facility quality-control efforts, and unintentional and intentional coder errors, such as misspecification, unbundling, and upcoding.

Conclusions. By clearly specifying the code assignment process and heightening their awareness of potential error sources, code users can better evaluate the applicability and limitations of codes for their particular situations. ICD codes can then be used in the most appropriate ways.

Key Words. ICD codes, accuracy, error sources

Nosology (the systematic classification of diseases) has always fascinated the sick and their would-be healers. Western societies developed an interest in nosology in the seventeenth and eighteenth centuries when they began to track the causes of sickness and death among their citizens. In the twentieth

century, when medical insurance programs made payers other than patients responsible for medical care, nosology became a matter of great interest to those public and private payers. The most commonly used nosologies include International Classification of Diseases (ICD), the American Medical Association's Current Procedural Terminology, 4th Edition (CPT-4); the Health Care Financing Administration (HCFA, now known as the Centers for Medicare and Medicaid Services) Health Care Common Procedural Coding System (HCPCS); the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, 4th Revision (DSM-IV); Europe's Classification of Surgical Operations and Procedures, 4th Revision (OPCS-4); and the Agency for Healthcare Research and Quality's Clinical Classification Software (CCS).

This paper focuses on the International Classification of Diseases, now in its ninth and soon to be tenth iteration; the most widely used classification of diseases. Beginning in 1900 with the ICD-1 version, this nosology has evolved from 179 to over 120,000 total codes in ICD-10-CM (ICD-10 2003; ICD-10-CM 2003). The use of codes has expanded from classifying morbidity and mortality information for statistical purposes to diverse sets of applications, including reimbursement, administration, epidemiology, and health services research. Since October 1 1983, when Medicare's Prospective Payment System (PPS) was enacted, diagnosis-related groups (DRGs) based on ICD codes emerged as the basis for hospital reimbursement for acute-care stays of Medicare beneficiaries (U.S. Congress 1985). Today the use of ICD coding for reimbursement is a vital part of health care operations. Health care facilities use ICD codes for workload and length-of-stay tracking as well as to assess quality of care. The Veterans Health Administration uses ICD codes to set capitation rates and allocate resources to medical centers caring for its 6 million beneficiaries. Medical research uses ICD codes for many purposes. By grouping patients according to their diagnoses, clinical epidemiologists use ICD codes to study patterns of disease, patterns of care, and outcomes

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of disease. Health services researchers use the codes to study risk-adjusted, cross-sectional, and temporal variations in access to care, quality of care, costs of care, and effectiveness of care. Medical and health services researchers commonly use ICD codes as inclusion and exclusion criteria to define sampling frames, to document the comorbidities of patients, report the incidence of complications, track utilization rates, and determine the case fatality and morbidity rates (see Calle et al. 2003 for a recent example) (Steinman, Landefeld, and Gonzales 2000; Calle et al. 2003; Charbonneau et al. 2003; Jackson et al. 2003; Martin et al. 2003; Studdert and Gresenz 2003). The widespread and diverse use of ICD codes demonstrates the central role nosology plays in health care.

Increased attention to code accuracy has occurred both as a result of the application of ICD codes for purposes other than those for which the classifications were originally designed as well as because of the widespread use for making important funding, clinical, and research decisions. Code accuracy, defined as the extent to which the ICD nosologic code reflects the underlying patient's disease, directly impacts the quality of decisions that are based on codes, and therefore code accuracy is of great importance to code users. Accuracy is a complicated issue, however, as it influences each code application differently. Using the codes for reporting case fatality rates in persons hospitalized for influenza, for example, might require a different level of accuracy than using codes as the basis for reimbursing hospitals for providing expensive surgical services to insured persons. Therefore, users of disease classifications, just as users of any measure, must consider the accuracy of the classifications within their unique situations. An appreciation of the measurement context in which disease classifications take place will improve the accuracy of those classifications and will strengthen research and health care decisions based on those classifications.

Researchers studying errors in the code assignment process have reported a wide range of errors. Studies in the 1970s found substantial errors in diagnostic and procedure coding. These error rates ranged from 20 to 80 percent (Institute of Medicine 1977; Corn 1981; Doremus and Michenzi 1983; Johnson and Appel 1984; Hsia et al. 1988). Studies in the 1980s reported slightly increased accuracy with average error rates around 20 percent, and most below 50 percent (Lloyd and Rissing 1985; Fischer et al. 1992; Jolis et al. 1993). Studies in the 1990s found rates similar to those of the 1980 studies, with error rates ranging from 0 to 70 percent (Benesch et al. 1997; Faciszewski, Broste, and Fardon 1997; Goldstein 1998). The inconsistency in the error rates and wide range of reported amounts of error is due largely to

differences across study methods (i.e., different data sets, versions of the ICD classifications, conditions studied, number of digits compared, codes examined, etc.) (Bossuyt et al. 2004). However, variation in error rates is also influenced by the many different sources of errors that influence code accuracy (Green and Wintfeld 1993). By clearly specifying the code process and the types of errors and coding inconsistencies that occur in each study, researchers can begin to understand which errors are most common and most important in their situation. They can then institute steps for reducing those errors.

If we think of the assignment of ICD codes as a common measurement process, then the person's true disease and the assigned ICD code represent true and observed variables, respectively. One approach to evaluating ICD code accuracy is to examine sources of errors that lead to the assignment of a diagnostic code that is not a fair representation of the patient's actual condition. Errors that differentiate the ICD code from the true disease include both random and systematic measurement errors. By understanding these sources of error, users can evaluate the limitations of the classifications and make better decisions based on them. In this manuscript, we (1) present the history of ICD code use, (2) summarize the general inpatient ICD coding process (from patient admission to the assignment of diagnostic codes), (3) identify potential sources of errors in the process, and (4) critique methods for assessing these errors.

BACKGROUND

History of ICD Codes

In 1893, the French physician Jacques Bertillon introduced the Bertillon Classification of Causes of Death. This first edition, had 179 causes of death. It was recommended that this classification system, subsequently known as the International Classification of Causes of Death (ICD), be revised every 10 years. With each revision, the numbers of codes increased, as did the appeal of using them for other purposes.

The World Health Organization (WHO) published the ninth revision of ICD in 1978. The ICD-9 is used to code mortality data from death certificates. To make the ICD more useful for American hospitals, the U.S. Public Health Service modified ICD-9 and called it the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). In the Clinical Modification (CM) of ICD-9, codes were intended to be more precise than those needed only for statistical groupings and trend analysis (The International Classification of Diseases, 9th Revision, Clinical Modification [ICD-9-CM], Sixth Edition 2002).

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The modified version expanded to three volumes, and a fifth-digit subclassification was introduced. The fifth digit adds increased specificity and is required when available. When identifying burns with codes 941 through 954, for example, a fourth digit indicates the depth of the burn and a fifth digit specifies the exact location. ICD-9-CM is used in the United States to code and classify diagnoses and procedures from inpatient and outpatient records, as well as inpatient procedures. The ninth revision contains over 12,000 diagnostic and 3,500 procedure codes.

The development of a tenth revision, International Statistical Classification of Diseases and Related Health Problems (ICD-10), introduces alphanumeric codes and greater specificity than ICD-9, and includes over 21,800 total codes (ICD-10 2003). In January 1999, the United States began using ICD-10 to code and classify mortality data from death certificates; however, at the time of this writing, the clinical modification version (ICD-10-CM), was still under development by the National Center for Health Statistics (NCHS) and has not been released.

The Process for Assigning ICD Codes

In this paper, we focus on codes assigned during hospital stays, and whereas basic coding procedures are similar across ambulatory settings, the reader is cautioned that some errors may be setting-specific. The basic process for assigning ICD codes for inpatient stays, presented in Figure 1, can be conceptualized as the dynamic interplay between the patient as he or she progresses through the health care system (called the "patient trajectory") and the creation of the medical record (called the "paper trail"). The basic process shown in Figure 1 is typical, even though details of any given step at any given facility may vary. The left side of Figure 1 portrays the patient trajectory through the system, from admission to discharge. The right side of Figure 1 represents the paper trail, or medical record creation, from the recording of the admitting diagnosis to the assignment of the ICD codes after discharge.

The patient trajectory starts when the patient arrives at the hospital, at which time some type of precertification (insurance) based on the admitting diagnosis is performed by the admission clerk (at least for insured patients). After admission, based on the physician's admitting diagnosis and the information generated by the initial workup, the patient undergoes diagnostic tests and procedures and/or other treatment, as ordered by the medical staff. The patient and medical staff members continue to meet throughout the hospital stay to exchange information, and additional tests, procedures, and/or

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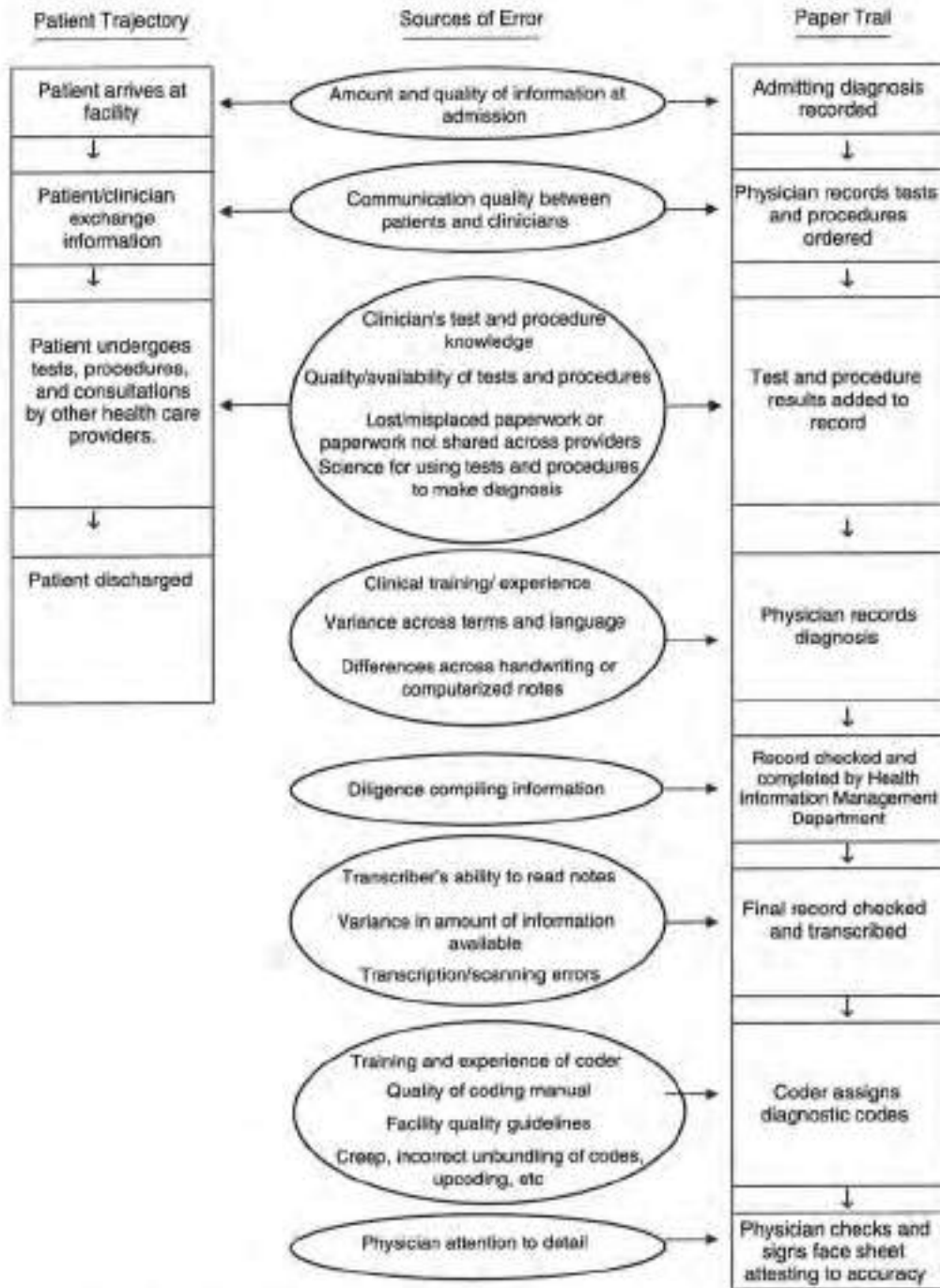


Figure 1: Overview of the Inpatient Coding Process.

treatments may be ordered. Test and procedure results are added to the medical record. The results from the tests and procedures often result in

changes in the admitting diagnosis. Furthermore, complications arising from care may also add to the list of diagnoses. The staff documents the hospital stay using either handwritten or electronic reporting. Upon discharge, the physician completes a narrative discharge summary that includes a list of primary and secondary diagnoses (word labels) and describes follow-up plans.

Upon discharge, the patient's medical record and all associated documentation are transferred to the medical record or health information management department. Concurrently, technicians check to ensure that all medical record information is accurate and complete (including the face sheet, history and physical, operative reports, radiology reports, physician's orders, progress and nursing notes, consultations, discharge summary, etc.). Coders then begin the process of classifying documentation, including diagnoses and procedures, using rigid ICD coding guidelines and conventions. Some facilities outsource medical transcription and coding.

After reviewing all pertinent medical record information, medical coders assign a code for the principal diagnosis, defined by the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital care" (Uniform Hospital Discharge Data Set 1985). The principal diagnosis assignment is made based on written documentation from the providers. Coders also assign a code for the principal procedure, or one performed for definitive treatment or that was necessary for treating a complication. They assign additional diagnostic codes (the code count being determined by the facility) for diagnoses that require clinical evaluation, therapeutic interventions, diagnostic procedures, extended lengths of stay (for inpatient stays), or increased nursing care and/or monitoring. Additional procedures are coded as well. The VA, for example, allows up to 10 diagnoses and five procedure codes per inpatient day (Department of Veterans Affairs 2002). Coders may also assign V-codes (codes describing conditions that coexist during a patient's stay that influence the stay, such as history of cancer or lack of housing), E-codes (supplementary classification of factors influencing the patient's health status and contact with health services), and M-Codes (supplementary classification of the morphology of neoplasms).

After the code assignments and the sequencing of the codes have been determined, a computerized software program, called a grouper, is often used to classify or group the codes for reimbursement purposes. When the coding process is complete, the codes are transmitted to the billing department for reimbursement purposes.

EXAMINING CODING ERRORS

Sources of Errors

Many sources of error are interposed between a person's disease (as it is in truth) and the word label (the diagnosis) applied to it by a clinician, and between the diagnosis and the nosologic code applied to it by a medical coder. A summary of these errors, organized according to the patient trajectory and the paper trail depicted in Figure 1.

Errors Along the Patient Trajectory

A "diagnosis" is a word label applied to the disordered anatomy and physiology (the disease) presumed to be causing a person's constellation of symptoms and signs. Several sources of error influence the diagnostic process from patient admission to discharge. "Diagnosis, is in the end, an expression of probability" (author of quotation is unknown). Hardly any diagnosis—even one made at autopsy—is certain (Ornelas-Aguirre et al. 2003; Silfvast et al. 2003). The certainty, or accuracy, of a diagnosis depends upon multiple factors such as the participants (e.g., patient, clinician, medical staff), disease type, current state of medical knowledge and technology, context within which the diagnosis is made, and translation of coding changes into practice.

The first potential sources of error along the trajectory in Figure 1 relate to communication. The quality and quantity of communication between the patient and his or her admitting clerk and treating clinicians are critical determinants of the accuracy of the admitting diagnosis. If the patient describes only a subset of symptoms or withholds important information, for example, the accuracy of the diagnosis may be compromised, leading the clinician down the wrong line of diagnostic reasoning. Clinicians can be poor communicators as well. The clinician may fail to ask the right questions, may not fully elicit the patient's history, or may misunderstand the patient, resulting in another source of error in the process.

When the clinician orders diagnostic tests and procedures, potential sources of error that may be introduced include the clinician's knowledge about the best diagnostic tests and procedures, the availability of these tests and procedures, and the clinician's ability to interpret the results. Diagnostic accuracy depends upon the state of scientific understanding regarding various presentations and etiologies of the disease. Further, the utility (sensitivity, specificity, and predictive value) of the tests and procedures available to the clinician impacts the certainty of the diagnosis. A disease for which tests have high sensitivity and specificity will result in higher diagnostic accuracy

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compared with a disease with vague manifestations and poor diagnostic tests. The accuracy of cancer diagnoses, for example, is typically higher than of schizophrenia diagnoses, in part because tumor histopathology and serum markers are less ambiguous than the behavioral diagnostic criteria for schizophrenia. Errors also occur when the physician records the diagnosis. Variance in the clinician's description of the diagnosis—often 5–10 synonyms exist for the same clinical entity—and clarity in the recording of the diagnosis, especially if handwritten, also introduce error into the coding process. Clinicians are notorious for undecipherable handwriting.

Consider how errors in the patient trajectory may influence the diagnosis of a patient with a stroke (a disruption of blood supply to the brain). The warning symptom for stroke, a transient ischemic attack (TIA), is a set of transitory neurological symptoms (in medical parlance, symptoms are subjective and not directly observable by others) and/or signs (signs are observable by others) thought to result from a temporary interference with arterial circulation to a discrete part of the brain. Some TIAs are over in seconds; by definition, all TIAs resolve within 24 hours or they are given a different label (Johnston et al. 2003). The signs and symptoms of TIA are nonspecific; that is, they can result from several other conditions besides a temporary interruption of blood flow to a part of the brain. Because the symptoms are nonspecific, the patient at admission might choose to share only a few (e.g., the patient reports headache but not dizziness), or the patient might not notice the more subtle symptoms (e.g., subtle visual field disturbances) and therefore not share them with the clinician. During the patient–clinician interaction, the clinician might make a decision based only on the symptoms reported by the patient and only on the most obvious signs. Furthermore, no blood or imaging test at present can confirm or disconfirm the occurrence of a TIA. Therefore, the diagnosis of TIA rests on a clinician's acumen, and acumen depends on training, experience, attention, thoroughness, and the ability to elicit information from the patient and/or available informants. Consequently, the interrater reliability of the diagnosis of TIA is very low, such as κ values just over 0.40 and overall agreement of 57 percent (Dewey et al. 1999; Goldstein et al. 2001; Wilson et al. 2002). Further, new diagnostic criteria for TIA have recently been proposed (Albers et al. 2002). If adopted, these criteria will compound the difficulty in monitoring the incidence and prevalence of TIAs over time.

As criteria for the diagnosis of diseases are constantly in flux because of the evolving nature of medical knowledge, new types of errors (or coding inconsistencies) are introduced into the process, and other errors may decrease as diagnostic accuracy increases. New errors may evolve from

clinicians' delay in learning about medical advances or new diagnostic tools. This is especially true for conditions for which no laboratory or imaging tests are available. A case in point is mental illness, the diagnosis of which is based on the DSM published by the American Psychiatric Association, now in its fourth major iteration (American Psychiatric Association 1994). Consider, for example, how "homosexuality" as a diagnosis evolved from being a nondiagnosis to a mental illness diagnosis to a "life style."

Even when laboratory or imaging tests are available for confirming or ruling out a diagnosis, medical technology evolves and the tests improve. For example, the diagnosis of acute stroke no longer requires a spinal tap and direct arteriography of cerebral vessels; the diagnosis can now be made noninvasively with a magnetic resonance imaging study of the brain (Provenzale et al. 2003).

Errors Along the Paper Trail

The first three error sources, those of communication and those related to tests and procedures the patient undergoes, that are listed in Figure 1 affecting the paper trail were described in the previous section. Another potential set of errors can be found in the record itself. Clinicians do not generally assign codes; coders assign them based on the labels recorded by clinicians in charts or on death certificates. Errors in this phase have been reported to range from 17.1 to 76.9 percent (Hsia et al. 1988). The variability in the error rates is best understood by considering the measurement contexts in which the code assignments take place.

One potential set of errors can be found in the record itself. In Figure 1, these are the fourth set of errors listed. In their written or electronically entered record, clinicians often use synonyms and abbreviations to describe the same condition. For example, synonyms for "stroke" include cerebrovascular accident, cerebral occlusion, cerebral infarction, and apoplexy, among others. The variance in terms is problematic, as each diagnostic code should represent one and only one disease entity. From the clinician's recorded diagnosis label, the coder must select the ICD code that best seems to match the clinician's terminology. The use of synonyms leads to imprecision. For example, a patient who had a stroke can be described by one doctor as having had an intracerebral hemorrhage (Code 431) and by another doctor as having had a cerebrovascular accident (Code 436) and both doctors would be technically correct. Errors can also occur because of physicians' and other staff's omissions in the medical record. In 1985, a study of 1,829 medical records in the Veterans Administration indicated that over 40 percent of physician errors

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were attributed to omissions (Lloyd and Rissing 1985). Another source of recorder error is in the transcription of the medical record. Transcription can be defined as the process of converting medical record information from voice (dictation) to hardcopy report or electronic format. Transcription or scanning errors are additional threats to code accuracy. The extent to which the chart information is complete influences the accuracy of the codes as well. Concurrent coding, coding that is performed before patient discharge, is implemented in some facilities in order to expedite the coding and billing processes. With the considerable pressure on hospitals to discharge patients these days (at least, in the U.S.), coders may have incomplete clinical information when they receive the chart. As a result, coders are required to assign codes with varying amounts of information, which impacts code accuracy.

Many potential errors originate with the coder. The fact that coders must pour through sometimes voluminous records to extract diagnoses can lead to several types of errors. One study examining coding variation found that when 11 experienced, active medical coders reviewed 471 medical records and were told they would be reevaluated, all of the coders differed in one or more data fields for more than half of the records (Lloyd and Rissing 1985). The adequacy of training the coder receives influences her or his ability to synthesize large amounts of information and assign precise codes. The American Health Information Management Association (AHIMA), the governing body for health information professionals, designates two types of certification: a 2-year certification (Registered Health Information Technician, previously Accredited Record Technician) and a 4-year certification (Registered Health Information Administrator, previously Registered Record Administrator). The existence of two levels of certification, based on length of academic programs and course content, may contribute to coding inconsistencies. In addition to these two professional credentials, AHIMA also offers multiple coder certification opportunities and credentials. Continuing education of coders, or lack thereof, also influences coding accuracy, as the codes and coding rules expand and change annually. For example, on October 1 2003, a new ICD-9 procedure code (00.15) was created to identify patients who receive high dose interleukin-2 treatment. As another example, a comparison of ICD-9-CM with ICD-10-CM indicates that the number of categories doubled from 4,000 to 8,000 and the number of death causes increased from 72 to 113 (Colorado Department of Public Health and Environment 2001). Changes in codes include reclassification of codes, such as moving of hemorrhage from the "circulatory" chapter to the "signs and symptoms" chapter, and changing of the four-digit numeric codes of ICD-9 to the four-digit alphanumeric codes of

ICD-10. Diabetes mellitus, for example, was coded 250 in ICD-9 and is coded E10-E14 in ICD-10 (ICD-10 2003). Without continuing education on code changes and additions, hospitals can lose reimbursement funds and researchers can lose data accuracy.

The coders' experience, attention, and persistence also affect the accuracy of coding. These errors are the fifth and sixth errors shown in Figure 1. When a patient is admitted with renal failure and hypertension, a novice coder may code each condition separately, whereas an experienced coder will look to see if there is a connection between the two conditions, and if so, will use the specific combination code. If coders are unsure of a diagnosis or which diagnosis constitutes the principal diagnosis, they are expected to contact the physician or gather the necessary information to record the correct diagnosis. If coders fail to recognize when they need additional information or if they are not persistent in collecting it, additional error is imposed into the coding system.

At the phase of the paper trail in which diagnostic labels are translated into ICD codes, some specific types of coder-level errors can be identified. These errors, the next to last set in Figure 1, include creep, upcoding, and unbundling, to name a few. Creep includes diagnostic assignments that deviate from the governing rules of coding. Creep errors have also been labeled as misspecification, miscoding, and resequencing errors (Hsia et al. 1988).

Misspecification occurs when the primary diagnosis or order for tests and procedures is misaligned with the evidence found in the medical record. Miscoding includes assignment of generic codes when information exists for assigning more specific codes, assignment of incorrect codes according to the governing rules, or assignment of codes without the physician attesting to their accuracy (Hsia et al. 1988). An example of miscoding for an ischemic stroke might involve using the more generic ICD-9 code of 436 (acute but ill-defined cerebrovascular disease) in place of the more specific ICD-9 codes of 433 (occlusion and stenosis of precerebral arteries) or 434 (occlusion of cerebral arteries) (Goldstein 1998).

Resequencing codes, or changing the order of them, comprises another potential error source. Take as an example the patient who had respiratory failure as a manifestation of congestive heart failure. The congestive heart failure should be the principal diagnosis and the respiratory failure the secondary diagnosis. Resequencing errors occur when these diagnoses are reversed (Osborn 1999). Most sequencing errors are not deliberate. Sequencing errors may comprise the commonest kind of errors in hospital discharge abstracts (Lloyd and Rissing 1985).

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Upcoding, assigning codes of higher reimbursement value over codes with lesser reimbursement value, is an additional source of error at the coder level. For example, upcoding a urinary tract infection to the more serious condition of septicemia results in an increase of over \$2,000 in reimbursement. Because upcoding misrepresents the true condition of the patient, it constitutes falsification of medical records and can often be detected by comparing the medical record to the codes listed in the discharge abstract. When coders assign codes for all the separate parts of a diagnosis instead of assigning a code for the overall diagnosis, the practice is called unbundling. Whether done in error or intentionally for gain, unbundling constitutes coding error. Although we label these errors as coder-level errors, systematic coding variation may be apparent at the hospital-level, as shown by some evidence from at least one study (Romano et al. 2002).

The final potential error listed in Figure 1 occurs when the physician attests to the accuracy of the coding information. As physicians treat many patients simultaneously and support heavy workloads, the time and attention physicians dedicate to checking the accuracy of the codes varies tremendously. Errors at the point of attestation include reviewing too quickly or not reviewing the face sheet and supporting documents, poor recall of the details of the patient's conditions, and incorrect recording on the attestation sheet.

Ways to Measure Code Accuracy

Five statistics are commonly used to summarize the amount of error in ICD coding: sensitivity, specificity, positive predictive value, negative predictive value, and κ coefficient. These statistics are simple to compute; that is, it is easy to come up with the "right answer." It is more challenging to state precisely what questions are answered by each of these statistics. In the current context, it is helpful to remember that the reliability of ICD coding is with respect to some other method of obtaining a diagnostic label. Sensitivity and specificity are statistics often used when some "gold standard" is available. As discussed above, however, there is no gold standard for diagnostic labeling.

A researcher whose question is, "How accurate are the diagnoses?" might compare the diagnostic labels assigned by two or more experts (e.g., physicians) evaluating the same sample of patients. A good choice of statistic for this research design might be the κ coefficient. This statistic quantifies beyond-chance agreement among experts; therefore, it would be an appropriate estimator of the reliability of diagnoses made by experts. However, if the research question is, "In medical chart reviews, how well do medical

coders' ICD code assignments match those of physicians?" then a true gold standard exists. In such a case, the researcher might prefer to calculate specificity, sensitivity, and predictive values using the physicians' reviews as the gold standard. What must be kept clearly in mind, however, is that the values of the statistics obtained in this scenario express nothing about the reliability of medical diagnosis. They estimate, in the context of medical chart review, the corroboration between physician and medical coders' ICD classifications.

Discussion

The process of assigning ICD codes is complicated. The many steps and participants in the process introduce numerous opportunities for error. By describing a brief history of ICD coding, detailing the process for assigning codes, identifying places where errors can be introduced into the process, and reviewing methods for examining code accuracy, we hope to demystify the ICD code assignment process and help code users more systematically evaluate code accuracy for their particular applications. Consideration of code accuracy within the specific context of code use ultimately will improve measurement accuracy and, subsequently, health care decisions based on that measurement.

Although this paper focused on errors influencing code accuracy, the goal was not to disparage ICD codes in general. ICD codes have proven incredibly helpful for research, reimbursement, policymaking, etc. In fact, without ICD codes, health care research, policy, and practice could not have advanced as far as they have. However, code use and decision making on the bases of codes is improved when code accuracy is well understood and taken into account. By heightening their awareness of potential error sources, users can better evaluate the applicability and limitations of codes in their own context, and thus use ICD codes in optimal ways.

One way to heighten code users' awareness of potential error sources is to create a tool for their use when evaluating ICD codes. Based on our evaluation of the code assignment process, we created Figure 1, which summarizes the basic inpatient process for code assignment. This flowchart is designed to focus code users' attention on key aspects of the code assignment process and facilitate their critique of codes. By identifying potential code errors, users may be able to specify bias that might influence data accuracy. Instead of weakening a study, the recognition of potential sources of code bias will strengthen researchers' interpretations of data analyses using the codes.

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A few practical recommendations can be made for code users. First, codes are likely to be most accurate under the following conditions: the disease has a clear definition with observable signs and symptoms, highly qualified physicians document information on the patient, experienced coders with full access to information assign the codes, and the codes are not new. Furthermore, codes are more likely to be accurate in calculating disease prevalence than in calculating disease incidence, as incidence requires identification of new cases, or cases without previous documentation. When the accuracy of a specified code is high, it would be appropriate to identify individuals for inclusion in patient registries or intervention studies. Codes considered less accurate are better suited for screening for potential study participants and for identifying pools of recruits. As code accuracy decreases, or becomes more questionable, researchers will want to use codes in combination with other measures. For example, codes from one occasion could be combined with test results or with codes from other occasions to improve the accuracy of disease classification. Suppose researchers wish to identify patients with stroke for an expensive intervention study. Given that past studies have found that using ICD-9 diagnostic codes of 433 through 436 from administrative databases are not very accurate for diagnosing stroke (Leibson et al. 1994; Benesch et al. 1997), researchers may decide to use codes 433 through 436 as an initial screener for including patients in the study. Then, to increase the accuracy of the diagnosis, researchers may wish to review these patients' hospitalization charts and outpatient records. Researchers can make study inclusion decisions based on the combination of ICD codes and clinical evidence, such as prior history of cerebral ischemic events, cerebrovascular risk factors, related procedures (carotid endarterectomy or angiography), and functional abilities. Although collecting the clinical evidence will take additional time and resources, it will improve the accuracy of the diagnoses and will likely lead to more appropriate study results.

Because the use of ICD codes is commonplace, and studies on code accuracy can be found in a wide variety of disease- and discipline-specific journals, code users need easy access to a resource for reviewing code accuracy studies. To meet this need, the Measurement Excellence and Training Resource Information Center (METRIC), a VA initiative for improving measurement in health care, has created a repository of abstracts from code accuracy studies. The repository is located at <http://www.measurementexperts.org/icd9ab.htm>. The METRIC started the repository, but recognizes many important study references are missing. METRIC encourages code users to visit the site, review the repository, and recommend other studies and

documents that can be added. With input from the many types of code users, this resource can become a valuable tool for evaluating ICD code accuracy. METRIC envisions this as a dynamic resource that will facilitate ICD code users' ability to access code accuracy information in an efficient and timely manner.

Although many studies have examined ICD code accuracy, knowledge in several areas is underdeveloped. Two important areas are the reliability of physician diagnoses and the factors that influence that reliability. Many ICD code accuracy studies consider the physician diagnosis as recorded in the medical record as the gold standard for measuring diagnoses (Lloyd and Rising 1985; Hsia et al. 1988; Fischer et al. 1992). In at least one study, researchers demonstrated that the medical record cannot be considered a gold standard, as measured against standardized patients, for example Peabody et al. (2000).

Little consideration is given to the process leading to the physician's diagnosis. Certainly the quality of the gold standard varies based on disease factors (type, knowledge, and progression) and physician factors (experience with the disease and knowledge of diagnostic tools for the disease). Further research examining which factors influence the quality of the physician's diagnosis and the extent to which these factors affect the gold standard is greatly needed.

As researchers, policy makers, insurers, and others strive to impose some organization on the complicated health care field, disease and procedure classification systems will receive increased attention. Although no system of classification will ever be perfect, our ability to improve taxonomies rests in our dedication to understanding the code assignment process and to sharing information about its strengths and weaknesses.

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EXHIBIT D-44

CHAPTER

4

**Issues for risk adjustment
in Medicare Advantage**

CHAPTER

4

Issues for risk adjustment in Medicare Advantage

Chapter summary

Health plans that participate in the Medicare Advantage (MA) program receive monthly capitated payments for each Medicare enrollee. Each capitated payment is the product of two general parts: a base rate, which reflects the payment if an MA enrollee has the health status of the national average beneficiary, and a risk score, which indicates how costly the enrollee is expected to be relative to the national average beneficiary. The purpose of the risk scores is to adjust MA payments so that they accurately reflect how much each MA enrollee would be expected to cost. In this chapter, we examine the performance of the risk-adjustment system in the MA program and offer alternatives for improving it.

Improving payment accuracy of the CMS-hierarchical condition category model

Currently, CMS uses the CMS-hierarchical condition category (CMS-HCC) model to risk adjust each MA payment. This model uses enrollees' demographics and medical conditions collected into 70 HCCs to predict their costliness. It has been shown to be a much better predictor of a beneficiary's costliness than the demographic-based model that preceded it. Analysis of the CMS-HCC model and the demographic model indicates that the CMS-HCC model explains about 11 percent of the variation in costliness among individual beneficiaries, whereas the demographic model explains only about 1 percent (Pope et al. 2004).

In this chapter

- Evidence that MA enrollees tend to be lower cost than FFS beneficiaries
- Improving predictive accuracy of the CMS-HCC model
- Issues related to financial neutrality between FFS Medicare and the MA program

The demographic model did not include factors that are important for predicting beneficiaries' costliness—such as conditions. Consequently, it systematically overpredicted costs for healthy beneficiaries and systematically underpredicted costs for beneficiaries in poor health. Because the CMS–HCC model includes beneficiaries' conditions as well as their demographic information, it explains more of the variation in beneficiaries' costliness and predicts costs more accurately than the demographic model. However, systematic overpredictions and underpredictions may remain under the CMS–HCC model. For example, for all beneficiaries who have the same condition, the CMS–HCC model adjusts MA payments by the same proportion. But the severity of a condition varies across beneficiaries, and those with greater severity tend to be more costly. In addition, research suggests that a minimum of 20 percent to 25 percent of the variation in beneficiaries' costliness may be predictable, so the CMS–HCC may leave half or more of the predictable variation unexplained (Newhouse et al. 1997). Therefore, for a given condition it is possible that plans can be financially advantaged or disadvantaged based on the risk profile (overall health status) of their enrollees.

To the extent that systematic prediction errors occur under the CMS–HCC model, we explored several policy options for reducing these errors:

- Add measures of income and indicators for race to the model. If beneficiaries in certain income categories or racial groups tend to have greater severity for given conditions, these additional variables could reduce prediction errors.
- Include measures for the number of conditions in the model. The cost of treating a certain condition may increase as more comorbidities are present.
- Use two years of beneficiaries' diagnoses to determine their condition categories. CMS currently uses one year of beneficiaries' diagnoses to determine their conditions, but we have found that providers often do not consistently code conditions on claims from year to year. Using two years of diagnosis data (when available) would help to fully identify beneficiaries' conditions.

Our analysis indicates that including beneficiaries' race and measures of income would not improve predictive accuracy. However, including the number of conditions would improve predictive accuracy for beneficiaries who have many conditions. Using two years of diagnoses to identify beneficiaries' conditions also would improve predictive accuracy for beneficiaries who have many conditions but to a lesser extent than adding the number of conditions. In addition, using two years of diagnoses would reduce year-to-year fluctuations in beneficiaries' risk scores, which would result in more stable revenue streams for MA plans.

Because adding the number of conditions and using two years of diagnosis data both have beneficial effects, but in different ways, we also examined the effects of adding both features to the CMS-HCC model. It resulted in more accurate predictions for high-risk beneficiaries and smaller year-to-year fluctuations in beneficiaries' risk scores.

Other issues for MA risk adjustment

On several occasions, the Commission has taken a position that payments for MA enrollees should equal what they would be expected to cost in FFS Medicare (financial neutrality) (Medicare Payment Advisory Commission 2001, Medicare Payment Advisory Commission 2002, Medicare Payment Advisory Commission 2004, Medicare Payment Advisory Commission 2005). An underlying rationale for this policy is that it encourages beneficiaries to enroll in whichever sector (MA or FFS) is more efficient in their local health care market. Two recently published papers have implications for the interaction between risk adjustment and financial neutrality. One paper shows that in FFS Medicare, regions that have high per capita service use also have high average risk scores, and areas that have low per capita service use have low average risk scores (Song et al. 2010). At least some of the regional difference in risk scores is due to differences in service use that do not reflect differences in health status; that is, risk scores are high in some regions simply because beneficiaries get more health care, not because they are sicker. If these same regional differences in service use and risk scores occur in the MA program, they drive MA payments higher in high-use regions. Adjustments could be made to eliminate these differences.

A second paper shows there are differences between FFS Medicare and a large MA plan in the relative costliness of treating conditions (Newhouse et al. 2011). If these cost differences between FFS Medicare and MA plans are widespread, risk adjustment underpredicts MA costs for some conditions and overpredicts MA costs for other conditions. An issue to consider is whether it is more appropriate for CMS to estimate the CMS-HCC model by using cost and diagnosis data from MA enrollees rather than FFS beneficiaries.

Both papers have implications for equity in the MA program: Adjusting MA risk scores to reduce the effects of regional differences in risk scores would reduce regional variations in MA payments, and using data from MA enrollees to estimate the CMS-HCC model would reduce incentives for plans to attract beneficiaries who have some conditions and avoid beneficiaries who have other conditions. However, both issues are inconsistent with the concept of financial neutrality between MA and FFS Medicare. These issues will have to be discussed in the future.

A final issue regarding risk adjustment is that analyses by CMS and the Government Accountability Office (GAO) both indicate that risk scores have increased at a faster rate in the MA program than in FFS Medicare (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). The higher growth rate in MA has resulted in MA enrollees having higher risk scores than they would have in FFS Medicare. In an effort to bring MA risk scores in line with those in FFS Medicare, CMS has made adjustments to MA risk scores, but GAO believes that larger adjustments should be made. ■

Health plans that participate in the Medicare Advantage (MA) program receive monthly capitated payments for each Medicare enrollee. Each capitated payment is the product of two general parts: a base rate, which reflects the payment if an MA enrollee has the health status of the national average Medicare beneficiary, and a risk score, which indicates how costly the enrollee is expected to be relative to the national average beneficiary.

Over the years, CMS has employed various methods for determining MA enrollees' risk scores. Currently, CMS uses the CMS-hierarchical condition category (CMS-HCC) risk-adjustment model, which uses enrollees' demographics and condition categories (such as diabetes and stroke) to predict their costliness. The demographic variables include age, sex, Medicaid status, institutional status, eligibility based on being disabled, and eligibility based on age but originally eligible because of disability.

All demographic variables are from the year for which beneficiaries' costs are to be predicted (the prediction year). The condition categories are based on diagnoses recorded on physician, hospital outpatient, and hospital inpatient claims in the year before beneficiaries' costs are to be predicted (the base year). This makes the CMS-HCC a prospective model, as opposed to a concurrent model, which would use conditions from the prediction year. It is logical to use a prospective model in the MA program because the express purpose of MA plans is to provide care to manage their enrollees' conditions. If concurrent risk adjustment were used, MA plans would be reimbursed as their enrollees' conditions occur, rather than being paid to manage existing chronic conditions.

An underlying feature of a prospective risk-adjustment model for beneficiaries with a given set of conditions is that it underpredicts costs for some beneficiaries, overpredicts for others, but predicts accurately on average. However, when prediction inaccuracies occur systematically with identifiable beneficiary characteristics, plans can benefit if their enrollees have characteristics predictive of lower-than-average costs (favorable selection) or be disadvantaged if their enrollees have characteristics predictive of higher-than-average costs (adverse selection). An ideal risk-adjustment system would eliminate all opportunities for favorable selection, but a risk adjuster can be less than ideal and still be effective if it makes efforts by plans to identify favorable risks prohibitively costly.

To the extent that favorable selection occurs in the MA program, it could be caused by the behavior of plans

or beneficiaries. Plans can attract favorable risks by structuring benefits that are attractive to relatively healthy beneficiaries or by marketing their products so that they attract healthy enrollees. Alternatively, relatively healthy beneficiaries may find the structure of managed care plans more attractive than do beneficiaries in poor health.

Selection problems can be reduced by improving risk adjustment to reduce the extent of systematic prediction errors. An alternative method for reducing selection problems is partial capitation, which would pay plans partly on the basis of capitated rates and partly on the actual costs of providing care. This would reduce the likelihood of plans experiencing large losses from very sick enrollees or large profits from healthy enrollees. However, it is not clear what fraction of the payments should be capitated and what fraction should be based on costs.

For each MA enrollee, CMS obtains from the enrollee's plan the condition codes from encounters with physicians, hospital outpatient departments, and hospital inpatient departments. CMS maps the condition codes into hierarchical condition categories (HCCs), which define broad condition categories, such as diabetes and congestive heart failure. All condition codes fall into one of the 189 CMS-defined HCCs. However, CMS uses only 70 HCCs in the CMS-HCC model, so many conditions have no effect on beneficiaries' risk scores.¹ Some conditions, such as diabetes and cancer, are actually represented by groups of several HCCs, which differ according to severity. CMS has determined that a beneficiary cannot have more than one HCC indicated in each of these condition groups. If CMS finds that a beneficiary has conditions that map into more than one HCC within a condition group, only the highest cost HCC is used in predicting the beneficiary's costliness. For example, the CMS-HCC model has five diabetes HCCs. If CMS finds that a beneficiary has condition codes that fit the HCC "diabetes with acute complications" and the HCC "diabetes without complications," CMS drops the HCC "diabetes without complications."

CMS calibrates the additional costliness associated with each demographic variable and each HCC in the model using cost, demographic, and diagnosis data from beneficiaries in fee-for-service (FFS) Medicare, but CMS has begun collecting data on MA beneficiaries and intends to use those data to calibrate the CMS-HCC model.² CMS applies linear regression methods to obtain coefficients on each variable in the model. If a beneficiary has a particular

variable represented in the CMS–HCC model, the coefficient on that variable indicates its marginal cost.

A model that CMS used before the CMS–HCC model included only beneficiaries’ demographic data (demographic model). The demographic model does not include important observable characteristics of beneficiaries that affect their costliness, such as medical conditions. Consequently, the demographic model explains a small fraction of the variation in beneficiaries’ Medicare costliness (about 1 percent) and, within a given demographic category, systematically overpredicts costs for relatively healthy beneficiaries and underpredicts costs for the sickest beneficiaries, leaving the potential for selection problems.

The CMS–HCC model has been shown to be a much better predictor of a beneficiary’s costliness. For example, it explains about 11 percent of the variation in beneficiaries’ costliness. Therefore, the CMS–HCC model likely mitigates selection problems in the MA program.

However, the CMS–HCC model has shortcomings such that it may not have fully eliminated systematic prediction inaccuracies:

- Research on variation in individual-level health care spending suggests that at least 20 percent to 25 percent of the variation in spending can be predicted, with the remaining being random and, hence, unpredictable (Newhouse et al. 1997). Because the CMS–HCC model explains about 11 percent of the variation in spending, it may leave half or more of the predictable variation unexplained.
- For all enrollees with a given health condition, the CMS–HCC model adjusts MA capitated payments by the same rate. For example, the CMS–HCC model increases capitated payments for all MA enrollees with acute myocardial infarction by 35.9 percent above the base rate. However, within condition categories, some beneficiaries are healthier and less costly than others, while some are sicker and more costly.

Because of these shortcomings of the CMS–HCC model, there is a potential for MA plans to benefit financially if they have a relatively healthy beneficiary profile or to be disadvantaged if they have a sicker beneficiary profile. This is especially relevant to plans that specialize in managing the care for the sickest beneficiaries, such as special needs plans (SNPs) and plans in the Program of All-Inclusive Care for the Elderly (PACE), because

payments may not be adequately adjusted to effectively provide care.

We have done an analysis that suggests that MA enrollees are healthier and less costly than their FFS counterparts, meaning that favorable selection may be occurring in the MA program. In this chapter, we discuss this analysis as well as options for modifying the CMS–HCC model to mitigate systematic prediction errors.

This chapter discusses two other issues concerning risk adjustment in the MA program:

- Research indicates that geographic differences in per capita service use in FFS Medicare lead to geographic differences in risk scores that do not reflect differences in health status among FFS beneficiaries (Song et al. 2010). If regional differences in service use also lead to regional differences in risk scores in the MA program, then plans in regions where service use is high have higher risk scores, which drive capitated payments in those regions above the level in lower use regions.
- The coefficients on the conditions in the CMS–HCC model indicate the relative costliness of treating those conditions in FFS Medicare. However, the CMS–HCC model is used to risk-adjust payments in the MA program, where the relative costs of treating conditions may differ from costs in FFS Medicare (Newhouse et al. 2011). This raises questions of whether it is more appropriate to continue to calibrate the CMS–HCC model using data on FFS beneficiaries, or to switch to data on MA enrollees.

Evidence that MA enrollees tend to be lower cost than FFS beneficiaries

Recently, there has been renewed interest in examining the extent to which favorable selection occurs in the MA program. One study found a substantial amount of favorable selection (Brown et al. 2011). Another study used cost data from a large MA plan and found little correlation between how costly a condition is to treat in FFS Medicare and the extent to which beneficiaries with that condition are profitable to that plan (Newhouse et al. 2011). This gives the plan little incentive to try to select against the sickest, highest cost beneficiaries.

Within a given HCC, the severity of the condition and hence the cost of treating it can vary. For example, we examined FFS beneficiaries who were grouped into

the HCC for congestive heart failure (CHF) in 2008 and had no other HCCs. In 2008, the beneficiary at the 95th percentile of costliness had more than \$37,000 in Medicare spending, while the beneficiary at the 5th percentile had \$115 in Medicare spending. Despite these large cost differences for beneficiaries who have the same condition, the CMS–HCC model adjusts the payment rate for each beneficiary who has CHF by the same proportion (41 percent). Therefore, it is possible that, for beneficiaries in a given HCC, some will be profitable to MA plans because they are low-severity cases while others will not be profitable because they are high-severity cases.

If beneficiaries who have the same condition are randomly selected into MA plans in sufficiently large numbers, those who are profitable will be offset by those who are unprofitable, resulting in no financial gain or loss for the plan. However, if the selection of these beneficiaries is not random, it is possible that those who enroll in MA plans are on average profitable. This could occur either through the actions of plans—perhaps through benefits that are attractive to healthier beneficiaries or marketing techniques that target those beneficiaries—or because relatively healthy beneficiaries find the structure of MA plans more attractive than do sicker beneficiaries.

We conducted a study using two measures that may suggest, but not confirm, whether MA enrollees are, on average, lower risk than FFS beneficiaries. We divided the beneficiaries who were in FFS Medicare in 2007 into two groups: those who stayed in FFS Medicare in 2008 (stayers) and those who enrolled in MA plans in 2008 (joiners). For each group, we calculated the mean FFS costliness in 2007 in each HCC and used beneficiaries' risk scores to adjust for differences in health status. We reasoned that, for each HCC, if the risk-adjusted mean cost of the joiners was below that of the stayers, it indicates that lower cost beneficiaries are more likely to enroll in the MA program. We also identified the beneficiaries who were in FFS Medicare in 2008 and divided them into two groups: those who were in FFS Medicare throughout 2007 and those who left an MA plan in 2007. For both groups, we calculated the mean FFS costliness in 2008 of the beneficiaries who had conditions in each HCC and used beneficiaries' risk scores to adjust for differences in health status. We reasoned that, for each HCC, if the risk-adjusted mean cost of the beneficiaries who left an MA plan in 2007 was above that of beneficiaries who were in FFS Medicare throughout 2007 and 2008, it indicates that beneficiaries who stay in MA plans tend to be lower cost than those who leave MA for FFS Medicare.

Our results from both analyses suggest that MA enrollees are, on average, lower cost than FFS beneficiaries. In the first analysis, for 68 of the 70 HCCs, beneficiaries who joined an MA plan in 2008 had lower FFS costs in 2007 than the beneficiaries who stayed in FFS Medicare in 2008. On average, the joiners had costs that were 15 percent lower than the stayers. In the second analysis, beneficiaries who left an MA plan in 2007 had FFS costs in 2008 that averaged 16 percent higher than beneficiaries who were in FFS Medicare throughout 2007. Moreover, for 69 of the 70 HCCs, beneficiaries who disenrolled from MA in 2007 had higher average costs in 2008 than those who were in FFS Medicare throughout 2007.

Although these results suggest that MA enrollees are lower cost than FFS beneficiaries, we emphasize that they are not conclusive. It is possible that beneficiaries with relatively low costs are more likely to enroll in an MA plan but that their costs increase after enrollment. Possible reasons this may occur include that their costs regress to the mean over time, they lacked supplemental coverage while in FFS Medicare, or they have low incomes and the more comprehensive coverage that often occurs in MA plans encourages them to increase their service use.

Improving predictive accuracy of the CMS–HCC model

We have evaluated three alternatives for improving the predictive accuracy of the CMS–HCC model so that systematic prediction errors are reduced. All three options involve using more data than are currently used in the CMS–HCC model:

- Add socioeconomic variables such as race/ethnicity and income to the model. This model includes all variables in the current CMS–HCC model plus race/ethnicity indicators (African American, Hispanic, White, other race) and income level, which we approximated by the per capita income in the beneficiary's county of residence.
- Add indicators for the number of conditions beneficiaries have. This model includes all variables in the current CMS–HCC model plus indicators of whether beneficiaries have zero, one, two, three, four, or five or more HCCs.³
- Use two years of diagnosis data (when available) to determine each beneficiary's HCCs rather than one

**TABLE
4-1****Adding indicators of race and
measure of income has little effect on
predictive accuracy of CMS-HCC model**

Category	Predictive ratio	
	Standard model	Race/income model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	0.99
Cancer	0.99	0.99
Mental illness	1.00	1.00
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.00
All strokes	1.01	1.00
Number of conditions		
0	0.94	0.94
1	1.02	1.02
2	1.03	1.03
3	1.03	1.02
4	1.02	1.02
5 or more	0.98	0.98
8 or more	0.95	0.94

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. Both models use one year of diagnosis data to determine beneficiaries' conditions.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

year of diagnosis data, which CMS currently uses. Obviously, two years of diagnosis data would not be available for beneficiaries in their first or second year of Medicare eligibility. For those in the first year of Medicare eligibility, the demographic model that CMS currently uses for new enrollees is a viable option. For those in the second year of eligibility, we could use the current version of the CMS-HCC model.

**Adding socioeconomic variables does not
improve predictive accuracy of CMS-HCC
model**

We calibrated a model that has all the variables of the current version of the CMS-HCC model, which has 70 HCCs (standard model). We also calibrated a version that has the same variables as the standard model plus race/

ethnicity indicators (African American, Hispanic, White, and other race) and income level, which we approximated by the per capita income in the beneficiary's county of residence (race/income model). For a description of the method we used to calibrate the models presented in this chapter, see the text box (pp. 106–107).

We evaluated the predictive accuracy of the standard and race/income versions using two measures:

- R^2 , a statistical measure of how much of the variation in costliness among individuals is explained by the model: The closer the R^2 is to 1.0, the more of the variation the model has explained.
- Predictive ratio: For a group of beneficiaries, it is the total costliness predicted by the model divided by the total actual costliness of the group. The closer the predictive ratio is to 1.0, the better the model has predicted the actual costs. Predictive ratios less than 1.0 indicate the predicted costs are below the actual costs (underprediction); predictive ratios greater than 1.0 indicate the predicted costs are above actual costs (overprediction).

The R^2 gives a general sense of how well a model accounts for variations in costs across individuals. However, strategies to attract favorable risks are typically based on characteristics such as conditions that define groups of beneficiaries, not on specific individuals. Therefore, many analysts prefer to use predictive ratios to evaluate the predictive accuracy of risk-adjustment models (Frogner et al. 2011, Pope et al. 2004, Pope et al. 2011). For beneficiaries with a given attribute, the predictive ratio indicates (on average) the extent to which a model overpredicts or underpredicts the costliness of the beneficiaries with the attribute and by how much.

The addition of race and income variables to the standard model did very little to enhance its predictive accuracy. Using the standard CMS-HCC model, we obtained an R^2 of 0.1100. Adding race and income variables had no effect on the R^2 .

We also used predictive ratios to examine how accurately these two models predict beneficiaries' costliness for nine condition categories. For most of these conditions, both models predict beneficiaries' costliness quite well, but they overpredict costs to some degree for acute myocardial infarction (AMI). Within each of these conditions—as well as all conditions represented in the CMS-HCC model—some beneficiaries are relatively healthy and have no other

conditions, while other beneficiaries are much sicker and have many other conditions. We analyzed categories of beneficiaries identified by number of conditions: zero, one, two, three, four, five or more, and eight or more. We found that both models underpredict costliness to some degree for beneficiaries who have five or more conditions and by a larger degree for those who have no conditions or eight or more conditions. Also, both models overpredict costliness to some degree for categories defined by one condition, two conditions, three conditions, and four conditions (Table 4-1).

These prediction errors can be seen when we parse the beneficiaries who have diabetes by how many other conditions they have. For diabetics who have one other condition (and would be in the two conditions group in Table 4-1), the predictive ratio is 1.03; for diabetics who have at least seven other conditions (and would be in the eight or more conditions group in Table 4-1), the predictive ratio is 0.93. However, these deviations from 1.0 are a concern only if there is systematic selection into MA plans of the beneficiaries who are in categories for which the predictive ratio is above 1.0.

The important points to take away from Table 4-1 are:

- The CMS-HCC model accurately predicts costs, on average, for most conditions that are represented in the model.
- However, among beneficiaries who have the same condition, some are relatively healthy and have no other conditions or only a few other conditions, while others are sicker and have many other conditions. For those who have only a few conditions, the CMS-HCC model slightly overpredicts costs, and for those who have many conditions, the model underpredicts costs, and the underprediction increases as the number of conditions increases. Consequently, SNPs and plans in PACE, which focus on the sickest beneficiaries, may be at a disadvantage, while plans that are able to attract the healthiest beneficiaries with a given condition may benefit.
- Adding race and income to the CMS-HCC model does little to improve the model's predictive accuracy.

Including number of conditions improves predictive accuracy

We used 2007 diagnosis data and 2008 demographic and program cost data to calibrate two versions of the CMS-

HCC model. One is the standard model that CMS uses in the MA program and is the same standard model in Table 4-1. The other is the conditions model, which adds to the standard model six indicators for how many conditions each beneficiary has, as determined by the beneficiary's diagnoses: zero, one, two, three, four, and five or more conditions. We define number of conditions as the number of HCCs that each beneficiary's conditions map into.

This standard model has an R^2 of 0.1100, indicating that it explains 11 percent of the variation in beneficiaries' Medicare costs. When we add the six measures indicating the number of conditions, the improvement in the R^2 is nearly imperceptible, 0.1105.

We also calculated predictive ratios for nine condition categories using both the standard and conditions models. For all nine conditions, the predictive ratios show little or no change between the two models. For most conditions, both predict reasonably well, with the exception being AMI, where there is some degree of overprediction under both models. As we saw in Table 4-1, the standard model underpredicts for beneficiaries who have zero conditions, five or more conditions, and eight or more conditions and overpredicts for one, two, three, and four conditions. In contrast, the conditions model predicts quite accurately for each of those groups (Table 4-2, p. 104). Because the conditions model predicts accurately for the sickest beneficiaries (those who have many conditions), it may be beneficial for SNPs and PACE plans.

Using two years of diagnosis data stabilizes risk scores and improves predictive accuracy

Previous research indicates that in FFS Medicare, a beneficiary who has a chronic condition indicated on a claim in one year often will not have that condition appear on a claim in the following year (Frogner et al. 2011, Medicare Payment Advisory Commission 1998). If this inconsistent coding of beneficiaries' chronic conditions also occurs among MA plans, beneficiaries' risk scores will often have large year-to-year changes.

We evaluated the extent to which beneficiaries who were coded for the HCCs for kidney failure, stroke, quadriplegia or paraplegia, diabetes, CHF, and chronic obstructive pulmonary disease in 2007 also were coded for those HCCs in 2008. We did this for both FFS enrollees and MA enrollees.

Our results indicate that coding for all of these conditions was not consistent from year to year. The same was true for beneficiaries in both FFS Medicare and MA plans

**TABLE
4-2****Adding number of conditions to
CMS-HCC model improves predictive
accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Conditions model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	0.99
Cancer	0.99	0.99
Mental illness	1.00	1.00
Schizophrenia	1.00	1.00
AMI	1.03	1.03
Unspecified stroke	1.01	1.01
All strokes	1.01	1.00
Number of conditions		
0	0.94	1.00
1	1.02	1.00
2	1.03	1.00
3	1.03	1.00
4	1.02	1.00
5 or more	0.98	0.99
8 or more	0.95	1.00

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. Both models use one year of diagnosis data to determine beneficiaries' conditions.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

(Table 4-3). This lack of consistent coding over time presents two problems for risk adjustment. First, in a given year, many FFS beneficiaries who have a condition will not have that condition appear on a claim. Because CMS uses conditions recorded on claims for FFS beneficiaries to calibrate the CMS-HCC model, the model may not accurately reflect the true additional cost of a particular condition. Second, inconsistent coding of conditions in MA results in greater year-to-year fluctuations in enrollees' risk scores, which leads to less stable payments and revenue streams to MA plans.

These problems related to inconsistent coding of conditions would be mitigated if CMS used two years of beneficiaries' diagnosis data rather than one year to calibrate the CMS-HCC model and determine

beneficiaries' risk scores. The Commission has recommended this position in the past (Medicare Payment Advisory Commission 2000).

We calibrated a version of the CMS-HCC model that is the same as the standard model, but we used two years of diagnosis data to assign beneficiaries to HCCs (two-year model). We found that this model produces risk scores that are more consistent over time than does the standard CMS-HCC model. For example, we found that the correlation coefficient between the 2008 and 2009 risk scores for more than 1 million beneficiaries was 0.62 using the standard model and 0.80 using the two-year model, where the correlation coefficient indicates how strongly one variable is correlated with another. The closer a correlation coefficient is to 1.0, the more closely two variables are correlated.

We also found that for specific conditions, there is little difference in predictive accuracy between the standard model and the two-year model, except for mental illness. However, the two-year model predicts more accurately for beneficiaries who have five or more conditions and for those who have eight or more conditions (Table 4-4). As we mentioned earlier, this means that for most conditions, both models pay accurately, on average, except for AMI, where there is some degree of overprediction of costs. However, for those who have five or more conditions and those who have eight or more conditions, the two-year model underpredicts by a lesser amount than does the

**TABLE
4-3****Beneficiaries who had chronic
condition on claim in 2007
often did not have same
condition on claim in 2008**

**Of those with condition
coded in 2007,
percent who did not have
it coded again in 2008**

Condition category	FFS Medicare	MA program
Diabetes	12.9%	10.9%
COPD	33.8	29.9
CHF	37.9	34.4
Kidney failure	35.4	28.9
Stroke	56.7	59.0
Quadriplegia/paraplegia	58.7	62.3

Note: FFS (fee-for-service), MA (Medicare Advantage), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure).

Source: MedPAC analysis of 2007 and 2008 risk score files from Acumen, LLC, and 2006 and 2007 Medicare denominator files from Acumen, LLC.

**TABLE
4-4****Using two years of diagnoses
in CMS-HCC model improves
predictive accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Two-year model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	1.00
Cancer	0.99	0.99
Mental illness	1.00	0.96
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.01
All strokes	1.01	1.01
Number of conditions		
0	0.94	0.92
1	1.02	1.00
2	1.03	1.02
3	1.03	1.03
4	1.02	1.03
5 or more	0.98	1.00
8 or more	0.95	0.97

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. The standard model uses one year of diagnosis data to determine beneficiaries' conditions; the two-year model uses two years of diagnosis data.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

standard model. In summary, the two-year model offers the advantages of smaller year-to-year fluctuations in risk scores and more accurate payments for the sickest beneficiaries.

**Including number of conditions and using
two years of diagnosis data have the
benefits of both**

We also analyzed the effects of a version of the CMS-HCC model that includes indicators for number of conditions and uses two years of diagnosis data to determine beneficiaries' HCCs (combined model). The combined model has the benefits of both the conditions model and the two-year model: It improves the predictive accuracy for beneficiaries who have many conditions and it reduces year-to-year fluctuations in beneficiaries'

risk scores (Table 4-5). However, the combined model underpredicts costliness for mental illness, which also occurs under the two-year model.

**Issues related to financial neutrality
between FFS Medicare and the MA
program**

CMS estimates the CMS-HCC model using cost, demographic, and diagnosis data from FFS beneficiaries. Therefore, the coefficients for each HCC indicate the relative costliness of treating those conditions in FFS Medicare. On several occasions, the Commission has

**TABLE
4-5****Adding measures for number
of conditions and using two years
of diagnoses in CMS-HCC model improves
predictive accuracy for beneficiaries
who have many conditions**

Category	Predictive ratio	
	Standard model	Combined model
Specific conditions		
Diabetes	1.00	1.00
COPD	1.01	1.01
CHF	0.99	1.00
Cancer	0.99	0.99
Mental illness	1.00	0.95
Schizophrenia	1.00	1.00
AMI	1.03	1.02
Unspecified stroke	1.01	1.01
All strokes	1.01	1.01
Number of conditions		
0	0.94	1.01
1	1.02	1.00
2	1.03	1.00
3	1.03	1.01
4	1.02	0.99
5 or more	0.98	0.99
8 or more	0.95	1.00

Note: CMS-HCC (CMS-hierarchical condition category), COPD (chronic obstructive pulmonary disease), CHF (congestive heart failure), AMI (acute myocardial infarction). We determined the number of conditions by counting the number of HCCs a beneficiary maps into. The standard model uses one year of diagnosis data to determine beneficiaries' conditions; the combined model uses two years of diagnosis data.

Source: MedPAC analysis of 5 percent standard analytic claims files and 5 percent Medicare denominator file.

Methods used in regression analysis

For this chapter, we estimated several versions of the CMS–hierarchical condition category (CMS–HCC) risk-adjustment model. We used the same general method to produce all of the regression-based results presented. The only differences between regressions are the explanatory variables. The results in all our regressions are based on a 5 percent sample of fee-for-service (FFS) beneficiaries.

In each regression, we used data from 2007 and 2008. The 2007 data are the HCCs based on diagnoses from hospital inpatient, hospital outpatient, and physician claims that we used to determine each beneficiary's condition categories for 2008, which are defined by 70 HCCs in the CMS–HCC model. Examples of conditions defined by the HCCs include diabetes with various degrees of severity, congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD). The 2008 data include the following for each beneficiary: total costliness to the Medicare program, age, sex, Medicaid status, whether institutionalized for three consecutive months, and whether eligible for Medicare on the basis of age but originally eligible because of disability.

To be included in the analysis, beneficiaries had to meet the following requirements: in both Part A and Part B of Medicare throughout 2007, in both Part A and Part B throughout their Medicare eligibility in 2008, no

Medicare Advantage enrollment at any time in 2007 or 2008, no hospice care in 2008, not classified as having end-stage renal disease in 2008, lived within the United States for all of 2007 and 2008, no Medicare as a secondary payer in 2007 or 2008, and not long-term institutionalized in 2008. In addition, the results in Tables 4-4 and 4-5 include analyses of versions of the CMS–HCC model that use two years of diagnosis data to determine each beneficiary's HCCs. For this regression, we used diagnoses from 2006 and 2007 claims; when we used data from 2007 to exclude beneficiaries in the other regressions, we used data from 2006 and 2007 to exclude beneficiaries in the two-year regression.

In each regression, the dependent variable was each beneficiary's 2008 costliness to FFS Medicare that we annualized if the beneficiary was in FFS Medicare for only a fraction of 2008. That is, we divided each beneficiary's 2008 costliness to FFS Medicare by the fraction of the year the beneficiary was in FFS Medicare in 2008. Each regression included the following explanatory variables:

- 70 HCCs;
- 24 categories indicating age and sex;
- 4 variables indicating Medicaid status;

(continued next page)

stated that payments to MA plans should be equal to what MA enrollees would cost in FFS Medicare (financial neutrality) (Medicare Payment Advisory Commission 2001, Medicare Payment Advisory Commission 2002, Medicare Payment Advisory Commission 2004, Medicare Payment Advisory Commission 2005). The current method of using cost and diagnosis data from FFS Medicare to estimate the CMS–HCC model is consistent with the goal of financial neutrality.⁴

In light of two recently published papers, more discussion about financial neutrality between FFS Medicare and the MA program may be appropriate. One study found that large regional differences in service use among FFS

beneficiaries lead to large regional differences in risk scores (Song et al. 2010). This study indicates that these regional differences in risk scores are due, at least in part, simply to differences in service use rather than differences in health status. It is not known if these regional differences in risk scores also occur in the MA program. If they do, higher risk scores in high-use regions will drive up MA payments not because MA enrollees are less healthy but simply because service use is higher.

A second study found that the relative cost of treating specific conditions differs widely between a large MA plan and FFS Medicare. For some conditions, the relative cost is

Methods used in regression analysis (continued)

- 2 variables indicating beneficiaries who are eligible because of age but were originally eligible because of disability;
- 5 categories indicating that beneficiaries are disabled and have 1 of 5 conditions: opportunistic infections, severe hematologic disorders, drug or alcohol psychosis, drug or alcohol dependence, and cystic fibrosis; and
- 6 disease interaction terms: diabetes and CHF, diabetes and cardiovascular disease, CHF and COPD, CHF with COPD and coronary artery disease, renal failure (RF) and CHF, and RF with CHF and diabetes.

These are the same dependent and explanatory variables that CMS includes in the version of the CMS–HCC model it currently uses.

We ran six weighted regressions to produce the results in Tables 4-1, 4-2, 4-4, and 4-5, where the weight is the fraction of the year each beneficiary was in FFS Medicare in 2008, which is the same fraction we used to annualize each beneficiary's costs. For Table 4-1, we ran a standard version of the CMS–HCC model, which includes all the variables listed above, and we ran a race/income version that includes the same variables plus indicators for each beneficiary's race (African American, Hispanic, White, or other) and income,

which we approximated by the per capita income in each beneficiary's county of residence.

For Tables 4-2, 4-4, and 4-5, we ran the following regressions:

- a conditions version, which includes all the variables in the standard version plus indicators of whether each beneficiary has zero, one, two, three, four, or five or more HCCs (Table 4-2);
- a two-year version, which includes all the variables in the standard version, but HCCs for each beneficiary are based on two years of diagnosis data rather than the single year used in the standard version (Table 4-4); and
- a version that combines the conditions version and the two-year version and includes all the variables in the standard version, whether each beneficiary has zero, one, two, three, four, or five or more HCCs, and HCCs that are based on two years of diagnosis data (Table 4-5).

We developed the analytic samples for each of these regressions from 5 percent samples of all FFS beneficiaries in 2008. It resulted in analytic samples of about 1.2 million beneficiaries for the standard and conditions versions and about 1.1 million beneficiaries for the two-year version and the version that combines the conditions and two-year versions. ■

lower in the MA plan; for other conditions, the relative cost in the MA plan is higher (Newhouse et al. 2011).

Should MA risk scores be adjusted for regional differences in service use?

Risk adjustment affects payments to MA plans through two mechanisms. First, county-level benchmarks depend directly on each county's per capita FFS spending, divided by the county's average CMS–HCC risk score among FFS beneficiaries. Second, CMS uses the risk scores to adjust MA payments for each enrollee.

CMS–HCC risk scores depend heavily on beneficiaries' conditions that providers have coded on claims. Research

indicates that among FFS beneficiaries, per capita service use is higher in some areas of the country than in others. Moreover, average risk scores among FFS beneficiaries are highest in regions where service use is highest and lowest in regions where service use is lowest (Song et al. 2010).

This correlation between regional differences in service use and regional differences in risk scores could occur for two reasons. First, it could occur because those in the high-use regions are sicker. In this case, the relatively high risk scores in the high-use regions accurately reflect regional differences in health status. Second, it could occur because beneficiaries in high-use areas simply use more

medical care without being sicker than beneficiaries in lower use areas. In this case, the relatively high risk scores in high-use areas do not reflect regional differences in health status. Research indicates that at least part of the regional differences in risk scores is due to beneficiaries in high-use regions using more medical care without actually being sicker. That is, beneficiaries in high-use areas would have lower risk scores if they lived in regions where service use was lower (Song et al. 2010).

To the extent that regional differences in service use cause differences in risk scores, there may be little effect on the county-level benchmarks. For example, if a county has a high level of service use, it is likely to be reflected in both high per capita FFS spending and a high average risk score among FFS beneficiaries. The high FFS spending and high average risk score should largely offset each other, so the county benchmark should be unaffected.

Regional differences in service use are more likely to have an effect on MA payments through the risk scores of MA enrollees. In regions with relatively high service use among MA enrollees, it is possible that providers' coding of conditions is more intensive than in other regions, leading to higher risk scores and MA payments in those regions. However, it is not clear whether the regional differences in service use and risk scores that occur in the FFS program also occur in the MA program because data are not available to make that determination. But, CMS has begun collecting beneficiary-level cost and diagnosis data from MA plans; after it has collected multiple years of these data, it may be possible to replicate the analysis by Song and colleagues for the MA population.

Addressing regional differences in risk scores due to differences in service use

The study by Song and colleagues (2010) divided the country into regions and determined per capita service use in FFS Medicare in each region. The regions were sorted into quintiles of per capita service use. The authors found that regional differences in service use led to regional differences in how intensively conditions are coded on claims, which resulted in average risk scores in the highest quintile of service use that were 15 percent higher than they would have been had the beneficiaries lived in a region in the lowest quintile.

If there are similar regional differences in the MA program, adjustments could be made to MA risk scores. Using the results from Song and colleagues as a hypothetical example, these adjustments could work as

follows. Regions that are in the middle (third) quintile of service use could be used as the baseline. MA enrollees residing in a region that is in the third quintile would have no adjustment to their risk scores. Relative to the third quintile, Song and colleagues found that regional differences in service use result in risk scores that are 5.2 percent lower in the first quintile, 1.7 percent lower in the second quintile, 5.7 percent higher in the fourth quintile, and 8.8 percent higher in the fifth quintile. MA risk scores in these four regions could be adjusted by these percentages to account for differences in coding.

Adjusting risk scores for MA enrollees for the effects of regional differences in service use should be considered alongside the Commission's previously stated position on financial neutrality between the MA and FFS programs. On the one hand, making regional adjustments to MA risk scores is somewhat inconsistent with financial neutrality because one sector (FFS or MA) would have a financial advantage over another sector for treating the same patient or condition. On the other hand, to the extent that regional differences in service use that are independent of beneficiaries' health status result in regional differences in risk scores among MA enrollees, plans in high-use regions would have higher payments than plans in lower use regions simply because of regional differences in use rates. It may be appropriate to discuss the merits of each alternative.

Should CMS use FFS or MA data to estimate the CMS-HCC model?

If the large differences found by Newhouse and colleagues between the cost of treating conditions in a large MA plan and FFS Medicare also occur in most or all other MA plans, the CMS-HCC model underpredicts the costs in MA plans for some conditions and overpredicts the costs in MA plans for other conditions. Obviously, it is financially beneficial for plans to have beneficiaries who have conditions for which costs are overpredicted and avoid beneficiaries who have conditions for which costs are underpredicted.

In light of the Commission's stance on financial neutrality and the findings from Newhouse and colleagues, it may be appropriate to have a discussion about whether CMS should continue using data from FFS beneficiaries to calibrate the CMS-HCC model or switch to using data from MA enrollees. An argument for continued use of FFS data is that it is consistent with a policy of financial neutrality, and financial neutrality encourages care to be provided in the sector where it can be provided more

efficiently (MA or FFS). Under financial neutrality, when plans are able to provide care at a lower cost than FFS Medicare, they may be able to offer enhanced benefits that are more attractive to beneficiaries than FFS Medicare. Alternatively, if plans cannot provide care at a lower cost than FFS Medicare, they may not be able to offer benefits that are competitive with FFS Medicare. An argument for use of MA data is that costs incurred by MA plans may differ from costs for FFS Medicare—perhaps because of different risk profiles between sectors or because of different models of care. To the extent these cost deviations occur between sectors, MA payments that reflect the cost of efficient providers require risk adjustment calibrated on data from MA enrollees.

Differences in coding between FFS Medicare and the MA program

MA plans have an incentive for providers to code their enrollees' conditions as completely as possible because MA risk scores and payments strongly depend on each enrollee's conditions. The incentive to code conditions is present but not as strong in FFS Medicare because FFS

payments often depend on the services provided rather than beneficiaries' conditions.

This discrepancy in incentives between the MA program and FFS Medicare may be reflected in analyses by CMS and the Government Accountability Office (GAO), which found differences in diagnostic coding intensity between the two sectors (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). In response to its finding, CMS has reduced risk scores of MA enrollees by 3.4 percent in 2010, 2011, and 2012. However, GAO asserts that CMS has underestimated the magnitude of the greater coding intensity in the MA program by at least 1.4 percentage points and by as much as 3.7 percentage points. Statutory adjustments in the Patient Protection and Affordable Care Act of 2010 (PPACA) are consistent with the findings of the GAO. Starting in 2014, PPACA requires CMS to reduce MA enrollees' risk scores by an amount greater than 3.4 percent in each year, unless CMS begins using diagnosis and cost data from MA enrollees to estimate the CMS-HCC model. ■

Endnotes

- 1 CMS arrived at which HCCs to retain and how many to retain by balancing several competing considerations, including data collection burden, predictive power, whether to retain rare high-cost conditions, and retaining only well-defined, clinically coherent conditions (Pope et al. 2004).
- 2 It is not clear when CMS intends to begin using the data from MA enrollees to estimate the CMS–HCC model.
- 3 When we estimated the model using regression analysis, we used zero conditions as the basis of comparison, so we excluded that variable from the regression.
- 4 Financial neutrality can be obtained only if coding of conditions is the same in FFS Medicare and the MA program. Research by CMS and the Government Accountability Office (GAO) indicates that differences in coding exist between these two sectors (Centers for Medicare & Medicaid Services 2009, Government Accountability Office 2012). CMS has made adjustments to account for these differences, but GAO believes the adjustments are too small.

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 6 OF 14
EXHIBITS D-45 THROUGH D-48
PAGES 1020 THROUGH 1219**

Hon. Fernando M. Olguin

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Hearing Time: 10:00 a.m.
Courtroom: 6D

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EXHIBIT D-45

TOOLKIT

To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes

December 2023 | A-07-23-01213

Amy Frontz

Deputy Inspector General
for Audit Services

U.S. Department of Health and Human Services
Office of Inspector General



1021

Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes

What Is the Toolkit?

This toolkit offers Medicare Advantage (MA) organizations information that will enable them to replicate Office of Inspector General's (OIG's) techniques to identify and evaluate high-risk diagnosis codes to ensure proper payments and provide better care for enrollees.

The Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations for each of their enrollees. These payments are based, in part, on the diagnoses that their enrollees receive from their providers. Using a system of risk adjustment, CMS pays MA organizations more for providing benefits to enrollees with diagnoses

associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. Accordingly, CMS relies on MA organizations not only to collect diagnosis codes from their providers and submit the associated codes to CMS, but also to implement an effective compliance program to monitor the accuracy of these diagnosis codes. In this respect, MA organizations generally review medical records in order to detect and correct inaccurate diagnosis codes.

We have identified certain diagnosis codes which, when paired with other circumstances, are at a high risk for being miscoded. This toolkit provides additional information about the circumstances under which these diagnosis codes could be miscoded and the actual programming codes that we used in our audits to identify them.

Why Did OIG Create This Toolkit?

We have performed several audits for which our objectives were to determine whether MA organizations submitted certain diagnosis codes—ones that when coupled with other data indicated that the codes were at high risk for being miscoded—to CMS for use in CMS's risk adjustment program in accordance with Federal requirements. Thus far, we have found that overall, approximately 70 percent of those diagnosis codes were not supported in the associated medical records. Moreover, some diagnosis codes were consistently not supported over 90 percent of the time. Although the audited MA organizations usually disagreed with our reports' recommendations and with various aspects of our audit methodologies, those MA organizations generally did not disagree with our determinations regarding these diagnosis codes, and some expressed a genuine interest in submitting corrections to CMS. Other MA organizations—including ones that we have not audited—have asked us to share with them how we decided which diagnosis codes were at high risk for being miscoded.

This toolkit is meant to be a practical, hands-on device that will help MA organizations improve the accuracy of their submitted diagnoses that are at high risk for being miscoded.

The purpose of this toolkit is to provide information as to the steps that we followed as well as the data supporting the process that we followed. Our hope is that the users of this toolkit will, at a minimum, use the information to detect and correct inaccurate diagnosis codes in their own systems. To a greater extent, we hope that MA organizations use this toolkit as a starting point to identify other diagnosis codes that are at high risk for being miscoded and take appropriate measures to prevent, detect, and correct such errors. Thus, our goals are to ensure that CMS makes accurate payments to the MA organizations and that the enrollees receive the correct level of care.

What Does This Toolkit Include?

We have compiled the high-risk groups identified in our audits for incorrect diagnosis codes that were consistently submitted to CMS.¹ We have also included explanations that demonstrate why these specific diagnosis codes, when coupled with other data (including procedure codes and prescription drug events (PDEs)), are at high risk for being miscoded. This toolkit contains the Structured Query Language (SQL)—a programming language used in many software programs—that we used in our audits to query CMS's systems. To provide further information as to what we analyzed, we have included all of the codes used in our programming language. The SQL language and codes included in this toolkit relate to the 2019 payment year.²

This toolkit enables an MA organization to adapt our actual programming codes in order to query its internal data systems so that it can more accurately identify the enrollees in the various high-risk groups.

To place our work in context, the figure below summarizes the errors that our audits identified for each of high-risk groups included in this toolkit.

Figure: Errors in High-Risk Groups as of November 2023

High-Risk Group	Total	Errors	Error %
Acute stroke	945	908	96%
Acute heart attack	791	751	95%
Embolism	754	593	79%
Lung cancer	391	345	88%
Breast cancer	390	373	96%
Colon cancer	390	368	94%
Prostate cancer	360	322	89%
Potentially mis-keyed diagnosis codes	522	421	81%
Totals	4,543	4,081	90%

¹ Not every high-risk group that we audited had incorrect diagnosis codes that were consistently submitted to CMS. This toolkit includes only those high-risk groups that had high error rates.

² Our various audits have spanned the 2013 through 2019 payment years. See our discussion on the next page for an explanation of "payment years."

Detailed information on our audits of the MA program, as well as related information on the high-risk diagnoses codes discussed in this toolkit, can be found at [Managed Care | HHS-OIG](#)

Background

Medicare Advantage Program—Risk-Adjusted Payments

Under the MA program, CMS makes advance payments each month to MA organizations. Federal requirements mandate that these payments be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.³

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: a base rate that CMS sets using bid amounts received from the MA organization and the risk score for that enrollee. These are described as follows:

- **Base rate:** Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁴ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.
- **Risk score:** A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and gender). This process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable provider types, including certain physicians and hospitals.⁵ MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs). Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for one year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA

³ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

⁴ The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

⁵ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures.

organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee. Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if diagnosis codes are incorrect, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.

Identifying High-Risk Groups of Diagnoses

For each of our audits, we used data mining techniques and discussed certain circumstances with medical professionals in order to identify diagnoses that were at higher risk for being miscoded.

Data Mining Techniques

After an enrollee receives a medical service, the provider of that service generates a claim for payment to the MA organization. Although MA organizations make their own payment arrangements with providers for these services, CMS requires MA organizations to submit copies of all claims to CMS. These claims include services that can be used for risk adjustment purposes (physician, outpatient, and inpatient) as well as claims whose services are not used for risk adjustment purposes (such as home health services, skilled nursing facility services, durable medical equipment, laboratory services, and x-rays, among other services).

We have developed computerized programs to access and analyze these claims data. For example, we identify the services that contain the risk-adjusted diagnoses and how often those diagnoses were submitted throughout the service year. In this regard, we analyze the data to see which diagnoses were submitted to CMS and when. We combine our knowledge of the MA program along with what we glean from our discussions with medical professionals to identify which diagnosis codes to review.

Discussions With Medical Professionals

For our audits, we have discussed various circumstances with medical professionals to ensure that we analyzed the data correctly. For example, CMS has identified 21 diagnosis codes that map to the HCC for Acute Myocardial Infarction. Our discussions with medical professionals revealed that 17 of those 21 diagnosis codes were at higher risk for being miscoded if: (1) they occurred through a face-to-face encounter with a physician, but (2) that same diagnosis did not occur on an inpatient claim within 6 months (before or after) that encounter. For instances of this nature, the medical professionals also explained to us what was likely supported in the medical records and what should have been submitted to CMS. Continuing the example, the medical professionals told us that the medical records likely supported an old myocardial infarction diagnosis (which does not map to an HCC) instead of an acute myocardial infarction diagnosis.

For this toolkit we have compiled the high-risk groups identified in our audits for incorrect diagnosis codes that were consistently submitted to CMS. We have also included explanations that demonstrate why these specific diagnosis codes, when coupled with other data (including procedure codes and PDEs), are at high risk for being miscoded. This toolkit contains the SQL, which is a programming language used in many software programs, that we used in our audits to query CMS's systems. To provide further information as to what we analyzed, we have included all of the codes used in our programming language.

Our goal is to enable an MA organization to adapt our actual programming codes in order to query its internal data systems, so that it can more accurately identify the enrollees in the various high-risk groups.

Data Analytics for High-Risk Groups

We have compiled data on the high-risk groups identified in our audits for incorrect diagnosis codes that were consistently submitted to CMS. For each of these high-risk groups, we are providing the following information:

- We have included explanations that demonstrate why these specific diagnosis codes, when coupled with other data (including procedure codes and PDEs), are at high risk for being miscoded. For example, one high-risk group included individuals who received one lung cancer diagnosis during a service year, but the encounters and the relevant PDE data did not indicate that the individuals received certain types of care and medication.
- Based on discussions with medical professionals, we have also provided in each case the diagnosis code that typically should have been submitted to CMS instead of the incorrect diagnosis code that actually was submitted. Continuing with the lung cancer diagnosis example, a history of lung cancer diagnosis is generally what was supported in the medical records.
- As a further extension of the narrative description, we have identified all the various codes and the names of the codes that we analyzed. For the example of the lung cancer high-risk group, we are providing a list of the codes and names for:
 - the lung cancer diagnoses,
 - the surgical therapy procedures,
 - the radiation treatment procedures, and
 - the chemotherapy drug treatment procedures.
- Finally, we have included the SQL—that programming language mentioned earlier—that we used in our audits to query CMS's systems. Our goal is to enable an MA organization to adapt our SQL codes in order to query its internal data systems, so that it can also identify the enrollees in the various high-risk groups.

1. Acute Stroke High-Risk Group

For the acute stroke high-risk group, we focused on enrollees who received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke (HCC 100)) on one physician claim during the service year but did not have an acute stroke diagnosis on a corresponding inpatient or outpatient hospital claim (Table 1.1). In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 1.1 includes the 94 acute stroke diagnosis codes used in our analysis:

Table 1.1: Acute Stroke Diagnosis Codes

Diagnosis Code	Description
I6300	Cerebral infarction (CI) due to thrombosis of unspecified precerebral artery
I63011	CI due to thrombosis of right vertebral artery
I63012	CI due to thrombosis of left vertebral artery
I63013	CI due to thrombosis of bilateral vertebral arteries
I63019	CI due to thrombosis of unspecified vertebral artery
I6302	CI due to thrombosis of basilar artery
I63031	CI due to thrombosis of right carotid artery
I63032	CI due to thrombosis of left carotid artery
I63033	CI due to thrombosis of bilateral carotid arteries
I63039	CI due to thrombosis of unspecified carotid artery
I6309	CI due to thrombosis of other precerebral artery
I6310	CI due to embolism of unspecified precerebral artery
I63111	CI due to embolism of right vertebral artery
I63112	CI due to embolism of left vertebral artery
I63113	CI due to embolism of bilateral vertebral arteries
I63119	CI due to embolism of unspecified vertebral artery
I6312	CI due to embolism of basilar artery
I63131	CI due to embolism of right carotid artery
I63132	CI due to embolism of left carotid artery
I63133	CI due to embolism of bilateral carotid arteries
I63139	CI due to embolism of unspecified carotid artery
I6319	CI due to embolism of other precerebral artery
I6320	CI due to unspecified occlusion or stenosis of unspecified precerebral arteries
I63211	CI due to unspecified occlusion or stenosis of right vertebral arteries

Diagnosis Code	Description
I63212	CI due to unspecified occlusion or stenosis of left vertebral arteries
I63213	CI due to unspecified occlusion or stenosis of bilateral vertebral arteries
I63219	CI due to unspecified occlusion or stenosis of unspecified vertebral arteries
I6322	CI due to unspecified occlusion or stenosis of basilar arteries
I63231	CI due to unspecified occlusion or stenosis of right carotid arteries
I63232	CI due to unspecified occlusion or stenosis of left carotid arteries
I63233	CI due to unspecified occlusion or stenosis of bilateral carotid arteries
I63239	CI due to unspecified occlusion or stenosis of unspecified carotid arteries
I6329	CI due to unspecified occlusion or stenosis of other precerebral arteries
I6330	CI due to thrombosis of unspecified cerebral artery
I63311	CI due to thrombosis of right middle cerebral artery
I63312	CI due to thrombosis of left middle cerebral artery
I63313	CI due to thrombosis of bilateral middle cerebral arteries
I63319	CI due to thrombosis of unspecified middle cerebral artery
I63321	CI due to thrombosis of right anterior cerebral artery
I63322	CI due to thrombosis of left anterior cerebral artery
I63323	CI due to thrombosis of bilateral anterior arteries
I63329	CI due to thrombosis of unspecified anterior cerebral artery
I63331	CI due to thrombosis of right posterior cerebral artery
I63332	CI due to thrombosis of left posterior cerebral artery
I63333	CI to thrombosis of bilateral posterior arteries
I63339	CI due to thrombosis of unspecified posterior cerebral artery
I63341	CI due to thrombosis of right cerebellar artery
I63342	CI due to thrombosis of left cerebellar artery
I63343	CI to thrombosis of bilateral cerebellar arteries
I63349	CI due to thrombosis of unspecified cerebellar artery
I6339	CI due to thrombosis of other cerebral artery
I6340	CI due to embolism of unspecified cerebral artery
I63411	CI due to embolism of right middle cerebral artery
I63412	CI due to embolism of left middle cerebral artery
I63413	CI due to embolism of bilateral middle cerebral arteries
I63419	CI due to embolism of unspecified middle cerebral artery
I63421	CI due to embolism of right anterior cerebral artery
I63422	CI due to embolism of left anterior cerebral artery
I63423	CI due to embolism of bilateral anterior cerebral arteries

Diagnosis Code	Description
I63429	CI due to embolism of unspecified anterior cerebral artery
I63431	CI due to embolism of right posterior cerebral artery
I63432	CI due to embolism of left posterior cerebral artery
I63433	CI due to embolism of bilateral posterior cerebral arteries
I63439	CI due to embolism of unspecified posterior cerebral artery
I63441	CI due to embolism of right cerebellar artery
I63442	CI due to embolism of left cerebellar artery
I63443	CI due to embolism of bilateral cerebellar arteries
I63449	CI due to embolism of unspecified cerebellar artery
I6349	CI due to embolism of other cerebral artery
I6350	CI due to unspecified occlusion or stenosis of unspecified cerebral artery
I63511	CI due to unspecified occlusion or stenosis of right middle cerebral artery
I63512	CI due to unspecified occlusion or stenosis of left middle cerebral artery
I63513	CI due to unspecified occlusion or stenosis of bilateral middle arteries
I63519	CI due to unspecified occlusion or stenosis of unspecified middle cerebral artery
I63521	CI due to unspecified occlusion or stenosis of right anterior cerebral artery
I63522	CI due to unspecified occlusion or stenosis of left anterior cerebral artery
I63523	CI due to unspecified occlusion or stenosis of bilateral anterior arteries
I63529	CI due to unspecified occlusion or stenosis of unspecified anterior cerebral artery
I63531	CI due to unspecified occlusion or stenosis of right posterior cerebral artery
I63532	CI due to unspecified occlusion or stenosis of left posterior cerebral artery
I63533	CI due to unspecified occlusion or stenosis of bilateral posterior arteries
I63539	CI due to unspecified occlusion or stenosis of unspecified posterior cerebral artery
I63541	CI due to unspecified occlusion or stenosis of right cerebellar artery
I63542	CI due to unspecified occlusion or stenosis of left cerebellar artery
I63543	CI due to unspecified occlusion or stenosis of bilateral cerebellar arteries
I63549	CI due to unspecified occlusion or stenosis of unspecified cerebellar artery
I6359	CI due to unspecified occlusion or stenosis of other cerebral artery
I638	Other CI
I639	CI, unspecified
I97810	Intraoperative cerebrovascular infarction during cardiac surgery
I97811	Intraoperative cerebrovascular infarction during other surgery
I97820	Postprocedural cerebrovascular infarction during cardiac surgery
I97821	Postprocedural cerebrovascular infarction during other surgery
I636	CI due to cerebral venous thrombosis, nonpyogenic

Table 1.2 includes two additional diagnosis codes that mapped to the HCC for Ischemic or Unspecified Stroke (HCC 100)); however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received either of these diagnoses were excluded from our analysis:

Table 1.2: Excluded Diagnosis Codes for the Acute Stroke High-Risk Group

Diagnosis Code	Description
I6381	Other cerebral infarction due to occlusion or stenosis of small artery
I6389	Other cerebral infarction

SQL Programming Language

Table 1.3 details the SQL programming language used to query CMS's systems in order to identify the acute stroke high-risk diagnosis codes.

Table 1.3: SQL Programming Language for Acute Stroke High-Risk Group

Step 1

We identified enrollees who received an acute stroke diagnosis (Table 1.1) in a physician setting without a corresponding inpatient or outpatient claim.

```

SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
,COUNT(raps.BENE_SK) AS BENE_LINES /*Counts the number of acute stroke diagnosis codes in an office (physician)
setting. Limited to one instance in Step #2*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Acute Stroke Diagnosis Codes Table*/
IN (
SELECT DX_CD /*Represents the diagnosis code field in the Acute Stroke Diagnosis Codes Table*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_STROKE_DX_CODES) /*Acute Stroke Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_PRVDR_TYPE_CD = '20' /*RAPS Provider Type Code "20" represents "physician" claims*/
AND BENE_RAPS_DGNS_DLT_SW = 'no' /*"no" indicates the RAPS diagnosis code is not deleted*/

/*Subquery to identify and exclude enrollees with an acute stroke diagnosis code in an inpatient or outpatient setting*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
NOT IN
SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis field used to match to Acute Stroke Diagnosis Codes Table*/
IN (
SELECT DX_CD /*Represents the diagnosis code field in the Acute Stroke Diagnosis Codes Table*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_STROKE_DX_CODES) /*Acute Stroke Diagnosis Codes Table*/

```

```
AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/  
AND BENE_RAPS_DGNS_DLT_SW = '0' /*"0" indicates the RAPS diagnosis code is not deleted*/  
AND BENE_RAPS_PRVDR_TYPE_CD IN ('01', '02', '10') /*RAPS Provider Type Code "01" and "02" represent "inpatient"  
claims and provider type code "10" represents "outpatient" claims*/
```

```
GROUP BY raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of an acute stroke diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's Risk Adjustment System (RAS) as including HCC 100.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/  
FROM CMS_ADM_OIG_OAS_PRD.ACUTE_STROKE_ENROLLEES_STEP_1 raps /*Output from Step #1*/  
WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of an acute stroke diagnosis code  
in an office (physician) setting*/  
AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/  
IN (  
  
SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/  
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCORE ras /*CMS RAS data*/  
  
WHERE BENE_PTC_HCC_100_SW = '1' /*Confirms HCC 100 was utilized in the payment risk score*/  
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/  
AND BENE_PTC_SCORE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record,  
not required for identifying enrollees for review, helps with computing efficiency*/  
AND BENE_RISK_SEQNC_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/  
AND (CLNDR_CY_NUM = 2019)) /*Specifies the payment year for the HCC confirmation*/
```

Downloadable Information

All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Acute-Stroke-High-Risk-Group.pdf>.

2. Acute Myocardial Infarction High-Risk Group

For the acute myocardial infarction high-risk group, we focused on enrollees who received one diagnosis (that mapped to the HCC for Acute Myocardial Infarction (HCC 86)) on only one physician or outpatient claim during the service year but did not have an acute myocardial infarction diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim) (Table 2.1). In these instances, a diagnosis indicating a history of myocardial infarction (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 2.1 includes the 17 acute myocardial diagnosis codes used in our analysis:

Table 2.1: Acute Myocardial Infarction Diagnosis Codes⁶

Diagnosis Code	Description
I2109	ST elevation myocardial infarction (STEMI) involving other coronary artery of anterior wall
I2111	STEMI involving right coronary artery
I2119	STEMI involving other coronary artery of inferior wall
I2129	STEMI involving other sites
I213	STEMI of unspecified site
I214	Non-ST elevation myocardial infarction (NSTEMI)
I2101	STEMI involving left main coronary artery
I2102	STEMI involving left anterior descending coronary artery
I2121	STEMI involving left circumflex coronary artery
I219	Acute myocardial infarction, unspecified
I220	Subsequent STEMI of anterior wall
I221	Subsequent STEMI of inferior wall
I222	Subsequent NSTEMI
I228	Subsequent STEMI of other sites
I229	Subsequent STEMI of unspecified site
I21A1	Myocardial infarction type 2
I21A9	Other myocardial infarction type

Table 2.2 on the following page includes 4 additional diagnosis codes that mapped to the HCC for Acute Myocardial Infarction (HCC 86) and all 20 diagnosis codes that mapped to the HCC for Unstable Angina and

⁶ The term "ST," used in many descriptions in this table, refers to the flat section of an echocardiogram (ECG). When an individual has the most severe type of heart attack, this segment will no longer be flat on the ECG but will appear abnormally elevated.

Other Acute Ischemic Heart Disease (HCC 87). We did not consider these codes to be at a high risk for being miscoded and therefore, enrollees who received any one of these diagnoses were excluded from our analysis:

Table 2.2: Excluded Diagnosis Codes for the Acute Myocardial Infarction High-Risk Group

Diagnosis Code	Description
I200	Unstable angina
I230	Hemopericardium as current complication following acute myocardial infarction
I231	Atrial septal defect as current complication following acute myocardial infarction
I232	Ventricular septal defect as current complication following acute myocardial infarction
I233	Rupture of cardiac wall without hemopericardium as current complication following acute myocardial infarction
I234	Rupture of chordae tendineae as current complication following acute myocardial infarction
I235	Rupture of papillary muscle as current complication following acute myocardial infarction
I236	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction
I237	Postinfarction angina
I238	Other current complications following acute myocardial infarction
I240	Acute coronary thrombosis not resulting in myocardial infarction
I241	Dressler's syndrome
I248	Other forms of acute ischemic heart disease
I249	Acute ischemic heart disease, unspecified
I25110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25730	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina
I25790	Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I511	Rupture of chordae tendineae, not elsewhere classified
I512	Rupture of papillary muscle, not elsewhere classified

SQL Programming Language

Table 2.3 details the SQL programming language used to query CMS's systems in order to identify the acute myocardial infarction high-risk diagnosis codes.

Table 2.3: SQL Programming Language for Acute Myocardial Infarction High-Risk Group

Step 1

We identified enrollees who received an acute myocardial infarction diagnosis (Table 2.1) in a physician or outpatient setting without a corresponding inpatient claim.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
, COUNT(raps.DGNS_CD) AS BENE_LINES /*Counts the number of acute myocardial infarction diagnosis codes in an office
(physician) or outpatient setting. Limited to one instance in Step #2*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Acute Myocardial Infarction Diagnosis Codes Table*/
IN ('I2109', 'I2111', 'I2119', 'I2129', 'I213', 'I214', 'I2101', 'I2102', 'I2121', 'I219', 'I220', 'I221', 'I222', 'I228', 'I229', 'I21A1',
'I21A9') /* Acute Myocardial Infarction Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*/
AND (BENE_RAPS_PRVDR_TYPE_CD = '20' /*RAPS Provider Type Code "20" represents "physician" claims*/
OR BENE_RAPS_PRVDR_TYPE_CD = '10' /*RAPS Provider Type Code "10" represents "outpatient" claims*/

/* Subquery to identify and exclude all enrollees with an acute myocardial infarction diagnosis in an inpatient setting*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN
SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Acute Myocardial Infarction Diagnosis Codes Table*/
IN ('I2109', 'I2111', 'I2119', 'I2129', 'I213', 'I214', 'I2101', 'I2102', 'I2121', 'I219', 'I220', 'I221', 'I222', 'I228', 'I229', 'I21A1',
'I21A9') /* Acute Myocardial Infarction Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND (BENE_RAPS_PRVDR_TYPE_CD = '01'
OR BENE_RAPS_PRVDR_TYPE_CD = '02' /*RAPS Provider Type Code "01" and "02" represent "inpatient" claims*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*/

GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of an acute myocardial infarction diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's Risk Adjustment System (RAS) as including HCC 86.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.MYOCARDIAL_INFARCTION_STEP_1 raps /*Output from Step #1*/
WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of an acute myocardial infarction
diagnosis code in an office (physician) or outpatient setting*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
IN (
```



```

SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCRE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_86_SW = '1' /*Confirms HCC 86 was utilized in the payment risk score*/
OR BENE_PTC_HCC_87_SW = '1' /*Confirms HCC 87 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCRE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SQNC_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) /*Specifies the payment year for the HCC confirmation*/

```

Step 3

Using the output from Step 2, we identified and removed the enrollees who had received one or more diagnoses that also mapped to HCC 86 or 87 that we did not consider to be at a high risk for being miscoded (Table 2.2).

```

SELECT DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.MYOCARDIAL_INFARCTION_STEP_2 fdr /*Output from Step #2*/

/*Subquery to identify and remove all enrollees that received diagnosis which maps to HCC 86 or 87 that we did not consider
to be at a high risk for being miscoded */

WHERE fdr.BENE_SK NOT IN

SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to the Excluded Diagnosis Codes for the Acute Myocardial
infarction High-Risk Group Table*/ IN ('1200', '1230', '1231', '1232', '1233', '1234', '1235', '1236', '1237', '1238', '1240', '1241',
'1248', '1249', '125110', '125700', '125710', '125720', '125730', '125750', '125760', '125790', '1511', '1512') /* Excluded Diagnosis
Codes for the Acute Myocardial Infarction High-Risk Group Table */

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /*"-" indicates the RAPS diagnosis code is not deleted*/

```

Step 4

Using the output from Step 3, we identified the Risk Adjustment Processing System (RAPS) record that included the acute myocardial infarction diagnosis. We then created a 60-day before-and-after date window using the RAPS "service thru date" field, which identified inpatient stays that occurred in the prior or preceding service year.

```

SELECT raps.*, /*selects the detail RAPS record from the CMS RAPS table*/
ADD_MONTHS(BENE_RAPS_SRVC_THRU_DT, 2) AS IP_60_DAYS_FROM_DT, /*Creates a date 60 days after the RAPS Thru
Date*/
ADD_MONTHS(BENE_RAPS_SRVC_THRU_DT, -2) AS IP_60_DAYS_BEFORE_DT, /*Creates a date 60 days before the RAPS
Thru Date*/
SUM (1) over (rows unbounded preceding) AS AATS_CLM_ID /*Create a unique RAPS record id*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.MYOCARDIAL_INFARCTION_STEP_3 fdr /*Output Enrollee List from Step #3*/
ON fdr.BENE_SK = raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan Identifier*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Acute Myocardial Infarction Diagnosis Codes Table*/
IN ('12109', '12111', '12119', '12129', '1213', '1214', '12101', '12102', '12121', '1219', '1220', '1221', '1222', '1228', '1229', '121A1',
'121A9') /*Acute Myocardial Infarction Diagnosis Codes Table */

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/

```


AND BENE_RAPS_DGNS_DLT_SW = 'N' /*'N' indicates the RAPS diagnosis code is not deleted*/

AND (BENE_RAPS_PRVDR_TYPE_CD = '10' /*RAPS Provider Type Code "10" represents "outpatient" claims*/
OR BENE_RAPS_PRVDR_TYPE_CD = '20') /*RAPS Provider Type Code "20" represents "physician" claims*/

Step 5

Using the output from Step 4, we identified and removed the enrollees for whom a physician or outpatient acute myocardial infarction diagnosis had occurred within the 60-day timeframe of an inpatient stay with an acute myocardial infarction diagnosis.

SELECT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.MYOCARDIAL_INFARCTION_STEP_4 fdr

/*Subquery to identify and remove all enrollees from the step #4 list that received an acute myocardial infarction diagnosis from an inpatient stay within the 60-day calculated timeframe*/

WHERE fdr.BENE_SK **NOT IN** (

SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.MYOCARDIAL_INFARCTION_STEP_4 fdr /*Output Enrollee List from Step #4*/
ON raps.BENE_SK = fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/

WHERE (raps.BENE_RAPS_SRVC_THRU_DT **BETWEEN** fdr.IP_60_DAYS_BEFORE_DT
AND fdr.IP_60_DAYS_FROM_DT) /*Specified calculated 60 day timeframe*/

AND raps.BENE_RAPS_DGNS_DLT_SW = 'N' /*'N' indicates the RAPS diagnosis code is not deleted*/
AND (raps.BENE_RAPS_PRVDR_TYPE_CD = '01'
OR raps.BENE_RAPS_PRVDR_TYPE_CD = '02') /*RAPS Provider Type Code "01" and "02" represent "inpatient"*/

AND raps.DGNS_CD /*RAPS diagnosis code field used to match to Acute Myocardial Infarction Diagnosis Codes Table*/ **IN**
 ('I2109', 'I2111', 'I2119', 'I2129', 'I213', 'I214', 'I2101', 'I2102', 'I2121', 'I219', 'I220', 'I221', 'I222', 'I228', 'I229', 'I21A1',
 'I21A9')); /* Acute Myocardial Infarction Diagnosis Codes Table*/

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Acute-Myocardial-Infarction-High-Risk-Group.pdf>.

3. Embolism High-Risk Group

For the embolism high-risk group, we focused on enrollees who received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) (HCCs 107 & 108) during the service year but did not have an anticoagulant medication dispensed on their behalf (Table 3.1). An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 3.1 includes the 63 embolism diagnosis codes used in our analysis:

Table 3.1: Embolism Diagnosis Codes

Diagnosis Code	Description
I2692	Saddle embolus of pulmonary artery without acute cor pulmonale
I2699	Other pulmonary embolism without acute cor pulmonale
I82290	Acute embolism and thrombosis of other thoracic veins
I82409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82419	Acute embolism and thrombosis of unspecified femoral vein
I82429	Acute embolism and thrombosis of unspecified iliac vein
I82439	Acute embolism and thrombosis of unspecified popliteal vein
I82449	Acute embolism and thrombosis of unspecified tibial vein
I82499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I824Y9	Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I824Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82629	Acute embolism and thrombosis of deep veins of unspecified upper extremity
I82A19	Acute embolism and thrombosis of unspecified axillary vein
I82B19	Acute embolism and thrombosis of unspecified subclavian vein
I82C19	Acute embolism and thrombosis of unspecified internal jugular vein
I2601	Septic pulmonary embolism with acute cor pulmonale
I2602	Saddle embolus of pulmonary artery with acute cor pulmonale
I2609	Other pulmonary embolism with acute cor pulmonale
I82401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
I82402	Acute embolism and thrombosis of unspecified deep veins of left lower extremity
I82403	Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I824Y1	Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I824Y2	Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I824Y3	Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I824Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity
I824Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity
I824Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral

Diagnosis Code	Description
I82411	Acute embolism and thrombosis of right femoral vein
I82412	Acute embolism and thrombosis of left femoral vein
I82413	Acute embolism and thrombosis of femoral vein, bilateral
I82421	Acute embolism and thrombosis of right iliac vein
I82422	Acute embolism and thrombosis of left iliac vein
I82423	Acute embolism and thrombosis of iliac vein, bilateral
I82431	Acute embolism and thrombosis of right popliteal vein
I82432	Acute embolism and thrombosis of left popliteal vein
I82433	Acute embolism and thrombosis of popliteal vein, bilateral
I82441	Acute embolism and thrombosis of right tibial vein
I82442	Acute embolism and thrombosis of left tibial vein
I82443	Acute embolism and thrombosis of tibial vein, bilateral
I82491	Acute embolism and thrombosis of other specified deep vein of right lower extremity
I82492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82621	Acute embolism and thrombosis of deep veins of right upper extremity
I82622	Acute embolism and thrombosis of deep veins of left upper extremity
I82623	Acute embolism and thrombosis of deep veins of upper extremity, bilateral
I82A11	Acute embolism and thrombosis of right axillary vein
I82A12	Acute embolism and thrombosis of left axillary vein
I82A13	Acute embolism and thrombosis of axillary vein, bilateral
I82B11	Acute embolism and thrombosis of right subclavian vein
I82B12	Acute embolism and thrombosis of left subclavian vein
I82B13	Acute embolism and thrombosis of subclavian vein, bilateral
I82C11	Acute embolism and thrombosis of right internal jugular vein
I82C12	Acute embolism and thrombosis of left internal jugular vein
I82C13	Acute embolism and thrombosis of internal jugular vein, bilateral
I7410	Embolism and thrombosis of unspecified parts of aorta
I7411	Embolism and thrombosis of thoracic aorta
I7419	Embolism and thrombosis of other parts of aorta
I742	Embolism and thrombosis of arteries of the upper extremities
I743	Embolism and thrombosis of arteries of the lower extremities
I744	Embolism and thrombosis of arteries of extremities, unspecified
I745	Embolism and thrombosis of iliac artery
I748	Embolism and thrombosis of other arteries
I749	Embolism and thrombosis of unspecified artery

There were 365 additional diagnosis codes that mapped to the Embolism HCCs; however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received any one of these diagnoses were excluded from our analysis. The table of 365 diagnosis codes can be downloaded at the link included in the Downloadable Information subsection found later in this section.

There were 812 National Drug Codes (NDCs) pulled from the PDE data used in our analysis. We removed enrollees in Step 3 of the SQL Programming Language who received one or more the drugs associated with these NDCs. The table of 812 NDCs can be downloaded at the link included in the Downloadable Information subsection found later in this section.

SQL Programming Language

Table 3.2 details the SQL programming language used to query CMS's systems in order to identify the embolism high-risk diagnosis codes.

Table 3.2: SQL Programming Language for Embolism High-Risk Group

Step 1

We identified enrollees who received an embolism diagnosis (Table 3.1). Additionally, we removed any enrollees who received one or more diagnoses that also mapped to HCC 107 or 108 that we did not consider to be at a high risk for being miscoded.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
COUNT(raps.DGNS_CD) AS BENE_LINES /*Counts the number of embolism diagnosis codes. Limited to one instance in Step
#2*/

FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Embolism Diagnosis Codes Table*/ IN ('I2692', 'I2699',
'I82290', 'I82409', 'I82419', 'I82429', 'I82439', 'I82449', 'I82499', 'I824Y9', 'I824Z9', 'I82629', 'I82A19', 'I82B19', 'I82C19',
'I2601', 'I2602', 'I2609', 'I82401', 'I82402', 'I82403', 'I824Y1', 'I824Y2', 'I824Y3', 'I824Z1', 'I824Z2', 'I824Z3', 'I82411', 'I82412',
'I82413', 'I82421', 'I82422', 'I82423', 'I82431', 'I82432', 'I82433', 'I82441', 'I82442', 'I82443', 'I82491', 'I82492', 'I82493',
'I82621', 'I82622', 'I82623', 'I82A11', 'I82A12', 'I82A13', 'I82B11', 'I82B12', 'I82B13', 'I82C11', 'I82C12', 'I82C13', 'I7410',
'I7411', 'I7419', 'I742', 'I743', 'I744', 'I745', 'I748', 'I749') /*Embolism Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '~' /*'~' indicates the RAPS diagnosis code is not deleted*/

/*Subquery to identify and remove all enrollees that received a diagnosis that maps to HCC 107 or 108 that we did not
consider to be a high risk for being miscoded*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (

SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE DGNS_CD /*RAPS diagnosis code field used to match to Embolism Diagnosis Codes Table*/ IN (
SELECT dx.DX_CD /*Represents the diagnosis code field in the Embolism Diagnosis Codes Table*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_PULMONARY_EMBOLISM_EXCLUDED_DX dx) /*Excluded Diagnosis Codes for the
Embolism High-Risk Group Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '~' /*'~' indicates the RAPS diagnosis code is not deleted*/
)

GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```


Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of an embolism diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's RAS as including HCC 107 or 108.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_PULMONARY_EMBOLISM_STEP_1 raps /*Output from Step #1*/
WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of an embolism diagnosis code*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
IN ( /*The following sub query identifies all enrollees from the Step #1 with HCC 107 or 108*/

SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCRE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_107_SW = '1' /*Confirms HCC 107 was utilized in the payment risk score*/
OR BENE_PTC_HCC_108_SW = '1') /*Confirms HCC 108 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCRE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SEQNC_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) ; /*Specifies the payment year for the HCC confirmation*/
```

Step 3

Using the output from Step 2, we identified enrollees who (according to their associated medical records) did not receive any of the embolism drugs (anticoagulant medication) during the time period of interest.

```
select DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_PULMONARY_EMBOLISM_STEP_2 fdr /*Output from Step #2*/

WHERE fdr.BENE_SK NOT IN ( /*The following sub query identifies all enrollees with a drug claim for one or more of the
NDC's provided*/

SELECT DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.ACTIVE_PULMONARY_EMBOLISM_STEP_2 fdr /*Output from Step #2*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr /*CMS Medicare Claim table data*/
ON fdr.BENE_SK = hdr.BENE_SK /*Joins enrollees from the step #2 results to the CMS Part D perscription drug claims*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin /*CMS Medicare Claim Line data*/
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLN_DT_SGNTR_SK = lin.CLN_DT_SGNTR_SK
AND hdr.CLN_TYPE_CD = lin.CLN_TYPE_CD
AND hdr.CLN_NUM_SK = lin.CLN_NUM_SK
AND hdr.CLN_FROM_DT = lin.CLN_FROM_DT /*Joins CMS Medicare Claims to the claim line table (Part D perscription drug
claims to the individual claim lines)*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE_RX rx /*CMS Medicare Claim Line RX table data*/
ON lin.GEO_BENE_SK = rx.GEO_BENE_SK
AND lin.CLN_DT_SGNTR_SK = rx.CLN_DT_SGNTR_SK
AND lin.CLN_TYPE_CD = rx.CLN_TYPE_CD
AND lin.CLN_NUM_SK = rx.CLN_NUM_SK
AND lin.CLN_LINE_NUM = rx.CLN_LINE_NUM /*Joins CMS Part D perscription drug claim lines to the individual Part D
speceific claim lines*/
```

```
INNER JOIN CMS_ADM_OIG_OAS_PRD.ACTIVE_PULMONARY_EMBOLISM_PDE_NDC_LIST ndc /*NDCs for Embolism High-
Risk Group Table */
ON lin.CLM_LINE_NDC_CD = ndc.NDC_CD /*Joins CMS Part D perscription drug claim line NDC code to the NDCs for
Embolism High-Risk Group Table*/

WHERE hdr.CLM_TYPE_CD IN (1,2,4) /*Represents Non-Deleted Part D Drug Claim types*/

AND hdr.clm_thru_dt BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/

AND hdr.clm_finl_actn_ind = 'Y' /*Indicates only Final Action Claims*/
AND rx.CLM_LINE_INGRDNT_CST_AMT > 0 /*Identifies non-zero pay claims*/
AND rx.CLM_DRUG_CVRG_STUS_CD='C'; /*Identifies only covered drug claims*/
```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Embolism-High-Risk-Group.pdf>.

4. Lung Cancer High-Risk Group

For the lung cancer high-risk group, we focused on enrollees who received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers (HCC 9)) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis (Table 4.1). In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 4.1 includes the 17 lung cancer diagnosis codes used in our analysis:

Table 4.1: Lung Cancer Diagnosis Codes

Diagnosis Code	Description
C33	Malignant neoplasm of trachea
C3400	Malignant neoplasm of unspecified main bronchus
C3401	Malignant neoplasm of right main bronchus
C3402	Malignant neoplasm of left main bronchus
C3410	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C3411	Malignant neoplasm of upper lobe, right bronchus or lung
C3412	Malignant neoplasm of upper lobe, left bronchus or lung
C342	Malignant neoplasm of middle lobe, bronchus or lung
C3430	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C3431	Malignant neoplasm of lower lobe, right bronchus or lung
C3432	Malignant neoplasm of lower lobe, left bronchus or lung
C3480	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C3481	Malignant neoplasm of overlapping sites of right bronchus and lung
C3482	Malignant neoplasm of overlapping sites of left bronchus and lung
C3490	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C3491	Malignant neoplasm of unspecified part of right bronchus or lung
C3492	Malignant neoplasm of unspecified part of left bronchus or lung

There were 93 additional diagnosis codes that mapped to the Lung and Other Severe Cancers HCCs; however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received any one of these diagnoses were excluded from our analysis. The table of 93 diagnosis codes can be downloaded at the link included in the Downloadable Information subsection found later in this section.

We used various Current Procedural Terminology (CPT) codes to further refine our analysis.⁷ We identified and removed enrollees who received at least one of the following:

1. Table 4.2 includes 19 chemotherapy drug treatment CPT codes that we identified as common procedure codes associated with an enrollee who received a chemotherapy drug treatment for an active cancer diagnosis.

Table 4.2: Chemotherapy Drug Treatment CPT Codes

CPT Code	Description
96420	Injection of chemotherapy using push technique into an artery
96402	Hormonal anti-neoplastic chemotherapy administration beneath the skin or into muscle
96405	Administration of chemotherapy into growth, 1 – 7
96406	Chemotherapy into a lesion, more than 7 lesions
96409	Infusion of chemotherapy into a vein using push technique
96411	Infusion of different chemotherapy drug or substance into a vein
96413	Infusion of chemotherapy into a vein up to 1 hour
96415	Infusion of chemotherapy into a vein
96401	Administration of non-hormonal anti-neoplastic chemotherapy under skin or into muscle
96417	Infusion of different chemotherapy drug or substance into a vein up to 1 hour
96549	Other chemotherapy procedure
96422	Infusion of chemotherapy into an artery up to 1 hour
96423	Infusion of chemotherapy into artery
96425	Prolonged chemotherapy infusion into artery by portable or implanted pump, more than 8 hours
96440	Chemotherapy administration into chest cavity requiring insertion of catheter
96446	Administration of chemotherapy into abdominal cavity
96450	Chemotherapy administration into spinal canal requiring spinal tap
96542	Injection of chemotherapy via reservoir under skin
96416	Prolonged chemotherapy infusion into a vein by portable or implanted pump more than 8 hours

2. Table 4.3 includes 22 radiation treatment CPT codes that we identified as common procedure codes associated with an enrollee who received radiation treatment for an active cancer diagnosis.

Table 4.3: Radiation Treatment CPT Codes

CPT Code	Description
77762	Application of organ cavity radiation source, intermediate
77402	Delivery of simple radiation treatment
77407	Delivery of intermediate radiation treatment
77412	Radiation treatment delivery, complex

⁷ The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

CPT Code	Description
77417	Therapeutic radiology port films
77423	Radiation treatment delivery, high energy
77424	Intraoperative single X-ray radiation treatment session
77425	Intraoperative electrons radiation treatment single session
77427	Radiation treatment management, 5 treatments
77401	Radiation treatment delivery, superficial
77761	Simple body cavity radiation source application
77799	Other administration of radiation therapy
77763	Complex body cavity radiation source application
77767	High dose brachytherapy through skin surface, 1 channel or up to 2.0 cm
77768	High dose brachytherapy through skin surface, 2 channels or more than 2.0 cm
77770	High dose radiation therapy, 1 channel
77771	High dose brachytherapy, 2 – 12 channels
77772	High dose brachytherapy, more than 12 channels
77778	Complex application of radiation source
77789	Surface application of radiation
77790	Supervision, handling, loading of radiation
77750	Infusion or instillation of radioelement solution

3. Table 4.4 includes 12 surgical therapy CPT codes that we identified as common procedure codes associated with an enrollee who received surgical therapy for an active lung cancer diagnosis.

Table 4.4: Lung Cancer Surgical CPT Codes

CPT Code	Description
32501	Repair of lung airway and removal of segment of lung
32491	Removal of a lung segment to reduce lung volume
32488	Removal of remaining lung after prior lung surgery
32486	Removal portion of lung tissue and segment of lung airway
32484	Removal of a segment of lung tissue
32482	Removal of two lobes of lung
32480	Removal of lobe of lung
32445	Removal of lung and chest cavity lining
32442	Removal of lung and portion of windpipe cartilage
32440	Removal of lung
32405	Needle biopsy of lung or chest tissue, accessed through the skin
32400	Needle biopsy of lining of lung, accessed through the skin

SQL Programming Language

Table 4.5 details the SQL programming language used to query CMS's systems in order to identify the lung cancer high-risk diagnosis codes.

Table 4.5: SQL Programming Language for Lung Cancer High-Risk Group

Step 1

We identified enrollees who received a lung cancer diagnosis (Table 4.1). Additionally, we removed any enrollees who received one or more diagnoses that also mapped to HCC 9 that we did not consider to be at high risk for being miscoded.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
COUNT(raps.DGNS_CD) AS BENE_LINES /*Counts the number of lung cancer diagnosis codes. Limited to one instance in
Step #2*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/
WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Lung Cancer Diagnosis Codes Table*/ IN ( 'C33',
'C3400', 'C3401', 'C3402', 'C3410', 'C3411', 'C3412', 'C342', 'C3430', 'C3431', 'C3432', 'C3480', 'C3481', 'C3482', 'C3490',
'C3491', 'C3492') /*Lung Cancer Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = 'no' /*"no" indicates the RAPS diagnosis code is not deleted*/

/*Subquery to identify and remove all enrollees that received a diagnosis that maps to HCC 9 that we did not consider to be
at a high risk for being miscoded*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (
SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Excluded Diagnosis Codes for the Lung Cancer High-
Risk Group Table*/ IN (
SELECT DX_CD

FROM CMS_ADM_OIG_OAS_PRD.LUNG_CANCER_EXCLUDED_DX) /* Excluded Diagnosis Codes for the Lung Cancer High-
Risk Group Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = 'no' /*"no" indicates the RAPS diagnosis code is not deleted*/
GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of a lung cancer diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's RAS as including HCC 9.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.LUNG_CANCER_STEP_1 raps /*Output from Step #1*/
WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of a lung cancer diagnosis code*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
IN (
```


*/*Subquery to identify all enrollees from Step #1 with HCC 9 */*

```
SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCRE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_9_SW = '1' /*Confirms HCC 9 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCRE_MODEL_SBTYP_CD = 'I02' /*Used subtype code "I02" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SEQNC_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) ; /*Specifies the payment year for the HCC confirmation*/
```

Step 3

Using the output from Step 2, we identified the RAPS record that included the targeted lung cancer diagnosis so that we could do an encounter claim search spanning the 6-months-before-and-after date window using the targeted diagnosis RAPS "service thru date" field in the following step.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
       raps.BENE_RAPS_SRVC_THRU_DT,
       raps.DGNS_CD
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.LUNG_CANCER_STEP_2 fdr /*Output from Step #2*/
ON RAPS.BENE_SK = fdr.BENE_SK /*Join on CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/

WHERE DGNS_CD IN ( 'C33', 'C3400', 'C3401', 'C3402', 'C3410', 'C3411', 'C3412', 'C342', 'C3430',
                  'C3431', 'C3432', 'C3480', 'C3481', 'C3482', 'C3490', 'C3491', 'C3492' ) /*Lung Cancer Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = 'N' /*"N" indicates the RAPS diagnosis code is not deleted*/
```

Step 4

Using the output from Step 3, we identified and removed the enrollees for whom there was a Part C encounter claim with one of the corresponding procedure codes related to a lung cancer treatment rendered within 6 months of submission of the targeted lung cancer diagnosis.

```
SELECT distinct fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.LUNG_CANCER_STEP_3 fdr /*Output from Step #3*/

/*Subquery to identify all enrollees to remove from the step #3 output who had a Part C encounter claim that contains a
lung cancer treatment procedure code. /

WHERE fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (

SELECT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.LUNG_CANCER_STEP_3 fdr /*Output from Step #3*/

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr
ON hdr.BENE_SK = fdr.BENE_SK /*Join enrollees from the step #3 results to the CMS Medicare Part C encounter claims*/

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLIN_DT_SGNTR_SK = lin.CLIN_DT_SGNTR_SK
AND hdr.CLIN_TYPE_CD = lin.CLIN_TYPE_CD
AND hdr.CLIN_NUM_SK = lin.CLIN_NUM_SK
```

```
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /*Joins CMS Medicare Part C encounter claim to the claim line table with the
individual claim lines*/

WHERE lin.CLM_LINE_THRU_DT BETWEEN fnd.BENE_RAPS_SRVC_THRU_DT-183
AND fnd.BENE_RAPS_SRVC_THRU_DT+183 /* Identifies enrollees with encounter submissions occurring 6 months before
and 6 months after which include a lung cancer treatment procedure code */

AND lin.CLM_LINE_HCPCS_CD IN ('32400', '32405', '32440', '32442', '32445', '32480', '32482', '32484', '32486', '32488',
'32491', '32501', /*Lung Cancer Surgical CPT Codes*/

'96401', '96402', '96405', '96406', '96409', '96411', '96413', '96415', '96416', '96417', '96420', '96422', '96423', '96425',
'96440', '96446', '96450', '96542', '96549', /*Chemotherapy Drug Treatment CPT Codes*/

'77401', '77402', '77407', '77412', '77417', '77423', '77424', '77425', '77427', '77750', '77761', '77762', '77763', '77767',
'77768', '77770', '77771', '77772', '77778', '77789', '77790', '77799') /*Radiation Treatment CPT Codes */

AND hdr.CLM_TYPE_CD > 3900 /*Identifies the encounter claim type codes*/
AND hdr.CLM_FINL_ACTN_IND = 'Y'; /*Indicates a final action encounter claim*/
```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Lung-Cancer-High-Risk-Group.pdf>.

5. Breast Cancer High-Risk Group

For the breast cancer high-risk group, we focused on enrollees who received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors (HCC 12)) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (Table 5.1). In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 5.1 includes the 54 breast cancer diagnosis codes used in our analysis:

Table 5.1: Breast Cancer Diagnosis Codes

Diagnosis Code	Description
C50011	Malignant neoplasm of nipple and areola, right female breast
C50012	Malignant neoplasm of nipple and areola, left female breast
C50019	Malignant neoplasm of nipple and areola, unspecified female breast
C50021	Malignant neoplasm of nipple and areola, right male breast
C50022	Malignant neoplasm of nipple and areola, left male breast
C50029	Malignant neoplasm of nipple and areola, unspecified male breast
C50111	Malignant neoplasm of central portion of right female breast
C50112	Malignant neoplasm of central portion of left female breast
C50119	Malignant neoplasm of central portion of unspecified female breast
C50121	Malignant neoplasm of central portion of right male breast
C50122	Malignant neoplasm of central portion of left male breast
C50129	Malignant neoplasm of central portion of unspecified male breast
C50211	Malignant neoplasm of upper-inner quadrant of right female breast
C50212	Malignant neoplasm of upper-inner quadrant of left female breast
C50219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50221	Malignant neoplasm of upper-inner quadrant of right male breast
C50222	Malignant neoplasm of upper-inner quadrant of left male breast
C50229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50311	Malignant neoplasm of lower-inner quadrant of right female breast
C50312	Malignant neoplasm of lower-inner quadrant of left female breast
C50319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50321	Malignant neoplasm of lower-inner quadrant of right male breast
C50322	Malignant neoplasm of lower-inner quadrant of left male breast
C50329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50411	Malignant neoplasm of upper-outer quadrant of right female breast
C50412	Malignant neoplasm of upper-outer quadrant of left female breast
C50419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50421	Malignant neoplasm of upper-outer quadrant of right male breast
C50422	Malignant neoplasm of upper-outer quadrant of left male breast

Diagnosis Code	Description
C50429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50511	Malignant neoplasm of lower-outer quadrant of right female breast
C50512	Malignant neoplasm of lower-outer quadrant of left female breast
C50519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50521	Malignant neoplasm of lower-outer quadrant of right male breast
C50522	Malignant neoplasm of lower-outer quadrant of left male breast
C50529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50611	Malignant neoplasm of axillary tail of right female breast
C50612	Malignant neoplasm of axillary tail of left female breast
C50619	Malignant neoplasm of axillary tail of unspecified female breast
C50621	Malignant neoplasm of axillary tail of right male breast
C50622	Malignant neoplasm of axillary tail of left male breast
C50629	Malignant neoplasm of axillary tail of unspecified male breast
C50811	Malignant neoplasm of overlapping sites of right female breast
C50812	Malignant neoplasm of overlapping sites of left female breast
C50819	Malignant neoplasm of overlapping sites of unspecified female breast
C50821	Malignant neoplasm of overlapping sites of right male breast
C50822	Malignant neoplasm of overlapping sites of left male breast
C50829	Malignant neoplasm of overlapping sites of unspecified male breast
C50911	Malignant neoplasm of unspecified site of right female breast
C50912	Malignant neoplasm of unspecified site of left female breast
C50919	Malignant neoplasm of unspecified site of unspecified female breast
C50921	Malignant neoplasm of unspecified site of right male breast
C50922	Malignant neoplasm of unspecified site of left male breast
C50929	Malignant neoplasm of unspecified site of unspecified male breast

There were 217 additional diagnosis codes that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors; however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received any one of these diagnoses were excluded from our analysis. The table of 217 diagnosis codes can be downloaded at the link included in the Downloadable Information subsection found later in this section.

We used various CPT codes to further refine our analysis. We identified and removed enrollees who received at least one of the following:

1. 19 chemotherapy drug treatment CPT codes that we identified as common procedure codes associated with an enrollee who received a chemotherapy drug treatment for an active cancer diagnosis (Table 4.2 in the preceding section).
2. 22 radiation treatment CPT codes that we identified as common procedure codes associated with an enrollee who received radiation treatment for an active cancer diagnosis (Table 4.3 in the preceding section).

3. Table 5.2 includes seven surgical therapy CPT codes (footnote 7) that we identified as common procedure codes associated with an enrollee who received surgical therapy for an active breast cancer diagnosis.

Table 5.2: Breast Cancer Surgical CPT Codes

CPT Code	Description
19301	Partial removal of breast
19302	Partial removal of breast and underarm lymph nodes
19303	Total removal of breast
19304	Removal of tumor and breast tissue, accessed beneath the skin
19305	Removal of breast, lymph nodes, and muscle
19306	Extensive removal of breast, chest muscle, underarm lymph nodes, and breast lymph nodes
19307	Removal of breast and underarm lymph nodes

There were 181 NDCs pulled from the PDE data used in our analysis. We removed enrollees who received one or more of these NDCs on a drug claim. The table of 181 NDCs can be downloaded at the link included in the Downloadable Information subsection found later in this section.

SQL Programming Language

Table 5.3 details the SQL programming language used to query CMS's systems in order to identify the breast cancer high-risk diagnosis codes.

Table 5.3: SQL Programming Language for Breast Cancer High-Risk Group

Step 1

We identified enrollees who received a breast cancer diagnosis (Table 5.1). Additionally, we removed any enrollees who received one or more diagnoses that also mapped to HCC 12 that we did consider to be at a high risk for being miscoded.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
COUNT(raps.DGNS_CD AS BENE_LINES /*Counts the number of breast cancer diagnosis codes. Limited to one instance in
Step #2*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE DGNS_CD /* RAPS diagnosis cod field used to match to the Breast Cancer Diagnosis Codes Table*/ IN ('C50011',
'C50012', 'C50019', 'C50021', 'C50022', 'C50029', 'C50111', 'C50112', 'C50119', 'C50121', 'C50122', 'C50129', 'C50211',
'C50212', 'C50219', 'C50221', 'C50222', 'C50229', 'C50311', 'C50312', 'C50319', 'C50321', 'C50322', 'C50329', 'C50411',
'C50412', 'C50419', 'C50421', 'C50422', 'C50429', 'C50511', 'C50512', 'C50519', 'C50521', 'C50522', 'C50529', 'C50511',
'C50612', 'C50619', 'C50621', 'C50622', 'C50629', 'C50811', 'C50812', 'C50819', 'C50821', 'C50822', 'C50829', 'C50911',
'C50912', 'C50919', 'C50921', 'C50922', 'C50929') /*Breast Cancer Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = 'N' /*N indicates the RAPS diagnosis code is not deleted*/

/*Subquery to identify and remove all enrollees that received a diagnosis that maps to HCC 12 that we did consider to be at
a high risk for being miscoded*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (
```



```
SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Excluded Diagnosis Codes for the Breast Cancer High-
Risk Group Table*/ IN(
SELECT DX_CD

FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_EXCLUDED_DX) /* Excluded Diagnosis Codes for the Breast Cancer
High-Risk Group Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted"
)
GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of a breast cancer diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's RAS as including HCC 12.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_1 raps /*Output from Step #1*/

WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of a breast cancer diagnosis code*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
IN (

/*Subquery to identify all enrollees from Step #1 with HCC 12 */

SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCORE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_12_SW = '1' /*Confirms HCC 12 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCORE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SEQ_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) ; /*Specifies the payment year for the HCC confirmation*/
```

Step 3

Using the output from Step 2, we identified the RAPS record that included the targeted breast cancer diagnosis so that we could do an encounter claim search spanning the 6-months-before-and-after date window using the targeted diagnosis RAPS "service thru date" field in the following step.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
       raps.BENE_RAPS_SRVC_THRU_DT,
       raps.DGNS_CD
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_2 fdr /*Output from Step #2*/
ON RAPS.BENE_SK = fdr.BENE_SK /*Join on CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```



```
WHERE raps.DGNS_CD IN ( 'C50011', 'C50012', 'C50019', 'C50021', 'C50022', 'C50029', 'C50111', 'C50112', 'C50119',
'C50121', 'C50122', 'C50129', 'C50211', 'C50212', 'C50219', 'C50221', 'C50222', 'C50229', 'C50311', 'C50312', 'C50319',
'C50321', 'C50322', 'C50329', 'C50411', 'C50412', 'C50419', 'C50421', 'C50422', 'C50429', 'C50511', 'C50512', 'C50519',
'C50521', 'C50522', 'C50529', 'C50611', 'C50612', 'C50619', 'C50621', 'C50622', 'C50629', 'C50811', 'C50812', 'C50819',
'C50821', 'C50822', 'C50829', 'C50911', 'C50912', 'C50919', 'C50921', 'C50922', 'C50929') /* Breast Cancer Diagnosis Codes
Table */
```

```
AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = 'N' /*'N' indicates the RAPS diagnosis code is not deleted*/
```

Step 4

Using the output from Step 3, we identified and removed the enrollees for whom there was a Part C encounter claim with one of the corresponding procedure codes related to a breast cancer treatment rendered within 6 months of submission of the targeted breast cancer diagnosis.

```
SELECT distinct fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_3 fdr /*Output from Step #3*/
```

/*Subquery to identify all enrollees to remove from the step #3 output who had a Part C encounter claim that contains a breast cancer treatment procedure code. /

```
WHERE fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN(
```

```
SELECT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_3 fdr /*Output from Step #3*/
```

```
JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr
```

```
ON hdr.BENE_SK = fdr.BENE_SK /*Join enrollees from the step #3 results to the CMS Medicare Part C encounter claims*/
```

```
JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin
```

```
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
```

```
AND hdr.CLM_DT_SGNTR_SK = lin.CLM_DT_SGNTR_SK
```

```
AND hdr.CLM_TYPE_CD = lin.CLM_TYPE_CD
```

```
AND hdr.CLM_NUM_SK = lin.CLM_NUM_SK
```

```
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /*Joins CMS Medicare Part C encounter claim to the claim line table with the
individual claim lines)*/
```

```
WHERE lin.CLM_LINE_THRU_DT BETWEEN fnd.BENE_RAPS_SRVC_THRU_DT-183
```

```
AND fnd.BENE_RAPS_SRVC_THRU_DT+183 /* Identifies enrollees with encounter submissions occurring 6 months before
and 6 months after which include a breast cancer treatment procedure code */
```

```
AND lin.CLM_LINE_HCPCS_CD IN ( /*Identifies all HCPCS/CPT Codes associated with encounter claim*/
```

```
'19301', '19302', '19303', '19304', '19305', '19306', '19307', /*Breast Cancer Surgical CPT Codes*/
```

```
'96401', '96402', '96405', '96406', '96409', '96411', '96413', '96415', '96416', '96417', '96420', '96422', '96423', '96425',
'96440', '96446', '96450', '96542', '96549', /*Chemotherapy Drug Treatment CPT Codes*/
```

```
'77401', '77402', '77407', '77412', '77417', '77423', '77424', '77425', '77427', '77750', '77761', '77762', '77763', '77767',
'77768', '77770', '77771', '77772', '77778', '77789', '77790', '77799') /*Radiation Treatment CPT Codes */
```

```
AND hdr.CLM_TYPE_CD > 3900 /*Identifies the encounter claim type codes*/
```

```
AND hdr.CLM_FINL_ACTN_IND = 'Y'; /*Indicates a final action encounter claim */
```


Step 5

Using the output from Step 4, we identified and removed the enrollees who had received a drug claim for any of the NDCs provided within 6 months (before or after) of the targeted breast cancer diagnosis.

```
select DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_4 fdr /*Output from Step #4*/

WHERE fdr.BENE_SK NOT IN (

/*Subquery to identify all enrollees with a drug claim for one or more of the NDC's provided*/

SELECT DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_STEP_4 fdr /*Output from Step #4*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr /*CMS Medicare Claim table data*/
ON fdr.BENE_SK = hdr.BENE_SK /*Joins enrollees from the step #4 results to the CMS Part D prescription drug claims*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin /*CMS Medicare Claim Line data*/
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLM_DT_SGNTR_SK = lin.CLM_DT_SGNTR_SK
AND hdr.CLM_TYPE_CD = lin.CLM_TYPE_CD
AND hdr.CLM_NUM_SK = lin.CLM_NUM_SK
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /*Joins CMS Medicare Claims to the claim line table (Part D prescription drug
claims to the individual claim lines)*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE_RX rx /*CMS Medicare Claim Line RX table data*/
ON lin.GEO_BENE_SK = rx.GEO_BENE_SK
AND lin.CLM_DT_SGNTR_SK = rx.CLM_DT_SGNTR_SK
AND lin.CLM_TYPE_CD = rx.CLM_TYPE_CD
AND lin.CLM_NUM_SK = rx.CLM_NUM_SK
AND lin.CLM_LINE_NUM = rx.CLM_LINE_NUM /*Joins CMS Part D prescription drug claim lines to the individual Part D
specific claim lines*/

INNER JOIN CMS_ADM_OIG_OAS_PRD.BREAST_CANCER_PDE_NDC_LIST ndc /*NDCs for Breast Cancer High-Risk Group
Table*/
ON lin.CLM_LINE_NDC_CD = ndc.NDC_CD /*Joins CMS Part D prescription drug claim line NDC code to the NDCs for Breast
Cancer High-Risk Group Table*/

WHERE hdr.CLM_TYPE_CD IN {1,2,4} /*Represents Non-Deleted Part D Drug Claim types*/

AND hdr.CLM_THRU_DT BETWEEN fdr.BENE_RAPS_SRVC_THRU_DT-183 AND fdr.BENE_RAPS_SRVC_THRU_DT+183
/*Specified six month before and after timeframe*/

AND hdr.clm_finl_actn_ind = 'Y' /*Indicates only Final Action Claims*/
AND rx.CLM_LINE INGRDNT_CST_AMT >0 /*Identifies non-zero pay claims*/
AND rx.CLM_DRUG_CVRG_STUS_CD='C') /*Identifies only covered drug claims*/
```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Breast-Cancer-High-Risk-Group.pdf>.

6. Colon Cancer High-Risk Group

For the colon cancer high-risk group, we focused on enrollees who received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers (HCC 11)) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (Table 6.1). In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 6.1 includes the 10 colon cancer diagnosis codes used in our analysis:

Table 6.1: Colon Cancer Diagnosis Codes

Diagnosis Code	Description
C180	Malignant neoplasm of cecum
C181	Malignant neoplasm of appendix
C182	Malignant neoplasm of ascending colon
C183	Malignant neoplasm of hepatic flexure
C184	Malignant neoplasm of transverse colon
C185	Malignant neoplasm of splenic flexure
C186	Malignant neoplasm of descending colon
C187	Malignant neoplasm of sigmoid colon
C188	Malignant neoplasm of overlapping sites of colon
C189	Malignant neoplasm of colon, unspecified

There were 123 additional diagnosis codes that mapped to the HCC for Colorectal, Bladder, and Other Cancers; however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received any one of these diagnoses were excluded from our analysis. The table of 123 diagnosis codes can be downloaded at the link included in the Downloadable Information subsection found later in this section.

We used various CPT codes to further refine our analysis. We identified and removed enrollees who received at least one of the following:

1. 19 chemotherapy drug treatment CPT codes that we identified as common procedure codes associated with an enrollee who received a chemotherapy drug treatment for an active cancer diagnosis (Table 4.2 in a preceding section).
2. 22 radiation treatment CPT codes that we identified as common procedure codes associated with an enrollee who received radiation treatment for an active cancer diagnosis (Table 4.3 in a preceding section).

3. Table 6.2 includes 31 surgical therapy CPT codes (footnote 7) that we identified as common procedure codes associated with an enrollee who received surgical therapy for an active colon cancer diagnosis.

Table 6.2: Colon Cancer Surgical CPT Codes

CPT Code	Description
44187	Creation of small bowel opening using an endoscope, non-tube
44140	Partial removal of large bowel
44141	Partial removal of large bowel with creation of opening to the skin
44143	Partial removal of large bowel with creation of opening
44144	Partial removal of large bowel with creation of small or large bowel opening
44145	Partial removal of large bowel and reattachment to rectum
44146	Partial removal of large bowel and reattachment to rectum and creation of large bowel opening
44147	Partial removal of large bowel, abdominal and transanal approach
44150	Removal of large bowel with attachment of small bowel to rectum or creation of small bowel opening
44151	Removal of large bowel with creation of small bowel opening
44155	Removal of large bowel and rectum and creation of opening from end of small bowel to skin through abdomen
44156	Removal of large bowel and rectum with creation of small bowel opening
44157	Removal of large bowel and rectum with attachment of small bowel to anus
44158	Removal of large bowel and rectum with attachment of small bowel to anus and creation of small bowel reservoir
44139	Release of large bowel from spleen and abdominal wall
44206	Partial removal of large bowel with creation of opening using an endoscope
44227	Closure of large or small bowel opening using an endoscope
44213	Partial release of large bowel and partial removal of large bowel using an endoscope
44212	Removal of large bowel and rectum with creation of small bowel opening using an endoscope
44211	Removal of large bowel and rectum with attachment of small bowel to anus and creation of small bowel opening using an endoscope
44210	Removal of large bowel with attachment of small bowel to rectum or creation of small bowel opening using an endoscope
44160	Partial removal of small and large bowel with attachment of small and large bowel
44207	Partial removal of large bowel and reattachment to rectum using an endoscope
44186	Creation of small bowel opening using an endoscope
44205	Partial removal of small and large bowel with attachment of small and large bowel using an endoscope
44204	Partial removal of large bowel using an endoscope
44203	Partial removal of small bowel using an endoscope, each additional resection and connection
44202	Partial removal and reconnection of small bowel using an endoscope
44188	Creation of large bowel opening using an endoscope
44238	Bowel procedure using an endoscope
44208	Partial removal of large bowel and reattachment to rectum and creation of opening from large bowel to skin using an endoscope

SQL Programming Language

Table 6.3 details the SQL programming language used to query CMS's systems in order to identify the colon cancer high-risk diagnosis codes.

Table 6.3: SQL Programming Language for Colon Cancer High-Risk Group

Step 1

We identified enrollees who received a colon cancer diagnosis (Table 6.1). Additionally, we removed any enrollees who received one or more diagnoses that also mapped to HCC 11 that we did not consider to be at a high risk for being miscoded.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
COUNT(raps.DGNS_CD) AS BENE_LINES /*Counts the number of colon cancer diagnosis codes. Limited to one instance in
Step #2*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Colon Cancer Diagnosis Codes Table*/ IN ( 'C180',
'C181', 'C182', 'C183', 'C184', 'C185', 'C186', 'C187', 'C188', 'C189') /*Colon Cancer Diagnosis Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*/

/*Subquery to identify and remove all enrollees that received a diagnosis that maps to HCC 11 that we did not consider to be
at a high risk for being miscoded*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (

SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Excluded Diagnosis Codes for the Colon Cancer High-
Risk Group Table*/ IN (

SELECT DX_CD
FROM CMS_ADM_OIG_OAS_PRD.COLON_CANCER_EXCLUDED_DX) /*Excluded Diagnosis Codes for the Colon Cancer High-
Risk Group Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*
)
GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of a colon cancer diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's RAS as including HCC 11.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.COLON_CANCER_STEP_1 raps /*Output from Step #1*/

WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of a colon cancer diagnosis code*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```


IN (

*/*Subquery to identify all enrollees from the Step #1 with HCC 11 */*

```
SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_I_SCRE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_11_SW = '1' /*Confirms HCC 11 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCRE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SEQNC_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) ; /*Specifies the payment year for the HCC confirmation*/
```

Step 3

Using the output from Step 2, we identified the RAPS record that included the targeted colon cancer diagnosis so that we could do an encounter claim search spanning the 6-months-before-and-after date window using the targeted diagnosis RAPS "service thru date" field in the following step.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
       raps.BENE_RAPS_SRVC_THRU_DT,
       raps.DGNS_CD
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.COLON_CANCER_STEP_2 fdr /*Output from Step #2*/
ON RAPS.BENE_SK = fdr.BENE_SK /*Join on CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/

WHERE DGNS_CD IN ('C180', 'C181', 'C182', 'C183', 'C184', 'C185', 'C186', 'C187', 'C188', 'C189') /*Colon Cancer Diagnosis
Codes Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '~' ; /*"~" indicates the RAPS diagnosis code is not deleted*/
```

Step 4

Using the output from Step 3, we identified and removed the enrollees for whom there was a Part C encounter claim with one of the corresponding procedure codes related to a colon cancer treatment rendered within 6 months of submission of the targeted colon cancer diagnosis.

```
SELECT distinct fdr.BENE_SK
FROM CMS_ADM_OIG_OAS_PRD.COLON_CANCER_STEP_3 fdr /*Output from Step #3*/

/*Subquery to identify all enrollees to remove from the step #3 output who had a Part C encounter claim that contains a
colon cancer treatment procedure code. /

WHERE fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (

SELECT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.COLON_CANCER_STEP_3 fdr /*Output from Step #3*/

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr
ON hdr.BENE_SK = fdr.BENE_SK /*Join enrollees from the step #3 results to the CMS Medicare Part C encounter claims*/

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLN_DT_SGNTR_SK = lin.CLN_DT_SGNTR_SK
```

```
AND hdr.CLM_TYPE_CD = lin.CLM_TYPE_CD
AND hdr.CLM_NUM_SK = lin.CLM_NUM_SK
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /*Joins CMS Medicare Part C encounter claim to the claim line table with the
individual claim lines)*/

WHERE lin.CLM_LINE_THRU_DT BETWEEN fnd.BENE_RAPS_SRVC_THRU_DT-183
AND fnd.BENE_RAPS_SRVC_THRU_DT+183 /* Identifies enrollees with encounter submissions occurring 6 months before
and 6 months after which include a colon cancer treatment procedure code */

AND lin.CLM_LINE_HCPCS_CD IN ('44139', '44140', '44141', '44143', '44144', '44145', '44146', '44147', '44150', '44151',
'44155', '44156', '44157', '44158', '44160', '44186', '44187', '44188', '44202', '44203', '44204', '44205', '44206', '44207',
'44208', '44210', '44211', '44212', '44213', '44227', '44238' /*Colon Cancer Surgical CPT Codes*/

'96401', '96402', '96405', '96406', '96409', '96411', '96413', '96415', '96416', '96417', '96420', '96422', '96423', '96425',
'96440', '96446', '96450', '96542', '96549', /*Chemotherapy Drug Treatment CPT Codes*/

'77401', '77402', '77407', '77412', '77417', '77423', '77424', '77425', '77427', '77750', '77761', '77762', '77763', '77767',
'77768', '77770', '77771', '77772', '77778', '77789', '77790', '77799') /*Radiation Treatment CPT Codes */

AND hdr.CLM_TYPE_CD > 3900 /*Identifies the encounter claim type codes*/
AND hdr.CLM_FINL_ACTN_IND = 'Y'; /*Indicates a final action encounter claim*/
```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Colon-Cancer-High-Risk-Group.pdf>.

7. Prostate Cancer High-Risk Group

For the prostate cancer high-risk group, we focused on enrollees who were 74 years old or younger and received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors HCC 12)) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (Table 7.1). In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

Codes Used in Our Analysis

Table 7.1 includes the single prostate cancer diagnosis code used in our analysis:

Table 7.1: Prostate Cancer Diagnosis Code

Diagnosis Code	Description
C61	Malignant neoplasm of prostate

There were 270 additional diagnosis codes that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors; however, we did not consider these codes to be at a high risk for being miscoded. Therefore, enrollees who received any one of these diagnoses were excluded from our analysis. The table of 270 diagnosis codes can be downloaded at the link included in the Downloadable Information subsection found later in this section.

We used various CPT codes to further refine our analysis. We identified and removed enrollees who received at least one of the following:

1. 19 chemotherapy drug treatment CPT codes that we identified as common procedure codes associated with an enrollee who received a chemotherapy drug treatment for an active cancer diagnosis (Table 4.2 in a preceding section).
2. 22 radiation treatment CPT codes that we identified as common procedure codes associated with an enrollee who received radiation treatment for an active cancer diagnosis (Table 4.3 in a preceding section).
3. Table 7.2 on the following page includes 10 surgical therapy CPT codes (footnote 7) that we identified as common procedure codes associated with an enrollee who received surgical therapy for an active prostate cancer diagnosis.

Table 7.2: Prostate Cancer Surgical CPT Codes

CPT Code	Description
55866	Surgical removal of prostate and surrounding lymph nodes using an endoscope
55845	Removal of prostate gland and surrounding lymph nodes on both sides of the pelvis through abdominal incision
55842	Removal of prostate gland and lymph node biopsy through abdominal incision
55840	Removal of prostate gland
55831	Partial removal of the prostate gland
55821	Partial removal of prostate (suprapubic)
55815	Removal of prostate gland through incision between scrotum and anus and removal of surrounding lymph nodes on both sides of the pelvis
55812	Removal of prostate gland with lymph node biopsy through incision between scrotum and anus
55810	Removal of prostate gland, glands for sperm movement, and sperm duct
55801	Partial removal of prostate gland through incision between scrotum and anus

There were 119 NDCs pulled from the PDE data used in our analysis. We removed enrollees who received one or more of these NDCs on a drug claim. The table of 119 NDCs can be downloaded at the link included in the Downloadable Information subsection found later in this section.

SQL Programming Language

Table 7.3 details the SQL programming language used to query CMS's systems in order to identify the prostate cancer high-risk diagnosis codes.

Table 7.3: SQL Programming Language for Prostate Cancer High-Risk Group

Step 1

We identified enrollees who received a prostate cancer diagnosis (Table 7.1). Additionally, we removed any enrollees who received one or more diagnoses that also mapped to HCC 12 that we did not consider to be at a high risk for being miscoded.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
COUNT(raps.DGNS_CD AS BENE_LINES /*Counts the number of prostate cancer diagnosis codes. Limited to one instance in Step #2*/
```

```
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/
```

```
WHERE DGNS_CD /* RAPS diagnosis cod field used to match to Prostate Cancer Diagnosis Codes Table*/ IN (
'C61') /*Prostate Cancer Diagnosis Codes Table*/
```

```
AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*/
```

```
/*Subquery to identify and remove all enrollees that received a diagnosis that maps to HCC 12 that we did not consider to be at a high risk for being miscoded*/
```

```
AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/ NOT IN (
```



```
SELECT DISTINCT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.DGNS_CD /*RAPS diagnosis code field used to match to Excluded Diagnosis Codes for the Prostate Cancer
High-Risk Group Table*/ IN (
SELECT DX_CD

FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_EXCLUDED_DX) /* Excluded Diagnosis Codes for the Prostate Cancer
High-Risk Group Table*/

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND BENE_RAPS_DGNS_DLT_SW = '-' /* '-' indicates the RAPS diagnosis code is not deleted*/
)
GROUP BY raps.BENE_SK; /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```

Step 2

Using the output from Step 1, we then limited our results to those enrollees who had only one instance of a prostate cancer diagnosis during the time period of interest and those enrollees whose risk scores were confirmed in CMS's RAS as including HCC 12.

```
SELECT raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_1 raps /*Output from Step #1*/

WHERE raps.BENE_LINES < 2 /*Criteria to limit enrollees to those with a single instance of a prostate cancer diagnosis
code*/

AND raps.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
IN (

/*Subquery to identify all enrollees from Step #1 with HCC 12 */

SELECT ras.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RISK_PTC_1_SCORE ras /*CMS RAS data*/

WHERE (BENE_PTC_HCC_12_SW = '1' /*Confirms HCC 12 was utilized in the payment risk score*/
AND BENE_FINL_RISK_IND = 'F' /*"F" represents the final RAS record*/
AND BENE_PTC_SCORE_MODEL_SBTYP_CD = '102' /*Used subtype code "102" since all enrollees have this subtype record, not
required for identifying enrollees for review, helps with computing efficiency*/
AND BENE_RISK_SEQ_NUM = '1' /*Used the RAS risk sequence "1" since it represents the RAPS based RAS record*/
AND (CLNDR_CY_NUM = 2019)) /*Specifies the payment year for the HCC confirmation*/
AND BENE_PTC_SCORE_AGE_BRKT_NUM IN ('7074', '6569', '6064', '5559', '4554', '3544')) /*Specifies men
under the age of 74*/
```

Step 3

Using the output from Step 2, we identified the RAPS record that included the targeted prostate cancer diagnosis so that we could do an encounter claim search spanning the 6-months-before-and-after date window using the targeted diagnosis RAPS "service thru date" field in the following step.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
       raps.BENE_RAPS_SRVC_THRU_DT,
       raps.DGNS_CD
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_2 fdr /*Output from Step #2*/
ON RAPS.BENE_SK = fdr.BENE_SK /*Join on CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
```



```
WHERE raps.DGNS_CD IN
('C61') /* Prostate Cancer Diagnosis Codes Table */

AND BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /* Specified timeframe */
AND BENE_RAPS_DGNS_DLT_SW = '~' /* '~' indicates the RAPS diagnosis code is not deleted */
```

Step 4

Using the output from Step 3, we identified and removed the enrollees for whom there was a Part C encounter claim with one of the corresponding procedure codes related to a prostate cancer treatment rendered within 6 months of submission of the targeted prostate cancer diagnosis.

```
SELECT distinct fdr.BENE_SK
FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_3 fdr /* Output from Step #3 */

/* Subquery to identify all enrollees to remove from the step #3 output who had a Part C encounter claim that contains a
prostate cancer treatment procedure code. */

WHERE fdr.BENE_SK /* CMS enrollee unique identifier, replace with HIC, MBI or plan identifier */ NOT IN (

SELECT fdr.BENE_SK /* CMS enrollee unique identifier, replace with HIC, MBI or plan identifier */
FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_3 fdr /* Output from Step #3 */

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr
ON hdr.BENE_SK = fdr.BENE_SK /* Join enrollees from the step #3 results to the CMS Medicare Part C encounter claims */

JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLM_DT_SGNTR_SK = lin.CLM_DT_SGNTR_SK
AND hdr.CLM_TYPE_CD = lin.CLM_TYPE_CD
AND hdr.CLM_NUM_SK = lin.CLM_NUM_SK
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /* Joins CMS Medicare Part C encounter claim to the claim line table with the
individual claim lines */

WHERE lin.CLM_LINE_THRU_DT BETWEEN fnd.BENE_RAPS_SRVC_THRU_DT-183
AND fnd.BENE_RAPS_SRVC_THRU_DT+183 /* Identifies enrollees with encounter submissions occurring 6 months before
and 6 months after which include a prostate cancer treatment procedure code */

AND lin.CLM_LINE_HCPCS_CD IN ( /* Identifies all HCPCS/CPT Codes associated with encounter claim */

'55801', '55810', '55812', '55815', '55821', '55831', '55840', '55842', '55845', '55866' /* Prostate Cancer Surgical CPT Codes */

'96401', '96402', '96405', '96406', '96409', '96411', '96413', '96415', '96416', '96417', '96420', '96422', '96423', '96425',
'96440', '96446', '96450', '96542', '96549', /* Chemotherapy Drug Treatment CPT Codes */

'77401', '77402', '77407', '77412', '77417', '77423', '77424', '77425', '77427', '77750', '77761', '77762', '77763', '77767',
'77768', '77770', '77771', '77772', '77778', '77789', '77790', '77799' /* Radiation Treatment CPT Codes */

AND hdr.CLM_TYPE_CD > 3900 /* Identifies the encounter claim type codes */
AND hdr.CLM_FINI_ACTN_IND = 'Y' /* Indicates a final action encounter claim */
```

Step 5

Using the output from Step 4 we identified and removed the enrollees who had received a drug claim for any of the NDCs provided within 6 months (before and after) of the targeted prostate cancer diagnosis.

```

select DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_4 fdr /*Output from Step #4*/

WHERE fdr.BENE_SK NOT IN ( /*The following sub query identifies all enrollees with a drug claim for one or more of the
NDC's provided*/

SELECT DISTINCT fdr.BENE_SK /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
FROM CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_STEP_4 fdr /*Output from Step #4*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_hdr /*CMS Medicare Claim table data*/
ON fdr.BENE_SK = hdr.BENE_SK /*Joins enrollees from the step #4 results to the CMS Part D perscription drug claims*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE lin /*CMS Medicare Claim Line data*/
ON hdr.GEO_BENE_SK = lin.GEO_BENE_SK
AND hdr.CLM_DT_SGNTR_SK = lin.CLM_DT_SGNTR_SK
AND hdr.CLM_TYPE_CD = lin.CLM_TYPE_CD
AND hdr.CLM_NUM_SK = lin.CLM_NUM_SK
AND hdr.CLM_FROM_DT = lin.CLM_FROM_DT /*Joins CMS Medicare Claims to the claim line table (Part D perscription drug
claims to the individual claim lines)*/

INNER JOIN CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_CLM_LINE_RX rx /*CMS Medicare Claim Line RX table data*/
ON lin.GEO_BENE_SK = rx.GEO_BENE_SK
AND lin.CLM_DT_SGNTR_SK = rx.CLM_DT_SGNTR_SK
AND lin.CLM_TYPE_CD = rx.CLM_TYPE_CD
AND lin.CLM_NUM_SK = rx.CLM_NUM_SK
AND lin.CLM_LINE_NUM = rx.CLM_LINE_NUM /*Joins CMS Part D perscription drug claim lines to the individual Part D
speceific claim lines*/

INNER JOIN CMS_ADM_OIG_OAS_PRD.PROSTATE_CANCER_PDE_NDC_LIST ndc /*NDCs for Prostate Cancer High-Risk
Group Table*/
ON lin.CLM_LINE_NDC_CD = ndc.NDC_CD /*Joins CMS Part D perscription drug claim line NDC code to the NDCs for Prostate
Cancer High-Risk Group Table*/

WHERE hdr.CLM_TYPE_CD IN (1,2,4) /*Represents Non-Deleted Part D Drug Claim types*/

AND hdr.CLM_THRU_DT BETWEEN fdr.BENE_RAPS_SRVC_THRU_DT-183 AND fdr.BENE_RAPS_SRVC_THRU_DT+183
/*Specified six month before or after timeframe*/

AND hdr.clm_finl_actn_ind = 'Y' /*Indicates only Final Action Claims*/
AND rx.CLM_LINE INGRDNT_CST_AMT > 0 /*Identifies non-zero pay claims*/
AND rx.CLM_DRUG_CVRG_STUS_CD='C' ; /*Identifies only covered drug claims*/

```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Prostate-Cancer-High-Risk-Group.pdf>.

8. Potentially Mis-Keyed Diagnosis Codes High-Risk Group

For the high-risk group involving potentially mis-keyed diagnosis codes, we focused on enrollees who received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-10 diagnosis code I720 (which maps to the HCC for Vascular Disease) could be transposed as diagnosis code I270 (which maps to the HCC for Congestive Heart Failure and in this example would be unvalidated). Using an analytical tool that we developed, we identified 3,780 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed or because other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

Codes Used in Our Analysis

The table of 3,780 potentially mis-keyed diagnosis code pairs can be downloaded at the link included in the Downloadable Information subsection found later in this section.

SQL Programming Language

Table 8.1 details the SQL programming language used to query CMS's systems in order to identify the potentially mis-keyed diagnosis codes.

Table 8.1: SQL Programming Language for Potentially Mis-Keyed Diagnosis Codes High-Risk Group

Step 1

We Identified non-deleted RAPS records for all enrollees with a diagnosis code listed in the payment year 2019 RAPS Version 22 (V22) HCC mapping file published by CMS.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
raps.BENE_RAPS_SRVC_FROM_DT,
raps.BENE_RAPS_SRVC_THRU_DT, /*RAPS Diagnosis Code Service Dates*/
raps.CNTRCT_NUM, /*RAPS Submitter Contract Number*/
raps.BENE_RAPS_SRVC_THRU_DT(FORMAT 'YYYY')(CHAR(4)) AS THRU_YEAR, /*Capture RAPS Service Thru Year*/
raps.DGNS_CD, /*RAPS diagnosis code field used to match to CMS Diagnosis Code Mapping Table*/
dx.V22 /*HCC from the CMS Diagnosis Code Mapping Table*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

JOIN CMS_ADM_OIG_OAS_PRD.RSK_ADJ_DX_PY19_RAPS_OP_PHYSN_HCC_MAPPING dx
on raps.DGNS_CD = dx.DX_CD /*CMS Diagnosis Code Mapping Table*/

WHERE raps.BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND raps.BENE_RAPS_DGNS_DLT_SW = '~'; /*'~' indicates the RAPS diagnosis code is not deleted*/
```

Step 2

Using the output from Step 1, we created a distinct list of potentially incorrect diagnosis codes by matching the diagnosis codes from Step 1 to the Office of Inspector General (OIG) Mis-Keyed Diagnosis Codes Table.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
raps.CNTRCT_NUM, /*RAPS Submitter Contract Number*/
raps.DGNS_CD, /*RAPS diagnosis code used to match to OIG Mis-Keyed Diagnosis Codes Table*/
fnd.FLIPPED_HCC_VAL, /*Potential Incorrect Diagnosis Code Value from OIG Mis-Keyed Diagnosis Codes Table*/
```

*COUNT (DGNS_CD) as CNT_FLIPPED_DX /*Count of occurrence of potentially incorrect diagnosis submissions from the OIG Mis-keyed Diagnosis Codes Table*/*

*FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_1 raps /*Output from Step #1*/*

JOIN CMS_ADM_OIG_OAS_PRD.DASH_PY19_FD_FLIPPED_DX_CD fnd

*ON fnd.FLIPPED_DIAG = raps.DGNS_CD /*The OIG Mis-Keyed Diagnosis Codes Table contains potential incorrect mis-keyed diagnosis codes and the HCC Value; and the corresponding correct diagnosis and HCC value*/*

*WHERE raps.BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/*
AND raps.BENE_RAPS_DGNS_DLT_SW = '~'; /~ indicates the RAPS diagnosis code is not deleted*/*

*GROUP BY BENE_SK,CNTRCT_NUM, DGNS_CD, FLIPPED_HCC_VAL; /*Group records to create distinct list of potentially mis-keyed diagnosis codes*/*

Step 3

Using the output from Step 2, we identified all enrollees with only one instance of the possible mis-keyed diagnosis code.

SELECT fnd. /* Pull the entire record from Step #2*/*

*FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_2 fnd /*Output from Step #1*/*

*WHERE CNT_FLIPPED_DX = 1; /*Limits the results to a single instance of a potentially incorrect diagnosis*/*

Step 4

Using the output from Step 1, we grouped all the RAPS records that mapped to an HCC by enrollee, contract number, and HCC. We also counted the number of diagnosis codes that mapped to an HCC.

*SELECT BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/*

*CNTRCT_NUM, /*RAPS Submitter Contract Number*/*

*V22, /*HCC from the CMS Diagnosis Code Mapping Table*/*

*COUNT (V22) AS CNT_BENE_HCC /*Represent diagnosis submission count by HCC*/*

*FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_1 /*Output from Step #1*/*

*GROUP BY BENE_SK, CNTRCT_NUM, V22; /*Group RAPS records to create distinct list enrollee HCC with a diagnosis submission count*/*

Step 5

Using the output from Step 4, we identified enrollees with only one instance of a diagnosis code that mapped to an HCC.

SELECT fnd. /* Pull the entire record from Step #4*/*

*FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_1 fnd /*Output from Step #4*/*

*WHERE CNT_BENE_HCC = 1; /*Limits the results to a single instance of a potentially incorrect diagnosis*/*

Step 6

Using the outputs from Step 3 and Step 4, we joined the two tables on the enrollee identification number and HCC to identify potentially incorrect diagnosis codes that were used to support the HCC.

*SELECT t2.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/*

*t2.CNTRCT_NUM, /*RAPS Submitter Contract Number*/*

*t1.DGNS_CD, /*RAPS potentially incorrect diagnosis*/*

*t2.V22 /*RAPS potentially incorrect diagnosis HCC (V22)*/*

*FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_3 t1 /*Output from Step #3*/*


```
JOIN CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_5 t2 /*Output from Step #5*/
ON t1.BENE_SK = t2.BENE_SK /*Join on enrollee identifier*/
and t1.FLIPPED_HCC_VAL = t2.V22 /*Join on mis-keyed diagnosis HCC and single diagnosis HCC*/
```

Step 7

Using all RAPS data, we prepared an enrollee summary by grouping the information by the enrollee, contract number, diagnosis code, and the count of diagnosis code submissions.

```
SELECT raps.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
raps.CNTRCT_NUM, /*RAPS Submitter Contract Number*/
raps.DGNS_CD, /*RAPS potentially incorrect diagnosis*/
COUNT(raps.DGNS_CD) AS BENE_DX_CNT /*Represent diagnosis submission count by enrollee*/
FROM CMS_VDM_VIEW_MDCR_PRD.V2_MDCR_BENE_RAPS_MAO_DGNS raps /*CMS RAPS data*/

WHERE raps.BENE_RAPS_SRVC_THRU_DT BETWEEN '2018-01-01' AND '2018-12-31' /*Specified timeframe*/
AND raps.BENE_RAPS_DGNS_DLT_SW = 'N'; /*'N' indicates the RAPS diagnosis code is not deleted*/

GROUP BY raps.BENE_SK, raps.CNTRCT_NUM, raps.DGNS_CD /*Group RAPS records to create distinct list of enrollees by contract and diagnosis*/
```

Step 8

Using the output from Step 7, we identified enrollees with more than one instance of a diagnosis code submission.

```
SELECT BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
CNTRCT_NUM, /*RAPS Submitter Contract Number*/
DGNS_CD, /*RAPS potentially incorrect diagnosis*/
BENE_DX_CNT /*Represent diagnosis submission count by enrollee*/
FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_7 /*Output from Step #5*/
WHERE BENE_DX_CNT > 1 /*Diagnosis submission count greater than one*/
```

Step 9

Using the outputs from Step 6 and Step 8 and the OIG Mis-Keyed Diagnosis Codes Table, we identified enrollees with multiple instances of what appeared to be the correct diagnosis and HCC and a single instance of what appeared to be the potentially incorrect diagnosis or HCC.

```
SELECT t6.BENE_SK, /*CMS enrollee unique identifier, replace with HIC, MBI or plan identifier*/
t6.CNTRCT_NUM, /*RAPS Submitter Contract Number*/
fnd.DIAG_CORRECT, /*Mis-Keyed Diagnosis Codes Table correct diagnosis match to step #8 output*/
fnd.HCC_CORRECT_DX_VAL, /* Mis-Keyed Diagnosis Codes Table correct diagnosis HCC value*/
t8.BENE_DX_CNT, /*Count of correct diagnosis from Step 8 output*/
fnd.FLIPPED_DIAG, /* Mis-Keyed Diagnosis Codes Table incorrect diagnosis match to step #6 output*/
fnd.FLIPPED_HCC_VAL, /* Mis-Keyed Diagnosis Codes Table incorrect diagnosis HCC value*/
'2019' AS PMT_YR /*Identifies payment year*/
FROM CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_6 t6 /*Output from Step #6, contains enrollee list of potentially incorrect diagnosis*/

JOIN CMS_ADM_OIG_OAS_PRD.DASH_PY18_FD_FLIPPED_DX_CD fnd /*OIG Mis-Keyed Diagnosis Codes Table*/
ON (t6.V22 = fnd.FLIPPED_HCC_VAL /*OIG Mis-Keyed Diagnosis Codes Table potentially incorrect diagnosis HCC */
AND t6.DGNS_CD = fnd.FLIPPED_DIAG) /*OIG Mis-Keyed Diagnosis Codes Table potentially incorrect diagnosis*/

JOIN CMS_ADM_OIG_OAS_PRD.FLIPPED_DGNS_STEP_8 t8 /*Output from Step 8, contains enrollee list of what appears to be the correct diagnosis*/
ON ( t6.BENE_SK = t8.BENE_SK
AND fnd.DIAG_CORRECT = t8.DGNS_CD)
```

Downloadable Information

- All of the codes used in this analysis along with the SQL programming language can be found at <https://oig.hhs.gov/oas/toolkit/Potentially-Mis-Keyed-Diagnosis-Codes-High-Risk-Group.pdf>.

Notice

Note that OIG is providing this toolkit, including the associated SQL programming code, to assist users in analyzing large datasets of MA claims data to identify individuals who received diagnosis codes that are at a high risk of being miscoded. This toolkit was prepared as a technical resource and is not intended to, and does not, create any rights, privileges, or benefits, substantive or procedural, enforceable by a party against the United States; its agencies or instrumentalities; its officers or employees; or any other person. The toolkit is provided in "as-is" condition, and OIG and its employees, agents, and staff disclaim any express or implied representation, warranty, or guarantee, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In particular, no representation is made that the information included in the toolkit, or any data the toolkit produces, is error free. The toolkit is not intended to be used to determine compliance with any laws, regulations, or other guidance. In no event shall OIG or its employees, agents, or staff be liable for any claim, damages, or liability, whether in an action of contract, tort or otherwise, and including direct, indirect, incidental, special, exemplary, or consequential damages, however caused, and on any theory of liability, arising in any way out of the use of this toolkit or its associated code, even if advised of the possibility of such damage. Compatibility of the toolkit with any user systems is not guaranteed, and any manipulation or alteration of the code is to the sole responsibility of the user.

EXHIBIT D-46

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE COMPLIANCE
AUDIT OF SPECIFIC DIAGNOSIS CODES
THAT CIGNA-HEALTHSPRING
LIFE & HEALTH INSURANCE
COMPANY, INC. (CONTRACT H4513)
SUBMITTED TO CMS**

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**Amy J. Frontz
Deputy Inspector General
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**March 2023
A-07-19-01192**

Office of Inspector General

<https://oig.hhs.gov/>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: March 2023
Report No. A-07-19-01192

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, Cigna-HealthSpring Life & Health Insurance Company, Inc. (Cigna), and focused on nine groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 300 unique enrollee-years with the high-risk diagnosis codes for which Cigna received higher payments for 2016 through 2017. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$720,395.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS

What OIG Found

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 200 of the 300 sampled enrollee-years, the medical records that Cigna provided did not support the diagnosis codes and resulted in \$468,372 in overpayments. As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Cigna received at least \$6.24 million in overpayments for 2016 and 2017.

What OIG Recommends and Cigna Comments

We recommend that Cigna: (1) refund to the Federal Government the \$468,372 of overpayments; (2) identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and (3) continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

Cigna did not concur with our recommendations and did not concur with our findings for 6 sampled enrollee-years which, according to Cigna, were supported by the medical records. Cigna did not directly agree or disagree with our findings for the remaining enrollee-years. Cigna did not agree with our audit methodology, use of extrapolation, and standards for data accuracy, coding, and documentation requirements.

After reviewing Cigna's comments and the additional information that Cigna provided, we revised the number of enrollee-years in error from 201 to 200 for this final report. After we had issued our draft report, CMS updated regulations for audits in its risk adjustment program to specify that extrapolated overpayments could only be recouped beginning with payment year 2018. Because our audit period covered payment years 2016 and 2017, we revised our first recommendation to specify a refund of only the overpayments for the sampled enrollee-years. We made no changes to our other recommendations. We followed a reasonable audit methodology and correctly applied applicable Federal requirements underlying the MA program.

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INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, gender, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.¹ We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 29 major depressive disorder diagnoses into 1 group.) This audit covered Cigna-HealthSpring Life & Health Insurance Company, Inc. (Cigna), for contract number H4513 and focused on nine groups of high-risk diagnosis codes for payment years 2016 and 2017.³

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD Coding Guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

² See Appendix B for a list of related Office of Inspector General reports.

³ All subsequent references to "Cigna" in this report refer solely to contract number H4513.

BACKGROUND

Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.⁴ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

Under the MA program, CMS makes advance payments each month to MA organizations for the expected costs of providing health care coverage to enrollees. These payments are not adjusted to reflect the actual costs that the organizations incurred for providing benefits and services. Thus, MA organizations will either realize profits if their actual costs of providing coverage are less than the CMS payments or incur losses if their costs exceed the CMS payments.

For 2020, CMS paid MA organizations \$317.1 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁵

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: a base rate that CMS sets using bid amounts received from the MA organization and the risk score for that enrollee. These are described as follows:

- **Base rate:** Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁶ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁷

⁴ The Balanced Budget Act of 1997, P.L. No. 105-33, as modified by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act, P.L. No. 109-173, established the MA program.

⁵ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

⁶ The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

⁷ CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic beneficiary premium for the benefits.

- **Risk score:** A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and gender). This process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes from providers based on information documented in the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁸ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

As a part of the risk adjustment program, CMS consolidates certain HCCs into related-disease groups. Within each of these groups, CMS assigns an HCC for only the most severe manifestation of a disease in a related-disease group. Thus, if MA organizations submit diagnosis codes for an enrollee that map to more than one of the HCCs in a related-disease group, only the most severe HCC will be used in determining the enrollee's risk score.

For enrollees who have certain combinations of HCCs, CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes for an enrollee that map to the HCCs for lung cancer and immune disorders, CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the two HCC factors and by an additional factor for the disease interaction.

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for one year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process: As HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total monthly Medicare payment that an MA organization receives for each enrollee before applying the budget

⁸ During our audit period CMS calculated risk scores based on the Version 22 CMS-HCC model.

sequestration reduction.⁹ Thus, if the factors used to determine an enrollee's risk score are incorrect, CMS will make an improper payment to an MA organization. Specifically, if medical records do not support the diagnosis codes that an MA organization submitted to CMS, the HCCs are unvalidated, which causes overstated enrollee risk scores and overpayments from CMS.¹⁰ Conversely, if medical records support the diagnosis codes that an MA organization did not submit to CMS, validated HCCs may not have been included in enrollees' risk scores, which may cause those risk scores to be understated and may result in underpayments.

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on nine high-risk groups:

- *Acute stroke*: An enrollee received one acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim. In these instances, a diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician or outpatient claim). In these instances, a diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, a major depressive disorder diagnosis may not be supported in the medical records.

⁹ Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (Aug. 2, 2011)). Under the BCA, the sequestration of mandatory spending began in April 2013.

¹⁰ 42 CFR § 422.310(e) requires MA organizations (when undergoing an audit conducted by the Secretary) to submit "medical records for the validation of risk adjustment data." For purposes of this report, we use the terms "supported" or "unsupported" to denote whether or not the reviewed diagnoses were evidenced in the medical records. If our audit determines that the diagnoses are supported or unsupported, we accordingly use the terms "validated" or "unvalidated" with respect to the associated HCC.

- **Embolism:** An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism HCCs) during the service year but did not have an anticoagulant medication dispensed on his or her behalf. An anticoagulant medication is typically used to treat an embolism. In these instances, a diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.
- **Vascular claudication:** An enrollee received one diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) during the service year, but had not received one of these diagnoses during the 2 preceding years and had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹² In these instances, the diagnosis related to vascular claudication may not be supported in the medical records.
- **Lung cancer:** An enrollee received one lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period either before or after the diagnosis. In these instances, a diagnosis of history of lung cancer (which does not map to an HCC) typically should have been used.
- **Breast cancer:** An enrollee received one breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of breast cancer (which does not map to an HCC) typically should have been used.
- **Colon cancer:** An enrollee received one colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis. In these instances, a diagnosis of history of colon cancer (which does not map to an HCC) typically should have been used.
- **Prostate cancer:** An enrollee 74 years old or younger received one prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after

¹² Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

the diagnosis. In these instances, a diagnosis of history of prostate cancer (which does not map to an HCC) typically should have been used.

In this report, we refer to the diagnosis codes associated with these groups as "high-risk diagnosis codes."

Cigna-HealthSpring Life & Health Insurance Company, Inc.

Cigna is an MA organization based in Nashville, Tennessee. As of December 2017, Cigna provided coverage under contract number H4513 to 82,539 enrollees. For the 2016 and 2017 payment years (audit period), CMS paid Cigna approximately \$2.1 billion to provide coverage to its enrollees.^{12, 13}

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the nine high-risk groups during the 2015 and 2016 service years, for which Cigna received increased risk-adjusted payments for payment years 2016 and 2017, respectively. Because enrollees could be classified into more than one high-risk group or could have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years."

We identified 8,667 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$19,537,407). We selected for audit a stratified sample of 300 enrollee-years as shown in Table 1 on the following page.

¹² The 2016 and 2017 payment year data were the most recent data available at the start of the audit.

¹³ All of the payment amounts that CMS made to Cigna and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute stroke	30
2. Acute heart attack	30
3. Major depressive disorder	60
4. Embolism	30
5. Vascular claudication	30
6. Lung cancer	30
7. Breast cancer	30
8. Colon cancer	30
9. Prostate cancer	30
Total for All High-Risk Groups	300

Cigna provided medical records as support for the selected diagnosis codes associated with 288 of the 300 sampled enrollee-years.¹⁴ We used an independent medical review contractor to review the medical records to determine whether the HCCs associated with the sampled enrollee-years were validated. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the Federal regulations.

FINDINGS

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 100 of the 300 sampled enrollee-years, the medical records

¹⁴ Cigna could not locate medical records for the remaining 12 sampled enrollee-years.

validated the reviewed HCCs.¹⁵ For the remaining 200 enrollee-years, however, either the medical records that Cigna provided did not support the diagnosis codes or Cigna could not locate the medical records to support the diagnosis codes and the associated HCCs were therefore not validated. As a result, Cigna received \$468,372 in overpayments.

As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Cigna received at least \$6.24 million in overpayments for 2016 and 2017.¹⁶

FEDERAL REQUIREMENTS

Payments to MA organizations are adjusted for risk factors, including the health status of each enrollee (the Social Security Act § 1853(a)). CMS applies a risk factor based on data obtained from the MA organizations (42 CFR § 422.308).

Federal regulations state that MA organizations must follow CMS's instructions and submit to CMS the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner (42 CFR § 422.310(b)). MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR §§ 422.504(l) and 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (42 CFR § 422.504(a)).

CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded

¹⁵ For 1 of the 100 enrollee-years, Cigna informed us that it could not locate the associated medical record because the record had been destroyed in a natural disaster. CMS provides guidance for medical records that are unavailable because of "extraordinary circumstances" (*Contract-Level Risk Adjustment Data Validation CMS Submission Instructions*). Based on our assessment of the information provided by Cigna, we determined that an extraordinary circumstance prevented Cigna from locating the medical record for this enrollee-year, and we treated the sample item as a non-error.

¹⁶ Specifically, we estimated that Cigna received at least \$6,247,399 of overpayments. To be conservative, we estimate overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

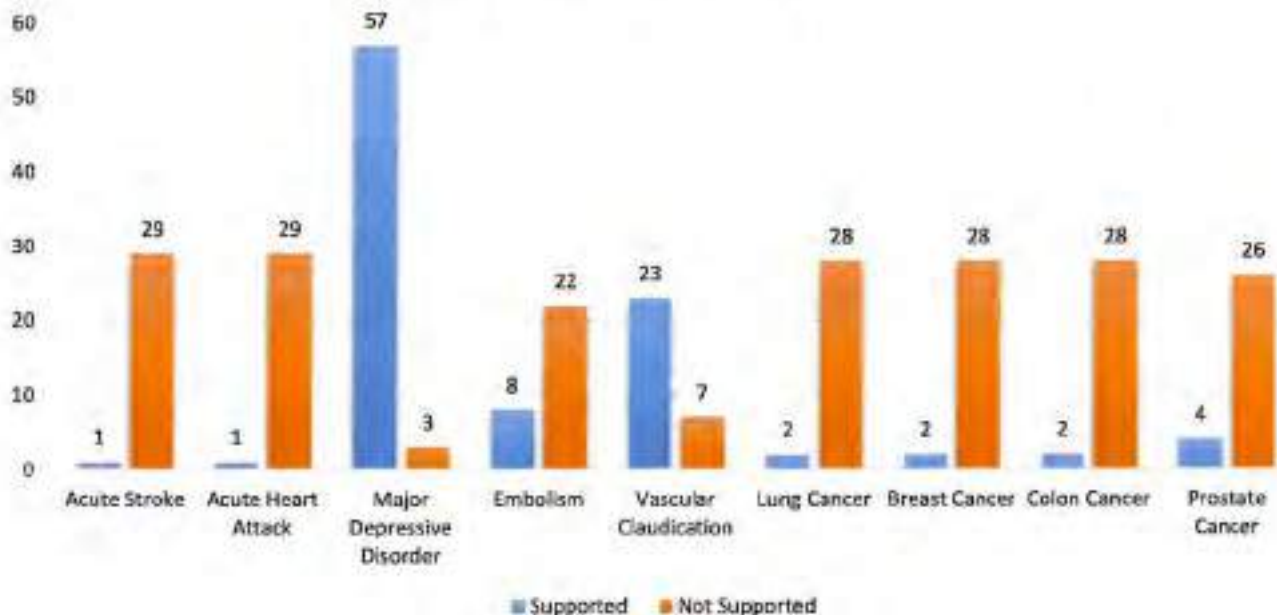
according to the International Classification of Diseases (ICD), Clinical Modification, *Official Guidelines for Coding and Reporting* (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must “adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements” Further, MA organizations must establish and implement an effective system for routine monitoring and identification of compliance risks (42 CFR § 422.503(b)(4)(vi)).

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program did not comply with Federal requirements. Specifically, as shown in the figure below, the medical records for 200 of the 300 sampled enrollee-years did not support the diagnosis codes. In these instances, Cigna should not have submitted the diagnosis codes to CMS and received the resulting overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Cigna incorrectly submitted diagnosis codes for acute stroke for 29 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC or a related HCC. There is mention of a history of a stroke [diagnosis] but no description of residuals or sequelae that should be coded."¹⁷ The history of stroke diagnosis code does not map to an HCC.

- For the remaining 6 enrollee-years, the medical records in each case did not support an acute stroke diagnosis.¹⁸

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [for Ischemic or Unspecified Stroke] or a related HCC. Although [there] is mention of a cerebral infarction [diagnosis] in the current assessment there is no indication that this condition is active."¹⁹

As a result of these errors, the HCC for Ischemic or Unspecified Stroke was not validated, and Cigna received \$62,466 in overpayments for these 29 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Cigna incorrectly submitted diagnosis codes for acute heart attack for 29 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records indicated in each case that the individual had an old myocardial infarction diagnosis, but the records did not justify one of the

¹⁷ Residuals or sequelae are the late effects of an injury that can occur only after the acute phase of the injury or illness has passed.

¹⁸ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC was a magnetic resonance imaging (MRI) report. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

¹⁹ A cerebral infarction, or stroke, is defined as a brain lesion in which a cluster of brain cells dies due to lack of blood.

diagnoses that mapped to an Acute Heart Attack HCC at the time of the physician's service.²⁰

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. There is documentation of a past medical history of myocardial infarction [diagnosis] that does not result in an HCC."

- For 9 enrollee-years, the medical records in each case did not support the submitted diagnosis that mapped to an Acute Heart Attack HCC. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to the HCC for Angina Pectoris, which is a less severe manifestation of the related-disease group.²¹

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Unstable Angina and Other Acute Ischemic Heart Disease]. There is documentation of [an] angina pectoris [diagnosis] that results in [the] HCC [for Angina Pectoris]"

- For 6 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Acute Heart Attack HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Acute Myocardial Infarction]. The discharge final diagnosis stated that the patient was ruled out for an acute myocardial infarction."

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support a diagnosis that mapped to an Acute Heart Attack HCC; therefore, an Acute Heart Attack HCC was not validated.

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Cigna received \$41,309 in overpayments for these 29 sampled enrollee-years.

²⁰ An "old myocardial infarction" is a distinct diagnosis that represents a myocardial infarction that occurred more than 4 weeks previously, has no current symptoms directly associated with that myocardial infarction, and requires no current care.

²¹ Angina pectoris is defined as a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Cigna incorrectly submitted diagnosis codes for major depressive disorder for 3 of 60 sampled enrollee-years. Specifically:

- For 2 enrollee-years, the medical records in each case did not support a major depressive disorder diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Major Depressive, Bipolar, and Paranoid Disorders]."

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support the major depressive disorder diagnosis; therefore, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated.

As a result of these errors, the HCC for Major Depressive, Bipolar, and Paranoid Disorders was not validated, and Cigna received \$7,247 in overpayments for these 3 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Cigna incorrectly submitted diagnosis codes for embolism for 22 of 30 sampled enrollee-years. Specifically:

- For 13 enrollee-years, the medical records in each case did not support a diagnosis that mapped to an Embolism HCC.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]. Per . . . ultrasound test results, there was no evidence of deep vein thrombosis."²²

- For 8 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify a diagnosis that mapped to an Embolism HCC at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]. There is documentation of a past medical history of deep vein thrombosis [diagnosis] that does not result in an HCC."

²² Deep vein thrombosis is defined as a blood clot that forms in one or more of the deep veins in the body, usually in the legs.

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support a diagnosis that mapped to an Embolism HCC; therefore, an Embolism HCC was not validated.

As a result of these errors, the Embolism HCCs were not validated, and Cigna received \$51,125 in overpayments for these 22 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Cigna incorrectly submitted diagnosis codes for vascular claudication for 7 of 30 sampled enrollee-years. Specifically:

- For 6 enrollee-years, the medical records in each case did not support a vascular claudication diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Vascular Disease]."

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support the vascular claudication diagnosis; therefore, the HCC for Vascular Disease was not validated.

As a result of these errors, the HCC for Vascular Disease was not validated, and Cigna received \$12,872 in overpayments for these 7 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Lung Cancer

Cigna incorrectly submitted diagnosis codes for lung cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 14 enrollee-years, the medical records indicated in each case that the individual had previously had lung cancer, but the records did not justify a lung cancer diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC for [Lung and Other Severe Cancers]. There is documentation of a past medical history of lung cancer [diagnosis] that does not result in an HCC."

- For 10 enrollee-years, the medical records in each case did not support a lung cancer diagnosis.²³

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Lung and Other Severe Cancers]. There was not enough documentation to support that the lung cancer was an active condition on this date of service.”

- For 2 enrollee-years, the medical records in each case did not support a lung cancer diagnosis. However, for each of these enrollee-years, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Cigna should not have received an increased payment for the submitted lung cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.
- For each of the remaining 2 enrollee-years, Cigna could not locate any medical records to support the lung cancer diagnosis; therefore, the HCC for Lung and Other Severe Cancers was not validated.

As a result of these errors, the HCC for Lung and Other Severe Cancers was not validated, and Cigna received \$169,930 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Breast Cancer

Cigna incorrectly submitted diagnosis codes for breast cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 20 enrollee-years, the medical records indicated in each case that the individual had previously had breast cancer, but the records did not justify a breast cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There is documentation of a past medical history of breast cancer [diagnosis] that does not result in an HCC.”

²³ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC contained only laboratory test results. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

- For 7 enrollee years, the medical records in each case did not support a breast cancer diagnosis.²⁴

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors] There was not enough documentation to support that the breast cancer was an active condition on this date of service.”

- For the remaining 1 enrollee-year, Cigna could not locate any medical records to support the breast cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Cigna received \$31,104 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Colon Cancer

Cigna incorrectly submitted diagnosis codes for colon cancer for 28 of 30 sampled enrollee-years. Specifically:

- For 18 enrollee-years, the medical records indicated in each case that the individual had previously had colon cancer, but the records did not justify a colon cancer diagnosis at the time of the physician’s service.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of a diagnosis that results in [the] HCC [for Colorectal, Bladder, and Other Cancers]. There is documentation of a past medical history of colon cancer [diagnosis] that does not result in an HCC.”

- For 5 enrollee-years, the medical records in each case did not support a colon cancer diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that “there is no documentation of any condition that will result in the assignment of [the] HCC [for Colorectal, Bladder, and Other Cancers]. The medical documentation does not indicate an active diagnosis of colon cancer.”

- For 3 enrollee-years, the medical records in each case did not support a colon cancer diagnosis. However, for each of these enrollee-years, we identified support for another

²⁴ For 1 of these enrollee-years, the medical record that Cigna provided to support the reviewed HCC was a radiology order requisition. This record was not from an acceptable data source (a face-to-face encounter with a provider, physician, or other practitioner) (42 CFR § 422.310(d)(3)); the Manual, chap. 7, §§ 40 and 120.1).

diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, in each case Cigna should not have received an increased payment for the submitted colon cancer diagnosis, but it should have received a lesser increased payment for the other diagnosis identified.

- For each of the remaining 2 enrollee-years, Cigna could not locate any medical records to support the colon cancer diagnosis; therefore, the HCC for Colorectal, Bladder, and Other Cancers was not validated.

As a result of these errors, the HCC for Colorectal, Bladder, and Other Cancers was not validated, and Cigna received \$56,923 in overpayments for these 28 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Prostate Cancer

Cigna incorrectly submitted diagnosis codes for prostate cancer for 26 of 30 sampled enrollee-years. Specifically:

- For 23 enrollee-years, the medical records indicated in each case that the individual had previously had prostate cancer, but the records did not justify a prostate cancer diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors] . . . History of prostate cancer [diagnosis] should have been assigned . . . and does not result in an HCC."

- For each of 2 enrollee-years, Cigna could not locate any medical records to support the prostate cancer diagnosis; therefore, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated.
- For the remaining 1 enrollee-year, the medical records did not support a prostate cancer diagnosis. Specifically, the independent medical review contractor stated that "there is no documentation of any condition that will result in the assignment of [the] HCC [for Breast, Prostate, and Other Cancers and Tumors]. There was not enough documentation to support that the prostate cancer was an active condition on this date of service."

As a result of these errors, the HCC for Breast, Prostate, and Other Cancers and Tumors was not validated, and Cigna received \$35,396 in overpayments for these 26 sampled enrollee-years.

Summary of Incorrectly Submitted Diagnosis Codes

In summary and with respect to the nine high-risk groups covered by our audit, Cigna received \$468,372 in overpayments for the 200 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY HAD TO PREVENT, DETECT, AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS COULD BE IMPROVED

As demonstrated by the errors found in our sample, the policies and procedures that Cigna had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations at 42 CFR § 422.503(b)(4)(vi), could be improved.

During our audit period, Cigna had compliance procedures in place that were designed to prevent providers from submitting incorrect diagnosis codes. These procedures included a variety of provider-specific outreach efforts to help educate its providers on medical record documentation, including accurately differentiating between: (1) conditions that were manifesting as acute and (2) conditions that were not currently active but had been historically present, such as stroke, myocardial infarction, and cancer. In addition, Cigna routinely educated its coders on best coding practices and acceptable medical documentation guidelines, and coders were expected to identify codes with at least 95-percent accuracy.

Cigna also had compliance procedures in place that were designed to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included the use of internal data quality reviews that selected diagnosis codes from specific claims and compared them to the diagnoses that were documented on the associated medical records. Cigna had several criteria governing its selection of these diagnosis codes, including: (1) the frequency of usage by specific physicians and (2) the presence of diagnosis codes that met certain conditions (such as diagnosis codes for acute conditions that could be inaccurate when coded in an outpatient setting). Cigna's procedures also included guidance on how its reviewers should address the coding of certain conditions, including acute stroke, myocardial infarction, cancer, and the use of "history of" diagnosis codes. If the reviewers detected a compliance problem, Cigna's policies and procedures provided guidance on how to communicate the correction of the problem to CMS.

Although Cigna had policies and procedures that addressed some incorrect high-risk diagnosis codes, Cigna did not identify these diagnosis codes as problematic unless they appeared on a specific claim that was selected for review. For this reason, we concluded that Cigna's policies and procedures to prevent, detect, and correct miscoded high-risk diagnoses during our audit period could be improved.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY RECEIVED OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Cigna received at least \$6,247,399 in overpayments for 2016 and 2017. (See Appendix D for sample results and estimates).

Because of Federal regulations that limit the use of extrapolation in Risk Adjustment Data Validation (RADV) audits for recovery purposes, we are reporting the estimated overpayment amount but are recommending a refund of only the \$468,372 in overpayments that Cigna received for the 200 sampled enrollee-years.²⁵

RECOMMENDATIONS

We recommend that Cigna-HealthSpring Life & Health Insurance Company, Inc.:

- refund to the Federal Government the \$468,372 of overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and
- continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Cigna did not concur with some of our findings and did not concur with any of our recommendations. More specifically, Cigna did not concur with our findings for 6 of the 201 enrollee-years in error identified in our draft report. For these 6 enrollee-years, Cigna provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs. Cigna did not directly agree or disagree with our findings for the HCCs under audit for each of the remaining 195 enrollee-years.²⁶ With respect to the estimated overpayments, Cigna stated that our audit was "skewed toward identifying 'overpayments'" and that the basic premise of our audit was inconsistent with Federal requirements.

We reviewed the entirety of Cigna's comments and the additional information that it provided and, accordingly, reduced the number of enrollee-years in error from 201 to 200 and adjusted our calculation of overpayments for this final report. After we issued our draft report, CMS updated its regulations for RADV audits to specify that extrapolated overpayments could only

²⁵ After we had issued our draft report, CMS updated Federal regulations that limit the use of extrapolation in RADV audits to payment years 2018 and forward (88 Fed. Reg. 6643 (Feb. 1, 2023)). RADV audits are conducted to verify that diagnoses submitted by MA organizations for risk-adjusted payment are supported by medical record documentation.

²⁶ For 19 of the 195 enrollee-years, Cigna provided additional information that was outside the scope of our audit; accordingly, this information did not impact our audit results.

be recouped beginning with payment year 2018 (footnote 25). Because our audit period covered payment years 2016 and 2017, we revised the amount in our first recommendation to reflect only the overpayments for the 200 sampled enrollee-years. We maintain that our second and third recommendations remain valid.

A summary of Cigna's comments and our responses follows. Cigna's comments appear as Appendix F. We excluded attachments (which Cigna identified as Exhibit A and Exhibit B in its comments) because they contained personally identifiable information. We are separately providing Cigna's comments and attachments in their entirety to CMS.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT REFUND OVERPAYMENTS

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General's Findings for 6 Sampled Enrollee-Years

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our findings for 6 of the sampled enrollee-years (as shown in Table 2) and provided explanations as to why it believed that the medical records that it previously gave us validated the reviewed HCCs.

Table 2: Summary of Enrollee-Years for Which Cigna-HealthSpring Life & Health Insurance Company Disagreed With Our Findings

High-Risk Group	Number of Sampled Enrollee-Years
Prostate cancer	4
Vascular claudication	1
Lung cancer	1
Total	6

Office of Inspector General Response

For 1 of the 6 enrollee-years that Cigna specifically disputed, our independent medical review contractor reversed its original decision after reviewing the explanation that Cigna submitted, and determined that the HCC was validated.

Specifically, for the 1 enrollee-year from the vascular claudication high-risk group, Cigna cited the medical record's reference to a physical exam that noted "dorsalis pedis pulses . . . a follow up lower extremity arterial doppler was performed 3 weeks later . . . confirming a diagnosis of

[peripheral vascular disease] PVD.”²⁷ After reviewing Cigna’s explanation for this enrollee-year, our independent medical review contractor reversed its original decision. In so doing, the contractor stated: “[t]here is documentation of [a] lower extremity claudication [diagnosis] that results in [the] HCC [for Vascular Disease].”

Accordingly, we reduced the number of enrollee-years in error from 201 (in our draft report) to 200 for this final report. We also revised our findings and reduced the associated monetary recommendation. Our independent medical review contractor confirmed that Cigna’s written comments and additional explanations had no impact on the decisions that the contractor made for other sampled enrollee-years and stated that there were no “systemic issues identified” in its reviews.

For the remaining 5 enrollee-years for which Cigna disagreed with the results of our independent medical review contractor’s coding review, our contractor reaffirmed that the HCCs were not validated and thus upheld its original decision. For example, for 1 enrollee-year from the prostate cancer high-risk group, the contractor stated that “[t]he medical record for the date of service . . . indicates a past history of prostate cancer that was under surveillance.” Further, the contractor stated that “[t]here is no medical record evidence to support the diagnosis of prostate cancer, including no documentation of PSA [prostate-specific antigen] [test], monitoring or treatment.”²⁸

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Focused Only on Identifying Overpayments

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that our “audit methodology was so targeted that it could not equally identify overpayments and underpayments.” Furthermore, Cigna stated that our audit targeted “specific diagnosis categories that OIG [Office of Inspector General] hypothesized . . . [are] likely to have resulted in an ‘overpayment.’” Cigna also stated that we did not allow it “to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited [enrollees] that were unrelated to the target diagnosis codes.” Furthermore, according to Cigna, “OIG only focused on samples that it viewed to be high-risk diagnoses so that it could only identify a potential overpayment.” Cigna added that this “biased targeting resulted in findings that do not ensure accuracy because the audit was

²⁷ The dorsalis pedis artery is the main source of blood supply to the foot. A lower extremity arterial doppler is an ultrasound test used to check the blood flow of the arteries and veins in the lower extremities (leg, ankle and foot). PVD is a systemic disorder that involves the narrowing of peripheral blood vessels (i.e., vessels situated away from the heart or the brain). Both PVD and vascular claudication map to the HCC for Vascular Disease.

²⁸ The PSA blood test measures the amount of PSA in the blood and is used primarily to screen for prostate cancer.

not designed to look at payment accuracy, which would include both overpayments and underpayments.”

For these reasons, Cigna stated that it was concerned “that the proposed overpayment figure used by OIG cannot be an adequate basis” for the audit results in this report.

Office of Inspector General Response

Our objective was to determine whether selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. We identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into nine specific high-risk groups. This process involved a carefully designed audit methodology (see Appendix A) rather than “hypothesized” categories of diagnoses. Our objective did not extend to diagnosis codes not previously submitted by Cigna or to HCCs that were beyond the scope of our audit. A valid calculation of overpayments, given the objective of our audit, does not need to take into consideration all potential HCCs or underpayments within the audit period. Although for this final report we reduced the amount in our first recommendation (as discussed above), we based our calculation of overpayments on the results of the independent medical review contractor’s review; this calculation addressed only the accuracy of the portion of payments related to the reviewed HCCs and does not extend to HCCs that were beyond the scope of this audit.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Follow CMS’s Established Risk Adjustment Data Validation Methodology

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that our audit methodology did not account for a payment principal known as “actuarial equivalence,” because we did not apply an adjustment called a Fee-for-Service (FFS) Adjuster. The FFS Adjuster, according to Cigna, “incorporate[s] the FFS error rate into [CMS’s] methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits.” Cigna noted that, to address the FFS error rate, CMS published a notice in 2012 that notified MA organizations that it planned to calculate and apply an FFS Adjuster to payment recoveries in RADV audits to adjust for diagnosis coding errors in claims data from traditional Medicare.²⁹ Cigna also cited recent Federal court cases that have dealt with the principle of actuarial equivalence and mentioned that a CMS final rule on this issue (that CMS proposed in 2018) is still pending. In addition, Cigna stated that because we did not apply an FFS Adjuster, we “violate[d]” requirements for notice-and-comment Federal rulemaking and departed from how we addressed the FFS adjuster in a previous report.³⁰

²⁹ Cigna’s comment in this respect cited to CMS’s *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits* (Feb. 24, 2012), pages 3-4.

³⁰ The previous report to which Cigna referred was *Risk Adjustment Data Validation of Payments Made to PacificCare of California for Calendar Year 2007 (Contract Number H0543)* (A-09-09-00045; Nov. 2012).

Cigna added that “[the] actuarial equivalence requirement extends to OIG’s estimation and extrapolation of a potential ‘overpayment’ amount in this audit,” and that because we did not apply an FFS Adjuster, “it is not possible for OIG to determine whether Cigna received an overpayment.”

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with the unvalidated HCCs for each sample item. Specifically, we used the results of the independent medical review contractor’s review to determine which HCCs were not validated and, in some instances, to identify HCCs that should have been used but were not used in the associated enrollees’ risk score calculations. We followed CMS’s risk adjustment program requirements to determine the payment that CMS should have made for each enrollee and to estimate overpayments. With respect to Cigna’s comment regarding actuarial equivalence in our overpayment calculations, we note that after we issued our draft report, CMS stated that it “will not apply an adjustment factor (known as an FFS Adjuster) in RADV audits.”³¹ In the context of CMS’s requirements and updated guidance, we recognize that CMS—not OIG—was responsible in 2012 and is responsible now for making operational and program payment determinations for the MA program.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General’s Audits Were Inconsistent With CMS Standards for Data Accuracy

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that we “designed and conducted an audit that was inconsistent with RADV regulations and CMS standards for data accuracy.” According to Cigna, “[t]he perfection standard posited by [our report] reflects either a misunderstanding of CMS regulations or a rejection of the data standards set by CMS.” Specifically:

- Cigna stated that we misunderstood Federal regulations at 42 CFR § 422.504(l), “in taking the position that MA organizations ‘are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS.’” Cigna added that this regulation also states that when submitting data to CMS, an MA organization attests to the accuracy of those data according to its “best knowledge, information and belief.” In this context, Cigna said that CMS has stated that there is no requirement that MA organizations need to verify every diagnosis submitted by providers. Cigna also referred to a CMS comment that MA organizations “cannot reasonably be expected to know that every piece of data is correct.”³²

³¹ 88 Fed. Reg. 6643 (Feb. 1, 2023).

³² For this comment, Cigna cited 65 Fed. Reg. 40170, 40268 (Jun. 29, 2000).

- Additionally, Cigna commented that the “perfection standard reflected in [our report] also is inconsistent with the realities and limitations of attempting to perform a risk adjustment function.” Cigna elaborated on this position in several ways:
 - Cigna referred to the “inherently subjective” nature of diagnosis coding and stated that we did not take into account that “[a]lthough [Cigna] make[s] coding and documentation training available to . . . providers, [Cigna] ultimately cannot control their submissions.” Cigna also said that CMS generally “allows providers to use their best professional judgment.”
 - Cigna also alluded to various difficulties in obtaining medical records from providers. Cigna said that the 5 to 6 years between the encounters at issue and the audit, as well as the onset of COVID-19 during the audit and resulting staff shortages, made it difficult to obtain the necessary records from providers. Moreover, according to Cigna, this 5-to-6-year “gap creates a significant data validation issue for Cigna,” because of providers that are no longer in its network and various recordkeeping challenges.
 - Furthermore, Cigna stated that the “consolidation of hospital systems and large provider groups and the increasing number of providers who are publicly traded or private investor-backed has led to some large groups and health systems refusing to respond to records requests [from MA organizations] in a timely fashion, if at all.”

Office of Inspector General Response

We disagree with Cigna’s statement that we misunderstood regulations or rejected the data standards set by CMS. Specifically, we do not agree with Cigna’s interpretation of the Federal requirements at 42 CFR § 422.504(l). We recognize that CMS applies a “best knowledge, information and belief” standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program.³³ We recognize as well that, as Cigna said, there is no CMS requirement that MA organizations verify every diagnosis submitted by providers. We also acknowledge that Cigna cannot “reasonably be expected to know that every piece of data is correct.”

However, our audit revealed a significant error rate (200 of 300 enrollee-years) with unsupported diagnosis codes (see Appendix D)) for the high-risk areas we audited. Federal regulations require MA organizations to implement procedures for “promptly responding to compliance issues as they are raised” and to “[correct] such problems promptly and thoroughly to reduce the potential for recurrence” (42 CFR § 422.503(b)(4)(vi)(G) (see Appendix E)). Accordingly, we believe that Cigna is responsible for addressing the issues that resulted in that significant error rate. Correcting these issues will also assist Cigna in attaining better assurance

³³ 79 Fed. Reg. 29844, 29926 (May 23, 2014).

with regard to the “accuracy, completeness and truthfulness” of the risk adjustment data that it submits in the future.

With respect to Cigna’s comment about the “inherently subjective” coding process, we designed our audit methodology (see Appendix A) to be as objective as possible—that is, to minimize the effects of any potential coding subjectivities on our overpayment calculations. Our independent medical review contractor followed a specific process when reviewing the medical records that Cigna gave to us, to determine whether the diagnosis codes that Cigna submitted to CMS for risk-adjustment purposes were supported. If the first reviewer (a senior coder) found that a diagnosis was not supported on the medical records, then a second senior coder (and sometimes a third reviewer, a physician) performed a separate review of the same medical records. Two reviewers needed to agree that the diagnosis was unsupported for it to be counted as an error and be included in our overpayment calculations.

Moreover, CMS’s RADV Submission Instructions, issued to MA organizations, recognizes that “there may be extraordinary circumstances that prevent an MA Organization . . . from submitting medical records for the audited enrollee(s) and CMS-HCC(s) in accordance with . . . audit requirements.”³⁴ However, CMS also notes in these instructions that “extraordinary circumstances do not typically include ordinary issues encountered during the process of requesting medical records and attestations from providers.” These ordinary issues include, but are not limited to, (1) difficulty in communicating with the provider, (2) provider difficulty in locating the record, and (3) delay caused by health information management system issues, including issues with third-party companies or vendors.

During our audit work, we worked with Cigna officials to extend (by several months) the medical record collection timeframe to account for the collection difficulties associated with the COVID-19 pandemic. Furthermore, Cigna did not convey to us during the audit that it was confronting any other extraordinary circumstances that prevented it from obtaining and providing to us medical records that would have supported the diagnosis codes submitted to CMS and validated the HCCs under review.

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General’s Use of Extrapolation

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna disagreed with our use of extrapolation to calculate overpayments for the following reasons:

- Cigna did not agree with the fact that we used the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount. Cigna noted that

³⁴ Contract-Level Risk Adjustment Data Validation CMS Submission Instructions, Sep. 7, 2016.

CMS follows the “statistically valid and more robust practice” of using the lower limit of a 95-percent or 99-percent confidence interval for its RADV audits.

- Cigna also stated that it “do[es] not believe that extrapolation has been authorized by Congress. . . . Part C of the Medicare statute does not authorize extrapolated recoveries and, in the absence of explicit Congressional authorization, we believe extrapolation is not available.” In addition, Cigna stated that “[e]ven if extrapolation were permitted, the methodology used would have to adhere to the final methodology established by CMS.”

Office of Inspector General Response

As stated above, for this final report our recommendation to refund overpayments is limited to the overpayments associated with the 200 sampled enrollee-years, rather than to an estimate (footnote 25). However, we believe that the results of our sampling, as well as our estimate of overpayments (Appendix D), provide a reasonable basis for our findings and conclusions—and support our recommendation that Cigna continue to examine its existing compliance procedures to identify areas where improvements can be made.

OIG is an independent oversight agency; therefore, our estimation methodology does not need to mirror CMS’s estimation methodology. Our policy recommends recovery at the lower limit of a two-sided 90-percent confidence interval. We believe that the lower limit of a two-sided 90-percent confidence interval provides a reasonably conservative estimate of the total amount overpaid to Cigna for the enrollee-years and time period covered in our sampling frame. This approach, which is routinely used by HHS for recovery calculations,³⁵ results in a lower limit (the estimated overpayment amount) that is designed to be less than the actual overpayment total 95 percent of the time.

With respect to Cigna’s comments that we are not authorized to extrapolate, we note that neither Federal statute nor any other authority limits our ability to recommend a recovery to CMS based on extrapolation. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Further, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in

³⁵ For example, HHS has used the two-sided 90-percent confidence interval when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See e.g., *New York State Department of Social Services*, HHS Departmental Appeals Board (DAB) No. 1358, 13 (1992); *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

Medicare and Medicaid.³⁶ The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.³⁷ We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Thus, we did not revise the amount in our first recommendation based on Cigna's comments; rather, we revised the amount in response to the updated regulations that CMS published after we issued our draft report.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S MEDICAL RECORD CODING REVIEW PROCESS

Cigna-HealthSpring Life & Health Insurance Company Did Not Agree With the Office of Inspector General's Use of Medicare Administrative Contractors

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna disagreed with our use of a Medicare Administrative Contractor (MAC) to identify HCCs that were at a high risk for noncompliance. Cigna stated that our "sampling methodology was arbitrary and relied on a source [a MAC] that lacks sufficient MA experience," and added that furthermore, "[n]o MAC is assigned to evaluate the MA risk adjustment system." Cigna stated that we did not: explain why a MAC was consulted, disclose the MAC that was consulted, or indicate the qualifications and level of expertise of the MAC medical professionals whom we consulted. Cigna described these considerations as indicative of a "lack of transparency" that prevented it from being able to evaluate the standards to which it and its contracted providers were being held.

Office of Inspector General Response

Cigna's assertions regarding our use of a MAC are not accurate. In order to accomplish our objective, we used a reasonable approach to identify diagnoses that were at higher risk for being miscoded. The MAC medical professionals whom we consulted advised us only on information that we had previously gathered from other sources, including information on some of the high-risk groups identified in this report. We did not ask the MAC professionals to

³⁶ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

³⁷ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

provide opinions related to the MA risk adjustment process or to perform a coding review for the sampled enrollee-years; rather we relied only on our independent medical review contractor to perform the coding reviews. Thus, we do not believe that identifying the MAC would provide additional information that is relevant to our findings and recommendations.

Cigna-HealthSpring Life & Health Insurance Company Stated That Coding and Documentation Standards Used During the Audit Were Not Validly Established

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that the "coding and documentation standards" applied during our audit were not validly established through the notice-and-comment rulemaking process that is required by the Administrative Procedure Act³⁸ and more broadly by Medicare statute.³⁹ Cigna argued that "[t]he Supreme Court has explained that this [notice and comment] obligation is broad and is likely to invalidate many policies found only in the Medicare manuals." In addition, Cigna stated that "[a]s applied to this audit, the coding and documentation standards are offered as the difference between valid risk adjustment payments and alleged overpayments. The audit uses sub-regulatory standards" (i.e., policies found only in Medicare manuals) to determine whether any overpayments occurred. For these reasons, Cigna stated that our "potential reliance on these standards is improper."

Office of Inspector General Response

We disagree with Cigna's assertion that our reliance on the Manual to differentiate between a valid risk adjustment payment and an overpayment was improper. We designed our audit to comply with Federal requirements. Specifically, our audit methodology required that our independent medical review contractor review medical records to determine whether the diagnosis codes that Cigna submitted to CMS for risk-adjustment purposes were supported. With regard to Cigna's comment about *Azar v. Allina Health Services*, our reliance on the Manual does not constitute the creation of new payment rules. Rather, we have designed our audit to determine whether Cigna complied with Federal requirements.

Moreover, the Manual is legally binding on an MA organization, a fact that is based not only on regulation, but also on the organization's contract with CMS. Federal regulations state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards.⁴⁰ In addition, MA organizations that contract with CMS must agree to

³⁸ 5 U.S.C. § 553.

³⁹ 42 U.S.C. § 1395hh(a)(2) as acknowledged in *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019).

⁴⁰ 42 CFR §§ 422.504(l) and 422.310(d)(1).

follow CMS's instructions, including the provisions of the Manual.⁴¹ Cigna has agreed to operate in compliance with the Manual under the terms of its contract with CMS and is bound by the requirements of that contract, including any applicable provisions of the Manual.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Did Not Provide Any Information Regarding the Independent Medical Review Contractor and the Coding Standards Used for This Audit

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that it had concerns regarding our independent medical review contractor's review and that the review methodology was "[n]eedlessly [o]paque." With regard to these concerns, Cigna made several related points:

- Cigna stated that we should identify our independent medical review contractor so that Cigna can assess: (1) whether there is a conflict of interest, (2) the contractor's credentials, coding policies, procedures, and training, (3) consistency between this audit and prior work, and (4) the results of each level of medical review as well as any inter-rater reliability (IRR) reviews.⁴²
- Cigna stated that we did not provide the coding or documentation standards used by the independent medical review contractor. In this context, Cigna referred to "inconsistencies and variations" in the ICD-9-CM and ICD-10-CM coding guidelines (footnote 1) and added that we should identify the specific coding and documentation standards used to evaluate the high-risk groups of diagnoses.
- Cigna cited our report's discussion of multiple levels of reviews performed by our independent medical review contractor, and stated that Cigna received only the final medical review determinations. Cigna added that "the subjective nature of coding determinations" made it important for Cigna to be able to evaluate the results of each level of review.
- In addition, Cigna stated that it believed "that OIG's contractor went beyond assessing coding and questioned the clinical validity of providers' diagnostic statements . . . [because] the audit methodology indicate[d] that a physician was required to serve as a tie-breaker when at least one coder already determined a code to be supported."

⁴¹ 42 CFR § 422.504(a).

⁴² IRR reviews verify the accuracy of medical record decisions and identify the consistency of decisions between two reviewers.

Office of Inspector General Response

We do not agree with Cigna's comments that we should provide additional information about the independent medical review contractor and results of each level of the contractor's reviews. Specifically:

- It is not our practice to name our independent medical review contractor. However, our audit process includes measures to ensure that there are no conflicts of interest among the parties involved in the audit. The name of the independent medical review contractor would not provide information about the contractor's qualifications beyond what we state in this audit report. Furthermore, during the course of our audit, we informed Cigna that our medical reviews were performed by professional coders credentialed by the American Health Information Management Association (AHIMA) and the American Academy of Professional Coders (AAPC).⁴³ These coders were experienced in coding ICD-9-CM and ICD-10-CM diagnosis codes for hospital inpatient, outpatient, and physician medical records.

The independent medical review contractor's quality review process included IRR reviews along with additional supervisory review of case determinations. The quality review process identified and made corrections, if needed. We do not believe that providing the results of those internal IRR reviews would provide additional information, as the results of the quality review process are reflected in the coding determinations that serve as the bases for our findings.

- Our independent medical review contractor used the following coding and documentation standards: (1) the CMS-published Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance,⁴⁴ (2) 2011 ICD-9-CM Official Guidelines for Coding and Reporting,⁴⁵ (3) 2015 ICD-10-CM Official Guidelines for Coding and

⁴³ Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), CPC – Instructor, and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs. This information also appears in a footnote in Appendix A of both our draft and final reports.

⁴⁴ CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance As of 9/27/2017*. Available online at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/coders-guidance.pdf>. Accessed on Nov. 18, 2022.

⁴⁵ *ICD-9-CM Official Guidelines for Coding and Reporting Effective October 1, 2011*. Available online at https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf. Accessed on Nov. 18, 2022.

Reporting,⁴⁶ (4) the American Hospital Association (AHA), Coding Clinic for ICD-9-CM, and (5) the AHA Coding Clinic for ICD-10-CM and ICD-10-PCS.⁴⁷ We provided Cigna information regarding the coding guidelines and guidance during the course of our audit.

- As explained in our audit methodology (Appendix A), the coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC. At the conclusion of this process, we used only the final coding review determination for each sampled enrollee-year to calculate overpayments or underpayments (if any). We provided Cigna the final coding review determinations for each sampled enrollee-year.
- The independent medical review contractor used both skilled coders and physicians (when necessary) to review medical record documentation in accordance with the relevant CMS guidance,⁴⁸ which states, “reviewers should evaluate all listed conditions for consistency within the full provider documentation” (emphasis added). The coders and physicians did not make clinical judgments, but rather applied coding rules to accurately assign applicable ICD codes that translated to HCCs. Physician input was not an assessment of clinical support; rather, it constituted an assessment of documented evidence in support of the assignment of diagnosis codes. We believe that the use of a physician to serve as the final decision maker (i.e., tiebreaker), was a reasonable method for determining whether the medical records adequately supported the reported diagnosis codes.

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used an Arbitrary Date Range That Prohibited Cigna From Submitting Documentation That Would Substantiate a Diagnosis

Cigna stated that our “narrowly defined documentation requirements conflicted” with our sampling methodology. Specifically, Cigna stated that we developed “parameters for when a diagnosis would be considered a high risk of noncompliance” but prohibited Cigna from submitting documentation from the same time periods as were contained within those parameters. Cigna also stated that because of this conflict, “records that would substantiate a diagnosis were not accept[ed] if outside of the narrow time frame of the audit.” Cigna offered

⁴⁶ ICD-10-CM Official Guidelines for Coding and Reporting FY 2015. Available online at <https://www.cdc.gov/nchs/data/icd/10cmguidelines-2015-updated-9-26-14.pdf>. Accessed on Nov. 18, 2022.

⁴⁷ The “PCS” acronym in the ICD-10-PCS refers to the Procedure Coding System, which is a medical classification coding system that tracks various health interventions taken by medical professionals. See also footnote 1.

⁴⁸ CMS, Contract-Level Risk Adjustment Data Validation, Medical Record Reviewer Guidance, for reviews 3/20/2019. Available online at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>. Accessed on Nov. 18, 2022.

examples of cases in which enrollees received diagnoses near the end of one calendar year and treatments or prescriptions the following calendar year. Cigna argued that “[t]his disregard of documentation and support for a diagnosis code based on an arbitrary date range . . . ignores the fact that for MA [enrollees] and their plan providers, the end of a calendar year does not change how providers deliver care.”

Office of Inspector General Response

Cigna incorrectly linked the methodology we used to develop the sampling frame with CMS’s medical record documentation requirements. As explained in Appendix C, our sampling methodology identified specific diagnoses that occurred only once during the service year along with other information that we took into consideration. Although the dates associated with this other information may have spanned consecutive calendar years, they helped us determine whether the identified diagnoses were at high risk for being miscoded. Thus, our sampling methodology has no correlation to CMS’s medical record documentation requirements.

With respect to the medical record documentation, CMS uses the diagnosis codes that the enrollee received for one calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Accordingly, the medical record documentation that we considered for each enrollee-year involved only the service year associated with the scope of the audit (service years 2015 and 2016).

Cigna-HealthSpring Life & Health Insurance Company Stated That the Office of Inspector General Used Problematic Standards To Determine the Validity of Diagnoses

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna stated that OIG used “problematic and arbitrary” standards “to supplant its medical knowledge years later for that of . . . treating providers.” Cigna added that it knows of “no CMS guidance suggesting that the health status of [an enrollee] . . . is disproved solely by whether a provider prescribes a certain course of treatment or whether [an enrollee] elects to follow through with such treatment.” As an example, Cigna cited a sampled enrollee-year in which the individual had been diagnosed with prostate cancer and who had elected to undergo “watchful waiting with monitoring of his PSA levels.”⁴⁹ Cigna stated that “[i]dentifying such a diagnosis as unsupported was clinically inaccurate . . . and this finding results in OIG and its MAC consultant supplanting the member’s personal choices with their own.”

In addition, Cigna stated that we “ignored information regarding [enrollees] seeking care outside of the Medicare program.” For example, Cigna cited a sampled enrollee-year in which the individual “was diagnosed with and treated for prostate cancer in 2006, and continued to

⁴⁹ “Watchful waiting” involves closely watching a patient’s condition but not giving treatment unless symptoms appear or change.

be prescribed Lupron for his prostate cancer in 2016.”⁵⁰ In addition, the enrollee was obtaining followup care through the Department of Veterans Affairs (VA). Because this individual filled the prescription using a means other than the Cigna MA plan and “was obtaining oncology follow-up care through the VA, OIG invalidated the diagnosis.”

Office of Inspector General Response

We disagree with Cigna’s characterizations of the standards used during the medical review process. We used a reasonable approach to identify diagnoses that were at higher risk for being miscoded. This approach involved, among other things, discussions with medical professionals regarding the treatment of certain conditions; and used that information to identify enrollee-years with high-risk diagnosis codes. This sampling methodology has no correlation to the CMS medical record documentation requirements that our independent medical review contractor used to determine whether or not the diagnoses were supported.

For this audit, our objective was to determine whether selected high-risk diagnosis codes that Cigna submitted to CMS for use in CMS’s risk adjustment program complied with Federal requirements. For each of the sampled enrollee-years, we asked Cigna to provide up to five medical records of its choosing to support the reviewed HCC. We asked our independent medical review contractor to review all the medical records that Cigna provided to determine whether the information documented in the medical records supported any diagnoses that mapped to the reviewed HCC. During its review, the independent medical review contractor did not make clinical judgments, but rather used applicable coding and documentation standards to accurately assign the appropriate diagnosis codes that translate to HCCs.

With respect to Cigna’s example of the individual who had been diagnosed and treated for prostate cancer through the VA, the associated enrollee-year is one for which we reviewed the additional explanations provided by Cigna for this final report. Specifically, our independent medical review contractor reviewed the additional information that Cigna provided and determined that there was no documentation that the individual was being actively treated for prostate cancer, stating that “the patient had a radical prostatectomy in the past. There is no evidence of active cancer.”⁵¹

More generally, our audit does not supplant provider decision making or enrollee choice. We acknowledge that providers have choices in prescribing courses of treatment, and that enrollees also have choices regarding treatment, some of which are outside of the Medicare program. Nevertheless, Medicare requirements are clear that in order for a diagnosis code that has been submitted to CMS to be appropriately included in the calculation of the risk score, the diagnosis needs to be documented in, and supported by, an acceptable medical record.

⁵⁰ Lupron is a type of hormone therapy that doctors typically use in combination with other treatments to treat people with prostate cancer.

⁵¹ In a radical prostatectomy operation, the surgeon removes the entire prostate gland as well as some of the tissue around it.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE OR AFTER THE AUDIT PERIOD

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our second recommendation—that it perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period. According to Cigna, “MA regulations do not require the sort of audits that OIG recommends and do not require data perfection.” Cigna also stated that this recommendation holds MA organizations to standards that are “unknown, vague, and nonexistent.” Further, Cigna stated that if it “undertook an audit similar to OIG’s, it could not result in ‘risk adjustment payment integrity and accuracy’” because “a payment audit designed to target errors without considering and recognizing diagnoses that are supported but not previously submitted, does not ensure payment accuracy and is improper.”

Office of Inspector General Response

We do not agree with Cigna’s interpretation of the Federal requirements. Contrary to Cigna’s assertions, we maintain that our recommendation that Cigna review whether similar instances of high-risk diagnoses occurred before or after our audit period remains valid and conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (Appendix E)).

These Federal regulations state that MA organizations must “implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS’ program requirements.” Further, these regulations specify that Cigna’s compliance plan “must, at a minimum, include [certain] core requirements,” which include “an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program.” These regulations also require MA organizations to implement procedures and a system for investigating “potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence.” Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

With respect to Cigna’s comments stating that audits like ours do not result in payment accuracy, we note that our findings are not indicative of the overall accuracy of diagnosis codes that Cigna submitted to CMS. We limited our audit and recommendations to certain diagnosis codes that we determined to be at high risk for being miscoded. We believe that the error rate identified in our audit (200 of 300 enrollee-years (see Appendix D)) demonstrates that Cigna has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain the validity of our recommendation that Cigna

identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period.

CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY DID NOT CONCUR WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION THAT IT ENHANCE ITS EXISTING COMPLIANCE PROCEDURES

Cigna-HealthSpring Life & Health Insurance Company Comments

Cigna did not concur with our third recommendation—that it continue to examine its existing compliance procedures for diagnoses that are at high risk for being miscoded and enhance those procedures as necessary. Specifically, Cigna stated that it “has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements,” and that it had made numerous changes to its compliance program since 2015 and 2016. In addition, Cigna said that it has “put forth significant effort to educate providers regarding the appropriate use of some of the specific codes targeted by OIG in this audit.” Further, Cigna noted that in 2021, it underwent a CMS program audit that had no findings related to Cigna’s compliance program. Cigna also cited a recent OIG contract-level RADV audit (of another contract) that described Cigna’s policies and procedures as generally effective.⁵²

Cigna also stated that we made “potentially misleading statements” with regard to the Federal regulations that MA organizations are required to follow regarding compliance programs. Cigna said that it believed that we have “expanded [CMS’s] MA compliance program requirements” because we did not take into consideration that CMS gives MA organizations “broad discretion to design their own compliance and risk adjustment data accuracy programs,” and that MA organizations “are not held to a standard of guaranteeing the accuracy of the risk adjustment data that [are] submitted.”

Finally, Cigna stated that “[t]he fact that OIG identified supposedly unsupported diagnoses . . . does not indicate that Cigna’s compliance program is ineffective, particularly when measured by MA program guidance.”

Office of Inspector General Response

Cigna’s response implied that we opined on the effectiveness of its entire compliance program. That was not our intention or our focus for this audit. Rather, we limited our audit to selected diagnoses that we determined to be at high risk for being miscoded. Our audit revealed a significant error rate for some of these high-risk groups. Although a prior CMS program audit did not result in any findings, and although the OIG contract-level RADV audit—which had a different objective than this audit—found Cigna’s policies and procedures to be

⁵² *Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*. Available online at <https://oig.hhs.gov/oas/reports/region3/31800002.pdf>. Accessed on Nov. 18, 2022. See also Appendix B of this report.

generally effective, we continue to believe that Cigna should enhance its compliance procedures with respect to these high-risk groups of diagnoses.

Moreover, although we acknowledge that CMS gives discretion to MA organizations when designing a compliance plan, Federal regulations also require MA organizations to implement procedures for "promptly responding to compliance issues as they are raised" and to "[correct] such problems promptly and thoroughly to reduce the potential for recurrence" (42 CFR § 422.503(b)(4)(vi)(G)). The continued improvement of Cigna's existing procedures and internal data quality reviews (based on the results of this audit) will assist Cigna in attaining better assurance with regard to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our third recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Cigna \$2,140,237,283 to provide coverage to its enrollees for 2016 and 2017. We identified a sampling frame of 8,667 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2015 and 2016 service years. Cigna received \$134,347,953 in payments from CMS for these enrollee-years for 2016 and 2017. We selected for audit 300 enrollee-years with payments totaling \$4,939,748.

The 300 enrollee-years included 30 acute stroke diagnoses, 30 acute heart attack diagnoses, 60 major depressive disorder diagnoses, 30 embolism diagnoses, 30 vascular claudication diagnoses, 30 lung cancer diagnoses, 30 breast cancer diagnoses, 30 colon cancer diagnoses, and 30 prostate cancer diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$720,395 for our sample.

Our audit objective did not require an understanding or assessment of Cigna's complete internal control structure, and we limited our review of internal controls to those directly related to our objective.

We performed audit work from August 2019 through April 2022.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a MAC, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 74 diagnosis codes for acute stroke,
 - 38 diagnosis codes for acute heart attack,
 - 29 diagnosis codes for major depressive disorder,
 - 85 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication,
 - 24 diagnosis codes for lung cancer,

- 65 diagnosis codes for breast cancer
 - 20 diagnosis codes for colon cancer, and
 - 2 diagnosis codes for prostate cancer.
- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
 - Risk Adjustment Processing System (RAPS)⁵³ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)⁵⁴ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)⁵⁵ to identify enrollees for whom CMS made monthly Medicare payments to Cigna, before applying the budget sequestration reduction, for the relevant portions of the service and payment years (Appendix C),
 - Encounter Data System (EDS)⁵⁶ to identify enrollees who received specific procedures, and
 - Prescription Drug Event (PDE) file⁵⁷ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Cigna officials to gain an understanding of: (1) the policies and procedures that Cigna followed to submit diagnosis codes to CMS for use in the risk adjustment program and (2) Cigna's monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
- We selected for audit a stratified random sample of 300 enrollee-years (Appendix C).

⁵³ MA organizations use the RAPS to submit diagnosis codes to CMS.

⁵⁴ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

⁵⁵ The MARx identifies the payments made to MA organizations.

⁵⁶ The EDS contains information on each item (including procedures) and service provided to enrollees.

⁵⁷ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for the 300 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.⁵⁸
- The independent medical review contractor's coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments (if any) for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS's risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total overpayment made to Cigna during the audit period.

⁵⁸ Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), CPC – Instructor, and Certified Risk Adjustment Coder (CRC). RHITs have completed a 2-year degree program and have passed an AHIMA certification exam. AHIMA also credentials individuals with CCS and CCS-P certifications and the AAPC credentials both CPCs and CRCs.

- We limited the total overpayment that we recommended for recovery to the sampled enrollee-years.⁵⁹
- We discussed the results of our audit with Cigna officials on February 28, 2022.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁵⁹ Federal regulations at 42 CFR § 422.311 state: “the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.” Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary’s payment error extrapolation and recovery methodologies. CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years. 88 Fed. Reg. 6643, 6655 (Feb. 1, 2023).

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS</i>	<u>A-07-19-01193</u>	12/22/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BCBS of Rhode Island (Contract H4152) Submitted to CMS</i>	<u>A-01-20-00500</u>	11/16/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS</i>	<u>A-09-19-03001</u>	11/10/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS</i>	<u>A-05-19-00039</u>	9/30/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS</i>	<u>A-03-19-00001</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS</i>	<u>A-07-19-01195</u>	9/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS</i>	<u>A-05-18-00020</u>	9/26/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS</i>	<u>A-09-20-03009</u>	9/13/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS</i>	<u>A-04-19-07084</u>	8/29/2022
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS</i>	<u>A-03-18-00002</u>	8/19/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS</i>	<u>A-02-20-01009</u>	7/18/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health (Contract H1961) Submitted to CMS</i>	<u>A-06-18-05002</u>	5/25/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS</i>	<u>A-01-19-00500</u>	2/14/2022

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS</i>	<u>A-07-17-01169</u>	2/3/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS</i>	<u>A-02-18-01029</u>	1/5/2022
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS</i>	<u>A-07-19-01188</u>	11/5/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS</i>	<u>A-07-17-01173</u>	10/28/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<u>A-07-19-01187</u>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<u>A-07-16-01165</u>	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	<u>A-02-18-01028</u>	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<u>A-07-17-01170</u>	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Cigna enrollees who: (1) were continuously enrolled in Cigna throughout all of the 2015 or 2016 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2015 or 2016 or in January of the following year, and (3) received a high-risk diagnosis during 2015 or 2016 that caused an increased payment to Cigna for 2016 or 2017, respectively.

We presented the data for these enrollees to Cigna for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Cigna. After we performed these steps, our finalized sampling frame consisted of 8,667 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2016 or 2017.

SAMPLE DESIGN AND SAMPLE SIZE

The design for our statistical sample comprised nine strata of enrollee-years. For the enrollee-years in each respective stratum, each individual received:

- an acute stroke diagnosis (that mapped to the HCC for Ischemic or Unspecified Stroke) on only one physician claim during the service year but did not have that diagnosis on a corresponding inpatient or outpatient hospital claim (1,399 enrollee-years);
- a diagnosis (that mapped to an Acute Heart Attack HCC) on only one physician or outpatient claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician or outpatient claim (609 enrollee-years);
- a major depressive disorder diagnosis (that mapped to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on only one claim during the service year but did not have an antidepressant medication dispensed on his or her behalf (4,869 enrollee-years);
- a diagnosis (that mapped to an Embolism HCC) on only one claim during the service year but did not have an anticoagulant medication dispensed on his or her behalf (256 enrollee-years);

- a diagnosis related to vascular claudication (that mapped to the HCC for Vascular Disease) on only one claim during the service year (a diagnosis that had not been documented during the 2 years that preceded the service year), but had medication for neurogenic claudication dispensed on his or her behalf (442 enrollee-years);
- a lung cancer diagnosis (that mapped to the HCC for Lung and Other Severe Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the lung cancer diagnosis administered within a 6-month period before or after the diagnosis (119 enrollee-years);
- a breast cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments related to the breast cancer diagnosis administered within a 6-month period before or after the diagnosis (448 enrollee-years);
- a colon cancer diagnosis (that mapped to the HCC for Colorectal, Bladder, and Other Cancers) on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (243 enrollee-years); or
- a prostate cancer diagnosis (that mapped to the HCC for Breast, Prostate, and Other Cancers and Tumors), for an individual 74 years old or younger, on only one claim during the service year but did not have surgical therapy, radiation treatments, or chemotherapy drug treatments administered within a 6-month period before or after the diagnosis (282 enrollee-years).

The specific strata are shown in Table 3 on the following page.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee-Years	CMS Payment for HCCs in Audited High-Risk Groups	Sample Size
1 – Acute stroke	1,399	\$2,853,179	30
2 – Acute heart attack	609	1,121,163	30
3 – Major depressive disorder	4,869	11,853,541	60
4 – Embolism	256	638,640	30
5 – Vascular claudication	442	903,526	30
6 – Lung cancer	119	759,024	30
7 – Breast cancer	448	515,140	30
8 – Colon cancer	243	563,755	30
9 – Prostate cancer	282	329,439	30
Total	8,667	\$19,537,407	300

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We sorted the items in each stratum by beneficiary identification number and then consecutively numbered the items in each stratum in the stratified sampling frame. After generating 300 random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of overpayments to Cigna at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES**Table 4: Sample Details and Results**

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Unvalidated HCCs	Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute stroke	1,399	\$2,853,179	30	\$66,086	29	\$62,466
2 – Acute heart attack	609	1,121,163	30	51,144	29	41,309
3 – Major depressive disorder	4,869	11,853,541	60	143,843	3	7,247
4 – Embolism	256	638,640	30	71,322	22	51,125
5 – Vascular claudication	442	903,526	30	59,197	7	12,872
6 – Lung cancer	119	759,024	30	190,116	28	169,930
7 – Breast cancer	448	515,140	30	33,276	28	31,104
8 – Colon cancer	243	563,755	30	64,177	28	56,923
9 – Prostate cancer	282	329,439	30	41,234	26	35,396
Total	8,667	\$19,537,407	300	\$720,395	200	\$468,372

**Table 5: Estimated Overpayments in the Sampling Frame
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$6,897,950
Lower Limit	\$6,247,399
Upper Limit	\$7,548,502

**APPENDIX E: FEDERAL REGULATIONS REGARDING COMPLIANCE PROGRAMS
THAT MEDICARE ADVANTAGE ORGANIZATIONS MUST FOLLOW**

Federal regulations (42 CFR § 422.503(b)) state:

Any entity seeking to contract as an MA organization must

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

- (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
- (2) Describe compliance expectations as embodied in the standards of conduct;
- (3) Implement the operation of the compliance program;
- (4) Provide guidance to employees and others on dealing with potential compliance issues;
- (5) Identify how to communicate compliance issues to appropriate compliance personnel;
- (6) Describe how potential compliance issues are investigated and resolved by the organization; and
- (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The

system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

- (G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.
- (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
 - (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.
 - (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

APPENDIX F: CIGNA-HEALTHSPRING LIFE & HEALTH INSURANCE COMPANY COMMENTS



July 11, 2022

Thomas A. Young
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Cigna Medicare

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U.S. Department of Health & Human Services
Office of Inspector General
Office of Audit Services, Region VII
Attn: James Korn
Regional Inspector General for Audit Services
601 East 12th Street, Room 0429
Kansas City, MO 64106

Re: Response to Draft Report Number: A-07-19-01192

Cigna HealthSpring Life & Health Insurance Company, Inc. ("Cigna") appreciates the opportunity to respond to the Draft Report provided by the U.S. Department of Health and Human Services Office of Inspector General ("OIG") in connection with the Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna (contract H4513) Submitted to CMS.^{1/} Through contract H4513, Cigna provides healthcare and prescription drug benefits to more than 115,000 Medicare Advantage ("MA") beneficiaries in Texas.

We are a committed partner to OIG, the Centers for Medicare & Medicaid Services ("CMS"), and the MA program. We believe the MA program serves Medicare beneficiaries so well because of the partnership between CMS and MA organizations ("MAOs") like Cigna. In the spirit of that partnership, we previously shared details regarding our risk adjustment policies, procedures, and practices with CMS a number of times over the course of many years. CMS has not instructed us that we are required to make any changes to our risk adjustment program.

We believe that the basic premise of OIG's audit is inconsistent with risk adjustment data validation regulations and CMS standards for data accuracy. OIG's sampling methodology targeted diagnoses that were already suspected to not be supported and did not include looking for unreported, unrelated diagnoses. OIG ignored the fact that there may be supported diagnoses not submitted to CMS.

^{1/} OIG, DRAFT – Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna -HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS, A-07-19-01192 (April 2022) ("Draft Report").

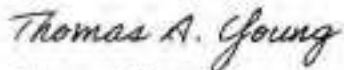
As a result, OIG's audit was skewed toward identifying "overpayments" and was not an unbiased audit seeking to promote payment integrity and accuracy.

We believe these issues affected the audit results. In particular, we do not believe the audit results reflect the strength of Cigna's compliance activities. Cigna has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. Cigna's current compliance program recently received positive feedback from both CMS and OIG. In Cigna's contract-level RADV audit of H5410 in 2021, OIG observed that Cigna "ha[s] a compliance program to ensure that [it] submitted accurate diagnosis codes for use in CMS' risk adjustment program" and that our "policies and procedures [are] generally effective." Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to the effectiveness of Cigna's compliance program.

As we describe in detail below, Cigna requests that OIG revise its Draft Report and withdraw its recommendations. We stand ready to work collaboratively with OIG, CMS, and other stakeholders to address the attached response together in an open, cooperative, and transparent way. We would appreciate the opportunity to meet prior to the finalization of the Draft Report to discuss our feedback and how it might be incorporated into the Final Report.

Thank you for your consideration.

Sincerely,



Thomas A. Young
Medicare Compliance Officer

CC: Aparna Abburi, President, Medicare and Care Allies
Erin Wessling, Chief Counsel

Attachments

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

EXECUTIVE SUMMARY

Cigna appreciates the opportunity to respond to the Draft Report provided by OIG. Through contract H4513, Cigna provides healthcare and prescription drug benefits to more than 115,000 MA beneficiaries in Texas.

We believe that the basic premise of OIG's audit is inconsistent with risk adjustment data validation ("RADV") regulations and CMS standards for data accuracy and that the audit methodology was flawed. These issues affected the audit results.

- OIG's audit was skewed toward identifying "overpayments" and was not an unbiased audit seeking to ensure payment integrity and accuracy.
- OIG's sampling methodology targeted diagnoses that were already suspected to not be supported and the review did not include looking for unreported, unrelated diagnoses. This type of biased review cannot produce a comprehensive picture of accuracy because it deliberately ignores the fact that there may be supported diagnoses not submitted to CMS.
- The audit methodology shared with us does not discuss how OIG and its contractor identified or evaluated potential underpayments. In general, the overall intent of MAO payment audits is to determine whether the MAO has been accurately paid. However, targeting nine specific diagnoses to the exclusion of anything that had previously not been submitted, artificially inflates the proposed "overpayment." OIG should have considered the previously unreported diagnosis codes when considering and calculating its proposed "overpayment."
- The flaws in OIG's audit methodology are evidenced by the fact that no MAO has performed well during any of the audits targeting high-risk diagnoses. Even MAOs like Cigna, that have had very high accuracy ratings in contract-level RADVs, have scored much lower because of many flaws in the methodology. In fact, OIG shared that Cigna's performance is in the "upper echelon" of MAOs under review in this audit series.
- We believe that 6 of the sampled enrollee-years that OIG and its contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. Our review also indicates that OIG and its contractor did not capture 19 previously unreported diagnoses that accurately reflect our enrollees' health status.
- OIG determined whether a diagnosis was at high-risk for noncompliance and was valid based on what a provider decided to recommend to a member, whether a member decided to seek recommended treatment within an OIG-defined period of time, and where or how a member sought treatment. This is inherently problematic and arbitrary. By applying these arbitrary standards of medical practice and "health status," OIG supplants its medical knowledge for that of members' treating providers and in turn applies arbitrary payment standards to Cigna.
- OIG's narrowly defined documentation timing standards conflicted with its sampling methodology. Specifically, OIG included members' diagnoses in its sample based on whether a provider recommended and a member followed up with treatment within an OIG-defined period of time. But, when OIG's defined period of time for treatment (for example, 6 months after a cancer diagnosis) fell outside of the audit time (2015 and 2016 dates of service), OIG refused to

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RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

consider documentation outside of the audit time, even if the records were from a patient visit two or three days removed from when the original diagnosis was reached. By rigidly adhering to an artificially limited time period, and refusing to consider records from subsequent visits based solely on how the calendar fell, OIG improperly limited Cigna's ability to offer substantiating proof.

- OIG's extrapolation of potential overpayments is not appropriate or authorized by Congress.

In addition to these flaws in the OIG's audit methodology, Cigna does not agree with OIG's recommendation to conduct additional audits related to the high-risk diagnoses and Cigna does not agree with OIG's recommendation that Cigna examine existing compliance procedures.

For these reasons, discussed in greater detail below, we respectfully request OIG recalculate its estimated overpayment amount to account for these errors and withdraw its recommendations for extrapolation, additional auditing, and compliance program review.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

I. Cigna Does Not Concur with OIG's Findings Because the Audit Design and Intent is Inconsistent with RADV Regulations and Standards for Data Accuracy.

We respectfully request that OIG withdraw its findings given that its overall audit design and intent are inconsistent with risk adjustment data validation regulations and CMS standards for data accuracy. Specifically, (a) OIG's audit does not ensure payment accuracy; (b) OIG's sampling and review methodology was improperly skewed toward identifying "overpayments"; (c) OIG ignores the long-standing principle that MAOs are not required to have perfect data; and (d) OIG fails to recognize that perfection in risk adjustment data is not possible.

a. OIG's Audit Does Not Ensure Payment Accuracy

MA regulations at 42 C.F.R. §§ 422.2 and 422.311(a) establish that a payment audit of an MAO conducted by the Secretary of HHS ensures the integrity and accuracy of risk adjustment payment data. Over the last fifteen years, CMS has developed and proposed multiple audit and sampling methodologies and has undergone multiple rounds of industry engagement, in an attempt to establish a sampling methodology that ensures payment integrity and accuracy. However, OIG's audit was not designed to ensure risk adjustment payment integrity and accuracy.

OIG's audit methodology was so targeted that it could not equally identify overpayments and underpayments. In particular, the sample frame targeted nine specific diagnosis categories that OIG hypothesized, prior to conducting the audit, are likely to be at high risk for noncompliance based on medical claims data and prescription drug claims data, and therefore likely to have resulted in an "overpayment." This biased targeting resulted in findings that do not ensure accuracy because the audit was not designed to look at payment accuracy, which would include both overpayments and underpayments. OIG neither (1) simultaneously conducted an audit of members for which Cigna was most likely underpaid (i.e., members with no or few submitted HCCs), nor (2) allowed Cigna to demonstrate support for and receive credit for diagnosis codes that had not previously been submitted to CMS for the audited members that were unrelated to the target diagnosis codes ("net new").

These issues affected the audit results. In our view, the issues indicate that OIG's audit methodology is not sufficiently designed to identify underpayments, and, as a consequence, does not appear to generate a statistically valid "net" overpayment figure for the audit sample. And, as discussed in more detail below, this reinforces our concern that the proposed overpayment figure used by OIG cannot be an adequate basis for a valid extrapolation.

The flaws in OIG's targeted audit methodology are evidenced by the fact that no MAO has performed well during any of the audits targeting high-risk diagnoses. Even MAOs like Cigna, which recently completed a contract-level RADV audit of H5410 that resulted in a 97% payment accuracy rate finding, are scoring much lower because of the flawed audit methodology. In fact, OIG shared that Cigna's performance is in the "upper echelon" of MAOs under review in this audit series. Further, it indicates that if OIG's targeted audit was designed for payment accuracy, as required by 42 C.F.R. § 422.311(a), then the findings would be different and would be a much more accurate reflection of the MAO's risk adjustment data validation.

Finally, the timing of the audit also makes payment accuracy unachievable as a practical matter. This audit covered dates of service in 2015 and 2016. The five and six year gap between the encounters at issue and the audit creates a significant data validation issue for Cigna. Providers may have moved, left our network, retired, or passed away. Paper records may have been lost. Electronic health record (EHR)

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systems may have been upgraded or replaced, making older electronic records harder or impossible to access. Facilities and other practices may not cooperate with requests seeking records from that far in the past (and they face no realistic sanction for deciding they cannot or do not wish to cooperate). These and similar practical realities make it impossible for OIG to assess payment accuracy via a RADV-styled audit of targeted high-risk diagnoses.

b. *OIG's Sampling and Review Methodology was Improperly Skewed Towards Identifying "Overpayments"*

i. Sampling Methodology

OIG's sampling methodology targeted diagnoses that were already suspected to not be supported and as a result, OIG's audit was not an unbiased audit seeking to promote payment integrity and accuracy. OIG's audit was first biased towards overpayment by creating a universe of members who had only certain diagnoses, then OIG and a Medicare Administrative Contractor ("MAC") (as discussed below) limited that universe to instances where such diagnoses did not have evidence of Medicare-reimbursed follow-up care which the OIG determined to be an indication that the diagnosis was at high-risk of noncompliance, and then identified a sample from that limited universe. OIG only focused on samples that it viewed to be high-risk diagnoses so that it could only identify a potential overpayment. OIG did not simultaneously create a sample of members for whom it would seek to identify under-reported diagnoses or underpayments. As a result, OIG skewed any potential findings to only identify overpayments and exclude all other diagnoses.

Further, OIG's development of its sampling methodology was arbitrary and relied on a source that lacks sufficient MA experience. OIG relied on medical professionals from a MAC to identify HCCs that were at a high risk for noncompliance.^{2/} As CMS describes, "a MAC is private health care insurer that

/ MACs do not process MA claims or encounter data.

MACs are assigned to CMS-established jurisdictions, and there are currently 12 MACs that focus on Parts A and B FFS claims. No MAC is assigned to evaluate the MA risk adjustment system. OIG did not explain why it consulted a MAC, disclose the MAC it consulted, indicate whether the MAC it consulted had expertise to assist OIG in determining which diagnoses submitted by an MA plan may be "high risk for noncompliance," or disclose the type of or qualifications of medical professionals employed by the MAC that OIG relied upon. This lack of transparency results in Cigna being unable to evaluate how the standards it, and its contracted treating providers, are being held to, were developed or the qualifications of the entity developing such standards. Further, given that MACs have expertise in identifying potential errors in FFS data, OIG's reliance on a MAC and its recognition of a MAC's familiarity with FFS errors further

^{2/} See Draft Report, Appendix A: Audit Scope and Methodology, page 19.

^{3/} See CMS, "What's a MAC?" at [https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#:~:text=A%20Medicare%20Administrative%20Contractor%20\(MAC,%20Service%20\(FFS\)%20beneficiaries](https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#:~:text=A%20Medicare%20Administrative%20Contractor%20(MAC,%20Service%20(FFS)%20beneficiaries).

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underscores the need for a FFS Adjuster. But as discussed below in *Section II.e*, OIG did not apply a FFS Adjuster to any of its findings.

In addition, OIG's sampling methodology arbitrarily used the lack of Medicare prescription drug data or a member's decision to not seek follow up care that was evidenced in Medicare data within an OIG-invented timeframe to flag diagnoses as being at high risk for noncompliance. By developing and applying this sampling methodology, OIG was replacing its clinical expertise for that of members' treating providers. Further, OIG's reliance on the lack of Medicare prescription drug data to flag and potentially invalidate a provider-reported diagnosis stands in stark contrast to MA risk adjustment rules, which do not recognize pharmacies and prescription drug data as acceptable sources for risk adjustment data.

ii. Review Methodology

OIG's review of medical records was also skewed to only identify overpayments. Once OIG identified the sample of members that it considered to have the targeted high-risk diagnoses, OIG's reviewers only reviewed the limited acceptable medical records for such members for evidence of the targeted high-risk diagnosis or a related diagnosis. OIG ignored the fact that for each identified member, there may be supported diagnoses not previously submitted to CMS (i.e., "underpayments"), creating additional bias toward identifying "overpayments." As OIG is aware, an MAO cannot reopen payment years to add diagnoses that it determines were not previously reported. The payment years subject to this audit were closed multiple years ago. By OIG limiting its review to only instances of potential "overpayments," OIG knew that Cigna would be unable, on its own, to demonstrate that it was not in fact "overpaid" because Cigna is not able to submit diagnoses identified in 2021 as support for dates of services in 2015 and 2016. The only way for Cigna to be credited for such previously unreported codes, and for this audit to ensure payment accuracy, is for OIG to take such diagnoses into account.

We also note that the medical record review was not limited to coding and documentation issues. Instead, it incorporated a review of the clinical validity of the provider's diagnosis. CMS requires that plans only be responsible for the accuracy of the coding of the diagnosis as provided by a practitioner.^{4/} The ICD Guidelines and American Hospital Association (AHA) Coding Clinic similarly state that coders do not have the ability or authority to question a provider's diagnostic statement, as documented.^{5/} For that reason, CMS has not permitted the certified coders conducting its medical record reviews to attempt to assess the clinical validity of diagnoses.^{6/} Unfortunately, we believe that OIG's contractor went beyond assessing coding and questioned the clinical validity of providers' diagnostic statements. For instance, the audit methodology indicates that a physician was required to serve as a tie-breaker when at least one coder already determined a code to be supported. The fact that a practitioner submitted the code to the MAO

^{4/} 65 Fed. Reg. 40170, 40251 (June 29, 2000) ("we have restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding.") CMS also has refused on a number of occasions to specific clinical criteria for particular diagnoses. See *supra* n.30.

^{5/} ICD-10-CM Official Guidelines for Coding and Reporting, 13 (2019) ("[A]ssignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient."); AHA Coding Clinic, *Ask the Editor* (2016) ("Coders should not be disregarding physician documentation and deciding on their own, based on clinical criteria, abnormal test results, etc., whether or not a condition should be coded.")

^{6/} CMS, *Statement of Work for the Recovery Audit Program*, 23 (2011) ("[C]ertified coders shall ensure they are not looking beyond what is documented by the physician. ... Clinical validation is beyond the scope of [a coding] validation, and the skills of certified coder.")

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and at least one coder found it to be supported should not require a physician tie-breaker unless that physician was questioning the clinical validity of the provider's diagnostic statements.^{7/}

Further, in direct conflict with the Coding Guidelines and the Coding Clinic, as discussed in Section II.c.v, OIG's review methodology was specifically designed to question a provider's diagnostic statement, as documented, because OIG's methodology was clinically targeted to determine whether a given member was prescribed or received care that OIG determined should have been provided.

c. OIG Disregards that MAOs Are Not Required to Have Perfect Data

The perfection standard posited by the Draft Report reflects either a misunderstanding of CMS regulations or a rejection of the data standards set by CMS. For instance, the Draft Report cites 42 C.F.R. § 422.504(f) in taking the position that MA organizations "are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS." Importantly, however, the attestation referred to in the Draft Report and defined by subsection 422.504(f) is limited to the plan's "best knowledge, information and belief." CMS included this limitation to "allow for honest mistakes and unavoidable margins of error"^{8/} and "in recognition of the fact that [MA organizations] cannot reasonably be expected to know that every piece of data is correct."^{9/} CMS also recognized at the time that "it would be unfair and unrealistic to hold [MA organizations] to a '100 percent accuracy' certification standard."^{10/} CMS has since reiterated that there is no requirement "to verify every diagnosis submitted by every provider."^{11/} OIG, itself, also has recognized that an MA organization's attestation "does not constitute an absolute guarantee of accuracy."^{12/}

The Draft Report also cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an "effective" compliance program, to suggest that because OIG concluded that some HCCs were not valid, Cigna should evaluate its compliance program to ensure compliance with 42 C.F.R. § 422.503(b)(vi). Perfection is not required in order for a compliance program to be "effective." OIG has "recognize[d] that the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization."^{13/}

^{7/} Because the information has not been provided to date, we do not know how many records were subject to physician review during this audit. However, a recent report regarding another MA organization indicated that the physician reviewed the medical records related to approximately 10% of the audit sample. See OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes that Humana, Inc. (Contract H1036) Submitted to CMS, A-07-16-01165*, 15 n.14 (Apr. 2021).

^{8/} 65 Fed. Reg. 40170, 40250 (June 29, 2000).

^{9/} *Id.* at 40268.

^{10/} *Id.*

^{11/} 79 Fed. Reg. 29843, 29925 (May 23, 2014).

^{12/} 64 Fed. Reg. at 61900. The draft report also appears to suggest that perfection is required by 42 C.F.R. § 422.310(d)(1), which states that MA organizations "must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards." That regulation, however, does not relate to data validation. That rule refers to the "national standards" that define the format used by providers to submit claims in the FFS program. See 63 Fed. Reg. 34968, 35006 (June 26, 1998) ("The format of the data we will require will be identical to the data we require of original Medicare providers..."); see also *id.* at 35007 (directing the use of the HCFA 1500 paper form or the electronic UB-92).

^{13/} 64 Fed. Reg. 61893, 61895 (Nov. 15, 1999). See also United States Sentencing Manual § 8B2.1(a) ("The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct."); Application Note 2(A)(i) ("effectiveness" must be assessed based on "a applicable industry practice or the standards called for by any applicable governmental regulation"). We are not aware of OIG ever having indicated that an "effective" compliance program in any context needs to or is required to achieve perfection. Cf. Fed. Reg. 23731, 23732 (May 5, 2003) ("The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from

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A perfection standard also would conflict with the "same methodology" requirement in 42 U.S.C. § 1395w-23(b)(4)(D). This provision mandates CMS calculate risk adjustment payments in the MA program using the "same methodology" as when calculating the average risk factor for the FFS program. CMS does not audit the FFS data it uses to establish the average FFS risk score using the RADV documentation standards; it, therefore, accepts that those data contain significant errors. Similarly, as discussed in greater detail below in connection with the extrapolation methodology used to prepare the Draft Report, a perfection standard also would violate the actuarial equivalence requirement in 42 U.S.C. § 1395w-23(a)(1)(C)(i).^{14/} Finally, we note that the federal courts uniformly decline to require perfection as a standard of measure in the Medicare program.^{15/}

d. Perfection in Risk Adjustment Is Not Possible.

The perfection standard reflected in the Draft Report also is inconsistent with the realities and limitations of attempting to perform a risk adjustment function. As CMS has recognized, risk adjustment data "come into [MAOs] in great volume and from a number of sources."^{16/} In particular, an overwhelming majority of the risk adjustment data for our Texas contract (more than 64%) were submitted by the healthcare providers that treated our enrolled beneficiaries. Although we do make coding and documentation training available to those providers, we ultimately cannot control their submissions.

In addition, coding and documentation disagreements are inevitable and often arise from factors outside the control of any MAO. Diagnosis coding is an inherently subjective process and there often are substantial differences in interpretation and opinion among health care practitioners and certified coders regarding a broad array of coding issues. CMS generally does not require providers to use any particular diagnostic or clinical criteria and allows providers to use their best professional judgment.^{17/} OIG is aware of these differences in interpretation as evidenced by its review methodology that included multiple reviewers for coding disagreements. "One study examining coding variation found that when 11 experienced, active medical coders reviewed 471 medical records and were told they would be reevaluated, all of the coders differed in one or more data fields for more than half of the records."^{18/} In addition, the coding standards (which have never gone through notice and comment) are often vague and ambiguous and the source of variable coding throughout the health care industry.^{19/}

the operations of a pharmaceutical manufacturer."); 70 Fed. Reg. 4858, 4859 (Jan. 31, 2005) ("The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers.").

^{14/} See *infra* at Section II.e.

^{15/} See, e.g., *U.S. ex rel. Janssen v. Lawrence Mem. Hosp.*, 949 F.3d 533, 543-44 (10th Cir. 2020) (citing *U.S. ex rel. Conner v. Salina Reg. H. Ctr.*, 543 F.3d 1211, 1220-21 (10th Cir. 2008)); *U.S. ex rel. Wilkins v. United Health Group, Inc.*, 559 F.3d 295, 310 (3d Cir. 2011).

^{16/} 65 Fed. Reg. at 40528.

^{17/} See, e.g., 75 Fed. Reg. at 73401 ("We believe that physicians can use their best clinical judgment in the detection and diagnosis of cognitive impairments...."); 76 Fed. Reg. at 73308 (similar quote).

^{18/} Kimberly O'Malley, *Measuring Diagnoses: ICD Code Accuracy*, 40 Health Serv. Res. 1620 (2005).

^{19/} For instance, in a series of prior audits, OIG identified Kwashiorkor as a condition that had been frequently miscoded. OIG, *CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor*, A03-14-00010 (Nov. 2017) ("We reviewed the medical records for 2,145 inpatient claims at 25 providers and found that all but 1 claim incorrectly included the diagnosis code for Kwashiorkor...."). OIG determined that the root cause of this problem was an ambiguity in the ICD guidelines adopted by CMS. See *Id.* ("The ICD-CM coding classification contained a discrepancy between the tabular list and the alpha index on the use of diagnosis code 260. In the alpha index, four other malnutrition diagnoses corresponded to diagnosis code 260, but in the tabular list, diagnosis code 260 was only for Kwashiorkor.").

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We do not think it is correct to automatically conclude that a diagnosis is unsupported if the relevant medical record is missing. When a provider submits a diagnosis code, that submission is evidence that the provider in fact made the relevant diagnosis. We agree that MAOs should be required to make a good faith effort to locate the relevant records. However, when the record cannot be obtained from the provider through reasonable diligence, particularly after a significant period of time has elapsed, the absence of the record is not, in our view, a sufficient basis to reject a diagnosis code submitted by a provider.^{20/}

Additionally, obtaining medical records from providers is often very challenging. For many of our provider partners who seek to provide such records, responding to medical record requests for visits that occurred five to six years prior can be administratively burdensome, and such burden has been further exacerbated by the COVID-19 public health emergency and staff shortages. For MAOs, the consolidation of hospital systems and large provider groups and the increasing number of providers who are publicly traded or private investor-backed has led to some large groups and health systems refusing to respond to records requests in a timely fashion, if at all, especially when they know that an MAO requires their participation in certain areas to satisfy network adequacy requirements. MAOs have very little leverage, and almost no recourse, when providers do not provide the medical records requested, even though the consequence of a provider's lack of cooperation is significant for the MAO, as is demonstrated by the Draft Report.

OIG designed and conducted an audit that was inconsistent with RADV regulations and CMS standards for data accuracy. By not focusing on payment accuracy and reviewing for both "overpayments" and "underpayments," OIG skewed any potential results towards identifying "overpayments." Further, OIG ignored long-standing principles that perfection in risk adjustment data is not possible and MAOs are not required to have perfect data. For these reasons, we respectfully request OIG withdraw its findings and reconsider its audit design and methodology.

II. Cigna Does Not Concur with OIG's Estimated and Extrapolated Repayment Amount and Respectfully Requests OIG Recalculate to Address Errors in OIG's Analysis of Certain Enrollee-Years, Remove The Impact of Underlying Biases, and Ensure Actuarial Equivalence

We respectfully request OIG withdraw its recommended repayment amount and recalculate it, when possible, to (a) address errors in OIG's analysis of certain enrollee-years; (b) include previously unreported diagnoses; (c) remove the impact of underlying biases; and (c) ensure actuarial equivalence.

a. OIG's Recommended Repayment Amount is Incorrect Because Certain Sample Enrollee-years that OIG Found to be Unsupported are Supported by Documentation in the Relevant Medical Records

^{20/} Because RADV audits are not defined by statute, the Administrative Procedure Act (APA) places the burden on OIG to advance an adequate basis to overturn CMS's risk adjustment payments. See 5 U.S.C. § 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof."); see also *DWCP v. Greenwich Collieries*, 512 U.S. 267, 276 (1994) ("the drafters of the APA used the term 'burden of proof' to mean the burden of persuasion"); *Steadman v. SEC*, 450 U.S. 91, 95 (1981) (APA defines "the degree of proof which must be adduced by the proponent of a rule or order to carry its burden of persuasion in an administrative proceeding").

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We believe that 6 of the sampled enrollee-years that OIG and its contractor did not validate should have been validated under the applicable statutes, regulations, and CMS guidance. Discussions of these enrollee-years are attached at Exhibit A. Please note that these exhibits contain protected health information and are not eligible for public disclosure.

b. OIG's Recommended Repayment Amount is Incorrect Because It Does Not Consider Previously Unreported Diagnoses

Similarly, our review indicates that OIG and its contractor did not capture 19 other previously unreported diagnoses that accurately reflect our enrollees' health status. This includes diagnoses that are related to the targeted high-risk categories and some that are unrelated. A list of these enrollee-years are attached at Exhibit B. Though documented, OIG did not validate any of these diagnosis codes.

For a number of reasons, discussed above, we are concerned that the audit methodology was not structured to equally identify both overpayments and underpayments. In particular, the audit methodology shared with us does not discuss how OIG and its contractor identified or evaluated potential underpayments, including the additional diagnoses we identified in our review. In general, the overall intent of payment audits is to determine whether the MAO has been paid accurately. However, targeting nine specific diagnoses to the exclusion of anything that previously had not been submitted artificially inflates the proposed "overpayment." When calculating a proposed "overpayment" amount, OIG should have sought to determine accuracy, which must offset any proposed "overpayments" by underpayments.

c. OIG's Review Methodology was Needlessly Opaque and Did Not Adequately Identify the Independent Medical Review Contractor or the Coding and Documentation Standards Applied during the Medical Record Review. OIG Should Update its Draft Report to Include Additional Information Regarding its Medical Record Review.

i. OIG did not provide information regarding its independent medical review contractor or the credentials of reviewers.

We request that OIG provide additional information regarding its review. For example, OIG has not identified the "independent medical record review contractor." Given the importance of this audit, we believe we have the right to know who is performing the review so we can evaluate whether there is a conflict of interest, assess the contractor's credentials, coding policies, procedures, and training, and see if the positions taken are consistent with prior work undertaken by the contractor, or statements made by it.

Further, Cigna received only the "final" determination by the medical record review contractor. The Draft Report indicates, however, that there were two or three levels of review. We believe it is important for us to be able to evaluate the results at each level, as the subjective nature of coding determinations would be revealed by differing conclusions among contractor personnel. It also does not appear the individuals conducting each level of review were consistently subject to inter-rater reliability ("IRR") (which we believe to be a standard practice in CMS audits). If they were subject to IRR, we should have the ability to evaluate the results of such reviews. We believe these issues affect our appeal rights under 42 C.F.R. § 422.311 and should be disclosed pursuant to the Data Quality Act and generally accepted audit practices.

ii. OIG did not provide the coding and document standards applied during its review.

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MAOs, and their network providers, are expected to submit diagnosis codes in accordance with ICD-10 coding guidelines. But, because of the lack of specificity, CMS has directed providers and plans to rely on coding and documentation guidance from industry experts such as the American Health Information Management Association (AHIMA), the American Medical Association (AMA), the American Hospital Association (AHA), and the American Academy of Professional Coders (AAPC). The scope of these resources is quite broad, they are not always consistent with one another, and they change over time. For example, while ICD-10 greatly increased the codes and descriptive nature of such codes when compared to ICD-9, ICD-10 still does not have a code for every specific diagnosis that a provider may make. There are many times where providers must decide whether the medical diagnosis that they are making aligns with one ICD-10 versus another, and coding sources do not consistently align the same diagnosis with the same ICD-10. Further, the sources that CMS recommends providers rely on often do not respond to questions in a timely manner (e.g., the AHA Coding Clinic, a well-respected source, takes more than six months to respond). Because of these inconsistencies and variations, OIG should identify the specific coding and documentation standards that were used to evaluate the targeted high-risk diagnoses, as required by relevant auditing standards.

iii. Any coding and documentation standards applied during OIG's review were not validly established.

Even if OIG were to provide its coding and document standards, any standards applied during OIG's review were not validly established. The Medicare statute provides that any "policy" that "establishes or changes a substantive legal standard governing ... payment" must be established through notice and comment rulemaking.^{21/} The Supreme Court has explained that this obligation is broad and is likely to invalidate many policies found only in the Medicare manuals.^{22/} The HHS Office of General Counsel has further advised that, when a Medicare manual "set[s] forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because ... it was not validly issued."^{23/} In late 2020, HHS promulgated regulations stating that a component of HHS may not "use any guidance" to compel regulated entities "to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation."^{24/}

As applied to this audit, the coding and documentation standards are offered as the difference between valid risk adjustment payments and alleged overpayments. The audit uses sub-regulatory standards to define the scope of Cigna's entitlement to retain risk adjustment payments from CMS. CMS indicated in a 2018 proposed rule that the RADV coding and documentation guidance defines "the

^{21/} 42 U.S.C. § 1395hh(a)(2). The APA requires that all substantive rules be established through notice and comment. 5 U.S.C. § 553. However, because the notice and comment obligation imposed by the Medicare statute is broader than the equivalent APA requirement, see generally *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), we focus on the Medicare statute.

^{22/} See *Allina Health*, 139 S. Ct. at 1814.

^{23/} Memorandum from Kelly M. Cleary, *Impact of Allina on Medicare Payment Rules*, 2 (Oct. 31, 2019); see also, e.g., *Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916 (E.D. Pa. 2019).

^{24/} 45 C.F.R. § 1.3(a)(2). Although HHS has proposed to rescind this regulation, it has not finalized that proposal, and the regulation therefore remains binding on the agency.

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payment standard" for MA risk adjustment payments.^{25/} To be valid, that standard must be established through notice and comment.

The notice and comment issue is made more significant by the fact that many aspects of the payment standard are defined by private entities. The ICD-CM coding guidelines are a core RADV requirement. Those guidelines are established jointly by CMS and two private entities (the AHA and AHIMA) through a largely closed process that does not involve notice and comment. As noted above, the RADV process also relies on publications from the AMA, AHIMA, the AAPC, and others, which do not involve public input, are not always consistent with each other, and change without notice. The Medicare statute and the APA do not allow CMS to delegate its responsibility to establish risk adjustment standards to private, non-governmental entities.^{26/} OIG's potential reliance on these standards is improper for all of the reasons stated.

iv. OIG's narrowly defined documentation requirements conflicted with OIG's sampling methodology such that records that would substantiate a diagnosis were not acceptable if outside of the narrow time frame of the audit.

For many of the targeted high-risk diagnoses, OIG's determining factor for whether such diagnosis should be in the sample was whether a subsequent or previous claim or diagnosis was submitted to the MAO and then to CMS. For example:

- Diagnoses for lung, breast, colon, and prostate cancer were considered suspect by OIG and therefore included in the potential sample, if CMS had not received evidence of "surgical therapy, radiation treatments, or chemotherapy treatment drugs administered within a 6-month period before or after the diagnosis."
- Acute heart attack diagnoses from outpatient providers were included in the potential sample if the diagnosis was not also reported from an inpatient hospital encounter either 60 days prior or after the diagnosis in question.
- Acute stroke diagnoses from outpatient providers were included in the potential sample if the diagnosis was not also reported by either another outpatient encounter or an inpatient encounter.
- Both major depressive disorder and embolism diagnoses were included in the potential sample if the diagnosed member did not fill a prescription drug associated with the condition through their Medicare Part D plan, with no specific time frame set forth.

OIG developed the parameters for when a diagnosis would be considered a high risk of noncompliance; however, OIG's documentation requirements relating to timing prohibited Cigna from submitting documentation that would substantiate a diagnosis. For example, records for members diagnosed with cancer in late 2016 who later sought treatment in early 2017 would not be reviewed by OIG even though such treatment was obtained within OIG's arbitrarily defined 6-month window. Further,

^{25/} See 83 Fed. Reg. 54928, 55041 (Nov. 1, 2018) ("If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met.").

^{26/} See, e.g., *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565-56 (D.C. Cir. 2004) ("subdelegations to outside parties are assumed to be improper absent an affirmative showing of congressional authorization").

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for members who were diagnosed with major depressive disorder or embolism late in a plan year and filled a related prescription early in the following plan year, records for such a prescription fill would both be time barred as being outside of the audit time period and not considered to be a valid source of risk adjustment data. This disregard of documentation and support for a diagnosis code based on an arbitrary date range in such a targeted audit ignores the fact that for MA members and their plan providers, the end of a calendar year does not change how providers deliver care. Further, as discussed directly below, when, where or whether a member elects to obtain follow-up care is not a valid basis to determine that a documented diagnosis is not supported.

v. OIG Determining Whether a Diagnosis is Valid Based on What a Provider Decides to Recommend to a Member, Whether a Member Decides to Seek Recommended Treatment, or Where or How a Member Seeks Recommended Treatment is Inherently Problematic and Arbitrary.

We know of no CMS guidance suggesting that the health status of a member that is reported through a diagnosis submitted by their treating provider is disproved solely by whether a provider prescribes a certain course of treatment or whether a member elects to follow through with such treatment. We believe that, absent indicia of fraud, the treating provider's notation of a diagnosis should be given wide latitude and deference, especially when significant time has passed from when the patient was seen and when the OIG reviewer evaluates the medical record. And we do not believe "indicia of fraud" includes a provider deciding to not prescribe treatment identified by OIG as being appropriate or by a member electing to not follow up. By applying these arbitrary standards of medical practice and "health status," OIG seeks to supplant its medical knowledge years later for that of members' treating providers.

As we discussed, OIG identified diagnoses that were at high risk of noncompliance by consulting with medical professionals at an MAC. How are a non-clinical federal agency and a randomly selected federal contractor well-suited to determine clinical guidelines that will identify whether a member has a given diagnosis assigned by the member's treating provider? If a member's provider decides not to prescribe a drug because such drug would interact poorly with the member's other drugs, this audit would identify the diagnosis as at high risk of noncompliance based on the provider's clinical decision making. Identifying such diagnoses as unsupported would be clinically inaccurate and such a finding would result in OIG and its MAC consultant supplanting the provider's clinical decision making with their own. OIG does not have this authority.

Further, if a provider counseled a member on treatment options all of the following common situations would result in the OIG considering the provider's diagnosis as being at "high risk of noncompliance:" (1) the member elected to not follow up, (2) the member was not able to afford the cost share charged for their prescribed prescription so they did not fill the prescription, (3) the member elected to fill a prescription through their Veterans Affairs ("VA") pharmacy, (4) the member paid cash and used a discount card (e.g., GoodRx, SingleCare, etc.), and (5) the member elected to use widely available manufacturer coupons (which continue to be offered by manufacturers to Part D members, sometimes with OIG's approval²⁷⁷). All of these situations result in an MA plan not receiving a claim or PDE for the

²⁷⁷ See e.g., OIG Advisory Opinion No. 14-05 (Jul. 21, 2014) (approving manufacturer's direct-to-patient products sales program that offers a brand name drug (for which there is a generic equivalent) at a discount much lower than the manufacturer's wholesale acquisition cost, allowing the patient to pay for the drug out of pocket with no charge to the insurer); OIG Advisory Opinion No. 07-04 (Mar. 30, 2007) (approving pharmaceutical company patient assistance program that provides

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member filling a prescribed drug, but do not suggest that a member does not have a diagnosis that their provider assigned to them. Identifying such diagnoses as unsupported would be clinically inaccurate and such a finding would result in OIG and its MAC consultant supplanting the member's personal choices with their own. OIG does not have this authority.

For example, Cigna member assigned as "audit sample #11-280" was diagnosed with prostate cancer in 2014. The member was informed of the diagnosis and discussed treatment options with his provider, and elected to undergo watchful waiting with monitoring of his PSA levels. In 2015, the provider continued to monitor the member's PSA levels in June and documented in September that the member will continue to be monitored. Current American Society of Clinical Oncology guidelines state that men with low-volume Gleason prostate cancer (which this member had) may be considered for active surveillance, and that is what the member and his provider elected. The OIG invalidated the diagnosis of prostate cancer. Identifying such a diagnosis as unsupported was clinically inaccurate, as summarized on **Exhibit A**, and this finding results in OIG and its MAC consultant supplanting the member's personal choices with their own.

Additionally, OIG ignored information regarding members seeking care outside of the Medicare program. The most blatant example of this is care provided through the VA. Cigna, like many MAOs, offers MA plans to many veterans who receive benefits from the Veterans Health Administration as well as an MA plan. Such members may elect to see providers under either benefit. Under OIG's audit, diagnoses that are documented by the member's provider are at "high risk of noncompliance" if such member seeks follow up care at the VA, because such care does not produce a Medicare claim. Invalidating on such basis is clinically inaccurate.

For example, Cigna member assigned as "audit sample #11-292" was diagnosed with and treated for prostate cancer in 2006, and continued to be prescribed Lupron for his prostate cancer in 2016. Further, in 2016, the member was prescribed an additional drug to treat prostate cancer (Casodex) and his treating provider noted that that member was obtaining oncology follow-up care through the VA. As OIG is well aware,^{28/} Lupron is a widely used drug to treat prostate cancer, covered under a member's medical benefit and not under Part D. Even though the member was actively being treated with Lupron and Casodex, and was obtaining oncology follow-up care through the VA, OIG invalidated the diagnosis. Identifying such a diagnosis as unsupported was clinically inaccurate, as summarized on **Exhibit A**.

vi. Cigna understands some of the coding and documentation standards applied during this audit are inconsistent with the statute and/or medical practice.

As the Draft Report recognizes, the Medicare statute requires that risk adjustment payments be made based on the "health status" of each enrolled member.^{29/} The risk adjustment system relies on the ICD-CM diagnosis codes only as a proxy for such statuses.^{30/} Often, however, the coding and documentation standards published by the AHA, AHIMA, the AAPC, etc. turn on formalities or criteria that do not address the beneficiary's health status. Such standards also have the effect of preventing Cigna and other plans from presenting important, credible evidence regarding their members' health statuses.

free outpatient prescription drugs to financially needy Part D enrollees entirely outside of the Part D benefit); OIG Advisory Opinion No. 06-04 (Apr. 18, 2006) (same).

^{28/} See OIG, *Medicare Reimbursement for Lupron*, OIG-03-03-00250, January 2004.

^{29/} See Draft Report at 1, 2, 3, and 5.

^{30/} See *Id.* at 1 ("To determine the health status of enrollees, CMS relies on ... diagnosis codes ...").

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Cigna has submitted detailed comments to OIG and CMS previously relating to examples of how the coding and documentation standards applied during RADV audits, including this type of audit, are inconsistent with the statute that establishes payment based on health status. Some examples include the limited definition of a "medical record,"^{31/} limitations on physician^{32/} and provider and source types,^{33/} the signature requirement,^{34/} exclusion of attestations for all matters other than signatures, and inaccurate clinical guidelines.^{35/}

In this specific audit, the exclusion of prescription data as a validation source when OIG itself used the lack of prescription data to determine whether certain diagnoses were considered high-risk for noncompliance, is arbitrary and further demonstrates the inaccuracy of the audit results. Additionally, the fact that RADV guidance currently precludes MAOs from using prescription data to establish beneficiary health status, even though the relationship between some medications and health status is clear (e.g., insulin is prescribed for diabetes), is particularly problematic given that the RADV rules for the Affordable Care Act expressly allow for the use of prescription data in risk adjustment.^{36/}

We believe many of the above issues would have been addressed if the RADV rules and payment standards for MA had been established through notice and comment, and OIG had followed them. As the Supreme Court recently explained: "Notice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision."^{37/} The partnership between CMS and committed plans, like Cigna, works best when policy is the product of full and frank dialogue as occurs in notice and comment rulemaking. Because this dialogue has not taken place as it applies to documentation standards, it is inappropriate for OIG to rely on such standards in this audit.

d. Extrapolation of Potential Overpayments is Inappropriate and Not Authorized by Congress

We do not believe that extrapolation has been authorized by Congress in this situation. Part C of the Medicare statute does not authorize extrapolated recoveries and, in the absence of explicit Congressional authorization, we believe extrapolation is not available.^{38/}

Significantly, Congress addressed extrapolation in Part E of the Medicare statute. That provision states that an audit involving a contractor "may not use extrapolation... unless the Secretary determines that—(A) there is a sustained or high level of payment error; or (B) documented educational intervention

^{31/} CMS, *Risk Adjustment User Group 2007/2008 – February 2008 Questions & Answers* (Feb. 13, 2008).

^{32/} Gregory C. Pope, et al., *Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment – Final Report*, ES-11 to ES-13 (Dec. 21, 2000) (prepared for the Health Care Financing Administration pursuant to Contract No. 500-95-048) ("Final HCC Report").

^{33/} *Id.* at 5-6 and 5-8.

^{34/} See, e.g., 74 Fed. Reg. 54634, 54675 (Oct. 22, 2009).

^{35/} Compare AHA Coding Clinic 3Q1993, with AHA Coding Clinic Q1 2019.

^{36/} HHS, *Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCLs) to HHS Drug Classes (RXC) Crosswalk* (Sept. 18, 2017).

^{37/} *Allina Health*, 139 S. Ct. at 1816.

^{38/} We note that CMS previously told Congress that it lacked such authority and unsuccessfully requested a legislative change to authorize extrapolation in RADV audits. See Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations for 2011: Hearings Before the H.R. Comm. on Appropriations, 111th Cong. pt. 7 at 14 (2010) (written statement of William Corr, Deputy Sec'y, Dep't of Health & Human Servs.); see also Ctrs. for Medicare & Medicaid Servs., Dep't of Health & Human Servs., *Fiscal Year 2011 Performance Budget 177* (2010) (describing proposal that would "[c]larify in statute that CMS can extrapolate the error rate found in the risk adjustment validation (RADV) audits to the entire MA plan payment for a given year when recouping overpayments"). We believe this reflects an acknowledgement that CMS does not have the authority. See *U.S. House of Representatives v. Burwell*, 185 F. Supp. 3d 165, 186 (D.D.C. 2016).

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has failed to correct the payment error.”^{39/} Neither of these conditions have been met here. Because of the many faults in the sampling and review methodology of this audit, discussed in detail above, we believe it is not possible to accurately identify a sustained or high level of payment error with the targeted methodology used by OIG in this audit. Further, Cigna did not fail to correct a payment error after receiving documented educational intervention by OIG or CMS. Instead, five to six years after diagnoses were reported by treating providers, OIG elected to work with an undisclosed MAC to develop a list of diagnoses and criteria for such diagnoses that OIG and the MAC determined were high risk. Cigna only received notice of what conditions OIG and the MAC considered high risk when it received the audit notice in 2019.^{40/}

Even if extrapolation were permitted, the methodology used would have to adhere to the final methodology established by CMS. In 2010, CMS created regulations governing the conduct of RADV audits using the Secretary’s authority to establish MA program standards.^{41/} At the time, the regulations applied only to audits conducted by CMS.^{42/} Four years later, however, the regulations were amended to apply to all RADV audits conducted by any component of HHS, including OIG.^{43/} The preamble explained that the amendments were intended to clarify that the RADV regulations applied to RADV audits conducted by OIG pursuant to its authority under the Inspector General Act.^{44/} The preamble also addressed the statistical sampling and extrapolation methodologies to be used during such audits.^{45/} It stated that audits would be conducted using the methodology published by CMS in February 2012,^{46/} unless an updated methodology was published after opportunity for stakeholder comment.^{47/} To date, no update has been made to that methodology.^{48/} Even to the extent that extrapolation has been authorized by statute (which we believe is not the case), the 2014 rulemaking made the February 2012 methodology binding for all RADV audits.^{49/} And, as discussed further below, the February 2012 methodology adopted the use of a “FFS adjuster” to function as “an offset” to “account[] for the fact that the documentation standard used in RADV audits ... is different from the documentation standard used” in the FFS program.^{50/} OIG’s proposed extrapolation disregarded this necessary adjustment.

^{39/} 42 U.S.C. § 1395ddd(f)(3).

^{40/} As OIG is aware, while Cigna received notice of the audit in 2019, the audit was postponed because of the COVID-10 Public Health Emergency and the burden that record collection would place on health professionals during the PHE.

^{41/} See 74 Fed. Reg. 54634, 54674-75 (Oct. 22, 2009) (explaining that the RADV appeals process was created pursuant to section 1856(b)(1) of the Social Security Act); 75 Fed. Reg. 19678, 19742 (Apr. 15, 2010) (same).

^{42/} See 75 Fed. Reg. at 19804 (former 42 C.F.R. § 422.2: the term RADV audit meant “a CMS-administered payment audit”); *id.* at 19806 (former 42 C.F.R. § 422.311(a): “CMS annually conducts RADV audits ...”). We note, however, that OIG generally adhered to CMS’s RADV policies in place at that time.

^{43/} See 42 C.F.R. § 422.2 (RADV audit means “a payment audit of a MA organization administered by the Secretary”); 42 C.F.R. § 422.311(a) (“the Secretary annually conducts RADV audits ...”).

^{44/} See 79 Fed. Reg. 29843, 29934 (May 23, 2014).

^{45/} See *id.* at 29927-28 (discussing the Final RADV Methodology).

^{46/} CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* (Feb. 24, 2012) (“Final RADV Methodology”).

^{47/} See *supra* n.45.

^{48/} We are, of course, aware that CMS published a proposal to change the final methodology in November 2018. As discussed below, however, the February 2012 methodology remains binding on OIG until a new approach is finalized and takes effect.

^{49/} We note that the decision by HHS to standardize all RADV audits is sound policy. It would be inconsistent with the APA for different components of HHS to conduct the same type of audits using different methodologies. This would raise the possibility of identically situated MA plans receiving different audit outcomes based on which HHS component conducted the audit.

^{50/} Final RADV Methodology at 4-5.

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OIG's audit was designed to analyze targeted high-risk diagnoses that OIG expected to fail. As discussed earlier, this process is contrary to the data validation processes set forth in the February 2012 methodology. We are not aware of an analysis establishing that OIG's approach is superior to the final audit methodology that HHS adopted through the 2014 rulemaking, and warrants extrapolation. For these reasons, extrapolation is inappropriate and unauthorized by Congress.

e. *OIG's Estimated and Extrapolated Repayment Amount is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence*

Statute and regulation require CMS to pay MAOs an amount that is "actuarially equivalent" to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MAO's enrollees.^{53/} CMS does this by making risk-adjusted payments to MAOs that are based on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with differing health statuses.^{54/}

Actuarial Standard of Practice 45, section 3.2 requires that the "type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model."^{55/} In 2011, the American Academy of Actuaries wrote that the inconsistency between the unaudited data to create the HCC model and extrapolation in RADV audits "not only creates uncertainty, it also may create systematic underpayment, undermining the purpose of the risk-adjustment system and potentially in payment inequities."^{56/} More recently, most qualified statisticians and actuaries to consider the question concluded that a significant FFS adjuster was essential to meeting the statutory requirement of actuarial equivalence.^{55/}

CMS developed the MA risk adjustment model using FFS claims data from the traditional Medicare program. The FFS claims data is unaudited and contains numerous errors that CMS must account for when determining whether similar errors for MA enrollees resulted in an overpayment. In 2012, CMS published a notice stating that it would incorporate the FFS error rate into its methodology for calculating recovery amounts for unsupported HCCs identified during its RADV audits. CMS said that it would first identify a "payment recovery amount" based on the value of supported and unsupported HCCs identified during its review.^{56/} Then, "to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service

^{53/} 42 U.S.C. § 1395w-24(a)(5)(A), (a)(6)(A)(i)-(iii).

^{54/} 42 U.S.C. § 1395w-23(b)(4)(C), (D).

^{55/} CMS is required to follow actuarial standards. See HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, Part II: HHS Agency Responsibilities and Guide Lines, E. Centers for Medicare & Medicaid Services, V. Agency Quality Assurance Policies, Standards and Processes (Oct. 1, 2002).

^{56/} Letter from Thomas F. Wildsmith, American Academy of Actuaries, to Cheryl Rice, Acting Director, Medicare Plan Payment Group, Re: Comment on RADV Sampling and Error Calculation Methodology, 2 (Jan 21, 2011).

^{55/} See, e.g., Avalere Health, Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment (Mar. 2019); Avalere Health, Impact of Eliminating the FFS Adjuster May Vary Based on Plan Enrollee Characteristics (Aug. 21, 2019); Sean Creighton, The FFS Adjuster matters for accurate Medicare Advantage payment: An examination of the methodology and evidence behind a regulatory proposal to eliminate the adjuster, RISE Health (Dec. 11, 2019); Rob Pipich, Milliman, Medicare Advantage RADV FFS adjuster: White paper (Aug. 23, 2019); Matthew G. Mercurio, Response to CMS "Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits" Announcement (Aug. 27, 2019); Bo Martin, Ankura Consulting Group, Comment Regarding CMS's Proposals Not to Implement a "Fee-for-Service Adjuster" For RADV Audits and To Implement a Sub-Cohort Audit Method (Aug. 27, 2019); Ross Winkelman, Wakely Consulting Group, Actuarial Report on CMS' November 1, 2018 Proposed Rule (Aug. 27, 2019); Julia Lambert, Wakely Consulting Group, Actuarial Report on Medicare Advantage FFS Adjuster (Aug. 28, 2019); Stefan Boedeker, Comment on The Centers for Medicare and Medicaid Services Proposed Rule (Aug. 28, 2019).

^{56/} CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits, at 3-4 (Feb. 24, 2012).

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Adjuster ("FFS Adjuster") amount as an offset to the preliminary recovery amount.^{57/} The FFS Adjuster would be based "on a RADV-like review of records submitted to support [traditional Medicare] claims data."^{57/}

CMS tried to shift away from this principle in 2014 when it implemented a rule stating that MAOs receive an "overpayment" when they submit any diagnosis code to CMS that is not sufficiently supported by underlying medical records, without adjusting for error rates in traditional Medicare data.^{58/} This rule was struck down when a federal district court found that it violated the actuarial equivalence mandate by defining "overpayment" as the payment of funds to MAOs based on unsupported diagnosis codes without applying a FFS Adjuster or other mechanism to maintain actuarial equivalence.^{59/} Although the district court's ruling was partially overturned by the D.C. Circuit's finding that actuarial equivalence does not apply to the overpayment rule,^{60/} the D.C. Circuit itself distinguished the overpayment rule from the actuarial equivalence standard that applies to CMS' calculation and disbursement of monthly payments to MAOs^{61/} and from RADV audits, which more broadly impact payments to MAOs because such audits are designed to require repayment for all unsupported diagnosis codes.^{62/}

Amidst this litigation, CMS issued a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs.^{63/} Many MAOs and numerous other parties, including actuarial and statistical experts, submitted comments to CMS explaining that the 2018 proposal does not satisfy the actuarial equivalence requirement. CMS was required to take action on this rule in November 2021 but instead, CMS extended its deadline for an additional year to November 2022 as it continues to contemplate how to handle this significant issue and potential significant change in practice and policy.^{64/} As a result, the proposed rule remains subject to the administrative rulemaking process.

The actuarial equivalence requirement extends to OIG's estimation and extrapolation of a potential "overpayment" amount in this audit. OIG did not apply a FFS Adjuster to account for errors in the data used to create the risk adjustment payment model. The lack of FFS Adjuster violates important principles of administrative law, in particular the requirement for prospective notice and comment rulemaking. It also would mark a departure from OIG's past audit practices. In prior contract-level RADV audits, OIG

^{57/} *Id.*

^{58/} See 79 Fed. Reg. 29844, 29921 (May 23, 2014), implementing 42 C.F.R. § 422.326.

^{59/} *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 187–90 (D.D.C. 2018). The court concluded that by measuring overpayments without adjusting for error rates in traditional Medicare, "The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed." *Id.* at 187. This position was reaffirmed on January 27, 2020 when the same court denied the government's request to reconsider the court's prior holding. *Azar*, No. 16-cv-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

^{60/} See *UnitedHealthcare Inc. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), cert. denied, No. 21-1140, 2022 WL 2203436 (U.S. June 21, 2022).

^{61/} See *id.* at 884.

^{62/} See *id.* at 892. Cigna does not agree with the D.C. Circuit's decision regarding the overpayment rule because actuarial equivalence in the MA risk adjustment system is statutorily required and cannot be achieved or maintained without it applying to all payment contexts within the risk adjustment system, but in any event, the D.C. Circuit's decision by its own terms was limited to the overpayment rule and "expresses no opinion" with respect to actuarial equivalence in RADV audits. *Id.* at 893 n.1.

^{63/} 83 Fed. Reg. 54982, 55041 (Nov. 1, 2018).

^{64/} See CMS, *Extension of Timeline To Finalize a Rulemaking*, 86 Fed. Reg. 58,245.

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acknowledged that the actuarial equivalence requirement made it inappropriate to estimate an extrapolated audit liability in the absence of a FFS Adjuster:

Although an analysis to determine the potential impact of error rates inherent in FFS data on MA payments was beyond the scope of our audit, we acknowledge that CMS is studying this issue and its potential impact on audits of [MAOs]. Therefore, because of the potential impact of these error rates on the CMS model that we used to recalculate MA payments for the beneficiaries in our sample, we (1) modified one recommendation to have [the MAO] refund only the overpayments identified for the sampled beneficiaries rather than refund the estimated overpayments and (2) added a recommendation that [the MAO] work with CMS to determine the correct contract-level adjustments for the estimated overpayments.^{65/}

OIG made similar statements in two prior audits involving Cigna affiliates.^{66/} Because the relevant circumstances have not changed since those prior audits, the APA requires, in our view, that OIG follow the same approach in this audit.^{67/}

Considering this history, it is not possible for OIG to determine whether Cigna received an overpayment without establishing an actuarially sound methodology that takes into account diagnosis coding errors in the FFS data. As a result, OIG's estimated and extrapolated repayment amount is both legally and actuarially unsound.

f. *OIG's Extrapolated Repayment Amount Relies on a Confidence Interval that is Too Conservative and Inconsistent with CMS RADV Audit Practice*

OIG acknowledged it was taking a conservative position by using the lower limit of a two-sided 90-percent confidence interval to calculate the extrapolated repayment amount, rather than the statistically valid and more robust practice of using the lower limit of a 95-percent or 99-percent confidence interval.^{68/} OIG provides no explanation for its decision to do so, which is unusual because CMS uses the lower limit of a 99-percent confidence interval when calculating extrapolated repayment amounts for its Medicare Advantage RADV audits.

For the reasons discussed here, we believe that OIG's estimated and extrapolated repayment amounts are incorrect. We respectfully request OIG withdraw its recommended repayment amount and recalculate it to (a) address errors in OIG's analysis of certain enrollee-years; (b) include previously unreported diagnoses; (c) remove the impact of underlying biases; (d) disregard unwarranted extrapolation, and (d) ensure actuarial equivalence.

^{65/} OIG, *Risk Adjustment Data Validation of Payments Made to PacificCare of California for Calendar Year 2007* (Contract Number H0543), A-09-09-00045, ii-iii (Nov. 2012).

^{66/} OIG, *Bravo Health Pennsylvania, Inc. (Contract H3949), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007*, A-03-09-00003, 7 (Sept. 2013); OIG, *Cigna Healthcare of Arizona, Inc. (Contract H0354), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007*, A-0710-01082, iii (May 2013).

^{67/} See, e.g., *Bracca Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 31 (D.D.C. 1997).

^{68/} Draft Report at 8.

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III. Cigna Does Not Concur with OIG's Recommendation that Cigna Conduct Additional Auditing Related to the High-Risk Diagnoses Included in the Audit and Respectfully Requests that OIG Update its Draft Report to Withdraw this Recommendation

OIG recommends that Cigna "identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]"^{69/} However, MA regulations do not require the sort of audits that OIG recommends and do not require data perfection. By making this recommendation, OIG is holding MAOs to standards that are unknown, vague, and nonexistent. Further, if Cigna undertook an audit similar to OIG's, it could not result in "risk adjustment payment integrity and accuracy"^{70/} because Cigna would not be permitted to submit diagnosis codes that it determined were supported but not previously submitted given that all plan years other than 2021, and 2022 are closed for resubmissions.

As discussed above in Section I, a payment audit designed to target errors without considering and recognizing diagnoses that are supported but not previously submitted, does not ensure payment accuracy and is improper. For OIG to recommend that Cigna repeat such an audit across multiple years on its own is excessively penal. We respectfully request that OIG withdraw its recommendation that Cigna conduct additional audits.

IV. Cigna Does Not Concur with OIG's Recommendation that Cigna Examine Existing Compliance Procedures and Respectfully Requests that OIG Update its Draft Report and Withdraw its Recommendation

OIG recommends that Cigna "continue its examination of its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements...and take the necessary steps to enhance those procedures."^{71/}

However, Cigna has a strong and effective compliance program that is designed to comply with all relevant legal and regulatory requirements. In fact, in 2021, when conducting a contract-level RADV audit of H5410, OIG observed that Cigna "ha[s] a compliance program to ensure that [it] submitted accurate diagnosis codes for use in CMS' risk adjustment program" and that our "policies and procedures [are] generally effective." Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to Cigna's compliance program.

During its audit, OIG reviewed Cigna's diagnosis data from 2015 and 2016, and issued a finding regarding the overall effectiveness of policies and procedures that are in place today. But as part of its ongoing efforts to further strengthen its compliance program, Cigna has made numerous changes to that program over the last several years. This is standard practice for a company like Cigna. The current policies and procedures have no bearing on 2015 and 2016 dates of service and as such, there is no basis for findings related to Cigna's current compliance program. It is beyond the scope of OIG's audit to make recommendations related to Cigna's current compliance activities.

OIG's audit was not designed to determine whether Cigna's current practices would have addressed the issues potentially identified in 2015/2016 data. Cigna's current compliance program

^{69/} Draft Report at 18.

^{70/} See 42 C.F.R. §422.311(a).

^{71/} Draft Report at 18.

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recently received positive feedback from both CMS and OIG. Cigna's recent contract-level RADV in Florida found a 97% coding accuracy rate and included positive statements regarding Cigna's compliance program. Also in 2021, Cigna underwent a CMS Program Audit and there were no findings related to Cigna's compliance program.

The Draft Report cites 42 C.F.R. § 422.503(b)(vi), which requires organizations to adopt an "effective" compliance program. But, as stated above, OIG has "recognize[d that] the implementation of an effective compliance program may not entirely eliminate fraud, abuse and waste from an organization."^{72/} OIG's Draft Report makes two potentially misleading statements in this respect.^{73/}

First, the Draft Report states that "[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS."^{74/} However, this statement is incomplete. CMS gives MAOs broad discretion to design their own compliance and risk adjustment data accuracy programs and has declined to require MAOs to implement any specific oversight measures.

Second, the Draft Report also states that federal regulations "state that [MAOs] are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes."^{75/} This statement is again incomplete because it fails to account for the qualified attestation standard that CMS explicitly adopted. MAOs are not held to a standard of guaranteeing the accuracy of the risk adjustment data that is submitted. Instead, MAOs have to attest that the submissions are accurate to their best knowledge, information and belief.

Relying on these misleading broad characterizations of CMS regulations, OIG has inappropriately expanded the MA compliance program requirements. CMS is undoubtedly aware of industry-wide trends related to the high-risk diagnoses audited by OIG. Nevertheless, CMS has not opted to take any action to implement regulations or additional requirements, let alone the broad recommendations OIG makes in its Draft Report. We observe again that we have shared details regarding our risk adjustment policies and procedures with CMS many times over the years. CMS has not asked us to change our policies or procedures or identified any specific areas that require additional enhancements. For this reason, too, we think that the second recommendation should be withdrawn.

OIG's recommendations based on 2015 and 2016 dates of service also fail to consider changes in medical documentation practices that have occurred over the last 6 to 7 years. During that time, MAOs, including Cigna, have put forth significant effort to educate providers regarding the appropriate use of some of the specific codes targeted by OIG in this audit (e.g., when to use acute stroke versus history of stroke, heart attack versus history of a heart attack). OIG's recommendation ignores this effort and the likely effect of this effort on coding in 2022.

Additionally, at the end of 2015, which was after many of the service dates at issue in the audit, providers transitioned from ICD-9 to ICD-10 coding. The more specific diagnosis codes available under ICD-10 changed physician diagnosis coding practices so that they were more easily able to identify "history of" codes as being the appropriate code to report for their applicable patients. As a result, the related

^{72/} 64 Fed. Reg. 61894, 61895 (Nov. 15, 1999).

^{73/} 64 Fed. Reg. at 61900. The Draft Report also appears to suggest that perfection is required by 42 C.F.R. § 422.310(d)(1), which states that MA organizations "must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards." However, 310(d)(1) does not establish or reference any standards that require 100% accuracy in order for a compliance program to be effective.

^{74/} Draft Report at 9.

^{75/} Draft Report at 8.

RESPONSE TO DRAFT AUDIT REPORT A-07-19-01192

compliance functions required today are entirely different from those needed to ensure compliance under ICD-9.

It also seems that, simply by virtue of the fact that it discovered supposedly unsupported diagnosis codes through its targeted audit, OIG believes Cigna's compliance policies and procedures must not have been effective. But as we have discussed throughout our comments, perfection is not the standard that CMS imposes and OIG has long recognized that. The fact that OIG identified supposedly unsupported diagnoses, through its skewed audit sampling and review methodology, does not indicate that Cigna's compliance program is ineffective, particularly when measured by MA program guidance.

V. Conclusion

For the reasons described, we believe that the overall intent and design of OIG's audit is contrary to MA regulations and the goal of payment accuracy audits. Cigna respectfully requests OIG withdraw its recommendations and update its Draft Report to account for the inherent bias in such a targeted audit. Cigna further requests that OIG revise its Draft Report and withdraw its recommendations that Cigna (a) refund to the Federal Government \$6,281,045 of estimated overpayments, (b) identify similar instances of noncompliance outside of the audit period and refund any resulting overpayments, and (c) examine existing compliance procedures to identify where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements.

EXHIBIT D-47

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE ADVANTAGE
COMPLIANCE AUDIT OF SPECIFIC
DIAGNOSIS CODES THAT
HEALTHFIRST HEALTH
PLAN, INC.,
(CONTRACT H3359)
SUBMITTED TO CMS**

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for Audit Services

January 2022
A-02-18-01029

Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: January 2022
Report No. A-02-18-01029

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations according to a system of risk adjustment that depends on the health status of each enrollee. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources than to healthier enrollees, who would be expected to require fewer health care resources.

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

For this audit, we reviewed one MA organization, Healthfirst Health Plan, Inc. (Healthfirst), and focused on seven groups of high-risk diagnosis codes. Our objective was to determine whether selected diagnosis codes that Healthfirst submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

How OIG Did This Audit

We sampled 240 unique enrollee-years with the high-risk diagnosis codes for which Healthfirst received higher payments for 2015 through 2016. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$787,928.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS

What OIG Found

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Healthfirst submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 155 of the 240 enrollee-years, the diagnosis codes that Healthfirst submitted to CMS were not supported in the medical records and resulted in net overpayments of \$516,509.

These errors occurred because the policies and procedures that Healthfirst had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that Healthfirst received at least \$5.2 million in net overpayments for these high-risk diagnosis codes in 2015 and 2016.

What OIG Recommends and Healthfirst Comments

We made a series of recommendations to Healthfirst, including that it: refund to the Federal Government the \$5.2 million of net overpayments; identify, for the diagnosis codes described in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure diagnosis codes that are at high risk for being miscoded comply with Federal requirements and take the necessary steps to enhance those procedures.

Healthfirst objected to all of our recommendations; however, it did not object to any of the errors we identified. Instead, Healthfirst requested we limit our recommended recovery to the overpayments identified in our sample—not the extrapolated value of those overpayments. Healthfirst stated that OIG lacked the authority to use extrapolation to recommend a repayment and disagreed with our extrapolation methodology. It also stated that our audit methodology did not account for a payment principle known as "actuarial equivalence" and disagreed that it should perform audits of high-risk diagnoses or enhance its compliance program. After reviewing Healthfirst's comments, we maintain that our findings and recommendations are valid. No statutory authority limits our use of extrapolation to estimate a recovery and we correctly applied Federal requirements underlying the MA program.

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INTRODUCTION

WHY WE DID THIS AUDIT

Under the Medicare Advantage (MA) program, the Centers for Medicare & Medicaid Services (CMS) makes monthly payments to MA organizations based in part on the characteristics of the enrollees being covered. Using a system of risk adjustment, CMS pays MA organizations the anticipated cost of providing Medicare benefits to a given enrollee, depending on such risk factors as the age, sex, and health status of that individual. Accordingly, MA organizations are paid more for providing benefits to enrollees with diagnoses associated with more intensive use of health care resources relative to healthier enrollees, who would be expected to require fewer health care resources. To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS.¹ We are auditing MA organizations because some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS.

This audit is part of a series of audits in which we are reviewing the accuracy of diagnosis codes that MA organizations submitted to CMS.² Using data mining techniques and considering discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. (For example, we consolidated 27 major depressive disorder diagnoses into 1 group.) This audit covered Healthfirst Health Plan, Inc. (Healthfirst),³ for contract number H3359⁴ and focused on seven groups of high-risk diagnosis codes for payment years 2015 and 2016.

OBJECTIVE

Our objective was to determine whether selected diagnosis codes that Healthfirst submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements.

¹ The providers code diagnoses using the International Classification of Diseases (ICD), Clinical Modification (CM), *Official Guidelines for Coding and Reporting* (ICD Coding Guidelines). The ICD is a coding system that is used by physicians and other health care providers to classify and code all diagnoses, symptoms, and procedures. Effective October 1, 2015, CMS transitioned from the ninth revision of the ICD coding guidelines (ICD-9-CM) to the tenth revision (ICD-10-CM). Each revision includes different diagnosis code sets.

² See Appendix B for a list of related Office of Inspector General reports.

³ Healthfirst Health Plan, Inc. is a subsidiary of Healthfirst, Inc.

⁴ All subsequent references to "Healthfirst" in this report refer solely to contract number H3359.

BACKGROUND

Medicare Advantage Program

The MA program offers beneficiaries managed care options by allowing them to enroll in private health care plans rather than having their care covered through Medicare's traditional fee-for-service program.⁵ Beneficiaries who enroll in these plans are known as enrollees. To provide benefits to enrollees, CMS contracts with MA organizations, which in turn contract with providers (including hospitals) and physicians.

Under the MA program, CMS makes advance payments each month to MA organizations for the expected costs of providing health care coverage to enrollees. These payments are not adjusted to reflect the actual costs that the organizations incurred for providing benefits and services. Thus, MA organizations will either realize profits if their actual costs of providing coverage are less than the CMS payments or incur losses if their costs exceed the CMS payments.

For 2019, CMS paid MA organizations \$273.8 billion, which represented 34 percent of all Medicare payments for that year.

Risk Adjustment Program

Federal requirements mandate that payments to MA organizations be based on the anticipated cost of providing Medicare benefits to a given enrollee and, in doing so, also account for variations in the demographic characteristics and health status of each enrollee.⁶

CMS uses two principal components to calculate the risk-adjusted payment that it will make to an MA organization for an enrollee: a base rate that CMS sets using bid amounts received from the MA organization and the risk score for that enrollee. These are described as follows:

- **Base rate:** Before the start of each year, each MA organization submits bids to CMS that reflect the MA organization's estimate of the monthly revenue required to cover an enrollee with an average risk profile.⁷ CMS compares each bid to a specific benchmark amount for each geographic area to determine the base rate that an MA organization is paid for each of its enrollees.⁸

⁵ The Balanced Budget Act of 1997, P.L. No. 105-33, as modified by section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act, P.L. No. 108-173, established the MA program.

⁶ The Social Security Act (the Act) §§ 1853(a)(1)(C) and (a)(3); 42 CFR § 422.308(c).

⁷ The Act § 1854(a)(6); 42 CFR § 422.254 *et seq.*

⁸ CMS's bid-benchmark comparison also determines whether the MA organization must offer supplemental benefits or must charge a basic beneficiary premium for the benefits.

- **Risk score:** A risk score is a relative measure that reflects the additional or reduced costs that each enrollee is expected to incur compared with the costs incurred by enrollees on average. CMS calculates risk scores based on an enrollee's health status (discussed below) and demographic characteristics (such as the enrollee's age and sex). This process results in an individualized risk score for each enrollee, which CMS calculates annually.

To determine an enrollee's health status for the purposes of calculating the risk score, CMS uses diagnoses that the enrollee receives from acceptable data sources, including certain physicians and hospitals. MA organizations collect the diagnosis codes that physicians document on the medical records and submit these codes to CMS. CMS then maps certain diagnosis codes, on the basis of similar clinical characteristics and severity and cost implications, into Hierarchical Condition Categories (HCCs).⁹ Each HCC has a factor (which is a numerical value) assigned to it for use in each enrollee's risk score.

As a part of the risk adjustment program, CMS consolidates certain HCCs into related-disease groups. Within each of these groups, CMS assigns an HCC for only the most severe manifestation of a disease in a related-disease group. Thus, if MA organizations submit diagnosis codes for an enrollee that map to more than one of the HCCs in a related-disease group, only the most severe HCC will be used in determining the enrollee's risk score.

For enrollees who have certain combinations of HCCs (in either the Version 12 model or the Version 22 model), CMS assigns a separate factor that further increases the risk score. CMS refers to these combinations as disease interactions. For example, if MA organizations submit diagnosis codes (in the Version 12 model) for an enrollee that map to the HCCs for acute stroke, acute myocardial infarction, and chronic obstructive pulmonary disease (COPD), CMS assigns a separate factor for this disease interaction. By doing so, CMS increases the enrollee's risk score for each of the three HCC factors and by an additional factor for the disease interaction.

The risk adjustment program is prospective. Specifically, CMS uses the diagnosis codes that the enrollee received for 1 calendar year (known as the service year) to determine HCCs and calculate risk scores for the following calendar year (known as the payment year). Thus, an enrollee's risk score does not change for the year in which a diagnosis is made. Instead, the risk score changes for the entirety of the year after the diagnosis has been made. Further, the risk score calculation is an additive process—as HCC factors (and, when applicable, disease interaction factors) accumulate, an enrollee's risk score increases, and the monthly risk-adjusted payment to the MA organization also increases. In this way, the risk adjustment

⁹ CMS transitioned from one HCC payment model to another during our audit period. As part of this transition, for 2015, CMS calculated risk scores based on both payment models. CMS refers to these models as the Version 12 model and the Version 22 model, each of which has unique HCCs. CMS blended the two separate risk scores into a single risk score that it used to calculate a risk-adjusted payment. Accordingly, for 2015, an enrollee's blended risk score is based on the HCCs from both payment models. For 2016, CMS calculated risk scores on the Version 22 model.

program compensates MA organizations for the additional risk of providing coverage to enrollees expected to require more health care resources.

CMS multiplies the risk scores by the base rates to calculate the total Medicare monthly payment that an MA organization receives for each enrollee before applying the budget sequestration reduction.¹⁰ Miscoded diagnoses submitted to CMS may result in HCCs that are not validated and incorrect enrollee risk scores, which may lead to improper payments (overpayments) from CMS to MA organizations. Conversely, correctly coded diagnoses that MA organizations do not submit to CMS may lead to improper payments (underpayments).

High-Risk Groups of Diagnoses

Using data mining techniques and discussions with medical professionals, we identified diagnoses that were at higher risk for being miscoded and consolidated those diagnoses into specific groups. For this audit, we focused on seven high-risk groups:¹¹

- *Acute stroke*: An enrollee received one acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim. A diagnosis of history of stroke (which does not map to an HCC) typically should have been used.
- *Acute heart attack*: An enrollee received one diagnosis that mapped to either the HCC for Acute Myocardial Infarction or to the HCC for Unstable Angina and Other Acute Ischemic Heart Disease (Acute Heart Attack HCCs) on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim (either within 60 days before or 60 days after the physician's claim). A diagnosis for a less severe manifestation of a disease in the related-disease group typically should have been used.
- *Acute stroke and acute heart attack combination*: An enrollee met the conditions of both the acute stroke and acute heart attack high-risk groups in the same year.¹²
- *Embolism*: An enrollee received one diagnosis that mapped to either the HCC for Vascular Disease or to the HCC for Vascular Disease With Complications (Embolism

¹⁰ Budget sequestration refers to automatic spending cuts that occurred through the withdrawal of funding for certain Federal Government programs, including the MA program, as provided in the Budget Control Act of 2011 (BCA) (P.L. No. 112-25 (8-2-2011)). Under the BCA, the sequestration of mandatory spending began in April, 2013.

¹¹ Unless otherwise specified, the HCCs described in this report have the same name under both the Version 12 and Version 22 models.

¹² We combined these enrollees into one group because an individual's risk scores could have been further increased if that enrollee also had a COPD diagnosis (which was not part of our audit). If our audit identified an error that invalidated either the acute stroke or acute heart attack HCC, then the disease interaction factor would also be identified as an error. By combining these enrollees in one group, we eliminated the possibility of including the disease interaction factor twice in overpayment calculations (if any).

HCCs) but did not have an anticoagulant medication dispensed on his or her behalf. An anti-coagulant medication is typically used to treat an embolism. A diagnosis of history of embolism (an indication that the provider is evaluating a prior acute embolism diagnosis, which does not map to an HCC) typically should have been used.

- *Vascular claudication*: An enrollee did not receive a diagnosis related to vascular claudication (which maps to the HCC for Vascular Disease) for 2 years and then, in the subsequent year, received that diagnosis but had medication dispensed on his or her behalf that is frequently dispensed for a diagnosis of neurogenic claudication.¹³ In these instances, the vascular claudication diagnoses may not be supported in the medical records.
- *Major depressive disorder*: An enrollee received one major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) during the service year but did not have an antidepressant medication dispensed on his or her behalf. In these instances, the major depressive disorder diagnoses may not be supported in the medical records.
- *Potentially mis-keyed diagnosis codes*: An enrollee received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition (which mapped to a possibly unvalidated HCC). For example, ICD-9 diagnosis code 250.00 (which maps to the HCC for Diabetes Without Complication) could be transposed as diagnosis code 205.00 (which maps to the HCC for Metastatic Cancer and Acute Leukemia and, in this example, would be unvalidated). Using an analytical tool that we developed, we identified 811 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed or other data entry errors occurred that could have resulted in the assignment of an unvalidated HCC.

In this report, we refer to the diagnosis codes associated with these groups as “high-risk diagnosis codes.”

Healthfirst Health Plan, Inc.

Healthfirst is an MA organization based in New York, New York. As of December 31, 2016, Healthfirst provided coverage under contract number H3359 to approximately 136,875

¹³ Vascular claudication and neurogenic claudication are different diagnoses. Vascular claudication is a condition that can result in leg pain while walking and is caused by insufficient blood flow. Neurogenic claudication is a condition that can also result in leg pain but is caused by damage to the neurological system, namely the spinal cord and nerves.

enrollees. For the 2015 and 2016 payment years (audit period),¹⁴ CMS paid Healthfirst approximately \$3.3 billion to provide coverage to its enrollees.¹⁵

HOW WE CONDUCTED THIS AUDIT

Our audit included enrollees on whose behalf providers documented diagnosis codes that mapped to one of the seven high-risk groups during the 2014 and 2015 service years, for which Healthfirst received increased risk-adjusted payments for payment years 2015 and 2016, respectively. Because enrollees could be classified in more than one high-risk group or have high-risk diagnosis codes documented in more than 1 year, we classified these individuals according to the condition and the payment year, which we refer to as "enrollee-years." We identified 5,721 unique enrollee-years and limited our review to the portions of the payments that were associated with these high-risk diagnosis codes (\$14,847,742). We selected for audit a sample of 240 enrollee-years, which comprised (1) a stratified random sample of 200 (out of 5,646) enrollee-years for the first 6 high-risk groups and (2) a non-statistical sample of 40 (out of 75) enrollee-years for the remaining high-risk group.

Table 1 details the number of sampled enrollee-years for each high-risk group.

Table 1: Sampled Enrollee-Years

High-Risk Group	Number of Sampled Enrollee-Years
1. Acute Stroke	49
2. Acute Heart Attack	30
3. Acute Stroke/Acute Heart Attack combination	11
4. Embolism	30
5. Vascular Claudication	35
6. Major Depressive Disorder	45
Total for Stratified Random Sample	200
7. Potentially Mis-keyed Diagnosis Codes	40
Total for All High-Risk Groups	240

Healthfirst provided medical records as support for the selected diagnosis codes associated with the 240 enrollee-years. We used an independent medical review contractor to review the medical records to determine whether the selected diagnosis codes that Healthfirst submitted to CMS were supported. If the contractor identified a diagnosis code that should have been submitted to CMS instead of the selected diagnosis code, we included the financial impact of the resulting HCC (if any) in our calculation of overpayments.

¹⁴ The 2015 and 2016 payment year data were the most recent data available at the start of the audit.

¹⁵ All of the payment amounts that CMS made to Healthfirst and the overpayment amounts that we identified in this report reflect the budget sequestration reduction.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Healthfirst submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 85 of the 240 sampled enrollee-years, the medical records supported the diagnosis codes that Healthfirst submitted to CMS. However, for the remaining 155 enrollee-years, the diagnosis codes were not supported in the medical records.

These errors occurred because the policies and procedures that Healthfirst had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Healthfirst received at least \$5.2 million in net overpayments for 2015 and 2016.¹⁶

FEDERAL REQUIREMENTS

Payments to MA organizations are adjusted for risk factors, including the health status of each enrollee (the Social Security Act (the Act) § 1853(a)). CMS applies a risk factor based on data obtained from the MA organizations (42 CFR § 422.308).

Federal regulations state that MA organizations must follow CMS's instructions and submit to CMS the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner (42 CFR § 422.310(b)). MA organizations must obtain risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service (42 CFR § 422.310(d)(3)).

Federal regulations also state that MA organizations are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes and that such data must conform to all relevant national standards (42 CFR § 422.504(l) and 42 CFR

¹⁶ Specifically, we estimated that Healthfirst received at least \$5,221,901 (\$5,023,530 for the statistically sampled groups plus \$198,371 for the group of potentially mis-keyed diagnosis codes) in net overpayments. To be conservative, we recommend recovery at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

§ 422.310(d)(1)). In addition, MA organizations must contract with CMS and agree to follow CMS's instructions, including the *Medicare Managed Care Manual* (the Manual) (see 42 CFR § 422.504(a)).

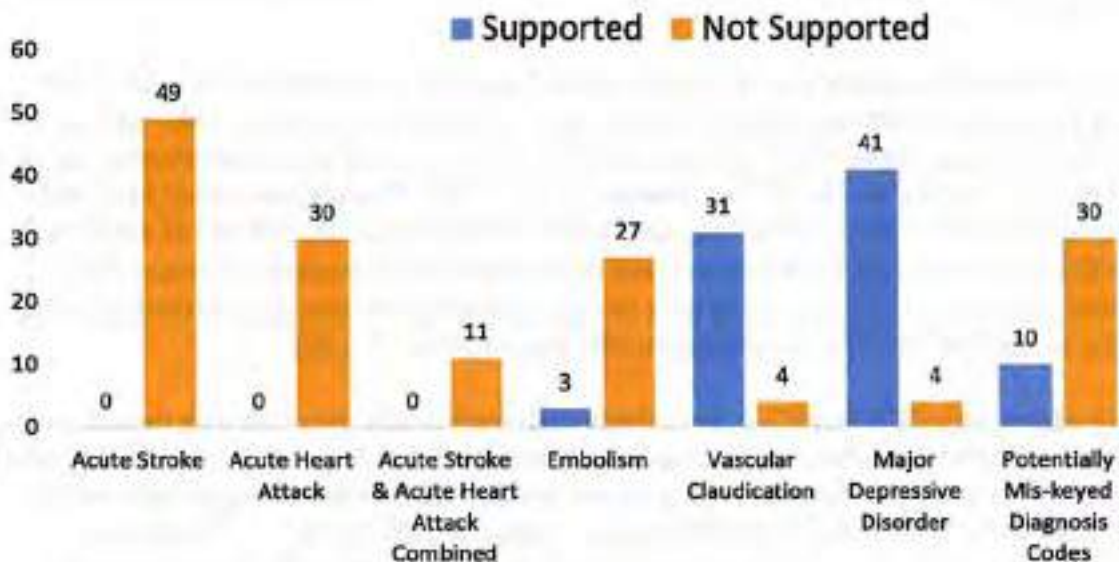
CMS has provided instructions to MA organizations regarding the submission of data for risk scoring purposes (the Manual, chap. 7 (last rev. Sept. 19, 2014)). Specifically, CMS requires all submitted diagnosis codes to be documented in the medical record and to be documented as a result of a face-to-face encounter (the Manual, chap. 7, § 40). The diagnosis must be coded according to the ICD Coding Guidelines (42 CFR § 422.310(d)(1) and 45 CFR §§ 162.1002(b)(1) and (c)(2)-(3)). Further, the MA organizations must implement procedures to ensure that diagnoses come only from acceptable data sources, which include hospital inpatient facilities, hospital outpatient facilities, and physicians (the Manual, chap. 7, § 40).

Federal regulations state that MA organizations must monitor the data that they receive from providers and submit to CMS. Federal regulations also state that MA organizations must "adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements" Further, MA organizations must establish and implement an effective system for routine monitoring and identification of compliance risks (42 CFR § 422.503(b)(4)(vi), See Appendix E).

MOST OF THE SELECTED HIGH-RISK DIAGNOSIS CODES THAT HEALTHFIRST SUBMITTED TO CMS DID NOT COMPLY WITH FEDERAL REQUIREMENTS

Most of the selected high-risk diagnosis codes that Healthfirst submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As shown in the figure on the following page, the medical records for 155 of the 240 sampled enrollee-years did not support the diagnosis codes. In these instances, Healthfirst should not have submitted the diagnosis codes to CMS and received the resulting net overpayments.

Figure: Analysis of High-Risk Groups



Incorrectly Submitted Diagnosis Codes for Acute Stroke

Healthfirst incorrectly submitted diagnosis codes for acute stroke for all 49 sampled enrollee-years. Specifically:

- For 26 enrollee-years, the medical records indicated in each case that the individual had previously had a stroke, but the records did not justify an acute stroke diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the medical record (for a service that occurred in 2014) indicated that the individual had an acute stroke in 1998. The independent medical review contractor noted that "there is no evidence of an acute stroke or any related condition that would result in an assignment of the submitted HCC [Ischemic or Unspecified Stroke] or a related HCC. There is mention of a history of a stroke [diagnosis]" The history of stroke diagnosis code does not map to an HCC.

- For 21 enrollee-years, the medical records did not contain sufficient information to support an acute stroke diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor stated that "there is no documentation of any condition that will result in assignment of [the] HCC [for Ischemic or Unspecified Stroke]. The patient was admitted from [the] emergency room for suspected acute [Cerebrovascular Accident] which was ruled out at discharge."

- For the remaining 2 enrollee-years, Healthfirst did not provide any medical records to support the acute stroke diagnosis; therefore, the HCC for Ischemic or Unspecified Stroke was not validated.

As a result of these errors, the HCCs for Ischemic or Unspecified Stroke were not validated, and Healthfirst received \$129,370 in overpayments for these 49 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Acute Heart Attack

Healthfirst incorrectly submitted diagnosis codes for acute heart attack for all 30 sampled enrollee-years. Specifically:

- For 19 enrollee-years, the medical records did not support an acute myocardial infarction diagnosis. However, we identified support for another diagnosis of a less severe manifestation of the related-disease group as detailed below:
 - For 14 enrollee-years, we identified support for an old myocardial infarction diagnosis.
 - For 8 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Healthfirst should not have received an increased payment for the acute myocardial infarction diagnosis. Rather, it should have received a lesser increased payment for the old myocardial infarction diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the Unstable Angina and Other Acute Ischemic Heart Disease] HCC. There is documentation of history of myocardial infarction [diagnosis] that results in [the] HCC [for Angina Pectoris/Old Myocardial Infarction] which should have been assigned instead of the submitted HCC."

- For 6 enrollee-years, which occurred in payment year 2016, the old myocardial infarction diagnosis did not map to an HCC.¹⁷ Accordingly, Healthfirst should not have received an increased payment for acute myocardial infarction.

¹⁷ In contrast to the enrollee-years that occurred in payment year 2015 (for which CMS used the Version 12 model), for payment year 2016, CMS used only the Version 22 model, which did not include an HCC for Old Myocardial Infarction, to calculate risk scores (footnote 9).

- For 2 enrollee-years, which occurred in payment year 2016, we identified support for an acute ischemic heart disease diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Healthfirst should not have received an increased payment for the acute myocardial infarction diagnosis. Rather, it should have received a lesser increased payment for the acute ischemic heart disease diagnosis.
- For 2 enrollee-years, which occurred in payment year 2015, we identified support for both an old myocardial infarction diagnosis and an unspecified angina pectoris diagnosis,¹⁸ both of which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Healthfirst should not have received an increased payment for the acute myocardial infarction diagnosis. Rather, it should have received a lesser increased payment for the old myocardial infarction and unspecified angina pectoris diagnoses.
- For the remaining 1 enrollee-year, which occurred in payment year 2016, we identified support for an unspecified angina pectoris diagnosis, which mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Healthfirst should not have received an increased payment for the acute myocardial infarction diagnosis. Rather, it should have received a lesser increased payment for the unspecified angina pectoris diagnosis.
- For 10 enrollee-years, the medical records did not support either an acute myocardial infarction diagnosis or a diagnosis of a less severe manifestation of the related-disease group.
- For the 1 remaining enrollee-year, Healthfirst did not provide any medical records to support the acute myocardial infarction diagnosis; therefore, the HCC for Acute Heart Attack was not validated.¹⁹

As a result of these errors, the Acute Heart Attack HCCs were not validated, and Healthfirst received \$49,653 in net overpayments for these 30 sampled enrollee-years.

¹⁸ Angina pectoris is defined as a disease marked by brief sudden attacks of chest pain or discomfort caused by deficient oxygenation of the heart muscles, usually due to impaired blood flow to the heart.

¹⁹ For this 1 enrollee-year, we found in CMS's Risk Adjustment Processing System (RAPS) and Encounter Data System (EDS) a diagnosis code submitted by Healthfirst that mapped to an HCC for a less severe manifestation of the related-disease group, which we included in our calculation of the overpayment.

Incorrectly Submitted Diagnosis Codes for Acute Stroke and Acute Heart Attack Combination

Healthfirst incorrectly submitted diagnosis codes for all 11 of the sampled enrollee-years for which physicians had documented conditions for both the acute stroke and acute heart attack high-risk groups in the same year (footnote 12).

For 10 enrollee-years, the medical records did not support either the acute stroke diagnosis, the acute myocardial infarction diagnosis, or both (table 2).

Table 2: Acute Stroke and Acute Heart Attack Combination Findings

Count of Enrollee-Years	Acute Stroke HCC		Acute Heart Attack HCC	
	Medical Record Validated HCC	Support for Different HCC Found	Medical Record Validated HCC	Support for Different HCC Found
4	No	No	No	Yes – Old Myocardial Infarction ²⁰
4	No	No	No	No
1	No	No	No	Yes – Angina Pectoris
1	No	No	Yes	N/A

For the one remaining enrollee-year, Healthfirst did not provide any medical records to support either diagnosis; therefore, the HCCs for Acute Heart Attack and Acute Stroke were not validated.²¹

As a result of these errors, the HCCs for either Ischemic or Unspecified Stroke, Acute Heart Attack, or both, were not validated, and Healthfirst received \$46,496 in net overpayments for these 11 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Embolism

Healthfirst incorrectly submitted diagnosis codes for embolism for 27 of 30 sampled enrollee-years. Specifically:

- For 16 enrollee-years, the medical records did not contain sufficient information to support an embolism diagnosis.

²⁰ For these 4 enrollee-years, which occurred in payment year 2015, the old myocardial infarction diagnosis mapped to an HCC for a less severe manifestation of the related-disease group.

²¹ For this enrollee-year, we found in CMS's RAPS a diagnosis code submitted by Healthfirst that mapped to an HCC for a less severe manifestation of the heart attack related-disease group, which we included in our calculation of the overpayment.

For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [an Embolism] HCC. There is documentation of deep vein thrombosis [diagnosis] as a working diagnosis that would not be coded based on outpatient guidelines of suspected/ruled out diagnoses."²²

- For 7 enrollee-years, the medical records indicated in each case that the individual had previously had an embolism, but the records did not justify an embolism diagnosis at the time of the physician's service.

For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [an Embolism] HCC. There is documentation of a history of deep vein thrombosis [diagnosis] that does not result in an HCC."

- For the remaining 4 enrollee-years, Healthfirst did not provide any medical records to support the embolism diagnoses; therefore, the Embolism HCCs were not validated.

As a result of these errors, the Embolism HCCs were not validated, and Healthfirst received \$72,442 in overpayments for these 27 sampled enrollee-years.

Incorrectly Submitted Diagnosis Codes for Vascular Claudication

Healthfirst incorrectly submitted diagnosis codes for vascular claudication for 4 of 35 sampled enrollee-years. Specifically:

- For 3 enrollee-years, the medical records did not support a vascular claudication diagnosis.

For example, for 1 enrollee-year, the independent medical review contractor noted that "there is no documentation of any condition that would result in the assignment of [the Vascular Disease] HCC."

- For the 1 remaining enrollee-year, Healthfirst did not provide any medical records to support the vascular claudication diagnosis; therefore, the HCC for Vascular Disease was not validated.

As a result of these errors, the HCCs for Vascular Disease were not validated, and Healthfirst received \$8,738 in overpayments for these 4 sampled enrollee-years.

²² ICD-9-CM Coding Guidelines, which were applicable for the reviewed diagnosis code, state that diagnoses documented as "suspected" or "rule out" should not be coded for outpatient services.

Incorrectly Submitted Diagnosis Codes for Major Depressive Disorder

Healthfirst incorrectly submitted diagnosis codes for major depressive disorder for 4 of 45 sampled enrollee-years. Specifically:

- For 2 enrollee-years, the medical records did not support a major depressive disorder diagnosis.²³

For example, for 1 enrollee-year, the independent medical review contractor noted that “there is no documentation of any condition that will result in the assignment of [the Major Depressive, Bipolar, and Paranoid Disorders] HCC. There is [an] assessment of anxiety [diagnosis] which does not result in an HCC.”

- For the remaining 2 enrollee-years, Healthfirst did not provide any medical records to support the major depressive disorder diagnoses; therefore, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated.

As a result of these errors, the HCCs for Major Depressive, Bipolar, and Paranoid Disorders were not validated, and Healthfirst received \$11,438 in overpayments for these 4 sampled enrollee-years.

Potentially Mis-keyed Diagnosis Codes

Healthfirst submitted potentially mis-keyed diagnosis codes for 30 of 40 sampled enrollee-years. In each of these cases, the enrollee-years received multiple diagnoses for a condition but received only one—potentially mis-keyed—diagnosis for an unrelated condition.

- For 24 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. Because of these errors, Healthfirst submitted unsupported diagnosis codes that mapped to unvalidated HCCs to CMS.

For example, for 1 enrollee-year, Healthfirst submitted 107 diagnosis codes for acute myeloid leukemia (205.00) and only one diagnosis code for diabetes mellitus (250.00) to CMS. The independent medical review contractor limited its review to the diabetes mellitus diagnosis, for which it did not find support.

- For 3 enrollee-years, the medical records did not support the diagnosis for the unrelated condition. However, we identified support for another diagnosis that mapped to an HCC for a less severe manifestation of the related-disease group. Accordingly, Healthfirst should not have received an increased payment for the submitted diagnosis.

²³ For these 2 enrollee-years, the independent medical review contractor identified support for a diagnosis code for a milder form of depression, which does not map to an HCC.

Rather, it should have received a lesser increased payment for the other diagnosis identified.

For example, for 1 enrollee-year, the medical records did not support a dissection of aorta diagnosis, which maps to the HCC for Vascular Disease With Complications. The independent medical review contractor noted that "there is no documentation of any condition that will result in the assignment of [the Vascular Disease with Complications] HCC. There is documentation of abdominal aortic aneurysm [diagnosis,] which results in [the Vascular Disease] HCC [that] should have been assigned instead of the submitted HCC." Accordingly, Healthfirst should not have received payment for the dissection of aorta diagnosis. Rather, it should have received a lesser increased payment for the abdominal aortic aneurysm diagnosis.

- For the remaining 3 enrollee-years, Healthfirst did not provide any medical records to support the potentially mis-keyed diagnosis code; therefore, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated.²⁴

Appendix F contains the HCCs that were not validated for the 30 enrollee-years (Table 6) and the HCCs for the less severe manifestation of the related-disease group that were supported for the 4 enrollee-years (Table 7).

As a result of these errors, the HCCs associated with the potentially mis-keyed diagnosis codes were not validated, and Healthfirst received \$198,371 in net overpayments for these 30 sampled enrollee-years.

THE POLICIES AND PROCEDURES THAT HEALTHFIRST USED TO DETECT AND CORRECT NONCOMPLIANCE WITH FEDERAL REQUIREMENTS WERE NOT ALWAYS EFFECTIVE

The errors we identified occurred because the policies and procedures that Healthfirst had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations (42 CFR § 422.503(b)(4)(vi)), were not always effective.

Healthfirst had compliance procedures in place during our audit period to determine whether the diagnosis codes that it submitted to CMS to calculate risk-adjusted payments were correct. These procedures included a provider education program that was designed to promote accurate diagnosis codes, which provided instructions to its providers on the proper coding of several frequently miscoded diagnoses, one of which was acute stroke. In addition, Healthfirst's compliance procedures included routine internal medical reviews to compare diagnosis codes from a random sample of claims to the diagnoses that were documented on the associated medical records. However, these internal medical reviews did not focus on any

²⁴ For 1 enrollee-year, we found in CMS's RAPS and CMS's EDS a diagnosis code submitted by Healthfirst that mapped to an HCC for a less severe manifestation of the related-disease group, which we included in our calculation of the overpayment.

specific high-risk diagnosis codes, including those we identified as being at a higher risk for being miscoded. As a result, Healthfirst's compliance procedures to prevent and detect incorrect high-risk diagnoses during our audit period were not always effective. Additionally, Healthfirst was not always able to obtain medical records from its providers to support diagnosis codes submitted to CMS to calculate risk-adjusted payments.²⁵

Healthfirst explained that, after our audit period, it revised its procedures for conducting internal medical reviews to include reviews of targeted diagnosis codes that we identified as being at a higher risk for being miscoded. In addition, Healthfirst updated its provider education program to include steps to notify providers of errors identified during the internal medical reviews, and provide them with guidance on how to avoid coding errors.

HEALTHFIRST RECEIVED NET OVERPAYMENTS

As a result of the errors we identified, the HCCs for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Healthfirst received at least \$5,221,901 in net overpayments (\$5,023,530 for the statistically sampled groups plus \$198,371 for the group of potentially mis-keyed diagnosis codes) in 2015 and 2016. (See Appendix D for sample results and estimates).

RECOMMENDATIONS

We recommend that Healthfirst Health Plan, Inc.:

- refund to the Federal Government the \$5,221,901 of estimated net overpayments;
- identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government;
- identify, for the potentially mis-keyed diagnosis codes described in this report, similar instances of noncompliance that occurred during our audit period but were not included in our non-statistical sample and refund any resulting overpayments to the Federal Government; and
- continue its examination of existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes that are at high risk for being miscoded comply with Federal requirements (when submitted to CMS for use in CMS's risk adjustment program) and take the necessary steps to enhance those procedures.

²⁵ For example, Healthfirst stated that the records associated with some patients were not in the providers' electronic record systems or were not available because the associated physician or medical practice was no longer active.

HEALTHFIRST COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Healthfirst objected to all of our recommendations. However, it did not object to any of the errors we identified. Instead, Healthfirst requested we limit our recommended recovery to the overpayments identified in our sample rather than the extrapolated value of those overpayments. Specifically, Healthfirst stated that OIG lacked the authority to use extrapolation to recommend a repayment and disagreed with our extrapolation methodology. Moreover, Healthfirst argued that our audit methodology did not account for a payment principle known as “actuarial equivalence.” Healthfirst also disagreed that it should perform additional audits of the high-risk diagnoses included in this report. Lastly, Healthfirst stated that, although it regularly evaluates its compliance programs, it believes its current compliance program is sufficient to meet its current obligations.

After reviewing Healthfirst’s comments and for the reasons detailed below, we maintain that our findings and recommendations are valid.

A summary of Healthfirst’s comments and our responses follows. Healthfirst’s comments are included in their entirety as Appendix G.

HEALTHFIRST DID NOT AGREE WITH THE EXTRAPOLATION METHODOLOGY THAT THE OFFICE OF INSPECTOR GENERAL USED TO ESTIMATE OVERPAYMENTS

Healthfirst Comments

Healthfirst stated that OIG lacks the authority to base a recommendation for recovery on an extrapolation of individual overpayment amounts across a “broader universe.” Specifically, Healthfirst referenced 42 U.S.C. § 1395ddd(f)(3), stating that it provides only “limited authority for CMS to extrapolate, and such authority is limited to *contractors* auditing *providers* under Medicare Parts A and B in limited circumstances not present here with respect to [MA organizations]” (emphasis in original). It further argued that there is “simply no statutory authority for the use of extrapolation of audit results of MAOs providing services under Part C.”

Additionally, Healthfirst stated that CMS drafted regulations on extrapolation for 2011 through 2013; however, according to Healthfirst, nothing was published and there is no approved extrapolation methodology for the audit period (payment years 2015 and 2016). Healthfirst noted that using an unpublished extrapolation methodology is inconsistent with the Act’s rulemaking requirements for notice and comment set forth in *Azar v. Allina Health Services*,²⁶ and therefore, “any purported authority for such extrapolation fails to comply with the required rule-making processes.”

Healthfirst further claimed that retroactivity is prohibited by Federal law. Specifically, it stated that the Act “prohibits retroactive rules absent a statutory requirement, significant public

²⁶ *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

safety concern or other critical need [42 U.S.C. § 139hh(e)(1)(A)], none of which are present here.” Additionally, Healthfirst noted that seeking records from providers to support HCCs for services provided in 2015 and 2016 is often difficult. Healthfirst stated that, for these reasons, it believes that “even if a valid rule authorizing extrapolation i[s] promulgated, it should not be applied retroactively, and that extrapolation by the OIG based on audit findings from 201[5]-2016 is similarly not permissible.”

Healthfirst also stated that our methodology for calculating the extrapolated repayment amount is faulty. Healthfirst specifically referenced our use of the 90-percent confidence interval instead of, according to Healthfirst, the “statistically valid and more robust practice” of using the lower limit of the 95- or 99-percent confidence interval. Additionally, Healthfirst noted that CMS uses the lower limit of the 99-percent confidence interval level for calculating extrapolated repayment amounts for its Risk Adjustment Data Validation (RADV) audits. Healthfirst stated that, if it were permissible to extrapolate, OIG would have to use the lower limit of the 99-percent confidence interval to be consistent with CMS’s practice for RADV audits.

Office of Inspector General Response

Healthfirst relies on 42 U.S.C. § 1395ddd(f)(3) to say that OIG has no authority to extrapolate. This conclusion is misguided. No statutory or other authority limits our ability to recommend a recovery to CMS based upon sampling and extrapolation. Extrapolation has long been recognized as a permissible method of calculating overpayments in Medicare. Further, current case law supports the use of extrapolation as a means to determine overpayments so long as the methodology used is statistically valid.^{27, 28}

Healthfirst alleged that OIG cannot use extrapolation without publishing our methodology through notice-and-comment rulemaking. OIG disagrees. We also note that because we are not recommending the application of any new statutory or regulatory requirements, the criteria cited by Healthfirst that prohibit retroactivity is not applicable to this audit.

Additionally, our estimation methodology does not need to mirror CMS’s estimation methodology. Our use of the lower limit of a two-sided 90-percent confidence interval provided a reasonably conservative estimate of the total amount overpaid to Healthfirst for the

²⁷ See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at *12 (W.D. Pa. 2012), *aff’d* 555 F. App’x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff’d*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at *17 (S.D. Fla. 2012); and *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

²⁸ We properly executed our statistical sampling methodology in that we defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., the OIG, Office of Audit Services, statistical software RAT-STATS) to apply the correct formulas for the extrapolation.

enrollee-years and time period covered in our sampling frame. Further, we note that this approach, which is routinely used by the Department of Health and Human Services (HHS) for recovery calculations,²⁹ results in a lower limit (the estimated overpayment amount to refund) that is less than the actual overpayment amount 95 percent of the time.

HEALTHFIRST DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S APPLICATION OF CMS REQUIREMENTS FOR CALCULATING OVERPAYMENTS

Healthfirst Comments

Healthfirst stated that OIG's extrapolated calculation of overpayments violated certain CMS requirements mandated under the MA program. Specifically, Healthfirst stated that OIG's methodology did not account for a payment principle known as "actuarial equivalence," which, according to Healthfirst, is mandated by the Act.

Healthfirst cited the provision of the Act that mandates that risk-adjusted payments be made in a manner that ensures "actuarial equivalence" between CMS payments for health care coverage under MA and CMS payments under Medicare's traditional Fee-for-Service (FFS) program. Healthfirst stated that "CMS developed the [MA] risk adjustment model using unaudited [FFS] claims data from the traditional Medicare program, which CMS has acknowledged contain high levels of erroneous diagnoses. Accordingly, in order to ensure actuarial equivalence between the FFS and MA programs, CMS should measure overall rates of erroneous diagnoses in the [MA] program against the rates of erroneous diagnoses found within the traditional Medicare FFS program." It further stated that, in 2012, "CMS said that it would first identify a 'payment recovery amount' based on the value of supported and unsupported HCCs identified during its review. Then, 'to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster [(FFSA)] amount as an offset to the preliminary recovery amount'"

Healthfirst stated that "CMS departed from the principle that an FFSA is necessary by issuing a proposed rule in 2018 suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to [MA organizations] and released a corresponding study purporting to support this premise." Healthfirst added that this rule is not final and is still subject to the administrative rule-making process.

Healthfirst also noted that a Federal district court vacated a different MA rule implemented by CMS because "the rule violated the [Act's] actuarial equivalence mandate by defining

²⁹ HHS has used the two-sided 90-percent confidence level when calculating recoveries in both the Administration for Child and Families and Medicaid programs. See, for example, *New York State Department of Social Services*, DAB No. 1358, 13 (1992); and *Arizona Health Care Cost Containment System*, DAB No. 2981, 4-5 (2019). In addition, HHS contractors rely on the one-sided 90-percent confidence interval, which is less conservative than the two-sided interval, for recoveries arising from Medicare FFS overpayments. See, for example, *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); and *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 17-18 (E.D.N.Y. 2012).

'overpayment' as the payment of funds to [MA organizations] based on unsupported diagnosis codes, while not applying the same documentation standards to the traditional Medicare data used to calculate payments to [MA organizations]."³⁰ Healthfirst noted that the Federal district court decision concluded "that CMS systematically devalues [MA organization] payments when it uses unaudited traditional Medicare data to set [MA organization] payment rates while measuring [MA organization] 'overpayments' based on audited patient records." Healthfirst cited to the opinion by the U.S. Court of Appeals for the D.C. Circuit, which ruled on the U.S. District Court's decision; specifically, Healthfirst highlighted that the Appeals Court held that "the actuarial-equivalence requirement does not pertain to the statutory overpayment-refund obligation" ³¹ However, Healthfirst noted that the court did not invalidate actuarial equivalence for use in RADV audits, for which the court stated "[w]e express no opinion on whether the actuarial equivalence requirement . . . requires such an adjuster in the [contract-level RADV audit . . .] context."

Healthfirst asserted that "the [MA] program requirements apply to OIG's audits" and that, without applying the FFSA, OIG's extrapolated repayment calculations violate the "actuarial equivalence" mandate. Accordingly, Healthfirst requested that OIG withdraw our overpayment calculation and limit any recovery to the specific encounters reviewed during this audit and for which the unsupported codes were found.

Office of Inspector General Response

Our audit methodology correctly applied CMS requirements to properly identify the overpayment amount associated with unsubstantiated HCCs for each sample item.

We used the results of the independent medical review contractor's review to determine which HCCs were not substantiated and, in some instances, to identify HCCs that should have been used but were not used in the sampled enrollees' risk score calculations. We followed CMS's risk adjustment program requirements to determine the payment that CMS should have made for each enrollee. We used the overpayments and underpayments identified for each enrollee to estimate net overpayments.

Healthfirst stated that we did not consider "actuarial equivalence" in our overpayment calculations. To this point, we recognize that CMS, not OIG, is responsible for making operational and program payment determinations for the MA program, including the application of any FFSA. Moreover, CMS has not issued any requirements that compel us to reduce our net overpayment calculations.³² If CMS deems it appropriate to apply an FFSA, it will adjust our overpayment finding by whatever amount it determines necessary. Thus, we

³⁰ *UnitedHealthcare Ins. Co. v. Azar II*, 330 F. Supp. 3d 173 (D.D.C. 2018).

³¹ *United Healthcare Insurance Co. v. Becerra*, 9 F.4th 868 (D.C. Cir. 2021).

³² In 2018, CMS proposed not to include an FFSA in any final RADV payment error methodology (Proposed Rule at 83 Fed. Reg. 54982, 55041).

believe that the steps that we followed for this audit provide a reasonable basis for our findings and recommendations, including our estimation of net overpayments.³³

HEALTHFIRST DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO PERFORM ADDITIONAL REVIEWS BEFORE AND AFTER THE AUDIT PERIOD

Healthfirst Comments

Healthfirst disagreed with our second recommendation—that Healthfirst perform additional reviews to determine whether similar instances of high-risk diagnoses occurred before or after the audit period and to refund any overpayments—because, according to Healthfirst, “[MA] regulations do not require the sort of audits that OIG recommends.” In addition, Healthfirst stated that it does not have the information necessary to identify additional potentially mis-keyed diagnosis codes similar to those that we identified and for which we recommended that Healthfirst refund any resulting overpayments to the Federal Government (third recommendation).

Healthfirst stated that MA regulations “do not require [MA organizations] to ensure data perfection as the [d]raft [r]eport implies.” In this respect, Healthfirst stated that “[t]he government has long acknowledged that [MA organizations] are not expected to submit perfect risk adjustment data” and that “OIG has issued non-binding guidance stating that [MA organizations] should establish an ‘information collection and reporting system reasonably designed to yield accurate information.’” Moreover, Healthfirst stated that CMS recognizes that MA organizations submit encounter data “in great volume from a number of sources” and that for the certification of these data, CMS holds MA organizations responsible for making good faith efforts to certify their accuracy, completeness, and truthfulness.

In this respect, Healthfirst stated that our citations of Federal regulations for MA organizations like Healthfirst to monitor the data that they receive from providers and submit to CMS were misleading. Specifically, Healthfirst stated that our citations did not address the “broad discretion” that CMS provided to MA organizations to design their own compliance programs and did not “account for the qualified ‘good faith’ attestation standard that CMS explicitly adopted.” Thus, according to Healthfirst, OIG’s second recommendation “would dramatically expand the [MA] compliance program requirements.”

³³ OIG audit findings and recommendations do not represent final determinations by CMS. Action officials at CMS will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. In accordance with 42 CFR § 422.311, which addresses audits conducted by the Secretary (including those conducted by the OIG), if a disallowance is taken, MA organizations have the right to appeal the determination that an overpayment occurred through the Secretary’s RADV appeals process.

Office of Inspector General Response

We do not agree with Healthfirst's interpretation of Federal requirements. We recognize that MA organizations have the latitude to design their own federally mandated compliance programs. We also recognize that CMS applies a "good faith attestation" standard when MA organizations certify the great volume of data that they submit to CMS for use in the risk adjustment program. However, contrary to Healthfirst's assertions, we believe that our second recommendation conforms to the requirements specified in Federal regulations (42 CFR § 422.503(b)(4)(vi) (see Appendix D)).

These Federal regulations state that MA organizations must "implement an effective compliance program, which must include measures that prevent, detect, and correct noncompliance with CMS' program requirements." Further, these regulations specify that Healthfirst's compliance plan "must, at a minimum, include [certain] core requirements," which include "an effective system for routine monitoring and identification of compliance risks . . . [including] internal monitoring and audits and, as appropriate, external audits to evaluate . . . compliance with CMS requirements and the overall effectiveness of the compliance program." These regulations also require MA organizations to implement procedures and a system for investigating "potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence." Thus, CMS has, through the issuance of these Federal regulations, assigned the responsibility for dealing with potential compliance issues to the MA organizations.

We believe that the error rates identified in this report demonstrate that Healthfirst has compliance issues that need to be addressed. These issues may extend to periods of time beyond our scope. Accordingly, we maintain that our second recommendation is valid.

With regard to the potentially mis-keyed diagnosis codes, during the course of our audit work, we explained to Healthfirst officials how we selected each target area, including mis-keyed diagnosis codes. Additionally, after the issuance of our draft report we provided Healthfirst with a spreadsheet detailing the 811 scenarios that we identified in which diagnosis codes could have been mis-keyed. Therefore, Healthfirst has the information necessary to identify additional mis-keyed diagnosis codes similar to those that we identified. Accordingly, we maintain that our third recommendation is also valid.

HEALTHFIRST DID NOT AGREE WITH THE OFFICE OF INSPECTOR GENERAL'S RECOMMENDATION TO ENHANCE ITS EXISTING COMPLIANCE PROGRAM

Healthfirst Comments

Healthfirst noted that it made changes to its compliance program after the end of our audit period. Additionally, Healthfirst stated that it regularly evaluates its compliance programs to respond to regulatory changes and to identify opportunities for improvement. Healthfirst

stated that it believes its current compliance program is sufficient to meet its current obligations and requested that we withdraw our fourth recommendation.

Office of Inspector General Response

We limited our review to selected diagnoses and HCCs that we determined to be at high risk for noncompliance (i.e., miscoded). Our audit revealed a significant error rate for some of these areas. After our audit period, Healthfirst revised its procedures to include internal medical reviews of these high-risk diagnoses. The continued improvement of those procedures, based on the results of this audit, as well as the results of Healthfirst's internal medical reviews, will assist Healthfirst in attaining better assurance with regard to the "accuracy, completeness and truthfulness" of the risk adjustment data that it submits in the future. Accordingly, we maintain that our fourth recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

CMS paid Healthfirst \$3,333,485,481 to provide coverage to its enrollees for 2015 and 2016. We identified a sampling frame of 5,721 unique enrollee-years on whose behalf providers documented high-risk diagnosis codes during the 2014 and 2015 service years. Healthfirst received \$107,579,597 in payments from CMS for these enrollee-years for 2015 and 2016. We selected for audit 240 enrollee-years with payments totaling \$5,432,013.

The 240 enrollee-years included 49 acute stroke diagnoses, 30 acute heart attack diagnoses, 11 acute stroke diagnosis and acute heart attack diagnosis combinations, 30 embolism diagnoses, 35 vascular claudication diagnoses, 45 major depressive disorder diagnoses, and 40 potentially mis-keyed diagnoses. We limited our review to the portions of the payments that were associated with these high-risk diagnosis codes, which totaled \$787,928 for our sample.

Our audit objective did not require an understanding or assessment of Healthfirst's complete internal control structure, and we limited our review of internal controls to those directly related to our objective.

We performed audit work from August 2019 through September 2021.

METHODOLOGY

To accomplish our objective, we performed the following steps:

- We reviewed applicable Federal laws, regulations, and guidance.
- We discussed with CMS program officials the Federal requirements that MA organizations should follow when submitting diagnosis codes to CMS.
- We identified, through data mining and discussions with medical professionals at a Medicare administrative contractor, diagnosis codes and HCCs that were at high risk for noncompliance. We also identified the diagnosis codes that potentially should have been used for cases in which the high-risk diagnoses were miscoded.
- We consolidated the high-risk diagnosis codes into specific groups, which included:
 - 6 diagnosis codes for acute stroke,
 - 35 diagnosis codes for acute heart attack,
 - 56 diagnosis codes for embolism,
 - 4 diagnosis codes for vascular claudication, and
 - 27 diagnosis codes for major depressive disorder.

- We developed an analytical tool that identified 811 scenarios in which either ICD-9 or ICD-10 diagnosis codes, when mis-keyed into an electronic claim because of a data transposition or other data entry error, could result in the assignment of an incorrect HCC to an enrollee's risk score. For each of the 811 occurrences, the tool identified a potentially mis-keyed diagnosis code and the likely correct diagnosis code. Accordingly, we considered the potentially mis-keyed diagnosis codes to be high risk.
- We used CMS's systems to identify the enrollee-years on whose behalf providers documented the high-risk diagnosis codes. Specifically, we used extracts from CMS's:
 - Risk Adjustment Processing System (RAPS)³⁴ to identify enrollees who received high-risk diagnosis codes from a physician during the service years,
 - Risk Adjustment System (RAS)³⁵ to identify enrollees who received an HCC for the high-risk diagnosis codes,
 - Medicare Advantage Prescription Drug System (MARx)³⁶ to identify the total Medicare payments that CMS calculated, before applying the budget sequestration reduction, for Healthfirst for the payment years, and
 - Prescription Drug Event (PDE) file³⁷ to identify enrollees who had Medicare claims with certain medications dispensed on their behalf.
- We interviewed Healthfirst officials to gain an understanding of (1) the policies and procedures that Healthfirst followed to submit diagnosis codes to CMS for use in the risk-adjustment program and (2) Healthfirst's monitoring of those diagnosis codes to identify and detect noncompliance with Federal requirements.
- We selected for audit a sample of 240 enrollee-years that included (1) a stratified random sample of 200 enrollee-years and (2) a non-statistical sample of 40 enrollee-years.

³⁴ MA organizations use the RAPS to submit diagnosis codes to CMS.

³⁵ The RAS identifies the HCCs that CMS factors into each enrollee's risk score calculation.

³⁶ The MARx identifies the payments made to MA organizations.

³⁷ The PDE file contains claims with prescription drugs that have been dispensed to enrollees through the Medicare Part D (prescription drug coverage) program.

- We used an independent medical review contractor to perform a coding review for the 240 enrollee-years to determine whether the high-risk diagnosis codes submitted to CMS complied with Federal requirements.³⁸
- The independent medical review contractor's coding review followed a specific process to determine whether there was support for a diagnosis code and the associated HCC:
 - If the first senior coder found support for the diagnosis code on the medical record, the HCC was considered validated.
 - If the first senior coder did not find support on the medical record, a second senior coder performed a separate review of the same medical record:
 - If the second senior coder also did not find support, the HCC was considered to be not validated.
 - If the second senior coder found support, then a physician independently reviewed the medical record to make the final determination.
 - If either the first or second senior coder asked a physician for assistance, the physician's decision became the final determination.
- We used the results of the independent medical review contractor to calculate overpayments or underpayments for each enrollee-year. Specifically, we calculated:
 - a revised risk score in accordance with CMS's risk adjustment program and
 - the payment that CMS should have made for each enrollee-year.
- We estimated the total net overpayment made to Healthfirst during the audit period.
- We discussed the results of our audit with Healthfirst officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

³⁸ Our independent medical review contractor used senior coders all of whom possessed one or more of the following qualifications and certifications: Registered Health Information Technician (RHIT), Certified Coding Specialist (CCS), Certified Coding Specialist – Physician-Based (CCS-P), Certified Professional Coder (CPC), and Certified Risk Coder (CRC). RHITs have completed a 2-year degree program and have passed an American Health Information Management Association (AHIMA) certification exam. The AHIMA also credentials individuals with CCS and CCS-P certifications and the American Academy of Professional Coders credentials both CPCs and CRCs.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS</i>	<u>A-07-19-01187</u>	5/21/2021
<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS</i>	<u>A-07-16-01165</u>	4/19/2021
<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS</i>	<u>A-02-18-01028</u>	2/24/2021
<i>Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements</i>	<u>A-07-17-01170</u>	4/30/2019

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We identified Healthfirst enrollees who (1) were continuously enrolled in Healthfirst throughout all of the 2014 or 2015 service year and January of the following year, (2) were not classified as being enrolled in hospice or as having end-stage renal disease status at any time during 2014 or 2015 or in January of the following year, and (3) received a high-risk diagnosis during 2014 or 2015 that caused an increased payment to Healthfirst for 2015 or 2016, respectively.

We presented the data for these enrollees to Healthfirst for verification and performed an analysis of the data included on CMS's systems to ensure that the high-risk diagnosis codes increased CMS's payments to Healthfirst. After we performed these steps, our finalized sampling frame consisted of 5,721 enrollee-years.

SAMPLE UNIT

The sample unit was an enrollee-year, which covered either payment year 2015 or 2016.

SAMPLE DESIGN

The design for our statistical sample was comprised of six strata of enrollee-years with either:

- an acute stroke diagnosis (which maps to the HCC for Ischemic or Unspecified Stroke) on one physician claim during the service year but did not have that diagnosis on a corresponding inpatient hospital claim (1,071 enrollee-years);
- a diagnosis that mapped to an Acute Heart Attack HCC on only one physician claim but did not have that diagnosis on a corresponding inpatient hospital claim either 60 days before or 60 days after the physician claim (560 enrollee-years);
- an acute stroke diagnosis and a diagnosis that mapped to an Acute Heart Attack HCC in the same year and that met the criteria mentioned in the previous two bullets (11 enrollee-years);
- a diagnosis that mapped to an Embolism HCC but for which an anticoagulant medication was not dispensed (362 enrollee-years);
- a vascular claudication diagnosis (which maps to the HCC for Vascular Disease) on one claim during the service year (and did not occur during the 2 years that preceded the service year), but for which medication was dispensed for neurogenic claudication during the service year (1,547 enrollee-years); or

- a major depressive disorder diagnosis (which maps to the HCC for Major Depressive, Bipolar, and Paranoid Disorders) on one claim during the service year but for which antidepressant medication was not dispensed (2,095 enrollee-years).

The specific strata are shown in Table 3.

Table 3: Sample Design for Audited High-Risk Groups

Stratum (High-Risk Groups)	Frame Count of Enrollee- Years	CMS Payment for HCCs in Audited High-Risk Groups*	Sample Size
1 – Acute Stroke	1,071	\$2,712,635	49
2 – Acute Heart Attack	560	1,203,268	30
3 – Acute Stroke / Acute Heart Attack Combination	11	54,748	11
4 – Embolism	362	954,907	30
5 – Vascular Claudication	1,547	3,712,264	35
6 – Major Depressive Disorder	2,095	5,839,986	45
Total – First Six Strata	5,646	\$14,477,808	200

*Rounded to the nearest whole dollar amount.

After we selected the 200 enrollee-years, we identified an additional group of 75 enrollee-years, from which we non-statistically selected 40 enrollee-years that represented individuals who received 1 of the 811 potentially mis-keyed diagnosis codes (which mapped to a potentially unvalidated HCC) and multiple instances of diagnosis codes for unrelated conditions that were likely keyed correctly. Thus, we selected for audit a total of 240 enrollee-years.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General (OIG), Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the items in each stratum in the stratified sampling frame. After generating 200 random numbers according to our sample design, we selected the corresponding frame items for review. We also systematically selected a non-statistical sample of 40 items from the potentially mis-keyed group. This resulted in at least 1 enrollee-year being selected from each HCC group.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of net overpayments to Healthfirst at the lower limit of the two-sided 90-percent confidence interval (Appendix D). Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time. We also identified the net overpayments from the non-statistical sample of 40 potentially mis-keyed diagnosis codes and added that amount to the estimate for the statistical sample to obtain the total net overpayments.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Details and Results

Audited High-Risk Groups	Frame Size	CMS Payment for HCCs in Audited High-Risk Groups (for Enrollee-Years in Frame)	Sample Size	CMS Payment for HCCs in Audited High-Risk Groups (for Sampled Enrollee-Years)	Number of Sampled Enrollee-Years With Incorrect Diagnosis Codes	Net Overpayment for Unvalidated HCCs (for Sampled Enrollee-Years)
1 – Acute Stroke	1,071	\$2,712,635	49	\$129,370	49	\$129,370
2 – Acute Heart Attack	560	1,203,268	30	63,009	30	49,653
3- Acute Stroke/ Acute Heart Attack Combination	11	54,748	11	54,748	11	46,496
4 – Embolism	362	954,907	30	79,669	27	72,442
5 – Vascular Claudication	1,547	3,712,264	35	82,178	4	8,738
6 – Major Depressive Disorder	2,095	5,839,986	45	126,317	4	11,438
Totals— First Six Strata	5,646	\$14,477,808	200	535,291	125	\$318,137
7 – Potentially Mis-keyed Diagnoses	75	\$369,934	40	\$252,638	30	\$198,371
Totals – All	5,721	\$14,847,742	240	\$787,928*	155	\$516,509*

* Difference in total is due to rounding.

Table 5: Estimated Net Overpayments in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

	Estimated Net Overpayment for Statistical Sample	Overpayment for Potentially Mis-keyed Diagnosis Group	Total Estimated Net Overpayments
Point Estimate	\$5,593,899	\$198,371	\$5,792,270
Lower Limit	\$5,023,530	\$198,371	\$5,221,901
Upper Limit	\$6,164,268	\$198,371	\$6,362,639

**APPENDIX E: FEDERAL REGULATIONS REGARDING COMPLIANCE PROGRAMS
THAT MEDICARE ADVANTAGE ORGANIZATIONS MUST FOLLOW**

Federal regulations (42 CFR § 422.503(b)) state:

Any entity seeking to contract as an MA organization must

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

- (1) Articulate the organization's commitment to comply with all applicable Federal and State standards;
- (2) Describe compliance expectations as embodied in the standards of conduct;
- (3) Implement the operation of the compliance program;
- (4) Provide guidance to employees and others on dealing with potential compliance issues;
- (5) Identify how to communicate compliance issues to appropriate compliance personnel;
- (6) Describe how potential compliance issues are investigated and resolved by the organization; and
- (7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. . . .

- (F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.
- (G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.
 - (1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
 - (2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.
 - (3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

APPENDIX F: BREAKOUT OF POTENTIALLY MIS-KEYED DIAGNOSIS CODES**Table 6: Potentially Mis-keyed Diagnosis Codes and Associated Overpayments**

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Net Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
6	714.9	Unspecified Inflammatory Polyarthropathy	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	174.9	Malignant Neoplasm of Breast (Female), Unspecified	\$20,123
4	205.00	Acute Myeloid Leukemia, Without Mention of Having Achieved Remission	Metastatic Cancer and Acute Leukemia	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	75,495
3	200.00	Reticulosarcoma, Unspecified Site, Extranodal and Solid Organ Sites	Lymphatic, Head and Neck, Brain, and Other Major Cancers (Version 12 model) and Lymphoma and Other Cancers (Version 22 model)	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	17,859
2	205.90	Unspecified Myeloid Leukemia, Without Mention of Having Achieved Remission	Lung, Upper Digestive Tract, and Other Severe Cancers (Version 12 model) and Lung and Other Severe Cancers (Version 22 model)	250.90	Diabetes With Unspecified Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	16,752
2	482.0	Pneumonia Due to Klebsiella Pneumoniae	Aspiration and Specified Bacterial Pneumonias	428.0	Congestive Heart Failure, Unspecified	9,450

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Net Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
2	493.20	Chronic Obstructive Asthma, Unspecified	Chronic Obstructive Pulmonary Disease	493.02	Extrinsic Asthma With (Acute) Exacerbation	8,261
2	402.01	Malignant Hypertensive Heart Disease With Heart Failure	Congestive Heart Failure	402.10	Benign Hypertensive Heart Disease Without Heart Failure	7,027
1	205.02	Acute Myeloid Leukemia, in Relapse	Metastatic Cancer and Acute Leukemia	250.02	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Uncontrolled	18,997
1	433.01	Occlusion and Stenosis of Basilar Artery With Cerebral Infarction	Ischemic or Unspecified Stroke	433.10	Occlusion and Stenosis of Carotid Artery Without Mention of Cerebral Infarction	4,027
1	249.20	Secondary Diabetes Mellitus With Hyperosmolarity, Not Stated as Uncontrolled, or Unspecified	Diabetes With Acute Complications	294.20	Dementia, Unspecified, Without Behavioral Disturbance	3,988
1	482.1	Pneumonia Due to Pseudomonas	Aspiration and Specified Bacterial Pneumonias	428.1	Left Heart Failure	3,961

Number of Sampled Enrollee-years	One Diagnosis for a Condition (Determined To Be Incorrect)			Multiple Diagnoses for a Condition (Not Reviewed)		Net Overpayment
	Diagnosis Code	Diagnosis Code Description	Hierarchical Condition Category That Was Not Validated	Diagnosis Code	Diagnosis Code Description	
1	250.00	Diabetes Mellitus Without Mention of Complication, Type II or Unspecified Type, Not Stated as Uncontrolled	Diabetes Without Complication	205.00	Acute Myeloid Leukemia, Without Mention of Having Achieved Remission	3,768
1	209.21	Malignant Carcinoid Tumor of the Bronchus and Lung	Breast, Prostate, Colorectal and Other Cancers and Tumors (Version 12 model) and Breast, Prostate, and Other Cancers and Tumors (Version 22 model)	290.21	Senile Dementia With Depressive Features	2,385
1	E32.9	Disease of Thymus, Unspecified	Other Significant Endocrine and Metabolic Disorders	F32.9	Major Depressive Disorder, Single Episode, Unspecified	2,349
1	441.01	Dissection of Aorta, Thoracic	Vascular Disease With Complications	414.01	Coronary Atherosclerosis of Native Coronary Artery	1,969
1	441.00	Dissection of Aorta, Unspecified Site	Vascular Disease With Complications	414.00	Coronary Atherosclerosis of Unspecified Type of Vessel, Native or Graft	1,960
30						\$198,371

Table 7: Hierarchical Condition Categories (HCCs) That Were Not Validated, But We Found Support for an HCC for a Less Severe Manifestation of the Related-Disease Group

Count of Enrollee-Years	More Severe Hierarchical Condition Category That Was Not Validated	Less Severe Hierarchical Condition Category That Was Supported
2	Vascular Disease With Complications	Vascular Disease
1	Aspiration and Specified Bacterial Pneumonias	Pneumococcal Pneumonia, Emphysema, Lung Abscess
1	Metastatic Cancer and Acute Leukemia	Breast, Prostrate, Colorectal and Other Cancers and Tumors (Version 12 model)/Breast, Prostate, and Other Cancers and Tumors (Version 22 model)

APPENDIX G: HEALTHFIRST COMMENTS



VIA Electronic Mail "KiteWorks" to brenda.bernier@oig.hhs.gov

October 18, 2021

Brenda M. Tierney
Regional Inspector General for Audit Services
Office Of Audit Services
Region II
Jacob K. Javits Federal Building
25 Federal Plaza
Room 3900
New York, NY 10278

RE: Report Number: A-02-18-01029

Dear Ms. Tierney:

Healthfirst Health Plan, Inc. ("Healthfirst") writes in response to the United States Department of Health and Human Services ("HHS") Office of Inspector General's ("OIG's") Draft Report for Audit No. A-02-18-01029 ("Draft Report"). For the reasons described below, Healthfirst respectfully requests that OIG withdraw its recommendations that Healthfirst (i) repay an extrapolated amount of \$5,221,901 (and instead limit repayment to the \$516,509 in erroneous payments that were actually identified) and (ii) conduct additional self-audits beyond OIG's sample for periods during, prior to and after OIG's audit period and calculate any repayments based on those audits. Healthfirst objects to OIG's recommendations because (A) extrapolation is not permitted, (B) even if permitted, the proposed extrapolation methodology is inconsistent with the legal and regulatory requirements underlying the Medicare Advantage ("MA") program, and (C) there are currently open CMS audits in process for periods preceding the OIG's audit period and thus any self-audit would be duplicative and premature.

A. The Recommended Repayment Amount is Based on Extrapolation, For Which OIG Has No Authority and Which is Calculated Incorrectly

OIG reviewed medical records from a sample of Healthfirst beneficiaries and found overpayments totaling \$516,509. The remaining over \$4.5 million dollars OIG seeks to recoup is based on OIG's proposed extrapolation of those specific individual overpayments across a broader universe. Thus, OIG proposes to essentially use a sample to calculate a contract-wide error rate for similar codes and recover "overpayments" on that larger amount. OIG lacks authority to base its recovery on such an extrapolation. The Social Security Act ("SSA") only provides limited authority for CMS to extrapolate, and such authority is limited to contractors auditing providers under Medicare Parts A and B in limited circumstances not present here with respect to Medicare Advantage Organizations ("MAOs").¹ The applicable statute, entitled "LIMITATION ON USE OF EXTRAPOLATION," states:

A [Medicare contractor] may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless [CMS] determines that—

(A) there is a sustained or high level of payment error; or

¹ 42 U.S.C. § 1395dd(f)(3).

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(B) documented educational intervention has failed to correct the payment error.

The language of that section does not provide CMS with authority to use extrapolation for anyone other than providers and suppliers under Medicare Parts A and B. There is simply no statutory authority for the use of extrapolation of audit results of MACs providing services under Part C.²

While CMS purported to enact draft regulations regarding extrapolation for 2011, 2012 and 2013, they were never published with a prior notice and comment period.³ More recently, CMS published for comment a methodology for audits of Part C contractors for 2020 and 2021, which have received substantial negative comments, in part based on the actuarial equivalence argument discussed in paragraph B below.

There is no published methodology whatsoever for the 2015 and 2016 audit period here, and therefore there was no opportunity for the public or the MACs to understand the details of the methodology or make comments. Utilizing unpublished extrapolation methodology is inconsistent with the SSA requirements for notice-and-comment rulemaking as indicated by the Supreme Court in *Azar v. Allina Health Services*.⁴ Thus any purported authority for such extrapolation fails to comply with the required rule-making processes.

In addition, the methodology OIG employs in its extrapolation is faulty. OIG used the lower bound of a 90% confidence interval to calculate the extrapolated repayment amount, rather than the statistically valid and more robust practice of using the lower bound of a 95% or 99% confidence interval.⁵ In CMS's most recent disclosure of its own methodology for calculating extrapolated repayment amounts for its RADV audits, CMS stated that it uses the lower bound of a 99% confidence interval.⁶ Accordingly, although we believe that extrapolation is impermissible here, Healthfirst respectfully requests that even if OIG were permitted to extrapolate, it would have to recalculate the extrapolated "overpayment" amount using the lower bound of the more statistically robust 99% confidence interval consistent with CMS practice for RADV audits.

² That this section is limited providers and suppliers under Medicare Parts A and B is clear from the context and from additional language in this section: "There shall be no administrative or judicial review under section 1869 [referring to appeal rights specific to Medicare Parts A and B], section 1878 [referring to additional appeal rights specific to certain providers of services under Part A], or otherwise, of determinations by [CMS] of sustained or high levels of payment errors under this paragraph." See *America's Health Insurance Plans, Comments to the Proposed Rule* (August 17, 2019), www.ahip.org/wp-content/uploads/AHIP_RADV_comments_FTS&L_8-27-19.pdf at 25.

³ CMS proposed its methodology for conducting RADV audits, including extrapolation, via the CMS website on December 20, 2010, instead of the Federal Register. See *Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*, 83 Fed. Reg. 54982, 55038 (proposed Nov. 1, 2018).

⁴ 139 S. Ct. 1804 (2019).

⁵ Federal Judicial Center, National Academies Press, *Reference Manual on Scientific Evidence* 245 (3d ed. 2011) ("The 95% confidence level is the most popular, but some authors use 99%, and 90% is seen on occasion.")

⁶ Centers for Medicare and Medicaid Services, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation for Contract-Level Audits*, at 4 (Feb. 24, 2012) (to be codified at 42 C.F.R. Parts 422, 423, 438, and 498) (hereinafter *Notice of Error Calculation*).

B. The Recommended Extrapolated Repayment Amount is Incorrect Because it is Not Adjusted to Ensure Actuarial Equivalence to the Fee-For-Service Medicare Program as Required by Law

The SSA requires CMS to pay MACs an amount that is "actuarially equivalent" to the expected cost that CMS would have otherwise incurred had it provided required Medicare benefits directly to the MACs' enrollees. Actuarial equivalence measures whether different benefit packages have "the same value, based on the estimated spending that would be incurred by the insurer."⁷ Because the SSA ties Medicare Advantage compensation to the expected cost of providing traditional Medicare benefits to an enrollee of average risk, the "actuarial equivalence" mandate requires CMS to base risk-adjusted payments on actuarially sound calculations of the expected cost of providing traditional Medicare benefits to enrollees with different health status.⁸ That conclusion is confirmed by the SSA's separate requirement that CMS report to Congress on the "actuarial soundness" of the agency's proposed risk adjustment methodology.⁹ CMS developed the Medicare Advantage risk adjustment model using unaudited Fee-for-Service ("FFS") claims data from the traditional Medicare program, which CMS has acknowledged contain high levels of erroneous diagnoses. Accordingly, in order to ensure actuarial equivalence between the FFS and MA programs, CMS should measure overall rates of erroneous diagnoses in the Medicare Advantage program against the rates of erroneous diagnoses found within the traditional Medicare FFS program.¹⁰ CMS previously formally signaled its agreement with the requirement of measuring error rates in Medicare Advantage diagnoses against those in the traditional Medicare program. In 2012, CMS published a notice stating that it was adopting this requirement as part of its methodology for calculating recovery amounts for unsupported Hierarchical Condition Categories ("HCCs") identified during its RADV audits. Specifically, CMS said that it would first identify a "payment recovery amount" based on the value of supported and unsupported HCCs identified during its review.¹¹ Then, "to determine the final payment recovery amount, CMS [would] apply a Fee-for-Service Adjuster ('FFS Adjuster') amount as an offset to the preliminary recovery amount," and base the FFS Adjuster "on a RADV-like review of records submitted to support [traditional Medicare] claims data."¹²

This announcement reflected CMS's view (stated in internal CMS documents) that without applying an FFS Adjuster to calculated repayment amounts, audited MACs are underpaid.¹³ In a CMS presentation titled "Model Calibration Factor," for example, CMS explained that:

⁷ U.S. Department of Health & Human Services, Payment for Medicare Advantage Plans: Policy Issues and Options (June 2009), available at <https://aspe.hhs.gov/reports/payment-medicare-advantage-plans-policy-issues-options-0>

⁸ 42 U.S.C. § 1395w-24(a)(5)(A), (b)(6)(A)(i)-(ii); see also *UnitedHealthcare Ins. Co. v. Azar*, No. 16-cv-157 (D.D.C. Dec. 4, 2017), ECF No. 57, 1 (acknowledging, in the government's motion for summary judgment, that there must be equivalence "between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional . . . Medicare, and the payments made to [MACs] for covering an individual with those same characteristics").

⁹ See 42 U.S.C. § 1395m-23(b)(4)(C), (D).

¹⁰ See generally Wakeley Consulting Group, Actuarial Report on CMS's November 1, 2018 Proposed Rule (Aug. 27, 2019) (enclosure to Letter from Anthony Mader, Vice President, Public Policy, Anthem, Inc., to Seema Verma, Administrator, Ctrs. for Medicare & Medicaid Servs. (Aug. 28, 2019), available at <https://beta.regulations.gov/comment/CMS-2018-0133-0260>).

¹¹ Notice of Error Calculation, *supra* note 6, at 3-4.

¹² *Id.* at 4-5.

¹³ See *Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-3) (Document authored by CMS titled "Model Calibration Factor"); *Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (ECF 44-4) (Document authored by CMS titled "Three RADV Policy Issues").

"[i]n RADV audits, we expect coding perfection from [MAOs],¹⁴ while "[i]n [traditional] Medicare, some portion of diagnoses on [traditional Medicare] claims are not documented in medical records."¹⁵

As a result, for RADV audits, MAOs "are being held to a different (higher) standard for diagnoses"¹⁶ absent an FFS adjuster.

CMS said that these different document standards matter because traditional Medicare data were used to calculate MA payments and the "[i]nclusion of undocumented diagnoses tends to reduce risk adjustment values."¹⁴ CMS then used numerical examples to demonstrate that MAOs would be underpaid (i.e., MAOs' costs would exceed CMS reimbursement) if MAOs were audited to a standard of data perfection without properly calibrating the overpayment amount to account for traditional Medicare data errors.¹⁷ CMS departed from the principle that a FFS adjuster is necessary by issuing a proposed rule in 2018¹⁸ suggesting that diagnosis coding errors in unaudited traditional Medicare data do not systematically impact payments to MAOs¹⁹ and released a corresponding study purporting to support this premise.²⁰ Healthfirst and numerous other parties, including actuarial and statistical experts, have submitted comments to CMS objecting to this approach and advocating for the use of a "fee-for-service adjuster" as originally proposed in connection with the proposed rule.²¹

In September 2018, a federal district court in *UnitedHealthcare Ins. Co. v. Azar II* ("Azar"), 330 F. Supp. 3d 173 (D.D.C. 2018), vacated CMS's Medicare Advantage Overpayment Rule because the rule violated the SSA's actuarial equivalence mandate by defining "overpayment" as the payment of funds to MAOs based on unsupported diagnosis codes, while not applying the same documentation standards to the traditional Medicare data used to calculate payments to MAOs.²² In doing so, the court concluded that CMS systematically devalues MAO payments when it uses unaudited traditional Medicare data to set MAO payment rates while measuring MAO "overpayments" based on audited patient records.²³ CMS presented a study that purported to deny the need for a fee-for-service adjuster, but the court in Azar

¹⁴ *Azar*, 1:16-cv-00157-RMC (D.D.C. Oct. 2, 2017) (SCP 44-3) at 8.

¹⁵ *Id.*

¹⁶ *Id.* at 7.

¹⁷ *Id.* at 8-9.

¹⁸ Notably, the 2018 proposed rule is not final and is still subject to administrative rulemaking process.

¹⁹ Medicare and Medicaid Programs, Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program for All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, 83 Fed. Reg. 54982 (proposed Nov. 1, 2018) (to be codified at 42 C.F.R. §§ 422, 423, 438, 498) (hereinafter "Proposed Rule").

²⁰ Centers for Medicare and Medicaid Services, *Fee for Service Adjuster & Payment Recovery for Contract Level Risk Adjustment Data Validation Audit* (Oct. 26, 2018), available at <https://tinyurl.com/ve3753d>; CMS, *Addendum to the Fee-For-Service Adjuster Study* (June 28, 2019).

²¹ See Public Comments on Proposed Rule (e.g., Anthem Letter dated August 28, 2019, *supra* n.12; Cigna Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0254>; CVS Health Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0259>; Humana Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0257>; Kaiser Permanente Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0267>; UnitedHealth Group Letter dated August 28, 2019, available at <https://www.regulations.gov/document?D=CMS-2018-0133-0263>).

²² *Azar*, 330 F. Supp. 3d at 187-90; *Azar*, Case No. 16-cv-157 (RMC), 2020 WL 417867 (D.D.C. Jan. 27, 2020).

²³ *Id.* at 186-87 ("[T]he 'expected' value of payments from CMS for healthcare costs [to MAOs] will be lower than the 'expected' payments CMS itself will make under traditional Medicare, since CMS does not audit or engage in similar self-examination for accuracy of its own records. The consequence is inevitable: while CMS pays for all diagnostic codes, erroneous or not, submitted to traditional Medicare, it will pay less for Medicare Advantage coverage because essentially no errors would be reimbursed.")

found that CMS's study "does not persuade" and concluded that the government had failed to "adequately respond" to criticisms of the study raised during litigation.²⁴ On January 27, 2020, the same court reaffirmed this position in denying the government's request to reconsider the court's prior holding.²⁵ The D.C. Circuit in *United Healthcare Insurance Co. v. Becerra*, 9 F.4th 868 (D.C. Cir. 2021), while overturning *Azar* in part, recognized the requirement of actuarial equivalence in conducting RADV audits. The *Becerra* court recognized that "the system-level adjustment that CMS said it would apply in the context of contract-level RADV audits came in direct response to concerns about actuarial equivalence." *Becerra*, 9 F.4th at 872. The court expressly limited its holding, striking down actuarial equivalence in the overpayment context: "we hold that the actuarial-equivalence requirement does not pertain to the statutory overpayment-refund obligation, or the Overpayment Rule challenged here . . ." *Id.* The Court, however, noted that it was not invalidating actuarial equivalence as applied to RADV audits, saying "[w]e express no opinion on whether the actuarial equivalence requirement . . . requires such an adjuster in the [contract-level RADV audit] context." *Id.* at n. 1 (emphasis added). Notably, the Overpayment Rule itself applies only to known overpayments. *Id.* at 880. Any RADV audit can necessarily only identify individual overpayments, and it is therefore not proper to require repayment of extrapolated results across the contract without adjusting to account for the error rate in the FFS program in order to ensure actuarial equivalency (if such extrapolation is indeed ever proper, as discussed above).

These Medicare Advantage program requirements apply to OIG's audits and calculation of estimated repayment amounts for the same program. Thus, OIG's extrapolated repayment calculations, by failing to apply an FFS adjuster, violate the "actuarial equivalence" mandate that underpins the Medicare Advantage program.

Healthfirst accordingly requests that OIG withdraw its overpayment calculation and limit any recovery in this audit to the specific encounters that were reviewed during this audit and for which the unsupported codes were found.

C. Retroactivity is Prohibited By Federal Law and is Unnecessary and Unjustified

This audit relates to services provided in 2015 and 2016, necessarily requiring looking back to significantly prior periods. The SSA prohibits retroactive rules absent a statutory requirement, significant public safety concern or other critical need²⁶, none of which are present here. In addition, retroactivity poses major operational barriers for MAOs and providers. Seeking records from providers for services provided in 2015 and 2016 to support HCCs reported on claims related to those services is often difficult. Most provider records from that period and earlier were paper, and while many providers have now converted to electronic records, it is not likely that they converted their older paper records. Additionally, providers have often moved, closed their practices, or may be deceased, all of which makes obtaining supporting records difficult even they existed at the time the claims were submitted.

Both because retroactivity is prohibited and because, practically speaking, provider records are sparse if available for past periods, we believe that even if a valid rule authorizing extrapolation if promulgated, it should not be applied retroactively, and that extrapolation by the OIG based on audit findings from 2016-2016 is similarly not permissible.

²⁴ *Azar*, 2020 WL 417867, at *1, *5.

²⁵ *Id.*

²⁶ 42 U.S.C. § 1395h(e)(1)(A): "A substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that- (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest."

D. Healthfirst Requests that OIG Withdraw Its Recommendation that Healthfirst Undertake Additional Auditing for the Condition Categories Subject to OIG's Audit

OIG recommends that Healthfirst "identify, for the high-risk diagnoses included in [the Draft Report], similar instances of noncompliance that occurred before or after [the] audit period and refund any resulting overpayments to the Federal Government[.]"²⁷ As further set forth below, MAOs are not required to audit to the standard that OIG suggests. Medicare Advantage regulations do not require the sort of audits that OIG recommends and certainly do not require MAOs to ensure data perfection as the Draft Report implies. In fact, the *Bacerra* court notes that "[n]othing in the Overpayment Rule obligates insurers to audit their reported data," a fact the court notes that CMS did not dispute. *Bacerra* at 884. Even if Healthfirst were to undertake additional audits, OIG has not provided Healthfirst with the information necessary to identify additional "potentially miskeyed diagnoses" similar to those audited by OIG here. Further, the implementation of ICD-10 in 2016 introduced a more precise alpha-numeric coding system which greatly reduced the likelihood of miskeying errors, which would likely moot this category of errors with respect to that year and going forward.

The government has long acknowledged that MAOs are not expected to submit perfect risk adjustment data. For example, it has stated that MAOs "cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and [the U.S. Department of Justice] believe is reasonable to enforce."²⁸ OIG has issued non-binding guidance stating that MAOs should establish an "information collection and reporting system reasonably designed to yield accurate information."²⁹ This guidance affords MAOs broad discretion in designing compliance mechanisms. As the federal district court acknowledged in *Azar*, there is a disconnect when the government "treats diagnosis codes as categorically valid for its own purposes under traditional Medicare," but then requires "Medicare Advantage insurers to certify 'based on best knowledge, information, and belief' that the information they provide to CMS, including all diagnosis codes, is 'accurate, complete, and truthful.'"³⁰

This understanding is reflected in MAOs' annual data accuracy attestation requirements. MAOs are required to certify that their risk adjustment data is accurate based on their "best knowledge, information, and belief."³¹ CMS has acknowledged that "[t]he requirement that the CEO or CFO certify as to the accuracy, completeness and truthfulness of data, based on best knowledge, information and belief, does not constitute an absolute guarantee of accuracy."³² CMS has stated that MAOs "will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted."³³ This "good faith" standard is not defined by CMS or OIG but it recognizes "that encounter data [can] come into [MAOs] in great volume from a number of sources, presenting significant verification challenges for the organizations."³⁴

²⁷ Draft report at "Report in Brief".

²⁸ 65 Fed. Reg. 40169, 40268 (June 29, 2000).

²⁹ 64 Fed. Reg. 61893, 61900 (Nov. 15, 1999) (noting also that MAOs "should exercise due diligence to ensure that these systems are working properly" but that "[t]he exact methods used . . . can be determined by the organization and that these methods 'should ordinarily [include] sample audits and spot checks of this system to verify whether it is yielding accurate information'").

³⁰ *Azar*, 330 F. Supp. 3d at 179–80.

³¹ 42 C.F.R. § 422.504(j)(2).

³² 64 Fed. Reg. at 61900.

³³ 65 Fed. Reg. at 40268.

³⁴ *Id.* Notably, OIG's Draft Report appears at times to conflate the source of diagnosis codes in a manner that suggests MAOs have more information than they actually do about the accuracy of the risk adjustment data submitted to CMS. See, e.g., Draft Report at 3 ("MA organizations collect the diagnosis codes that physicians document on the medical records and submit th[ose] codes to CMS."); *id.* at 12 ("Healthfirst had submitted diagnosis codes in which physicians had documented conditions. . . ."). Providers document patient encounters in their medical records and submit claims to MAOs with diagnosis codes based on those encounters. MAOs then

OIG's Draft Report makes two potentially misleading statements in this respect. First, the Draft Report states that "[f]ederal regulations state that [MAOs] must monitor the data that they receive from providers and submit to CMS."³⁹ As noted above, given the high volume of diagnosis codes that are submitted to MAOs through provider claims submissions, CMS gives MAOs broad discretion to design their own compliance and risk adjustment data accuracy programs. CMS has declined to require MAOs to implement any specific oversight measures, and certainly does not require verification of every code submitted by a provider. Second, the Draft Report also states that federal regulations "state that [MAOs] are responsible for the accuracy, completeness, and truthfulness of the data submitted to CMS for payment purposes."⁴⁰ This statement is misleading and not accurate because it suggests that the standard for accuracy, completeness and truthfulness is absolute and fails to account for the qualified "good faith" attestation standard that CMS explicitly adopted.

Accordingly, OIG's recommendation would dramatically expand the Medicare Advantage compliance program requirements.⁴¹ CMS is certainly aware of industry-wide trends pertaining to the seven categories audited by OIG through CMS's years of RADV audits, communications with MAOs, and review of the traditional Medicare data it uses to calculate MAO payments. But CMS has not opted to take any steps to implement regulations in response to these trends, let alone the expansive steps OIG proposes in its Draft Report. Healthfirst therefore respectfully requests that OIG withdraw this recommendation.

E. Healthfirst Will Continue to Identify Opportunities to Enhance its Existing RADV Compliance Program

As OIG acknowledges, Healthfirst has made significant changes to its RADV compliance program since the close of OIG's audit period. While Healthfirst regularly evaluates its compliance programs in order to both respond to regulatory changes and to identify opportunities for improvement, Healthfirst believes that its current RADV compliance program is sufficient to meet its current obligations. Accordingly, Healthfirst requests that OIG withdraw its recommendation that Healthfirst make changes to its existing RADV compliance program.

CONCLUSION

For the foregoing reasons, Healthfirst requests that OIG withdraw all recommendations, with the exception of the recommendation that Healthfirst repay actual overpayments in the amount of \$516,509.

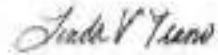
extract diagnosis codes from provider claims data to submit to CMS. Contrary to OIG's description in the Draft Report, the majority of the diagnosis codes MAOs submit to CMS come from the claims data submitted to MAOs by providers and are not identified by MAOs following a review of patient medical records. Recognizing that MAOs are not the original source of most risk adjustment data, CMS applies a "good faith" standard to the sexual data accuracy attestation, having expressly acknowledged that MAOs are not guaranteeing through that attestation absolute accuracy. OIG's Draft Report, and in particular its audit recommendations, appear to be in direct conflict with this express guidance from CMS.

³⁹ Draft Report at 8.

⁴⁰ *Id.* at 7.

⁴¹ The fact that the CMS compliance requirements are not more comprehensive and prescriptive is consistent with (1) the fact that HCC coefficients are based on unaudited traditional Medicare data and (2) the implausibility of expecting MAOs to audit more than a small subset of the vast amount of data submitted to CMS that is generated by healthcare providers who are neither employed by an MAO nor under the direction and control of the MAO.

Sincerely yours,



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Chief Legal Officer and General Counsel

cc: Pet Wang
 President and Chief Executive Officer

 Christine Logreira
 Vice President, Regulatory Affairs

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EXHIBIT D-48



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Measuring Coding Intensity in the Medicare Advantage Program

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Background: In 2004, Medicare implemented a system of paying Medicare Advantage (MA) plans that gave them greater incentive than fee-for-service (FFS) providers to report diagnoses.

Data: Risk scores for all Medicare beneficiaries 2004–2013 and Medicare Current Beneficiary Survey (MCBS) data, 2006–2011.

Measures: Change in average risk score for all enrollees and for stayers (beneficiaries who were in either FFS or MA for two consecutive years). Prevalence rates by Hierarchical Condition Category (HCC).

Results: Each year the average MA risk score increased faster than the average FFS score. Using the risk adjustment model in place in 2004, the average MA score as a ratio of the average FFS score would have increased from 90% in 2004 to 109% in 2013. Using the model partially implemented in 2014, the ratio would have increased from 88% to 102%. The increase in relative MA scores appears to largely reflect changes in diagnostic coding, not

real increases in the morbidity of MA enrollees. In survey-based data for 2006–2011, the MA-FFS ratio of risk scores remained roughly constant at 96%. Intensity of coding varies widely by contract, with some contracts coding very similarly to FFS and others coding much more intensely than the MA average. Underpinning this relative growth in scores is particularly rapid relative growth in a subset of HCCs.

Discussion: Medicare has taken significant steps to mitigate the effects of coding intensity in MA, including implementing a 3.4% coding intensity adjustment in 2010 and revising the risk adjustment model in 2013 and 2014. Given the continuous relative increase in the average MA risk score, further policy changes will likely be necessary.

Keywords: Medicare, payment systems, FFS, Capitation, risk adjusted payments, Managed Care Organizations

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Introduction

General

Enrollment in the Medicare Advantage Program has increased dramatically, growing from 9.3 million beneficiaries in March 2008 to 15.4 million in March 2014, an increase of 66% in just six years.

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout the history of Medicare contracting with health maintenance organizations and other private plans. In the late 1980s, Medicare paid health plans using a system that adjusted for demographic factors such as age and gender, but plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, and, as a result, health plans were estimated to be overpaid by approximately 11% (Brown, Bergeron, Clement, Hill, & Retchin, 1993).¹

In order to reward health plans for attracting sicker-than-average enrollees, and to discourage plans from constructing business models designed to avoid risk, Medicare and other payers have increasingly turned to diagnosis-based risk-adjusted payment systems in which health plans are paid more for enrollees expected to need more care. While mitigating the incentive to enroll only healthy people, diagnosis-based risk adjustment creates another set of incentives: to find and report as many diagnoses as possible. Risk-adjusted payment using plan-reported diagnostic information creates a dilemma—there are strong policy reasons to pay plans more if they enroll sicker people,

¹ Systems in which payment is based, at least in part, on patient diagnoses create an incentive for providers or plans to report all appropriate diagnoses. Most notably, after the advent of the inpatient prospective payment system, which used diagnosis related groups (DRGs), hospital case-mix increased.

but measuring morbidity using plan-reported diagnostic data provides strong incentives for plans to increase the reported morbidity of enrollees (Government Accountability Office, 2012).

Medicare Risk Adjustment

The first Medicare risk program was established under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. From 1982 to 1999, this program paid health plans (known as TEFRA health maintenance organizations [HMOs]) a monthly amount per enrollee based on 95 percent of the estimated costs of treating an average beneficiary in the traditional fee-for-service (FFS) program. This amount was adjusted for demographic factors such as age and gender (Hellinger & Wong, 2000; Lichtenstein, Thomas, Adams-Watson, Lepkowski, & Simone, 1991).

The Balanced Budget Act of 1997 made significant changes under the Medicare+Choice (M+C) program, including requiring the development of a new risk adjustment system that incorporated morbidity information. Medicare began using diagnoses from inpatient hospitalizations in 2000 to adjust payments to health plans. The Benefits Improvement Protection Act of 2000 required the use of ambulatory diagnoses in Medicare risk-adjustment, and Medicare implemented the CMS-HCC (Centers for Medicare & Medicaid Services-Hierarchical Condition Categories) risk adjustment model in 2004 and fully phased it in by 2007. The CMS-HCC incorporated both inpatient and ambulatory diagnoses that were categorized into 70 HCCs that were determined to be predictive of costs (Pope, *et al.*, 2004). In 2003 the Medicare Modernization Act (MMA) renamed the program "Medicare Advantage (MA)."

The MA payment system uses diagnostic information to assign a risk score to each beneficiary, where the average beneficiary in

fee-for-service has a risk score of 1.0. MA plans are paid the product of their bid multiplied by the enrollee's risk score—that is, if an MA plan bids \$1,000/month for an enrollee with a risk score of 1.0, and then enrolls a beneficiary with a risk score of 1.2, the plan gets paid \$1,200/month for that enrollee ($1.2 * \$1,000/\text{month}$).

This payment system creates incentives for MA plans to find and report as many diagnoses as can be supported by the medical record. For office-based services, physicians billing FFS are paid based on the procedures performed—for example, one amount for an intermediate office visit, a different amount for a skin biopsy—but are not paid based on the number of diagnoses that are reported (provided there is at least one that supports the need for the service provided). If, for example, a FFS patient with quadriplegia and a urinary tract infection (UTI) has an office visit for treatment of the UTI, the payment to the physician will be no more if both the UTI and quadriplegia are reported on the claim than if only the UTI is reported. Coding guidelines specify that the quadriplegia can legitimately be coded if it contributes to the complexity of care, but unlike the situation for MA plans, in FFS there is no incentive to report more than one diagnosis. In contrast, MA plans have a strong incentive to do so. In addition to the incentives to report more completely, the method of collecting diagnostic information also provides MA plans additional opportunities to increase risk scores. FFS diagnoses are drawn only from health care claims submitted for payment. MA plans may also review medical records and can report all diagnoses that are supported in the record, including those that were not reported by physicians on any health care claim or encounter record. MA plans can also employ nurses to visit enrollees in their homes to conduct health assessments and report diagnoses that are found.

As noted, payment to MA plans is calibrated based on coding patterns in FFS. If, for example, Jane Doe would have a risk score of 1.0 if she were in FFS, the implicit assumption in the design of the MA payment system is that she would have the same risk score of 1.0 if she were enrolled in MA. Alternatively, if the same Jane Doe had a risk score of 1.1 if enrolled in MA, then her plan would be overpaid. As we use the phrase, 'coding intensity' is the difference between the scores that a group of beneficiaries would have if enrolled in MA and their scores in FFS.

If we find that MA plans code with high intensity, that does not provide information about whether MA plans are 'overcoding' or whether FFS providers are 'undercoding.' Similarly, one cannot infer whether MA coding is any more or less accurate than FFS. However, for the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically different than those risk scores would be in FFS, and not which set of scores is more accurate. Suppose, for example, that average expenditure per FFS beneficiary is \$10,000/year, and that the average risk score for all FFS beneficiaries is 1.0. The goal of the payment system is to assure that—if all of those beneficiaries were to enroll in MA—the average payment to MA plans would be approximately \$10,000 per beneficiary. If, however, FFS systematically underreports diagnoses and MA reports them more completely, then the average risk score in MA would be greater than 1.0, and MA plans would be paid more than \$10,000 per beneficiary. The goal of the risk adjustment system is to assure that MA plans that enroll sicker-than-average beneficiaries are paid appropriately, but not to increase payment for an average beneficiary.

As a result of concern about the effects of incentives to increase coding intensity on MA plan payment levels, the Deficit Reduction Act

of 2005 directed CMS to measure and adjust for coding intensity (Department of Health and Human Services, 2007), and in the 2010 payment year CMS adjusted risk scores by 3.41% to reflect anticipated differences between MA and FFS coding (Department of Health and Human Services, 2009). The Government Accountability Office (2012) estimated that in 2010 MA beneficiary risk scores were at least 4.8% and perhaps as much as 7.1% higher than they likely would have been if the same beneficiaries had been continuously enrolled in FFS. The Affordable Care Act directs CMS to increase the coding intensity adjustment to at least 4.71% in 2014, and further increase it to at least 5.71% by 2018 (PPACA & HCERA, 2010). The American Taxpayer's Relief Act of 2012 further increases the minimum coding intensity adjustment to 4.91% in 2014 and 5.91% in 2018.

The risk adjustment model implemented in 2004 was recalibrated in 2007, 2009, and 2013.³ These changes slowed the growth in measured MA risk scores somewhat. Further, as described in more detail below, since 2014, CMS has adopted substantial changes to the model, particularly relating to several diagnoses that have been subject to coding intensity efforts by MA plans (Department of Health and Human Services, 2013). In 2014 the risk score is a blend, weighting the risk score calculated using the 2013 model by 25% and the risk score calculated using the 2014 model by 75%.

Concerns about coding intensity in MA plans would be minor if coding in FFS were relatively complete, because in that case there would be little opportunity for MA plans to legitimately increase risk scores through efforts at increasing diagnostic

³ HCCs are constrained for a variety of reasons, including methodological and policy reasons. Starting in 2013, the coefficients for the four most severe diabetes HCCs were constrained to the same amount, eliminating the opportunity to increase revenue by increasing the reported severity of diabetes within these four HCCs.

reporting. However, FFS coding is known to be both incomplete and variable. Incomplete coding is evidenced by lack of persistence in coding of chronic conditions. For instance, among Medicare beneficiaries diagnosed with quadriplegia in one year, only 61% had a diagnosis of quadriplegia reported in the subsequent year (Medicare Payment Advisory Commission, 1998). Coding intensity also varies geographically; in the Hospital Referral Regions (HRRs) with the most intense practice patterns, the probability that a beneficiary is diagnosed with three or more chronic conditions is double the probability in low-intensity HRRs, with no evidence of differences in underlying prevalence (Welch, Sharp, Gottlieb, Skinner, & Wennberg, 2011).

Incomplete and variable coding provide ample opportunities for MA plans to increase risk scores of beneficiaries through coding intensity efforts, and a number of vendors actively market services that help plans to do so (Gorman Health Group, 2013; Leprechaun, 2013), often advertising high returns on investment (ROIs) for their services.

This paper uses recent data as well as improved methods to estimate the effects of coding intensity on MA risk scores, with particular attention to variation over time in coding intensity, variation in coding intensity across plans, and variation in the diagnoses most subject to coding intensity efforts. Before describing our methods, we'll review what is known about risk selection in the MA program.

Evidence on Risk Selection

Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout its history of contracting with HMOs and other private plans. For example, Brown *et al.* (1993) found that health plans were overpaid by approximately 11% under the Medicare risk program during the late 1980s

because plans experienced favorable selection; on average, risk plan enrollees were healthier than fee-for-service beneficiaries with the same demographic characteristics, with lower prior reimbursements and fewer indicators of chronic health problems (Brown *et al.*, 1993). Several studies confirmed that the favorable risk selection for early HMOs continued during the early 1990s (Mello, Stearns, Norton, & Ricketts, 2003; Call, Dowd, Feldman, & Maciejewski, 1999; Physician Payment Review Commission, 1996; Riley, Chiang, Ingber, & Tudor, 1996). For example, Mello *et al.* (2003) found that Medicare beneficiaries with a history of cancer or stroke were significantly less likely to be enrolled in HMOs.

Recent analyses suggest that the various policy changes that have been implemented over the past decade—such as the implementation of the CMS-HCC model, the addition of an open enrollment period, and additional refinements of the risk adjustment system—have reduced the degree of selection bias between Medicare Advantage (MA) and the traditional FFS program. For example, Newhouse, Price, Huang, McWilliams, & Hsu (2012) recently found that differences in risk scores for beneficiaries switching from the traditional FFS program to MA and beneficiaries remaining in the traditional program narrowed by a factor of 3 between 2004 and 2008 (with the difference between risk scores for beneficiaries switching into MA and those staying in the traditional FFS program changing from -0.113 to -0.037); and differences in adjusted mortality rates narrowed by a factor of 2 between 1988 and 2008 (with mortality among beneficiaries in MA as a percentage of mortality among beneficiaries in the traditional FFS program increasing from 85 percent to 93 percent) and were almost equal between persons enrolled in MA for five or more years and traditional FFS enrollees (Newhouse *et al.*, 2012). Similarly, McWilliams,

Hsu, and Newhouse (2012) found reductions in differences between MA and FFS for self-reported health and health care use between 2001 and 2003 and between 2006 and 2007. However, there continues to be evidence of selection bias in disenrollment from MA plans (Riley, 2012; Medicare Payment Advisory Commission, 2012; Morrissey, Kilgore, Becker, Smith, & Delzell, 2012).

Methods

Ideally, we would measure coding intensity by running an experiment with a large group of beneficiaries, in which one-half of the group was randomly assigned to MA, the other half to FFS, and we observed the risk scores of each group. The difference between the average score in MA and FFS would be a good estimate of coding intensity. In the absence of performing this experiment, we use a variety of inferential approaches. As shown below, average MA risk scores increased much more rapidly than average FFS scores from 2004 to 2013. There are three potential explanations for the relative increase in MA scores. First, the composition of MA enrollment might have changed; for example, MA enrollees in 2013 might be older, relative to FFS, than MA enrollees in 2004, and, as a result have higher risk scores. Second, even if there were no change in the composition of MA enrollees, MA enrollees might have gotten sicker more quickly than FFS beneficiaries. Third, it is possible that coding intensity increased in MA. Below, we assess the plausibility of each of these three potential explanations concluding that greater coding intensity is by far the most likely explanation.

We evaluate whether changes in MA scores relative to FFS scores are due to coding intensity efforts or to changes in the composition of enrollees by analyzing the contribution of changes in risk scores for four types of beneficiaries: stayers,

leavers, joiners, and switchers—where stayers are beneficiaries in either MA or FFS for two consecutive years; leavers are beneficiaries, primarily decedents, who were in one sector in the first year, but not Medicare eligible in the second year; joiners are beneficiaries, primarily those turning 65, who were not Medicare eligible in the first year; and switchers are beneficiaries who move from FFS to MA (or vice-versa) between two consecutive years. To the extent that the contribution of leavers, joiners, or switchers differed between MA and FFS, then we will have evidence that part of the differential growth in risk scores between MA and FFS is a result of differences arising from enrollment decisions or mortality of beneficiaries, or “caseload dynamics” for shorthand. However, if risk scores increase more rapidly for MA stayers than for similar FFS stayers, then we will have evidence that coding intensity accounts for part of the more rapid growth in MA scores.

Our analysis assumes that in the absence of coding intensity efforts, the risk score for a given MA beneficiary would increase, on average, at the same rate as the risk score for an otherwise similar FFS beneficiary from one year to the next. This appears to be a reasonable assumption, and would only be incorrect if MA beneficiaries were actually getting sicker more quickly than FFS beneficiaries. We analyze changes in the relative mortality rate of MA and FFS enrollees as an independent method of assessing the relative morbidity of beneficiaries in the two sectors. If MA enrollees are, in fact, getting sicker more quickly than FFS beneficiaries, we would expect to see MA mortality rates increase relative to FFS mortality.

Data

For each year from 2004 to 2013, we used three Medicare administrative files with beneficiary level data: the Enrollment Database (EDB); the

Common Medicare Environment, which contains the MA contract number; and the Risk Adjustment Processing System, which contains the risk score. For each year from 2004 to 2013, we computed the risk score using each HCC's coefficient (i.e., weight) that was used to pay plans in 2004–2006. Analyses of coding intensity based on risk scores have not appeared in the peer-reviewed literature.

We excluded beneficiaries not enrolled in both Parts A and B, because diagnostic information would be incomplete. Beneficiaries enrolled in cost contracts, hospice, or the ESRD program were also excluded, because of differences in payment methodology. Risk scores were computed prior to any normalization and MA-wide adjustment for differences in coding.

Decomposition of Risk Score Growth

To decompose the changes in risk scores, we analyze beneficiaries based on their enrollment as of July 1 of each of two consequent years (called a “cohort”). We analyze nine cohorts, from the first cohort under the new adjustment system in 2004–2005 through the most recent one in 2012–2013, estimating the contribution of each type of beneficiary—stayers, joiners, leavers, and switchers—to the overall change in risk score. The decomposition method is described in the Supplemental Appendix.

Contract-Level Analyses

To assess the extent to which coding intensity differs across contracts, we calculate the rate of increase in risk scores for stayers for contracts that continuously participated in Medicare from 2004 through 2011, had at least 10,000 enrollees in both 2004 and 2011, and whose ratio of 2011 enrollment to 2004 enrollment was between 25% and 300%. The subset of contracts account for approximately 85% of enrollment in 2004 and 42% in 2011.

For each contract and cohort, we define the excess increase in risk score for stayers as the difference between the increase in risk scores for stayers in the contract and the increase in risk scores for FFS beneficiaries, controlling for age and decedent status (details are in the Supplemental Appendix).³ The cumulative excess increase in risk score is the sum of this amount over the seven cohorts from 2004 to 2005 through 2010 to 2011. Contracts are divided into deciles (weighted by 2011 enrollment) based on the cumulative excess increase in scores for stayers.

The growth in relative prevalence of each HCC was calculated separately for the MA and FFS sector as well as by decile of coding intensity among the continuously participating contracts.

Analysis of Medicare Current Beneficiary Survey (MCBS) Data

We analyze the MCBS to provide an assessment of the relative risk of MA and FFS beneficiaries that is independent of the data reported by MA plans or FFS providers. As described more fully in the Supplemental Appendix, in the first stage of the analysis, we use MCBS data from 2004 to 2011 to estimate a regression model to predict the sum of Part A plus Part B expenditures. The regression is estimated on FFS enrollees. Independent variables are demographic characteristics (age, gender, Medicaid status, and institutional status), self-reported health status (excellent, very good, good, fair, or poor), and self-report of whether the respondent has ever been diagnosed with hypertension, heart attack, heart failure, stroke, cancer, or diabetes, and dummy variables for each year. In the second stage, we use the regression coefficients to predict expenditures for each FFS

³ The contract-level analysis implicitly assumes that the increase in FFS risk scores for a beneficiary of a given age and decedent status is uniform geographically.

and MA respondent in the sample, and compare the average predictions for MA and FFS.

Results

Mean risk scores in MA increased faster than in FFS from 2004 to 2013—by 0.305 in MA, compared to 0.106 in FFS (Exhibit 1). As measured using the risk model in effect in 2004, MA scores grew from 90.2% of FFS scores in 2004 to 109.1% in 2013, an increase of 18.9 percentage points.⁴

Decomposition of Risk Score Growth

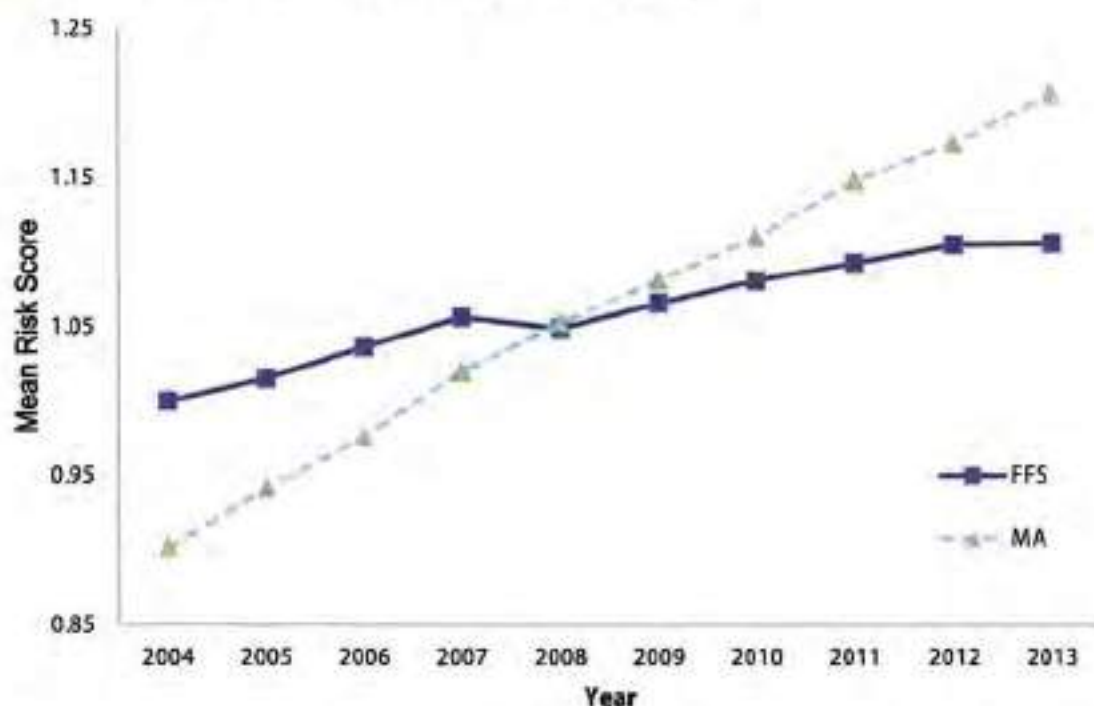
Risk scores among MA stayers increased more quickly than risk scores among FFS stayers in every

cohort (Exhibit 2). Across the two-year cohorts, the growth in risk scores for FFS stayers averaged 0.088. In contrast, in MA the growth in mean risk scores for stayers was 0.106 in 2004–2006, 0.119 in 2006–2010, and 0.132 in 2010–2013. The difference between the rate of growth in risk scores for MA and FFS stayers is substantial, with average MA scores increasing one-third more rapidly than FFS scores.

As was shown in Exhibit 1, the average MA risk score increased 0.025 more rapidly than the average FFS score from 2004 to 2005. Differential changes between MA and FFS in caseload dynamics account for approximately one-half of this 0.025 difference (Exhibit 3). As was shown in Exhibit 2, risk scores for FFS stayers increase by approximately 0.088 per year. However, as was shown in Exhibit 1, the

⁴ As noted, the payment rules, however, did change in a variety of ways.

Exhibit 1. Mean Risk Scores, MA vs. FFS, 2004–2013 (2004 Model)



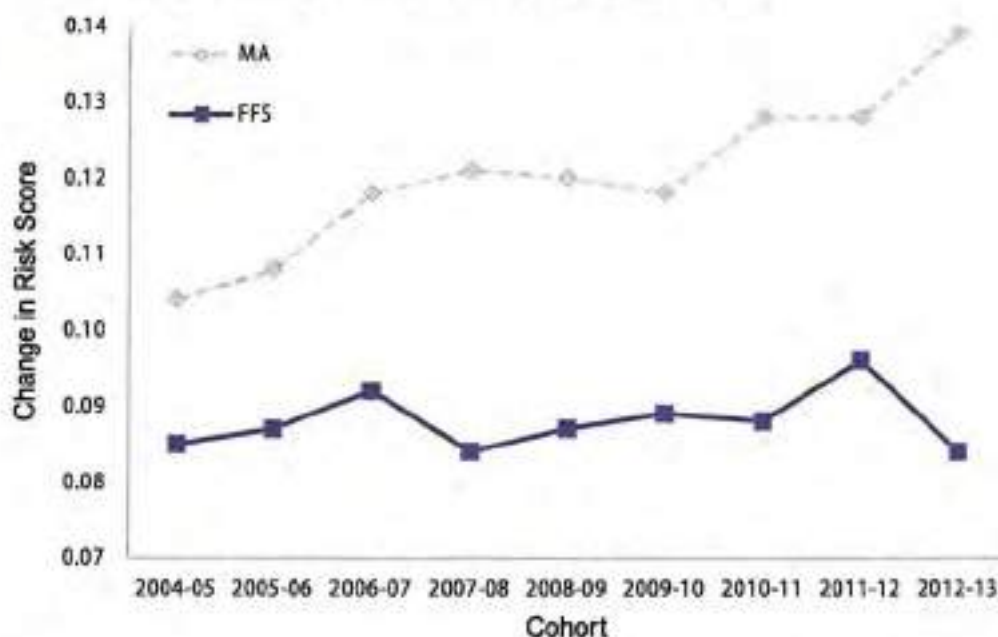
NOTE: 2004 HCC model, which here has been normalized to 1.00 for FFS in 2004. For payment purposes, this model was modified and recalibrated in 2007, 2009, 2013, and 2014. Risk scores were adjusted by -3.41%, starting in 2010. Diagnoses from FFS diagnostic radiology claims were excluded starting in 2008.

SOURCE: Authors' analysis of Medicare administrative data.

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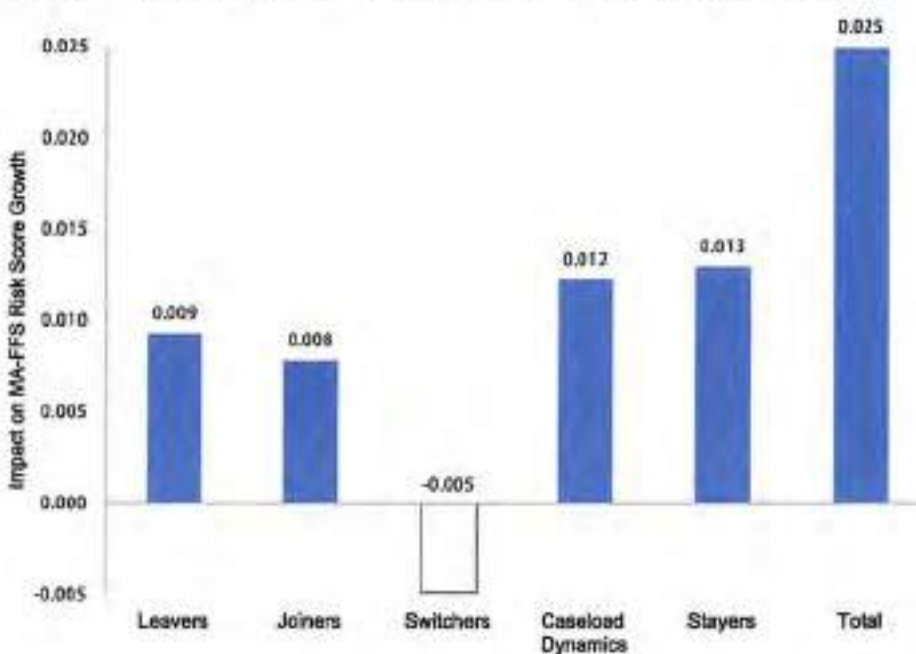
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Exhibit 2. Growth in Risk Scores Among Stayers, MA vs. FFS, 2004–2013



NOTE: 2004 model. Stayers are beneficiaries who were enrolled in MA (or in FFS) on July 1 of two consecutive years.
SOURCE: Authors' analysis of Medicare administrative data.

Exhibit 3. Sources of Differential Growth in MA and FFS Risk Scores, 2004–2005



NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.
SOURCE: Authors' analysis of Medicare administrative data.

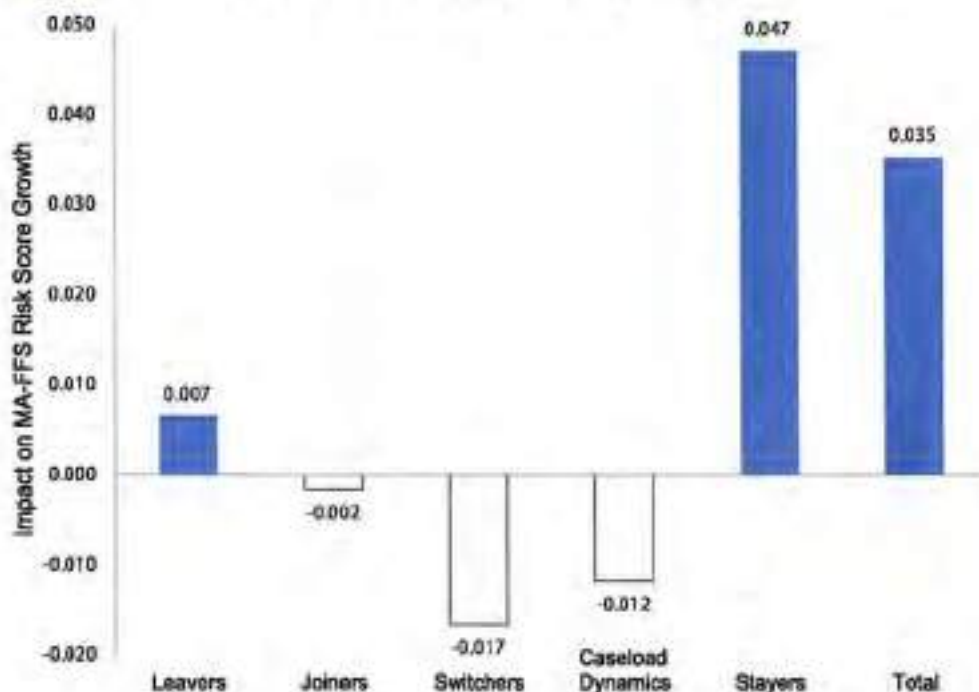
average FFS risk score increases by approximately 0.012 per year. Caseload dynamics account for the difference between the 0.088 growth for stayers and the 0.012 for all FFS beneficiaries—relatively high risk score decedents exit the caseload and are replaced by relatively low risk score 65 year olds.

From 2004 to 2005, caseload dynamics caused greater restraint in the growth of FFS risk scores than in MA (Exhibit 3). Decedents are a greater proportion of FFS beneficiaries than of MA enrollees and, similarly, 65 year olds are a greater proportion of FFS than of MA. Primarily as a result of the greater proportion of decedents in FFS, the average MA risk score in 2005 increased by 0.009 more than the average FFS score. Similarly, as a result of the greater proportion of 65 year olds in FFS, the average MA score increased by 0.008 more than the average FFS score. These

effects were partially balanced by the effects of switchers—relatively low risk beneficiaries switching from FFS to MA, and relatively high risk beneficiaries switching from MA to FFS. Despite the partially counterbalancing effect of switchers, the net effect of caseload dynamics was to cause the average MA score to increase 0.012 more rapidly than the average FFS score from 2004 to 2005. The remaining 0.013 of the difference in growth rate between MA and FFS scores is accounted for by the fact that risk scores for stayers increased more rapidly in MA than in FFS.

Although caseload dynamics accounted for part of the more rapid growth in MA risk scores in 2004–2005, in 2012–2013 the effects of caseload dynamics reversed, causing the average MA risk score to grow more slowly than FFS (Exhibit 4). Decedents have a similar effect in 2012–2013 as in

Exhibit 4. Sources of Differential Growth in MA and FFS Risk Scores, 2012–2013



NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.

SOURCE: Authors' analysis of Medicare administrative data.

2004–2005, but the effects of joiners and switchers are different in the latter period than in the former. In contrast to the 2004–2005 results, in 2012–2013 the proportion of 65 year olds was similar in MA and FFS, and joiners do not have much effect on the difference between MA and FFS in risk score growth rates. Switchers had a small negative effect in 2004–2005, but a much larger negative effect in 2012–2013.⁵ As was shown in Exhibit 2, the difference between MA and FFS in the rate of increase in risk scores for stayers widened in 2013, accounting for the larger effect of stayers in Exhibit 4 than in Exhibit 3.

On average over the 2004–2013 period, caseload dynamics had virtually no net effect on

the difference between MA and FFS in the rate of growth of risk scores, and the greater increase in risk scores for MA stayers compared to FFS appears to account for most of the reason for the differential growth (Exhibit 5). Caseload dynamics led to more rapid increases in risk scores in MA in the early part of the period, but to slower increases in the latter part and, on balance, made very little contribution to the differential growth in scores.

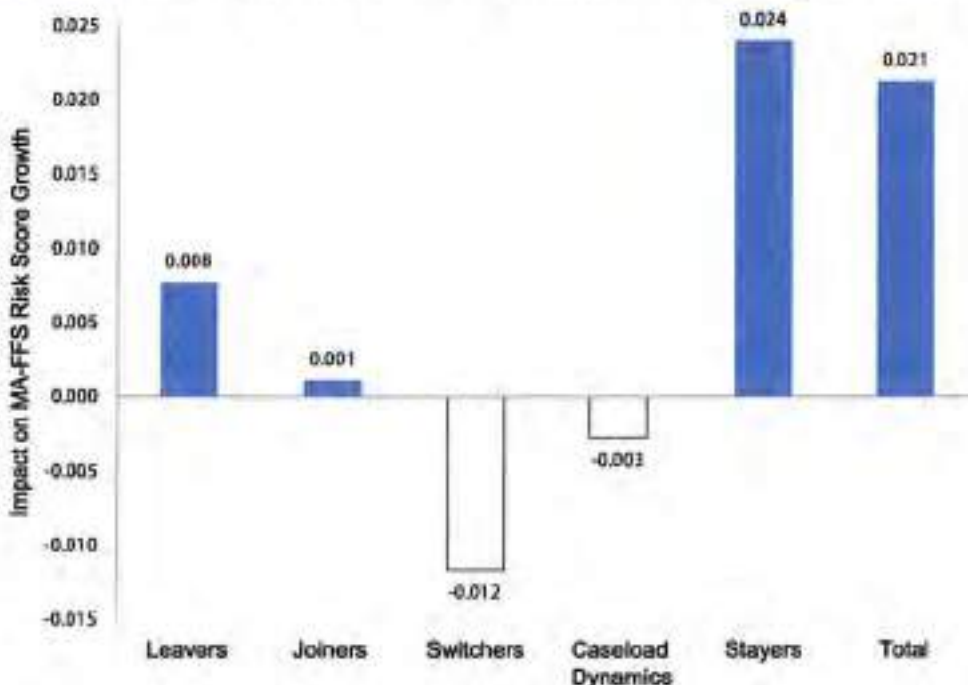
We have shown that more rapid increase in risk scores for MA stayers than for FFS stayers largely accounts for the more rapid growth in MA risk scores seen in Exhibit 1.

Relative Morbidity of MA Enrollees: Analyses of Mortality and MCBS Data

We analyze mortality rates in MA and FFS during the 2004–2012 period to test the hypothesis that

⁵ The difference between 2004–05 and 2012–13 is primarily a result of the fact that disenrollees from MA to FFS had higher risk scores in the latter cohort than in the earlier one.

Exhibit 5. Sources of Differential Growth in MA and FFS Risk Scores, Average 2004–2013



NOTE: 2004 model. Caseload dynamics is the sum of leavers (e.g., decedents), joiners (e.g., newly eligibles), and switchers. Total is the sum of caseload dynamics and stayers.

SOURCE: Authors' analysis of Medicare administrative data.

MA beneficiaries declined in health relative to FFS beneficiaries. Mortality rates declined somewhat more rapidly in MA than in FFS from 2004 to 2012, providing no support for the hypothesis that the underlying morbidity of MA beneficiaries increased relative to FFS (See Supplemental Appendix Exhibit A3 & A4). As noted earlier, mortality rates were lower in MA than in FFS.

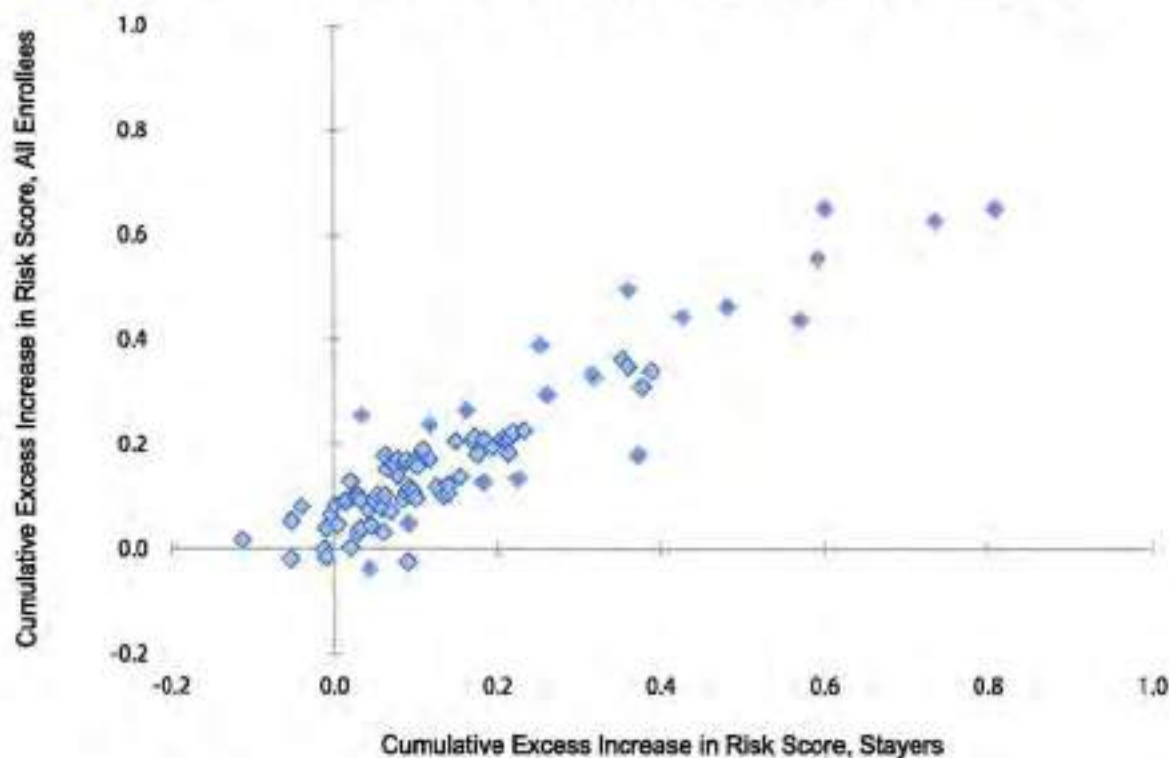
We use MCBS data to provide an assessment of relative risk of MA and FFS beneficiaries that is independent of data reported by MA plans or FFS providers. As described in the Supplemental Appendix, we predict spending for each MA and FFS beneficiary using demographic information, self-reported health status, and the respondent's report of whether she has ever been diagnosed with hypertension, heart attack, heart failure, stroke, cancer, or diabetes. Predicted expenditures for MA

enrollees average approximately 96% of predicted expenditures for FFS beneficiaries, and the ratio does not appear to have changed systematically over the 2006 to 2011 period. Results from this analysis are shown in the Supplemental Appendix Exhibit A8.

Contract-Level Analyses

There is a striking amount of heterogeneity across MA contracts in the extent to which risk scores for stayers increased from 2004 to 2011 (Exhibit 6). The fourteen contracts accounting for 10% of MA enrollment that coded least aggressively had cumulative increases in risk scores for stayers at or below the level in FFS (i.e., cumulative excess increase at or below zero). Conversely, the four contracts in the top decile, including one with over 200,000 members, had a cumulative excess increase

Exhibit 6. Cumulative Excess Increase in Risk Scores, All Enrollees vs. Stayers Only, by Contract, 2004–2011



NOTE: 2004 model. Continuously participating contracts (N=86).

SOURCE: Authors' analysis of Medicare administrative data.

of 0.59 or more (at least 0.08 per year). Contracts in which risk scores for stayers increased more rapidly than in FFS also had overall risk scores that increased more rapidly than FFS ($r=.92$).

Increases in diagnostic coding are especially large in a relatively small number of largely discretionary HCCs (Exhibit 7).⁶ For example, in 2012, 1.2% of FFS beneficiaries were coded with drug or alcohol dependence, compared to 8.1% of beneficiaries in the 10% of MA contracts with the highest level of coding intensity (as measured by the cumulative excess increase in risk scores for stayers shown in Exhibit 6). Similarly, polyneuropathy is recorded three times as often in the top decile of MA plans as in FFS. In addition, MA plans, particularly those in the top decile of coding intensity, both increased the rate at which diabetes was reported, and shifted the distribution towards the highest paying diabetes HCC (HCC 15). Among the top decile of plans, the prevalence of this HCC increased from 2.5% in 2004 to 20.1% in 2012. In contrast, for diagnoses such as heart attack and hip fracture, where there is little discretion in diagnosis, prevalence in the top decile of plans is similar to, or below, FFS levels (see Supplemental Appendix Exhibit A5).

In 2014 Medicare started using a revised model, which we term the “2014 model.” In part as a result of the analysis shown in Exhibit 7, the polyneuropathy HCC was restructured to remove diabetic neuropathy, and the renal failure HCC was restructured to exclude chronic kidney disease stages 1–3 and was split into acute and

chronic kidney conditions, among other changes. These changes build on the changes made in 2013 that constrained the payment weights for each of the four most severe diabetes HCCs to be equal, removing the ability of MA plans to generate extra revenue by increasing the reported severity of diabetes within these four HCCs.

As a result of the changes to the model in 2013 and 2014, the impact of coding effort on risk scores is smaller using the new 2014 model than with the older 2004 model. As shown in Exhibit 8, if the 2014 model had been in place in 2013, the average MA risk score in 2013 would have been slightly higher than the average FFS score. Even using the new model, the average MA score increased substantially relative to the average FFS score from 2004 to 2013, but the rate of increase was somewhat slower than when measured with the 2004 model—an increase of 2.2% per year in relative MA score using the 2004 model (Exhibit 1)—compared to approximately 1.6% per year using the 2014 model. This result suggests that some coding intensity efforts—such as increasing the reported severity of diabetes or coding chronic kidney disease more aggressively—have been neutralized by the 2014 model, but others have not.

Discussion

In the 2004–2013 period, the mean MA risk score increased 2.2 percentage points per year more quickly than the mean FFS score using the 2004 model and 1.6 percentage points more quickly using the 2014 model. Comprehensive risk adjustment was first implemented in Medicare Advantage in 2004 and was not fully phased in until 2007 when 100% of Part C payments were risk adjusted. It is possible that during this phase-in period when plans were first reporting diagnosis codes from ambulatory settings, the level of coding by MA plans was not as comprehensive

⁶ An HCC is considered “discretionary” if it is based on diagnoses that providers may or may not record for patients having the diagnosis. For example, there is relatively little discretion in whether a diagnosis of “hip fracture” should be recorded for a patient presenting with an apparent hip fracture. In contrast, there is substantial discretion about whether a patient being assessed in an annual wellness visit should be recorded as exhibiting “alcohol or drug abuse.” Discretion might also result from either a choice of ICD-9 codes (e.g., pneumonia vs. sepsis in an inpatient setting) or underlying ambiguity of the condition (e.g., depression vs. anxiety).

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Exhibit 7. Top Ten HCCs of Relative Prevalence in the Top Decile of MA Contracts, 2004 vs. 2012.

Rank	HCC	Description	Prevalence							
			2004				2012			
			FFS Mean	MA Mean	MA Top Decile	Ratio, Top Decile:FFS	FFS Mean	MA Mean	MA Top Decile	Ratio, Top Decile:FFS
1	52	Drug/Alcohol Dependence	0.6%	0.4%	0.5%	0.75	1.2%	1.7%	8.1%	6.64
2	15	Diabetes with Renal or Peripheral Circ. Manifest.	2.5%	2.5%	2.5%	0.98	4.0%	7.1%	20.1%	5.07
3	131	Renal Failure	3.5%	2.7%	2.7%	0.79	9.9%	14.6%	38.2%	3.85
4	71	Polyneuropathy	3.8%	3.1%	3.3%	0.85	6.5%	10.1%	20.1%	3.09
5	83	Angina Pectoris/Old Myocardial Infarction	5.3%	4.6%	5.0%	0.96	4.9%	7.9%	15.0%	3.03
6	55	Major Depressive, Bipolar, & Paranoid Disorders	3.9%	2.4%	3.0%	0.76	5.7%	7.5%	14.1%	2.50
7	105	Vascular Disease	11.2%	7.8%	8.1%	0.73	13.6%	15.4%	33.3%	2.44
8	108	Chronic Obstructive Pulmonary Disease	13.4%	10.7%	12.5%	0.93	13.3%	14.5%	25.3%	1.90
9	100	Hemiplegia/Hemiparesis	1.1%	0.8%	0.6%	0.57	1.2%	1.3%	2.0%	1.77
10	157	Vertebral Fractures without Spinal Cord Injury	1.1%	0.8%	0.7%	0.62	1.1%	1.0%	1.7%	1.58

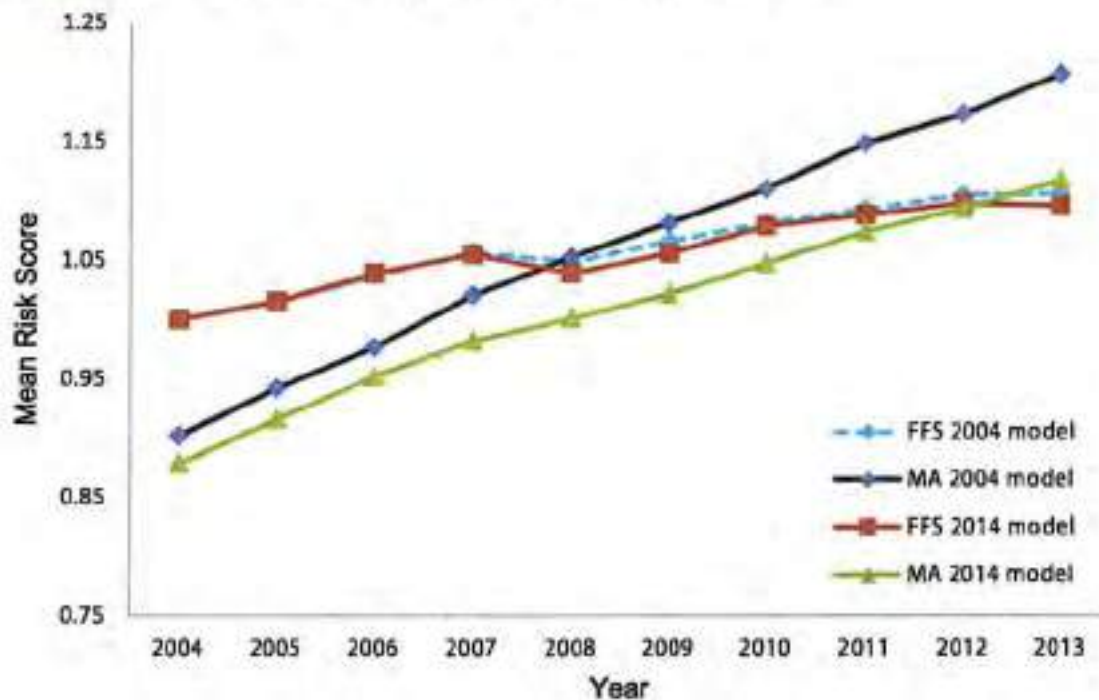
NOTE: 2004 model. Low-prevalence HCCs (<1% in 2012) were excluded.

Top decile defined using 2004–2011 data.

SOURCE: Authors' analysis of Medicare administrative data.

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Exhibit 8. Mean Risk Scores, MA vs. FFS, 2004–2013 (2004 & 2014 Models)

NOTE: CMS will use the "2014 model" for payment purposes for the first time in 2014, when it will receive a weight of 75%. This exhibit simulates past payment assuming full implementation. Here, both models have been normalized to 1.00 of the FFS mean in 2004.

SOURCE: Authors' analysis of Medicare administrative data.

as FFS. If that were the case, the relatively faster growth in risk scores during this period could be attributable to plans "catching up" to FFS, rather than coding more intensely than FFS. The true difference in average MA and FFS risk, which is beyond the scope of this paper, is a worthy topic for future research.

It appears that most of the reason that MA risk scores increased more quickly than FFS scores is due to increases in relative coding intensity—measured as increases in risk scores for stayers—with little of it accounted for by changes in enrollment mix. There is little sign of coding intensity slowing; in fact, Exhibit 2 shows that it may be increasing (using the 2004 model).

Our conclusion is supported by several findings. Our analysis of joiners, leavers, switchers, and stayers shows clearly that changes in the

composition of the MA caseload do not account for the increase in relative MA risk scores. Risk scores for stayers increased more quickly for MA enrollees than for FFS beneficiaries—by an average of 0.088 for FFS stayers, compared to 0.120 for MA stayers (Exhibit 2), and it is this difference that accounts for the relative increase in MA risk scores (Exhibit 5).

In principle, risk scores for stayers could have increased more quickly in MA because of differences in characteristics at baseline; for example, risk scores typically increase more quickly for older beneficiaries than for younger beneficiaries. If MA enrollees were older than FFS beneficiaries, then MA scores (unadjusted for age) would have increased more quickly than FFS, even if there were no change in coding intensity. However, the age distribution of MA enrollees is

relatively similar to the age distribution of FFS beneficiaries, and slight differences between the sectors in the age distribution do not account for differences in the rate of growth of risk scores. As a second example, risk scores may increase more quickly for beneficiaries with lower initial risk scores than for those with higher initial scores, because of regression toward the mean. However, baseline risk scores are higher in MA than in FFS in the later part of the analysis period, precluding a regression-toward-the-mean explanation for MA's more rapid growth in scores.

In addition, if MA enrollees were actually sicker, relative to FFS beneficiaries, in 2013 than in 2004, then we would have expected to see some reflection of this in our analysis of mortality rates and of self-reported health status information. In contrast, mortality rates in MA declined more quickly than mortality rates in FFS, and there was no evidence of a trend in self-reported illness, suggesting that MA enrollees did not actually become relatively sicker over the time period.

In an observational study such as this one, it is never possible to conclusively rule out all alternative hypotheses. MA risk scores increased more rapidly than FFS scores. We have shown that this did not result from a change in the composition of MA enrollees. And we have shown that using two independent measures of health status—self-reported health from the MCBS and information on mortality—that there is no indication that MA enrollees actually were getting any sicker than FFS beneficiaries. While it is theoretically possible that some explanation other than greater coding intensity accounts for the relative increase in MA risk scores, we are unable to suggest any plausible alternative hypotheses.

We have also shown that there is substantial heterogeneity across plans in coding intensity, with some plans coding at approximately the same level

as FFS, while several others created a cumulative increase in coding intensity from 2004 to 2011 of 60% or more.

Coding more carefully may have real health benefits. Better identification of problems and better documentation of problems that have been identified could improve the quality of treatment provided and may even lower costs—or they may lead to unnecessary treatment and higher costs. In either case, however, the purpose and design of the risk-adjusted payment system is not to improve the quality of coding. It is to ensure that plans are paid according to the health of the patients they enroll. It is unlikely that the increased payments achieved by plans through increased coding intensity are related to substantial health benefits that better coding might produce.

CMS and the Congress have responded to the increase in risk scores over time in several ways. First, starting in 2010, CMS lowered payment by 3.41% by applying an across-the-board coding adjustment. The coding intensity adjustment will increase to 4.91% in 2014 and to at least 5.91% in 2018. Second, starting in 2013, CMS set the four most severe diabetes HCCs (HCC15-HCC18) to have the same payment coefficient (Department of Health and Human Services, 2012). As a result, recording diagnoses that move enrollees from HCC18 (diabetes with ophthalmologic or unspecified manifestation) into HCC15 (diabetes with renal or peripheral circulatory manifestation) will no longer increase revenue for MA plans. Third, CMS made further changes to the model in 2014, removing some of the HCCs that were the subject of MA efforts at increasing coding intensity.⁷

⁷ CMS is also recovering overpayments identified by risk adjustment data validation (RADV) audits of selected MA contracts.

Relative MA risk scores have been increasing at least 1% per year (Exhibit 8) and are likely to continue to do so, even though MCBS-based risk scores have been roughly constant.^a The legislated increase in coding intensity adjustment is 0.25% per year from 2014 through 2018. The President's Budget for 2015 proposes increasing the minimum adjustment to 0.67% per year through 2020, plateauing at 8.51% in 2020 and thereafter, much closer to the expected increase in relative risk scores. The across-the-board adjustments do not address the substantial heterogeneity in plan-level results shown in Exhibit 6.

It is challenging to accurately measure the effects of coding intensity on MA risk scores and even more challenging to devise optimal policy responses. Uncertainty about the extent to which coding intensity would persist beyond the early years of using diagnostic information, uncertainty about whether some of the changes observed in MA risk scores might have been due to changes in underlying morbidity of MA enrollees, and heterogeneity across plans in coding intensity each create challenges in evaluating appropriate policy responses. In addition, it is unclear to what extent MA plans coded less completely than FFS in 2004, and how much of the increase in coding intensity reflects MA simply catching up to FFS levels, and how much represents going above and beyond. The Department of Health and Human Services is continuing its analysis of the relative risk of MA and FFS enrollees to improve the ability of the Medicare program to accurately pay for MA beneficiaries.

Disclaimer

The authors report no conflicts of interest related to this analysis. The content is solely the responsibility of the

authors and does not necessarily reflect the views of the Department of Health and Human Services.

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^a Some would expect that MA plans will react to the 2013 and 2014 model changes by finding other HCCs on which to focus their efforts, and the success of coding intensity efforts may well increase in the future.

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 7 OF 14
EXHIBITS D-49 THROUGH D-66
PAGES 1220 THROUGH 2103**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT D-52

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.

BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al.,

Defendants

EXPERT REPORT OF JEAN ACEVEDO

SEPTEMBER 29, 2023

Amended April 5, 2024

I. QUALIFICATIONS

1. I am a Certified Professional Coder (“CPC”) and Certified ENT Coder (“CENTC,” i.e., coding focused on ear, nose, and throat conditions), and have been so designated since 1999 and 2008, respectively, through the American Academy of Professional Coders (“AAPC”).¹ I achieved AAPC Fellow status in January 2017, which indicates that I have been recognized for my professional achievements in coding and continuous adherence to the ethical and professional standards of the AAPC.² I have also held the Certified in Healthcare Compliance (“CHC”) certification from the Health Care Compliance Association (“HCCA”) since 2002.³ Additionally, I have been a health care risk manager since 1989 (currently inactive).

2. I have experience in all areas of medical coding and reimbursement, particularly with Current Procedural Terminology (“CPT”), Healthcare Common Procedure Coding System (“HCPCS”), the International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM)⁴ diagnosis coding,⁵ and third-party payer billing and payment rules, including the Centers for Medicare and Medicaid Services (“CMS”) Medicare Advantage risk adjustment program.

3. From 2007 through 2022, I developed and taught the regulatory and compliance modules of the Certificate in Medical Business Management program at Florida Atlantic University’s School of Business.

4. For the past twenty-three years, I have maintained an active healthcare consulting practice as the founder and senior consultant of Acevedo Consulting Incorporated (“ACI”). ACI assists clients in the healthcare industry in all areas concerning reimbursement, including coding

¹ *Coding Certifications*, AAPC, <https://www.aapc.com/certifications?tag=coding> (last visited Sept. 29, 2023).

² *AAPC Fellow Application Process*, AAPC, <https://www.aapc.com/recognition/aapc-fellow.aspx> (last visited Sept. 29, 2023) (“Fellows are highly experienced in their position within the business of healthcare. This status indicates your professional achievement and continuous adherence to the ethical and professional standards of AAPC. Fellowship is earned through hard work, written demonstration of your professional expertise, and regular commitment to dedicated leadership in the healthcare community.”).

³ *Certified in Healthcare Compliance (CHC)*, HCCA, <https://www.hcca-info.org/certification/become-certified/chc> (last visited Sept. 29, 2023).

⁴ For purposes of this report, I use the term “ICD-9” to refer to “ICD-9-CM” and “ICD-10” to refer to “ICD-10-CM,” respectively. Furthermore, I use the term “ICD” to refer both to ICD-9 and ICD-10.

⁵ See *ICD-10, ICD-10-CM, & ICD-10-PCS*, University of Kansas Medical Center, <https://guides.library.kumc.edu/icd10> (last visited Sept. 29, 2023).

and medical records review. The firm's clients span the gamut of the United States' healthcare system, from large Medicare Advantage Organizations ("MAOs") to small private health insurers, small physician practices to large healthcare systems, and the federal government.

5. I have provided education on ICD coding rules to large and small physician organizations, Accountable Care Organizations ("ACOs"), and a national MAO. I have also advised physician practice groups on accuracy and compliance with the coding and Medicare Advantage risk adjustment rules on a proactive basis as well as assisting them through risk adjustment audits by any one of the Medicare contractors. I have had a longstanding contract with a large Program of All-Inclusive Care for the Elderly ("PACE") to provide documentation and education on ICD-10 coding, and to provide monthly quality reviews and feedback on the accuracy and completeness of the providers' documentation.

6. A copy of my Curriculum Vitae, including a list of all publications I have authored, is attached as **Appendix A**. A list of my prior testimony is attached as **Appendix B**.

II. COMPENSATION

7. My contract with the United States Department of Justice is on an hourly basis. For my work on this case, I am being compensated at my standard billing rate of \$325.00 per hour for guidance and development of my report. My rate for testifying at a deposition or appearing at any proceeding is \$468.75 per hour. My compensation is not contingent on the content of my opinions or the outcome of this matter.

III. SCOPE OF ASSIGNMENT

8. I have been engaged by the Plaintiffs to provide expert testimony in this matter. Specifically, I have been asked to provide background on medical record coding, including ICD-9 and ICD-10 diagnosis coding, and its relationship to the Hierarchical Condition Categories ("HCCs") used in the Medicare Advantage risk adjustment program. I have also been asked to provide expert testimony on the following topics: (1) the documentation standards required in risk adjustment coding; (2) the standards and guidelines governing medical record coding; and (3) industry best practices for achieving accurate and complete coding in the Medicare Advantage context. The relevant time period for my report covers dates of service in 2008 through 2016.

9. I reserve the right to supplement or revise my opinions should additional information become available.

IV. BASIS FOR OPINIONS

10. I have reviewed publicly-available materials for the relevant time period, including the ICD-9 official Coding Guidelines applicable during the 2008–2014 dates-of-service years and the ICD-10 official Coding Guidelines applicable during the 2015–2016 dates-of-service years; the CMS 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide (“2008 Participant Guide”); the CMS Medicare Managed Care Manual, Chapter 7 – Risk Adjustment; and various publications regarding coding. I have also reviewed deposition transcripts from this case. A complete list of the materials that I have relied upon as a basis for my opinions rendered in this report is attached as **Appendix C**.

V. BACKGROUND

A. Introduction to Medical Record Coding

11. When an individual goes to a doctor’s office, an urgent care center, hospital, or other health care facility, the physician or other provider documents one or more of the following in the patient’s medical record: the patient’s complaint and related history, a physical examination, and the assessment/impression and plan. In determining whether to pay for a healthcare service, the patient’s insurance company or other payer generally requires information on what was done to the patient (i.e., the medical service provided), and why. There are industry-standard medical “codes” used to report “what was done” and “why” on claims made to insurance companies. These codes ensure that all healthcare providers are speaking the same language when submitting a claim for payment.

12. While the American Medical Association has created Current Procedural Terminology (“CPT”) codes to describe “what was done” (e.g., an office visit, an ultrasound, a blood draw, etc.), ICD diagnosis codes tell the insurer “why”—i.e., what health condition the medical service addresses. ICD diagnosis codes designate diseases, symptoms, abnormal findings, and other elements of the patient’s diagnosis. For example, when a physician sees a patient for a new patient office visit, the CPT code may be 99204, which represents the service provided. If the medical record appropriately documents that the patient exhibits symptoms of

diabetes and that blood tests confirm that the patient has diabetes mellitus, the proper ICD-10-CM code is E11.9, which represents the diagnosis.

13. When insurance payment is on a “fee-for-service” basis, the physician is paid based on the specific CPT code submitted for the office visit, and the payment amount is the same regardless of how sick the patient is. Continuing the example from paragraph 12, the physician would be paid based on CPT code 99204 (new patient office visit), regardless of the patient’s confirmed diabetes mellitus diagnosis (E11.9). The ICD code does not impact the payment.

14. By contrast, in the Medicare Advantage program discussed further below, the reported ICD codes are relevant because payment is on a “risk adjusted” basis. This means that CMS pays MAOs a monthly amount per beneficiary based on the risk profile of that beneficiary. Generally, the sicker a beneficiary is, the higher the payment. The risk adjustment system sets the monthly payment amount by estimating the healthcare expenditures a patient is likely to require in a given year, based in part on the health status of the patient, which in turn is based on the Hierarchical Condition Categories (“HCCs”) reported for that patient. As explained below, ICD codes underlie HCCs, and therefore, may impact payment in this system.

B. ICD-9 and ICD-10 Coding

15. The International Classification of Diseases is a medical classification system maintained by the World Health Organization (“WHO”) and used worldwide for health management and clinical purposes. WHO issues new revisions of the ICD periodically.

16. At the beginning of the relevant time period, ICD-9 was the operative classification system. There were approximately 14,000 ICD-9 diagnosis codes. When the United States Department of Health and Human Services switched to ICD-10 in 2015, that number rose to almost 70,000, because ICD-10 allows for greater specificity and more granularity in describing a patient’s condition, variants of that condition, or complications present with certain conditions.⁶

⁶ *International Classification of Diseases, (ICD-10-CM/PCS) Transition - Background*, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm (last visited Sept. 29, 2023).

17. Depending on the date-of-service year in the relevant time period, the authoritative source for diagnosis coding is the ICD-9 or ICD-10 Coding Guidelines published by the Centers for Disease Control and Prevention (CDC).⁷ There are a number of additional sources that explain coding rules and guidelines that must be followed for proper reporting of diagnoses. These additional sources include coding guidelines, manuals, and training published by CMS.⁸ Organizations such as hospitals and MAOs also subscribe to the American Hospital Association's "Coding Clinic," another recognized source for ICD-9 and ICD-10 guidance.

18. There are two recognized organizations that certify professional coders, the AAPC and American Health Information Management Association ("AHIMA"). The main credential provided by the AAPC is the CPC (Certified Professional Coder) and the main credential provided by AHIMA is the CCS (Clinical Coding Specialist).⁹

19. Coding certification from either the AAPC or AHIMA requires following the AAPC and AHIMA's guidelines for ethical coding.¹⁰

C. ICD Coding and Reporting Process

20. In the Medicare Advantage context, both ICD and CMS have set out rules on the provider documentation (and content of that documentation) needed to assign and report particular ICD codes on insurance claims. Historically, before this process became electronic, physicians handwrote notes in patient charts, the billing staff looked up the applicable diagnosis code(s) supported by notes in patient charts in an ICD code book, and then the staff would report the assigned ICD codes on a claim submitted for payment.

21. With the adoption of electronic medical records (EMRs) beginning in 2011, it has become increasingly common for physicians to select the ICD-9 or ICD-10 code(s) as they

⁷ *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)*, Centers for Disease Control and Prevention, <https://www.cdc.gov/nchs/icd/icd-10-cm.htm> (last visited Sept. 29, 2023); *ICD-9-CM Addenda, Conversion Table, and Guidelines*, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm (last visited Sept. 29, 2023).

⁸ See, e.g., *ICD-10 Resources*, Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-resources> (last visited Sept. 29, 2023).

⁹ See *Certified Professional Coder (CPC) Certification*, AAPC, <https://www.aapc.com/certifications/cpc> (last visited Sept. 29, 2023); *Certified Coding Specialist (CCS)*, AHIMA, <https://www.ahima.org/certification-careers/certification-exams/ccs/> (last visited Sept. 29, 2023).

¹⁰ See *Code of Ethics*, AAPC, <https://www.aapc.com/about-us/code-of-ethics> (last visited Sept. 29, 2023); *Ethics*, AHIMA, <https://www.ahima.org/who-we-are/governance/ethics/> (last visited Sept. 29, 2023).

complete their notes in the EMR system. This is especially true in an outpatient office or clinic setting. As a physician starts to type “diabetes” in the section of the note where diagnoses are listed, the EMR presents a list of possible ICD codes. For example, if the patient has Type 2 diabetes mellitus without complications, the physician should select E11.9 as the corresponding ICD-10 code. Billing staff may verify that the physician selected the correct code(s) and then include them on an insurance claim. In hospital settings, which tend to have more resources than the typical outpatient provider’s office, dedicated coders may look at the appropriate sections of medical charts and, following the applicable payer rules for the type of medical facility, report diagnosis codes on the insurance claim.

D. Medicare Advantage Program

22. The federal government’s Medicare program provides health insurance for people ages 65 or older as well as younger individuals with certain disabilities.¹¹ Medicare beneficiaries have the option to enroll in “Traditional Medicare” or “Medicare Advantage.” Medicare Advantage beneficiaries enroll in plans administered by private insurance companies known as “Medicare Advantage Organizations,” or “MAOs.”¹²

23. CMS enters into annual contracts with MAOs that participate in the Medicare Advantage program and imposes numerous requirements on the MAOs pursuant to statutes, regulations, guidance materials, and through the contracts.¹³

Risk Scores Under the CMS-HCC Risk Adjustment Model

24. In the Medicare Advantage program, CMS pays MAOs a monthly premium for each beneficiary enrolled in the MAOs’ plans.¹⁴ The amount of payment depends in part on the beneficiary’s “risk score,” which is calculated using the CMS Hierarchical Condition Category (“HCC”) Risk Adjustment Model.¹⁵

25. Each beneficiary’s risk score is newly calculated each payment year based on health conditions documented in the beneficiary’s medical records during the prior year (referred

¹¹ 42 U.S.C. § 426 *et seq.*; 42 C.F.R. § 406.5; 42 C.F.R. §§ 406.10–406.13.

¹² 42 U.S.C. § 1395w *et seq.*; 42 C.F.R. § 422 *et seq.*

¹³ 42 U.S.C. § 1395w *et seq.*; 42 C.F.R. § 422 *et seq.*

¹⁴ 42 U.S.C. § 1395w-23(a)(1)(A); 42 C.F.R. § 422 *et seq.*

¹⁵ 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. §§ 422.300–422.308.

to as the “service year” or “date-of-service” (“DOS”) year). For example, a beneficiary’s risk score for payment year 2016 is based on conditions documented in that beneficiary’s medical records during encounters that took place in 2015, but that risk score would not reflect conditions documented in that beneficiary’s medical records during encounters in 2014 or in 2016.

26. The purpose of these individualized risk scores is to capture anticipated differences in the costs of coverage for beneficiaries given differences in their health status and demographic background.¹⁶ Thus, the risk score is calculated based on both the health status of the beneficiary and demographic factors (e.g., a patient’s gender and age, disability status, institutional status).¹⁷

Hierarchical Condition Categories (HCCs)

27. The health status component of the risk score is based on the HCCs or Hierarchical Condition Categories reported for the beneficiary. CMS groups ICD-9/ICD-10 diagnosis codes with other clinically similar diagnosis codes.¹⁸ These diagnosis code groupings are in turn grouped into “condition categories.”¹⁹ Similar “condition categories” are organized hierarchically based on severity of the condition and cost implications, such that the most severe and costly condition category is at the “top” of the hierarchy.²⁰ Once hierarchically organized, these condition categories become HCCs.

28. This hierarchical organization ensures a beneficiary’s risk score will incorporate only the HCC that represents the most severe and costly manifestation of a disease documented in a given year. For example, if claims data shows a patient has both diabetes without complications (ICD-10 code E11.9, HCC 19), and diabetes with acute complications (ICD-10 code E11.8, HCC 18), only HCC 18 is used in computing the patient’s risk score, as it is the more severe form of diabetes.

¹⁶ See Medicare Managed Care Manual, Ch. 7, § 20 (June 7, 2013) (“Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs Risk scores measure individual beneficiaries’ relative risk and risk scores are used to adjust payments for each beneficiary’s expected expenditures.”).

¹⁷ See *id.* § 70 (“Risk scores are used to adjust payments and bids based on the health status (diagnostic data) and demographic characteristics (such as age and gender) of an enrollee.”).

¹⁸ *Id.* § 70.1.

¹⁹ *Id.*

²⁰ *Id.*

29. Each year, CMS determines the groupings of diagnosis codes that “map” to a given HCC.²¹ If a beneficiary has a condition corresponding to a diagnosis code that maps to an HCC, that HCC will be incorporated into the calculation of the beneficiary’s risk score. For example, under the current CMS-HCC Risk Adjustment Model, of the approximately 70,000 total ICD-10 codes, over 9,700 of those codes map to one or more of the 86 HCCs in the model.²²

30. Multiple ICD codes can map to the same HCC. ICD-10 codes each contain up to 7 characters. Although slight variations in the last characters in the code string leads to distinct ICD-10 codes, these distinct ICD-10 codes may still map to the same HCC. For example:

- a. E11.10 (Type 2 diabetes mellitus with ketoacidosis without coma) and E11.11 (Type 2 diabetes mellitus with ketoacidosis with coma) both map to HCC 17 (diabetes with acute complications).
- b. M35.00 (Sjögren syndrome, unspecified) and M35.3 (Polymyalgia rheumatica) both map to HCC 40 (Rheumatoid arthritis and inflammatory connective tissue disease).

31. However, certain diagnosis codes indicating historical conditions or potential risk for future conditions may be documented in the patient’s medical record and assigned an ICD code, but they would not map to an HCC. For example:

- a. If an individual is diagnosed with thyroid cancer, it is appropriate to assign the ICD-10 code C73 (malignant neoplasm of the thyroid gland). After the thyroid is removed, if the patient is asymptomatic and no further treatment is being provided, then Z85.850 (personal history of malignant neoplasm of thyroid) is the proper ICD-10 code to report.
- b. If a patient’s blood sugar has been elevated on lab tests, but there is not enough information to diagnose the patient with diabetes mellitus, the proper code to report in this situation is a code for abnormal glucose (R73.09), rather than E11.9 (diabetes mellitus without complications).

²¹ Not all ICD-9/ICD-10 diagnosis codes map to an HCC included in the CMS-HCC Risk Adjustment Model, and therefore not all ICD-9/ICD-10 diagnosis codes affect risk adjustment payments.

²² Amerigroup, *CMS-HCC Risk Adjustment Model (V24), ICD-10-CM to CMS-HCC Crosswalk*, https://provider.amerigroup.com/dam/publicdocuments/ALL_CARE_CMSHCCRAModel_mrdcoding_tip_s.pdf (last visited Sept. 29, 2023).

32. Where a patient has several diseases corresponding to several HCCs, the risk adjustment model allows those multiple HCCs to be assigned and accounted for in the risk score. The number of HCCs reported and the severity of the HCCs tend to increase the risk score. Thus, a 72-year-old male with COPD, diabetes mellitus, and coronary artery disease would have a higher risk score than a 72-year-old male with diabetes mellitus only.

Medical Record Documentation to Support HCCs Under CMS Rules

33. During the relevant time period, CMS had specific rules governing the submission of diagnosis codes for inclusion in the HCC risk adjustment model. HCC coding requires clinical support in medical record documentation.

34. As explained in the 2008 Participant Guide, CMS requires that diagnosis codes submitted for risk adjustment result from a face-to-face encounter between a beneficiary and a provider of a qualifying physician specialty.²³ In addition, the medical record for a particular encounter used as the basis for submission of a diagnosis code must be signed and include the provider's credentials.²⁴

35. In addition, both the ICD guidelines and CMS specify that all conditions reported should be based on documentation showing that conditions exist at the time of the encounter/visit and "require or affect patient care, treatment or management."²⁵

36. Importantly, regulations and official CMS publications require all diagnosis codes submitted by MAOs to be documented in the medical record, and ICD Coding Guidelines must be followed for coding and reporting.²⁶ For example, the Medicare Managed Care Manual, Chapter 7 states that MAOs must:

²³ 2008 Participant Guide, § 7.2.4.2; *see also id.* Table 3H (setting forth acceptable physician specialties, which include physicians and other qualified healthcare providers, such as nurse practitioners and physician assistants).

²⁴ *Id.* § 7.2.4.2 ("For purposes of risk adjustment data submission and validation, the MA organizations must ensure that the provider of service for face-to-face encounters is appropriately identified on medical records via their signature and physician specialty credentials.").

²⁵ ICD-9, § IV.K (effective Oct. 1, 2011), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; *see also* 2008 Participant Guide, § 6.4.1.

²⁶ *See, e.g.*, 45 C.F.R. § 162.1002(a)(1)(i), (b)(1), (c)(2)(i) (establishing the ICD, including the ICD Guidelines, as the national standard for diagnosis coding); 42 C.F.R. § 422.310(d)(1) ("MA organizations

Ensure the accuracy and integrity of risk adjustment data submitted to CMS. ***All diagnosis codes submitted must be documented in the medical record*** and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting.²⁷

In addition, the 2008 Participant Guide states:

Standard ICD-9-CM coding practices support the CMS-HCC model. ***In all cases, the documentation must support the code selected and substantiate that the proper coding guidelines were followed.***²⁸

OPINIONS

a. Diagnosis Codes Submitted for Risk Adjustment Must Be Supported By Documentation in the Medical Record Meeting CMS Requirements.

37. The principal requirement for assigning and reporting diagnosis codes in the Medicare Advantage risk adjustment model is that the codes are supported by appropriate medical record documentation.²⁹

38. As referenced above, the medical record cannot merely contain a list of the patient's conditions without supporting documentation showing that the conditions "require or affect patient care, treatment or management."³⁰ In the absence of such documentation, the coder cannot assign codes for listed conditions. In my experience, such documentation may include physician notes on disease progression or stabilization, patient response to the treatment, and whether test results were reviewed by the physician.

39. In sum, the diagnosis codes that MAOs submit to CMS for risk adjustment purposes must be (1) based on a face-to-face encounter; (2) by a qualified provider (either a physician or other qualified healthcare provider); (3) documented in the medical record; and (4) coded in compliance with the ICD Guidelines.³¹

must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.").

²⁷ Medicare Managed Care Manual, Ch. 7, § 40 (emphasis added).

²⁸ 2008 Participant Guide, § 6.4 (emphasis added).

²⁹ See Medicare Managed Care Manual, Ch. 7, § 40; 2008 Participant Guide, § 6.4.

³⁰ ICD-9, § IV.K (effective Oct. 1, 2011),

https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; see also 2008 Participant Guide, § 6.4.1.

³¹ 2008 Participant Guide, § 7.2.4.2.

b. Coding is Governed by Objective Standards and Guidelines.

40. It is my opinion that, if a coder is knowledgeable of the official ICD and CMS coding rules discussed above, he or she should be able to identify an objectively correct ICD code or set of ICD codes that can be reported based on a particular medical record and thus there should be little variance in code assignment among coders.

41. The coding rules are by design clear, consistent, and specific. They offer detailed instructions on what codes should be assigned based on features of a patient's condition and what is documented in the medical record. If qualified coders properly follow these rules, they are able to identify appropriate ICD codes and rule out inappropriate codes.

Coding is a Methodical Step-By-Step Process.

42. To begin, coders must follow a methodical step-by-step process in arriving at a code assignment under the ICD guidelines. The "Alphabetical Index" and "Tabular List" in both the ICD-9 and ICD-10 set out these directions.

43. The Alphabetical Index lists conditions and subvariants of conditions in alphabetical order. At the first step of coding, a coder looks up in the Alphabetical Index a condition he or she identifies that meets the medical record documentation requirements.

44. This Index supplies the initial ICD code string for that condition. For example, for Parkinson's disease with dementia a coder would look up "Parkinsonism," under which there are sub-listings of around twenty variations of "Parkinsonism," including with "dementia."³²

³²ICD-10-CM Index to Diseases and Injuries, *available at* https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/ (Table and Index zip.zip) (last visited April 5, 2024).

Parkinsonism (idiopathic) (primary) G20
 - with neurogenic orthostatic hypotension (symptomatic) G90.3
 - arteriosclerotic G21.4
 - dementia G31.83 [F02.80]
 - - with behavioral disturbance G31.83 [F02.81]
 - due to
 - - drugs NEC G21.19
 - - - neuroleptic G21.11
 - medication-induced NEC G21.19
 - neuroleptic induced G21.11
 - postencephalitic G21.3
 - secondary G21.9
 - - due to
 - - - arteriosclerosis G21.4
 - - - drugs NEC G21.19
 - - - - neuroleptic G21.11
 - - - encephalitis G21.3
 - - - external agents NEC G21.2
 - - - syphilis A52.19
 - - specified NEC G21.8
 - syphilitic A52.19
 - treatment-induced NEC G21.19
 - vascular G21.4

The index directs the coder that “Parkinson’s with Dementia without behavioral disturbance” may be coded with the ICD code strings “G20” (Parkinsonism) and “F02.80.”

Next, the coder must consult the “Tabular List” for further step-by-step instructions on the requirements to assign a code.³³ In this case, the Tabular List entry for “G20” (Parkinson’s disease) instructs the coder to: Use additional code to identify: dementia with behavioral disturbance (F02.81) dementia without behavioral disturbance (F02.80). Therefore, the proper codes for Parkinson’s with dementia without behavioral disturbance are G20 and F02.80.

³³ ICD-10-CM Tabular List of Diseases and Injuries, *available at* https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/ (Table and Index zip.zip) (last visited April 5, 2024).

G20 Parkinson's disease

Hemiparkinsonism
Idiopathic Parkinsonism or Parkinson's disease
Paralysis agitans
Parkinsonism or Parkinson's disease NOS
Primary Parkinsonism or Parkinson's disease

Use additional code to identify:

dementia with behavioral disturbance (F02.81)
dementia without behavioral disturbance (F02.80)

Excludes1: dementia with Parkinsonism (G31.83)

45. As shown above, the coding rules provide clear instructions on (1) the specific items the medical record documentation must contain to support a condition, *supra* ¶¶ 37–39, (2) how to look up a particular condition or variants of a condition in the Alphabetical Index to identify the ICD code and further requirements for assigning the code, and (3) the step-by-step process of applying those requirements to arrive at code assignment.

46. In addition, there are rules about how a coder should use these resources. For example, it is well established a coder must use the Alphabetical Index and Tabular List sequentially and follow the instructional notations in both.³⁴ Coders may never select a final code based just on what the Alphabetical Index provides. As long as the coder follows this order of operations, the instructions in the Alphabetical Index and Tabular List are consistent and will lead the coder to the proper code assignment.

Coding Rules Are Highly Specific and Particularized to Features of Patients' Conditions.

47. The ICD guidelines provide specific rules for assigning ICD codes regarding how particular features of a patient's condition should be coded. This specificity makes clear to coders under what circumstances a particular ICD code should be assigned.

48. For example, ICD-10 specifies the codes to assign when a condition occurs on the left or right side of the body, and in some cases provides a code indicating that a condition occurs on both sides of the body (bilaterally). If the medical record does not specify which side the condition occurs, the rules generally require the coder to assign the code denoting the side is

³⁴ ICD-9, § I.B.1–2 (effective Oct. 1, 2015), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § I.A.1, § I.B.1 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

unspecified.³⁵ If, however, the condition occurs bilaterally, but there is no specific ICD code designating that the condition occurs bilaterally, the guidelines require the coder to report the ICD codes for both the right and left sides of the body separately.³⁶

49. For example, ICD-10 provides codes based on where the condition staphylococcal arthritis manifests: M00.011 (Staphylococcal arthritis, right shoulder), M00.012 (Staphylococcal arthritis, left shoulder), and M00.019 (Staphylococcal arthritis, unspecified shoulder). There is no code designating this condition as bilateral. If the medical record indicates that the patient has staphylococcal arthritis in both shoulders, the coder should report *both* M00.011 (right shoulder) and M00.012 (left shoulder) as there is no specific ICD code designating this condition as bilateral.

Difficult Coding Scenarios Do Not Indicate that Coding is a Subjective or Ambiguous Process.

50. The existence of difficult coding scenarios does not mean coding itself is a subjective process with no right answers as to whether a code is properly assigned or not. Nor do these difficult scenarios show that the coding guidelines themselves are ambiguous or fail to provide objective rules for a coder to follow.

51. Rather, difficult scenarios generally are caused by and reflect (1) the varying degrees of skill level and experience among coders; (2) errors in how those coders apply the guidelines and rules; and (3) problems extrinsic to the guidelines and the required coding process, such as problems with the medical record documentation itself. All of these issues, however, are far less likely to be present in sophisticated coding programs that use certified, well-trained coders and implement sufficient quality assurance processes to check coders' work.

52. Below, I address some potentially difficult coding scenarios, and explain why they do not demonstrate the coding process and guidelines are fundamentally subjective or ambiguous:

- a. **Updated coding guidelines:** One potential source of error during the relevant time period was coders' relative levels of experience with and training on operative coding

³⁵ ICD-10, § I.B.13 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

³⁶ *Id.*

guidelines. The CDC transitioned from ICD-9 to ICD-10 in 2015. While some less-experienced coders may have erred in applying the new ICD-10 guidelines, this does not indicate that the guidelines themselves were unclear or ambiguous.

For example, as the table below shows, under ICD-10, coders are required to assign a single combination code (E11.331) where a patient has both diabetes mellitus with diabetic retinopathy. ICD-9, however, provided a different rule where these conditions were required to be coded separately (250.52, 362.05). Under the new rule, the objectively correct code is the single combination code. In my experience, coders who were unfamiliar with the operative ICD-10 rules might attempt to search for two separate codes or simply miss the combination code and apply a different diabetes code. This example does not illustrate that ICD-10 is itself ambiguous or allows for varying or inconsistent results (i.e., different diabetes code assignments) among coders. Rather, it indicates that lack of experience with the operative rules may lead to error.

ICD-9 Coding	ICD-10 Coding
250.52 – Diabetes with ophthalmic manifestations, type II or unspecified type, controlled	E11.331 – Type II diabetes mellitus with moderate non-proliferative diabetic retinopathy with macular edema
362.05 – Moderate non-proliferative diabetic retinopathy	

Notably, the coding industry attempts to provide training and other resources to address varying levels of experience on the part of coders. For example, during the transition to ICD-10, there were numerous continuing education classes that focused on educating coders on the new rules. The AAPC also required its certified members to pass a proficiency assessment on ICD-10 “format and structure, groupings and

categories of codes, ICD-10-CM official guidelines, and coding concepts.”³⁷ A major focus on my work during this time was providing trainings on ICD-10 rules, including trainings customized for specific practice groups.

- b. **Problems extrinsic to coding rules, guidelines, and resources:** Some difficult coding scenarios are due to problems extrinsic to the coding rules, for example, issues in the medical record documentation itself or its legibility. These issues do not indicate that the coding rules or process themselves are subjective, and experienced coders are trained to handle these circumstances properly.

For example, a provider might use the abbreviation “PE” in a medical record, which typically stands for “pulmonary embolism,” but may also mean “pulmonary edema” or “physical exam.” Under this circumstance, unless the coder is able to verify the meaning of the ambiguous or illegible term (e.g., via a physician query), the coder should not assume the meaning of the term and base a coding assignment on it.³⁸ Rather, a code assignment is only appropriate if based on clear and consistent medical record documentation.³⁹

53. I also reviewed the deposition transcripts of some United witnesses that discuss difficult coding scenarios. For example, United coding supervisor, Tammy Dickey, testified: “if

³⁷ See *ICD-10 Proficiency Assessment*, AAPC (Mar. 26, 2013), <https://www.aapc.com/blog/24145-icd-10-proficiency-assessment/#:~:text=The%20assessment%20will%20measure%20your,for%20other%20exams%20or%20assessments>.

³⁸ ICD-10 at 1 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf> (stating that “The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved.”). The AHIMA Standards of Ethical Coding also provide that coders should “[a]ssign and report . . . only the codes and data that are clearly and consistently supported by health record documentation in accordance with applicable code set and abstraction conventions” and should “[q]uery and/or consult as needed with the provider for clarification and additional documentation prior to final code assignment in accordance with acceptable healthcare industry practices.” *American Health Information Management Association Standards of Ethical Coding (2016 Version)*, AHIMA (revised and approved Dec. 12, 2016), https://bok.ahima.org/doc?oid=302237#.X0-0BRNKg_U.

³⁹ *Id.*

you gave the same record to ten coders, you would probably be get [sic] five sets of answers.”⁴⁰ To the extent this example illustrates that coding is subjective and the rules lack clarity, I disagree. In my opinion, what Ms. Dickey describes does not reflect a phenomenon in ICD coding. ICD coding is highly specific and governed by a set of particularized rules. In my opinion and experience, there is not substantial variance in ICD coding among qualified coders, nor have I experienced this level of variance in my own practice.

c. There Are Well-Established Industry Best Practices For Achieving Complete and Accurate Coding.

54. In the Medicare Advantage context, there are industry best practices for achieving accurate and complete coding. In my opinion, these best practices include: (1) requiring coders to be certified; (2) providing extensive and ongoing training to the coders, including training in Medicare Advantage risk adjustment; (3) requiring coders to meet high quality standards in order to graduate from training; (4) requiring coders to maintain high quality standards after training; (5) providing coders with resources to address coding questions; (6) providing remedial training to coders who fall below the organization’s standards; (7) terminating coders who fail to perform up to the organization’s standards despite remedial training; and finally, (8) maintaining robust quality assurance processes to check the coders’ work on an ongoing basis. Issues with coding accuracy and completeness are more likely to be avoided when an organization’s policies and procedures encompass these elements.

55. Although coders approach their work with varying types of experience, the impact of these variances is limited when they are certified and provided with training that augments their prior work experience. For example, coders who have only worked on electronic medical records should be trained on coding from handwritten records and vice versa. In addition, coders should be exposed to different medical specialties during training if they had previously only worked in one specialty.

56. As discussed throughout this report, using certified coders is key in ensuring accurate and complete coding. Coders certified by the AAPC or AHIMA have had their knowledge tested by an independent body and must obtain a number of Continuing Education Credits (“CEUs”) to retain their certification. In addition, organizations participating in the

⁴⁰ Dickey Dep. 195:8–12, 220:17–23, May 24, 2022.

Medicare Advantage risk adjustment program should ensure that their coders are trained in risk adjustment coding.

Signed on April 5, 2024.

A handwritten signature in dark ink, appearing to read "Jean Acevedo", is positioned above a horizontal line.

Jean Acevedo

EXHIBIT D-53

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.

BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al.,

Defendants

EXPERT REBUTTAL REPORT OF JEAN ACEVEDO TO
SEPTEMBER 29, 2023 EXPERT REPORT OF BARBARA BLAIR
January 29, 2024

I. INTRODUCTION

1. I have reviewed the September 29, 2023 expert report of Barbara Blair (“Blair Report”). I respond below to Blair’s opinions section-by-section. This report incorporates my September 29, 2023 expert report (“Opening Report”) and assumes familiarity with the case background and abbreviations used there.

2. I have three overarching concerns with Blair’s opinions that I discuss more fully in the body of this rebuttal:

3. **First**, Blair’s two overarching opinions, which she refers to as Opinion One and Opinion Two, are at odds with each other, and she unjustifiably switches between them depending on the conclusion she is trying to support. In her first opinion, she seems to claim that MA program coding tends to be more reliable than provider coding (to justify programs like chart reviews, which supplement provider-reported codes with additional codes identified by a chart review coder to address “undercoding”). Yet, in her second opinion, she opines that provider coding tends to be more reliable than MA program coding (apparently to justify why the codes reported only by the provider coder, but not identified by the MA chart review coder, tend to be correct and should not be deleted from claims, therefore rejecting that provider “overcoding” is an issue). In my experience, the deficiencies in provider coding that Blair describes in her first opinion lead *both* to provider undercoding and overcoding. Throughout her report, Blair improperly and implausibly focuses only on how provider coders’ lack of experience, expertise, and training in ICD coding leads to error in one direction (i.e., missed codes) but not the other (i.e., unsupported or misassigned codes).

4. **Second**, the explanation that Blair provides for why provider coding should be deferred to over MA program coding violates fundamental principles of coding. Blair claims that provider

coders deserve deference because they may have access to unique information about a patient's condition to support assigned codes that is unavailable to the MA program coder. But Blair's examples are all instances where the provider coders' information is *not* clearly documented in the medical record, as ICD and MA program rules require. For instance, Blair gives the example of a provider coder who is on-site at the provider's office, infers when undated additions to a chart were made, and then assigns a code based on that unwritten date-of-service (DOS) information. Blair Report ¶ 59. Another example Blair gives is a provider coder who can uniquely interpret the provider's handwriting, idiosyncratic note-taking, or abbreviations while the MA program coder (or any coder outside the provider's office) cannot. *Id.* ¶¶ 29, 58. Blair's opinion that these are circumstances in which the provider-only codes are "properly supported" in the medical record is oxymoronic and violates the fundamental rule of coding: all diagnosis codes submitted by MAOs for payment under the MA program must be clearly and unambiguously documented in the medical record per ICD Coding Guidelines and MA program rules.¹ A coder's idiosyncratic assumptions or reliance on unwritten information to support code assignment are not proper. Unless clear written documentation for a code is obtained, such as through a physician query or retrieval of additional medical records, the codes in Blair's examples are not properly supported under ICD.

5. ***Third***, Blair relies throughout her report on hypotheticals to support her conclusions. Based on my experience, each of her hypotheticals is highly theoretical. They do not reflect actual, common, or likely scenarios in ICD coding. Rather, the hypotheticals appear designed to support predetermined conclusions, rather than describe realistic extrinsic support for those conclusions.

¹ ICD-9, § IV.K (effective Oct. 1, 2011), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; see also 2008 Participant Guide, § 6.4.1.

II. REBUTTAL TO BACKGROUND SECTION

A. Medical Record Documentation and Diagnosis Coding

6. Blair begins the background section with an overview of the MA diagnosis coding process. In describing common coding errors, Blair's overview is skewed. She identifies only "undercoding" (or instances where provider coders miss reporting codes documented in the medical record) and entirely ignores "overcoding" (or instances where provider coders report codes not properly documented in the medical record). In my significant experience working with providers of varying sizes and with varying resources, both types of errors are common.

7. In ¶ 18 of her report, Blair recognizes providers have "historically" received less training in MA diagnosis coding than in fee-for-service (FFS) procedure and services coding. But Blair opines that this deficiency in training and experience somehow leads only to undercoding: "providers did not always submit all of a patient's applicable diagnosis codes on a claim." Blair Report ¶ 18. In my experience, the relative lack of training and experience in MA diagnosis coding causes provider coders to report codes not properly supported in the medical record and not compliant with ICD and MA program rules.

8. Blair also takes inconsistent positions on the reliability of MA program coding versus provider coding. On the one hand, she emphasizes in ¶ 18 that MA coders provide a useful corrective to provider coding: "MA Plan chart reviews may identify these additional diagnosis codes that are supported by documentation in a patient's medical record but that were not submitted on the claim" by the provider coder. On the other hand, Blair takes the position that provider coders are more reliable than MA coders. She opines at ¶ 58: "A coder in the provider's office may be better situated [than an MA coder] to identify many properly supported diagnosis codes."

9. Blair provides no credible explanation for how MA program coders are both (i) more effective than provider coders at identifying the complete set of properly supported codes in a medical record, and yet (ii) tend to miss properly supported codes only the provider coder can identify.

10. Blair's attempt to explain the inconsistency is not valid, because she relies on an improper approach to coding (dubbed "assumption coding"), *see infra* ¶ 74. She opines that provider coders are able to identify "properly supported" codes that MA program coders miss, because the former possess unique (often unwritten) information about a patient's condition. Blair Report ¶¶ 29, 57-62. This justification violates a fundamental rule of MA program coding. A code cannot be assigned unless it is clearly and unambiguously supported by written documentation in the medical record. "Assumption coding" defeats the purpose of the ICD rules to enforce uniform coding, by leading to non-uniform interpretation of medical records and assignment of codes.

11. Ultimately, as discussed in my Opening Report at ¶¶ 54-55, accuracy and completeness in coding is contingent on how experienced and well-trained coders are, whether they are held to quality control standards, and whether they are subject to oversight. Coders subject to these processes and standards code more accurately and completely than coders lacking such qualifications, standards, and resources. In my experience, working in both provider and MA program settings, these measures tend to be more institutionalized in the latter context. Consequently, MA program coding tends to be more reliable, accurate, and complete than provider coding on average.

B. Sources of Coding

12. Blair discusses at ¶¶ 20-22 in her report "Sources of Coding." She claims that there is a "multitude" of sources governing MA diagnosis coding and that they provide only a "framework"

for coders. She opines that the various “Sources of Coding” sometimes offer conflicting guidance and that coders are forced to apply their own “judgment and experience.”

13. I disagree. Coding rules do not provide merely a “framework” for coding. Nor are the rules in conflict. Blair describes coding rules and guidance as an assortment of miscellaneous references from which coders may pick and choose on what to rely, but this is inaccurate.

14. For example, in ¶¶ 20-21, Blair states that coding guidance includes, but is not limited to, the ICD-9 and ICD-10 and their Tabular List and Alphabetic Index, the Coding Clinic, CMS materials, and providers’ own references about how to interpret the coding guidelines.

15. As I explained in my Opening Report, there is a clear and definitive hierarchy among “Sources of Coding.” The ICD-9/10 (and their Tabular List and Alphabetic Index) are the authoritative rules on diagnosis coding and trump other references that Blair identifies.

16. As Blair recognizes at ¶¶ 19-20, the ICD-9/10 provides a highly specific code set and particularized rules for assigning each code. United’s own coders agreed in their depositions that ICD-9/10 are the definitive set of coding guidelines.² Coders are trained to apply the ICD-9/10 and these other sources in accordance with this hierarchy.

17. In ¶ 21 of her report, Blair opines that the “Sources of Coding” conflict with one another. However, she does not provide any actual examples of such conflicts. *See infra* ¶ 39. As discussed in my Opening Report at ¶ 17, no such conflicts exist in my experience. Rather, the ICD-9/10 guidelines provide the authoritative rules that trump other coding guidance and complement MA program requirements. *See infra* ¶¶ 18-19, 50.

18. Blair further claims in ¶ 21 that, due to the purported conflicts in the “Sources of Coding,” “[c]oders therefore use the available guidance as a framework but ultimately must also

² Dickey Dep. 34:18–35:10, May 24, 2022; Bradberry Dep. 34:2–10, 104:19–105:3, July 1, 2021.

rely on their judgment and experience.” Again, ICD-9/10 is an authoritative set of highly specific rules and not a “framework.” See ICD-9 (“These guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-9-CM itself.”).³ Further, use of ICD-10 for reporting diagnosis codes is mandated by the Department of Health and Human Services in the Health Insurance and Portability Act’s Transactions and Code Sets rule.⁴

19. The “Sources of Coding” that Blair lists beyond the ICD-9/10 (discussed below, ¶¶ 19(a)-(d)) do not provide coding rules that trump or conflict with the ICD-9/10:

- a. **The Coding Clinic** – This is a secondary source that provides answers to coder-submitted questions regarding highly specific scenarios under ICD-9/10. Blair has not identified any credible support or example of an instance where the Coding Clinic contradicts ICD-9/10. This is because the Coding Clinic applies, but does not supplant, ICD-9/10. For example, a question that was posed to the Coding Clinic was: “What is the correct code for a 20-year-old patient with gestational diabetes who presents due to diabetes with ketoacidosis?” The answer provided by the Coding Clinic was “Assign codes O24.419, Gestational diabetes mellitus in pregnancy, unspecified control, and E87.2, Acidosis, for gestational diabetes with ketoacidosis. Codes from categories E10 and E11 would not be appropriate if the patient does not have pre-existing diabetes mellitus.”⁵ This answer provided by the Coding Clinic mirrors the ICD-9/10 guidelines. ICD codes for diabetes mellitus, such as E10 and E11 noted, both have instructions to never assign either code (“Excludes 1”);

³ ICD-9 (effective Oct. 1, 2011), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf, at 1.

⁴ *International Classification of Diseases, (ICD-10-CM/PCS) Transition – Background*, Centers for Disease Control and Prevention (last reviewed Nov. 6, 2015), https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm.

⁵ *Gestational Diabetes and Diabetic Ketoacidosis*, 7 AHA Coding Clinic for ICD 30 (Third Quarter 2020).

pointing the coder to “gestational diabetes (O24.4-).” Both the Coding Clinic and ICD instruct coders to assign the gestational diabetes code (O24.419) for a pregnant woman who developed diabetes mellitus during pregnancy and presents with ketoacidosis. The Coding Clinic’s instructions complement the ICD for reporting ICD codes.

- b. **CMS guidance on the MA program** – CMS sources, like the CMS 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide (“2008 Participant Guide”), do not provide rules at the level of the ICD-9/10 code set or instruct how to assign those codes. Rather, they discuss MA program requirements. For example, the Participant Guide limits the types of providers and medical record documentation acceptable in the MA program. *See e.g.*, 2008 Participant Guide, §§ 3.2.3, 7.2.4.1. By contrast, the ICD-9/10 guidelines do not provide rules for assigning codes based on types of provider or unacceptable types of medical record documentation.

This is not a contradiction between CMS guidance and the ICD-9/10 guidelines. Rather, the CMS guidance and ICD-9/10 guidelines are complementary. CMS guidance expressly incorporates, and requires all submitted codes in the MA program to comply with, ICD-9/10. *See* 2008 Participant Guide, § 7.2.4. While ICD-9/10 provides requirements for code selection, CMS provides further requirements for when and under what circumstances those codes should be reported in the MA program (i.e., only if the code resulted from a diagnosis made by particular types of providers and supported by particular types of documentation from those providers).

- c. **CMS RADV guidance** – RADV guidance applies only in the RADV audit context. Based on my years of experience, coders do not rely on this guidance as a source for rules on code

assignment and would not defer to RADV guidance over ICD-9/10, and certainly not outside the RADV audit context.

CMS itself is clear – including in the RADV source that Blair cites – that this “Contract-Level Risk Adjustment Data Validation (RADV) Medical Record Reviewer Guidance has been created to provide information on the RADV medical record process” and that the “guidance does not give advice for specific diagnosis coding.”⁶ CMS further emphasizes that this guidance “does not contradict the *ICD-9-CM Official Guidelines for Coding and Reporting*.” *Id.* Blair ignores these clear statements by suggesting, in her misleading quoting of this source, that RADV guidance conflicts with (and thus, must carry the same authority as) ICD-9/10 in dictating how diagnosis codes are assigned. *See, e.g.,* Blair Report ¶¶ 37-41.

This is wrong. Blair’s suggestion that coders may use RADV guidance as a source for assigning and reporting codes in the MA program is practically impossible. She ignores that CMS publishes RADV guidance for auditing a particular DOS year many years *after* the submission window for diagnosis codes in that DOS year has closed. For example, in ¶ 53, Blair implies that RADV guidance issued in 2019, which may apply to DOS 2013 codes that are undergoing RADV audits in 2019 and onward, should somehow govern the coding of DOS 2013 codes at the time of their submission. But a coder assigning and

⁶ See Centers for Medicare & Medicaid Services, *Contract-Level Risk Adjustment Data Validation – Medical Record Reviewer Guidance* (effective Mar. 20, 2019) (“2019 RADV Guidance”), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>, at 6-7.

submitting codes for DOS 2013 would have been doing so in 2015 at the latest,⁷ years before the 2019 guidance ever existed.

Furthermore, Blair's reliance on *future* RADV guidance not in existence at the time of the DOS violates the basic rule of coding that coders must apply the coding rules in effect during the DOS year and not the rules in effect after the fact. Blair herself emphasizes this rule. In ¶ 35, she writes: "MA Plan coders reviewing a medical record in 2013 that was created on the date of the patient visit in 2012 should apply the guidance that was effective on the date of service (2012), not the guidance effective on the date of review (2013)." The effective date for ICD codes is October 1 of the current year through September 30 of the subsequent year (e.g. 10/1/2023 through 9/30/2024).⁸ CMS is clear that one must only use the then-current Guidelines when assigning ICD-10 codes.⁹ By way of example, CMS's current guidance states, "The 2024 ICD-10-CM files below contain information on the ICD-10-CM updates for FY 2024. These 2024 ICD-10-CM codes are to be used for discharges occurring from October 1, 2023 through September 30, 2024 and for patient encounters occurring from October 1, 2023 through September 30, 2024."¹⁰ Blair's suggestion that RADV guidance issued in 2019 should nevertheless govern codes in the DOS period of this dispute (DOS 2009-2016) is wrong.¹¹

⁷ See Centers for Medicare & Medicaid Services, *Corrected Deadline for Submitting RAPS Data for Use in Risk Score Calculation Runs for Payment Years 2014, 2015, 2016* (Sept. 11, 2014), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/correction%20-%20hpms%202014_2015_2016%20payment%20run%20notice_172.pdf (indicating the final submission deadline for DOS January 1, 2013 to December 31, 2023 was January 31, 2015).

⁸ ICD-9 and ICD-10, all years.

⁹ ICD-10 (updated Oct. 1, 2023), <https://www.cms.gov/files/document/fy-2024-icd-10-cm-coding-guidelines.pdf>.

¹⁰ *2024 ICD-10-CM*, Centers for Medicare & Medicaid (last modified Sept. 6, 2023), <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>.

¹¹ Blair's cited RADV guidance (*see, e.g.*, Footnotes 22 and 34 in the Blair Report) does not apply to DOS 2009-2016. Blair relies on RADV guidance that came into effect only on March 20, 2019, applying at the earliest to audits beginning on September 27, 2017. Blair Report ¶¶ 37-41. Although Blair claims those audits

Blair’s opinion also ignores the specific process and methodology of the RADV program in contrast to coding for MA program submission. I regularly provide consulting services for providers and plans that will undergo or are undergoing a RADV audit, and am experienced in this process. Blair’s suggestion that coding assignment rules and RADV guidance should be treated apples-to-apples is misleading.

Unlike in the former context, a RADV audit is a back-and-forth process between CMS and plans regarding particular HCCs under audit and the medical record support the plans must furnish to justify their assigned HCCs. Even if plans had failed to identify adequate medical record support for their submitted HCCs, they may attempt to correct or supplement this during the RADV audit with support that the plans did not (and could not have properly) relied on at the time that they submitted the HCCs for payment. *See, e.g.*, 2019 RADV Guidance at 8 (“CMS understands the constraint when provider medical records are incomplete or documented inadequately. Therefore, the RADV process . . . allows for multiple medical record submissions from multiple approved providers from any encounter date in the data collection period, even if a diagnosis from that encounter was not previously submitted to Medicare.”) (emphasis added).¹² In other words, although the plan had reported an “inadequately” “documented” HCC, the RADV process uniquely allows plans to re-submit the HCC based on a different medical record for a different DOS, even if the plan had never reported any diagnoses from that medical record previously.

may review codes from DOS 2013 onward, plainly this RADV guidance did not exist during the DOS years of this dispute.

¹² *See also* Centers for Medicare & Medicaid Services, *Contract-Level Industry-Wide Training Event* (Jan. 29, 2019), <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/radv-industry-slide-deck.pdf>, at 13 (allowing plans subject to RADV audit 20 weeks to provide supporting documentation, and allowing the plan to research and obtain documentation that may not have been available at the time of claim submission).

Given the unique context of RADV, Blair’s attempt at ¶ 31 to show a purported “conflict” between the official coding rules and RADV guidance is misleading. She writes:

“In a RADV audit, when a coder encounters abbreviations with multiple meanings, CMS instructs: ‘If more than one meaning applies or documentation is too limited to differentiate, and this is the only diagnosis listed within the record, evaluate on a case-by-case basis. Otherwise, use discretion to report or not based on other circumstances in the record.’”

Blair implies that the above-quoted language from RADV guidance is authorization by CMS to “a coder” to make a “discretion[ary]” inference about the meaning of an abbreviation during code assignment, even if the medical record is “too limited” to provide definitive clarity on the meaning.

This misquotes the source. In reality, Blair is quoting from a chart in the RADV guidance regarding the “Action” that a “RADV Auditor” may take when a medical record submitted to support an HCC under audit shows red flags. 2019 RADV Guidance at 59.

What the Reviewer May Encounter	Explanation/Examples	Reviewer Guidance	RADV Auditor Action
Non-English Documentation	Coder Guidance: The record submitted includes diagnoses, but the words are not English.	Identify the documentation that validates the CMS- HCC. If it is legible and can be translated, then it is acceptable to submit.	Refer to Medical Record Review Contractor (MRRC) Project Manager regarding resources for medical translation of pertinent sections of the medical record.
Abbreviation with Multiple Meanings	Coder Guidance: Several common abbreviations have more than one meaning. <i>Examples:</i> MD – major depression, muscular dystrophy, macular degeneration CRF – chronic renal failure, chronic respiratory failure	Evaluate the abbreviation within the context of the full medical record before submitting to support the condition.	If more than one meaning applies or documentation is too limited to differentiate, and this is the only diagnosis listed within the record, evaluate on a case- by-case basis. Otherwise, use discretion to report or not based on other circumstances in the record.

Per the chart above, during the RADV process, CMS's diagnosis coder (referred as the RADV Medical Record "Reviewer"¹³) must first review the medical record and determine whether the meaning of an "abbreviation" used by the provider is established "within the context of the full medical record before submitting [that record] to support the condition." Consistent with my opinion, only if the "medical record" clearly documents the abbreviation's meaning may that coder or "reviewer" then credit that record as proper "support [for] the condition."

Blair's key quote, which she claims shows the purported "discretion" of a diagnosis coder generally, is from the last column in the chart regarding the options that a RADV Auditor has and *not* the RADV coder: "If more than one meaning applies or documentation is too limited," then the auditor, not the coder, may investigate further on a "case-by-case basis" or consider "other circumstances in the record." This guidance confers "discretion" on the RADV auditor, consistent with the RADV process discussed above in which a plan may work to redress inadequate documentation with guidance from the auditor.

The above RADV guidance does not show a conflict in coding rules, because as explained, this is not guidance on code assignment for coders. Rather, this is guidance about how a RADV auditor performs the audit. Throughout the rest of this RADV guidance, *see generally* 2019 RADV Guidance, CMS makes clear that the coding rules to which plans are subject are the ICD-9/10 and the basic principles I have discussed

¹³ In the RADV audit context, the medical record coder (or "Reviewer") and the RADV Auditor play different roles. As the 2019 RADV Guidance at 14 explains: "CMS RADV reviewers are certified coders, experienced in risk adjustment data validation that are familiar with a variety of medical record layouts, electronic medical record entries, and handwritten medical record documentation. The following table presents . . . guidance on the action auditors may use to evaluate and resolve the issue[s]" regarding the "MA Organization's decision to submit [particular] medical record" support for HCCs under audit.

throughout my two reports.¹⁴ Regardless of CMS’s approach during a RADV audit, the fundamental coding rule is that there must be clear and unambiguous medical record documentation to support codes submitted for payment.

- d. **Provider-created reference documents** – Documents made by providers to summarize or interpret coding guidelines have no authority. Coders should not (and are trained not to) defer to such documents. Nor is it best practice for coders to rely on these informal references developed by and for the provider offices. Based on my experience training coders at provider offices, I have observed these internal reference documents, and they are frequently outdated, incomplete, or inaccurate under the coding rules. For example, some provider offices will list only common diagnosis codes applicable to their patients. Other times, provider references fail to keep up with updates to rules, such as during the transition to ICD-10. The best practice for coders in any setting is to refer back to the primary source itself (ICD-9/10), which provides comprehensive, specific, and uniform rules.

III. OPINION ONE – REBUTTAL

20. Blair summarizes her Opinion One as: “The identification of diagnosis codes supported by documentation in a medical record is a complex process, informed by a variety of coding guidance and dependent on a coder’s training, experience, and judgment.” Blair Report at 11.

¹⁴ A stark example is that, at the bottom of every page of the 2019 RADV guidance, the following reminder about the authoritative coding rules is stamped: “The general guidance in this document is not exclusive. . . . [The] rules, requirements, and instructions relating to medical record documentation substantiation of diagnoses and the coding of diagnoses [that] apply, includ[e], but [are] not limited to, that the supporting medical records be clear and unambiguous, the requirements set forth in Chapter 7 of the Medicare Managed Care Manual, the requirements of the International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting (ICD-9-CM)”

21. I disagree. None of Blair's positions affect my core opinions in the Opening Report. The coding rules are designed to limit coder discretion. The rules dictate the specific content that a medical record must clearly contain to support a code. They provide important defaults in coding, for instance, unless the medical record unquestionably documents the required information to support a code, the code cannot be assigned.

A. Blair's Description of Coding As "Complex" Is Not Meaningful.

22. The main opinion Blair offers is that medical record coding is "complex." This description is vague. Whatever "complex" means to Blair, coding is more precisely described as a professional technical skill, not a lay skill. Like any professional technical skill, coders must receive specialized training, and improve their coding abilities through repeated practice and experience. Coding accuracy is impacted by oversight of experienced coders and requirements that coders meet quality-control standards (like United's 95% accuracy standard for its chart review coders, Opening Report ¶¶ 51, 54-56).

23. Industry-wide, as Blair acknowledges at ¶ 44, there is a well-established norm that coders meet a 95% accuracy standard. Her acknowledgment of this standard shows codes can be objectively evaluated, determined to be correct or incorrect, and thus support the calculation of a coder's accuracy rate. In my experience, coders are capable of performing at this standard, because it is a professional expectation.

B. Variation in Coder Ability Does Not Undermine Objectivity of Coding Process.

24. Contrary to Blair's suggestion at ¶¶ 23-25, the reality that coders' abilities may vary and in turn impact coding accuracy does not mean that coding itself lacks objectively correct or incorrect answers under the coding rules. Opening Report ¶¶ 50-56. As discussed above, United

itself recognized this, as it measured coders' error rates, and required coders to stay under certain error rates to remain "in production" as an active coder.¹⁵

C. Coding is Not "Subjective."

25. I disagree with Blair's opinion that coding "involves judgment and can be a subjective exercise where coders may not always agree." Blair Report ¶ 22. Blair fails to define what she means by "subjective" and "involves judgment." The Opening Report sets out my opinions. Opening Report ¶¶ 40-56.

26. Throughout her report, Blair frequently claims that assignment of diagnosis codes may be based on what a coder subjectively "believes" about the medical record or coding guidelines. *See* Blair Report ¶ 34. This is misleading. Code assignment based on anything other than objectively clear, legible documentation – what a coder may "believe" or infer about a medical record does not qualify – is not an acceptable practice. *See, e.g.,* AHIMA's Standards of Ethical Coding ("AHIMA Standards") ("3. Assign and report, in any format, only the codes and data that are clearly and consistently supported by health record documentation in accordance with applicable code set and abstraction conventions, and requirements.").¹⁶

27. For any content in the medical record that is unclear, ambiguous, or subject to interpretation and disagreement, the coder must ignore that portion of the medical record, unless the coder obtains definitive clarity (for instance, through a physician query). *See id.* ("4.3. Query with established practice brief guidance when there is conflicting, incomplete, illegible, imprecise, or ambiguous information.").

¹⁵ Dickey Dep. 198:14–199:3, May 24, 2022.

¹⁶ *American Health Information Management Association Standards of Ethical Coding (2016 version)*, AHIMA (revised and approved Dec. 12, 2016), <https://bok.ahima.org/topics/coding-compliance-and-revenue-cycle/american-health-information-management-association-standards-of-ethical-coding-2016-version/>.

28. That coders may disagree on the proper code assignment also does not mean coding itself lacks objectively correct or incorrect answers. Blair assumes that the differing codes proposed by various coders based on a hypothetical medical record are somehow all defensible, but this is wrong. Neither Blair's report nor any of United's witnesses have to date identified an actual example where the same medical record documentation properly supports multiple coding assignments for the same condition.

D. Blair's "Six Factors"

29. The bulk of Blair's analysis in Opinion One discusses six factors that she claims make coding "complex" or "subjective" and causes coders to reach "different conclusions" when reviewing the same medical record:

Factor 1: Coder Certification, Experience, and Training

30. In my Opening Report, I discuss how varying levels of coder experience and training impact the accuracy and quality of coders' work. I refer back to and incorporate those opinions here. *See* Opening Report ¶¶ 51, 52(a), 52(b), 55.

31. Blair opines that "a coder with more specialized diagnosis code training, such as a coder with a CRC certification, may make different coding determinations than a coder with a more generalized training background." Blair Report ¶ 25. Blair also opines that "coders who work in an office with a medical specialist who focuses in one area, such as cardiology," may have more limited coding knowledge than coders with less of a specialized focus. *Id.* ¶ 23.

32. I agree with Blair that coders who have experience only in a specialized area and who lack training in risk adjustment coding generally code less accurately and completely in the MA context. I have observed that providers' coders will assign and report diagnosis codes improperly, because they do not understand or apply the ICD-9/10 rules properly.

33. By contrast, in organizations that require coder certification, ongoing training, and oversight and quality control of coders' work, the resulting coding tends to be more accurate and complete than at organizations that lack these requirements. These requirements also help minimize differences in coding ability across coders who came from different coding experiences or specialty areas.

Factor 2: Availability, Legibility, and Variability of Provider Documentation

34. Blair next opines that issues with provider documentation, such as the availability, legibility, and format of records, may cause variability in coding results across coders.

35. Proper application of coding rules constrains such variability. The basic rule of coding is that unless every factor necessary for assignment of a particular code is clearly documented in the medical record the coder is reviewing, the code cannot be assigned.

36. Blair raises issues of incomplete provider documentation, where providers may not turn over all their records, records may be missing pages, or records may not have been obtained from all providers. Blair Report ¶ 26. As discussed below at ¶ 75 and in my Opening Report at ¶ 35, the simple response is that coding rules require that a coder rely on the medical record before it. The coder cannot assume that a "theoretical" medical record or portion of a medical record not yet retrieved or accessible exists to support the code.

37. Blair further observes that legibility of provider records impacts coding: "[A] coder who cannot read a provider's handwriting may not identify a diagnosis code during a chart review that is, in fact, properly supported by documentation in the medical record." Blair Report ¶ 29. But Blair's claim is oxymoronic. A code is not "in fact, properly supported by documentation in the medical record" when that record is not legible except to those uniquely familiar with a provider's handwriting. That coder or any other coder may misinterpret the illegible documentation.

38. The rules forbid a coder to base code assignment on illegible or ambiguous records precisely to reduce variability in coding. *See* 2008 Participant Guide Table 6C (requiring that acceptable documentation supporting code assignment is documentation that is: “legible.”); ICD-10 (“consistent, complete documentation” is required and “[w]ithout such documentation accurate coding cannot be achieved.”).¹⁷ Until a coder obtains proper and clear documentation (redressing the illegibility), the code cannot be assigned.

Factor 3: Sources of Coding Guidance

39. Throughout her report, Blair makes general claims about how various sources of coding provide insufficient, confusing, or conflicting guidance. But Blair does not give any actual or realistic examples of these issues. Instead, working backwards from the conclusion she seeks to support, Blair constructs several hypotheticals to make her point. But these do not reflect likely real-world scenarios and are not extrinsic evidence that support her conclusion.

40. *First*, in ¶ 34, Blair opines that the coding rules are deficient because they fail to inform coders how to interpret ambiguous abbreviations like “CRF” in a medical record. According to Blair, “CRF” can mean either “chronic renal failure or chronic respiratory failure,” yet the ICD 9/10 provides no guidance on which to pick and how to assign the proper code. Along the same line of thinking, Blair complains that the ICD-9/10 Alphabetic Index and Tabular List do not list “CRF.”

41. This is a complete red herring. The problem in this scenario is *not* the ICD-9/10, but the medical record. The ICD-9/10 is clear that, under such a circumstance where the meaning of an abbreviation (i.e., CRF) is not clear, the coder cannot rely on this note in the medical record to

¹⁷ ICD-10 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>, at 1.

assign a code. The coder must first obtain clarification from the provider about this note before proceeding to assign a code.

42. Blair's complaint about the absence of "CRF" in the ICD-9/10 index reveals how unrealistic this hypothetical is. Any coder with minimal training knows that the Alphabetic Index and Tabular List are not organized by abbreviation, but by the full names of conditions and diagnosis codes (to avoid the ambiguity of abbreviations such as this).

43. **Second**, Blair presents a hypothetical in ¶ 35 that coders have trouble keeping straight the coding rules that apply when the coder is performing coding in the present, but for conditions examined in another DOS year. This again is an unrealistic hypothetical. It is an elementary rule that a coder must apply the coding rules in effect during the applicable DOS year and not the coding rules in effect at the time coding is taking place. *See infra* ¶ 53. This is not an example of confusion in the rules at all, because there is an applicable well-known rule.

44. **Third**, in ¶ 36, Blair poses that the coding rules have been unclear on how a coder should interpret the phrase "evidence of" a given condition in a medical record. Blair claims that, until the Coding Clinic "clarified" how coders should interpret the term "evidence of" in 2009, there was widespread confusion among coders.

45. Blair cites no evidence of this industry-wide confusion. Nor does she cite any support or evidence for her claim that the Coding Clinic's 2009 Q&A response about "evidence of" represented a sea change in how the industry approached interpreting "evidence of" language in a medical record.

46. In my experience, and to the best of my recollection, this was not a widespread issue prior to 2009. Nor does the Coding Clinic's 2009 Q&A response suggest it was. Rather, the

response is a typical Coding Clinic entry where it provides an expert coding view on how to handle a specific scenario posed by a single questioner:

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NUMBER 3 2009, Page 7

Coding Uncertain Diagnoses

Question: Is it appropriate to report codes for diagnoses recorded as “evidence of cerebral atrophy” and “appears to be a nasal fracture,” when documented on outpatient radiology reports?

Answer: The phrase “appears to be,” listed in the diagnostic statement fit the definition of a probable or suspected condition and would not be coded in the **outpatient** setting. The *Official Guidelines for Coding and Reporting*, Section IV.I. state, ‘Do not code diagnoses documented as “probable,” “suspected,” “questionable,” “rule out,” or “working diagnosis” or other similar terms indicating uncertainty. Rather, code the condition(s) to the highest degree of certainty for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit.’ In terms of coding and reporting for hospital inpatients, according to the *Official Guidelines for Coding and Reporting*, Section III.B., it would not be appropriate to code abnormal findings from radiology reports.

However, when the provider documents “evidence of” a particular condition, it is not considered an uncertain diagnosis and should be appropriately coded and reported in the **outpatient** setting.

47. Before and after the 2009 Coding Clinic response, a coder in the MA context could never base a code assignment on the term “evidence of” alone. It is well-established that a condition may only be assigned a code if the medical record shows the condition was being treated, monitored, or managed on the given DOS. Blair puts too much emphasis on the single phrase “evidence of” to justify coding in a MA context.

48. I further disagree with Blair’s characterization that the Coding Clinic provides “guidance” on par with official coding guidelines. Blair Report ¶¶ 55, 61. The Coding Clinic does not set generally applicable guidelines or authoritative requirements. Rather, it is a secondary source for coders to ask questions about applying ICD-9/10 guidelines in the specific context the coders identify. Per AHIMA, *AHA Coding Clinic for ICD-10-CM/PCS and AHA Coding Clinic for HCPCS*, published quarterly by the AHA Central Office, provides expert guidance supporting coders,

auditors, and insurers with coding advice.¹⁸ In referring to previously published Coding Clinic Q&As, a coder must proceed with caution in determining whether a particular, specific Q&A response regarding a specific scenario is applicable to the scenario before the coder.

49. **Fourth**, Blair once again opines that conflict between RADV guidance and coding rules has led to coder confusion. Blair Report ¶¶ 37-41. But as addressed above in ¶ 19(c), RADV guidance is not guidance that coders are permitted to apply, nor have I observed coders applying it outside the RADV context. I have also explained above why Blair's opinion at ¶ 31 in her report – about how 2019 RADV guidance authorizes coder discretion or guesswork based on the coder's unique subjective judgment – is misleading. *Supra* ¶ 19(d). I have also discussed why it is improper for a coder to rely on RADV guidance issued many years after the relevant DOS year and effective only for years after that DOS. *Supra* ¶ 19(c).

50. In my experience, I have not encountered coders applying RADV guidance of the type cited by Blair in lieu of ICD-9/10 coding rules or as an interpretive source about those rules. As discussed above, RADV guidance focuses on describing how the audit process works and specifies the different roles and responsibilities of parties involved (e.g., the auditor). *Supra* ¶ 19(d). But the authoritative source of coding rules remains ICD-9/10. RADV guidance makes this explicit and repeatedly warns that ICD-9/10 must be deferred to and that RADV guidance is not intended to conflict with those rules (even if a reader misinterprets the guidance to create a conflict, as Blair does).

51. My opinion is based on extensive experience in training, educating, and reviewing the coding of both providers and MA plans, as well as working with providers with plans undergoing RADV and understanding the different process and RADV-specific guidance applicable there.

¹⁸ *AHA Coding Clinic*, AHIMA, <https://www.ahima.org/landing-pages/ghealth/ahima-ghealth-associates-directory/associates/aha-coding-clinic/> (last visited Jan. 22, 2024).

The record is not clear on what experience or background Blair bases her contrary opinions treating RADV guidance such as the 2019 guidance as “source of interpretation and application of coding guidelines.”

52. *Fifth*, in ¶ 40, Blair claims there is a lack of consensus around whether coders should apply the MEAT guidelines. But, as Blair recognizes, the MA guidelines are clear that MEAT is not required. As discussed in my Opening Report at ¶ 35, what is required is documentation showing that a condition existed at the time of the encounter/visit and “require[d] or affect[ed] patient care, treatment or management.”¹⁹

Factor 4: Human Error

53. Blair opines that another reason coding results vary across coders is human error – for instance, coders sometimes get tired or make mistakes and typos in what they code. In ¶ 42, Blair opines “this can lead coders to experience fatigue while reviewing medical records, which can result in mistakes, including missed diagnosis codes.”

54. Human error is inevitable, but Blair provides no evidence or explanation why human error is more likely to cause undercoding rather than overcoding. A “mistyping” error may just as well result in reporting a nonexistent and unsupported condition. For instance, mistyping the first letter of E08 (Diabetes mellitus due to underlying condition without complications) versus C08 (Malignant neoplasm of major salivary gland, unspecified), both from the ICD-10 code set, results in vastly different diagnoses. Nor does Blair explain why variability in coding due to inevitable human error is relevant. Mistakes in coding do not show that coding lacks objectively correct and incorrect results.

¹⁹ ICD-9, § IV.K (effective Oct. 1, 2011), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; see also 2008 Participant Guide, § 6.4.1.

55. The fact that “human error” is responsible for reporting of nonexistent and unsupported codes was identified in a recent HHS Office of the Inspector General (OIG) report.²⁰ While not all related to human error, for some diagnosis codes that were not supported, the error rate was as high as 90%. The Toolkit used data from various audits OIG conducted from 2013 through 2019 payment years and identified possible “mis-keyed diagnosis codes” within the high-risk code groups addressed. OIG provides the following example: “For example, ICD-10 diagnosis code I720 (which maps to the HCC for Vascular Disease) could be transposed as diagnosis code I270 (which maps to the HCC for Congestive Heart Failure and in this example would be unvalidated). Using an analytical tool that we developed, we identified 3,780 scenarios in which diagnosis codes could have been mis-keyed because numbers were transposed or because other data-entry errors occurred that could have resulted in the assignment of an unvalidated HCC.” Again, a mistyped or mis-keyed error may just as well result in reporting a nonexistent or unsupported diagnosis.

Factor 5: Transition from ICD-9 to ICD-10

56. Blair opines that the transition from ICD-9 to ICD-10 led to confusion among coders in how to properly apply the new ICD-10. As discussed in my Opening Report at ¶ 16, ICD-10 made coding even more granular and particularized and provides more specific rules for code assignment than in ICD-9. The effect is that ICD-10 directs coders even more precisely to the correct code(s) and thus limits discretion.

57. That some coders were less familiar or experienced with ICD-10 coding rules causing them to err was a short-term issue. As discussed in my Opening Report at ¶ 52, during the transition period from ICD-9 to ICD-10, there were industry-wide efforts to ensure coder

²⁰ Amy Frontz, OIG, *Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes* (Dec. 2023), <https://oig.hhs.gov/oas/reports/region7/72301213.pdf>, at 43.

competence and training in ICD-10. To maintain certifications, the AAPC required certified coders to take and pass an ICD-10-CM proficiency test. These efforts helped improve coder accuracy under ICD-10. In any case, errors based on lack of training or experience with ICD-10 do not indicate that ICD-10 itself is unclear or ambiguous.

Factor 6: Gray Areas of Coding

58. Blair opines in ¶ 48: “There are several additional areas in which coding involves a degree of subjectivity (often called “gray areas”), because they are open for interpretation and debated among medical coders and even the organizations that offer diagnosis coding guidance.”

59. Blair does not provide a clear definition of what she means by “gray areas” in coding. She claims only that any “area[] in which coding involves a degree of subjectivity” may “often [be] called ‘gray areas.’” Blair Report ¶ 48. I do not know in what context or to whom Blair is referring when she states this term is “often” used.

60. The only four examples Blair gives of “gray areas” do not meet her vague definition. *First*, Blair gives the example of problem lists. Blair Report ¶¶ 51-53. She claims that there has been confusion regarding problem lists, because CMS’s guidance on problem lists in the 2008 Participant Guide conflicts with CMS RADV guidance issued in 2019 on problem lists. This is another example in which Blair invents a change in guidance to create a purported conflict that does not in fact exist, just as she did in the context of coding abbreviations with multiple meanings, *see supra* ¶¶ 17-19. Blair correctly writes at ¶ 52:

“In 2008, CMS stated, ‘an acceptable problem list must be comprehensive and show evaluation and treatment for each condition that relates to an ICD-9 code on the date of service, and it must be signed and dated by the physician or physician extender.’”

But she goes on at ¶ 53 to mischaracterize 2019 RADV guidance to create the supposed conflict:

“The [2019] guidance stated, ‘[p]roblem lists are evaluated on a case-by-case basis when the problem list is not clearly dated as part of the face-to-face encounter indicated on the

coversheet, or there are multiple dates of conditions both before and after the DOS.’ In other words, CMS acknowledged the fact that problem lists may or may not relate to a given date of service, so the guidance left it to the discretion of individual coders to determine whether a problem list included sufficient details regarding what diagnoses were current.”

Once again, Blair is quoting from a chart in the RADV guidance that applies to “Actions” that a “RADV Auditor” may take. 2019 RADV Guidance at 42.

What the Reviewer May Encounter	Explanation/Examples	Reviewer Guidance	RADV Auditor Action
Problem Lists (within a medical record)	See related topic of Chronic and Other Additional Diagnoses . Lists of diagnoses (conditions, problems) may be numbered, bulleted, or separated by commas. A list may be documented in the patient history, assessment, discharge summary, or other areas of a medical record. When conditions commonly associated are listed under the same number or bullet, the conditions can assume to be linked. These diabetes examples are effective for ICD-9-CM and will be updated for ICD-10-CM. Example 1: 1. Hypertension 2. DM, neuropathy (link diabetes and neuropathy) Example 2: 1. Hypertension 2. DM 3. Neuropathy (do not link diabetes and neuropathy)	Evaluate the problem list for evidence of whether the conditions are chronic or past and if they are consistent with the current encounter documentation (i.e., have they been changed or replaced by a related condition with different specificity). Evaluate conditions listed for chronicity and support in the full medical record, such as history, medications, and final assessment. Do not submit conditions from lists labeled as PERTINENT NEGATIVES.	Problem lists are evaluated on a case-by-case basis when the problem list is not clearly dated as part of the face to face encounter indicated on the coversheet or there are multiple dates of conditions both before and after the DOS. Lists of conditions written by the patient are not acceptable. Lists of code numbers without narratives are not acceptable.

The chart above directs the coder (referred to as the “Reviewer”) to “evaluate the problem list” to determine “whether conditions are chronic or past” and, consistent with my opinion and with CMS’s longstanding guidance on coding from problem lists, the coder must decide “if th[ose conditions] are consistent with the current encounter documentation.”

Blair’s quote, which she claims shows the “discretion” of “individual coders” in fact comes from the far-right column that applies to a RADV Auditor and not to a coder. The chart allows the auditor, *not* the coder, the option to “evaluate[] on a case-by-case basis” under specific circumstances such as “when the problem list is not clearly dated.” In these instances, the RADV auditor, *not* the coder, is given certain “discretion.”

61. There is no conflict in the applicable guidance for coders. Furthermore, as discussed above, RADV guidance does not supplant the ICD-9/10 coding rules that govern code assignment and submission. *Supra* ¶¶ 17-19, 50.

62. **Second**, Blair gives the example in ¶ 54 of chronic conditions as another “gray area” in coding, due to variability in how providers may document, treat, or discuss chronic conditions with patients. But the examples Blair gives do not show a “gray area” in coding rules or invite coder discretion. Rather, they all address problems in medical record documentation, and the coding rule to apply in this context is clear: unless and until there is further clarification from the provider or additional unambiguous documentation is obtained, the coder cannot code the chronic condition in each of Blair’s examples. I quote these examples and give my contrary opinions below:

- “Providers may take varying amounts of time to document each chronic condition assessed as part of a visit” – documentation of chronic condition does not yet exist.
- “Patient might not have discussed her chronic condition at each visit” – chronic condition not addressed at visit and thus not documented for that DOS.
- “The provider might in fact have taken the chronic condition into account when considering treatment for other conditions addressed at a patient visit and might have included documentation supporting chronic condition” – no confirmation that adequate documentation exists if providers fail to note they assessed and treated the condition on a given DOS.

63. All of the above are hypotheticals by Blair regarding the possibility a patient has a chronic condition, but where either the provider did not properly or clearly document such a condition or where such documentation “might” exist but has yet to be located. These scenarios raise problems with documentation, not a “gray area” permitting a coder to code the chronic condition anyway based on his own judgment.

64. **Third**, Blair claims in ¶ 55 that coders may be confused when coding chronic conditions because different rules for coding chronic conditions apply to inpatient versus outpatient medical

records. This example is baffling because it is a basic rule of coding that any coder has to apply the coding rules that govern in a particular clinical setting where the patient encounter occurred.

65. Blair's specific example is even more baffling. She claims at ¶ 55 that there is an inconsistency between Coding Clinic guidance on coding chronic conditions *in the inpatient setting* versus ICD rules on coding chronic conditions in the *outpatient setting*. However, these are not conflicting coding references. A coder would not attempt to apply both at the same time since one addresses inpatient records and the other outpatient records.

66. Furthermore, if a coder mistakenly believed these rules somehow are both relevant simultaneously, a coder is trained to defer to the ICD rules and not a secondary source, like the Coding Clinic. *Supra* ¶¶ 17-19. This is not a "gray area" but shows the opposite: the clarity and specificity of the ICD rules and the hierarchy of rules a coder is trained to follow.

67. **Fourth**, Blair claims in ¶ 48 that "MA Plan coders performing a blind chart review may approach coding gray areas differently based on their knowledge and experience which may differ from that of the provider or coder in the provider's office that submitted diagnosis codes on the claim, which can cause discrepancies between the diagnosis codes identified by both."

68. To the extent there are "discrepancies" between the MA plan coder's and the provider coder's coding results, Blair's statement appears to make the basic point that different levels of coder experience and training impact coding accuracy. Blair also gives no support for her point that MA plan coders in fact "approach coding gray areas differently." As discussed above, MA plan coders are not permitted to assign codes in the examples Blair gives of "gray areas" (e.g., where the medical record is unclear as to a chronic condition or a coder mistakenly attempts to apply in-patient coding rules to an out-patient chart), let alone use different "approach[es]" to assign codes.

69. Blair continues to make conclusory and vague statements about “gray areas” in ¶ 50: “While regulators and the healthcare industry . . . attempt to clarify gray areas, disagreements remained unresolved for long periods of time in many cases and some remain unresolved today, rendering it difficult for coders to consistently approach these areas.” Blair does not explain what “gray areas” she is describing, what “disagreements” are unresolved, and based on what sources she is making these broad-stroke points. Presumably, because Blair is claiming to describe how the coding industry and government regulators have already “attempt[ed]” to address these issues, there should be some sources supporting these events, but she does not offer any.

IV. OPINION TWO – REBUTTAL

70. In Blair’s second opinion, she switches to opining on why provider coding may be more reliable than MA Plan coding: “During blind chart reviews, if a coder does not identify a diagnosis code that a healthcare provider submitted on a claim to the MA Plan, that code may still be supported by documentation in the patient’s medical record.” Blair Report at 27.

71. Blair justifies her position by suggesting (1) provider-submitted codes tend to be more reliable than MA plan coding and (2) provider coders are “better situated to identify many properly supported diagnosis codes” based on information that Blair admits cannot be found in the medical record. I disagree with both of these points.

72. **First**, the opposite of what Blair newly claims in Opinion Two (but that she endorsed in Opinion One) is true: in my extensive experience, working with both providers and MA plans, MA plan coding has typically been more reliable and accurate than provider coding. In all but the largest physician practices and academic medical centers, provider coders may not hold coding certifications. And, in the settings in which they do, there are rarely any checks or safeguards – such as the quality assurance programs at MA organizations – to ensure accuracy of coding.

73. As discussed, MA organizations tend to institutionalize industry best practices to support coding accuracy, while provider organizations do much less, if at all. For instance, articles by AHIMA and Rise Health cite to the importance of a 95% coding accuracy as an industry best practice.²¹ MA organizations tend to require such best practices, including that coders must be certified, continually trained, held to performance and quality control standards (e.g., 95% coding accuracy and completeness), and be subject to oversight and supervision by experienced coders.

74. **Second**, Blair’s rationale for why provider coding is more reliable than MA coding is that the former knows better than the latter whether a patient in fact has a condition irrespective of how it is documented in the medical record. Blair seems to equate a patient having a condition with a code being “properly supported” or sufficiently “document[ed] in the patient’s medical record.” Blair Report ¶¶ 57-62. So long as documentation *could* be obtained, because the patient in fact has the condition, then Blair’s position is it is appropriate to describe that condition and the corresponding code as “properly documented.” *Id.* at ¶¶ 57-59.

75. This opinion is at odds with the fundamental principle of coding that the medical record is the source of “truth” for code assignment. If a condition is clearly and unambiguously documented in the medical record, the code can be assigned; if not, the code cannot be assigned. That a medical record could be obtained or that a condition could be assumed to exist is not sufficient. United’s own coding leadership recognized this fundamental principle as the “golden rule of coding.” *See* Dickey Dep. 145:10–12, May 24, 2022 (The “golden rule of coding [is] that if it’s not documented, then you don’t code it.”). Blair attempts to support her opinion based on several hypotheticals. I disagree with each:

²¹ *See Body of Knowledge*, AHIMA, <https://bok.ahima.org/> (last visited Jan. 22, 2024); Erik Simonsen, *Is 95% coding accuracy good enough?*, RISE (Dec. 23, 2021), <https://www.risehealth.org/insights-articles/is-95-coding-accuracy-good-enough/>.

Hypothetical: Provider coder is uniquely familiar with provider idiosyncrasies

76. Blair argues that the provider coder uniquely comprehends the provider's handwriting, abbreviations, or documentation practices, can ask the provider questions about the patient's condition, or can find additional medical records to support a code. Blair Report ¶ 58. Each of these points shows why the medical record documentation as it exists or is known fails to support a code, because the documentation is ambiguous, illegible, or incomplete.

77. As I have explained, where there is no clear support for a particular condition in the medical record, a coder has only three options: (1) Ask the physician for any additional documentation that exists; (2) Query the provider to obtain clarification on the medical record; or (3) Not code the suspected but undocumented condition.²²

78. For instance, ICD-10 repeatedly instructs coders that the proper way of handling ambiguous documentation (such as unclear handwriting and language or an incomplete record) is to query the provider: "Query the provider for clarification, if the complication is not clearly documented." (Complications of Care); "Whenever the documentation is unclear regarding a borderline condition, coders are encouraged to query for clarification." (Borderline Diagnosis); "If the documentation is not clear as to whether acute respiratory failure and another condition are equally responsible for occasioning the admission, query the provider for clarification." (Sequencing of acute respiratory failure and another acute condition). ICD-10, § I.B.16-17, § I.C.10.b.3.²³

²² See, e.g., AHIMA Standards (revised and approved Dec. 12, 2016), <https://bok.ahima.org/topics/coding-compliance-and-revenue-cycle/american-health-information-management-association-standards-of-ethical-coding-2016-version/> ("3. Assign and report, in any format, only the codes and data that are clearly and consistently supported by health record documentation in accordance with applicable code set and abstraction conventions, and requirements," "4. Query and/or consult as needed with the provider for clarification and additional documentation prior to final code assignment in accordance with acceptable healthcare industry practices.").

²³ ICD-10 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

Hypothetical: Condition listed only in undated problem list

79. In Figure 4 of her report at ¶ 59, Blair presents a hypothetical in which a provider coder reported respiratory failure and a MA Plan coder did not, where the problem list made a note suggesting the patient had the condition but “no date [was] specifically assigned” to the note.

80. Despite the improper lack of a date, Blair imagines in the hypothetical that the provider coder “might have included . . . respiratory failure on the claim” anyway because that coder knew, from being at the provider’s office, the relevant note was added “on the date of service, which means that respiratory failure was, in fact, a current condition for this patient.” Blair Report ¶ 59. Blair then claims that the “MA Plan coder might have determined that because there is no date on the problem list and the information within it, they are unable to support the coding of respiratory failure during their review.” *Id.*

81. This hypothetical is nonsensical and again violates a basic rule of coding: Blair characterizes the provider coder as having properly coded respiratory failure when that coder relied on information about the date of service *not in the medical record*. As discussed above at ¶ 78, any person attempting to assign the respiratory failure code must first take steps – such as a physician query – to obtain the necessary medical record support.

Hypothetical: Diagnosis code not linked to medication

82. In Blair’s next hypothetical, in ¶ 60 of her report at Figure 5, a MA Plan coder fails to identify a COPD diagnosis in a medical record even though COPD was included on the problem list and the record “documented that the provider renewed the medication Albuterol, a medication used to treat COPD, but did not explicitly mention COPD otherwise in the note.” “While the Albuterol was not specifically linked to a COPD diagnosis in the chart, COPD was the only past condition that would require this medication, and the orders noted that Albuterol was being

renewed, indicating the COPD was still current.” Blair Report ¶ 60. Blair’s hypothetical suggests “a coder at the provider’s office may have drawn this linkage” while “an MA Plan coder may fail to identify [the] diagnosis that is supported by the medical record.” *Id.*

83. This is another unrealistic hypothetical. It assumes, without explanation, that the MA Plan’s certified, highly trained coder, who is subject to quality control review, would miss the obvious link between a well-established COPD medication (Albuterol) and the management of COPD, even though the condition appears in the problem list before the MA Plan coder. In my experience, this is unlikely to occur, particularly at a MA organization enforcing strict performance standards. Blair does not explain how this hypothetical justifies that a provider coder is more likely than a MA coder to approach this situation correctly.

Hypothetical: Failure to identify specific diabetes subtype

84. In Blair’s final hypothetical, “[a]n MA Plan coder may see diabetes supported by the medical record but assume the diabetes does not have complications because the record does not include an additional diagnosis for the complication. The [provider’s] coder, on the other hand, may have more *intimate* knowledge of the patient’s current diagnoses and can identify a diabetes diagnosis with complications. For instance, if the provider or coding personnel at the provider’s office reviewed the record and noted an order for an arterial scan of the lower legs, which subsequently showed a diagnosis of peripheral artery disease, then they might have coded diabetes with complications.” *Id.* at ¶ 61 (emphasis added).

85. Blair provides a medical chart at Figure 6 that accompanies the hypothetical, but the chart only shows why the hypothetical and Blair’s points fail. Based on the chart, the MA Plan coder who did not code a diabetes complication for DOS 1/1/2015 is correct. The hypothetical chart has no indication that an arterial scan of the lower legs was actually performed, but only that

it was ordered. Nor does the record reflect a face-to-face encounter where a provider addressed the peripheral artery disease. As a result, the medical record does not provide adequate documented support for a coder to link peripheral artery disease to diabetes at the 1/1/2015 visit. As in Blair's other hypotheticals, it is irrelevant the provider's coder might theoretically and "intimately" know additional information about the patient, which Blair assumes is not documented in the record.

86. The opinions above are based on information currently available to me. I reserve the right to supplement or modify these opinions as necessary if new information later becomes available.

Signed on January 29, 2024.

A handwritten signature in cursive script, appearing to read "Jean Acevedo", written in dark ink.

Jean Acevedo

Appendix A

Resources Relied Upon

I. Publicly-Available Resources

2024 ICD-10-CM, Centers for Medicare & Medicaid (last modified Sept. 6, 2023), <https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm>

AHA Coding Clinic, AHIMA, <https://www.ahima.org/landing-pages/ghealth/ahima-ghealth-associates-directory/associates/aha-coding-clinic/>

American Health Information Management Association Standards of Ethical Coding (2016 version), AHIMA (revised and approved Dec. 12, 2016), <https://bok.ahima.org/topics/coding-compliance-and-revenue-cycle/american-health-information-management-association-standards-of-ethical-coding-2016-version/>

Amy Frontz, OIG, *Toolkit To Help Decrease Improper Payments in Medicare Advantage Through the Identification of High-Risk Diagnosis Codes* (Dec. 2023), <https://oig.hhs.gov/oas/reports/region7/72301213.pdf>

Body of Knowledge, AHIMA, <https://bok.ahima.org/>

Centers for Medicare & Medicaid Services, *Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide* (2008), <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>

Centers for Medicare & Medicaid Services, *Contract-Level Industry-Wide Training Event* (Jan. 29, 2019), <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-risk-adjustment-data-validation-program/other-content-types/radv-docs/radv-industry-slide-deck.pdf>

Centers for Medicare & Medicaid Services, *Contract-Level Risk Adjustment Data Validation – Medical Record Reviewer Guidance* (effective Mar. 20, 2019), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>

Centers for Medicare & Medicaid Services, *Corrected Deadline for Submitting RAPS Data for Use in Risk Score Calculation Runs for Payment Years 2014, 2015, 2016* (Sept. 11, 2014), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/correction%20-%20hpms%202014_2015_2016%20payment%20run%20notice_172.pdf

Centers for Medicare & Medicaid Services, *ICD-9-CM Official Guidelines for Coding and Reporting FY 2011* (2010), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf

Centers for Medicare & Medicaid Services, *ICD-10-CM Official Guidelines for Coding and Reporting FY 2023* (2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>

Centers for Medicare & Medicaid Services, *ICD-10-CM Official Guidelines for Coding and Reporting FY 2024* (2023), <https://www.cms.gov/files/document/fy-2024-icd-10-cm-coding-guidelines.pdf>

Erik Simonsen, *Is 95% coding accuracy good enough?*, RISE (Dec. 23, 2021), <https://www.risehealth.org/insights-articles/is-95-coding-accuracy-good-enough/>

Gestational Diabetes and Diabetic Ketoacidosis, 7 AHA Coding Clinic for ICD 30 (Third Quarter 2020)

International Classification of Diseases, (ICD-10-CM/PCS) Transition – Background, Centers for Disease Control and Prevention (last reviewed Nov. 6, 2015), https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm

II. Case Documents

Tammy Dickey Deposition Transcript, May 24, 2022

Tracey Bradberry Deposition Transcript, July 1, 2021

EXHIBIT D-54

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

Civil Action No. 16-08697

UNITED STATES OF AMERICA

ex rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

EXPERT REPORT OF
BARBARA BLAIR, RN, MSN, CCS, CPC, CPCO, CRC

CONFIDENTIAL



Barbara Blair, RN, MSN, CCS, CPC, CPCO, CRC

Senior Director

FTI Consulting, Inc.

September 29, 2023

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I. Qualifications

1. I, Barbara Blair, am a Senior Director at FTI Consulting (“FTI”). I received my Associate Degree from Rockland Community College in 1986, followed by my Bachelor of Science in Nursing from the University of Rochester in 1991 and, ultimately, my Master of Science in Nursing from the University of Rochester in 1992. Upon receiving my Associate Degree, I passed the exam to become a licensed Registered Nurse. I practiced as a Registered Nurse from 1986 to 1995 in different specialties, including medical/surgical, emergency medicine, short-stay patients, oncology, and cardiac critical care, and I have maintained my Registered Nurse license to date. Upon receipt of my master’s degree, I passed the exam to become a certified Adult Nurse Practitioner. I practiced as an Adult Nurse Practitioner from 1992 to 1995. As a Registered Nurse and an Adult Nurse Practitioner, I worked in a variety of medical settings, including a large metropolitan hospital, a private hospital, and a teaching hospital.
2. I transitioned from being a provider to being a consultant in 1995. I provide consulting services to healthcare organizations, working with providers and various members of their healthcare teams, including but not limited to nurses, therapists, and nutritionists. My work focuses on provider documentation and medical diagnosis coding. I lead trainings at hospitals, physician offices, and outpatient clinics. I became a Certified Coding Specialist (“CCS”) in 2000 and subsequently obtained several coding and compliance certifications, set forth more fully on my curriculum vitae, including Certified Professional Coder (“CPC”), Certified Risk Adjustment Coder (“CRC”), Certified Professional Compliance Officer (“CPCO”), a certificate of completion for Certified Documentation Expert Inpatient (“CDEI”), and am an American Health Information Management Association (“AHIMA”) ICD-10-Clinical Modification/Procedure Coding System trainer.
3. For the past twenty years, I have served as a lead coder for FTI, where I work with clients, including health insurance plans and providers. I provide clinical and coding expertise for various reviews related to diagnosis code identification and assignment. As part of these reviews, one of my focus areas is the proper identification of support for diagnosis codes in medical records for providers and Medicare Advantage Plans (“MA Plans”) with risk adjustment reimbursement models. My work in this area includes reviewing company policies and procedures around diagnosis coding; reviewing internal training related to

proper diagnosis coding; creating coder education related to proper diagnosis code identification; reviewing diagnosis coding in connection with internal and external investigations; supporting reviews related to due diligence for potential acquisitions; and providing support for mock Risk Adjustment Data Validation (“RADV”) reviews.

4. For a detailed summary of my experience, please refer to Exhibit A for my CV. I have been retained by counsel for UnitedHealth Group, Inc. in the matter of *United States ex rel. Poehling v. UnitedHealth Group, Inc. et al.* to opine on the topics as set forth in this report. FTI is being paid \$560 per hour for my work in this case. In addition, other employees of FTI have worked under my direction in this matter. The billing rates for these individuals range from \$350-\$625 per hour. Compensation for FTI’s services is not based on the outcome of this matter or the content of my opinions.

II. Introduction and Summary of Opinions

5. Health insurance programs in the United States are administered by the government, private companies, or a combination of both. At age 65 (or as a result of certain disabilities or other conditions), individuals become eligible to receive their healthcare coverage through Medicare, which includes the option to receive healthcare coverage either through the federal government or through private health plans. Medicare Parts A and B, also known as Traditional Medicare, are administered by the Centers for Medicare & Medicaid Services (“CMS”).¹ Medicare Part C, also known as Medicare Advantage (“MA”), is administered by private health insurance companies called MA Plans.²
6. In contrast to a fee-for-service model where a healthcare provider’s payment is based on the services provided, CMS pays MA Plans based on its risk adjustment model, which takes into account a patient’s health status and certain demographic details, rather than the healthcare services a provider rendered to a patient. MA Plans obtain information regarding a patient’s health status from providers who submit healthcare claims, which contain

¹ See CMS, *Fact Sheet: Introduction to Medicare*, available at <https://www.cms.gov/outreach-and-education/find-your-provider-type/employers-and-unions/fs1-intro-to-medicare.pdf>.

² See Medicare.gov, *Your health plan options*, available at <https://www.medicare.gov/health-drug-plans/health-plans/your-health-plan-options>.

- diagnosis codes, to the MA Plan.³ Diagnosis codes are a lengthy set of standardized codes used by providers and health insurance plans to identify and track a patient's health conditions. CMS uses diagnosis codes as a basis for reimbursement in the MA program.
7. After a patient visit, a provider submits the claim to the patient's MA Plan, which contains information about the patient visit, such as the services provided and relevant diagnosis codes. A provider may identify the diagnosis code(s) to submit on the claim or the provider may rely on coders to review the information documented in a patient's medical record and translate this information into diagnosis codes. The MA Plan then, in turn, submits the diagnosis codes for all of its beneficiaries to CMS, and CMS uses this information (along with other characteristics of the beneficiary, including demographic information) to determine payment to the MA Plan for providing health coverage to this beneficiary.
 8. After the submission of a claim, MA Plans often use certified coders to perform a separate review of patient medical records, sometimes called "chart review," during which a coder reviews the medical records to determine which diagnosis codes she believes are supported by the documentation in the medical record. MA Plan chart reviews typically occur retrospectively, meaning after the provider submitted diagnosis codes to the MA Plan.
 9. One form of chart review employed by MA Plans is referred to as a "blind review," meaning the coder reviews a patient's medical record without knowledge of any diagnosis codes assigned by other coders who may have reviewed the documentation, or any diagnosis codes submitted by a provider to the MA Plan on a claim. In a blind chart review, the coder identifies diagnosis codes the coder believes have supporting documentation in the patient's medical record. This determination of diagnosis codes entails judgment and can be subjective, often relying on a coder's training, experience, and interpretation and application of coding guidance, which is not always definitive. Although coding medical records is standard practice in the healthcare industry, for the variety of reasons noted and discussed in more detail below, coders may not agree as to which diagnosis codes have documentation in a medical record sufficient to support coding the diagnosis code.

³ The "diagnosis codes" (otherwise known as ICD-9-CM and ICD-10-CM codes) that are used by providers in the United States are derived from the International Classification of Diseases ("ICD") developed by the World Health Organization. ICD codes were developed to classify the cause of death for mortality statistics. *See* CDC, *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)*, available at <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>.

Therefore, coders may identify different diagnosis codes than the diagnosis codes identified by a provider, a coder in a provider's office, or another coder performing a chart review.

10. Based on the materials I have relied upon (listed in Exhibit B) and my experience as a clinician and certified coder, I have the following opinions:

Opinion One: The identification of diagnosis codes supported by documentation in a medical record is a complex process, informed by a variety of coding guidance and dependent on a coder's training, experience, and judgment.

Opinion Two: During blind chart reviews, if a coder does not identify a diagnosis code that a healthcare provider submitted on a claim to the MA Plan, that code may still be supported by documentation in the patient's medical record.

11. My opinions are based on my experience as a nurse and certified coder, my consulting experience, and my 25+ years working in the healthcare industry. I also considered various industry writings from accredited organizations such as AHIMA and the American Academy of Professional Coders ("AAPC"). A list of the documents I relied upon in reaching my opinions is included in Exhibit B.

III. Background

Medical Record Documentation and Diagnosis Coding

12. Healthcare providers evaluate patients to determine and provide appropriate care. When meeting with a patient, the provider assesses the patient's chief complaint, presentation, medical history, signs and symptoms and then documents these pertinent details in the patient's medical record (also referred to as "provider documentation"). The provider is also supposed to determine any relevant diagnoses for the patient (e.g., rheumatoid arthritis), which should be noted in the patient's medical record. Figure 1 below is a condensed example of a hypothetical medical record on a specific visit date (1/1/2014):

Figure 1: Example Patient Medical Record

- **Jane Smith, MD – 1/1/2014**
- **John Doe (1/1/1947)**
- **Chief Complaint:** Swelling and joint pain in hand
- **History of Present Illness:** Onset of joint pain in the past two weeks with recent swelling
- **Medication** Aspirin
- **Medical History/Problem List:** Chronic Back Pain, Hip Replacement, Diabetes
- **Lab/Imaging:** x-ray of right hand
- **Exam:** Well-nourished, well-developed male, tenderness in right hand
- **Assessment/Plan:** right hand pain due to rheumatoid arthritis, start prednisone, continue diabetic diet

13. In this example, the medical record states that a hypothetical patient complained of pain and swelling in his hand. The doctor examined the patient's hand, reviewed the patient's relevant medical history, documented the patient's diagnosis of rheumatoid arthritis, and developed a personal care plan to address the patient's hand pain. While meeting with the patient to discuss his hand pain, the doctor also discussed how the patient was managing his diet for diabetes.
14. At some point following the patient visit, the provider submitted a claim to the MA Plan specifying the services the provider rendered to the patient (e.g., x-ray of hand) as well as the diagnosis codes that described the patient's underlying health status (e.g., rheumatoid arthritis in the example described in Figure 1). The provider's office included diagnosis codes on the claim form using the standardized set of diagnosis codes.
15. An important step in the patient visit and claim creation process is the assignment of diagnosis codes on a claim. Although the provider typically submits diagnosis codes on the health insurance claim, the resulting claim may not include all diagnosis codes supported by documentation in the medical record. In the example in Figure 1, the record supported the diagnosis codes for both rheumatoid arthritis and diabetes. Given that the patient's hand pain, which the provider determined to be rheumatoid arthritis, was the primary focus of the visit, the provider's office might have inadvertently failed to include a diagnosis code for diabetes on the claim, even though the provider discussed the diet plan for diabetes with the patient during the same visit and documented diabetes in the medical record.
16. Separate and apart from the submission of diagnosis codes on the claim, an MA Plan may conduct its own reviews of medical records through a chart review process. Although these reviews can be performed in a variety of ways, one option is a "blind chart review." In a

blind chart review, a certified coder reviews the patient's medical record without knowledge of any diagnosis code(s) previously submitted by the provider on the claim, or diagnosis code(s) identified for that patient by another coder. The MA Plan coder will identify the diagnosis codes she determines—based on the coder's judgment, training, education, experience, interpretation of the medical record, and applicable coding guidance—are supported by documentation in the medical record. The documentation the MA Plan coder reviews may contain information captured from a single date of service, such as the example in Figure 1 above, or information captured on many dates of service. In the single date of service example in Figure 1, the provider submitted only the diagnosis code for rheumatoid arthritis on the claim, but the MA Plan coder later reviewing the medical record may have added a diagnosis code for diabetes through chart review because diabetes was supported by documentation in the medical record.

17. MA Plans often conduct chart reviews to determine whether additional diagnosis codes not included in the provider's claim are documented in the underlying medical records. These reviews help MA Plans obtain a more complete picture of a patient's health status, which is an important part of a patient's overall care management and helps ensure the coordination of comprehensive patient care.
18. Providers had historically received more training for the documentation of procedures and services under the fee-for-service model, as provider reimbursement was more commonly derived from the procedures providers performed or services providers rendered, rather than derived from a patient's diagnoses and the documentation of diagnoses. In the past, providers did not always submit all of a patient's applicable diagnosis codes on a claim and in fact may have submitted only one diagnosis code on a claim as the basis and support for the services rendered or procedures performed even though other diagnosis codes may have applied for the visit. During their blind reviews, coders conducting MA Plan chart reviews may identify these additional diagnosis codes that are supported by documentation in a patient's medical record but that were not submitted on the claim.

Establishment and Evolution of Diagnosis Coding

19. Diagnosis codes changed in a variety of ways between 2008 and 2016. Most significantly, a new version of diagnosis codes (ICD-10-CM or "ICD-10") was established in October

2015 after the previous version (ICD-9-CM or “ICD-9”) had been in use in the United States since 1979.⁴ There are over 68,000 unique codes in the current ICD-10-CM code set, which uses up to seven alphanumeric characters per diagnosis. There were roughly 13,000 unique codes in the ICD-9-CM code set, which was limited to a five numeric character format.⁵ The transition between ICD-9-CM and ICD-10-CM represented a significant improvement in terms of tracking and analyzing patient care. The larger set of unique diagnosis codes in ICD-10-CM allows for a higher degree of specificity when categorizing a particular diagnosis and can account for additional factors like laterality (right or left side of the body), recurrence, and severity.⁶

Sources of Coding

20. In order to assign diagnosis codes, coders rely on guidance from many sources to review provider documentation and translate the information contained in the medical record into diagnosis codes. Several key resources from professional organizations provide guidance to coders on numerous aspects of coding. These include, but are not limited to, the below examples:

- An official list of diagnosis codes contained within the Tabular List and Alphabetic Index is included in the vast majority of coding reference books with instructions and is annually updated by the National Center for Health Statistics (“NCHS”).⁷
- The Official Guidelines for Coding and Reporting are jointly published on an annual basis by AHA,⁸ AHIMA,⁹ CMS, and NCHS as a “companion document” to the NCHS diagnosis code list.¹⁰

⁴ See CDC, *International Classification of Diseases, (ICD-10-CM/PCS) Transition - Background*, available at https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm.

⁵ See AHIMA, *ICD-10-CM Primer*, available at <https://library.ahima.org/doc?oid=106177>.

⁶ *Id.*

⁷ See, e.g., CDC, *FY 2016 release of ICD-10-CM - ICD-10-CM List of codes and Descriptions*, available at https://www.cdc.gov/nchs/data/icd/icd10cm/2016/ICD10CM_FY2016_code_descriptions.zip.

⁸ American Hospital Association is the national organization that represents and serves all types of hospitals, health care networks, and their patients and communities. See <https://www.aha.org/about>.

⁹ American Health Information Management Association is a global nonprofit association of health information professionals focused on health information management. See <https://www.ahima.org/who-we-are/about-us/>.

¹⁰ See, e.g., CMS, *ICD-10-CM Official Guidelines for Coding and Reporting: FY 2016*, available at <https://www.cms.gov/medicare/coding/icd10/downloads/2016-icd-10-cm-guidelines.pdf>.

- AHA, AHIMA, CMS, and NCHS coordinate to provide a quarterly newsletter referred to as the Coding Clinic, which has provided additional guidance since 1984 on topics that lack clarity in the code instructions or official guidelines.¹¹
- Coders also rely on materials published by CMS for MA Plans, which contain additional coding guidance. This includes feedback provided in connection with CMS's RADV audits of medical records for patients enrolled in MA Plans, the coding sections (Module 6 – Diagnosis Codes & Risk Adjustment, Module 7 – Risk Adjustment Data Validation) of the Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide (“coding sections of the CMS Participant Guide”),¹² and Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance (“RADV Reviewer Guidance”).¹³
- Coders may also rely on a provider's own coding references. It is not uncommon for providers to summarize their own interpretation of the above sources to assist coders with code assignment.

21. These resources, among others, provide coders with guidance on how to interpret documentation in a medical record and how to properly assign diagnosis codes. Even with the multitude of guidance described above, coders often use their own judgment to assign diagnosis codes because the coding guidance may be silent or ambiguous on a specific issue and the guidance alone does not address all areas of ambiguity present in diagnosis coding. And in certain cases, one set of coding guidance may actually conflict with another set of coding guidance. Coders therefore use the available guidance as a framework but ultimately must also rely on their judgment and experience.

¹¹ See Coding Clinic, *What is Coding Clinic for ICD-10-CM and ICD-10-PCS?*, available at <https://www.codingclinicadvisor.com/about-icd-10-coding>.

¹² See CMS, *2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide*, at Module 6 – Diagnosis Codes & Risk Adjustment, Module 7 – Risk Adjustment Data Validation, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012183293-yv-participant-guide-publish_052909.pdf.

¹³ See, e.g., CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019*, (last updated, Nov. 14, 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>.

IV. Opinions

Opinion One: The identification of diagnosis codes supported by documentation in a medical record is a complex process, informed by a variety of coding guidance and dependent on a coder's training, experience, and judgment.

22. In chart review, MA Plan coders review the available medical record documentation and translate the information within it into the applicable diagnosis codes supported by the documentation in the medical record. Provider documentation varies in terms of format, legibility, source of information, length, and complexity, which can impact and potentially complicate a coder's review. Determining which diagnosis codes are supported by documentation in the medical record involves judgment and can be a subjective exercise where coders may not always agree. Different coders may reach different conclusions as to which diagnosis codes are supported by documentation in a given medical record for a variety of reasons, including but not limited to (1) the coder's professional experience and training; (2) availability, legibility, and variability of provider documentation; (3) the interpretation and application of various sources of coding guidance; (4) human error; (5) the transition from ICD-9 to ICD-10 diagnosis code sets; and (6) coding "gray areas."

Coder Certification, Experience, and Training

23. Certified coders have varying levels of experience and training, as well as different coding certifications. For instance, one coder may have years of experience coding certain specific diagnoses, while another coder may have limited experience with those same diagnoses. This is seen often with coders who work in an office with a medical specialist who focuses in one area, such as cardiology. As a result of the provider's specialization, the coder focuses on a relatively small number of conditions. The coder in that specialized practice will have extensive coding experience with the conditions the cardiologist treats but less coding experience with conditions outside of the provider's specialty. The cardiology coder's experience differs from a coder supporting a family medicine practice, who experiences a different and likely broader range of conditions based on the patients the family practitioner treats.

24. Similarly, while some coders focus on coding the services (using procedure codes, for example) performed during the patient visit, and may only give cursory consideration to coding diagnoses, other coders may focus more closely on the documentation of diagnosis

codes. Still, other coders may have roles that require a detailed focus on the coding of both procedures and diagnoses for the same medical chart. The coder's work experience may influence her ability to identify diagnosis codes supported by documentation in a patient's medical record. For example, a coder who is more experienced with procedure codes and less experienced with diagnosis codes may be less effective at identifying all the diagnosis codes supported by the documentation in the medical record than a coder whose career focuses heavily on diagnosis coding.

25. Training, including various certifications coders may receive, also varies from coder to coder. Certain coding certifications are general, such as the Certified Professional Coder (CPC) certification, and include training for multiple types of medical codes like procedure codes and diagnosis codes.¹⁴ Other certifications, such as the Certified Risk Adjustment Coder (CRC) certification, are more specialized and focus only on diagnosis coding, including coding for complicated medical diagnoses like diabetes or depression. The AAPC explains that "Healthcare professionals earning their CRC credential possess demonstrated expertise in the complexity of diseases associated with chronic conditions and comorbidities, as well as mastery of ICD-10-CM guidelines and risk adjustment guidelines."¹⁵ While a coder with a more generalized training background and certification may understand the basics of what is required to generally identify diagnosis codes from within a medical record, that coder may not have the same depth of understanding and experience as a coder who received specific training for identifying diagnosis codes supported by documentation in a medical record. As a result, a coder with more specialized diagnosis code training, such as a coder with a CRC certification, may make different coding determinations than a coder with a more generalized training background.

Availability, Legibility, and Variability of Provider Documentation

26. In addition to varied coder backgrounds, the provider documentation available to coders during chart review varies greatly. MA Plans typically retrieve some of the patient's medical records from providers for review by the MA Plan's coders. This process can involve outreach to multiple providers for specific patients and, in some cases, working

¹⁴ See AAPC, *Certified Professional Coder (CPC)® certification*, available at <https://www.aapc.com/certifications/cpc>.

¹⁵ AAPC, *Certified Risk Adjustment Coder (CRC)® certification*, available at <https://www.aapc.com/certifications/crc>.

with those providers to supply the particular medical records. The medical record documentation retrieved for a given patient may be incomplete, as MA Plan chart reviews are limited to the documentation providers supply. As a result, the medical documentation provided may only contain a portion of the visits the patient had with the provider for a given year or may be missing key pages of the medical record related to the days those visits occurred. For example, scanned medical record documentation may only show the odd-numbered pages (pages 1, 3, 5, etc.) because the original medical record documentation was double-sided, and the provider's office only scanned in one side of the record. As another example, providers may have document retention limitations and store only the last year of records in their office and may store older records at an offsite location. A provider could have difficulty retrieving the offsite records for an MA Plan because they do not have time to go to the offsite location to retrieve the records, lack organization of those records, or find it difficult to identify records for a specific patient. Therefore, a provider's office may provide only what is stored on-site, which may not include information regarding every visit a patient had with the provider in a given year.

27. Additionally, due to the advanced age of patients enrolled in MA Plans, these patients often see multiple providers in a given year. These providers may be at the same location, or they could be spread out across various locations. Each provider may also have a different medical record for the patient. All of these factors make it challenging to collect complete medical records for patients. Even if an MA Plan retrieves multiple medical records for a patient for a given year, the MA Plan still may not have access to all of the patient's medical records, or all pages of a medical record, that may exist for every visit the patient had with a provider in a given year. Due to the large volume of records retrieved and also records reviewed, the MA Plan's coder may not know that documentation is missing or incomplete.
28. The completeness of medical records can influence whether a coder identifies a particular diagnosis code as being appropriately supported by documentation in the medical record. For example, consider a hypothetical case in which a patient visited a primary care physician the morning of May 5, 2016, and was diagnosed with an abnormal pap smear. Upon checkout, the office staff noted the group's oncologist had availability that afternoon to perform a biopsy. The biopsy ultimately confirmed that the patient had cervical cancer. The claim submission for May 5, 2016, would likely contain the diagnosis code for cervical

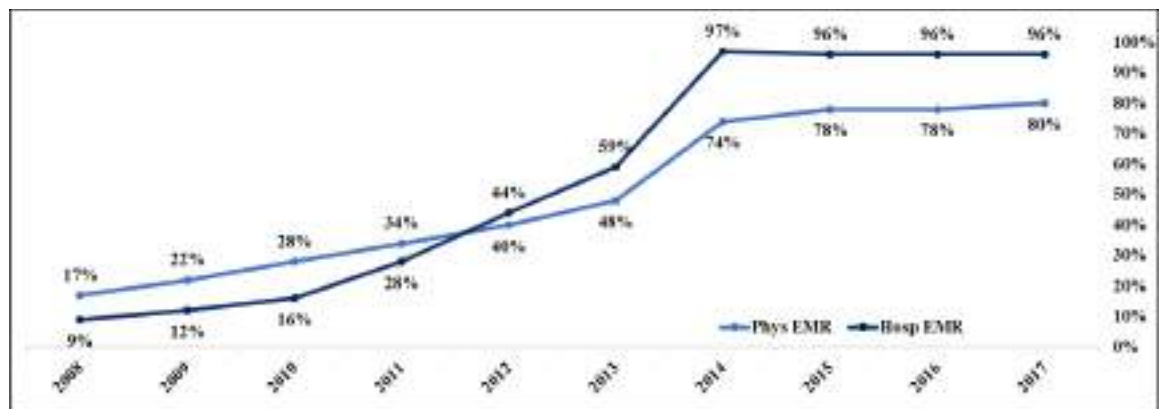
cancer. But when the MA Plan contacted the group to obtain the patient's medical records, the MA Plan got routed to the receptionist in the primary care physician's office to ask for the medical records for the patient's May 5, 2016, visit. The receptionist went into the primary care physician's electronic health record system, printed out the notes from the visit with the primary care physician on the morning of May 5, 2016, and sent those records to the MA Plan. In this example, if an MA Plan coder only had access to the primary care physician's notes in the patient's medical record for the morning of May 5, 2016, the coder likely would not have assigned the cancer diagnosis code because the conclusive pathology report from that afternoon indicating the patient had cancer was not included in what was provided to the MA Plan. Even though another provider diagnosed the patient with cervical cancer, which was documented in her medical records, the MA Plan coder may not have identified that diagnosis code in the course of chart review because the MA Plan coder did not have the full medical record.

29. In addition, the legibility and clarity of the available documentation affect a coder's ability to identify diagnosis codes. For example, a coder who cannot read a provider's handwriting may not identify a diagnosis code during a chart review that is, in fact, properly supported by documentation in the medical record.¹⁶ Some coders may be able to interpret the same provider's handwriting and identify the diagnosis code as supported by documentation in the medical record. A coder working closely with a provider, for example, may develop a familiarity with that provider's handwriting style, shorthand, and abbreviations and can better decipher the provider's handwriting than an MA Plan's coder less familiar with the provider. A coder in the provider's office could have also asked the provider to clarify what was documented in a medical record whereas an MA Plan coder would not have had the same opportunity.
30. The format of a medical record further impacts a coder's ability to assign diagnosis codes. For example, medical records stored only in hard-copy format are more likely to be unavailable or incomplete due to loss, damage, misfiling, or other issues. Electronic medical records ("EMR") may also be unavailable or incomplete. For instance, a patient's

¹⁶ See AAPC, *Medical Record Entries: What Is Timely and Reasonable?* (last updated, Sept. 1, 2013), available at <https://www.aapc.com/blog/25667-medical-record-entries-what-is-timely-and-reasonable>.

providers may use different EMR systems that store her medical records in varied formats. Additionally, providers may fail to update a shared EMR. Obtaining complete medical records for any given patient can be challenging if different portions of the patient's chart exist in hard-copy and electronic format or if a provider uses both hard-copy charts and EMR in a given year. Handwritten records remained common and were used by more than 50% of providers until 2013. As shown in Figure 2 below, less than 20% of physician offices and hospitals utilized EMRs in 2008 but by 2014 the vast majority of physician offices and hospitals utilized EMRs.¹⁷

Figure 2: Electronic Medical Record Transition¹⁸



31. Even after the majority of providers transitioned to EMR by 2014, some continued to use handwritten medical records or a combination of EMR and handwritten records.¹⁹ Even within an EMR, providers sometimes use shorthand or abbreviations without clear or consistent meaning. In a RADV audit, when a coder encounters abbreviations with multiple meanings, CMS instructs: “If more than one meaning applies or documentation is too limited to differentiate, and this is the only diagnosis listed within the record, evaluate on a case-by-case basis. Otherwise, use discretion to report or not based on other circumstances in the record.”²⁰ MA Plan coders do the same case-by-case evaluation and

¹⁷ See HealthIT.gov, *National Trends in Hospital and Physician Adoption of Electronic Health Records*, available at <https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019* at 59, (last updated, Nov. 14, 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>.

- employ their own discretion to conduct a chart review of medical records that contain abbreviations or shorthand. One coder may choose to interpret the shorthand or abbreviation as support for a particular diagnosis code while another may not. In either scenario, RADV guidance supports the coder's choice to consider the shorthand or abbreviation on a case-by-case basis.
32. Varied provider practices for documenting a patient's condition(s) may also impact a coder's ability to determine whether a diagnosis code is supported by documentation in the medical record. Patients enrolled in MA Plans generally see a variety of healthcare providers, including providers from different specialties (e.g., oncologists, cardiologists, and primary care physicians). These providers have different practices and processes for documenting patient health information in the medical record. For example, providers do not consistently document information about a patient's visit in the same location in a medical record. This may be confusing for coders that do not work with a specific provider on a regular basis or with specialists in a particular area. MA Plan coders often lack familiarity with how and where the provider documents conditions. Given all of the different ways providers may document their visits with patients, it can be difficult for an MA Plan coder reviewing documentation from a variety of providers to understand and identify all diagnosis codes potentially supported by documentation in the medical records reviewed.

The Interpretation and Application of Various Sources of Coding Guidance

33. Coders rely on a variety of sources of coding guidance. I have listed various sources of coding guidance above in the background section within. *See supra* at Paragraph 20. This coding guidance comes from nationally recognized organizations, including NCHS, AHA, AHIMA and CMS. The guidance includes annual guidance, such as the Official Guidelines for Coding and Reporting, and quarterly guidance, such as the Coding Clinic. MA Plan coders also need to understand and consider coding guidance published on an ad-hoc basis, including the coding sections of the CMS Participant Guide and RADV Reviewer Guidance, which is specific to diagnosis coding for the CMS Risk Adjustment program.
34. Coders interpret and apply various sources of coding guidance when conducting a chart review. This task is made more complicated by the number of sources of coding guidance,

the complexity and technical nature of the coding guidance, ambiguity or lack of clarity in coding guidance, changes to coding guidance over time, and conflicts in coding guidance. Despite the volume of available coding guidance, not every nuance or subject area of medical record documentation is addressed. Coders will therefore sometimes not identify diagnosis codes that are, in fact, supported by documentation in the medical record. Two coders that review the same medical record could reach different conclusions about whether a diagnosis code is supported by documentation in the medical record because they interpret or apply the coding guidance—or a lack thereof—differently. For example, in the medical record the physician may have written the standard abbreviation of “CRF.” A coder may look up “CRF” in the ICD coding index and find no guidance as to the appropriate code for “CRF.” CRF is a common abbreviation for either chronic renal failure or chronic respiratory failure. One coder may not feel comfortable assigning either of the chronic renal failure or chronic respiratory failure diagnoses based on the abbreviation due to there being more than one possible meaning whereas another coder may assign one of the diagnoses because the coder—based on her experience, training, and judgement—believes it is supported by the documentation in the record.

35. Coding guidance, such as the Coding Clinic referenced above, is effective as of a specified date. For example, updates to the Official Coding Guidelines specify the time period they relate to (e.g., FY 2016 or October 1, 2015-September 30, 2016). When coding charts, including those for MA patients, coders consider the dates of service in the review and identify and utilize the applicable coding guidance relevant to the dates of service in the review. Ultimately, the date of the patient visit will dictate the coding guidance applicable for reviewing a specific record. For example, MA Plan coders reviewing a medical record in 2013 that was created on the date of the patient visit in 2012 should apply the guidance that was effective on the date of service (2012), not the guidance effective on the date of review (2013). Coders may even be tasked with reviewing dates of service spanning multiple years in a single review such as a coder performing a review in 2013 on dates of service from 2010-2012, which means the coder would have to consider and apply different sources for different years while performing the same review.

36. As noted above, coders must consider which sources and versions of guidance should be applied at the relevant time. For example, in the third quarter of 2009, the Coding Clinic

issued guidance to address the use of the common phrase “evidence of” in provider documentation for diagnosis coding. Before this new guidance was issued, coders used their independent judgment to interpret whether the phrase “evidence of” and other context was enough for the coder to determine if a diagnosis was supported by documentation in the medical record. Before the new guidance was issued, if a medical record contained the phrase “evidence of COPD” some coders may have interpreted this as a conclusive statement supporting a diagnosis code for COPD. Other coders may have interpreted that statement to suggest the doctor saw signs of COPD but did not ultimately conclude the patient had COPD and accordingly not coded COPD. However, the third quarter 2009 Coding Clinic’s guidance states that “when the provider documents ‘evidence of’ a particular condition, it is not considered an uncertain diagnosis and should be appropriately coded and reported in the outpatient setting.”²¹ Therefore, after this guidance was issued, if a medical record contained “evidence of COPD,” this was enough for a coder to code COPD even though the medical record did not specifically state that the patient had COPD. If a coder identified the phrase “evidence of” in the medical record, she would consider if the date of the patient’s visit was before the conclusive guidance was issued. This is just one of the many clarifications and changes that have occurred over the past 15 years in the applicable coding guidance references that coders have to take into consideration.

37. In addition, CMS publishes RADV Reviewer Guidance periodically, and sometimes for each calendar year, in connection with its RADV audit process. CMS uses RADV audits to determine if an MA Plan can provide documentation to support the diagnosis codes submitted to CMS in a given year for a sample of beneficiaries. RADV Reviewer Guidance includes a summary of the diagnosis coding guidelines for the MA program. The RADV Reviewer Guidance also provides topics, examples, and guidance based on CMS’s review of RADV audit samples and notes “medical records can be unique in format, legibility, content, organization, etc.” and “the guidance and examples are not exhaustive in content,” and therefore “documentation issues will be considered on a case-by-case basis.”²²

²¹ AHA, Coding Clinic for ICD-9-CM, Volume 26, Number 3, Third Quarter, 2009 at 7.

²² CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019* at 7, (last updated, Nov. 14, 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>.

- Similarly, the RADV Reviewer Guidance itself notes that it is merely a resource and other sources must be considered.²³
38. Once CMS completes the RADV audit process for a given year, CMS provides audit results to MA Plans that were subject to the audit. These RADV audit results help demonstrate the RADV coding auditors' interpretations of industry guidance, such as Coding Clinic guidance or the application of RADV Reviewer Guidance. While the RADV Reviewer Guidance only formally applies to the coders CMS engages to perform RADV audits on behalf of CMS, industry participants (including providers, plans, and their coders) look to RADV Reviewer Guidance—and the results of RADV audits—as a source of interpretation and application of coding guidelines. The results showing diagnoses the RADV coding auditors determine are supported in specific scenarios provide further coding guidance for MA Plan coders in similar situations in their own reviews.
39. For example, the RADV Reviewer Guidance states that reviewers may encounter a Consultation Report, which is a report prepared by a consulting physician to assist with a patient's care. The coding guidance specifies that if the consultation report contains an unconfirmed diagnosis and the diagnosis is not ruled out elsewhere, but also is not mentioned in the final discharge diagnosis, a decision to support the diagnosis should be made on a case-by-case basis.²⁴ Similarly, when discussing a RADV coding auditor's evaluation of diagnostic testing documentation, the guidance states that "the reviewer must use judgment based on the type of procedure/test or other documentation available when determining if a chief complaint or reason for a test is a current diagnosis or was a condition to be ruled out."²⁵
40. In addition to official coding guidance and CMS RADV guidance (such as the RADV Reviewer Guidance and the RADV audit results), the coding industry has also developed a variety of criteria for coders to use to identify diagnosis codes supported by documentation in a medical record. One common set of coding criteria is referred to as "MEAT" where the provider documentation must sufficiently show that a diagnosis is

²³ *Id.* (providing on each of the 72 pages that the RADV Reviewer Guidance contains general guidance that is not exclusive).

²⁴ *Id.* at 22.

²⁵ *Id.* at 34.

monitored/managed, evaluated, assessed and/or treated in order for a diagnosis code to be assigned.²⁶ For example, a provider can demonstrate evaluation (an element of MEAT) of Type 2 Diabetes by documenting “A1c results reviewed and discussed with patient” in the medical record. The adoption of the MEAT criteria, in the early 2010s, coincides with guidance from CMS available at the time to describe supporting documentation, but CMS has never officially defined, required, or codified the MEAT coding standard. As a result, one medical coder may follow the MEAT standard while others may follow a different coding standard. Providers may also determine how many elements of MEAT are necessary to support the diagnosis code and this varies across practices. Similarly, MA Plans may differ on how to implement the MEAT criteria when performing the chart reviews because CMS does not require MEAT. Some coders look for multiple elements of MEAT before assigning a diagnosis code, while other coders look for only one element. For example, one coder may have found a notation of “Type 2 Diabetes on Metformin,” which demonstrated one element of MEAT, and coded the condition. Another coder may have found that notation insufficient to support the diagnosis code because it related to only one element of MEAT rather than multiple. The lack of consensus on the use of MEAT among coders may result in coders reaching different conclusions about whether a condition is properly supported by documentation in a medical record.

41. General diagnosis coding guidance, results of CMS RADV audits, and ever-evolving industry guidance are all important sources of information for coders to consider. The available guidance changed (and continues to change) as diagnosis codes are published. Additionally, in certain instances, the available coding guidance lacks clarity, which makes it challenging for chart review coders to interpret and apply the available coding guidance in a similar manner. Even when guidance is available, coders may still have questions about what diagnosis codes are supported based on what information is documented in the medical record. In response to a series of questions posed by MA Plans, CMS recognized this complexity and the individualized nature of diagnosis code assignment and noted it is “unable to respond specifically to individual questions regarding risk adjustment requests for interpretation of RADV coding and reporting questions as a full review of the

²⁶ See AHIMA, *Cut Through the ICD-10 Noise with Documentation Guidelines*, (last updated Jan. 2015), available at <https://bok.ahima.org/doc?oid=300844>.

documentation is required before reporting or coding any diagnosis. For the purposes of risk adjustment data validation, all review is considered on a case by case basis due to multiple coding rules that may apply.”²⁷ The necessary interpretation of the changing guidance from various sources can lead coders to apply the guidance differently and ultimately find different diagnosis codes supported in medical records.

Human Errors

42. Coders also reach different conclusions as to which diagnosis codes are supported in a medical record because of human error. Coders review large volumes of technical medical documentation from a variety of sources and apply their judgment to determine which conditions are supported by documentation in a medical record. This may include reviewing information in varied formats with challenging handwriting and unique, unfamiliar abbreviations. This may also include long days reviewing medical records, some of which can be very complicated and hundreds of pages long. For example, records for multi-day stays in a hospital or emergency department, where the providers must detail every checkpoint, result, and decision, can be 75-100 pages long for each encounter. Medicare beneficiaries tend to have particularly voluminous records, as it is not uncommon for them to have multiple acute and chronic conditions. Based on a 2010 study, 36.4% of Medicare beneficiaries had four or more chronic conditions.²⁸ All of this can lead coders to experience fatigue while reviewing medical records, which can result in mistakes, including missed diagnosis codes.

43. Coders also sometimes mistype the diagnosis code at issue. For instance, coders might accidentally type in a similar, yet different, code than the one intended. For example, ICD-9-CM 402.01 (hypertensive heart disease, malignant, with heart failure) is a high-severity code, and ICD-9-CM 402.10 (hypertensive heart disease, benign, without heart failure) is

²⁷ CMS, *Question and Answer Session – CY 2011 RADV Industry Training* at 2 (last updated, March 20, 2014), available at <https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvtrainingquestions.pdf>.

²⁸ *See* Kimberly Lochner & Christine Cox, *Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010* (last updated Apr., 25, 2013), available at https://www.cdc.gov/pcd/issues/2013/12_0137.htm.

a less severe code,²⁹ but the codes are almost the same. This typographical error, while simple, is not uncommon.

44. Organizations that administer coder guidelines and training acknowledge that coders cannot be expected to be correct 100% of the time. AHIMA notes that a minimum of 95% (not 100%) is best practice for coding quality standards.³⁰ CMS historically has also targeted an 85-95% consistency standard for its Inter-Rater Reliability (IRR) quality control measures used in audit activities of non-MA Plan data.³¹ Furthermore, actual error rates may be higher than these numbers suggest, as these targets and thresholds do not guarantee that those levels are actually achieved.

Transition from ICD-9-CM to ICD-10-CM Code Sets

45. While providers had used the ICD-9 diagnosis code set since 1979, CMS mandated that providers exclusively use the ICD-10 diagnosis code set beginning in October 2015. This increased the total number of diagnosis codes fivefold and created a substantial number of new diagnosis codes that providers and coders needed to consider when reviewing medical records. Requiring this change midyear added more confusion for coders reviewing a medical record with patient visits in 2015.
46. Due to the transition from ICD-9 to ICD-10, coders performing a chart review for patient visits in 2015 had to consider whether the date of service was before or after October 1, 2015. If the date of service was before October 1, 2015, the coder had to use ICD-9 diagnosis codes. If the date of service was on or after October 1, 2015, the coder had to use ICD-10 diagnosis codes. This added layer of complexity could lead to coders missing diagnosis codes that were supported by documentation in the medical record.
47. As noted previously, the diagnosis code sets vary greatly in form and structure. Given that ICD-10 added tens of thousands of additional unique diagnosis codes, the code sets cannot be compared in a one-to-one manner. For example, a provider may have diagnosed a patient experiencing severe neck pain after a fall with a broken neck (first cervical vertebra). The

²⁹ See CDC, *ICD-9-CM Index to Diseases (FY12)*, at Dindex12.zip, available at https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/.

³⁰ See AHIMA, *Benchmarking Coding Quality – Audio Seminar/Webinar* (2008).

³¹ See 45 CFR § 153.630(b)(8).

relevant diagnosis would be a fracture of the first cervical vertebra. While there is one code for this diagnosis in ICD-9, there are ten possible diagnosis codes under ICD-10. If this diagnosis occurred on or after October 1, 2015, a coder was tasked with determining which specific ICD-10 diagnosis code, from the choice of ten, applied based on the type and severity of the broken neck. Figure 3 below shows the one ICD-9 code related to a fracture of the first cervical vertebra, along with the corresponding ten possible ICD-10 codes. Providers would also have to learn how to document with the level of detail and specificity that aligned with and would support the new ICD-10 codes.

Figure 3: ICD-9-CM to ICD-10-CM Translation ³²

Fracture of First Cervical Vertebra (Broken Neck)			
ICD-9-CM		ICD-10-CM	
Code	Code	Code	Code Description
805.01	Closed fracture of first cervical vertebra	S12.000A	Unspecified displaced fracture of first cervical vertebra, initial encounter for closed fracture
		S12.001A	Unspecified nondisplaced fracture of first cervical vertebra, initial encounter for closed fracture
		S12.01XA	Stable burst fracture of first cervical vertebra, initial encounter for closed fracture
		S12.02XA	Unstable burst fracture of first cervical vertebra, initial encounter for closed fracture
		S12.030A	Displaced posterior arch fracture of first cervical vertebra, initial encounter for closed fracture
		S12.031A	Nondisplaced posterior arch fracture of first cervical vertebra, initial encounter for closed fracture
		S12.040A	Displaced lateral mass fracture of first cervical vertebra, initial encounter for closed fracture
		S12.041A	Nondisplaced lateral mass fracture of first cervical vertebra, initial encounter for closed fracture
		S12.090A	Other displaced fracture of first cervical vertebra, initial encounter for closed fracture
		S12.091A	Other nondisplaced fracture of first cervical vertebra, initial encounter for closed fracture

Gray Areas of Diagnosis Coding

48. There are several additional areas in which coding involves a degree of subjectivity (often called “gray areas”), because they are open for interpretation and debated among medical coders and even the organizations that offer diagnosis coding guidance. There is

³² See CDC, *ICD-9-CM Index to Diseases (FY12)*, at Dindex12.zip, available at https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/ and CDC, *FY 2016 release of ICD-10-CM - ICD-10-CM List of codes and Descriptions*, available at https://www.cdc.gov/nchs/data/icd/icd10cm/2016/ICD10CM_FY2016_code_descriptions.zip.

voluminous discussion and debate about these gray areas within the healthcare industry, and coders and applicable organizations like AHIMA or CMS frequently cannot agree on how to handle these topics. Since coders and the industry may have differing views on how to approach these gray areas, and because the guidance may be unclear or confusing, there is no uniform way for coders to resolve gray areas. Importantly, MA Plan coders performing a blind chart review may approach coding gray areas differently based on their knowledge and experience which may differ from that of the provider or coder in the provider's office that submitted diagnosis codes on the claim, which can cause discrepancies between the diagnosis codes identified by both.

49. When coders encounter gray areas, they may devote significant time and attention to try to resolve these gray areas and determine if a diagnosis code is properly supported by documentation in the medical record. This may result in a coder missing other diagnosis codes that may in fact be supported by documentation in the medical record. For example, a coder may spend a significant amount of time reviewing the medical record for a particular condition to try to identify whether there are enough details in the medical record to support that the condition is current and can be coded. The MA Plan coder may miss other properly supported diagnoses in the medical record because they are focused on assessing these gray areas that lack clarity or consistency in coding guidance.
50. Some of the most common gray areas that can cause coding discrepancies are the appropriate handling of "problem lists" and "chronic conditions," which are discussed in more detail below. The overarching concern is that most diagnosis coding guidelines require, among other things, that a condition be present or current on the date the patient visits their provider for a diagnosis code to be supported by documentation in the medical record. However, uniform and consistent handling of these gray areas adds complexity to the review of documentation to assess if a diagnosis code is supported. While regulators and the healthcare industry recognize this and attempt to clarify gray areas, disagreements remained unresolved for long periods of time in many cases and some remain unresolved today, rendering it difficult for coders to consistently approach these areas.

Gray Areas of Diagnosis Coding - Problem Lists

51. Providers use many different parts of a patient's medical record to keep track of a patient's history and current visit. Problem lists are a running list or database of the patient's diagnoses and are one part of a medical record that a provider may use to maintain information about a patient. This list may be on a sheet of paper within the patient's physical record or in a specific area in the EMR.
52. Problem lists have historically caused confusion because CMS guidance regarding problem lists varied over time. In 2008, CMS stated, "an acceptable problem list must be comprehensive and show evaluation and treatment for each condition that relates to an ICD-9 code on the date of service, and it must be signed and dated by the physician or physician extender."³³ This guidance defines the problem list as a portion of the medical record capturing only those conditions that are treated on a specific date of service. Under this definition, a coder can often rely on a signed and dated problem list to identify supported diagnosis codes because it includes a list of a patient's diagnoses current at the time of the visit diagnoses.
53. EMRs introduced further ambiguity and a lack of clarity regarding when the conditions listed in a problem list should be coded or not. In 2019, CMS issued guidance that applied retroactively to audits commencing after September 27, 2017 and covered dates of service going back as far as 2013. The guidance stated, "[p]roblem lists are evaluated on a case-by-case basis when the problem list is not clearly dated as part of the face-to-face encounter indicated on the coversheet, or there are multiple dates of conditions both before and after the DOS."³⁴ In other words, CMS acknowledged the fact that problem lists may or may not relate to a given date of service, so the guidance left it to the discretion of individual coders to determine whether a problem list included sufficient details regarding what diagnoses were current. The change in guidance, as well as the lack of additional guidance

³³ CMS, *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide* at Section 7.2.4.3., available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012183293-yv-participant-guide-publish_052909.pdf.

³⁴ CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019* at 42, (last updated, Nov. 14, 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>.

clarifying how individual coders should exercise their discretion on a case-by-case basis, makes it difficult for coders to use problem lists uniformly.

Gray Areas of Diagnosis Coding – Chronic Conditions

54. Chronic conditions have historically been another coding gray area and a source of debate and discrepancies. “Chronic conditions” are generally defined as conditions that are ongoing, last an extended period of time (sometimes defined as a year or more), and either require continuous medical maintenance or routinely limit daily activities. Examples of chronic conditions include heart disease, cancer, and diabetes.³⁵ A patient might not have discussed her chronic condition at each visit she had with a provider. This did not mean the patient no longer had that medical condition. The provider might in fact have taken the chronic condition into account when considering treatment for other conditions addressed at a patient visit and might have included documentation supporting chronic condition diagnoses. Coders may disagree, however, as to whether a provider has adequately documented a particular chronic condition in the medical record. Providers may take varying amounts of time to document each chronic condition assessed as part of a visit, which can lead to varying judgment calls for coders reviewing medical records.

55. Furthermore, the coding guidance varies depending on the care setting. In the inpatient setting, guidance published by the Coding Clinic notes that chronic systemic diseases should generally be coded even in the absence of documented intervention or further evaluation at the time of care.³⁶ In other words, MEAT, or a similar coding standard, is not required to support diagnosis codes in the inpatient setting for these diseases. The official ICD guidance for outpatient services, on the other hand, instructs coders to code chronic diseases “as many times as the patient receives treatment and care for the condition(s)” but also specifies that coders should “code all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management.”³⁷

³⁵ See CDC, *About Chronic Diseases*, available at <https://www.cdc.gov/chronicdisease/about/index.htm#:~:text=Chronic%20diseases%20are%20defined%20broadly,disability%20in%20the%20United%20States>.

³⁶ See AHA, Coding Clinic for ICD-9-CM, Volume 24, Number 3, Third Quarter, 2007 at 13-14.

³⁷ CMS, *ICD-9-CM Official Guidelines for Coding and Reporting: FY 2011*, available at https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf.

Setting aside the fact that coders may be unsure how to interpret the two pieces of outpatient guidance in tandem, the Coding Clinic and official ICD guidance on chronic conditions differ. Certain coders may find that a record that simply lists the diagnoses is sufficient to support a code, based on the Coding Clinic Guidance, while an MA Plan coder may find that record insufficient by mistakenly applying the additional requirements included in the outpatient guidelines to an inpatient record.

Opinion Two: During blind chart reviews, if a coder does not identify a diagnosis code that a healthcare provider submitted on a claim to the MA Plan, that code may still be supported by documentation in the patient's medical record.

56. Due to the many complexities detailed above, an MA Plan coder conducting a blind chart review may not identify diagnosis codes that a provider submitted on the claim that are in fact supported by documentation in the medical record.
57. As an initial matter, for all of the reasons discussed above, an MA Plan coder may fail to identify a properly supported diagnosis code due to differences in coder experience, the limited availability or quality of provider documentation, the wide variety of available guidance subject to individual interpretation and judgment, the potential for human error, and changes in diagnosis code sets. It is therefore possible that a provider or a coder in the provider's office will identify a properly supported diagnosis code that an MA Plan chart review coder will not identify during their blind chart review. Simply because the MA Plan coder does not identify the same diagnosis code during a blind chart review does not mean the code is not supported by documentation in the medical record.
58. A coder in the provider's office may be better situated to identify many properly supported diagnosis codes. For instance, coders in a provider's office may have access to a more complete set of the patient's medical records than an MA Plan coder. They are also more familiar with the provider and the provider's specialty and more likely to be able to interpret a provider's handwriting, abbreviations, or other documentation practices or be able to ask the provider to clarify what is documented in the record. All of these factors can lead to additional diagnosis codes submitted on a claim than those an MA Plan coder identifies in a blind chart review.

59. To give an example, the hypothetical condensed medical record shown in Figure 4 had no date specifically assigned to the problem list. The coder responsible for reviewing the medical record in the provider's office might have reviewed the record and found support in documentation outside the problem list for all conditions on the problem list except for respiratory failure. That coder might have included a diagnosis code for respiratory failure on the claim because the updated language about "fitting for nasal cannula scheduled" associated with respiratory failure was added to the record on the date of service, which means that respiratory failure was, in fact, a current condition for this patient, even if respiratory failure was only included in the problem list section of the medical record. At a later date, an MA Plan coder was asked to do a blind review on the same medical record. The MA Plan coder might have determined that because there is no date on the problem list and the information within it, they are unable to support the coding of respiratory failure during their review. In this case, a MA Plan coder did not code for respiratory failure during a chart review, while the original coder properly included it as a diagnosis code on the claim.

Figure 4: Supported Diagnoses – Only Noted in Problem List

- **Jane Smith, MD – 1/1/2016**
- **John Doe (1/1/1948)**
- **Chief Complaint:** Annual Wellness Visit
- **History of Present Illness:** Patient last seen during semi-annual visit
- **Medication:** Aspirin, Coumadin (1/1/2016)
- **Medical History/Problem List:** Depression, DVT right leg, High blood pressure, Respiratory Failure – has fitting for nasal cannula scheduled
- **Exam:** Well-nourished, well-developed male, right leg swelling decreased
- **Assessment/Plan:** Renew medications, HTN - stable, Depression - stable, DVT resolving

60. Another example where an MA Plan coder may fail to identify a diagnosis that is supported by the medical record is when a diagnosis is not explicitly linked to the management of that diagnosis in the provider documentation. For instance, the hypothetical medical record in Figure 5 included COPD on the patient's problem list. The chart also documented that the provider renewed the medication Albuterol, a medication used to treat COPD, but did not explicitly mention COPD otherwise in the note. The claim may have contained the diagnosis code for COPD given the renewal of the medication, whereas an MA Plan chart review coder may not have coded the diagnosis since the provider did not explicitly document the language "COPD" outside of the problem list or in relation to the Albuterol

renewal. While the Albuterol was not specifically linked to a COPD diagnosis in the chart, COPD was the only past condition that would require this medication, and the orders noted that Albuterol was being renewed, indicating the COPD was still current. A coder at the provider's office may have drawn this linkage and been comfortable including this diagnosis code on the claim given the "case-by-case" guidance around problem lists.

Figure 5: Supported Diagnoses – Diagnosis Not Linked to Medication

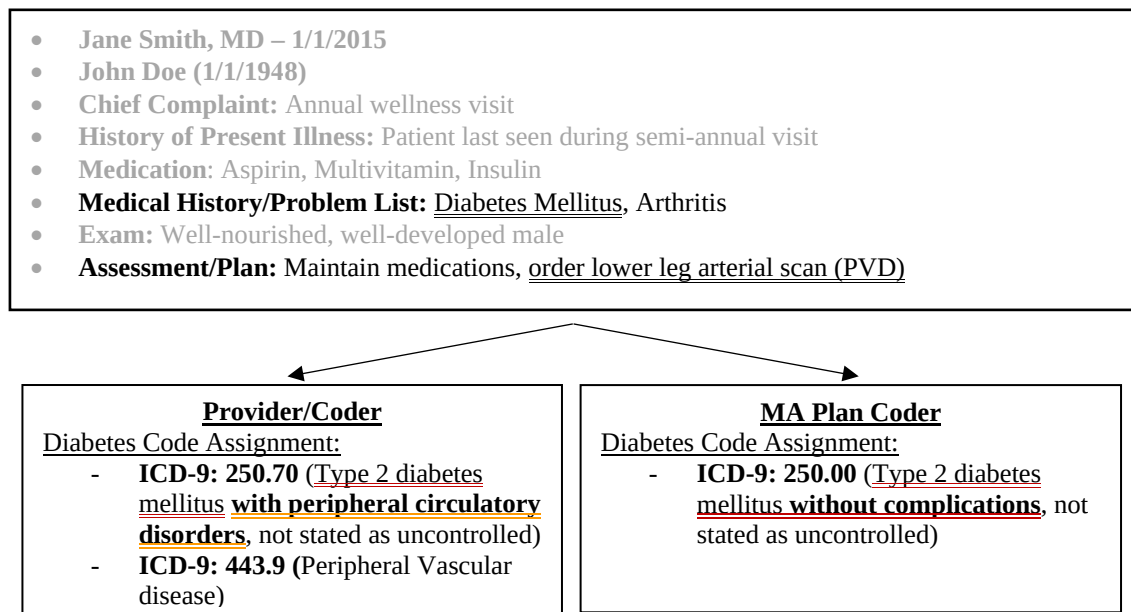
- Jane Smith, MD – 1/1/2018
- John Doe (1/1/1948)
- **Chief Complaint:** High blood pressure
- **History of Present Illness:** Persistent headache, coinciding with elevated blood pressure
- **Medication:** Lisinopril, Albuterol
- **Medical History/Problem List:** COPD, High Blood Pressure
- **Exam:** Well-nourished, well-developed male
- **Assessment/Plan:** Increase dosage of Lisinopril
- **Orders:** Change dose of Lisinopril to 10mg and renew Albuterol

61. Further, an MA Plan coder may fail to identify a specific diagnosis code related to a diabetic complication. There are a wide range of diagnosis codes associated with diabetes, which can cause discrepancies. Depending on the diabetes diagnosis code selected, the diagnosis code may correspond to different risk adjustment categories that range in severity (e.g., Diabetes with Acute Complications, Diabetes with Chronic Complications, and Diabetes without Complications). An MA Plan coder may see diabetes supported by the medical record but assume the diabetes does not have complications because the record does not include an additional diagnosis for the complication. The coder, on the other hand, may have more intimate knowledge of the patient's current diagnoses and can identify a diabetes diagnosis with complications. For instance, if the provider or coding personnel at the provider's office reviewed the record and noted an order for an arterial scan of the lower legs, which subsequently showed a diagnosis of peripheral artery disease, then they might have coded diabetes with complications. Guidance from the Coding Clinic, the coding index for ICD-10, and RADV Reviewer Guidance has differed over time on whether the linkage between diabetes and the complication can be assumed.³⁸ As demonstrated in

³⁸ Coding Clinic advice prior to Q2 2009 instructed coders to not assume a causal relationship between diabetes and certain manifestations as the physician should establish the relationship with terms such as "due to diabetes". After that, Coding Clinic noted that the language "with" was sufficient to demonstrate the diabetes was due to or associated with the other condition. Finally, in RADV Reviewer Guidance, it notes diabetes should be listed on the same line as the condition to consider it linked. See AHA, Coding Clinic for ICD-9-CM, Second

Figure 6 below, the provider or coder assigning the diagnosis code on the claim may have assumed the linkage and included the diagnosis code for the complication, whereas an MA Plan coder might not have assigned a secondary code because they lacked the scan. An MA Plan coder might also not have assigned the secondary code because they might have used guidance that suggested there must be explicit linkage in order to code the secondary code.

Figure 6: Supported Diagnoses – Diabetes Specification



62. These examples illustrate where an MA Plan coder may not identify a diagnosis code during the chart review that is in fact supported by documentation in the chart. The inclusion of this diagnosis code on the claim submitted to the MA Plan may in fact be appropriate because the provider or coder in the provider's office believed it was supported, whether because of experience with documentation related to a specific condition, access to additional medical records or information, a reliance on specific guidance, or any of the other reasons discussed above.

Quarter, 2009 and CMS, *Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019* at 42, (last updated, Nov. 14, 2018), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>.

V. Conclusion

63. This report presents a summary of my work and opinions to date.

VI. Exhibits

Exhibit A – Curriculum Vitae

Exhibit B – Documents Relied Upon



Exhibit A

BARBARA BLAIR

ACADEMIC BACKGROUND:

University of Rochester	M.S.N.	1992
University of Rochester	B.S.N.	1991
Rockland Community College	A.S.	1986

CERTIFICATIONS AND LICENSES:

Certified Coding Specialist (CCS) - 2000

Certified Professional Coder (CPC) - 2004

Certified Professional Compliance Officer (CPCO) - 2013

Certified Risk Adjustment Coder (CRC) - 2016

Certificate of Completion for Certified Documentation Expert Inpatient (CDEI) - 2022

AHIMA Certified ICD-10-CM/PCS Trainer - 2013

Licensed Registered Nurse

Licensed Nurse Practitioner (Adult) - Retired

PROFESSIONAL AFFILIATIONS:

American Academy of Professional Coders (AAPC)

American Health Information Management Association (AHIMA)

American Association of Adult Nurse Practitioners (AANP)

EMPLOYMENT:

2003 – Present:	FTI Consulting, Inc., Senior Director (current position),
2000 – 2003:	KPMG LLP, Manager
1998 – 2000:	Orion Consulting Inc., Manager

1997 – 1998: Successful Solutions Inc., Manager

1995 – 1997: Hyatt, Imler, Ott & Blount LLP, Associate

SELECT PROFESSIONAL EXPERIENCE:

- Independent Review Organization (IRO): Lead reviewer on over a dozen reviews multi-year reviews for providers such as health systems, hospitals and medical centers, operating under Corporate Integrity Agreements with the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) for over 20 years.
- Risk Adjustment Data Validation (RADV) Audits: Lead reviewer on responses to RADV audits conducted by the Department of Health and Human Services (HHS) for over a decade. Assisted Medicare Advantage and commercial health plans and health systems with responses to Centers for Medicare & Medicaid Services (CMS) RADV audits, HHS audits and other RADV-like audit requests. The dates of service reviewed and analyzed spanned from 2007 through current. Frequently served in the capacity of a second level and quality control reviewer on large coding teams.
- Coding Reviews: Over the past 20 years, I have performed coding and clinical reviews to provide expertise and guidance for many different types of work. I have advised on corrective action and coding best practices based on the findings of reviews. These reviews included, but are not limited to the following:
 - o Department of Justice (DOJ) investigations
 - o Governmental response to contractor audits conducted by entities such as Recovery Audit Contractors, Medicare Administrative Contractors, Zone Program Integrity Contractors, Medicaid Integrity Contractors, etc.
 - o Disputes between payers and providers
 - o Due diligence for potential acquisitions
 - o Support of general compliance initiatives such as work plans, internal audits and focused reviews

EXPERT TESTIMONY IN PAST FOUR YEARS

N/A

PRESENTATIONS AND PUBLICATIONS – IN THE LAST TEN YEARS

N/A

CONTACT INFORMATION:

Barbara Blair, Senior Director at FTI Consulting, Inc.
(561) 866-1667 - barbara.blair@fticonsulting.com



Exhibit B

Public Sources

- Fact Sheet: Introduction to Medicare (<https://www.cms.gov/outreach-and-education/find-your-provider-type/employers-and-unions/fs1-intro-to-medicare.pdf>)
- Your Health Plan Options (<https://www.medicare.gov/health-drug-plans/health-plans/your-health-plan-options>)
- International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) (<https://www.cdc.gov/nchs/icd/icd-10-cm.htm>)
- International Classification of Diseases, (ICD-10-CM/PCS) Transition – Background (https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm)
- ICD-10-CM Primer (<https://library.ahima.org/doc?oid=106177>)
- FY 2016 release of ICD-10-CM: ICD-10-CM List of Codes and Descriptions (https://www.cdc.gov/nchs/data/icd/icd10cm/2016/ICD10CM_FY2016_code_descriptions.zip)
- ICD-9-CM Index to Diseases (FY12) (https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/)
- About the AHA (<https://www.aha.org/about>)
- Who We Are (<https://www.ahima.org/who-we-are/about-us/>)
- ICD-10-CM Official Guidelines for Coding and Reporting: FY 2016 (<https://www.cms.gov/medicare/coding/icd10/downloads/2016-icd-10-cm-guidelines.pdf>)
- ICD-9-CM Official Guidelines for Coding and Reporting: FY 2011 (https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf)
- What is Coding Clinic for ICD-10-CM and ICD-10-PCS? (<https://www.codingclinicadvisor.com/about-icd-10-coding>)
- Certified Professional Coder (CPC)® certification (<https://www.aapc.com/certifications/cpc>)
- Certified Risk Adjustment Coder (CRC)® certification (<https://www.aapc.com/certifications/crc>)
- Medical Record Entries: What Is Timely and Reasonable? (<https://www.aapc.com/blog/25667-medical-record-entries-what-is-timely-and-reasonable>)

EXHIBIT B

- National Trends in Hospital and Physician Adoption of Electronic Health Records (<https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records>)
- Cut Through the ICD-10 Noise with Documentation Guidelines (<https://bok.ahima.org/doc?oid=300844>)
- Question and Answer Session - CY 2011 RADV Industry Training (<https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvtrainingquestions.pdf>)
- About Chronic diseases (<https://www.cdc.gov/chronicdisease/about/index.htm>)
- Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010 (https://www.cdc.gov/pcd/issues/2013/12_0137.htm)
- 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide (https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012183293-yv-participant-guide-publish_052909.pdf)
- Contract-Level Risk Adjustment Data Validation Medical Record Reviewer Guidance In effect as of 03/20/2019. (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/Medical-Record-Reviewer-Guidance.pdf>)
- 45 CFR § 153.630(b)(8).

Other References

- Coding Clinic for ICD-9-CM, Volume 26, Number 3, Third Quarter, 2009
- Coding Clinic for ICD-9-CM, Volume 24, Number 3, Third Quarter, 2007
- Coding Clinic for ICD-9-CM, Second Quarter, 2009
- AHIMA, Benchmarking Coding Quality – Audio Seminar/Webinar (2008)

EXHIBIT D-55 INTENTIONALLY BLANK

EXHIBIT D-56

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,
Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et al.*
Defendants

No. CV 16-08697 MWF (SSx)

Expert Report of Mark Duggan, PhD

September 29, 2023

CONFIDENTIAL

**(Specific pages also designated Attorneys' Eyes Only
& Outside Counsel Only)**

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I. Qualifications

1. I am the Wayne and Jodi Cooperman Professor of Economics at Stanford University and the Trione Director of the Stanford Institute for Economic Policy Research. I received my B.S. and M.S. degrees in Electrical Engineering from the Massachusetts Institute of Technology in 1992 and 1994, respectively, and my Ph.D. in Economics from Harvard University in 1999. From 2009 to 2010, I served as the Senior Economist for Health Care Policy on the Council of Economic Advisers to the Executive Office of the President. I have previously served as a visiting or regular faculty member at the Wharton School of the University of Pennsylvania, the University of Maryland, the University of Chicago, and the Massachusetts Institute of Technology.

2. I am an expert in health economics. My research focuses on the effects of government programs such as Medicare, Medicaid, and Social Security on individuals and firms. I have studied diverse topics such as pharmaceutical pricing and utilization under the Medicare Part D and Medicaid programs,¹ the effectiveness of Medicare prescription drug coverage for seniors,² reimbursement issues in Medicare Advantage,³ and health insurance industry dynamics.⁴ My research has been published in leading economics journals, including the *American Economic Review*, the *Journal of Political Economy*, and the *Quarterly Journal of Economics*. I serve on

¹ Mark Duggan and Fiona Scott Morton, “The Distortionary Effects of Government Procurement: Evidence for Medicaid Prescription Drug Purchasing,” *Quarterly Journal of Economics*, 121(1), 2006, pp. 1–30; Mark Duggan and Fiona Scott Morton, “The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,” *American Economic Review*, 100(1), 2010, pp. 590–607; Mark Duggan and Fiona Scott Morton, “The Medium-Term Impact of Medicare Part D on Pharmaceutical Prices,” *American Economic Review*, 101(3), 2011, pp. 387–392; Abby Alpert, et al., “Perverse Reverse Price Competition: Average Wholesale Prices and Medicaid Pharmaceutical Spending,” *Journal of Public Economics*, 108, 2013, pp. 42–62.

² Mark Duggan, et al., “Providing Prescription Drug Coverage to the Elderly: America’s Experiment with Medicare Part D,” *Journal of Economic Perspectives*, 22(4), 2008, pp. 69–92.

³ Jason Brown, et al., “How Does Risk Selection Respond to Risk Adjustment? Evidence from the Medicare Advantage Program,” *American Economic Review*, 104(10), 2014 (“Brown et al., How Does Risk Selection Respond to Risk Adjustment”), pp. 3335–3364; Mark Duggan, et al., “Who Benefits when the Government Pays More? Pass-through in the Medicare Advantage Program,” *Journal of Public Economics*, 141, 2016 (“Duggan et al., Who Benefits when the Government Pays More”), pp. 50–67.

⁴ Leemore Dafny, et al., “Paying a Premium on Your Premium? Consolidation in the Health Insurance Industry,” *American Economic Review*, 102(2), 2012, pp. 1161–1185; Mark Duggan, et al., “The Consequences of Health Care Privatization: Evidence from Medicare Advantage Exits,” *American Economic Journal: Economic Policy*, 10(1), 2018 (“Duggan et al., The Consequences of Health Care Privatization”), pp. 153–186; Hui Ding, et al., “Getting the Price Right? The Impact of Competitive Bidding in the Medicare Program,” forthcoming at *Review of Economics and Statistics*.

the editorial board of the Journal of Policy Analysis and Management and previously served as a Co-Editor for the American Economic Journal: Economic Policy and for the Journal of Public Economics. I have also taught courses on health economics, public economics, and econometrics at the undergraduate and graduate levels and received the Stanford University Economics Department Distinguished Faculty Teaching Award in 2022. I received the 2010 ASHEcon Medal from the American Society of Health Economists, awarded once every two years to the leading health economist in the United States under the age of forty.

3. I have received several research grants from the Social Security Administration, National Science Foundation, other federal agencies, and private foundations to support my research. I am frequently invited to present my work at professional conferences and invited seminars. I have testified to Congress about my research on three occasions. My curriculum vitae, including a list of my prior testimony from the past four years and my published works, is attached as **Appendix A**.

4. For my work on this matter, I am being compensated at my standard billing rate of \$1,000 per hour. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. I receive compensation from Cornerstone Research based on its collected staff billings for its support of me in this matter. Neither my compensation in this matter nor my compensation from Cornerstone Research is in any way contingent or based on the content of my opinions or the outcome of this or any other matter.

II. Case Background and Summary of Allegations

5. UnitedHealth Group Incorporated (“UnitedHealth”) is a health care company with diversified businesses that fall under two platforms: health benefits and health services. The health benefits platform, UnitedHealthcare, provides health insurance. The health services platform, Optum, offers pharmacy, health care financial, and other services.⁵

6. UnitedHealth serves different customers and markets, such as employers and individual consumers through UnitedHealth Employer & Individual, and retirees and Medicare beneficiaries through UnitedHealth Medicare & Retirement. UnitedHealth Medicare &

⁵ UnitedHealth Group Incorporated, SEC Form 10-K for period ended December 31, 2021, filed on February 15, 2022 (“UnitedHealth 2021 Form 10-K”), pp. 1–2.

Retirement offers different products, including Medicare Advantage (“MA”) plans and Medicare Part D plans for seniors and other eligible Medicare beneficiaries.⁶

7. As described in more detail in Section V, Medicare beneficiaries can choose to receive their health benefits through MA plans managed by private insurers such as UnitedHealth rather than through the traditional Medicare fee-for-service program (“FFS Medicare”) that is managed by the federal government through the Centers for Medicare & Medicaid Services (“CMS”). The program is referred to as FFS Medicare because providers are paid based on the care that they deliver. FFS Medicare is sometimes called “Traditional Medicare,” or “TM.” For Medicare beneficiaries who elect to enroll in an MA plan, CMS pays the private insurers to coordinate and finance health benefits.⁷

8. In order to determine the amount that CMS will pay for each Medicare beneficiary who selects an MA plan, private insurers that provide MA plans are required to submit information using CMS’s Risk Adjustment Processing System (“RAPS”) on enrollees’ diagnoses stemming from one or more health care encounters.⁸ Each submission needs to cover the following items: the Medicare enrollee’s identification number, the date(s) of the health care encounter, the type of provider (e.g., physician or hospital), and the diagnosis code(s) reported by the provider for the encounter.⁹

9. In this matter, Plaintiffs allege that since 2005, UnitedHealth has conducted programs and engaged in activities to increase the number of diagnoses submitted to CMS.¹⁰ Plaintiffs

⁶ UnitedHealth 2021 Form 10-K, pp. 1, 4–5.

⁷ “What is Medicare Part C?,” U.S. Department of Health & Human Services, August 3, 2021 (“HHS, What is Medicare Part C”), available at <https://www.hhs.gov/answers/medicare-and-medicare/what-is-medicare-part-c>; “Medicare Managed Care Manual Chapter 8 – Payments to Medicare Advantage Organizations,” *Centers for Medicare & Medicaid Services*, revised September, 19, 2014 (“CMS, Medicare Managed Care Manual Chapter 8”), §§ 10, 140.2, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c08.pdf>.

⁸ Beginning in 2016, CMS also began incorporating data submitted by MA plans to its “encounter data system,” in addition to RAPS, to generate risk scores. MA plans submit detailed information about each encounter between MA enrollees and health care providers to the encounter data system. Over the period 2016–2021, CMS calculated risk scores using a combination of RAPS data and encounter data, with an increasing emphasis on encounter data over time. As of 2022, CMS has based risk scores for MA plans entirely on encounter data. See “Report to the Congress: Medicare Payment Policy,” *MedPAC*, March 2022 (“MedPAC, Report to the Congress”), p. 433, available at https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v3_SEC.pdf.

⁹ “Medicare Managed Care Manual Chapter 7 – Risk Adjustment,” *Centers for Medicare & Medicaid Services*, revised September 19, 2014, (“CMS, Medicare Managed Care Manual Chapter 7”), § 120, Table 12, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf>.

¹⁰ United States’ Amended Complaint-In-Partial-Intervention and Demand for Jury Trial, *United States of America ex rel. Benjamin Poehling v. UnitedHealth Group, Inc. et al.*, November 17, 2017 (“Complaint”), ¶ 122 (“Defendants conducted millions of medical record reviews as part of their revenue-generating national Chart Review program.”).

further allege that UnitedHealth knew that many of the subsequent diagnoses reported by its providers “were not supported and validated by the beneficiaries’ medical records.”¹¹ Plaintiffs also assert that MA plans “are obligated to delete invalid diagnoses previously submitted by them to RAPS or to use other available means to return [...] payments based on invalid diagnoses,” and that these deletions represent the main mechanism by which CMS can ensure that its compensation to MA plans is proper or that it recovers improper compensation that it made.¹² Plaintiffs allege that UnitedHealth knew that it was “obliged to undertake good faith efforts to identify and delete those unsupported and invalid diagnoses,” but that it failed to either delete these unsupported diagnoses in the RAPS program or to return the overcompensation generated by these unsupported diagnoses.¹³ Plaintiffs allege that, as a result, UnitedHealth received MA risk-adjustment payments to which it was “not entitled,” and that UnitedHealth failed to return the overcompensation to UnitedHealth.¹⁴

10. Moreover, there has been discussion as to whether CMS needs to account for unsupported codes in the FFS data when assessing whether compensation to MA plans is proper. In October 2018, CMS put forth a study (the “FFS Adjuster Study”) in which it claimed that unsupported codes in FFS data do not “systematically” impact CMS’s payments to MA plans, and therefore that there is no need for CMS to account for such unsupported codes when assessing whether MA plans were overpaid.¹⁵ In 2023, CMS adopted a “Final Rule” which finalized CMS’s decision to not apply an “FFS adjuster” that would account for unsupported codes in FFS data when assessing payments to MA plans.¹⁶

¹¹ Complaint, ¶ 122.

¹² Complaint, ¶ 103.

¹³ Complaint, ¶¶ 122, 342.

¹⁴ Complaint, ¶ 342 (“Specifically, Defendants knowingly concealed or knowingly and improperly avoided or decreased an obligation to repay risk adjustment payments to which they were not entitled from the Medicare Program. In particular, Defendants knowingly and improperly failed to delete in the RAPS system the invalid diagnoses that had been submitted to the Medicare Program for risk adjustment payments which were made by the Medicare Program to them or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses.”).

¹⁵ “Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits,” *Centers for Medicare & Medicaid Services*, October 26, 2018 (“CMS, FFS Adjuster Study”), p. 5, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Executive-Summary.pdf>.

¹⁶ Centers for Medicare & Medicaid Services and U.S. Department of Health & Human Services, Final Rule, “Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,” *Federal Register*, 88(21), February 1, 2023, pp. 6643–6665 (“CMS Final Rule”), available at <https://www.govinfo.gov/content/pkg/FR-2023-02-01/pdf/2023-01942.pdf>.

11. I understand from counsel for UnitedHealth that the damages period ends in 2017.

III. Assignment

12. I have been retained by counsel for UnitedHealth to evaluate several topics:

- First, I have been asked to provide historical information about FFS Medicare and MA, including explaining how MA compares to FFS Medicare;
- Second, I have been asked to evaluate whether the MA program has provided benefits to Medicare enrollees;
- Third, I have been asked to explain how CMS compensates MA plans for insuring Medicare enrollees;
- Fourth, I have been asked to evaluate whether MA plans would be properly compensated if they were required to identify and delete unsupported diagnosis codes;
- Fifth, I have been asked to evaluate the methodology and conclusions of CMS's FFS Adjuster Study; and
- Finally, I have been asked to evaluate, as a matter of economic theory, whether and how private insurers such as UnitedHealth would respond if they had been required to identify and delete unsupported diagnosis codes without the government making any changes in how MA plans are paid.

13. In the process of preparing this report, I have reviewed a variety of documents, including academic articles, reports from organizations such as the Medicare Payment Advisory Commission, documents and depositions produced in this matter, and CMS's FFS Adjuster Study. A complete list of the documents that I have relied upon in forming my opinions is attached as **Appendix B**.

14. My work in this matter is ongoing. I reserve the right to update my opinions as additional information becomes available.

IV. Summary of Opinions

15. First, I conclude that the MA program has provided value to plan enrollees (Section VI). MA plans provide Medicare beneficiaries with a greater number of health insurance plans to choose from, making it possible for individuals to choose a plan that better fits their preferences and needs. Consistent with this, data on Medicare enrollment indicates that many Medicare beneficiaries have preferred MA plans to FFS Medicare: the share of Medicare beneficiaries choosing MA has increased from 13 percent in 2003 to 51 percent in 2023. There are several reasons why Medicare beneficiaries may prefer MA plans over FFS Medicare, including that most MA enrollees enjoy benefits not available to enrollees in FFS Medicare (e.g., coverage for eye exams and glasses, dental and fitness benefits, and hearing aids) and that MA enrollees frequently pay less in premiums than FFS Medicare enrollees for plans with comparable or more extensive coverage. Evidence also indicates that MA plans have often provided more efficient care than FFS Medicare. This means that MA patients can achieve the same health outcomes as patients in FFS Medicare while using fewer resources (e.g., going to a hospital less), which is beneficial for patients. This also has positive spillover effects for all Medicare enrollees.

16. Second, I explain that CMS compensates MA plans for enrollees in a way that exposes insurers to financial risk (Section VII). CMS pays a fixed, pre-arranged monthly payment to MA plans for each enrollee. The payment amount is based on an estimate of predicted health care expenditures for the enrollee that accounts for the diagnosis codes, which are grouped into Hierarchical Condition Categories (“HCCs”), and demographic characteristics of the enrollee. These predicted health care expenditures are estimated from the FFS Medicare population using a regression model that predicts the incremental health care expenditures of a specific HCC or demographic trait relative to the average per capita predicted health care expenditures of FFS Medicare enrollees. Thus, MA plans have an incentive to identify and record all relevant diagnoses that an enrollee has so they can receive proper compensation. Accordingly, CMS adjusts the fixed payments to MA plans to account for different coding patterns between MA plans and FFS Medicare.

17. Third, I conclude that CMS would underpay MA plans if MA plans were required to identify and delete unsupported diagnosis codes without requiring CMS to do the same in FFS

Medicare when MA plans and FFS Medicare have identical populations with identical distributions of unsupported diagnosis codes (Section VIII.A). An MA plan is undercompensated relative to FFS Medicare if the total payment it receives is less than the total expected cost of treating FFS Medicare enrollees with identical risk scores as beneficiaries enrolled in the MA plan, while also accounting for the plan's bid. Requiring MA plans to identify and delete unsupported diagnosis codes in this situation, while maintaining the coefficients from the CMS-HCC model estimated on FFS data with unsupported diagnosis codes, mechanically reduces payments to MA plans even though the expected cost of treating the patients in the MA plan remains unchanged. This results in MA plans being undercompensated relative to what CMS would spend in FFS Medicare.

18. Fourth, I conclude that requiring MA plans to remove unsupported diagnosis codes without requiring CMS to do the same in FFS Medicare would also result in improper compensation to MA plans when MA plans and FFS Medicare have different pools of enrollees or different rates of unsupported diagnosis codes (Section VIII.B). Proper compensation requires that the CMS-HCC model provides the true incremental cost of the HCC under FFS, which is not the case when the model is estimated on FFS data with unsupported diagnosis codes. Evidence indicates that FFS data do contain unsupported diagnosis codes and that these data are typically unaudited before the estimation of the CMS-HCC model. The resulting impact of estimating the CMS-HCC model using FFS data with unsupported diagnosis codes versus audited FFS data on payments to an MA plan depends on the pool of enrollees and distribution of unsupported codes in the MA plan data relative to the FFS data. Thus, neither the MA plan nor CMS can determine whether the MA plan was properly compensated without information on the extent to which the plan's pool of enrollees and probabilities of unsupported codes differ compared to the FFS Medicare population.

19. Fifth, I conclude that the existence of unsupported codes in FFS data likely impacts payment to MA plans under the CMS-HCC model, contrary to what CMS concludes in its FFS Adjuster Study (Section IX). This study aimed to evaluate how removing unsupported codes from the FFS data would impact the dollar coefficients and relative factors estimated by the CMS-HCC model, and, as a consequence, the risk scores used to determine payments to MA plans. An impact would imply that an adjustment, referred to as the "FFS adjuster," was needed

when assessing whether MA plans were properly compensated. CMS concluded that an FFS adjuster is unnecessary. However, this conclusion is flawed. CMS reached this erroneous conclusion by relying on an incorrect and flawed methodology and by using data that does not allow it to reliably determine how unsupported diagnosis codes in FFS data affect risk scores and therefore payments to MA plans. Some of the methodological errors in CMS's methodology include: (1) flaws in estimating the probability that an HCC is unsupported in the FFS data; and (2) CMS inappropriately deflating the dollar coefficients estimated from the audited FFS data to purportedly adjust for the effects of the auditing process on expenditures, despite actual expenditures being unaffected by auditing. Other studies have also concluded that the FFS Adjuster Study is flawed, that unsupported diagnosis codes in the FFS data likely impact payments to MA plans, and that an FFS adjuster is necessary.

20. Sixth, I conclude that requiring MA plans to remove unsupported diagnosis codes while making no other changes to the way MA plans are paid would result in higher prices for Medicare beneficiaries or less generous plans (Section X). Economic theory predicts that a firm faced with declining reimbursement along with similar costs would adjust their behavior. I conclude that MA plans required to remove codes would respond in one or more of the following ways: (1) by increasing their bids, thereby increasing government and patient expenses; (2) by reducing the quality of benefits provided; and/or (3) by exiting the market, reducing the number of available MA plans to choose from and thereby reducing consumer welfare. I draw this conclusion based on predictions consistent with economic theory, as well as historical evidence of how MA plans responded to changes in the amount of compensation they received from CMS. Correctly estimating the change in government payments to UnitedHealth if UnitedHealth were required to identify and delete unsupported codes would therefore need to account for such changes in UnitedHealth's behavior.

V. Background on FFS Medicare and Medicare Advantage

21. In this section, I first describe some of the characteristics of health insurance generally, and then I provide information about the two specific health insurance options that are available to Medicare beneficiaries: FFS Medicare and Medicare Advantage.

A. Key Characteristics of Health Insurance

22. Health insurance is a type of insurance that typically provides payment or reimbursement to health care providers for some or all of the cost of covered health care expenditures incurred by an insured individual. In the United States, private insurers provide some health insurance products, while federal and/or state governments provide other health insurance products. Medicare and Medicaid are two examples of public health insurance programs offered by the U.S. government and collectively insured about 40 percent of Americans in 2021.¹⁷ About 12 million individuals were dually eligible for Medicare and Medicaid in 2022.¹⁸ Medicare primarily covers people aged 65 and older, with eligibility conferred regardless of income, medical history, or preexisting conditions.¹⁹ Medicaid is a public health insurance program primarily serving low-income individuals that is jointly funded by the federal and state governments.²⁰

23. Health insurance often does not pay for or reimburse all of the health care expenditures incurred by covered individuals. Instead, enrollees may face “out-of-pocket” costs for health care expenditures that are not covered by health insurance.²¹ In addition to the premium that

¹⁷ Medicaid is a means-tested public health insurance program jointly funded by the federal and state governments that covers low-income individuals who meet certain eligibility requirements. States have some flexibility in designing their programs and there are significant differences across state Medicaid programs. See “Who is Eligible for Medicaid?,” *U.S. Department of Health & Human Services*, December 8, 2022, available at <https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicaid>; Robin Rudowitz, et al., “10 Things to Know about Medicaid,” *Kaiser Family Foundation*, June 30, 2023 (“Rudowitz et al., 10 Things to Know about Medicaid”), available at <https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid>; “CMS Releases Latest Enrollment Figures for Medicare, Medicaid, and Children’s Health Insurance Program (CHIP),” *Centers for Medicare & Medicaid Services*, December 21, 2021, available at <https://www.cms.gov/newsroom/news-alert/cms-releases-latest-enrollment-figures-medicare-medicaid-and-childrens-health-insurance-program-chip>; “U.S. and World Population Clock,” *United States Census Bureau*, December 31, 2021, available at <https://www.census.gov/popclock>.

¹⁸ “Report to Congress on Medicaid and CHIP,” *Medicaid and CHIP Payment and Access Commission*, June 2023, p. 36, available at https://www.macpac.gov/wp-content/uploads/2023/06/MACPAC_June-2023-WEB-508.pdf.

¹⁹ Juliette Cubanski, et al., “A Primer on Medicare: Key Facts About the Medicare Program and the People it Covers,” *Kaiser Family Foundation*, March 20, 2015 (“Cubanski et al., A Primer on Medicare”), pp. 2–3, available at <https://files.kff.org/attachment/report-a-primer-on-medicare-key-facts-about-the-medicare-program-and-the-people-it-covers> (“Medicare was established in 1965 under Title XVIII of the Social Security Act to provide health insurance to people age 65 and older, regardless of income or medical history. [...] People age 65 and older qualify for Medicare if they are U.S. citizens or permanent legal residents with at least five years of continuous residence. Individuals qualify without regard to their medical history or preexisting conditions, and do not need to meet an income or asset test.”).

²⁰ “Medicaid,” *Medicare.gov*, available at <https://www.medicare.gov/basics/costs/help/medicaid>, (“Medicaid is a joint federal and state program that helps cover medical costs for some people with limited income and resources.”); Rudowitz et al., 10 Things to Know about Medicaid (“Medicaid is jointly financed by the federal government and states and administered by states within broad federal guidelines.”).

²¹ “Out-of-Pocket Costs,” *HealthCare.gov Glossary*, available at <https://www.healthcare.gov/glossary/out-of-pocket-costs>.

enrollees (and/or their employer) may pay for health insurance, enrollees may face out-of-pocket costs in the form of a deductible, copayment, and coinsurance, along with the costs for any uncovered health care services. These costs are defined below.

- Premiums are the amount that enrollees and/or their employers pay, usually on a monthly basis, to a health insurer in order for the enrollee to receive some insurance coverage for their future health care expenditures.²²
- A deductible represents the amount of money that an enrollee must pay out of pocket for health care expenditures before the health insurance plan begins to pay for benefits (e.g., \$500 or \$1,000 annually).²³
- Copayments are an amount of money that an enrollee pays for certain medical services or supplies such as physician visits or prescription drugs. They are typically a set amount rather than a percentage (e.g., a copayment could be \$10, \$20, or a different set amount).²⁴ For some services, plans can charge coinsurance instead of a copayment, which is a percentage of the total cost paid to the health care provider (e.g., 10 percent or 20 percent) instead of a set dollar amount.²⁵

24. The amount of out-of-pocket expenses an enrollee faces can vary substantially in health insurance plans. For example, plans can set out-of-pocket limits, which are an amount of total out-of-pocket expenses incurred by an enrollee over a plan year, above which enrollee out-of-pocket costs are eliminated. These out-of-pocket limits have varied substantially across plans. In 2023, the average annual out-of-pocket limit for MA plans ranges from \$4,033–\$9,643, depending on the plan type.²⁶ FFS Medicare has no limit on out-of-pocket expenses for services

²² “Premium,” *HealthCare.gov Glossary*, available at <https://www.healthcare.gov/glossary/premium>.

²³ “Understanding Medicare Advantage Plans,” *Centers for Medicare & Medicaid Services*, July 2022 (“CMS, Understanding Medicare Advantage Plans”), p. 11, available at <https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf>.

²⁴ CMS, *Understanding Medicare Advantage Plans*, p. 11.

²⁵ CMS, *Understanding Medicare Advantage Plans*, p. 11.

²⁶ The average annual out-of-pocket limit for MA plans refers to the enrollee-weighted average out-of-pocket limit by plan type for Part A and Part B services. HMOs have an average out-of-pocket limit of \$4,033, while Regional PPOs have an average out-of-pocket limit of \$6,842 for in-network services and \$9,643 for in-network and out-of-networks services combined. Nancy Ochieng, et al., “Medicare Advantage in 2023: Premiums: Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings,” *Kaiser Family Foundation*, August 9, 2023 (“Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings”), available at <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings>.

covered under Parts A and B.²⁷ In addition, as detailed further below, premiums under both FFS Medicare and MA vary widely by plan.

B. FFS Medicare

25. The federal government created Medicare in 1965 and then expanded it in 1972 to cover not only individuals aged 65 and over, but also certain people under 65 years old who have long-term disabilities. This program helps pay for a broad set of health care services, including hospitalizations, hospital outpatient visits, and physician visits.²⁸

26. From its inception in 1965 and until the introduction of the MA program, Medicare consisted of what is known today as Traditional Medicare, or FFS Medicare.²⁹ Under FFS Medicare, CMS typically pays health care providers on an FFS basis, meaning that CMS pays providers a specific amount for the health care services the provider rendered to the enrollee.³⁰

27. FFS Medicare provides two types of insurance that cover different health services:

²⁷ See “An Overview of Medicare,” *Kaiser Family Foundation*, February 13, 2019 (“KFF, An Overview of Medicare”), available at <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare>. Currently, Medicare Part D limits cost-sharing after an enrollee’s out-of-pocket spending reaches \$7,400, qualifying them for “catastrophic coverage.” Beginning in 2024, Medicare Part D recipients will no longer pay copayments or coinsurance for covered drugs after their out-of-pocket spending reaches \$8,000. See “Catastrophic coverage,” *Medicare.gov*, available at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/catastrophic-coverage>.

²⁸ People under 65 years old who receive benefits from the Social Security Disability Insurance (“SSDI”) program generally become eligible for Medicare after a two-year waiting period and people under 65 years old with end-stage renal disease and amyotrophic lateral sclerosis are eligible with no waiting period. See KFF, An Overview of Medicare.

²⁹ Medicare began contracting with private insurance plans through Medicare Part C in the mid-1980s with the name of this updated to Medicare + Choice in 1999 and to Medicare Advantage six years later. “Health Plans – General Information,” *Centers for Medicare & Medicaid Services*, modified September 6, 2023 (“CMS, Health Plans”), available at <https://www.cms.gov/medicare/enrollment-renewal/health-plans>; “History,” *Centers for Medicare & Medicaid Services*, modified September 6, 2023, available at <https://www.cms.gov/about-cms/who-we-are/history>. See also Thomas McGuire, et al., “An Economic History of Medicare Part C,” *The Milbank Quarterly*, 89(2), 2011 (“McGuire et al., Economic History of Medicare Part C”), pp. 289–332.

³⁰ See, e.g., “Fee Schedules – General Information,” *Centers for Medicare & Medicaid Services*, modified September 6, 2023, available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/feeschedulegeninfo>. Note that in some cases, diagnosis information may inform the reimbursement amount that providers receive under FFS Medicare. For example, for inpatient services, hospitals are paid a fixed payment for each patient discharged based on the Diagnoses Related Group (“DRG”), which combines information on the patient’s diagnosis and the services provided. See “Acute Inpatient PPS,” *Centers for Medicare & Medicaid Services*, modified September 6, 2023, available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>; “Glossary,” *Centers for Medicare & Medicaid Services*, available at <https://www.cms.gov/apps/glossary/> (“Diagnosis-Related Groups[:] A classification system that groups patients according to diagnosis, type of treatment, age, and other relevant criteria. Under the prospective payment system, hospitals are paid a set fee for treating patients in a single DRG category, regardless of the actual cost of care for the individual.”).

- Medicare Part A is the hospital insurance provided by FFS Medicare. This insurance covers inpatient care in hospitals and skilled nursing facilities, hospice care, and some home health care.³¹ Most enrollees do not have to pay a premium for Part A,³² but benefits are subject to a deductible and may require cost sharing.³³ In 2023, the deductible for each inpatient hospital benefit period is \$1,600.³⁴ Cost-sharing amounts for Part A are based on days of consecutive inpatient care. They can be as low as \$0 when an enrollee has less than sixty consecutive days of inpatient care, and up to the full cost of care when an enrollee has longer periods of care.³⁵
- Medicare Part B is medical insurance provided by FFS Medicare. This insurance helps cover the costs of physician visits, outpatient services, preventive services, and some home health visits.³⁶ Part B benefits are subject to an annual deductible (e.g., \$226 in 2023)³⁷ and, typically, a coinsurance payment of 20 percent.³⁸ Most Medicare enrollees pay a Part B premium, and these premiums are set at 25 percent of the projected average per capita Part B costs.³⁹ In 2023, the monthly Part B premium is \$164.90.⁴⁰

³¹ “What Part A Covers,” *Medicare.gov*, available at <https://www.medicare.gov/what-medicare-covers/what-part-a-covers>; “How Original Medicare works,” *Medicare.gov* (“CMS, How Original Medicare Works”), available at <https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/how-original-medicare-works>.

³² “Costs,” *Medicare.gov* (“CMS, Medicare Costs”), available at <https://www.medicare.gov/basics/costs/medicare-costs>.

³³ For example, a beneficiary may be responsible for the full cost of care for extended inpatient hospital and skilled nursing facilities stays. See CMS, Medicare Costs.

³⁴ Inpatient hospital benefit periods begin when a beneficiary is admitted as an inpatient and end after a beneficiary has not received any inpatient hospital or skilled nursing facility (“SNF”) care for 60 days. There is no limit to the number of benefit periods beneficiaries can have in a year. See CMS, Medicare Costs.

³⁵ In 2023, there is no copayment for the first 60 days of a benefit period. There is a \$400 daily copayment for days 61–90. After 90 days, beneficiaries can pay a \$800 daily copayment by using a “lifetime reserve day,” of which all beneficiaries receive 60 over the course of their lifetimes. After using all 60 lifetime reserve days, beneficiaries pay all costs for the remainder of a given stay. The copayment and deductible schedule resets whenever a beneficiary goes 60 consecutive days without care from a hospital or SNF. See CMS, Medicare Costs.

³⁶ KFF, An Overview of Medicare; CMS, How Original Medicare Works.

³⁷ “2023 Medicare Parts A & B Premiums and Deductibles 2023 Medicare Part D Income-Related Monthly Adjustment Amounts,” *Centers for Medicare & Medicaid Services*, September 27, 2022 (“CMS, 2023 Medicare Parts A & B Premiums and Deductibles”), available at <https://www.cms.gov/newsroom/fact-sheets/2023-medicare-parts-a-b-premiums-and-deductibles-2023-medicare-part-d-income-related-monthly>.

³⁸ CMS, Medicare Costs. No coinsurance or deductible is charged for some preventive services. See “What Part B Covers,” *Medicare.gov*, available at <https://www.medicare.gov/what-medicare-covers/what-part-b-covers>.

³⁹ Patricia A. Davis, “Medicare Part B: Enrollment and Premiums,” *Congressional Research Service*, May 19, 2022, available at <https://sgp.fas.org/crs/misc/R40082.pdf>.

⁴⁰ About seven percent of Part B recipients face higher premiums due to their relatively high incomes. See CMS, 2023 Medicare Parts A & B Premiums and Deductibles.

28. In 2021, FFS Medicare provided its enrollees with average benefits of \$5,207 and \$6,757 for Part A and Part B, respectively, with average cost sharing (excluding monthly premiums and uncovered services) of \$396 and \$1,621 for Part A and Part B, respectively.⁴¹

29. Since 2006, Medicare beneficiaries can also obtain coverage for outpatient prescription drugs.⁴² This type of insurance, offered through private insurers that contract with Medicare, is called Medicare Part D. Part D enrollees typically pay a monthly premium and are subject to other cost-sharing payments, with premiums, drug formularies, and other cost sharing varying substantially across plans.⁴³ For example, monthly premiums for Part D plans in 2023 range from \$1.60 to \$201.10.⁴⁴ In 2019, approximately 25 million FFS Medicare enrollees (about 66 percent of all FFS Medicare enrollees) were enrolled in a stand-alone prescription drug plan through Medicare Part D.⁴⁵

30. FFS Medicare has certain limitations. For example, it does not cover services such as long-term care, hearing aids, or dental care, and many services require significant cost sharing, such as the 20 percent copayment for Medicare Part B described above.⁴⁶ Moreover, among noninstitutionalized Medicare beneficiaries enrolled in FFS Medicare in 2020, Medicare covered 69 percent of total health care expenditures.⁴⁷ Because of the gaps in Medicare coverage, many FFS Medicare enrollees also enroll in Medicare supplemental insurance

⁴¹ “Health care spending and the Medicare program,” *MedPAC*, July 2023 (“MedPAC, Health care spending and the Medicare Program”), p. 12, available at https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_SEC.pdf.

⁴² “Prior to 2006, Medicare paid for some drugs administered during a hospital admission (under Medicare Part A), or a doctor’s office (under Medicare Part B). Medicare did not cover *outpatient* prescription drugs until January 1, 2006, when it implemented the Medicare Part D prescription drug benefit, authorized by Congress under the ‘Medicare Prescription Drug, Improvement, and Modernization Act of 2003.’” See “Part D/Prescription Drug Benefits,” *Center for Medicare Advocacy*, available at <https://www.medicareadvocacy.org/medicare-info/medicare-part-d>.

⁴³ “An Overview of the Medicare Part D Prescription Drug Benefit,” *Kaiser Family Foundation*, October 19, 2022 (“KFF, An Overview of the Medicare Part D Prescription Drug Benefit”), available at <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit>.

⁴⁴ KFF, An Overview of the Medicare Part D Prescription Drug Benefit.

⁴⁵ A further 19.7 million individuals received Part D coverage through Medicare Advantage plans. These figures include both employer-only group plans and non-employer plans. See Juliette Cubanski, et al., “10 Things to Know About Medicare Part D Coverage and Costs in 2019,” *Kaiser Family Foundation*, June 4, 2019, available at <https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019>; “Total Number of Medicare Beneficiaries by Type of Coverage,” *Kaiser Family Foundation*, 2019, available at <https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries>.

⁴⁶ CMS, Medicare Costs; “Medicare Advantage: A Policy Primer,” *Commonwealth Fund*, May 3, 2022, available at <https://www.commonwealthfund.org/publications/explainer/2022/may/medicare-advantage-policy-primer> (“Commonwealth Fund, Medicare Advantage: A Policy Primer”).

⁴⁷ This figure includes all public, private, and direct beneficiary spending on “all health care goods and services.” MedPAC, Health care spending and the Medicare program, p. 29.

policies, known as Medigap policies. Medigap plans are provided through private insurers and pay for costs not covered by FFS Medicare, including copayments.⁴⁸ These plans require enrollees to pay monthly premiums in addition to the premiums they may pay for Part B and Part D.⁴⁹

31. As an alternative to enrolling in FFS Medicare and supplementing it with Medigap, beneficiaries can choose to enroll in Medicare Advantage. This is described below.

C. Medicare Advantage

32. The federal government introduced the Medicare Advantage program within Medicare to (1) provide Medicare beneficiaries with health insurance plans that are an alternative to FFS Medicare, and (2) transfer to Medicare some of the efficiencies and cost savings that had been observed for health care plans in the private sector.⁵⁰ In particular, the Medicare Advantage program relies on private insurers to provide health insurance to Medicare enrollees through the use of managed care, whereby health care is provided through provider networks. Managed care plans use their capitation payments to manage the health care expenditures of enrollees.⁵¹ In this section, I first describe some features of current MA plans, and then briefly review the history of the MA program.

33. MA plans must provide enrollees with both Part A and Part B coverage, and may offer enrollees Part D prescription drug coverage as well.⁵² In 2023, 89 percent of MA plans offer prescription drug coverage and 97 percent of MA enrollees in “individual plans,” which are plans open for general enrollment to individual consumers, selected plans with this benefit.⁵³ MA plans can differ in the amount of premiums that they charge, the limits on out-of-pocket

⁴⁸ Commonwealth Fund, Medicare Advantage: A Policy Primer.

⁴⁹ Commonwealth Fund, Medicare Advantage: A Policy Primer.

⁵⁰ McGuire et al., Economic History of Medicare Part C, pp. 289–332 at p. 289.

⁵¹ “Managed Care,” *Centers for Disease Control and Prevention*, August 12, 2022, available at <https://www.cdc.gov/nchs/hus/sources-definitions/managed-care.htm>; Commonwealth Fund, Medicare Advantage: A Policy Primer; Deposition of Anne Hornsby (CMS), May 19, 2023 (“Hornsby Deposition”), pp. 11:24–12:3, 39:12–18 (“CMS pays the Medicare Advantage organization which, in turn, has developed contracted provider networks that they then pay for services.”).

⁵² CMS, Health Plans.

⁵³ Meredith Freed, et al., “Medicare Advantage 2023 Spotlight: First Look,” *Kaiser Family Foundation*, November 10, 2022 (“Freed et al., Medicare Advantage 2023 Spotlight: First Look”), available at <https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/>; Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. Individual plans exclude employer group health plans and Special Needs Plans.

costs,⁵⁴ and the structure of out-of-pocket costs.⁵⁵ For example, in 2023, about 73 percent of enrollees in individual MA plans that offer prescription drug coverage pay no “incremental premium” (i.e., a premium in addition to the standard Part B premium), while only about three percent have incremental premiums of \$100 or more per month.⁵⁶ Overall, the average enrollment-weighted incremental premium among individual MA plans offering prescription drug coverage, including those that do not pay a premium, is \$15 per month in 2023.⁵⁷ The average enrollment-weighted premium for just the Part D portion of covered benefits is \$10 per month among these MA plans.⁵⁸ In contrast, the stand-alone prescription drug plans available to FFS Medicare enrollees require an additional Part D premium, which averages \$40 per month in 2023.⁵⁹

34. If MA enrollees are interested in switching to another plan, such as a different MA plan with drug coverage through Part D, they can do so during the Medicare Advantage Open Enrollment period. The Open Enrollment period occurs annually from January through March, and during this time, MA enrollees may switch to another MA plan or return to FFS Medicare.⁶⁰

⁵⁴ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

⁵⁵ See Matthew Rae, et al., “Patient Cost-Sharing in Marketplace Plans, 2016,” *Kaiser Family Foundation*, November 13, 2015 available at <https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016> for a discussion of out-of-pocket costs.

⁵⁶ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

⁵⁷ These figures do not include the standard Medicare Part B premium all beneficiaries must pay. Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

⁵⁸ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

⁵⁹ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

⁶⁰ “What’s the Difference Between Medicare’s Open Enrollment Period and Medicare Advantage Open Enrollment?” *National Council on Aging*, November 12, 2022, available at <https://ncoa.org/article/whats-the-difference-between-medicare-open-enrollment-period-and-medicare-advantage-open-enrollment>.

35. MA plans vary according to their hospital and physician networks,⁶¹ their rules regarding how enrollees can access services,⁶² and the services they cover, which can include services not covered by FFS Medicare such as vision, hearing, or dental.⁶³ MA plan health care provider networks can be more limited than the set of providers that accept FFS Medicare.⁶⁴ In this regard, MA has more in common with an employer-sponsored plan than with FFS Medicare.⁶⁵

36. Medicare Advantage plans are offered by many of the same insurers that offer employer-sponsored health plans. Three private insurers account for approximately 61 percent of the 30.8 million enrollees in MA plans in 2023: 29 percent of MA enrollees have plans with UnitedHealth, 18 percent with Humana, and 14 percent with BlueCross BlueShield affiliates.⁶⁶ Other insurers offering MA plans include CVS Health, Kaiser Permanente, Centene, and Cigna, with shares ranging from 2 to 11 percent.⁶⁷

37. The MA program has undergone substantial changes over the course of its existence with regards to how the government compensates private insurers. The original version of the MA program began with the Social Security Amendments of 1972, which authorized the government to contract with private health insurers to offer private health plans as additional options for Medicare beneficiaries. However, a substantial increase in plan participation and enrollment only occurred when the Tax Equity and Fiscal Responsibility Act (“TEFRA”) of 1982 introduced some changes in the program’s risk sharing arrangements including, for

⁶¹ For example, a 2017 Kaiser Family Foundation study that examines 391 MA plans in 20 counties in 2015 finds heterogeneity in the size of plan’s physician networks: 22 percent of enrollees were in plans that included over 70 percent of physicians in the county in their network, while 35 percent of enrollees were in plans that included less than 30 percent of physicians in the county in their network. See Gretchen Jacobson, et al., “Medicare Advantage: How Robust Are Plans’ Physician Networks?,” *Kaiser Family Foundation*, October 5, 2017, Figure ES.1, available at <https://www.kff.org/medicare/report/medicare-advantage-how-robust-are-plans-physician-networks>. A similar 2016 Kaiser Family Foundation study also found heterogeneity in the size of plans’ hospital networks. See Gretchen Jacobson, et al., “Medicare Advantage Hospital Networks: How Much Do They Vary?,” *Kaiser Family Foundation*, June 20, 2016, Figure ES.1, available at <http://files.kff.org/attachment/Report-Medicare-Advantage-Hospital-Networks-How-Much-Do-They-Vary>.

⁶² HHS, What is Medicare Part C.

⁶³ CMS, Understanding Medicare Advantage Plans, p. 5.

⁶⁴ CMS, Understanding Medicare Advantage Plans, p. 5.

⁶⁵ As another example, MA plans and employer plans often have cost sharing that varies by service, whereas Medicare Part B enrollees pay a flat 20 percent. See CMS, Understanding Medicare Advantage Plans, p. 6. See also “Employer Health Benefits: 2021 Annual Survey,” *Kaiser Family Foundation*, November 2021, p. 92, available at <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf>.

⁶⁶ Nancy Ochieng, et al., “Medicare Advantage in 2023: Enrollment Update and Key Trends,” *Kaiser Family Foundation*, August 9, 2023 (“Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends”), available at <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends>.

⁶⁷ Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends.

example, allowing plans to reduce cost sharing for beneficiaries. By 1997, enrollment in these private health plans had grown to about six million beneficiaries, located primarily in urban counties.⁶⁸

38. CMS pays MA plans a fixed payment per enrollee in exchange for providing health care coverage to beneficiaries who enroll.⁶⁹ To estimate these payments in the 1980s and 1990s, CMS used a model based primarily on demographics, such as gender, age, Medicaid status, and disability status, along with the enrollee's county of residence. The demographic factors served as a proxy for health risks, which are associated with enrollees' health care expenditures. The model assessed the relationship between these demographic factors and total spending in Parts A and B of FFS Medicare.⁷⁰ This quantification of the relationship between these demographic factors and spending was then used to adjust payments to MA plans up or down based on whether the demographic profile of an enrollee represented a higher or lower health and medical expenditure risk. This process of adjusting payments to MA plans up or down to account for the risk of future health expenditures is known as "risk adjustment."⁷¹ This type of risk adjustment based on demographic factors was limited in that it did not include any disease or health variables in trying to predict an enrollee's total health and medical expenditures.⁷² Although the payment model was limited with regard to the direct use of such health variables, it did consider the geographic variation in Medicare costs.⁷³ Studies such as the Dartmouth Atlas have shown that geographic differences in per-recipient Medicare spending can be substantial, even after controlling for demographic factors.⁷⁴

39. The Balanced Budget Act of 1997 ("BBA") took Medicare's system of providing fixed payments to private health plans to cover enrollees, renamed these plans Medicare+Choice

⁶⁸ Office of Health Policy, "Payment for Medicare Advantage Plans: Policy Issues and Options," *Office of the Assistant Secretary for Planning and Evaluation*, June 2009, p. 2, available at <https://aspe.hhs.gov/system/files/pdf/75816/report.pdf>.

⁶⁹ I refer to these payments as "payments to MA plans" throughout the remainder of this report.

⁷⁰ Brown et al., *How Does Risk Selection Respond to Risk Adjustment*, pp. 3335–3364 at p. 3339.

⁷¹ MedPAC, *Report to the Congress*, p. 413.

⁷² Gregory Pope, et al., "Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model," *Health Care Financing Review*, 25(4), 2004 ("Pope et al., Risk Adjustment of Medicare Capitation Payments"), pp. 119–141 at p. 119.

⁷³ Pope et al., *Risk Adjustment of Medicare Capitation Payments*, pp. 119–141 at p. 119.

⁷⁴ For example, after adjusting for age, sex and race, FFS Medicare reimbursements per enrollee (Part A and Part B) for 2019 in the Des Moines hospital referral region ("HRR," a region with similar medical usage patterns used by the Dartmouth Atlas) was \$9,169.86. The same measure was \$14,675.29 in the Miami HRR. See "Medicare Reimbursements," *Dartmouth Atlas Project*, 2022, available at <https://www.dartmouthatlas.org/interactive-apps/medicare-reimbursements>; "FAQ," *Dartmouth Atlas Project*, available at <https://www.dartmouthatlas.org/faq>.

(“M+C”), and formally defined this system as Part C of Medicare.⁷⁵ The BBA required CMS to improve its risk-adjustment model by using health information (i.e., data on diagnoses of health care conditions for inpatients—but not for outpatients) in addition to demographic variables. CMS began to use this new model in 2000, but only 10 percent of the payments made to MA plans were based on the updated methodology of incorporating health information along with enrollee demographic variables.⁷⁶

40. In addition, the BBA authorized CMS to contract with private organizations to offer a variety of new health plan options (such as Health Maintenance Organization or Preferred Provider Organization plans, two types of plans that are commonly used in employer-sponsored health insurance) for enrollees in the M+C program.⁷⁷ The BBA also altered reimbursement to Part C plans, limiting plans’ reimbursements in many counties to be at most two percent higher than the prior year’s reimbursement.⁷⁸

41. The Benefits Improvement and Protection Act of 2000 (“BIPA”) addressed the limitation of a risk-adjustment model that only included data on diagnoses for inpatients by requiring the use of such data for outpatients as well.⁷⁹ Moreover, BIPA provided a phase-in schedule regarding the risk-adjusted portion of the payments to MA plans. This portion increased to 30 percent in 2004, to 50 percent in 2005, to 75 percent in 2006, and to 100 percent in 2007.⁸⁰

42. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) renamed the M+C program as the Medicare Advantage program.⁸¹ The MMA included the most significant changes to the Medicare program since its creation by establishing

⁷⁵ McGuire et al., Economic History of Medicare Part C, pp. 289–332 at pp. 306, 308.

⁷⁶ McGuire et al., Economic History of Medicare Part C, pp. 289–332 at pp. 308–309.

⁷⁷ CMS, Health Plans.

⁷⁸ McGuire et al., Economic History of Medicare Part C, pp. 289–332 at p. 309.

⁷⁹ Pope et al., Risk Adjustment of Medicare Capitation Payments, pp. 119–141 at p. 120.

⁸⁰ “Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates,” *Centers for Medicare & Medicaid Services*, March 28, 2003, pp. 4–5, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf>; “Advance Notice of Methodological Changes for Calendar Year (CY) 2005 Medicare Advantage (MA) Payment Rates,” *Centers for Medicare & Medicaid Services*, March 26, 2004, p. 6, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/advance2005.pdf>; “Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates,” *Centers for Medicare & Medicaid Services*, February 18, 2005, p. 8, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/advance2006.pdf>; “Advance Notice of Methodological Changes for Calendar Year 2007 for Medicare Advantage (MA) Payment Rates and Part D Payment,” *Centers for Medicare & Medicaid Services*, February 17, 2006, pp. 5–6, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2007.pdf>.

⁸¹ CMS, Health Plans.

a larger role for private health plans and enacting increases to payments to MA plans, effective in March 2004.⁸² The participation of plans in the MA program and enrollment both increased steadily after the MMA.⁸³

43. In more recent years, CMS has limited MA plans' profits through the implementation of a minimum Medical Loss Ratio ("MLR") to which MA plans must adhere. The MLR represents "the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit."⁸⁴ Starting in 2014, MA insurers needed to have an MLR of at least 85 percent for each contract—meaning that at least 85 percent of revenue must be used for patient care—or they could be subject to sanctions.⁸⁵ The MLR limits MA plans' ability to charge high premiums without offering patients correspondingly generous benefits, or to offer plans with few benefits without offering correspondingly low premiums.

VI. The Medicare Advantage Program Has Provided Value to Plan Enrollees

44. In this section, I explain why the Medicare Advantage program has provided value to Medicare enrollees. I first explain that Medicare enrollees are better off when they have more health insurance plans to choose from. This is because with more choices it is possible for individuals to choose a plan better tailored to their health care preferences and needs. Second, I discuss evidence indicating that Medicare beneficiaries have often preferred Medicare Advantage plans to FFS Medicare. Finally, I explain that Medicare Advantage plans have often provided better or more efficient care than FFS Medicare.

⁸² Gregory Pope, et al., "Impact of Increased Financial Incentives to Medicare Advantage Plans: Final Report," *RTI International*, September 2006 ("Pope et al., Impact of Increased Financial Incentives to Medicare Advantage Plans"), pp. 11–12, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Pope.pdf>.

⁸³ McGuire et al., *Economic History of Medicare Part C*, pp. 289–332 at pp. 313–314, Figure 2, Figure 4.

⁸⁴ "Medical Loss Ratio," *Centers for Medicare & Medicaid Services*, modified September 6, 2023 ("CMS, Medical Loss Ratio"), available at <https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio>.

⁸⁵ CMS, Medical Loss Ratio. See also Deposition of Kirk Limmer (CMS), June 21, 2023 ("Limmer Deposition"), pp. 14:9–16, 116:5–117:20 ("A The medical loss ratio was enacted—enacted by Congress—to my understanding is to place—to basically ensure that a certain percentage of benefits within the total revenue—or a minimum—say, a minimum level of benefits is being passed on to the beneficiaries. And that the—I guess, conversely, that the non—non-benefit—well, I don't want to use the word non-benefit because that might be confusing. The portion that is not medical is—is limited by a certain percentage, also. So for Medicare, it is set at 85 percent. [...] it could be greater than 85 percent. But as long as they are, as long as the results that—and using the medical loss ratio formula—as long as those results are over 85 percent or—then—then there's no payment. If there—if it's below that, there are—there are specified actions that would be taken, including possible payments to CMS.").

A. Medicare Advantage Plans Provide Medicare Beneficiaries with More Choices

45. MA plans provide Medicare beneficiaries with alternatives to FFS Medicare that may better fit their health care preferences and needs. Beneficiaries choose between FFS Medicare and MA plans, or among different MA plans, based upon their preferences and upon plan features such as premiums, cost sharing, limits on out-of-pocket expenses, provider networks, conditions to access care, and the availability of benefits not offered by FFS Medicare (e.g., vision care coverage). All else equal, Medicare beneficiaries are made better off if they have more plans to choose from because a broader menu of plans allows each beneficiary to choose a plan more tailored to their specific preferences and health care needs.

46. The concept that increased choice makes consumers better off is well understood in economics. Economists use the term “utility,” where an individual is better off if they have higher utility and worse off if they have lower utility.⁸⁶ Typical economic models demonstrate that expanding an individual’s choices will leave them at least equally well off, and in many cases better off.⁸⁷ In the context of discussing Medicare, and Medicare Advantage in particular, Newhouse et al. (2014) state that “[i]n conventional economic theory, more choices always benefit a consumer because more choices offer the possibility of a better match between what is bought and the consumer’s preferences.”⁸⁸ This principle is consistent with CMS statements as to why it supports the growth of MA. For example, a CMS-contracted study states that the 2003 MMA was intended “to increase the choice of plans available to beneficiaries.”⁸⁹ In 2018, CMS Administrator Seema Verma stated that “[o]ur priority is to ensure that our seniors have more choices [...] We are focused on addressing the specific needs of beneficiaries and providing new flexibilities for Medicare Advantage plans to offer new health-related benefits. This is a big win for patients.”⁹⁰ In other words, the utility of Medicare beneficiaries will be, on average,

⁸⁶ Robert S. Pindyck and Daniel L. Rubinfeld, *Microeconomics, Eighth Edition*, (Upper Saddle River: Pearson Education, Inc., 2013) (“Pindyck and Rubinfeld, *Microeconomics*”), p. 78.

⁸⁷ Pindyck and Rubinfeld, *Microeconomics*, pp. 67–95, 417–419.

⁸⁸ Joseph Newhouse and Thomas McGuire, “How Successful is Medicare Advantage,” *The Milbank Quarterly*, 92(2), 2014, pp. 351–394 at p. 356.

⁸⁹ Pope et al., *Impact of Increased Financial Incentives to Medicare Advantage Plans*, p. 7.

⁹⁰ “CMS proposes Medicare Advantage and Part D payment and policy updates to provide new benefits for enrollees, new protections to combat opioid crisis,” *Centers for Medicare & Medicaid Services*, February 1, 2018, available at <https://www.cms.gov/newsroom/press-releases/cms-proposes-medicare-advantage-and-part-d-payment-and-policy-updates-provide-new-benefits-enrollees>.

higher because of the increased choice that Medicare Advantage plans provide. This is because, for some individuals, the additional MA plan options will be a better fit than FFS Medicare or will be a better fit than already-existing MA plan options. This is an important reason why the Medicare Advantage program benefits Medicare beneficiaries.

B. Market Data and Academic Literature Indicate that Many Medicare Beneficiaries Have Preferred Medicare Advantage Plans to FFS Medicare

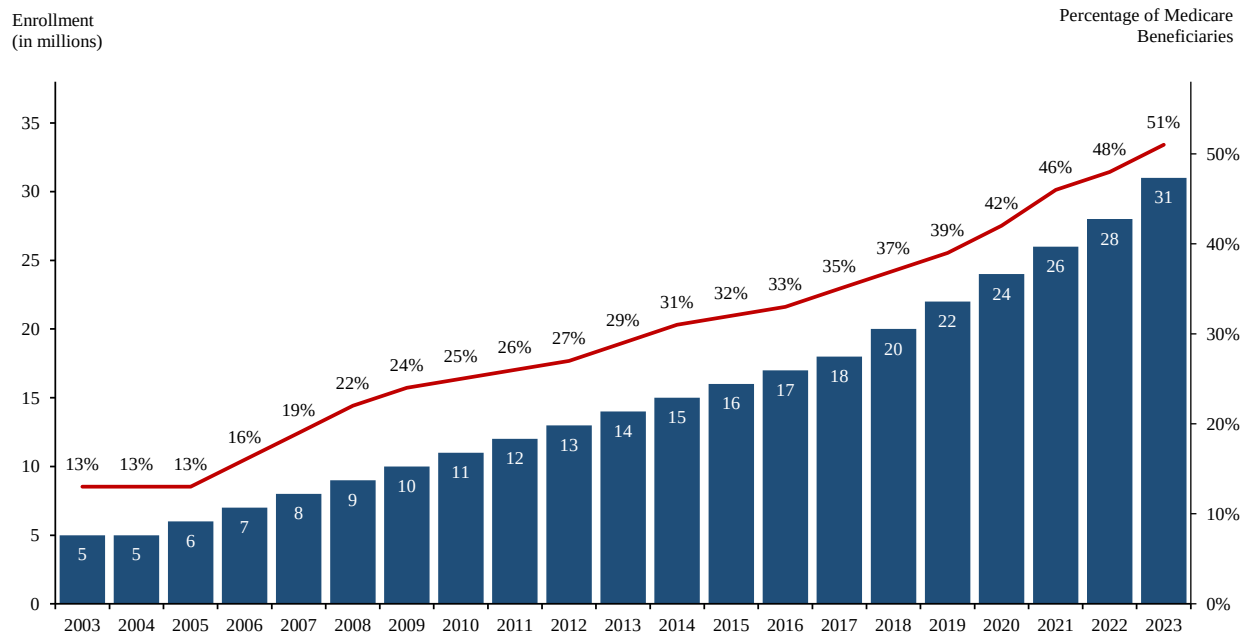
47. MA enrollment has grown tremendously over time since the passage of the MMA and the creation of the current MA program in 2003. As shown in Exhibit 1, MA plans enrolled approximately 5 million Medicare beneficiaries in 2003, and enrollment increased to approximately 31 million Medicare beneficiaries in 2023.

48. Enrollment has not only grown in absolute terms—the share of Medicare beneficiaries choosing Medicare Advantage has also increased over time. As shown in Exhibit 1, the share of Medicare beneficiaries selecting Medicare Advantage plans grew from 13 percent in 2003 to 51 percent in 2023. The Congressional Budget Office projects that under current law MA enrollment will continue to grow and could reach 62 percent of Medicare beneficiaries by 2033.⁹¹

⁹¹ Ochieng et al., Medicare Advantage in 2023: Enrollment and Key Trends.

Exhibit 1

Medicare Advantage Enrollment and Share of All Medicare Enrollment, 2003–2023



Source: Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends; Meredith Freed, et al., “A Dozen Facts About Medicare Advantage in 2020,” *Kaiser Family Foundation*, April 22, 2020 (“Freed et al., A Dozen Facts About Medicare Advantage in 2020”), available at <https://web.archive.org/web/20201210075019/https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020>.

Note: Enrollment data is from March of each year, with the exception of 2006, which is from April. KFF updated its methodology so that starting in 2010, the data do not include cost plans. Cost plans are a Medicare managed care plan that can also be reimbursed by FFS Medicare for out of network services. Data from before 2010 include cost plans. Data for the period 2007 – 2023 are from KFF’s 2023 report, while data for before 2007 are from KFF’s 2020 report. About 60.0 million people are enrolled in Medicare Parts A and B in 2023.

49. The fact that a substantial share of Medicare beneficiaries selects MA over FFS Medicare reveals that many individuals prefer MA. According to economic theory, if an individual has two items they can choose from, option A and option B, and both are within their budget, then one can infer from their selection of option A that they prefer option A to option B.⁹² Applied to the choice of Medicare products, the fact that 51 percent of Medicare beneficiaries selected an MA plan rather than FFS Medicare in 2023 reveals that many Medicare beneficiaries prefer MA plans over FFS Medicare. The steady growth in the share of individuals selecting MA plans

⁹² It is possible that an individual who selected option A is indifferent between option A and option B, but nonetheless selected option A. Economists would say the individual “weakly” prefers option A to option B in this instance. See David Besanko and Ronald Braeutigam, *Microeconomics, Fifth Edition*, (Jefferson City: John Wiley & Sons, Inc., 2014), p. 134.

over time also reveals that the fraction of Medicare beneficiaries who prefer MA plans to FFS Medicare is growing.

50. There is similar evidence indicating that UnitedHealth MA plans are attractive to Medicare beneficiaries. In 2023, UnitedHealth had more MA enrollees than any other insurer (29 percent for UnitedHealth as compared to 18 percent for Humana, 14 percent for BlueCross BlueShield, 11 percent for CVS Health, 6 percent for Kaiser Permanente, and 22 percent for all other plans). Additionally, UnitedHealth's share of enrollees among MA insurers has grown substantially over the past decade (from 22 percent in 2013 to 29 percent in 2023), while the share for many other leading MA insurers (such as Humana, BlueCross BlueShield, and Kaiser Permanente) has been relatively flat.⁹³ Taken together, these facts reveal that many Medicare beneficiaries prefer UnitedHealth MA plans to other MA plans and to FFS Medicare, and that the number of individuals with this preference has been increasing over time.

51. In addition to market data indicating that many Medicare beneficiaries prefer MA plans, survey data shows that MA plan enrollees are satisfied with their health insurance plans. For example, Duggan et al. (2016) analyze data from the 2007–2011 Consumer Assessment of Healthcare Providers and Systems (“CAHPS”) survey that contains enrollees’ ratings of plans for every MA plan that is at least one year old.⁹⁴ Surveyors questioned 600 individuals from each MA contract and collected responses from over 160,000 MA enrollees in each year between 2007 and 2011. Duggan et al. (2016) find that “MA enrollees are on average quite satisfied with their plans.”⁹⁵

52. There are several reasons why Medicare beneficiaries may prefer MA plans over FFS Medicare.

53. First, most MA enrollees enjoy benefits not available to their counterparts who are enrolled in FFS Medicare. For example, in 2023, more than 90 percent of MA plans offer coverage for eye exams and glasses, dental care, fitness benefits, and/or hearing aids, while FFS

⁹³ Humana saw slight growth in its share of enrollees from 17 percent to 18 percent, while both BlueCross BlueShield and Kaiser Permanente saw a decline in market share over the past decade. CVS Health's share of enrollees among MA insurers grew from 7 percent in 2013 to 11 percent in 2023, representing the only substantial growth in market share aside from UnitedHealth among insurers with at least 6 percent of MA enrollees. See Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends.

⁹⁴ Duggan et al., Who Benefits when the Government Pays More, pp. 50–67 at pp. 55, 62.

⁹⁵ Duggan et al., Who Benefits when the Government Pays More, pp. 50–67 at footnote 12.

Medicare does not cover these benefits.⁹⁶ Additionally some MA enrollees have access to other benefits not covered under FFS Medicare such as meal, transportation, and in-home support benefits.⁹⁷ As acknowledged by Sean Creighton, former Director for Payment Policy and Risk Adjustment at CMS, beneficiaries of MA plans enjoy “an array of additional benefits that are not available to them in fee-for-service,” including prescription drug coverage at a reduced cost and an out-of-pocket maximum that limits enrollees’ out-of-pocket spending.⁹⁸

54. Second, many MA enrollees pay less in premiums than FFS Medicare enrollees for plans with comparable coverage (health care expenditures covered under Parts A, B, and D) or even for plans with more extensive coverage (e.g., vision or dental coverage in addition to services covered under Parts A, B, and D).⁹⁹ In 2023, most MA plans (about 89 percent) offer prescription drug coverage, and most MA enrollees (about 92 percent) are enrolled in these plans.¹⁰⁰ Among MA plans with Part D coverage, 73 percent of MA enrollees with prescription drug coverage pay no incremental premium (i.e., no premium other than their Medicare Part B premium), and the average enrollment-weighted incremental premium for MA enrollees (across

⁹⁶ 97 percent of individual MA plans include telehealth benefits beyond what was allowed under FFS Medicare prior to the COVID-19 public health emergency. Freed et al., Medicare Advantage 2023 Spotlight: First Look. FFS Medicare currently covers a range of telehealth services, but most of this coverage is temporarily available due to a broad, but time-limited, expansion triggered by the COVID-19 pandemic. MA plans have been able to offer telehealth benefits since 2020 due to a pre-pandemic CMS policy adjustment. See Wyatt Koma, et al., “FAQs on Medicare Coverage of Telehealth,” *Kaiser Family Foundation*, May 23, 2022, available at <https://www.kff.org/medicare/issue-brief/faqs-on-medicare-coverage-of-telehealth/>; “CMS finalizes policies to bring innovative telehealth benefit to Medicare Advantage,” *Centers for Medicare & Medicaid Services*, April 5, 2019, available at <https://www.cms.gov/newsroom/press-releases/cms-finalizes-policies-bring-innovative-telehealth-benefit-medicare-advantage>.

⁹⁷ Freed et al., Medicare Advantage 2023 Spotlight: First Look.

⁹⁸ Deposition of Sean Creighton (CMS), March 23, 2022 (“Creighton Deposition, day 1”), pp. 33:7–34:6, 41:21–45:23.

⁹⁹ Statement of Jonathan Morse Acting Director of the Center for Program Integrity, Centers for Medicare and Medicaid Services on “Efforts to Combat Waste, Fraud and Abuse in the Medicare Program” before the U.S. House Ways and Means Committee, Subcommittee on Oversight, July 19, 2017, p. 1, available at <https://waysandmeans.house.gov/wp-content/uploads/2017/07/20170719OS-Testimony-Morse.pdf> (“Additionally, while average premiums have remained stable, access to most Medicare Advantage supplemental benefits has increased, and enrollment is growing faster than in original Medicare. Medicare Advantage plans may offer additional benefits and cost-sharing arrangements that are at least as generous as the standard Parts A and B benefits under original Medicare.”).

¹⁰⁰ Freed et al., Medicare Advantage 2023 Spotlight: First Look. I calculate the share of MA enrollees that are enrolled in an MA plan with Part D coverage using the number of MA-PD enrollees in 2023 (28.3 M), divided by the total number of MA enrollees in 2023 (30.8M). $28.3\text{M} / 30.8\text{M} = 92$ percent. See Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends; Juliette Cubanski and Anthony Damico, “Key Facts About Medicare Part D Enrollment and Costs in 2023,” KFF, July 7, 2023, available at <https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023>.

all plans that offer prescription drug coverage) is just \$15 per month in 2023.¹⁰¹ The average enrollment-weighted premium for just the Part D portion of covered benefits is \$10 per month among these MA plans.¹⁰²

55. In contrast, enrollees in FFS Medicare only receive prescription drug coverage if they enroll in Medicare Part D, which costs, on average, \$40 per month in additional premiums in 2023.¹⁰³ Individuals in FFS Medicare who have prescription drug coverage pay more in premiums, on average, than individuals in MA plans who have prescription drug coverage. That is, to receive all benefits listed under Medicare Parts A and B, and prescription drug coverage, MA enrollees on average pay the cost of the Part B premium, plus \$15 per month, while FFS Medicare enrollees on average pay the cost of the Part B premium, plus \$40 per month.¹⁰⁴ Indeed, Sean Creighton, testified that MA typically covers additional prescription drug benefits over those covered by FFS Medicare, and can offer prescription drug coverage at a reduced cost to beneficiaries.¹⁰⁵

56. Third, MA plans guarantee that annual out-of-pocket expenses will not exceed a maximum threshold while FFS Medicare offers no such guarantee.¹⁰⁶ This guarantee is

¹⁰¹ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹⁰² Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹⁰³ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. See also “What is a stand-alone prescription drug plan?” *Healthinsurance.org*, available at <https://www.healthinsurance.org/glossary/stand-alone-prescription-drug-coverage>.

¹⁰⁴ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. Some enrollees may have a reduced Part B premium. See Section VII.C and “Medicare Advantage Program Payment System,” *MedPAC*, November 2021 (“MedPAC, Medicare Advantage Program Payment System”), p. 3, available at https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_ma_final_sec.pdf.

¹⁰⁵ Creighton Deposition, day 1, p. 43:7–21 (“A. The other advantage is obviously that the medical and the drug benefit are integrated typically in Medicare Advantage. So these plans are both Part C, meaning Part A plus B equals C plans, and Part D plans. And within that there is a whole other level of advantage, too, because the Part C plans can use their rebate to reduce cost sharing for drugs under Part D, and generally do, and generally have better – they typically have co-pays rather than coinsurance for drugs under Part D, particularly for preferred drugs, generics or preferred brands. So there’s a whole range of additional benefits that accrue from joining a Medicare Advantage plan for a beneficiary.”), p. 44:14–15 (“You can also use the – Part C plans can use their money to reduce Part D premium.”).

¹⁰⁶ Creighton Deposition, day 1, pp. 42:12–43:5 (“Medicare Advantage has a concept called the maximum out-of-pocket, which means that in any given year the amount that a beneficiary can spend out of pocket is capped. It was around 6,800 recently, like that; it might be a little higher now. That does not exist in fee-for-service. There’s unlimited liability. So in fee-for-service, Medicare people either have to buy a supplemental insurance to cap their liability, or a lot of people in traditional fee-for-service still have supplemental insurance through either a Medicaid program or an employer program. So about 80 percent of fee-for-service – people in fee-for-service have or must have – you know, kind of have to have some other program to control the cost. You don’t need that in Medicare Advantage because of this concept of the maximum out-of-pocket.”).

beneficial for some individuals—for example those who expect to have very high health care expenditures or who have a fixed income and are unable to afford large, unanticipated spikes in out-of-pocket health care expenditures.¹⁰⁷ In 2023, MA plans are required to provide an out-of-pocket limit for Part A and Part B services that cannot exceed \$8,300 annually for in-network services and \$12,450 annually for in-network and out-of-network services combined.¹⁰⁸ The average out-of-pocket limit observed for MA plans in 2023 is lower than what was mandated: \$4,835 for in-network services and \$8,659 for in-network and out-of-network services combined.¹⁰⁹

57. In contrast, there is no annual out-of-pocket limit for FFS Medicare, and out-of-pocket spending for FFS Medicare enrollees can exceed out-of-pocket limits set by MA plans.¹¹⁰ As discussed above, FFS Medicare enrollees may be required to bear the full cost of care for long inpatient stays and typically face coinsurance payments of 20 percent on physician visits and outpatient services, both of which can contribute to high out-of-pocket expenditures. In 2018, FFS Medicare enrollees in the top 10 percent of spenders had out-of-pocket payments that exceeded the in-network out-of-pocket limit for MA plans.¹¹¹ Consequently, out-of-pocket spending can be considerably higher under FFS Medicare than under Medicare Advantage for many individuals. A risk of high out-of-pocket expenditures is especially concerning for many

¹⁰⁷ FFS Medicare has a 20 percent coinsurance requirement for Part B coverage, so out-of-pocket spending for FFS Medicare enrollees can be substantial in cases where enrollees need frequent or costly physician services. See CMS, Medicare Costs at a Glance.

¹⁰⁸ MA implemented the out-of-pocket spending limit in 2011. Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹⁰⁹ These figures represent enrollment-weighted averages. Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings. One way that MA plans can potentially manage enrollees' out-of-pocket expenses is by controlling service use and spending through utilization-management techniques (e.g., limited provider networks or coordination of care programs to deliver appropriate services more efficiently). These savings can lower costs for enrollees through lower cost sharing or through lower premiums. See Vilsa Curto, et al., "Health Care Spending and Utilization in Public and Private Medicare," *American Economic Journal: Applied Economics*, 11(2), 2019 ("Curto et al., Health Care Spending and Utilization in Public and Private Medicare"), pp. 302–332 at pp. 302, 328.

¹¹⁰ Claire Noel-Miller, "Medicare Beneficiaries' Out-of-Pocket Spending for Health Care," *AARP Public Policy Institute*, December 2021 ("Noel-Miller, Out-of-Pocket Spending"), p. 1, available at <https://www.aarp.org/content/dam/aarp/ppi/2021/12/medicare-beneficiaries-out-of-pocket-health-care-spending.doi.10.26419-2Fppi.00105.002.pdf>.

¹¹¹ Noel-Miller, Out-of-Pocket Spending, Table 1. In 2018, MA plans were required to provide an out-of-pocket limit for Part A and Part B services that could not exceed \$6,700 for in-network services. As I explain in Section V.C, MA plan provider networks (i.e., the set of providers that provide "in-network services") can be more limited than the set of providers that accept FFS Medicare. See Gretchen Jacobson, et al., "A Dozen Facts About Medicare Advantage," *Kaiser Family Foundation*, November 13, 2018, available at <https://web.archive.org/web/20181129174017/https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage>.

Medicare beneficiaries since many Medicare beneficiaries have very limited and/or fixed income. For example, in 2019, half of all Medicare beneficiaries had incomes below \$29,650.¹¹²

58. Moreover, academic literature has found that MA confers surplus (i.e., utility gains) to Medicare beneficiaries. For example, Miller et al. (2023) use data from 2008–2017 to estimate a Medicare beneficiary’s willingness to pay for additional features covered by MA plans but not covered by FFS Medicare, such as dental, vision, and hearing coverage. The authors find that over the period 2008–2017, average consumer willingness to pay was \$604 per year for dental, vision, and hearing coverage packages that MA plans typically offer to beneficiaries without any additional premium.¹¹³ These results indicate that MA plans provide substantial benefits to consumers. In fact, the authors show that MA plans generated \$4.62 billion of surplus (i.e., utility benefits) to enrollees in 2017.¹¹⁴ Likewise, Curto et al. (2021) estimate that MA plans conferred approximately \$15 billion of surplus to enrollees in 2018.¹¹⁵

59. In sum, economic theory, market data, survey data, and academic literature all indicate that many Medicare beneficiaries prefer and benefit from the Medicare Advantage program.

C. MA Plans Have Often Provided Better or More Efficient Care than FFS Medicare

60. Academic literature has also found that MA plans can provide better or more efficient care than FFS Medicare. Following economic literature, I define more efficient care to be health care that provides the same patient outcomes while using fewer resources (i.e., while having lower health care utilization).¹¹⁶ As noted in one study, because CMS pays MA plans fixed, risk-

¹¹² Wyatt Koma, et al., “Medicare Beneficiaries’ Financial Security Before the Coronavirus Pandemic,” *Kaiser Family Foundation*, April 24, 2020, available at <https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic>.

¹¹³ Keaton Miller, et al., “The Optimal Geographic Distribution of Managed Competition Subsidies,” Working Paper, January 20, 2023 (“Miller et al., The Optimal Geographic Distribution of Managed Competition Subsidies”), p. 4, available at https://static1.squarespace.com/static/56a1484625981dd79f45da68/t/63caf1235229f06b12bda94a/1674244394942/023-01-20-Optimal_Managed_Competition_Subsidies-paper.pdf.

¹¹⁴ Miller et al., *The Optimal Geographic Distribution of Managed Competition Subsidies*, p. 5. They also estimate that the surplus for insurance companies was \$3.10 billion.

¹¹⁵ Vilsa Curto, et al., “Can health insurance competition work? Evidence from Medicare Advantage,” *Journal of Political Economy*, 129(2), 2021, pp. 570–606 (“Curto et al., Can health insurance competition work? Evidence from Medicare Advantage”) at p. 598. The paper also finds that the surplus for insurance companies was \$33 billion. While the Miller et al. (2023) and Curto et al. (2021) estimates for the surplus generated by MA plans range in value, both sets of estimates are positive and substantial.

¹¹⁶ John Wennberg, et al., “Tracking the Care of Patients with Severe Chronic Illness: The Dartmouth Atlas of Health Care 2008,” *The Dartmouth Institute for Health Policy and Clinical Practice*, 2008, p. 54, available at

adjusted payments for the total cost of care, MA plans are incentivized to “use managed care techniques to limit their costs.”¹¹⁷ A recent study of Medicare enrollees found that those enrolled in MA had a lower overall utilization of health care when compared to enrollees in FFS Medicare, while not reporting less satisfaction with the quality of their care and having similar overall health outcomes to comparable enrollees in FFS Medicare.¹¹⁸ Another study found that MA enrollees experienced lower intensity of post-acute care and fewer hospital readmissions than FFS Medicare patients, indicating more efficient care by reducing cost and maintaining or improving patient outcomes.¹¹⁹ Duggan et al. (2018) show that hospital utilization (as measured by visits, procedures, and length of stay) increased for individuals who were forced out of MA plans when MA plans completely exited the individual’s county.¹²⁰ In other words, MA plans had reduced utilization for their enrollees relative to FFS Medicare.¹²¹ Additionally, Curto et al. (2019) compared spending in MA and FFS Medicare, controlling for enrollee county, risk score, and mortality, and found that health care spending per enrollee in MA was nine percent lower than FFS Medicare in 2010.¹²² In other words, similar enrollees that would achieve similar mortality outcomes had lower spending in MA, indicating more efficient care. The study

https://data.dartmouthatlas.org/downloads/atlas/2008_Chronic_Care_Atlas.pdf (“Remember, efficiency here means using less money and fewer resources to achieve high-quality care in treating a similar set of patients over a given period of time.”).

¹¹⁷ Rajender Agarwal, et al., “Comparing Medicare Advantage And Traditional Medicare: A Systematic Review,” *Health Affairs*, 40(6), 2021, pp. 937–944 at p. 937.

¹¹⁸ Sungchul Park, et al., “Health Care Utilization, Care Satisfaction, and Health Status for Medicare Advantage and Traditional Medicare Beneficiaries With and Without Alzheimer Disease and Related Dementias,” *JAMA Network Open*, 3(3), e201809, 2020, p. 9, available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2763477> (“Hence, a higher number of medical practitioner visits among TM beneficiaries compared with MA beneficiaries may indicate inefficient care delivery in TM associated with a lack of incentive to control utilization and coordinate care [...] We detected no differences in care satisfaction between MA and TM beneficiaries with or without [Alzheimer disease and related dementias (“ADRD”)] [...] There were no or negligible differences in health status between MA and TM beneficiaries with or without ADRD.”).

¹¹⁹ Peter Huckfeldt, et al., “Less Intense Postacute Care, Better Outcomes for Enrollees in Medicare Advantage Than Those in Fee-For-Service,” *Health Affairs*, 36(1), 2017, pp. 91–100 at pp. 91, 96, 98–99.

¹²⁰ Duggan et al., *The Consequences of Health Care Privatization*, pp. 153–186 at pp. 164–166, 179.

¹²¹ Duggan et al., *The Consequences of Health Care Privatization*, pp. 153–186 at p. 179.

¹²² Curto et al., *Health Care Spending and Utilization in Public and Private Medicare*, pp. 302–332 at pp. 303–304 (“Without either adjustment [for observable and unobservable characteristics], MA spending per enrollee-month is 30 percent lower than TM spending per enrollee-month. Holding county and risk score fixed, the spending difference becomes 25 percent, and adjusting for mortality differences further reduces it to 9 percent.”).

additionally found that states with higher FFS Medicare spending had greater MA “savings,” consistent with MA’s efficiency relative to FFS Medicare.¹²³

61. Consistent with this notion, former CMS Administrator Marilyn Tavenner has stated that MA is a “game-changer” which serves as an “innovative” insurance product for millions of beneficiaries.¹²⁴ During her deposition, she also emphasized why MA plans provide a “good alternative” to FFS Medicare, noting that MA allowed CMS to move toward paying for “outcomes and quality.”¹²⁵ This is consistent with MA plans providing better or more efficient care than FFS Medicare.

62. MA plans may be more efficient relative to FFS Medicare in part due to care coordination measures, such as prior authorization or limited provider networks.¹²⁶ Such

¹²³ Curto et al., *Health Care Spending and Utilization in Public and Private Medicare*, pp. 302–332 at p. 320 (“Figure 3 shows that states with higher TM spending have greater MA ‘savings’ as measured by the percentage difference between MA spending and adjusted TM spending. This is consistent with the ‘conventional wisdom’ that higher spending TM areas are less efficient or productive (e.g., Skinner 2011).”).

¹²⁴ Deposition of Marilyn B. Tavenner (CMS), February 28, 2018 (“Tavenner Deposition”), pp. 28:1–29:2, Exhibit 1000 (“‘Medicare Advantage is the game-changer. It’s the foundation for innovative, high-quality care delivery that seniors and the country demand,’ AHIP President and CEO Marilyn Tavenner said. ‘CMS should protect millions of beneficiaries who depend on Medicare Advantage and strengthen — not undermine — the program moving forward.’”), and pp. 49:19–50:4 (“Q Okay, and do you believe that Medicare Advantage is the foundation for innovative, high-quality care delivery? A Yes, sir, I do. Q And is that an opinion that you held while you were the administrator of CMS? A While I was the administrator of CMS, I probably learned what the Medicare Advantage program was about, and I felt it was a good alternative for a fee-for-service program, and I still feel that way today.”).

¹²⁵ Tavenner Deposition, pp. 49:25–50:25 (“A While I was the administrator of CMS, I probably learned what the Medicare Advantage program was about, and I felt it was a good alternative for a fee-for-service program, and I still feel that way today. Q And can you tell us why did you, why did you believe it was a good alternative to fee-for-service? A I can answer that, and the best way is to talk about what was going on with us and the Affordable Care Act at the time, which is to say that we were looking at a way to pay for – move away from fee-for-service and pay for outcomes and quality and cost, and the Medicare Advantage program offered that. Q And can you tell us in what way the Medicare Advantage service provided a superior alternative to fee-for-service? A ‘Superior alternative’ I don’t think is what I said. I just said that it offered an alternative to a fee-for-service model which tend to focus more on process, and we were trying to move toward outcomes, if that’s helpful. Q Did you believe the Medicare Advantage program allowed CMS to move toward outcomes? A I did.”).

¹²⁶ Bruce Landon, et al., “Analysis of Medicare Advantage HMOs Compared with Traditional Medicare Shows Lower Use of Many Services during 2003–2009,” *Health Affairs*, 31(12), 2012, pp. 2609–2617 at pp. 2609–10 (“Health plans may actively manage the provider networks through which they deliver care and employ programs to promote the delivery of appropriate services and avoid excessive utilization. In addition, plans use a variety of financial incentives to physicians to influence the quality and quantity of services delivered. These are all hallmarks of integrated care. In contrast, in traditional Medicare, physicians make clinical decisions for their patients with little or no oversight.”); Rajender Agarwal, et al., “Comparing Medicare Advantage And Traditional Medicare: A Systematic Review,” *Health Affairs*, 40(6), 2021, pp. 937–944 at p. 937 (“Evidence from forty-eight studies showed that in most or all comparisons, Medicare Advantage was associated with more preventive care visits, fewer hospital admissions and emergency department visits, shorter hospital and skilled nursing facility lengths-of-stay, and lower health care spending. [...] The Centers for Medicare and Medicaid Services (CMS) pays MA plans a fixed, risk-adjusted payment for the total cost of care. This payment method incentivizes MA plans to use managed care techniques to limit their costs. For example, health maintenance organizations (HMOs) require beneficiaries to use a defined network of providers, and these providers use utilization management policies and procedures (such as prior authorization) to prevent overuse.”).

provisions can require enrollees to seek approval before utilizing expensive services and encourage enrollees to use lower-cost providers.¹²⁷ Previous research has shown that MA plans save costs relative to FFS Medicare, while simultaneously generating surplus (i.e., utility gains) for enrollees even after accounting for any consumer disutility associated with having more-limited provider access.¹²⁸ In sum, evidence suggests that MA plans are more cost efficient than FFS Medicare.

63. Moreover, research shows that because MA insurers have an incentive to reduce overall health care expenditures for enrollees, MA plans with Part D coverage offer more generous prescription drug coverage than Medicare Part D prescription drug plans.¹²⁹

64. Evidence on aggregate Medicare spending also suggests that Medicare Advantage offers efficient care. Despite the steady growth in MA enrollment since 2006, as described in Section VI.B above, overall Medicare spending has not grown as rapidly as expected. In 2010, the Congressional Budget Office overestimated mandatory spending by the federal government for health care, which includes Medicare spending, in its projections for 2010–2020.¹³⁰ This overestimation was largely related to an overestimate of Medicare spending per beneficiary—the growth rate of Medicare spending per beneficiary dropped from 6.6 percent between 1987 and 2005 to 2.2 percent between 2013 and 2019.¹³¹ Indeed, growth in average Medicare spending per beneficiary has declined substantially after 2010.¹³² Furthermore, from 2010–2021, Medicare spending per beneficiary grew more slowly than per-capita private health care

¹²⁷ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹²⁸ Curto et al, Can health insurance competition work? Evidence from Medicare Advantage, pp. 570–606 at p. 604 (“Our estimates suggest that private plans are able to obtain cost savings over traditional Medicare, sufficiently large to generate net surplus even after accounting for consumer disutility from having limited provider access.”).

¹²⁹ Amanda Starc and Robert J. Town, “Externalities and Benefit Design in Health Insurance,” *The Review of Economic Studies*, 2020, 87(6), pp. 2827–2858 at pp. 2–3 (“Stand-alone PDPs have an incentive to minimize drug expenditures, ignoring the impact on medical spending, while MA-PD plans have an incentive to minimize overall medical and drug expenditures [...] Using the detailed prescription level data with over 123 million claims, we estimate that MA-PD plan enrollees spend between 8 and 11% less on average for an identical bundle of drugs. The differences across plan type are larger for sicker enrollees. Furthermore, consistent with externalities playing a key role, the expenditure differentials are largely driven by drugs that have been explicitly identified as having large medical care offsets and treat chronic conditions like asthma, diabetes, and high cholesterol.”).

¹³⁰ “CBO’s Projections of Federal Health Care Spending,” *Congressional Budget Office*, March 17, 2023 (“CBO, Projections of Federal Health Care Spending”), available at <https://www.cbo.gov/publication/58997>.

¹³¹ CBO, Projections of Federal Health Care Spending.

¹³² Margot Sanger-Katz, et al., “A Huge Threat to the U.S. Budget Has Receded. And No One is Sure Why,” *The New York Times*, September 4, 2023, available at <https://www.nytimes.com/interactive/2023/09/05/upshot/medicare-budget-threat-receded.html>.

spending.¹³³ And while overall Medicare Advantage spending has grown at a faster rate than overall FFS Medicare spending in recent years, that growth appears to be closely related to the overall growth in MA enrollment.¹³⁴

65. In addition to evidence showing that MA plans are more efficient than FFS Medicare, evidence shows that MA plans benefit the Medicare program as a whole. Specifically, a study from 2013 shows that increases in Medicare Advantage enrollment are associated with lower hospitalization costs and shorter hospital stays for all seniors, even those in FFS Medicare.¹³⁵

66. In sum, there are many reasons why Medicare Advantage provides value to plan enrollees, such as those I have discussed in this section. Medicare Advantage plans provide beneficiaries with increased choice, allowing individuals to choose plans that better fit their preferences and needs. The benefit of this increased choice is confirmed by market data, surveys, and academic literature that indicate that many individuals prefer and benefit from MA plans over FFS Medicare. Additional benefits, lower premiums, and lower out-of-pocket costs for MA plans as compared to FFS Medicare are all reasons why Medicare beneficiaries may prefer MA plans over FFS Medicare. And finally, evidence indicates that MA plans may provide better, or more efficient, care, and that Medicare Advantage has positive spillovers to the Medicare program more generally.

VII. CMS Payments to MA Plans Are Based on Predicted Health Care Expenditures and Account for Enrollee Risk Profiles, Plan Quality, and Other Factors

67. In this section I explain that MA plans receive fixed payments from CMS in exchange for providing health insurance to enrollees, and that CMS adjusts these payments to account for the financial risk borne by MA plans. In particular, the fixed payment for each enrollee accounts for factors that relate to their predicted future health care expenditures such as the enrollee's health

¹³³ "The Facts About Medicare Spending," *Kaiser Family Foundation*, June 2023, available at <https://www.kff.org/interactive/medicare-spending>.

¹³⁴ Juliette Cubanski and Tricia Neuman, "What to Know about Medicare Spending and Financing," *Kaiser Family Foundation*, January 19, 2023, available at <https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing> ("Historically, growth in spending on Medicare Advantage is due in large part to steady growth in private plan enrollment").

¹³⁵ Katherine Baicker, et al., "The Spillover Effects of Medicare Managed Care: Medicare Advantage and Hospital Utilization," *Journal of Health Economics*, 32(6), 2013, pp. 1289–1300 at p. 1299 ("We find that increasing MA penetration results in lower hospitalization costs and shorter lengths of stay system-wide. The magnitude of these spillovers is substantial, and taking them into account suggests higher optimal MA payments than would otherwise be the case.").

profile and demographic information. I also discuss other factors that are used to determine the fixed payment received by MA plans for each enrollee.¹³⁶

A. CMS Pays MA Plans a Fixed Fee for Each Enrollee, Exposing Insurers to Financial Risk

68. As explained in Section V, the MA program contracts with private insurers to provide health insurance to Medicare beneficiaries. Under MA, CMS pays MA plan providers (such as UnitedHealth) a fixed, pre-arranged monthly payment for each MA enrollee they cover, and this payment amount is updated based on bids provided annually by MA plans.¹³⁷ As I explain in more detail in Sections VII.B and VII.C, CMS's payment to MA plans does not depend on the actual health care expenditures incurred by plan enrollees. Instead, CMS payments to MA plans reflect an estimate of predicted health care expenditures for each enrollee in the MA plan. This predicted amount varies according to the characteristics of each enrollee.¹³⁸ For example, CMS would expect a 67-year-old woman with no known diagnoses for health conditions to have relatively low costs given her health status and relatively young age as a Medicare enrollee. As a result, CMS would predict that she would incur lower health care expenditures than another enrollee who was older or who already had known diagnoses. CMS would therefore pay less to an MA plan for insuring the 67-year-old healthy woman than for insuring an older enrollee in worse health. Sections VII.B and VII.C provide discussion on how CMS pays MA plans based on enrollees' demographics and diagnoses for health conditions.

69. Because CMS payments to MA plans do not depend on the *actual* health care expenditures of covered enrollees, MA plans are exposed to financial risk, since *actual* health care expenditures that the MA plans may have to pay for their enrollees may differ from the *estimated* health care expenditures that the MA plans receive from CMS. In the above example of the 67-year-old healthy woman, CMS would not adjust its fixed payment to the MA plan later in the year even if this enrollee experienced substantial unexpected health issues during the

¹³⁶ In total, MA plans are paid the sum of their per-enrollee payments. CMS, Medicare Managed Care Manual Chapter 8, § 80 ("Monthly payments to MA organizations reflect all beneficiaries with an effective enrollment in the MA plan in question for the month for which payment is made, including those whose enrollment was effective prior to that month, and those for whom enrollment is effective as of that month.").

¹³⁷ "Report to Congress: Risk Adjustment in Medicare Advantage," *Centers for Medicare & Medicaid Services*, December 2021 ("CMS, Report to Congress: Risk Adjustment in Medicare Advantage"), p. 3, available at <https://www.cms.gov/files/document/report-congress-risk-adjustment-medicare-advantage-december-2021.pdf>.

¹³⁸ CMS, Report to Congress: Risk Adjustment in Medicare Advantage, pp. 3–4.

year such as a serious accident requiring hospitalization. In this hypothetical, the MA plan would likely incur more expenditures associated with this enrollee's care than it would receive in payment from CMS that year.¹³⁹

70. This example illustrates why paying MA plans a fixed amount per enrollee creates a system in which MA plans assume financial risks even after CMS adjusts payments for predicted health care expenditures: this happens because actual health care expenditures can be different from predicted expenditures. That is, because enrollee expenses are not perfectly predictable and can deviate substantially from the prediction, an MA plan may not receive sufficient funds to cover its costs. This is one reason why it is particularly important that insurers are properly compensated for the risks they bear when providing insurance to Medicare enrollees.

B. CMS Uses Risk Adjustment to Ensure that Payments to MA Plans Account for the Individual Risk of Each Enrollee within the Plan

71. Payments made by CMS to MA plans reflect an estimate of future health care expenditures for the plan's enrollees, where the prediction is based on what these enrollees would cost if they were enrolled in FFS Medicare and takes into account geographic variation in costs.¹⁴⁰ These estimates are not the same for each enrollee because enrollees' expected health care expenditures vary due to differences in health status and demographics. Not surprisingly, sicker individuals are more likely to incur greater health care expenditures relative to healthier individuals,¹⁴¹ just as older individuals are more likely to incur greater health care expenditures relative to younger ones.¹⁴² As explained in Section V.C, risk adjustment is the process by which payments to MA plans are adjusted to account for the risk of future health care expenditures of

¹³⁹ MA plans consider the risk profile of the plan's population as opposed to each individual enrollee. This means that an MA plan does not consider the financial risk of taking on one enrollee, but of taking on the pool of enrollees that it insures. See "Actuarial Bid Training: Introduction to Bidding," available at [Introduction to Bidding.pdf](#) when accessing "Actuarial Bid Training (ZIP)" at "Actuarial Bid Training," *Centers for Medicare & Medicaid Services*, modified September 6, 2023 ("CMS, Actuarial Bid Training: Introduction to Bidding"), p. 6 ("Projected costs that are based on actual plan experience must reflect the risk profile of that plan's population"), available at <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/actuarial-bid-training>.

¹⁴⁰ MedPAC, Report to the Congress, p. 432; CMS, Report to Congress: Risk Adjustment in Medicare Advantage, pp. 3, 9.

¹⁴¹ CMS, Report to Congress: Risk Adjustment in Medicare Advantage, pp. 3–4; MedPAC, Report to the Congress, p. 432; Hornsby Deposition, pp. 36:20–37:8.

¹⁴² Jared Ortaliza, et al., "How do health expenditures vary across the population," *Peterson-KFF Health System Tracker*, November 12, 2021, available at <https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population>.

enrollees. In its current form, risk adjustment is based on health care diagnoses and certain demographic variables, all of which are associated with different expected health care expenditures.¹⁴³

72. A central goal of risk adjustment is to ensure that insurers receive proper compensation for the risk they bear in paying for the health care expenditures that their particular pool of enrollees will incur.¹⁴⁴ Without risk adjustment, insurers may be exposed to unacceptable risks and may not have sufficient funding to cover all of the health care expenditures associated with the sicker or older beneficiaries enrolled in a plan. Risk adjustment is intended to compensate insurers for covering beneficiaries who are expected to have high health care expenditures, for example due to poor health, so that insurers will not avoid covering such beneficiaries.¹⁴⁵

73. At a high level, CMS performs the risk adjustment process by first modeling the cost of various demographic characteristics and health conditions using data from FFS Medicare to estimate the “dollar coefficients” and “relative factors” of these components. Next, CMS applies the relative factors from the model to data from the MA plans on enrollee demographic characteristics and health conditions to arrive at MA patient risk scores. In this section, I describe these components in more detail, including providing information about the model, the relative factors obtained from the model, the information used from enrollees, and the process to estimate the risk scores for MA enrollees. Then, I provide an illustrative example showing how these components fit together.

¹⁴³ CMS, Medicare Managed Care Manual Chapter 7, §§ 70.1, 70.2; MedPAC, Report to the Congress, pp. 432–433.

¹⁴⁴ Hornsby Deposition, pp. 51:16–52:4 (“Q And CMS knew when it was creating the HCC model that it was creating incentives for MAOs to find and report diagnoses that were supported by the medical records, right? A The point of choosing an additive model is to pay an MA more for people with complex medical conditions who are sicker. That’s the point; because they do have more diagnoses and because they’re sicker. Therefore, they – the MAO should be paid more for those individuals. And conversely, to pay less for the people who really have very few diagnoses or – or just very non-serious conditions. That’s the – that’s the point of an additive model.”).

¹⁴⁵ Hornsby Deposition, p. 53:16–20 (“My – the testimony – CMS’ position is that this model is meant to encourage MAOs to enroll sicker beneficiaries and care for them, and then CMS would like to pay them for – more for those sicker beneficiaries. That’s CMS’ view.”); MedPAC, Report to the Congress, p. 432 (“The purpose of risk adjustment is to ensure that plans are adequately and fairly compensated for treating all categories of enrollees—those with high medical costs as well as those with less health care utilization. If the risk-adjustment system is flawed, misaligned incentives could result in ‘favorable selection,’ in which plans have an incentive to attract certain types of beneficiaries and avoid enrolling others. Plans can achieve unwarranted profits if the risk-adjustment system overpays for some enrollees and underpays for others.”).

1. The CMS-HCC Regression Model and the Relative Factors

74. Payments to MA plans are based on estimates of the costs associated with various demographic characteristics and health conditions in the FFS Medicare population. The model CMS used to estimate the costs associated with various demographic characteristics and health conditions is called the hierarchical condition category (“CMS-HCC”) model. The CMS-HCC model estimates the average Medicare Part A and Part B costs associated with various demographic characteristics and health conditions.¹⁴⁶ In particular, the model uses data from enrollees in FFS Medicare (“FFS data”) to estimate the contribution of certain demographic characteristics (e.g., age, gender, Medicaid enrollment, and disability status) and certain health conditions to the observed health care expenditures in FFS Medicare.¹⁴⁷ The model is considered to be a multivariate regression model because it relates a dependent variable (here Medicare Part A and B expenditures) to *multiple* explanatory variables (here demographic characteristics and health conditions) and aims to isolate the incremental contribution of each of these factors to the dependent variable.¹⁴⁸ The model is prospective, meaning that the demographic and health conditions of one calendar year are used to predict Medicare Part A and B expenditures of the enrollee in a subsequent calendar year.¹⁴⁹

75. CMS estimates the CMS-HCC model using data from beneficiaries enrolled in FFS Medicare.¹⁵⁰ These FFS data include information on expenditures for Parts A and B benefits for the enrollee, enrollee demographic information (such as age, gender, Medicaid status, and disability status), and enrollee health conditions.¹⁵¹ In order to measure and identify health conditions of FFS Medicare enrollees, CMS uses the diagnosis codes associated with health care services rendered to these enrollees, which are reported to CMS on claims from medical

¹⁴⁶ CMS estimates multiple regression models for different sub-populations of Medicare beneficiaries that CMS anticipates have substantively different health care expenditures. For example, CMS estimates separate regression models for Medicare beneficiaries who live in the community, who live in long-term institutionalized settings, who are new enrollees, or who have end-stage renal disease. See CMS, Medicare Managed Care Manual Chapter 7, §§ 70.2, 70.3.

¹⁴⁷ From here on, when I discuss health care expenditures in the context of the CMS-HCC regression model, I am referring to Medicare Part A and Part B expenditures.

¹⁴⁸ CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

¹⁴⁹ MedPAC, Report to the Congress, p. 433.

¹⁵⁰ CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

¹⁵¹ CMS, Medicare Managed Care Manual Chapter 7, §§ 70, 70.1; CMS, Report to Congress: Risk Adjustment in Medicare Advantage, p. 9.

providers.¹⁵² Diagnosis information from medical providers is stipulated using diagnosis codes from the International Classification of Diseases (“ICD”),¹⁵³ which defines more than 10,000 unique diagnosis codes.¹⁵⁴ Rather than using all of these individual diagnosis codes directly in the regression model, CMS groups these codes into roughly 200 different hierarchical condition categories (“HCCs”) and uses a subset of those HCCs within the model.¹⁵⁵ These HCCs are broad groups of diagnosis codes “based on similar clinical characteristics and severity, and cost implications.”¹⁵⁶

¹⁵² CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

¹⁵³ ICD codes are the medical standard used to classify medical conditions and procedures. See “CMS and AMA Announce Efforts to Help Providers Get Ready for ICD-10,” *Centers for Medicare & Medicaid Services*, July 6, 2015, available at <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/AMA-CMS-press-release-letterhead-07-05-15.pdf>. For example, the Medicare Provider Analysis and Review Hospital Stay File, which comprises inpatient hospitalization and skilled nursing facility claims, includes “up to 10 ICD-9-CM diagnoses and 6 ICD-9-CM procedures associated with each hospital or [skilled nursing facility] stay.” The Outpatient File, which comprises “claims from institutional outpatient providers,” likewise includes ICD-9-CM diagnosis and procedure codes, though “the reporting of these codes is sporadic.” See “Analytics Issues in Using the Medicare Enrollment and Claims Data Linked to NCHS Surveys,” *National Center for Health Statistics, Office of Analysis and Epidemiology*, December 3, 2012 (“NCHS, Analytic Issues in Using the Medicare Enrollment and Claims Data”), pp. 8–9, available at https://www.cdc.gov/nchs/data/datalinkage/cms_medicare_analytic_issues_final.pdf.

¹⁵⁴ See 2022 Midyear_Final ICD-1-CM Mappings.xlsx when accessing “2022 Midyear Final ICD-10 Mappings (ZIP),” at “2022 Model Software/ICD-10 Mappings,” *Centers for Medicare & Medicaid Services* (“CMS, 2022 Midyear Final ICD-10 Mappings”), available at <https://www.cms.gov/medicarehealth-plansmedicareadvtspecratestatsrisk-adjustors/2022-model-softwareicd-10-mappings>; Hornsby Deposition, pp. 184:14–15 (“There are 15,000 ICD-9 codes. There are about 3,000 in the payment model.”). See also, Deposition of Kathleen O. Baker (UnitedHealth), May 30, 2023 (“Baker Deposition”), pp. 20:6–13, 223:16–18 (“There’s thousands – tens of thousands of diagnosis codes. About 15,000 map to HCC.”).

155 In the CMS-HCC model used prior to 2011, CMS included only 70 out of 177 (or more) possible HCCs, while the model used in 2020 included 86 out of 204 possible HCCs. CMS, Report to Congress: Risk Adjustment in Medicare Advantage, pp. 14, 17, 19; “Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter,” *Centers for Medicare & Medicaid Services*, February 19, 2010 (“CMS, Advance Notice of Methodological Changes for 2011”), pp. 8, 45, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2011.pdf>. See also Hornsby Deposition, pp. 183:13–17 (“The original CMS-HCC model assigned all diagnosis codes to an HCC. And then subsequently, CMS developed a payment model, and the payment model has a smaller subset of HCCs.”); Deposition of Biggs Cannon (UnitedHealth), June 6, 2023 (“Cannon Deposition”), pp. 18:8–13, 229:4–10 (“Q Okay. And you have already testified that there’s some – there are some diagnosis codes that do not map to an HCC; correct? [...] THE WITNESS: Not all diagnosis codes map to an HCC in the Medicare Advantage risk adjustment model.”); Baker Deposition, p. 47:2–3 (“About 15,000 ICD-9 codes map to 70-something HCC codes.”). The CMS-HCC model has changed over time, including different HCCs and different interactions between HCCs as regressors, and changing which diagnosis codes correspond to which HCC. For two examples of model changes, see the discussions in the 2011 and 2020 Advance Notices: CMS, Advance Notice of Methodological Changes for 2011 pp. 7–10; “Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model,” *Centers for Medicare & Medicaid Services*, December 20, 2018, available at <https://www.cms.gov/medicare/health-plans/medicareadvtgsspecratestats/downloads/advance2020part1.pdf>.

¹⁵⁶ CMS, Medicare Managed Care Manual Chapter 7, § 70.1. For example, instead of having two different variables in the model for the “unspecified chronic bronchitis” and “interstitial emphysema” diagnoses, CMS groups these two diagnoses into one HCC named “Chronic Obstructive Pulmonary Disease” (“COPD”). The classification of diagnosis codes is exhaustive, so CMS assigns all diagnosis codes to an HCC. See CMS, 2022 Midyear Final ICD-

76. The CMS-HCC regression model estimates the average incremental (Part A and B) costs associated with each HCC.¹⁵⁷ It might be the case that many patients with one condition, say diabetes without complication, also have another condition, say a heart attack (acute myocardial infarction), which are two different HCCs. By using the data on the sum of Part A and B costs, demographics, and HCCs for a large number of FFS Medicare enrollees with various HCCs, the CMS-HCC model can estimate the average incremental Part A and B expenditures for each HCC—in this example the HCC associated with diabetes and the HCC associated with a heart attack. The estimates of the incremental costs associated with each HCC and each demographic trait are called “dollar coefficients.”¹⁵⁸

77. Once CMS estimates the CMS-HCC regression model and obtains dollar coefficient estimates associated with each demographic characteristic and HCC, it then uses the dollar coefficient estimates to calculate what are called “relative factors.” A relative factor measures the incremental predicted health care expenditure for a given HCC or demographic characteristic relative to the average spending per enrollee in FFS Medicare.¹⁵⁹ More specifically, CMS calculates relative factors by dividing the dollar coefficients for the demographic characteristics and HCCs by the average predicted health care expenditures for a FFS Medicare enrollee in a specific year (i.e., the “denominator year”).¹⁶⁰ The relative factors

10 Mappings; “Announcement of Calendar Year (CY) 2023 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, April 4, 2022, p. 127, available at <https://www.cms.gov/files/document/2023-announcement.pdf>; “Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantages and Part D Payment Policies and Final Call Letter,” *Centers for Medicare & Medicaid Services*, April 4, 2016, p. 81, available at <https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/downloads/announcement2017.pdf>; Pope et al., *Risk Adjustment of Medicare Capitation Payments*, pp. 119–141, Figure 3; Baker Deposition, pp. 43:18–44:10 (“Q [...] HCC refers to hierarchical condition categories; is that right? A Yes. Q Okay. And what are hierarchical condition categories? A They’re the risk adjustment disease categories related for risk adjustment. Q Okay. And they’re used in the CMS HCC model to determine risk adjustment payments, correct? [...] THE WITNESS: They are used to determine appropriate payment to health plans.”); Cannon Deposition, pp. 222:24–223:6 (“Q What is a hierarchical condition category? [...] THE WITNESS: Generally speaking, within Medicare Advantage CMS creates a mapping list of diagnosis codes and HCCs, and those HCCs are how they track conditions that are present for a given Medicare Advantage beneficiary.”).

¹⁵⁷ CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

¹⁵⁸ CMS, Medicare Managed Care Manual Chapter 7, § 70.1. I recognize that the coefficients from the CMS-HCC model represent correlations (or associations) and do not necessarily capture the causal impact of each HCC on Medicare expenditures. Despite this, I subsequently use causal language to describe the coefficients and relative factors, which is consistent with CMS’s description of them.

¹⁵⁹ CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

¹⁶⁰ Over time, CMS changes which years of FFS Medicare enrollees’ data are used to estimate the regression coefficients of the CMS-HCC model. This process is known as re-calibration. See CMS, Medicare Managed Care Manual Chapter 7, § 70.1.

are used along with information from the MA plan enrollees to calculate MA enrollee risk scores, as described next.

2. Using MA Plan Patient Data to Calculate MA Risk Scores

78. After CMS calculates the relative factors, it then calculates a “risk score” for each MA enrollee. The risk score of a specific MA enrollee depends on their demographic characteristics (e.g., age, sex, Medicaid enrollment, and disability status) and HCCs (e.g., dementia with complications (HCC51), congestive heart failure (HCC85), diabetes without complication (HCC19)).¹⁶¹ To calculate the risk score, CMS receives data from MA plans regarding diagnosis codes and demographic information for all its plan enrollees.¹⁶² For each enrollee, CMS first determines the associated HCCs, and then sums the relative factors associated with their HCCs as well as the relative factors associated with their demographic characteristics.¹⁶³ The enrollee’s risk score is therefore equal to the sum of all of their relative factors.¹⁶⁴

79. CMS uses the enrollee’s risk score in calculating the payment to the MA plan for each enrollee, such that all else being equal, payments will be higher for MA enrollees with higher risk scores and lower for enrollees with lower risk scores.¹⁶⁵ Exhibit 2 summarizes how CMS

¹⁶¹ MedPAC, Report to the Congress, p. 432; CMS, Report to Congress: Risk Adjustment in Medicare Advantage, Table 5-20a, pp. 80–83.

¹⁶² CMS, Medicare Managed Care Manual Chapter 7, §§ 20, 40, 120.3.2.

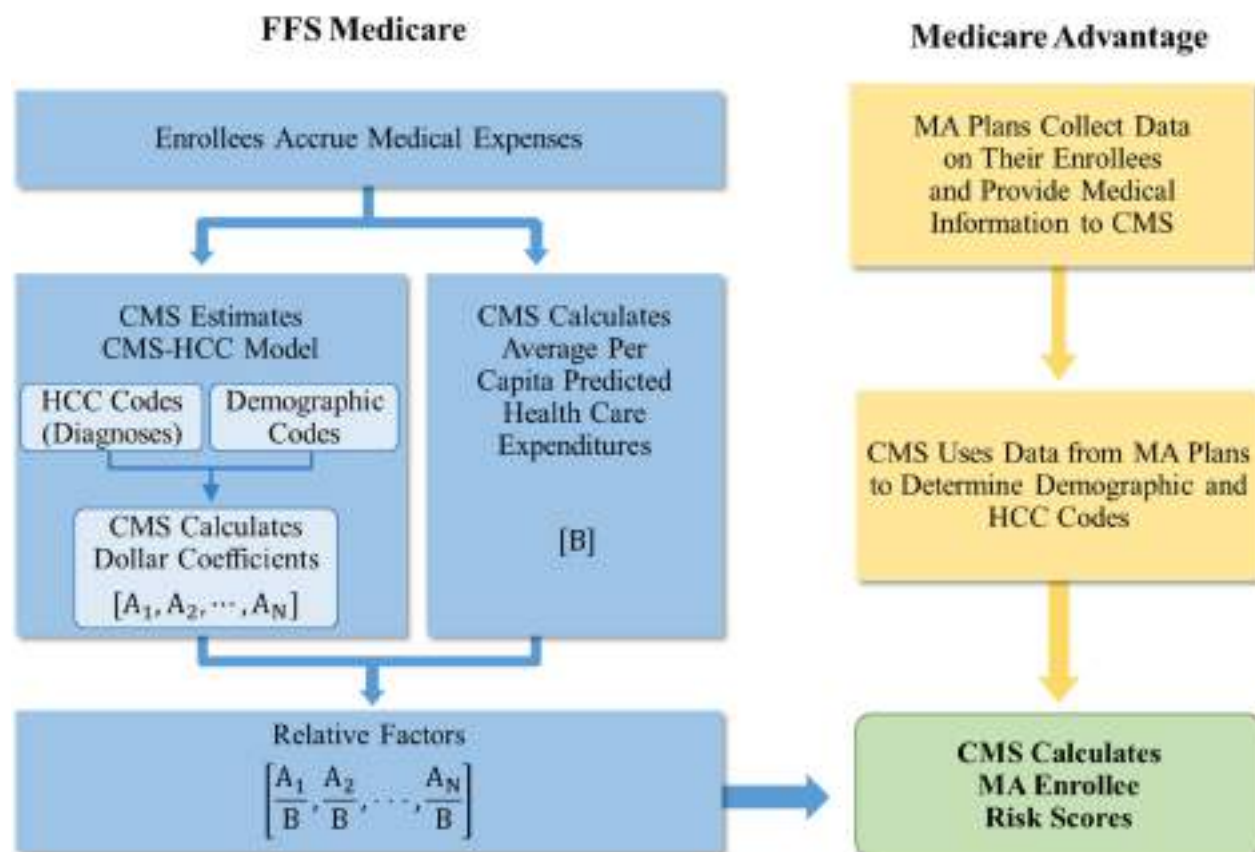
¹⁶³ CMS, Medicare Managed Care Manual Chapter 7, Table 2.

¹⁶⁴ See Limmer Deposition, pp. 66:9–68:7 (“Q The third bullet refers to a term ‘risk scores.’ What are the risk scores? Or what does the term ‘risk score’ refer to? A Risk scores are numerical calculations that provide a gauge or a value related to the – to individual beneficiaries; so its members, you know, seeking health care. And it’s related to their – their health status. So the degree to which the cost of their health care will – would be. Where 1.0 is representing an average risk, a number greater than 1.0 is representing someone that has potentially greater costs than the average, and under 1 is less than average. Q And just to be precise, you said it reflects the health status? As stated here, it reflects both the health status and the demographics characteristics of a beneficiary, correct? A The risk score is calculated from various factors, including demographics and health status. And I thought that you were asking, like, what it reflects in terms of – it reflects expected costs or projected costs relative to these – these factors. Q Right. And so the higher the risk score for a beneficiary, the more costly they’re likely to be compared to an average beneficiary? A Correct. Q And to obtain an individual beneficiary’s risk score, one would add up the values that the risk model has calculated as the appropriate values for each of the health conditions and demographic statuses for that beneficiary, correct? A It would be based on the form and processes defined in the risk model. I think – so if that – Yes, so if that model has various factors, numerical factors, then that are added together, then based on the – and there’s – there’s a lot of different categories, right? There’s – there’s, you know, all the demographic categories, all the health status categories. But basically, you go through the specifications that are laid out for the model, and you compile that – that final numerical number.”).

¹⁶⁵ MedPAC, Report to the Congress, p. 413.

calculates MA enrollee risk scores. Details of how risk scores influence payments to MA plans are discussed in Section VII.C.

Exhibit 2
How Risk Scores Are Calculated



Source: MedPAC, Report to the Congress; CMS, Medicare Managed Care Manual Chapter 7.

Note: For a given MA plan enrollee, the risk score is the sum of the relative factors that apply to that enrollee.

3. Illustrative Example of Calculating Relative Factors and Risk Score for Hypothetical Enrollee

80. Exhibit 3 below shows the components of the risk score calculation for a hypothetical enrollee. The enrollee is a male in the 70–74-year-old age bracket who has two HCCs—diabetes with chronic complications (HCC 18) and acute myocardial infarction (i.e., a heart attack)

(HCC 86).¹⁶⁶ The example in Exhibit 3 is adopted from a CMS “clinical vignette” that is based on the CMS-HCC model used in 2020.¹⁶⁷

81. The CMS-HCC model estimates dollar coefficients associated with gender and age categories, which reflect the average Part A and B expenditures for someone in each of these categories (putting aside any particular health conditions that person may have). In the example, the coefficient associated with being a male aged 70 to 74 years is \$5,615. The dollar coefficient from the CMS-HCC model associated with HCC 18 (diabetes with chronic complications) is \$3,181 and the coefficient associated with HCC 86 (acute myocardial infarction) is \$3,534. These dollar coefficients are shown in Exhibit 3.

82. To arrive at the relative factors, CMS normalizes the dollar coefficients by dividing each dollar coefficient by the average per capita predicted health care expenditure for beneficiaries in FFS Medicare in the denominator year, as described earlier. As shown in Exhibit 3, the relative factor for a 70–74-year-old male is calculated as 0.600 ($\$5,615 / \$9,365$). Similarly, the relative factor for HCC 18 (diabetes with chronic complications) is 0.340 ($\$3,181 / \$9,365$) and for HCC 86 (acute myocardial infarction) it is 0.377 ($\$3,534 / \$9,365$).

83. This individual’s risk score is therefore 1.317, calculated by summing the three relative factors.

¹⁶⁶ The HCC for heart attack is only relevant the year in which the heart attack occurs. CMS coding guidelines indicate that the ICD-10 code for acute myocardial infarction may be used with four weeks of the event. See “Hierarchical Condition Category Coding,” *American Academy of Family Physicians*, available at <https://www.aafp.org/family-physician/practice-and-career/getting-paid/coding/hierarchical-condition-category.html> (“Risk adjustment scores reset every year. Practices need to report active diagnoses annually, even chronic conditions.”); “ICD-10-CM Official Guidelines for Coding and Reporting,” *Centers for Medicare & Medicaid Services*, available at <https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-Coding-Guidelines.pdf>. (“For encounters occurring while the myocardial infarction is equal to, or less than, four weeks old, including transfers to another acute setting or a postacute setting, and the myocardial infarction meets the definition for “other diagnoses” (see Section III, Reporting Additional Diagnoses), codes from category I21 may continue to be reported. For encounters after the 4 week time frame and the patient is still receiving care related to the myocardial infarction, the appropriate aftercare code should be assigned, rather than a code from category I21. For old or healed myocardial infarctions not requiring further care, code I25.2, Old myocardial infarction, may be assigned.”)

¹⁶⁷ CMS, Report to Congress: Risk Adjustment in Medicare Advantage, pp. 14, 21; “Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter,” *Centers for Medicare & Medicaid Services*, January 30, 2019, pp. 38, 41, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Advance2020Part2.pdf>; “Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” *Centers for Medicare & Medicaid Services*, April 1, 2019 (“CMS, Announcement of 2020 Medicare Advantage Capitation Rates”), p. 81, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2020.pdf>. The CMS-HCC model used in 2020 was estimated using 2014 diagnostic data and 2015 spending data, and was normalized using 2015 as the denominator year.

84. By construction, the average risk score is 1.0 for the FFS Medicare population used to estimate the relative factors.¹⁶⁸ As such, a FFS Medicare enrollee with an “average health status” has a risk score of 1.0.¹⁶⁹ The hypothetical individual in the example with a risk score of 1.317 has demographic characteristics and HCCs associated with higher than average health risk, as is evidenced by the fact that their risk score is greater than 1.0.

Exhibit 3
Hypothetical Example of Calculating a Risk Score

Demographics and health conditions	Dollar Coefficient [a]	Average per capita predicted expenditure per year [b]	Relative factors [c] = [a] ÷ [b]
1. Male, age 70–74	\$5,615	\$9,365	0.600
2. Diabetes with chronic complications (HCC 18)	\$3,181	\$9,365	0.340
3. Acute myocardial infarction (HCC 86)	\$3,534	\$9,365	0.377
Risk score			1.317

Source: CMS, “Report to Congress: Risk Adjustment in Medicare Advantage,” pp. 20–22; CMS, Announcement of 2020 Medicare Advantage Capitation Rates, p. 81.

Note: This table is based on the “clinical vignette” hypothetical example from CMS. The Dollar Coefficients [a] are from the Version 24 CMS-HCC model for the Full Benefit Dual Aged community segment, as estimated using 2014 data on diagnoses and 2015 data on expenditures provided in the source. Numbers in this table are used for illustrative purposes.

C. CMS’s Payments to Medicare Advantage Plans Are Based on Enrollee Risk Scores and Account for Plan Quality

85. In this section, I explain how CMS’s payments to MA plans relate to the risk scores of the plans’ enrollees as well as to the quality of the plans. Specifically, CMS compensates MA plans using a methodology that compares a CMS benchmark against a bid from the MA plan. This methodology also incorporates enrollee risk scores and payment adjustments to reward plans for providing high-quality services. This payment methodology is described next.

¹⁶⁸ CMS, Medicare Managed Care Manual Chapter 7, §§ 70.1, 70.5.1. When the model is used to predict risk scores for years other than the denominator year, a normalization factor for each year is calculated so that the average FFS Medicare enrollee gets a risk score of 1.0 in subsequent years. See CMS, Medicare Managed Care Manual Chapter 7, § 90.

¹⁶⁹ “Average health status” in this context includes both the health conditions and the demographic factors associated with health. For example, to the extent being in an older age group and being male is associated with greater health costs than the Medicare population as a whole, an older male enrollee’s risk score will reflect the health risks associated with his demographics.

86. Payments from CMS to MA plans depend on a benchmark, which CMS calculates for each county, and which serves as a baseline for payments to MA plans.¹⁷⁰ The benchmark is based on the average expected health care expenditures for a resident of the county with average health status (i.e., a risk score of 1.0) in FFS Medicare.¹⁷¹ This benchmark factors in average per capita Part A and Part B monthly expenditures from FFS Medicare beneficiaries residing in the county.¹⁷² By creating a benchmark for each county, CMS pays MA plans in a way that accounts for differences in health care expenditures and utilization across different geographic regions. For example, in 2023, the benchmark in Wrangell, Alaska—a county with relatively high costs and/or high utilization—is \$1,468.31; the benchmark in Miami-Dade, Florida is \$1,105.92; while the benchmark in Marshall, Iowa—a relatively low cost and/or low utilization county—is \$936.54.¹⁷³ This means that, all else equal, an MA plan in Wrangell, Alaska or Miami-Dade, Florida will be paid more per enrollee than an MA plan in Marshall, Iowa.

87. Payments from CMS to MA plans also incorporate adjustments that reward plans for providing high-quality services through what is known as “star ratings.”¹⁷⁴ CMS created the star ratings system to measure plan quality and incentivize insurers to offer high-quality plans, as

¹⁷⁰ Limmer Deposition, pp. 52:6–53:7 (“Q So the phrase ‘release of MA Rate Book,’ what is the MA Rate Book? A The MA Rate Book is – it’s basically a compilation of the various rates that CMS would pay for – for individuals that enroll in the Medicare Advantage Program. So those are – they vary across the country by geographic area. And each – each area that – that’s represented in that rate book has a unique rate. Q And those are generally by county, correct? A Correct, by county. Q And the county rate, is that also sometimes called a benchmark? A Yes. Those – those two terms are similar. Q And the benchmark that’s published in the MA Rate Book by county, is it – is it accurate to say that it’s a – a standardized benchmark? A It is standardized for risk. Yes. Basically, yes, it’s a standardized benchmark, correct. Q And so what that means, it’s the benchmark set for a 1.0 population, correct? A Yes.”).

¹⁷¹ MedPAC, Report to the Congress, p. 419.

¹⁷² The counties are organized into quartiles based on this average FFS Medicare spending. “The highest spending quartile of counties has benchmarks set at 95 percent of local FFS Medicare spending. The next highest spending quartile of county benchmarks is set at 100 percent of FFS Medicare spending, followed by the third highest quartile set at 107.5 percent of FFS Medicare spending. The lowest spending quartile has benchmarks set at 115 percent of local FFS Medicare spending. (U.S. territories are treated like counties in this low-spending quartile.) Counties can move among quartiles from year to year and in doing so receive a blended quartile factor; for example, a county moving from the 100 percent quartile in 2021 to the 107.5 percent quartile in 2022 would have a blended rate of 103.75 percent.” See MedPAC, Report to the Congress, pp. 420–421, 455.

¹⁷³ See CountyRate2023.csv when accessing “2023 MA Rate Book (ZIP),” at “2023,” *Centers for Medicare & Medicaid Services*, available at <https://www.cms.gov/medicarehealth-plansmedicareadvgtgspecratestatsratebooks-and-supporting-data/2023>.

¹⁷⁴ See Jeannie Fuglesten Biniek, et al., “Spending on Medicare Advantage Quality Bonus Payments Will Reach at Least \$12.8 Billion in 2023,” *Kaiser Family Foundation*, August 9, 2023, available at <https://www.kff.org/medicare/issue-brief/spending-on-medicare-advantage-quality-bonus-payments-will-reach-at-least-12-8-billion-in-2023/> (“To encourage Medicare Advantage plans to compete for enrollees based on quality, the Affordable Care Act (ACA) established a quality bonus program that increases payments to plans based on a five-star rating system.”).

well as to provide Medicare beneficiaries with information about the quality and performance of MA plans.¹⁷⁵ The star rating system measures five broad “domains” of plan performance: offering screenings, tests, and vaccines for staying healthy, managing chronic care, enrollee experience, enrollee complaints, and customer service.¹⁷⁶ Plans are rated up to five stars, in half star increments.¹⁷⁷

88. MA plans are incentivized to offer attractive plans to potential enrollees and to perform well on their ratings.¹⁷⁸ There are two financial incentives. First, CMS provides “Quality Bonus Payments” which increase the relevant CMS benchmark (and thus the baseline for payments to MA plans) for plans that realize at least four stars in the star rating system.¹⁷⁹ The second incentive is a higher payment, through a “rebate multiplier,” for MA plans that bid below the benchmark. The rebate multiplier is applied to the difference between the bonus-adjusted benchmark and the bid, and as a result, plans with higher star ratings can receive greater rebate payments. Specifically, the difference between the bid and the benchmark is multiplied by the rebate multiplier, which is a factor equal to 50, 65, or 70 percent, depending on the plan’s star rating.¹⁸⁰ This leads to a rebate payment from CMS, which is also risk-adjusted based on the risk

¹⁷⁵ See MedPAC, Medicare Advantage Program Payment System, p. 1; “Medicare 2022 Part C & D Star Ratings Technical Notes,” *Centers for Medicare & Medicaid Services*, October 4, 2021 (“CMS, Medicare 2022 Part C & D Star Ratings Technical Notes”), p. 1, available at <https://www.cms.gov/files/document/2022-star-ratings-technical-notes-oct-4-2022.pdf>. During the coronavirus public health emergency, CMS relaxed MA quality reporting rules, impacting 2022 star ratings and 2023 payment rates (which are based on 2022 ratings). Some plans that would not otherwise have received quality bonuses in 2023 will receive bonus payments due to the relaxation of reporting rules. See MedPAC, Report to the Congress; p. 446.

¹⁷⁶ CMS, Medicare 2022 Part C & D Star Ratings Technical Notes, pp. 3–4, 10.

¹⁷⁷ CMS, Medicare 2022 Part C & D Star Ratings Technical Notes, p. 3.

¹⁷⁸ Plans rated at four-and-a-half or five stars receive a rebate payment of 70 percent of the difference between the bid and the benchmark. Plans rated at three-and-a-half or four stars, as well as new plans, receive a rebate payment of 65 percent. Finally, plans rated at three or fewer stars receive a rebate payment of 50 percent. See CMS, Advance Notice of Methodological Changes for 2023, Table II-3 on p. 23.

¹⁷⁹ As explained in fn. 172 above, counties are organized into quartiles based on average FFS Medicare spending, with benchmarks set at a certain percentage of local FFS Medicare spending depending on the quartile. For high-rated plans, CMS adds five percentage points to the benchmark percentage. For example, a five-star plan in a county with the lowest spending quartile would have a benchmark set at 120 percent of local FFS Medicare spending (115 percent + 5 percent). By contrast, a low-rated plan within the same county would have a benchmark set at 115 percent of local FFS Medicare spending. See CMS, Advance Notice of Methodological Changes for 2023, pp. 18–20, Table II-2. Quality Bonus Payments originated in 2012 after the Affordable Care Act required CMS to incorporate star ratings into payments to MA plans. See also “Evaluation of the Medicare Quality Bonus Payment Demonstration: Final Report,” *L&M Policy Research*, February 2016, p. 4, available at <https://innovation.cms.gov/files/reports/maqbpdemonstration-finalevalrpt.pdf>.

¹⁸⁰ “Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, February 2, 2022 (“CMS, Advance Notice of Methodological Changes for 2023”), Table II-3 on p. 23, available at <https://www.cms.gov/files/document/2023-advance-notice.pdf>.

score of the plan's enrollees.¹⁸¹ CMS requires the insurer to return these funds to its enrollees in some form, such as by providing supplemental benefits or reducing premiums.¹⁸² Most MA enrollees (71 percent) are in plans with star ratings of four or higher, which means that most MA enrollees are in plans that receive Quality Bonus Payments, as well as higher rebates (if bidding below the benchmark).¹⁸³

89. When proposing a plan for a particular county, MA plans submit a "bid" to CMS that is based on both the benefits (including financial parameters of the benefit structure such as copayments) that the plan will offer its enrollees as well as what the MA plans require as monthly compensation from CMS (based on historical trends).¹⁸⁴ To determine how much to pay the MA insurer for its plan in a particular county, CMS compares this bid against the benchmark.¹⁸⁵

90. MA plans choose both their plan benefits and their bid amount when making an offering. Both of these components can impact an insurer's prediction of future health care expenditures, and MA plans may face tradeoffs between these two components.¹⁸⁶ For example, the plan may choose to offer more benefits, but then could require a higher bid to cover any higher predicted costs. In turn, a particular bid amount would have implications for what benefits the insurer decides to cover.

¹⁸¹ MedPAC, Medicare Advantage Program Payment System, p. 3.

¹⁸² Plans can also allocate some of the rebate towards administrative expenses and margins. See MedPAC, Medicare Advantage Program Payment System, p. 3; MedPAC, Report to the Congress, p. 420.

¹⁸³ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹⁸⁴ 42 CFR § 422.254, "Submission of bids," available at <https://www.law.cornell.edu/cfr/text/42/422.254>; Deposition of Melissa Sedor (UnitedHealth), June 29, 2023 ("Sedor Deposition"), pp. 10:8–10, 28:3–31:24; CMS, Actuarial Bid Training: Introduction to Bidding, p. 4.

¹⁸⁵ MA plans can serve one or more counties, and CMS adjusts its payments based on the county or counties in which the enrollees reside. CMS pays local MA plans and regional MA plans slightly differently. Regional plans were created to improve access to Medicare Advantage plans for rural beneficiaries. They can cover statewide or multi-state regions. See MedPAC, Medicare Advantage Program Payment System, p. 1; Meredith Freed, et al., "Medicare Advantage in 2022: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings," *Kaiser Family Foundation*, August 25, 2022, available at <https://web.archive.org/web/20230211090856/https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings>. In this section, I focus on local plans, though the methodology for regional plans is conceptually similar. See CMS, Actuarial Bid Training: Introduction to Bidding, pp. 12–14.

¹⁸⁶ CMS, Actuarial Bid Training: Introduction to Bidding, pp. 4–6; Sedor Deposition, pp. 28:3–31:24 ("Q Okay. And then the number you give CMS is what amount of money it needs to cover the benefits it hopes to provide assuming the average risk score is 1; correct? A Correct. The 1.0 bid is the amount of money we would need from CMS assuming the average risk score was 1 to cover the benefits we have planned for that member for each plan.").

91. Insurers compete by offering plans with different attributes.¹⁸⁷ When bidding below the benchmark, plans must use the rebate to provide additional benefits to enrollees, whether that is through reduced cost sharing, reduced premiums, or supplemental benefits, such as dental or vision benefits.¹⁸⁸ Competition between MA plans and the desire to offer these additional benefits may incentivize insurers to place bids below the benchmark. Plans may also offer additional supplemental benefits not financed by the rebate and can charge premiums to enrollees to cover those benefits.¹⁸⁹

92. MA plans cannot submit excessively high bids: they must adhere to CMS policies that limit the maximum bid they are allowed to make above the Medicare benefits they need to cover, mandatory or optional supplemental benefits, and administrative and operational costs.¹⁹⁰ When choosing plan benefits and their bid amount, MA insurers must also consider that CMS limits their profits through the Medical Loss Ratio, or MLR, as discussed in Section V.C above. Because insurers are required to spend at least 85 percent of their premium revenues on patient care, they cannot, for example, charge high premiums without providing correspondingly more generous benefits.

93. Actual payments to an MA plan depend on whether their bid is higher or lower than the benchmark. If the bid is higher, the enrollees must pay a premium, and if the bid is lower, the plans receive a rebate, which as described above, depends on the difference between the benchmark and the plan bid, and on the plan's star rating. CMS uses risk adjustment to account for the fact that some beneficiaries have higher than average costs while others have lower than average costs. The rest of this section explains the scenarios where (1) the bid is equal to or

¹⁸⁷ MA insurers in more competitive markets are incentivized to offer more generous plans to attract beneficiaries. As one study demonstrates, reduced competition among MA insurers may reduce plan generosity. See Daria Pelech, "Paying more for less? Insurer competition and health plan generosity in the Medicare Advantage program," *Journal of Health Economics*, 61, 2018, pp. 77–92.

¹⁸⁸ MedPAC, Report to the Congress, p. 420. See also, Limmer Deposition, p. 149:9–21 ("Q And so I think this is what you were talking about before, which is the plan has to take that rebate amount that it calculated and it has to allocate it between these various categories of what we're calling supplemental benefits; namely, reducing A/B cost sharing, other A/B mandatory supplemental benefits; Part B premium buydown, Part B basic premium buydown, and Part D supplemental premium buydown, correct? A Yes. And those are the only options.").

¹⁸⁹ MedPAC, Report to the Congress, p. 420.

¹⁹⁰ CMS regulates MA plan's "gain/loss margin," or the revenue margin that the MA plan can accrue above the revenue required by the plan to cover Medicare-covered benefits, mandatory or optional supplemental benefits, and costs to cover the administration and operation of the MA bid. The aggregate "gain/loss margin" across an MA insurer's plans cannot be more than 5.5 percent without CMS approval. See "Instructions for Completing the Medicare Advantage Bid Pricing Tools For Contract Year 2023," *Centers for Medicare & Medicaid Services*, February 2022, available at <https://www.cms.gov/files/document/draft-instructions-completing-medicare-advantage-bid-pricing-tools-cy2023.pdf>, pp. 13, 25–27, 31.

higher than the benchmark, and (2) the bid is below the benchmark. These scenarios are also illustrated via numerical examples below.

1. MA Plan Bid Is Equal to or Higher than the Benchmark

94. If the insurer's MA plan bid is equal to or *higher* than the benchmark, CMS sets a monthly enrollee "base rate" equal to the benchmark. This base rate is then adjusted to account for the risk score of the plan's enrollees. When the bid is higher than the benchmark, each enrollee in the plan pays the insurer the same premium,¹⁹¹ which is equal to the difference between the insurer's bid and CMS's benchmark.¹⁹² CMS then makes an additional adjustment to the payment to the MA plan for each enrollee based on their individual risk score and on the MA plan's premium amount. This adjustment is called the "enrollee premium adjustment" and compensates the insurer for any risk it bears from receiving identical (i.e., not risk-adjusted) premiums from individual enrollees.¹⁹³ The sum of the enrollee premium adjustments is zero if the average enrollee risk scores across all enrollees in the plan is 1.0.

95. Exhibit 4 shows an example for the per-enrollee monthly payment that a plan would receive if it bid above the benchmark. Consider a simplified example, where the benchmark is \$1,000. The plan enrolls two individuals, one with a risk score of 0.9, and one with a risk score of 1.1. The plan bids \$1,100 to CMS. Exhibit 4 shows the payment for two different plans, one with a star rating of 3 (Plan Alpha), and one with a star rating of 5 (Plan Beta).

96. Since Plan Alpha has a 3-star rating, it does not qualify for the Quality Bonus Payment, so CMS uses the benchmark (\$1,000) as its base rate. The plan collects \$100 in premium from each enrollee, which is the difference between its bid and the benchmark. For each individual, CMS pays Plan Alpha an amount equal to the base rate multiplied by the individual's risk score, plus or minus any necessary enrollee premium adjustment (the individual premium adjustments are offset in aggregate if the average risk score across all enrollees is 1.0). Thus, for the low-risk individual with risk score 0.9, CMS pays Plan Alpha the risk-adjusted benchmark, \$900 ($\$1,000 \times 0.9$), minus \$10 ($\$100 \times (0.9 - 1)$), the enrollee premium adjustment, for a total of \$890. The

¹⁹¹ This premium is incremental to the Part B premium that all enrollees in Medicare pay (which is \$164.90 per month in 2023). See CMS, 2023 Medicare Parts A & B Premiums and Deductibles; MedPAC, Medicare Advantage Program Payment System, p. 2.

¹⁹² MedPAC, Medicare Advantage Program Payment System, pp. 2–3.

¹⁹³ MedPAC, Medicare Advantage Program Payment System, pp. 2–3.

individual pays a premium of \$100, but the plan will receive \$90 “in premium” for this individual (from the patient and CMS combined) due to the negative premium adjustment. For the high-risk individual with risk score 1.1, CMS pays Plan Alpha the risk-adjusted benchmark, \$1,100 ($\$1,000 \times 1.1$), plus \$10 ($\$100 \times (1.1 - 1)$), the enrollee premium adjustment, for a total of \$1,110. In this case, the plan receives more than the premium paid by the individual, as CMS pays a premium adjustment of \$10. The enrollee premium adjustment means that CMS, not enrollees, pays the risk adjustment associated with the \$100 premium for that enrollee.

97. Plan Beta has a 5-star rating, so it benefits from the bonus-adjusted benchmark. The plan receives a Quality Bonus Payment that increases the benchmark by 5 percent to \$1,050.¹⁹⁴ The plan collects \$50 from each enrollee, the difference between its bid (\$1,100) and the bonus-adjusted benchmark (\$1,050). For each enrollee, CMS pays Plan Beta an amount equal to the bonus-adjusted benchmark multiplied by the individual’s risk score, plus or minus any necessary premium adjustments. So, for the low-risk individual, CMS pays Plan Beta the risk-adjusted and bonus-adjusted benchmark, \$945 ($\$1,050 \times 0.9$) minus \$5 ($\$50 \times (0.9 - 1)$), the enrollee premium adjustment, for a total of \$940. For the high-risk individual, CMS pays Plan Beta the risk-adjusted and bonus-adjusted benchmark, \$1,155 ($\$1,050 \times 1.1$) plus \$5 ($\$50 \times (1.1 - 1)$), the enrollee premium adjustment, for a total of \$1,160.

98. The total payment that Plan Alpha receives from CMS for these two enrollees, with an average risk score of 1.0, is equivalent to twice the benchmark. The payment that Plan Beta receives from CMS is equivalent to twice the bonus-adjusted benchmark.

¹⁹⁴ Counties are organized into quartiles based on average FFS Medicare spending, with benchmarks set at a certain percentage of local FFS Medicare spending depending on the quartile. For high-rated plans, CMS adds five percentage points to the benchmark percentage. For the examples throughout Section VII.C, I assume the plan is in a county in the 2nd highest quartile of FFS Medicare spending, and thus has a benchmark set at 100 percent of local FFS Medicare spending. With the Quality Bonus Payment, this means the bonus-adjusted benchmark is 105 percent of local FFS Medicare spending. See fn. 179 above.

Exhibit 4**Illustration of Medicare Advantage Plan Payment for Plans Bidding Above the Benchmark**

		Plan Alpha Lower Quality Plan, 3 Stars		Plan Beta Higher Quality Plan, 5 Stars	
		Low Risk	High Risk	Low Risk	High Risk
1.	CMS Plan Benchmark	[a]	\$1,000	\$1,000	\$1,000
2.	Plan Star Rating Bonus Percentage	[b]	0%	5%	5%
3.	Quality Bonus Payment	[c] = [a] x [b]	\$0	\$50	\$50
4.	Bonus-Adjusted Benchmark	[d] = [a] + [c]	\$1,000	\$1,050	\$1,050
5.	Bid	[e]	\$1,100	\$1,100	\$1,100
6.	CMS Base Rate	[f] = [d]	\$1,000	\$1,050	\$1,050
7.	Risk Score	[g]	0.9	1.1	1.1
8.	Risk Adjusted Payment	[h] = [f] x [g]	\$900	\$1,100	\$1,155
9.	Enrollee Premium	[i] = [e] - [f]	\$100	\$50	\$50
10.	CMS Enrollee Premium Adjustment	[j] = ([g]-1) x [i]	-\$10	-\$5	\$5
11.	Total CMS Payment to Plan	[k] = [h] + [j]	\$890	\$940	\$1,160
12.	Total Payment to Plan	[l] = [i] + [k]	\$990	\$990	\$1,210

Source: MedPAC, Medicare Advantage Program Payment System; CMS, Advance Notice of Methodological Changes for 2023.

Note: In this example, there are two plans, one with a 3-star rating, and one with a 5-star rating. Each plan has two enrollees, one with a risk score of 0.9, and one with a risk score of 1.1. Since both plans are bidding above the bonus-adjusted benchmark, neither qualifies for rebates.

2. MA Plan Bid Is Lower than the Benchmark

99. If, the insurer's MA plan bid is *lower* than the benchmark, CMS sets the monthly enrollee base rate equal to the bid. The plan enrollees will not have an incremental premium to the Part B premium, and in some cases they may pay a reduced Part B premium.¹⁹⁵ One report indicates that over 7 in 10 MA enrollees pay no incremental premium, indicating that the insurer bids are often at or below CMS's benchmark.¹⁹⁶ CMS also adjusts the base rate to account for the risk scores of the plan's enrollees. In addition, when the MA plan bid is lower than the benchmark, CMS provides the MA plan with a rebate, as explained earlier, which depends on the plan's star rating and is also adjusted based on enrollees' risk scores.¹⁹⁷

100. Exhibit 5 shows an example of the per-enrollee monthly payment that a plan would receive if it bid below the benchmark. As in the previous example, the benchmark is \$1,000 and the plan enrolls two individuals, one with a risk score of 0.9, and one with a risk score of 1.1. Similar to the prior exhibit, Exhibit 5 shows two plans, one with a 3-star rating (Plan Gamma),

¹⁹⁵ MedPAC, Medicare Advantage Program Payment System, p. 3.

¹⁹⁶ Ochieng et al., Medicare Advantage in 2023: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings.

¹⁹⁷ MedPAC, Medicare Advantage Program Payment System, p. 3.

and one with a 5-star rating (Plan Delta). Plan Gamma has a 3-star rating and does not qualify for a Quality Bonus Payment, so its benchmark is not adjusted. Here, the plans bid \$900. CMS uses the bid as its base rate. For each enrollee, CMS pays Plan Gamma an amount equal to the base rate multiplied by the individual's risk score. So, for the low-risk enrollee with a risk score of 0.9, CMS pays Plan Gamma \$810 ($\900×0.9). For the high-risk individual with a risk score of 1.1, CMS pays Plan Gamma \$990 ($\900×1.1). Since Plan Gamma bids below the benchmark, it also receives a rebate from CMS for each enrollee (which the plan must redistribute to enrollees as additional benefits or as a reduced Part B premium).¹⁹⁸ As a 3-star plan, Plan Gamma's per-enrollee rebate multiplier is 50 percent.¹⁹⁹ For the low-risk individual, the rebate is equal to \$45, the difference between the risk-adjusted bid and the risk-adjusted benchmark, multiplied by the rebate multiplier $[(\$1,000 - \$900) \times 0.9] \times 0.5$. Plan Gamma receives a rebate of \$55 for the high-risk enrollee $[(\$1,000 - \$900) \times 1.1] \times 0.5$.

101. Plan Delta has a 5-star rating, so receives the Quality Bonus Payment. As in the previous example, the benchmark is increased five percent. For each enrollee, CMS pays Plan Delta an amount equal to the base rate (i.e., the bid) multiplied by the individual's risk score. Thus, for the low-risk individual, with risk score 0.9, CMS pays Plan Delta \$810 ($\900×0.9). For the high-risk individual, with risk score 1.1, CMS pays Plan Delta \$990 ($\900×1.1). Plan Delta also receives a rebate from CMS but is eligible for a 70 percent rebate multiplier due to its quality rating.²⁰⁰ For the low-risk individual, the rebate is equal to \$94.50, the difference between the risk-adjusted and bonus-adjusted benchmark and the risk-adjusted bid multiplied by the rebate multiplier $[(\$1,050 - \$900) \times 0.9] \times 0.7$. After a similar calculation, CMS pays Plan Delta \$115.50 as a rebate for the high-risk individual $[(\$1,050 - \$900) \times 1.1] \times 0.7$.

102. The total payment that Plan Gamma receives from CMS for these two enrollees is below twice the benchmark but above twice the bid due to the rebate (average payment of \$950). The total payment that Plan Delta receives from CMS for these two enrollees is above twice the benchmark (average payment of \$1,005) due to the rebate and the Quality Bonus Payment. And because the bid is below the benchmark, enrollees do not pay a premium.

¹⁹⁸ MedPAC, Medicare Advantage Program Payment System, p. 3.

¹⁹⁹ CMS, Advance Notice of Methodological Changes for 2023, Table II-3 on p. 23.

²⁰⁰ CMS, Advance Notice of Methodological Changes for 2023, Table II-3 on p. 23, available at <https://www.cms.gov/files/document/2023-advance-notice.pdf>.

Exhibit 5**Illustration of Medicare Advantage Plan Payment for Plans Bidding Below the Benchmark**

		Plan Gamma Lower Quality Plan, 3 Stars		Plan Delta Higher Quality Plan, 5 Stars	
		Low Risk	High Risk	Low Risk	High Risk
1.	CMS Plan Benchmark [a]	\$1,000	\$1,000	\$1,000	\$1,000
2.	Plan Star Rating Bonus Percentage [b]	0%	0%	5%	5%
3.	Quality Bonus Payment [c] = [a] x [b]	\$0	\$0	\$50	\$50
4.	Bonus-Adjusted Benchmark [d] = [a] + [c]	\$1,000	\$1,000	\$1,050	\$1,050
5.	Bid [e]	\$900	\$900	\$900	\$900
6.	CMS Base Rate [f] = [e]	\$900	\$900	\$900	\$900
7.	Risk Score [g]	0.9	1.1	0.9	1.1
8.	Risk Adjusted Payment [h] = [f] x [g]	\$810	\$990	\$810	\$990
9.	Rebate Multiplier [i]	0.5	0.5	0.7	0.7
10.	Rebate [j] = ([d]-[f]) x [i]	\$50	\$50	\$105	\$105
11.	Risk Adjusted Rebate [k] = [g] x [j]	\$45.00	\$55.00	\$94.50	\$115.50
12.	Total CMS Payment to Plan [l] = [h] + [k]	\$855.00	\$1,045.00	\$904.50	\$1,105.50

Source: MedPAC, Medicare Advantage Program Payment System; CMS, Advance Notice of Methodological Changes for 2023.

Note: In this example, there are two plans, one with a 3-star rating, and one with a 5-star rating. Each hypothetical plan has two enrollees, one with a risk score of 0.9, and one with a risk score of 1.1. Since both plans are bidding below the bonus-adjusted benchmark, both qualify for rebates.

D. Reporting Complete Diagnosis Information Is Important for Medicare Advantage Insurers

103. As explained earlier in this report and is further detailed above in Sections VII.A–C, enrollees’ diagnosis codes (i.e., ICD codes) affect risk scores, and these affect CMS payments to MA plans. These CMS payments ensure that plans can offer the full array of health care services to plan members. If the diagnosis information that determines payments to MA plans is incomplete, MA plans risk not being reimbursed sufficiently to cover their expected costs, and MA insurers might attempt to avoid providing insurance for those who are very sick. Because of this, MA insurers are incentivized to provide complete enrollee diagnosis information to CMS.²⁰¹ Additionally, having complete information about enrollee health status can be helpful in providing more efficient and/or better care.²⁰² For example, knowing that an enrollee has

²⁰¹ MedPAC, Report to the Congress, p. xxviii (“MA plans have a financial incentive to ensure that their providers record all possible diagnoses: Each diagnosis documented raises an enrollee’s risk score, and higher enrollee risk scores result in higher payments to the plan.”).

²⁰² “Importance of Documentation” *U.S. Department of Health & Human Services, Office of Inspector General*, January 30, 2012, available at <https://oig.hhs.gov/newsroom/oig-podcasts/importance-documentation> (“Good documentation is important to protect your patients. Good documentation promotes patient safety and quality of care. Complete and accurate medical recordkeeping can help ensure that your patients get the right care at the right time. At the end of the day, that’s what really matters.”).

diabetes before they develop significant complications can help MA plans and enrollees better manage care and can lead to better health outcomes.

104. Given these incentives to ensure a complete record of enrollee diagnosis information, MA plans, such as UnitedHealth, often take actions to capture complete diagnosis information for their plan enrollees.²⁰³ For example, MA plans have taken steps to review medical records and report all diagnoses that are supported in the medical record, even those that were not previously reported in claim submissions.²⁰⁴ MA plans have also used home visits to conduct health assessments of enrollees and report diagnoses that are found.²⁰⁵ Without this type of additional review, the plan's information about its enrollees' health conditions may not be complete.

105. MA insurers and FFS Medicare have different incentives concerning the submission of diagnosis codes to CMS. As explained above, MA insurers have an incentive to identify and record all relevant diagnoses so that they can receive adequate compensation for the risk they bear. In contrast, physicians billing to FFS Medicare are compensated by CMS for each procedure performed so long as there is a *single* diagnosis that supports a need for the services provided. Therefore, these physicians do not have the same incentives to submit complete diagnosis information.²⁰⁶ Indeed, information on diagnoses for claims submitted for FFS Medicare enrollees through Medicare Part B can be "sporadic," potentially reflecting these providers' diminished incentive to submit complete information on diagnoses.²⁰⁷

²⁰³ MedPAC, Report to the Congress, p. 437 ("MA plans use several mechanisms that do not exist in FFS Medicare to document diagnoses for their enrollees.").

²⁰⁴ MedPAC, Report to the Congress, p. 437 ("MA plans often identify enrollees with additional HCCs by using an enrollee's historical information (e.g., electronic health records, claims, or risk score data), when it is available, or by identifying likely diagnoses in data that are not used in MA risk adjustment, such as prescription drug data (e.g., a prescription for insulin likely indicates a diabetes diagnosis). Plans then need to ensure that all diagnoses are appropriately documented in the current year to count toward MA payment.").

²⁰⁵ Richard Kronick and Pete Welch, "Measuring Coding Intensity in the Medicare Advantage Program," *MMRR*, 4(2), 2014 ("Kronick and Welch, Measuring Coding Intensity"), p. E3; MedPAC, Report to the Congress, p. 438.

²⁰⁶ Kronick and Welch, Measuring Coding Intensity, p. E3 ("If, for example, a FFS patient with quadriplegia and a urinary tract infection (UTI) has an office visit for treatment of the UTI, the payment to the physician will be no more if both the UTI and quadriplegia are reported on the claim than if only the UTI is reported. Coding guidelines specify that the quadriplegia can legitimately be coded if it contributes to the complexity of care, but unlike the situation for MA plans, in FFS there is no incentive to report more than one diagnosis.").

²⁰⁷ NCHS, Analytic Issues in Using the Medicare Enrollment and Claims Data, p. 9.

106. This difference in incentives to report information on diagnoses led Congress to become concerned about a potential overpayment of MA plans.²⁰⁸ Specifically, in the Deficit Reduction Act of 2005, Congress instructed CMS to measure and adjust for the difference in diagnosis coding patterns between MA plans and FFS Medicare.²⁰⁹ This is explained next.

E. CMS Adjusts the Fixed Payments to MA Plans to Account for Differences in Diagnosis Coding Patterns between MA Plans and FFS Medicare

107. Analyses done by CMS have indicated that there is a difference in coding patterns between MA plans and FFS Medicare. Specifically, CMS observed that risk scores for MA enrollees were growing faster than risk scores for FFS Medicare enrollees.²¹⁰ In the course of its analysis, CMS noted that “we do not assume that the coding pattern differences that we found in our study are the result of improper coding.” Rather, it noted the need for an adjustment in cases where there is a “difference in coding patterns” between MA and FFS Medicare.²¹¹ This difference in coding patterns could be the result, for example, of the stronger incentive to record enrollee diagnosis information in MA when compared to FFS Medicare, as I discussed above in Section VII.D. As a result of this difference in coding patterns, the risk score of a beneficiary in an MA plan could be different when using the diagnosis codes recorded in an MA plan rather than the diagnoses that would be coded for the same beneficiary if they were enrolled in FFS Medicare.

108. As explained by Kronick and Welch (2014), “[i]f, for example, Jane Doe would have a risk score of 1.0 if she were in FFS, the implicit assumption in the design of the MA payment

²⁰⁸ United States Government Accountability Office, “Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices,” Report to Congressional Requesters GAO-12-51, January 2012 (“GAO, Report to Congressional Requesters”), available at <https://www.gao.gov/assets/gao-12-51.pdf> (“Policymakers raised concerns that differences in diagnostic coding between MA plans and Medicare FFS could lead to inappropriately high MA risk scores and payments to MA plans.”). See also Kronick and Welch, Measuring Coding Intensity, p. E2 (“Concerns about overpayment as a result of favorable risk selection have confronted the Medicare program throughout the history of Medicare contracting with health maintenance organizations and other private plans.”).

²⁰⁹ Kronick and Welch, Measuring Coding Intensity, p. E4.

²¹⁰ “Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, February 20, 2009 (“CMS, Advance Notice of Methodological Changes for 2010”), p. 8, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/downloads/Advance2010.pdf>.

²¹¹ “Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, April 6, 2009 (“CMS, Announcement of 2010 Medicare Advantage Capitation Rates”), p. 20, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Announcement2010.pdf>.

system is that she would have the same risk score of 1.0 if enrolled in MA.”²¹² However, due to the differences in coding patterns between MA and FFS Medicare, this assumption may not hold. Thus, the asymmetry of having a higher risk score in MA than the same individual would have in FFS Medicare could lead to payments to MA plans that are too high relative to FFS Medicare.²¹³

109. In response to the different observed coding patterns, in 2010, CMS first implemented a “coding adjustment,” commonly referred to as the “coding intensity adjustment.”²¹⁴ The coding intensity adjustment scales MA enrollee risk scores downward, amounting to an across-the-board reduction in risk-adjusted payments to an MA plan.²¹⁵ The coding intensity adjustment has been approximately 5.9 percent since 2018.²¹⁶ This means that since 2018, CMS has reduced MA risk scores—and therefore an individual enrollee’s payment to an MA plan—by

²¹² Kronick and Welch, Measuring Coding Intensity, p. E4.

²¹³ Hornsby Deposition, pp. 45:21–46:3 (“Q. And when you say that plans should be coding as fee-for-service coding occurs, the payments to plans are correct to the extent that the plans are coding similarly to fee-for-service as opposed to differently from fee-for-service, right? A. That is correct. And if plans code more intensely, then they are being overpaid under the model.”).

²¹⁴ 42 U.S.C. 1395w-23, “Payments to Medicare+Choice organizations,” § 1853(1)I(ii), available at https://www.ssa.gov/OP_Home/ssact/title18/1853.htm; CMS, Announcement Of 2010 Medicare Advantage Capitation Rates, p. 19. See also CMS, Advance Notice of Methodological Changes for 2010, pp. 7, 9; “Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, April 7, 2008, p. 18, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2009.pdf>; Hornsby Deposition, p. 116:10–12 and p. 89:2–11 (“Q. Okay. M—Ms. Hornsby, what was the impetus behind the coding intensity adjustment? A. Congress. Congress passed the requirement in the Deficit Reduction Act of 2005 for CMS to conduct research to determine whether there was more intense coding or a higher volume of coding in the Medicare Advantage program compared to fee-for-service. And if CMS found such a difference, CMS was to develop an adjustment to adjust risk scores for the coding intensity.”).

²¹⁵ The coding intensity adjuster is applied to risk scores for MA enrollees. All MA enrollees risk scores are scaled down by a percentage intended to capture faster increases in the number of diagnoses submitted by MA insurers compared to FFS Medicare providers. See CMS, Advance Notice of Methodological Changes for 2010, pp. 9–10. See also CMS, Medicare Managed Care Manual Chapter 7, § 100.

²¹⁶ The coding intensity adjustment was 5.91 percent in 2018 and has been 5.90 percent since 2019. See Kronick and Welch, Measuring Coding Intensity, p. E4; CMS, Advance Notice of Methodological Changes 2023, p. 60; “Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, January 15, 2021, p. 105, available at <https://www.cms.gov/files/document/2022-announcement.pdf>; “Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II,” *Centers for Medicare & Medicaid Services*, February 5, 2020, p. 34, available at <https://www.cms.gov/files/document/2021-advance-notice-part-ii.pdf>; CMS, Announcement of 2020 Medicare Advantage Capitation Rates, p. 5; “Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” *Centers for Medicare & Medicaid Services*, April 2, 2018, p. 4, available at <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/announcement2019.pdf>; “Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2018 Call Letter,” *Centers for Medicare & Medicaid Services*, February 1, 2017, p. 28, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advance2018_119.pdf.

approximately 5.9 percent. CMS performs this adjustment for all payments it makes to MA plans.

110. The minimum coding intensity adjustment has been set by congressional mandate since 2010.²¹⁷ The minimum adjustment was 3.4 percent in 2010–2013, 4.9 percent in 2014, and then was gradually increased until it reached its current level of approximately 5.9 percent in 2018.²¹⁸ Since its inception in 2010, CMS has never increased the coding intensity adjustment by any amount other than the legislative minimum.²¹⁹

111. CMS has stated that its “methodology results in an accurate measure of the coding differential between FFS and MA,” and that it “continually develops its understanding of coding trends and makes an assessment for each payment year regarding the appropriate adjustment based on specific considerations of both coding trends and other market changes.”²²⁰ As noted, CMS set the 2023 coding intensity adjustment at the statutory minimum of 5.9 percent, suggesting that CMS believes this level is the appropriate amount to adjust for any coding differences between MA and FFS Medicare.²²¹

112. In describing the need for the coding intensity adjustment, CMS stated that “MA plans must code the way Medicare Part A and B providers do for risk adjustments to be valid. This means that MA organizations are coding ‘accurately’ when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.”²²² CMS’s use of the coding intensity adjustment to determine payments to MA plans indicates that, when coding practices are distinct between MA plans and FFS Medicare, CMS attempts to restore coding symmetry (or to ensure that “MA organizations are coding ‘accurately,’” as described by CMS).²²³

²¹⁷ MedPAC, Report to the Congress, p. 439.

²¹⁸ MedPAC, Report to the Congress, p. 439, Figure 12–6.

²¹⁹ MedPAC, Report to the Congress, pp. 413, 440.

²²⁰ “Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” *Centers for Medicare & Medicaid Services*, April 2, 2012, p. 25, available at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf>.

²²¹ “2023 Medicare Advantage and Part D Advance Notice Fact Sheet,” *Centers for Medicare & Medicaid Services*, February 2, 2022, available at <https://www.cms.gov/newsroom/fact-sheets/2023-medicare-advantage-and-part-d-advance-notice-fact-sheet>.

²²² CMS, Announcement of 2010 Medicare Advantage Capitation Rates, p. 20.

²²³ CMS, Announcement of 2010 Medicare Advantage Capitation Rates, p. 20. (“Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to

VIII. Requiring MA Plans to Delete Unsupported Diagnosis Codes without FFS Medicare Doing the Same Would Result in Improper Compensation to MA Plans

113. In this matter, Plaintiffs allege that UnitedHealth “failed to delete in the RAPS system the invalid diagnoses [...] or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses.”²²⁴ In this section, I assess the consequences for payments to MA plans of requiring MA plans to remove unsupported diagnosis codes without FFS Medicare doing the same.

114. I first consider the situation in which an MA plan and FFS Medicare have an identical pool of enrollees and identical unsupported diagnosis codes.²²⁵ An identical pool of enrollees means that the MA plan and FFS Medicare have enrollees with the same demographic and diagnosis codes prior to any auditing being done. Identical unsupported diagnosis codes means that the probability that a diagnosis code is unsupported is the same in the MA plan and in FFS Medicare. In this situation, requiring MA plans to delete unsupported diagnosis codes without requiring FFS Medicare to do the same would lead MA plans to be undercompensated relative to FFS Medicare.

115. I then consider situations in which an MA plan and FFS Medicare have different populations or different rates of unsupported codes. I explain that in these situations, requiring MA plans to remove unsupported codes without FFS Medicare doing the same would result in improper compensation to MA plans.

compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding ‘accurately’ when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared.”).

²²⁴ Complaint, ¶ 342.

²²⁵ I understand that in this matter an unsupported diagnosis code is a code that is not supported by the underlying medical records of an enrollee.

A. Requiring MA Plans to Identify and Delete Unsupported Diagnosis Codes Would Result in CMS Undercompensating MA Plans Relative to FFS Medicare when MA Plans and FFS Medicare Have an Identical Pool of Enrollees and Identical Unsupported Diagnosis Codes

1. Defining What It Means for an MA Plan to Be Undercompensated Relative to FFS Medicare

116. I first discuss the situation where MA plans and FFS Medicare have an identical pool of enrollees and identical unsupported diagnosis codes. Although the pool of enrollees and probabilities of unsupported diagnosis codes are unlikely to be identical between a given MA plan and FFS, analyzing the situation in which they are both identical allows one to isolate the impact of deleting unsupported codes in the MA data on payments to MA plans. To understand whether a given policy results in proper compensation to MA plans in this situation, I first introduce the concept of being undercompensated relative to FFS. I define this as follows: MA plans are undercompensated relative to FFS Medicare when MA plans are paid less than what these same enrollees would be expected to cost if they were enrolled in FFS, while also accounting for the plan's MA bid (i.e., accounting for the fact that if a plan's bid is below the benchmark, CMS sets the base rate to be below the benchmark).

117. This definition means that for an insurer that bids at or above the benchmark for a plan with an average risk score of 1.0, an MA plan is undercompensated if it receives less than the benchmark amount, which is the maximum that the MA plan is entitled to receive from CMS for insuring this pool of enrollees. As I explained in Section VII.C, the benchmark is based on the expected health care expenditures that an average enrollee (with a risk score of 1.0) would incur in FFS Medicare (in a given county). Thus, when an MA insurer bids at or above the benchmark, CMS pays the plan the risk-adjusted benchmark, which is equivalent to the total expected cost of treating these same enrollees in FFS Medicare (with identical risk scores). The MA plan would be undercompensated in this scenario if the total payment it received from CMS were less than this total expected cost.²²⁶

²²⁶ MA plans cannot be overcompensated in this scenario, as model coefficients and thus relative factors are constrained to be positive. That is, risk scores for MA enrollees will mechanically decline as MA plans are required to remove codes. See Pope et al., Risk Adjustment of Medicare Capitation Payments, pp. 119–141 at pp. 121–122.

118. When an insurer bids below the benchmark for a plan, determining whether a plan is undercompensated will not be based on a direct comparison to the benchmark. This is because the plan expects to be paid below the benchmark (and thus below expected FFS Medicare costs for the same pool of enrollees) consistent with its bid for an average enrollee. When insurers bid below the benchmark, MA plans are undercompensated if the total payment they receive is less than the amount to which they are entitled, based on the plan's quality rating and the insurer's bid. Note that I apply this definition of undercompensation only to situations where MA plans and FFS Medicare have an identical pool of enrollees and identical probabilities of unsupported diagnosis codes.

119. Examining situations where MA plans and FFS Medicare have an identical pool of enrollees and identical probabilities of unsupported diagnosis codes is consistent with the origins of the CMS-HCC model.²²⁷ First, the basis of the CMS-HCC model is that, for an enrollee, CMS should pay MA plans the expected cost of covering that enrollee in FFS Medicare. For example, the 2003 MMA (described above in Section V.C) increased payments to plans to 100 percent of FFS Medicare costs, rather than 95 percent: "The 100 percent provision ensured that all plans were at least immediately brought to equality with [FFS Medicare]."²²⁸

120. Second, because the model relies on FFS Medicare enrollees to predict expenditures that are associated with each HCC for MA enrollees, it implicitly assumes that, for each HCC, the relative cost to treat enrollees is the same in FFS Medicare and MA plans.²²⁹ This assumption is only true when the distribution of unsupported diagnosis codes (and thus HCCs) is identical in

²²⁷ Gregory Pope, et al., "Principal Inpatient Diagnostic Cost Group Model for Medicare Risk Adjustment" *Health Care Finance Review*, 21(3), 2000 ("Pope et al., Principal Inpatient Diagnostic Cost Group Model"), pp. 93–118 at p. 93 ("The goal of implementing health-status-based risk adjustment for Medicare capitation payments is to fairly compensate the health plans for the expected cost associated with the disease burden of their enrollees.").

²²⁸ As I explained in Section VII.C, when an MA plan submits a bid equal to or higher than the benchmark, CMS pays the plan the expected cost of covering the same beneficiaries (with the same diagnosis codes) in FFS; when plans bid below the benchmark CMS will pay less than this expected cost. See Pope et al., Principal Inpatient Diagnostic Cost Group Model, pp. 93–118 at p. 97 ("The PIPDCG model has been developed and calibrated with data from the traditional Medicare fee-for-service (FFS) program, reflecting the legislative mandate that Medicare capitation be based on 95 percent of what a beneficiary is expected to cost in the FFS program, as it was under the previous AAPCC methodology. Risk adjustment factors developed from FFS data are in this sense consistent with the historical basis of Medicare's capitation payment methodology."); McGuire et al., *Economic History of Medicare Part C*, pp. 289–332 at p. 314.

²²⁹ Pope et al., Principal Inpatient Diagnostic Cost Group Model, pp. 93–118 at p. 98 ("The implicit assumption is that the relative cost of patients with specified levels of disease burden are similar in the FFS and managed care sectors.").

FFS Medicare and MA plans. Thus, the model is unlikely to accurately predict expenditures for MA enrollees unless the distribution of unsupported diagnosis codes (and thus HCCs) is identical in the FFS Medicare and MA populations (so that the incremental cost of an HCC is the same across the two populations).

2. MA Plans Would Be Undercompensated Relative to FFS Medicare If They Were Required to Identify and Delete Unsupported Diagnosis Codes without FFS Medicare Doing the Same when the Enrollee Populations and Unsupported Diagnosis Codes Are Identical

121. As discussed in Section VIII.A.1, when an MA plan has an identical enrollee population and identical probabilities of unsupported diagnosis codes as FFS Medicare, the MA plan would be properly compensated if CMS paid it the amount that the MA plan is entitled to receive based on the bid and the benchmark amount. As I explain below, in this scenario, requiring MA plans to delete unsupported diagnosis codes that result in the removal of HCCs, without making any other changes to CMS's payments to those plans, reduces payments to MA plans for a given enrollee without reducing the expected cost of that enrollee. Therefore, such a requirement would result in CMS undercompensating MA plans with an identical enrollee population as FFS Medicare.

122. Specifically, requiring MA plans to identify and delete unsupported diagnosis codes, while maintaining the coefficients from the CMS-HCC model estimated on FFS data with unsupported diagnosis codes, mechanically reduces payments to MA plans. This is because removing unsupported diagnosis codes would reduce the risk score for each MA plan enrollee.²³⁰ Hence, the total risk-adjusted payment that the MA plan would receive would decrease.

123. On the other hand, the expected costs to CMS of providing care for the identical population as an MA plan with identical diagnosis codes remains unchanged when the MA plan removes diagnosis codes. This is because removing diagnoses recorded for this hypothetical pool of FFS Medicare enrollees does not change their FFS Medicare expenditures in any way. That is, regardless of whether an FFS Medicare enrollee is designated as having a given

²³⁰ As discussed in Section VII.B.1, CMS groups related diagnosis codes into HCCs. Removing unsupported diagnosis codes can remove an HCC code for a patient if the remaining diagnosis codes for the patient in that calendar year do not support inclusion of that HCC.

diagnosis (for example, Type 1 diabetes mellitus without complications²³¹), services were rendered to the FFS Medicare enrollee that CMS paid for and that would factor into expected costs for the enrollee. Put another way, removing diagnosis codes for FFS Medicare enrollees would not change the benchmark against which plans bid.

124. The previous two paragraphs mean that when an MA plan has an identical enrollee population as FFS Medicare with an identical distribution of both supported and unsupported diagnosis codes, requiring that MA plans delete unsupported codes while not requiring CMS to do the same means that the MA plan would be undercompensated relative to FFS Medicare. As explained above, this is because when the MA plan has identical enrollees and an identical distribution of unsupported diagnosis codes as in the FFS data, it should receive as payment (when bidding at or above the benchmark) the total expected cost for the FFS Medicare enrollees. When the MA plan deletes unsupported codes, it receives less than this amount.

125. For clarity of exposition, consider the following example in which the total expected costs for the FFS Medicare population are \$100,000.²³² Then the CMS-HCC model, estimated on an FFS dataset that contains unsupported diagnosis codes, would distribute this \$100,000 across the set of supported and unsupported diagnosis codes to generate relative factors. Now suppose that an MA plan has an identical population with an identical set of both supported and unsupported diagnosis codes as FFS. This MA plan should receive \$100,000 in compensation (assuming it bid the benchmark). Requiring the MA plan to identify and delete unsupported diagnosis codes, without making any additional changes to how CMS pays the plan, mechanically means the plan receives less than \$100,000 (because the risk scores for its enrollees decline when it removes codes, as model coefficients and relative factors can never be negative). Hence, CMS would pay the MA plan less than what CMS would pay for these same enrollees under FFS, and therefore the MA plan would be undercompensated relative to FFS.

²³¹ “ICD-10-CM/PCS MS-DRGv33 Definitions Manual: MDC 10 Endocrine, Nutritional, & Metabolic Diseases & Disorders,” *Centers for Medicare & Medicaid Services*, available at https://www.cms.gov/icd10manual/version33-fullcode-cms/fullcode_cms/P0240.html.

²³² This example is intended to illustrate what it means to undercompensate or overcompensate a MA plan relative to FFS Medicare. As such, it does not consider instances in which MA plans code more intensely than FFS Medicare, as that type of difference in coding patterns is meant to be corrected for by the coding intensity adjuster. See Section VII.E for further discussion.

B. When an MA Plan and FFS Medicare Have Different Pools of Enrollees or Different Probabilities of Unsupported Codes, Requiring MA Plans to Remove Unsupported Codes without FFS Medicare Doing the Same Would Result in Improper Compensation to MA Plans

126. I now discuss situations in which an MA plan and FFS Medicare have different pools of enrollees or have different probabilities of unsupported codes. In these situations, MA plans that are required to remove unsupported codes would be properly compensated when FFS Medicare also removes its unsupported codes. Only when this happens will the coefficients from the CMS-HCC model reflect the true incremental cost of each HCC, resulting in proper compensation when MA plans remove their unsupported codes.

127. CMS has recognized that unsupported diagnosis codes exist in the FFS data. Additionally, I understand that Michael Salve, who has been retained by UnitedHealth in this matter, has conducted an analysis of 2013 FFS data and determined that 31.6 percent of HCCs are unsubstantiated.²³³ Consistent with this, a CMS document from 2009 explains that it is reasonable to expect that the FFS data used to estimate the CMS-HCC model contains unsupported diagnoses.²³⁴ Yet, CMS generally does not audit the FFS data for such unsupported diagnosis codes. Connie Leonard, Director of the Provider Compliance Group at the Center for Program Integrity at CMS, testified that CMS audits less than one percent of FFS Medicare claims.²³⁵ Of the FFS Medicare claims that are subject to a medical record review, diagnosis

²³³ Expert Report of Michael P. Salve, Ph.D., September 29, 2023, § I.

²³⁴ USBP001729882-4 at USBP001729882 (“As a consequence, it is reasonable to expect that there would be some inherent level of unsupported diagnoses in the FFS claims. Thus, that level of unsupported diagnoses would be calibrated into the model. Hence, the MA industry believes that their payments are subject to error inherent in FFS coding patterns.”).

²³⁵ Deposition of Connie Lynn Leonard (CMS), May 26, 2023 (“Leonard Deposition”), pp. 10:15–21, 24:20–25:10 (“Q. So for all of the auditing of fee for service claims that CMS conducts, it’s looking at less than 1 percent of this whole fee for service claim? [...] THE WITNESS: Okay. So from a claim perspective, when we conduct claim review and medical record, when we request medical records, then we typically do review less than 1 percent of all claims.”), p. 200:5–20 (“Q. Okay. And for 99 percent of the claims from which that data comes from, they have not been audited at all by CMS through a medical record review; correct? [...] THE WITNESS: CMS has stated that we only review less than 1 percent of all Medicare fee for service claims. So the majority of the claims in that data sample have not been audited by a medical records review, that is correct BY MR. MARTINEZ: By ‘majority,’ you mean more than 99 percent of the claims; right? A. Give or take 99 percent of the claims, yes.”).

codes are not always reviewed and audited.²³⁶ Thus, the overall rate of unsupported codes in the FFS data is unknown to MA plans.²³⁷

128. The existence of unsupported diagnosis codes in the FFS data affects the payments to MA plans because such unsupported diagnosis codes in the FFS data affect the size of the estimated dollar coefficients and relative factors from the CMS-HCC model. Indeed, a 2009 CMS document notes that “diagnostic error[s] [are] calibrated into the risk adjustment model that formulates MA payment.”²³⁸ This is also supported by CMS’s Addendum to its FFS Adjuster Study (“FFS Adjuster Study Addendum”), as described in more detail in Section IX below, which indicates that the average estimated dollar coefficient in the CMS-HCC model increases when unsupported codes are removed from the FFS data.²³⁹

²³⁶ Leonard Deposition, pp. 59:2–13 (“So just take a step back about how Medicare fee for service reviews. We review claims. Now, each claim has several—could, not all, could have several claim lines. Those lines could have several diagnosis codes. When we conduct medical record review, we’re reviewing that claim. During that medical record, we could or could not, maybe not, make it down to that diagnosis code. We may not. It would depend on the claim.”) and pp. 85:15–86:16 (“Q. So from time to time the government will conduct audits of diagnosis codes in the fee for service data; correct? [...] THE WITNESS: What we will do in the Medicare fee for service program is we will review a claim, the care, some type of benefit and during that review bringing the claim and the claim line and we may actually review the diagnosis code and compare it to the medical documentation in the medical record. [...] Q. In the auditing of claims that the government does, sometimes it will audit diagnosis codes as part of that process, but not always? [...] THE WITNESS: That is correct, that sometimes a claim audit will include a diagnosis code review, and sometimes it will not.”).

²³⁷ See Leonard Deposition, p. 229:2–5 (“[W]e do not calculate a diagnosis code error rate, improper payment rate, percentage of diagnosis codes that were incorrect on the claims. We do not track that in any way.”) and pp. 232:16–233:10 (“Q. So my question then is with that understanding, because CMS doesn’t track this information and doesn’t have this information, am I correct that CMS has not determined what the rate of unsupported diagnosis codes are in the fee for service data that’s been used to calibrate the risk adjustment model? [...] THE WITNESS: CMS does not track the diagnosis code error rates for claims that have been reviewed and presented based on unsupported documentation, and they would not have it before they ran the data to do the risk adjustment model.”).

²³⁸ USBP001729882–4 at USBP001729882 (“In fact, there is a certain level of diagnostic error calibrated into the risk adjustment model that formulates MA payment. The FFS claims from which the CMS-HCC model is estimated are not subject to RADV audit. As such, there is an error rate calibrated into the model, and as a consequence, factored into current payments to MA plans.”). See also DC027431–40 at DC027433 (“Medicare Advantage (MA) payment model (CMS-HCC model) is calibrated on diagnoses from FFS claims data, which contain a level of error due to diagnoses not supported by medical record documentation in FFS.”).

²³⁹ “Addendum to the Fee-For-Service Adjuster Study,” *Centers for Medicare & Medicaid Services*, June 2019, available at [Addendum to the Fee-for-Service Adjuster Study.pdf](#) when accessing “RADV Provision CMS 4185-N4 Data Release June 2019 (ZIP)” at “Medicare Risk Adjustment Data Validation Program Resources,” *Centers for Medicare & Medicaid Services* (“CMS, FFS Study Addendum”), modified September 6, 2023, p. 8, steps (3–6), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources> (“ $\bar{b} > \bar{b}$ ”). Note that $\bar{b}$ represents the average estimated dollar coefficient in the CMS-HCC model after auditing the FFS data, and $\bar{b}$ represents the average estimated dollar coefficient before auditing. In the FFS Adjuster Study, CMS applies an Inflated Post-Audit Risk Score (“IPARS”) adjustment to support its claim that unsupported HCC codes in the FFS data do not impact payments to MA plans. As I discuss in Section IX, I disagree with CMS’s use of an IPARS adjustment, and I disagree with CMS’s claim that unsupported codes in the FFS data do not impact payments to MA plans.

129. When an MA plan and FFS Medicare have different pools of enrollees or different probabilities of unsupported codes, requiring an MA plan to remove unsupported codes while failing to also remove unsupported codes from the FFS data used to estimate the CMS-HCC model would result in improper compensation to MA plans. In particular, if unsupported codes are removed from the data submitted by MA plans, proper compensation requires that the relative factors applied to each HCC in the audited MA plan data reflect the true incremental cost of the HCC according to similarly audited FFS data. However, when the CMS-HCC model is estimated on FFS data that contain unsupported codes, this will not be the case. In fact, CMS's FFS Adjuster Study Addendum indicates that the average of the estimated dollar coefficients (and thus relative factors) in the CMS-HCC model increases when unsupported codes are removed from the FFS data.²⁴⁰ CMS also found that for any given HCC, estimating the CMS-HCC model using FFS data with unsupported codes will result in a dollar coefficient that may be larger or smaller than the true incremental costs of the HCC under audited FFS data, depending on the relative likelihood that the HCC is unsupported in the FFS data.²⁴¹ Likewise, the estimated value of the relative factor for a given HCC may be larger or smaller relative to its true value based on audited FFS data. This means that if MA plans are required to remove unsupported codes, the FFS data used to estimate the CMS-HCC model must also remove unsupported codes in order for MA plans to be properly compensated.

130. The resulting impact of estimating the CMS-HCC model using unaudited FFS data versus audited FFS data on payments to the MA plan depends on the pool of enrollees and distribution of unsupported codes in the MA plan data relative to the FFS data. For example, if unsupported codes in the FFS data lead the CMS-HCC model to underestimate the dollar coefficient and relative factor for a particular HCC, and an MA plan has a relatively large number of enrollees for whom this HCC is supported, original payments to the MA plan could have been too low. In

²⁴⁰ CMS, FFS Study Addendum, p. 8, steps (3–6).

²⁴¹ Deposition of Sean Creighton (CMS), October 4, 2022 (“Creighton Deposition, day 2”), pp. 30:17–34:10. (“[...] Q. And going back to that notion of removing from the population the erroneous diagnosis codes so that you have the true population that suffer from the conditions, you would expect the costs, the incremental costs, of caring for that condition to rise? [...] THE WITNESS: That – that has been my expectation. The – our study showed that it was a bit more complicate than that. So, yeah, that’s normally the expectation [...] However, it turns out it’s not, like a lot of statistical stuff, it’s not quite as simple as that. So we found in our studies, sometimes they rise, sometimes they go down. But on—on average what you do know is they’re gonna be different, they’re... You know. So I agree with your initial hypothesis, it was my hypothesis, too. Turns out it’s not true for all conditions across the model. [...])”).

this case, removing unsupported codes from the FFS data and re-estimating the CMS-HCC model on the audited FFS data would lead the dollar coefficient and the relative factor for this HCC to increase. As a result, payments to the MA plan would likely increase because the risk scores of enrollees with this HCC would increase, due to the now higher relative factor from the higher CMS-HCC dollar coefficient (estimated using the audited FFS data) for this HCC. This example demonstrates that in cases where the MA plan and FFS Medicare have different pools of enrollees or different probabilities of unsupported codes, requiring MA plans to remove unsupported codes without FFS Medicare doing the same would result in improper compensation to MA plans.

131. Moreover, in order to determine whether CMS's payments based on unaudited FFS data constitute proper compensation to the MA plan, one would need to determine the extent to which the pool of enrollees and the probabilities of unsupported codes differed between the MA plan and the FFS Medicare population.²⁴² CMS, however, does not track the rate of unsupported codes in the FFS Medicare population.²⁴³ Without this information, neither the MA plan nor CMS can determine whether CMS has properly compensated the MA plan.

IX. CMS's FFS Adjuster Study Is Flawed

132. In February 2012, CMS released a notice presenting the mechanics of its contract-level audits of MA plans known as Risk Adjustment Data Validation ("RADV") audits.²⁴⁴ CMS has described the RADV audits as its "main corrective action for overpayments made to Medicare Advantage organizations [...] when there is a lack of documentation in the medical record to

²⁴² See Deposition of Jonathan D. Morse (CMS), August 17, 2022, pp. 25:15–27:6, 177:22–178:3 ("And so in order to know whether a particular plan would—would have an overpayment or an underpayment problem when you go and remove unsupported codes, you would need to know the distribution of that plan's particular disease and demographic characteristics— A. Right.").

²⁴³ See Leonard Deposition, p. 229:2–5 ("[W]e do not calculate a diagnosis code error rate, improper payment rate, percentage of diagnosis codes that were incorrect on the claims. We do not track that in any way.").

²⁴⁴ "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits," *Centers for Medicare & Medicaid Services*, February 24, 2012 ("CMS, Notice of Final Payment Error Calculation Methodology"), p. 1, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf>.

support the diagnoses reported for risk adjustment.”²⁴⁵ I note that by describing “corrective action for overpayments,” CMS is using the term “overpayments” to refer to what it considers to be excess compensation to MA plans when MA plans have not deleted any unsupported diagnosis codes.

133. In its notice, CMS stated that it would “apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount” in the RADV audits.²⁴⁶ The FFS adjuster was intended to account for the fact that the preliminary recovery amount resulting from RADV audits account for unsupported diagnosis codes from only MA enrollees, even though there are also unsupported diagnosis codes in the FFS data that are used in the CMS-HCC model.²⁴⁷ The presence of unsupported diagnosis codes in the FFS data implies that the coefficients from the CMS-HCC model do not accurately measure the incremental cost of HCCs in the FFS data,²⁴⁸ which can result in payments to MA plans that are too low if MA plans are required to remove unsupported diagnosis codes but FFS Medicare is not required to do so. Applying an FFS adjuster would decrease preliminary RADV audit recovery amounts to reflect the presence of unsupported codes in FFS data.²⁴⁹

134. In 2023, CMS adopted a Final Rule which indicated it would not apply an FFS adjuster.²⁵⁰ Prior to adopting this Final Rule, CMS released several documents related to its analysis of the impact of unsupported diagnosis codes in the FFS data on payments to MA

²⁴⁵ CMS Final Rule. See also Deposition of Christopher Gile Bresette (OIG), May 31, 2023, pp. 17:16–18:6, 42:14–25 (“The objective of our audit was to determine whether the diagnosis codes that – that they submitted to CMS complied with federal requirements. Q. And as part of the explanation for why [U.S. Department of Health & Human Services, Office of Inspector General (“OIG”)] did this – this audit, it notes in the second paragraph there that – that OIG was assessing whether MAOs had received improper payments. Is that right? A. If – if an MAO submits incorrect diagnosis, it will lead to improper payments. So – it could lead to improper payments; I clarify.”).

²⁴⁶ CMS, Notice of Final Payment Error Calculation Methodology, pp. 4–5 (“The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract’s payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).”). See also, Deposition of Thomas Kornfield (CMS), March 10, 2022 (“Kornfield Deposition”), pp. 20:21–21:1, 196:23–197:12.

²⁴⁷ See discussion in Section VIII; CMS, Notice of Final Payment Error Calculation Methodology, pp. 1, 4–5.

²⁴⁸ See further discussion in Section IX.B.2.

²⁴⁹ Deposition of Carolyn Kapustij (CMS), August 25, 2023, pp. 14:2–20, 161:5–23 (“Q. Okay. And if a fee-for-service adjuster had been applied to that \$98 million figure, that figure would have been even lower; correct? [...] THE WITNESS: It seems that the fee-for-service adjuster would reduce that amount. [...] Q. Assuming it’s a positive fee-for-service adjuster; correct? [...] THE WITNESS: Correct”) and pp. 214:21–215:5 (“Q. Okay. So if that’s what preliminary means according to CMS, then the recovery amounts that are listed in Exhibit 1187-1. Those recovery amounts are only going to decrease through the application of a fee-for-service adjuster or any appeals process; right? [...] THE WITNESS: That would seem to be the case.”).

²⁵⁰ CMS Final Rule.

plans. In October 2018, CMS put forth a study (the “FFS Adjuster Study”) in which it claimed that applying an FFS adjuster would not be “appropriate.”²⁵¹ Specifically, the study stated that “errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations.”²⁵² That is, CMS claimed that unsupported codes in FFS data do not “systematically” impact CMS’s payments to MA plans, and therefore that there is no need for CMS to account for such unsupported codes when assessing whether MA plans were overpaid. In November 2018, CMS released a “Proposed Rule” which included a proposal to not apply an FFS adjuster when assessing potential overpayments to MA plans.²⁵³ CMS subsequently published a technical addendum to the FFS Adjuster Study in 2019,²⁵⁴ and the Final Rule was adopted in 2023.²⁵⁵

135. As I explain in detail below, I disagree with CMS’s conclusion that unsupported diagnosis codes in the FFS data do not have a systematic effect on CMS’s payments to MA plans. CMS’s FFS Adjuster Study exhibits a number of methodological flaws that render it unreliable, and as a result, the Study fails to demonstrate that an FFS adjuster is unnecessary.

136. In this section, I first describe the methodological framework that CMS adopted in the FFS Adjuster Study to evaluate the impact of unsupported codes in FFS data on payments to MA plans. I then describe critical errors in CMS’s methodology, and, as a result, in CMS’s conclusion that unsupported codes in FFS data do not impact payments to MA plans. I then explain why the data that CMS used to calculate the FFS adjuster are inadequate to evaluate the impact of unsupported codes in FFS data on payments to MA plans. Finally, I explain that contrary to CMS’s conclusion, unsupported diagnosis codes in the FFS data likely impact payments to MA plans, and thus an FFS adjuster is necessary.

²⁵¹ CMS, FFS Adjuster Study, p. 6.

²⁵² CMS, FFS Adjuster Study, p. 5.

²⁵³ Centers for Medicare & Medicaid Services and US Department of Health & Human Services, Proposed Rule, “Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,” *Federal Register*, 83(212), November 1, 2018, pp. 54892–55088, available at <https://www.govinfo.gov/content/pkg/FR-2018-11-01/pdf/2018-23599.pdf>.

²⁵⁴ CMS replicated the initial study within this June 2019 addendum (the “FFS Adjuster Study Addendum”), finding results consistent with the initial implementation. See CMS, FFS Study Addendum, p. 1.

²⁵⁵ CMS Final Rule.

A. Overview of CMS Methodology to Estimate the Impact of Unsupported Codes in FFS Data on Payments to MA Plans

137. At a high level, CMS's methodology seeks to understand how removing unsupported codes from the FFS data would impact the dollar coefficients and relative factors estimated by the CMS-HCC model, and as a consequence, the risk scores used to determine payments to MA plans.²⁵⁶ CMS calculates for each MA enrollee the percentage difference between the risk score resulting from the model estimated with audited FFS data relative to the risk score resulting from the model estimated with unaudited FFS data. CMS then calculates the average of these percentage differences across MA enrollees in their study. According to CMS's framework, if this average percentage difference in risk scores is not a "large, positive percentage," then expected payments are not impacted and no FFS adjuster is needed.²⁵⁷ Thus, to evaluate the need for an FFS adjuster, CMS needs to understand how the dollar coefficients and the relative factors from the CMS-HCC model change when the FFS data are audited.

138. Because a comprehensive audit of all diagnosis codes in the FFS data is not feasible, CMS audits the diagnosis codes in only a sample of the FFS data in its FFS Adjuster Study, and then extrapolates the results from the sample to the overall FFS data.²⁵⁸ Using this sample, CMS seeks to implement the following methodology to estimate the impact of removing unsupported codes from the FFS data:²⁵⁹

- First, estimate the probability each HCC is unsupported at the patient level in a given year within the sample.
- Second, use these sample probabilities to estimate the probability that each HCC is unsupported at the patient level in that year for the overall FFS Medicare population.
- Third, apply these estimated FFS Medicare population-wide probabilities to the unaudited FFS data to simulate audited FFS data in which unsupported diagnosis codes are removed.

²⁵⁶ CMS, FFS Adjuster Study, pp. 1–4.

²⁵⁷ "Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits – Technical Appendix," *Centers for Medicare & Medicaid Services*, October 26, 2018 ("CMS, FFS Adjuster Study Technical Appendix"), pp. 13–16, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf>.

²⁵⁸ CMS, FFS Adjuster Study Technical Appendix, pp. 6–12.

²⁵⁹ CMS, FFS Adjuster Study Technical Appendix, p. 6–16. For this discussion, I do not address whether the framework used by the CMS FFS Adjuster Study is appropriate.

- Fourth, re-estimate the CMS-HCC model on the simulated audited data to estimate simulated audited relative factors.
- Fifth, compare the implied MA plan risk scores using simulated audited relative factors to the corresponding risk scores using unaudited relative factors from estimating the CMS-HCC model on the original, unaudited FFS data.

139. I now explain some of the critical methodological flaws leading CMS to conclude that unsupported codes in FFS data do not impact payments to MA plans.

B. CMS Uses a Flawed Methodology to Determine Whether an FFS Adjuster Is Necessary

140. In this sub-section, I address two errors that bias CMS's estimate of the impact of unsupported codes in the FFS data on the audited relative factors and the resulting MA risk scores, leading CMS to incorrectly conclude that payments to MA plans are unaffected: (1) CMS incorrectly estimates the beneficiary-level probability that an HCC is unsupported in the FFS data; and (2) CMS inappropriately adjusts for the effects of the auditing process on FFS Medicare costs, despite actual FFS Medicare costs being unaffected. Both of these errors bias CMS's estimate of the average audited relative factors and resulting MA risk scores downwards, and lead to incorrect conclusions regarding the impact of removing unsupported codes from the FFS data on payments to MA plans.

1. CMS's Methodology for Estimating the Probability That an HCC Is Unsupported Is Flawed

141. The FFS Adjuster Study relies on incorrect assumptions to estimate the probability that each HCCs is unsupported (the first two steps in the methodology outlined in Section IX.A).²⁶⁰ As a result, CMS's estimates of these probabilities are unreliable, as are its estimates of the resulting audited dollar coefficients, audited relative factors, and resulting MA risk scores.

²⁶⁰ For clarity of exposition, when I refer to HCCs being unsupported, it means the HCC is unsupported for a patient in a year. In addition, CMS defines an HCC as unsupported when none of the associated claims have a diagnosis code that maps to the HCC and that is supported by the medical record. CMS, FFS Adjuster Study, p. 3 ("The correctness of the status of an HCC in the profile is determined by the presence of at least one claim that both has a diagnosis that maps to that HCC and is supported by medical record documentation. For this reason, the impacts of the unsupported diagnoses in the claims on the model parameter estimates are driven by the number of HCCs in each beneficiary's profile that do not have at least one claim supported by medical record documentation.").

142. To estimate the probability that an HCC is unsupported, CMS relies on a sample from the 2008 Comprehensive Error Rate Testing (“CERT”) data containing 8,630 unique outpatient FFS Medicare claims and the underlying medical records that CMS uses to assess whether the diagnosis codes for each of these claims are supported.²⁶¹ These data do not include all claims for a beneficiary in a year, and thus, CMS cannot directly determine from these data whether an HCC is unsupported for a beneficiary in that year.²⁶² Instead, CMS estimates the probability that a particular HCC is unsupported for a given *claim* (i.e., the “claim-level probability”) by estimating the number of claims that are associated with the HCC but do not support the HCC, as a share of all the claims that are associated with the HCC (i.e., both claims with and without diagnosis codes and medical records that support the HCC).²⁶³

143. CMS uses these claim-level probabilities to estimate the likelihood that each HCC is unsupported for a given beneficiary. Specifically, for each HCC, CMS first estimates the average number of claims that include a diagnosis code within the HCC across beneficiaries. CMS estimates this average using a different dataset, namely a 2004 sample of FFS Medicare beneficiaries and their claims.²⁶⁴ For example, if there were two beneficiaries with diagnosis codes that indicate a particular HCC, one with two claims that have a diagnosis code associated with the HCC and the other with four claims that have a diagnosis code associated with the HCC, then the per-beneficiary average number of claims indicating the HCC would be three. CMS then estimates the probability that an HCC is unsupported at the beneficiary level as equal to the claim-level probability that an HCC is unsupported raised to an exponent equal to the average number of claims per beneficiary indicating that HCC.²⁶⁵ So, for example, if on average each beneficiary has three claims with an HCC, CMS would raise the claim-level probability that the HCC is unsupported to the power of three to account for the fact that the HCC would only be unsupported if all three claims were unsupported.

²⁶¹ CMS, FFS Adjuster Study Technical Appendix, p. 6.

²⁶² I further address issues with the adequacy of CMS’s data in Section IX.C.

²⁶³ CMS, FFS Adjuster Study Technical Appendix, p. 6, Table 2a. CMS provides its estimates of the claim-level probability that an HCC is unsupported in Table 2a of the FFS Adjuster Study Technical Appendix. CMS uses the term “sampled” to refer to the number of sampled claims associated with the HCC and the term “discrepant” to refer to the number of claims associated with the HCC that are unsupported. CMS estimates “%Discrepant” as the percent of “sampled” claims that are “discrepant.”

²⁶⁴ Specifically, CMS uses these data to identify all beneficiaries with claims indicating a given HCC and, among these beneficiaries, calculates the average number of claims indicating that HCC. CMS, FFS Adjuster Study, p. 3; CMS, FFS Adjuster Study Technical Appendix, pp. 9–11.

²⁶⁵ CMS, FFS Adjuster Study Technical Appendix, p. 9.

144. For CMS’s calculation to yield a correct estimate of the probability that an HCC is unsupported at the beneficiary level, two assumptions must hold. First, it must be the case that using the average number of claims per HCC among beneficiaries in the FFS sample data does not bias the calculation of the relevant probability. Second, it must be the case that the probability that a claim has an unsupported HCC is independent across claims within a beneficiary.²⁶⁶ As I discuss below, both of these assumptions likely do not hold, and both can bias downward the probability that an HCC is unsupported in the FFS data.

145. First, CMS’s use of the average number of claims per HCC would lead it to underestimate the probability an HCC is unsupported for a beneficiary.²⁶⁷ Using the average number of claims per HCC among beneficiaries implicitly assumes that every beneficiary with that HCC has the average number of claims. To see why this is not always the case, consider the following stylized example. Suppose that half of the beneficiaries with a given HCC have exactly one claim indicating that HCC and the other half have exactly five claims indicating that HCC. The average number of claims for the HCC among beneficiaries is three. Suppose further that each claim has a 30 percent probability of being unsupported and, for simplicity, that this probability does not vary across beneficiaries and is independent across claims.²⁶⁸ CMS’s approach would estimate that the probability that the HCC is unsupported for a beneficiary is 2.7 percent.²⁶⁹ In reality, the true probability would be much higher. Specifically, the probability of an unsupported HCC is 30 percent for beneficiaries with one claim and 0.243 percent for beneficiaries with five claims.²⁷⁰ Thus, the correct estimate for the probability that a randomly drawn beneficiary has the HCC is the weighted average of these two probabilities, where the weights are the proportions of beneficiaries with the given number of claims indicating the

²⁶⁶ Two events are independent if the occurrence of one event does not affect the probability of the occurrence of the other event. See, e.g., James H. Stock and Mark Watson, *Introduction to Econometrics, Second Edition*, (Boston: Addison Wesley, 2006), p. 34 (“Two random variables X and Y are independently distributed, or independent, if knowing the value of one of the variables provides no information about the other.”).

²⁶⁷ The findings of the Lambert Report also support this assertion. See Julia Lambert, “Actuarial Report on Medicare Advantage FFS Adjuster,” *Wakely*, August 28, 2019 (“Lambert Report”), pp. 26–29.

²⁶⁸ The assumption that each claim has the same probability of being unsupported is unlikely to hold. The probability a claim is unsupported is likely to decrease with the number of claims with a given diagnosis. For example, an individual that only has one claim with a diagnosis code for diabetes is likely to have a higher probability that the diabetes diagnosis is unsupported than an individual with five claims including a diagnosis code for diabetes.

²⁶⁹ $0.3^3 = 0.3 \times 0.3 \times 0.3 = 0.027$.

²⁷⁰ $0.3^1 = 0.3$, and $0.3^5 = 0.3 \times 0.3 \times 0.3 \times 0.3 \times 0.3 = 0.00243$.

HCC. In the example, this weighted average would be 15.12 percent—more than 5 times greater than the estimate derived from CMS’s methodology.²⁷¹

146. This example applies more generally. Specifically, as I describe in the example above, the correct method of calculating the probability that an HCC is unsupported for a beneficiary would use the actual distribution of claims underlying HCCs across beneficiaries instead of just the average number of claims associated with a particular HCC. Mathematically, the correct method will estimate a higher probability that an HCC is unsupported relative to CMS’s use of the average number of claims.²⁷² Likewise, Ms. Lambert, a health actuary retained by UnitedHealth to evaluate the CMS FFS Adjuster Study, demonstrates this flaw in CMS’s calculation.²⁷³ Underestimating the probability that an HCC is unsupported leads to lower estimates of the average audited relative factors,²⁷⁴ and contributes to CMS’s incorrect conclusion that unsupported codes in the FFS data have no impact on payments to MA plans. Thus, this error by CMS leads it to incorrectly conclude that an FFS adjuster is not needed.

147. Second, the probability that a claim does not support an HCC is not independent across claims within a beneficiary or across beneficiaries, and this assumption can also bias downward CMS’s estimates of the beneficiary-level probability that an HCC is unsupported, again biasing the average estimates of the audited relative factors downwards. Whether a claim supports an HCC for a given beneficiary is likely correlated across claims due to the types of diagnoses the beneficiary has and variation in physician coding practices that would similarly affect all claims

²⁷¹ 0.1512 ($0.5 \times 0.3 + 0.5 \times 0.00243$) is the weighted average of 30 percent and 0.243 percent, where the weights correspond to the fraction of beneficiaries with one claim indicating the HCC and five claims indicating the HCC, respectively. In my example, both weights are 50 percent.

²⁷² It is a mathematical fact known as the “Jensen’s Inequality” that raising a probability to the average of k numbers is higher than the average of that probability raised to each of the k numbers. See, for example, Patrick Billingsley, *Probability and Measure, Third Edition*, (New Delhi: Wiley India Edition, 1995), p. 80. To see why, consider two points on the graph of a convex function (an example of a convex function is a U-shaped curve). The average of the function values at those two points is greater than the value of the function at the average of the two points.

²⁷³ Ms. Lambert estimated a beneficiary-level HCC discrepancy rate of 13.716 percent, compared to CMS’s calculation of 2.115 percent. See Lambert Report, pp. 26–29. See also, Letter from Matthew Eyles (AHIP) to Seema Verma (CMS), “RE: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (‘Proposed Rule’),” August 27, 2019 (“Letter from Matthew Eyles to Seema Verma”), p. 20, available at https://ahiporg-production.s3.amazonaws.com/documents/AHIP_RADV_comments_FINAL_8_27.pdf.

²⁷⁴ CMS, FFS Study Addendum, p. 8, step (6).

for a beneficiary from the same physician.²⁷⁵ For example, if a given physician was systematically less accurate at medical coding than another physician, all of the first physician's claims would be more likely to have unsupported diagnosis codes. Deposition testimony from Thomas Kornfield, who was the Director of Payment Systems at CMS and a former Vice President at America's Health Insurance Plans ("AHIP"), supports this point: "CMS is assuming that [diagnoses are] independent when they probably aren't, meaning a provider that codes an error is probably going to code an error."²⁷⁶

148. Because claim-level probabilities are not independent, CMS cannot simply multiply them to estimate the probability that an HCC is unsupported. This is a fundamental law of probability.²⁷⁷ Instead, CMS would need to estimate how the presence of one unsupported diagnosis for a beneficiary impacts the likelihood that other diagnosis codes are unsupported for that beneficiary. CMS has not done so.

149. To see why this matters, consider the following simple example. There are 100 beneficiaries with a given HCC, and each beneficiary has 2 claims associated with the HCC. Two physicians, doctor A and doctor B, each treat 50 Medicare beneficiaries. Doctor A keeps high-quality medical records, and all of the claims—and thereby the HCCs associated with these claims—for the beneficiaries they treat are supported. By contrast, none of the claims for the beneficiaries treated by doctor B are supported. Thus, the data contain a total of 200 claims: 100 supported claims (i.e., 2 claims for each of doctor A's 50 patients) and 100 unsupported claims (i.e., 2 claims for each of doctor B's 50 patients). The FFS Adjuster Study methodology would estimate a 50 percent probability that a claim is unsupported (i.e., 100 unsupported claims divided by 200 total claims). Furthermore, each beneficiary has 2 claims, so the average number of claims per beneficiary is 2. Thus, the FFS Adjuster Study methodology would estimate a 25 percent probability that the HCC is unsupported for an FFS Medicare beneficiary

²⁷⁵ Correlation in the accuracy of a patient's claims may arise if there are common factors impacting the coding of patients' diagnoses. For example, physician qualities such as experience play a role in coding accuracy and hospitals differ in their rates of diagnosis code accuracy. See Kimberly O'Malley, et al., "Measuring Diagnoses: ICD Code Accuracy," *Health Services Research*, 40(5 Pt. 2), October 2005, pp. 1620–1639 at pp. 1627–1628; Pavani Rangachari, "Coding for Quality Measurement: the Relationship Between Hospital Structural Characteristics and Coding Accuracy from the Perspective of Quality Measurement," *Perspectives in Health Information Management*, 4(3), 2007.

²⁷⁶ Kornfield Deposition, pp. 19:18–21:22, 218:22–25.

²⁷⁷ See, e.g., Morris DeGroot and Mark Schervish, *Probability and Statistics, Fourth Edition*, (Boston: Addison Wesley, 2012), pp. 66–67.

(i.e., claim level probability of 50 percent raised to the power of 2). However, in this example, the actual probability that the HCC is unsupported for an FFS Medicare beneficiary is 50 percent: the HCC is unsupported for the 50 beneficiaries treated by doctor B, out of 100 beneficiaries total. In this example, CMS's methodology underestimates the probability that an HCC is unsupported for an FFS Medicare beneficiary because it fails to take into account potential correlation that claims could be supported (or unsupported) within beneficiaries (because of the systematic difference in coding patterns between doctor A and doctor B). If, as in the example above, CMS underestimates the probability that an HCC is unsupported, CMS's conclusions that the audited relative factors and resulting MA risk scores are unaffected and that an FFS adjuster is unnecessary will be incorrect.

2. No IPARS Adjustment Is Needed, and Its Use Biases the Impact of Unsupported Codes in the FFS Data on Audited Coefficients, Audited Relative Factors, and MA Risk Scores towards Zero

150. In its Addendum to the FFS Study, CMS shows that the removal of unsupported codes from the FFS data impacts the dollar coefficients estimated in its CMS-HCC model.²⁷⁸ However, CMS then makes a fundamental conceptual error—it reasons that “diagnoses cannot soundly be deleted in the CMS-HCC modeling context without making adjustments to account for the bias that the deletion procedure itself creates in expenditures.”²⁷⁹ In other words, CMS states that if it removes diagnosis codes from the FFS data, it also needs to adjust the observed expenditures under FFS Medicare when estimating the CMS-HCC model. Based on this fundamental misconception that FFS Medicare expenditures should be reduced, CMS makes an adjustment to the audited dollar coefficients, called an Inflated Post-Audit Risk Score (“IPARS”) adjustment.²⁸⁰ Mechanically, CMS calculates the IPARS adjustment by calculating a ratio of predicted average FFS Medicare expenditures.²⁸¹ Specifically, the numerator of this ratio is equal to the average predicted FFS Medicare expenditures estimated using *audited* dollar

²⁷⁸ CMS, FFS Study Addendum, p. 8, steps (3)–(6). As described in Section VIII.B, CMS's FFS Study Addendum notes that “ $\bar{b} > \bar{b}$,” where $\bar{b}$ represents the average of the dollar coefficient obtained from estimating the CMS-HCC model on audited FFS data, and $\bar{b}$ represents the average of the dollar coefficient obtained from estimating the model on unaudited FFS data.

²⁷⁹ CMS, FFS Study Addendum, p. 5.

²⁸⁰ CMS, FFS Study Addendum, pp. 5, 10.

²⁸¹ CMS, FFS Study Addendum, p. 10.

coefficients and *unaudited* FFS data. The denominator of this ratio is the average predicted FFS Medicare expenditures using *unaudited* dollar coefficients and *unaudited* FFS data, which equals the realized average FFS Medicare expenditures.²⁸² The IPARS adjustment is:

$$\frac{\text{Audited coefficients} \times \text{unaudited data}}{\text{Unaudited coefficients} \times \text{unaudited data}}$$

151. This ratio is always greater than one because, as CMS shows in the FFS Study Addendum, the average *audited* dollar coefficient is larger than the average *unaudited* dollar coefficient.²⁸³

152. CMS then divides the *audited* dollar coefficients by the IPARS adjustment, thereby deflating these dollar coefficients, the relative factors, and the subsequent risk scores in the MA data.²⁸⁴ CMS's use of the IPARS adjustment therefore systematically biases the impact of unsupported codes in the FFS data on average audited dollar coefficients, average audited relative factors, and subsequent MA risk scores towards zero. That is, this IPARS adjustment removes the very change in the dollar coefficients that CMS intends to measure. Indeed, Sean Creighton testified that the IPARS adjuster methodology was circular.²⁸⁵

153. To illustrate, first consider the impact of removing unsupported codes from the FFS data on the payments to MA plans, before applying any IPARS adjustment. Exhibit 6 provides a simplified example where there is a single HCC and no other regressors in the CMS-HCC model. Suppose there are 100 FFS Medicare beneficiaries that generated \$10,000 in FFS Medicare costs and suppose that the *unaudited* FFS data indicates that 50 of these beneficiaries have the HCC. Then the *unaudited* dollar coefficient for the HCC is \$200 (\$10,000 / 50). Now

²⁸² CMS, FFS Study Addendum, p. 10; Lambert Report, p. 18.

²⁸³ CMS, FFS Study Addendum, p. 8. See Steps (5) and (6). See also CMS, FFS Study Addendum, Figure 2.

²⁸⁴ Lambert Report, p. 18 ("A review of CPI's provided SAS code indicates that as part of the normalization process, before converting the revised dollar coefficients to relative factors (like in the baseline model), it first made a reduction to the resulting dollar coefficients by dividing them by an IPARS adjustment."). See also CMS, FFS Study Addendum, pp. 8–9, step (13) and p. 10. Elsewhere in the FFS Study Addendum, CMS defines the IPARS "adjustment factor" as the ratio of average realized expenditures to average predicted expenditures, or the inverse of the ratio shown in the text of the current report. For this definition, CMS indicates that the dollar coefficients would be multiplied, rather than divided, by the IPARS adjustment. This alternative process is mathematically equivalent to the process described in the text of the current report. See CMS, FFS Study Addendum, pp. 8–9.

²⁸⁵ Creighton Deposition, day 2, pp. 36:10–39:1. ("Q And you wrote [...] 'If CMS had found that the different [sic] was 10 percent, it would have divided all coefficients by 1.1 (in other words, in effect, CMS's approach is similar to multiplying a number by 10 and then dividing by 10).' A Correct. Q And am I correct in saying that—or what you said here is that the CMS methodology was circular? A Absolutely.").

suppose that after auditing these data, only 40 of these FFS Medicare beneficiaries have the HCC. Then the *audited* dollar coefficient for the HCC is \$250 ($\$10,000 / 40$). Assuming there are 100 MA beneficiaries, 40 of whom have the HCC after the MA data are audited, MA plans would have received \$8,000 ($\200×40) when payments were based on CMS-HCC model calibrated on *unaudited* FFS data. However, when the FFS data used to calibrate the model is *audited*, payment to MA plans would increase to \$10,000 ($\250×40).

Exhibit 6
Example of FFS Data Audits on Payments to MA Plans

		Unaudited FFS Data	Audited FFS Data
FFS			
Total FFS expenditure for 100 patients	[a]	\$10,000	\$10,000
FFS patients with HCC	[b]	50	40
Dollar coefficient	[c] = [a] / [b]	\$200	\$250
MA Plan			
MA patients with HCC (audited)	[d]	40	40
Total payment to MA plan	[e] = [c] x [d]	\$8,000	\$10,000

154. This simplified example provides two key results, which extend readily to the full CMS-HCC model: (1) removing unsupported HCCs from FFS enrollee data has the effect of spreading the same amount of expenditures incurred by CMS for FFS Medicare enrollee health care over fewer enrollees per HCC, and so per-enrollee payments per HCC—i.e., the dollar coefficient—must on average increase; and (2) MA plans that have enrollees for whom the payments per HCC increase would be paid more by CMS if CMS audited the FFS data. This intuition and the logic of this example are entirely consistent with the mathematics outlined in CMS’s FFS Study Addendum.²⁸⁶

155. CMS’s motivation for applying the IPARS adjustment derives from its claim in the FFS Study Addendum that it must “maintain coefficient values such that predicted FFS expenditures do not increase.”²⁸⁷ That is, CMS claims that the total predicted expenditures derived using *audited* dollar coefficients and unaudited data ($\$12,500 = \250×50 beneficiaries with the HCC,

²⁸⁶ CMS, FFS Study Addendum, p. 8, steps (3–7).

²⁸⁷ CMS, FFS Study Addendum, p. 9, step (11).

in the above example) should equal the total predicted expenditures derived using *unaudited* dollar coefficients and *unaudited* data (\$10,000 = \$200 x 50 beneficiaries with the HCC in the above example).²⁸⁸ As a practical matter, this statement would only be true if the *audited* and *unaudited* dollar coefficients were identical because both predicted expenditures are estimated using the same *unaudited* data. However, as the simplified example above demonstrates, removing unsupported codes from FFS data for a particular HCC would increase the average of the dollar coefficients estimated from the CMS-HCC model for that HCC. As CMS has shown, removing unsupported codes from FFS data increases the average of the dollar coefficients estimated from the CMS-HCC model.²⁸⁹ Thus, CMS's claim that these two predicted expenditures should be equal is incorrect. However, based on this incorrect claim, CMS applies an IPARS adjustment. Specifically, as explained above, the IPARS adjustment is the ratio of the average predicted FFS Medicare expense calculated using *audited* dollar coefficients multiplied by *unaudited* data to the average FFS Medicare expenditure using *unaudited* dollar coefficients and *unaudited* FFS data. CMS then divides the *audited* dollar coefficients by the IPARS adjustment (which is greater than one), thus deflating these coefficients and effectively cancelling out the increase in the average of the dollar coefficients that results from removing unsupported codes from the FFS data. That is, the IPARS adjustment incorrectly biases downward the dollar coefficients used to estimate the HCC relative factors and the MA risk scores.

156. The intuition for why this is the case is most easily seen in the example in Exhibit 7. In this example, CMS would calculate the IPARS adjustment as 1.25 $[(\$250 \times 50) / (\$200 \times 50)]$. CMS would then divide the *audited* coefficient of \$250 by this ratio and derive the exact same value as the *unaudited* coefficient: \$200. CMS would label this final value as the “audited”

²⁸⁸ This claim is clear by examining steps (2) through (12) in the FFS Study Addendum justifying a “General Expenditure Adjustment to Offset Deletion Bias.” CMS writes that “To maintain coefficient values such that predicted FFS expenditures do not increase, we need a factor Z such that [...] the total using the ‘new’ coefficients [is not] greater than the original predicted expenditures,” see steps (9) and (11). CMS estimates this “total using the ‘new’ coefficients” by multiplying the *audited* dollar coefficients by the “original number of ones” or, equivalently, the *unaudited* data, see step (7). CMS compares this with the “original predicted expenditures” calculated by multiplying the *unaudited* dollar coefficients by the *unaudited* data. See CMS, FFS Study Addendum, pp. 8–9.

²⁸⁹ See CMS, FFS Study Addendum, p. 8, steps (3–6).

coefficient despite their flawed, circular logic. Indeed, Mr. Kornfield testified that the CMS methodology “divided away the difference” it found in the coefficients.²⁹⁰

Exhibit 7
The IPARS Adjustment Is Circular

		Unaudited FFS Data	Audited FFS Data
FFS			
Total FFS expenditure for 100 patients	[a]	\$10,000	\$10,000
FFS patients with HCC	[b]	50	40
Dollar coefficient	$[c] = [a] / [b]$	\$200	\$250
MA Plan			
MA patients with HCC (audited)	[d]	40	40
Total payment to MA plan	$[e] = [c] \times [d]$	\$8,000	\$10,000
IPARS Payment Adjustment			
Audited Coefficient	[c (audited)]		\$250
CMS Claimed Expenses	$[f] = [b \text{ (unaudited)}] \times [c \text{ (audited)}]$		\$12,500
IPARS Adjustment	$[g] = [f] / ([b \text{ (unaudited)}] \times [c \text{ (unaudited)}])$		1.25
IPARS Adjusted Coefficient	$[h] = [c \text{ (audited)}] / [g]$		\$200
Total payment to MA plan after IPARS Adjustment	$[i] = [h] \times [d]$		\$8,000

157. As this example makes clear, through its use of the IPARS adjustment, CMS does not estimate the impact of unsupported codes in FFS data on the CMS-HCC model but rather uses a methodology that effectively assumes the presence of unsupported codes have no impact.

158. I note that CMS’s flawed reasoning leading to the IPARS adjustment is based on its incorrect claim in the FFS Study Addendum that the total predicted expenditures derived using *audited* dollar coefficients and *unaudited* FFS data (\$12,500 = \$250 x 50 FFS Medicare beneficiaries with the HCC, in the above example) should equal the total predicted expenditures derived using *unaudited* dollar coefficients and *unaudited* FFS data (\$10,000 = \$200 x 50 FFS Medicare beneficiaries with the HCC in the above example). This IPARS adjustment undoes the entire premise of deriving new coefficients based on audited data. Instead, total predicted expenditures derived using *audited* dollar coefficients and *audited* FFS data should be equal to total predicted expenditures derived using *unaudited* dollar coefficients and *unaudited* FFS data.

²⁹⁰ Kornfield Deposition, pp. 217:21-218:4 (“Q Do you agree that CMS’s methodology appears to be designed to minimize differences in payments under the two models? A Yeah, I don’t—I don’t remember the specifics of—of exactly how CMS did this, but—but if memory serves, the study that they did, there was a difference, but then they essentially divided away the difference to show that there wasn’t a difference. So yes, I agree with that.”).

As the simple example demonstrates, the total predicted expenditures are indeed equivalent—\$10,000 in both cases.

159. Moreover, there is no conceptual reason for CMS to “make adjustments” to FFS Medicare expenditures. The exercise of determining whether an FFS adjuster is necessary requires keeping FFS Medicare expenditures *constant* while removing unsupported diagnosis codes to derive audited dollar coefficients and audited relative factors. As discussed in Section VIII.A, the basis of the CMS-HCC model is that CMS should pay MA plans for a beneficiary the expected cost of covering that beneficiary in FFS Medicare. MA plans should not be paid less than what their enrollees would be expected to cost if they were enrolled in FFS Medicare, while also accounting for the plan’s MA bid.²⁹¹ The expected cost of covering a beneficiary in FFS Medicare includes expenditures that CMS incurs for claims with unsupported diagnosis codes.²⁹² Thus, the CMS-HCC model should compensate MA plans for these codes to preserve 100 percent parity to FFS Medicare. This also mirrors the fact that MA plans pay providers that provide services to the plans’ enrollees for claims with unsupported diagnosis codes.²⁹³ CMS’s use of an IPARS adjustment to reduce FFS Medicare expenditures in the audited data assumes that Medicare did not pay expenditures reported in the FFS data for claims with unsupported diagnosis codes and that MA plans *never* pay providers for claims with unsupported diagnosis codes, which is implausible.²⁹⁴

²⁹¹ As noted in Section VIII.A, when insurers bid below the benchmark, MA plans are undercompensated if the total payment they receive is less than the amount to which they are entitled, based on the plan’s quality rating and how far below the benchmark the insurer bid.

²⁹² In 2021, FFS Medicare found a 6.26 percent improper payment rate from claims submitted from July 2019 through June 2020, with 79.5 percent of improper payments attributed to incorrect coding or insufficient or no documentation. See “2021 Medicare Fee-for-Service Supplemental Improper Payment Data,” *U.S. Department of Health & Human Services*, December 7, 2021, pp. 1–2, available at <https://www.cms.gov/files/document/2021-medicare-fee-service-supplemental-improper-payment-data.pdf>.

²⁹³ In 2012, the Federal Bureau of Investigation reported that “fraudulent billings to health care programs, both public and private, are estimated between three and ten percent of total health care expenditures.” See “Financial Crimes Report To the Public, Fiscal Years 2010–2011,” *Federal Bureau of Investigation*, February 27, 2012, p. 16, available at <https://www.fbi.gov/file-repository/stats-services-publications-financial-crimes-report-2010-2011-financial-crimes-report-2010-2011.pdf/view>.

²⁹⁴ As noted above, CMS should not “make adjustments” to FFS Medicare expenditures through the IPARS adjustment. However, even setting this aside, CMS’s methodology to estimate the impact of removing unsupported codes in the FFS data is incorrect. Specifically, the IPARS adjustment assumes an equivalent expenditure reduction regardless of which diagnosis codes were removed, but this is unlikely to be the case. For example, diagnosis codes associated with outpatient services in FFS Medicare would not necessarily lead to a reduction in FFS Medicare expenditures because outpatient services are reimbursed based on health care services conducted, not solely on patient diagnoses. See Cubanski et al., *A Primer on Medicare*. It is possible that CMS believes that some of the unsupported codes they identified in the FFS data indicate that CMS should never have paid providers for those

160. In sum, CMS's reasoning for an IPARS adjustment is flawed. No such adjustment is needed.

C. CMS Uses Data Wholly Inadequate for the Task of Estimating the Impact of Unsupported Codes in FFS Data on the CMS-HCC Model

161. I now explain why the data that CMS used in the FFS Adjuster Study is inadequate for estimating the impact of unsupported codes in FFS data on MA risk scores and, as a result, payments to MA plans. Specifically, CMS uses a sample of 2008 CERT data in its FFS Adjuster Study to estimate the probability that an HCC is unsupported in the FFS data.²⁹⁵ However, using this CERT data sample is problematic, and its use for estimating the probability that an HCC is unsupported requires making assumptions that likely do not hold.

162. I discuss three key shortcomings of using the CERT data sample for estimation of the FFS Adjuster:

- First, the sample includes claims from only the year 2008;
- Second, the sample is unlikely to be nationally representative; and
- Third, the sample contains many HCCs with very few claims, in part because it relies only on claims for outpatient services.

163. CMS's methodology cannot overcome these shortcomings and so cannot recover credible estimates for the true probability that an HCC is unsupported. This renders CMS's conclusions that unsupported diagnosis codes in FFS data do not affect payments to MA plans unfounded and unreliable. I discuss each of these shortcomings further below.

164. First, the CERT data sample includes claims from only 2008—a single calendar year.²⁹⁶ Thus, CMS's estimates of the probability that an HCC is unsupported and of the impact of unsupported codes in the FFS data apply to only 2008. For CMS to extrapolate these estimates to all years after 2008 requires CMS to assume that there have been no changes in the coding accuracy in FFS or MA data for any HCC over time. Such an assumption is implausible for several reasons.

services. If that is the case, correctly calculating an FFS adjuster requires a comprehensive audit of all FFS Medicare claims to determine which claims do not support diagnoses and whether the expenditures on those claims need to be refunded to the government. Such an exercise is well beyond anything that CMS has done.

²⁹⁵ CMS, FFS Adjuster Study Technical Appendix, p. 6.

²⁹⁶ CMS, FFS Adjuster Study Technical Appendix, p. 6.

- CMS has added new HCCs and significantly changed the structure of the HCCs since 2008.²⁹⁷ CMS's FFS Adjuster Study has not investigated whether new HCCs or changes to groups of diagnoses in a given HCC would impact the probability that an HCC is unsupported for a given beneficiary in a year and, hence, the need for an FFS Adjuster.
- Since 2008 there has been an increase in the use of health information technology that could impact the accuracy of coding,²⁹⁸ as well as changes in diagnostic practices that could impact the probability that an HCC is unsupported.²⁹⁹
- When the underlying diagnoses that indicate a given HCC vary with respect to their probabilities of being unsupported, an increased share of beneficiaries with a diagnosis that has a higher probability of being unsupported would increase the probability that the HCC is unsupported. When using data only from 2008 to form its conclusions, CMS is ignoring all such possible changes that could have occurred since 2008.
- Finally, as discussed in Section VI.B, there has been a steady increase in the fraction of Medicare beneficiaries enrolled in MA over time. It is plausible that the average characteristics of these beneficiaries is changing over time (e.g., with sicker beneficiaries with a different distribution of HCCs enrolling in MA over time, or with beneficiary take-up of MA spreading across geographic regions in the United States so that newer beneficiaries are more likely to live in certain states, etc.).³⁰⁰ What this means is that the probability that HCCs are unsupported among remaining FFS Medicare patients would likewise change over time.

²⁹⁷ See fn. 155 above.

²⁹⁸ See, e.g., Jinhyung Lee and Jae-Young Choi, "Improved efficiency of coding systems with health information technology," *Scientific Reports*, 11, Article No. 10294, 2021, p. 1.

²⁹⁹ For instance, more advanced big data approaches can improve accuracy of diagnosis. See, e.g., "AI Improves Accuracy of Heart Condition Diagnosis," *Cedars-Sinai*, October 27, 2022, available at <https://www.cedars-sinai.org/newsroom/ai-improves-accuracy-of-heart-condition-diagnosis>. Similarly, there is evidence that the transition to the ICD-10 in 2015 impacted coding, improving accuracy over time in some settings. See Cindy Cai, et al., "Effect of ICD-9 to ICD-10 Transition on Accuracy of Codes for Stage of Diabetic Retinopathy and Related Complications: Results From the CODER Study," *Ophthalmology Retina*, 5 (4), April 2021, pp. 374–380.

³⁰⁰ One study found an increase in the share of Medicare Advantage enrollees who are young, black, and dually enrolled in Medicaid between 2011 and 2019. See William Weeks, et al., "Trends in Characteristics of Adults Enrolled in Traditional Fee-for-Service Medicare and Medicare Advantage, 2011–2019," *Medical Care*, 60(3), March 2022, pp. 227–231 at p. 227.

165. Second, the 2008 CERT data sample may not be nationally representative of the FFS Medicare population, and CMS has not provided any evidence that it is. Indeed, CMS conceded that the CERT data sample was “not designed to produce a representative sample of diagnoses.”³⁰¹ Without a representative sample, CMS must assume that the probability that an HCC is unsupported for the entire FFS Medicare population is the same as the probability estimated using the 2008 CERT data sample. This is an unsupported and implausible assumption. For example, the CERT data sample could oversample a healthier population, a younger population, or a wealthier population. Relatedly, the CERT data sample includes only outpatient claims, which may lead to bias in both the set of beneficiaries included in the sample and in the claim-level probability that a diagnosis code is unsupported, to the extent that the probability of unsupported codes is different between outpatient and inpatient claims.³⁰² In sum, any systematic differences between the 2008 CERT data sample and the overall FFS Medicare population (in terms of both demographic characteristics and HCCs) would result in differences between the estimated probability that an HCC is unsupported in the 2008 CERT data sample (and thus the FFS Adjuster Study) and in the overall FFS Medicare population.

166. Third, the 2008 CERT data sample contains many HCCs with an extremely small number of claims. CMS acknowledges that “for many of the diagnoses and by extension, the HCCs, we have an insufficient sample size to develop reliable discrepancy rates at the HCC level.”³⁰³ For example, the data sample includes only one claim with a diagnosis of extensive third-degree burns, and only two claims with a diagnosis of severe head injury.³⁰⁴ CMS admits that “[v]ariation [in HCC discrepancy rates] due to insufficient sample size confounds the analysis.”³⁰⁵ A fundamental principle of statistics (i.e., the Law of Large Numbers) is that statistics estimated on larger sample sizes are likely to be closer to the population value of the statistic (since the variance of an estimate declines with sample size).³⁰⁶ Thus, conclusions about population statistics drawn from small samples are inherently less reliable. Because of this, estimates of the probability that an HCC is unsupported based on a very small set of claims

³⁰¹ CMS, FFS Adjuster Study Technical Appendix, p. 8.

³⁰² CMS, FFS Adjuster Study Technical Appendix, p. 6.

³⁰³ CMS, FFS Adjuster Study Technical Appendix, p. 8.

³⁰⁴ CMS, FFS Adjuster Study Technical Appendix, p. 8.

³⁰⁵ CMS, FFS Adjuster Study Technical Appendix, p. 8.

³⁰⁶ Morris DeGroot and Mark Schervish, *Probability and Statistics, Fourth Edition*, (Boston: Addison Wesley, 2012), pp. 348–353.

from the 2008 CERT data sample would be unreliable. Thus, CMS's conclusions derived from the 2008 CERT data sample would be unreliable.

167. As further examples of the small number of claims in the 2008 CERT data sample, the data contain only one observation each for HCCs 70 (muscular dystrophy), 107 (cystic fibrosis), 150 (extensive third-degree burns), and 177 (amputation status, lower limb/amputation complications). For HCCs 70 and 150, the single claim is supported, and CMS estimates a probability of being unsupported of 0 percent. For HCCs 107 and 177, the single claim is unsupported, and CMS estimates a probability of being unsupported of 100 percent.³⁰⁷ These two estimates likely suffer from the small sample bias described above. CMS attempts to “mitigate” the impact of small sample size by replacing observed probabilities with “effective” probabilities. Specifically, CMS assigns all four of these HCCs a probability of being unsupported of 33.8 percent based on the overall probability in the entire CERT data sample.³⁰⁸ However, there is no reason to believe the actual probabilities of being unsupported for these HCCs are all equal to overall probability of 33.8 percent.

168. Further, the CERT data sample had no claims with HCC 77 (respirator dependence/tracheostomy status).³⁰⁹ In this case, CMS has no data with which to estimate the actual probability of being unsupported for this HCC. Again, CMS simply assigns a claim level probability of 33.8 percent to this HCC.³¹⁰ But again, there is no reason to believe that this 33.8 probability rate is accurate.

169. In sum, for all of the reasons discussed in this sub-section, the data that CMS used in the FFS Adjuster Study is inadequate for estimating the impact of unsupported codes in Medicare FFS data on audited relative factors, MA risk scores, and as a consequence, payments to MA plans. As such, CMS cannot use the FFS Adjuster Study to conclude that payments to MA plans are not systematically affected by unsupported codes in the Medicare FFS data.

³⁰⁷ CMS, FFS Adjuster Study Technical Appendix, pp. 7–8.

³⁰⁸ In general, CMS bucketed HCCs into high, baseline, and low probabilities of being unsupported based on the probability they estimated in the sample. HCCs were assigned to the high or low categories if they had a discrepancy rate that was statistically different from the overall discrepancy rate (at a 95 percent confidence level) and were assigned to the baseline category otherwise. For the four HCCs discussed in the text, because there was only one claim for each HCC in the sample, the probability that the HCC was unsupported was indistinguishable from the mean. These HCCs were therefore assigned to the baseline category, with a rate of being unsupported of 33.8 percent. See CMS, FFS Adjuster Study Technical Appendix, pp. 8–11.

³⁰⁹ CMS, FFS Adjuster Study Technical Appendix, p. 7.

³¹⁰ CMS, FFS Adjuster Study Technical Appendix, pp. 9–11.

D. Contrary to the Conclusion of CMS’s Flawed FFS Adjuster Study, an FFS Adjuster Is Necessary and Unsupported Diagnosis Codes that Exist in FFS Data Likely Impact Payments to MA Plans

170. Although CMS’s 2023 Final Rule indicated that CMS would not apply an FFS adjuster, CMS’s conclusion in its FFS Adjuster Study that unsupported codes in FFS data have no impact on payments to MA plans under the CMS-HCC model is incorrect. As I have explained in this section, CMS’s FFS Adjuster Study is based on unfounded assumptions, follows a deeply flawed methodology, and relies on problematic data. Accordingly, CMS’s analysis is unreliable and cannot be used to determine whether unsupported diagnosis codes in the FFS data impact payments to MA plans and if so, by how much. Also as discussed in this report, CMS’s methodology biases its estimate of the impact of unsupported diagnosis codes in the FFS data towards zero due to: (1) CMS likely underestimating the probability that an HCC is unsupported in the FFS Medicare population, which would lead it to underestimate audited relative factors on average; and (2) CMS inappropriately deflating the audited relative factors by the IPARS adjustment, which incorrectly adjusts FFS Medicare expenditures despite actual FFS Medicare expenditures being unaffected.

171. As I explained above, using FFS data with unsupported codes to estimate the CMS-HCC model leads to lower estimated dollar coefficients, on average, relative to using FFS data in which such unsupported codes are removed. Thus, removing such unsupported codes in FFS data increases, on average, the dollar coefficients estimated by the CMS-HCC model. Therefore, had CMS defined an FFS adjuster in a manner consistent with this increase in the average of the dollar coefficients, such an FFS adjuster would lead to increased payments to MA plans relative to the situation where only MA plans remove unsupported codes. Consistent with this, Hans Dutt, President and Principal Economist at Stat Analytics and author of the CMS FFS Adjuster Study, testified in his deposition that if diagnoses are deleted from the FFS data, the coefficients in the CMS-HCC model will increase.³¹¹ And as further supported by the evidence below, this contradicts CMS’s conclusion that the FFS Adjuster is unnecessary.

³¹¹ Deposition of Hans Dutt (Stat Analytics), September 28, 2022, pp. 34:9–12, 118:11–21 (“Q. And Dr. Dutt, do you agree with that mathematical phenomenon, that if you don’t adjust the expenditures but you delete certain diagnoses codes, the coefficients go up? A. Yes, so—so that is—I think you articulated it well. It is a mathematical certainty, right? It’s a phenomenon that’s going to happen, is if you have the expenditures staying the same, and you know, you basically delete the—make the—the denominator smaller, the coefficients are going to go up. That is going to happen.”).

172. In the remainder of this section, I highlight testimony in this matter as well as other sources that indicate that the removal of unsupported diagnosis codes from FFS data would impact payments to MA plans, and that an FFS adjuster is necessary.

173. First, officials have testified that the removal of unsupported diagnosis codes from FFS would impact payments to MA plans by changing the coefficients of the CMS-HCC model. For instance, Thomas Kornfield testified that the coefficients would be different if the FFS data did not have unsupported diagnoses.³¹² Sean Creighton also explained in his deposition that if CMS removes unsupported diagnosis from the FFS data used to estimate the dollar coefficients from the CMS-HCC risk adjustment model, the average of the dollar coefficients would change.³¹³ Thomas Hutchinson, former Director of Medicare Plan Payment Group at CMS, testified that an FFS adjuster was necessary to improve the accuracy of CMS's assessment as to whether MA plans were overpaid.³¹⁴

174. Additionally, CMS has performed or commissioned studies which have found that unsupported codes in the FFS data impact the dollar coefficients and relative factors from the CMS-HCC model, and consequently impact MA risk scores and payments to MA plans.³¹⁵ Specifically, a 2009 study suggested that a "proxy" for the FFS adjuster is equal to 3.9 percent.³¹⁶ A 2010 study proposed that an adjustment of approximately 4.9 percent be applied to MA risk scores when assessing compensation to MA plans, based on the estimated impact of

³¹² Kornfield Deposition, pp. 198:24–199:12.

³¹³ Creighton Deposition, day 2, pp. 30:17–34:10. ("[...] Q. And going back to that notion of removing from the population the erroneous diagnosis codes so that you have the true population that suffer from the conditions, you would expect the costs, the incremental costs, of caring for that condition to rise? [...] THE WITNESS: That – that has been my expectation. The – our study showed that it was a bit more complicate than that. So, yeah, that's normally the expectation [...] However, it turns out it's not, like a lot of statistical stuff, it's not quite as simple as that. So we found in our studies, sometimes they rise, sometimes they go down. But on—on average what you do know is they're gonna be different, they're... You know. So I agree with your initial hypothesis, it was my hypothesis, too. Turns out it's not true for all conditions across the model. [...]").

³¹⁴ Deposition of Thomas Hutchinson (CMS), January 26, 2022, pp. 18:12–19, 59:10–17 ("When I refer to 'accurate amount' or when I referred to 'accurate amount,' I meant the amount to—the amount of payment error that CMS measured in a RADV audit at a plan level. The accurate calculation of that payment amount needs to have a fee-for-service adjuster built into it to be maybe more accurate, we will say, rather than the perfect accuracy.")

³¹⁵ Hornsby Deposition, p. 83:9–20 ("Q. [...] Are you aware of a single document before 2016 where the government determined that using unaudited fee-for-service claims data really has no impact or an indeterminate impact on the calculation of coefficients and risk scores in the risk adjustment model? [...] A. I am not aware of any MPPG document that says there is no impact.").

³¹⁶ USBP001706860–63 at USBP001706861. This 3.9 percent "proxy" for the FFS Adjuster was based on a November 2008 "FFS CERT National Paid Claims Error Rate" of 3.9 percent.

removing unsupported codes from the FFS data.³¹⁷ Similarly, a 2011 document suggested that the average risk score in MA plans be adjusted upward by 5 percent to account for the impact of unsupported diagnosis codes in the FFS data when assessing overpayments to MA plans.³¹⁸ Around the time when CMS announced the RADV audits for MA plans in 2012, a CMS study proposed that an FFS adjuster be 8.1 percent.³¹⁹

175. Since the CMS FFS Adjuster Study was published in 2018, three separate studies published in 2019 by Avalere, Milliman, and the Wakely Consulting Group also concluded that an FFS adjuster is necessary.³²⁰ In particular, Avalere tested three alternatives to the assumptions made by CMS and concluded that the presence of coding errors in FFS claims data results in underpayments of nearly 8 percent to MA plans.³²¹ The Milliman study also found that the CMS FFS Adjuster Study cannot be used to conclude that the FFS adjuster is not necessary.³²² In contrast to CMS's findings, Milliman's estimates suggest that the audited CMS-HCC model increases risk scores for the MA population by 10–32 percent relative to the model run with unaudited FFS data.³²³ Likewise, a study conducted by the Wakely Group concluded that, after correcting errors in the FFS Adjuster Study, failing to use an FFS Adjuster would lead to underpayments to MA of almost 10 percent.³²⁴

³¹⁷ USBP052805236–8 at USBP052805236–7; Deposition of Mark Boward (Deloitte), September 20, 2022, Exhibit 1327-1.

³¹⁸ USBP001648100–1 at USBP001648100.

³¹⁹ CMS, Notice of Final Payment Error Calculation Methodology; Deposition of Cheri Rice (CMS), August 3, 2022, pp. 16:2–7, 101:7–17; USBP001565703–8 at USBP001565706 (“Based on this CERT RADV audit, we estimate the FFS adjuster to be 8.1%”).

³²⁰ Letter from Matthew Eyles to Seema Verma, p. 6 (“Since CMS published the Proposed Rule, two independent analyses – one by Avalere (the Avalere study) and one by Milliman (the Milliman study) – clearly demonstrate the need for a FFS adjuster. Importantly, neither analysis estimates the appropriate amount of the FFS adjuster. Rather, each study demonstrates that CMS’s methodology, after adjusting for methodological flaws, would lead to a FFS adjuster that is **not zero**.”).

³²¹ “Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment,” *Avalere Health*, March 2019, available at <https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf> (“Avalere tested 3 alternatives to the assumptions made by CMS, comparing the results. Avalere’s analysis finds that audit miscalibration bias yields underpayments of nearly 8%.”).

³²² Letter from Matthew Eyles to Seema Verma, p. 2 (“Milliman finds that the CMS technical analysis ‘cannot appropriately be used to conclude a FFS adjuster is not required.’ Milliman adjusts for errors in CMS’s methodology to find that an FFS adjuster is both positive and material. As such, Milliman’s study refutes CMS’s conclusion that a FFS adjuster is not necessary.”). See also, Rob Pipich, “Medicare Advantage RADV FFS adjuster: White paper,” *Milliman White Paper*, August 23, 2019 (“Milliman White Paper”), pp. 1, 4, available at https://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf (“Further analysis must be completed to calculate an accurate FFS adjuster. In any case, the range is wide and even the bottom end is material and significant.”).

³²³ Milliman White Paper, p. 21.

³²⁴ Lambert Report, p. 6.

176. In sum, contrary to the findings of the CMS FFS Adjuster Study, other studies have shown that the removal of unsupported diagnosis codes from the FFS data would impact assessment of the proper compensation to MA plans and that an FFS adjuster is needed. Indeed, these studies indicate that CMS's payments to MA plans would be too low if MA plans were required to remove unsupported diagnosis codes from their data, but FFS Medicare was not required to do the same.

X. Economic Theory and Historical Evidence Indicate that Requiring MA Plans to Remove Unsupported Diagnosis Codes Would Result in Higher Prices or Less Generous Plans

177. CMS alleges that UnitedHealth failed to delete unsupported codes.³²⁵ Removing unsupported diagnosis codes associated with certain MA enrollees lowers those enrollees' risk scores, thereby—all else equal—lowering CMS's payments to the MA plan. This, however, does not reduce the enrollees' actual health care expenditures. Hence, requiring that MA plans remove unsupported diagnosis codes, relative to the current world and making no other changes to the way MA plans are paid, would reduce MA plans' revenues while the costs associated with providing care to their enrollees would remain unchanged.

178. Economic theory predicts that a firm faced with falling revenues and similar costs would adjust their behavior.³²⁶ Indeed, both economic theory and historical evidence indicate that MA plans in a similar situation would act in one or more of the following ways: (1) increase their plan bids, with the consequence of increasing government or enrollee expenses, or increase

³²⁵ Complaint, ¶ 342.

³²⁶ It is possible that in the short run, a firm faced with falling revenues and similar costs (i.e., falling profits) may not alter its behavior. For example, suppose all firms in an industry face falling profits due to a short-term industry-wide shock. In this context, firms face an opportunity cost by remaining in the industry—they could gain higher returns on investments, capital, and labor in other industries or sectors. In the short run, these firms may also face costs to switching their resources to alternate uses and so may not change their behavior. In the long run, these same firms would alter their behavior: economic theory tells us that firms facing systematically better opportunities (i.e., better returns on investing its resources) by allocating these resources differently will do so. MA insurers are particularly unlikely to absorb profit losses without altering their behavior because MA plan profits are capped through the MLR. As discussed in ¶ 43, MLR is the proportion of premium revenues that a health insurance company spends on clinical services and quality improvement. MA insurers are required to have an MLR of at least 85 percent, meaning that only the remaining 15 percent of premium revenues can be spent on administrative costs and profits. Due to this constraint on how an MA plan can allocate its revenues, MA plans are likely to adjust their behavior. See CMS, Medical Loss Ratio. See also, "Medical Loss Ratio," *Centers for Medicare & Medicaid Services*, modified September 6, 2023, available at <https://www.cms.gov/marketplace/private-health-insurance/medical-loss-ratio>; Pindyck and Rubinfeld, *Microeconomics*, p. 205.

enrollee cost sharing; (2) reduce the quality and/or number of benefits associated with their plans; and/or (3) exit the market altogether, with the consequence of reducing the options available to Medicare beneficiaries and thereby reducing consumer welfare. I discuss each of these potential responses by MA plans in Sections X.A–C below.

179. As a matter of economics, accurately estimating the change in government payments to UnitedHealth or the change in consumer welfare when requiring UnitedHealth to remove unsupported codes necessitates accounting for such dynamic effects. I discuss this further in Section X.D below.

A. If Payments to MA Plans Decline, Some MA Plans Would Increase Their Bids, Thereby Increasing Government and Enrollee Expenses, or Increase Enrollee Cost Sharing

180. Requiring MA plans to identify and delete unsupported codes would lead to lower payments from CMS to MA plans. In turn, MA plans would have an incentive to increase their bids to compensate for these lower payments. MA plans would also have an incentive to increase enrollee cost sharing to compensate for lower payments.

181. As discussed in Section VII.C, CMS compensates an MA plan based on a comparison between a CMS benchmark and the bid from the MA plan, while incorporating the risk scores of the MA plan enrollees and the quality of the MA plan. When an MA plan anticipates a reduction in risk scores (which would reduce payments to the MA plan, all else equal), the plan can increase its bid and thereby compensate for the impact that this reduction in risk scores would have on payments to the plan.

182. If an MA plan were to increase its bid, there are three scenarios to consider: (1) a plan that would bid *below* the benchmark both before and after the rule change; (2) a plan that would bid *below* the benchmark before the rule change but *above* the benchmark after; and (3) a plan that would bid *above* the benchmark both before and after the rule change.

- If the plan's bid is originally below the benchmark, and the plan increases its bid to a value that remains below the benchmark, then CMS would pay more for each of this plan's enrollees via a higher agreed-upon payment for an enrollee with the average health status. As the plan's bid is now closer to the benchmark, CMS would provide a smaller rebate to the MA plan for each enrollee, mechanically leading to lower

incremental benefits for its enrollees.³²⁷ As discussed in Section VI.B, these benefits can include eye exams and glasses, dental and fitness benefits, and hearing aids. It is thus likely that such benefits would become less widely available following an increase in plan bids.

- If the plan's bid is originally below the benchmark, and the plan increases its bid to a value above the benchmark, then CMS would pay more for each of this plan's enrollees *and* the plan's enrollees would now be required to pay the MA plan premiums to cover the shortfall between the benchmark and the plan's bid.³²⁸ In this case, the plan would no longer receive any rebates from CMS. The elimination of the rebate would reduce incremental benefits for plan enrollees. Enrollees might leave the plan due to the absence of incremental benefits or due to the additional cost of an incremental premium.
- If the plan's bid is originally above the benchmark, and the plan further increases its bid, then the plan's enrollees would need to pay the MA plan higher premiums for the same insurance product and benefits. Enrollees might leave the plan rather than pay these higher premiums.

183. From the perspective of the MA plan's enrollees, an increase in an MA plan's bid results in either reduced incremental benefits, higher premiums, or both. In all cases, there is a loss to the enrollee. Moreover, in the first two cases discussed above, any savings realized by CMS from removing unsupported codes and decreasing the risk scores for some MA plan enrollees could be partially or even fully offset by the resulting increase in the plan bids, and thus result in some additional payments to the MA plans.

184. Additionally, some MA insurers would increase enrollee cost sharing (e.g., drug copayments) for their MA plans in response to a reduction in payments from CMS. As I discuss below, in order to ensure that the plan can cover enrollee health care expenditures, a plan could require enrollees to pay a larger share of some of their procedures out-of-pocket. Such a change

³²⁷ MA plan rebates can be used to add additional benefits or to reduce plan premiums or cost-sharing requirements. I use the expression "incremental benefits" to refer to the variety of uses plans have for rebates. See MedPAC, Medicare Advantage Program Payment System, p. 3.

³²⁸ For examples of how plans are compensated when bidding at or above the benchmark, see Section VII.C.1.

would directly reduce the welfare of MA enrollees and potentially drive MA enrollees to leave the plan.

185. Historical evidence confirms that MA insurers have responded to legislated changes in the generosity of CMS payments to MA plans by adjusting cost-sharing requirements and premiums. As discussed in Section V, two major changes in Medicare law, first the BBA (passed in 1997) and later the MMA (passed in 2003), impacted the size of the payments CMS provided to MA plans. The BBA first imposed a cap on payments, and the MMA went on to remove this cap and increase payments.³²⁹ Following the MMA, CMS contracted a study to assess the effects of these legislated changes in payment provisions.³³⁰ The CMS study noted that “plans responded to the payment update restrictions of the BBA and rising medical cost inflation by attempting to raise revenue through higher premiums.”³³¹ It also noted that “[c]ost sharing increased substantially in the early years of the decade, then declined or stabilized post MMA.”³³²

186. Other academic research affirms this point as well. A paper by Cabral and coauthors (2018), for example, shows that an increase in payments to private plans reduced both premiums and enrollee cost sharing.³³³ Duggan et al. (2016) also find suggestive evidence that increases in payments to MA plans pass through to consumers, especially in the most competitive markets.³³⁴ Similarly, Pelech and Song (2023) find that the ACA-induced reductions

³²⁹ See ¶¶ 39–42.

³³⁰ Pope et al., Impact of Increased Financial Incentives to Medicare Advantage Plans, p. 7.

³³¹ Pope et al., Impact of Increased Financial Incentives to Medicare Advantage Plans, p. 3.

³³² Pope et al., Impact of Increased Financial Incentives to Medicare Advantage Plans, p. 4. See also, Daria Pelech and Zirui Song, “Pricing and Pass-Through in Response to Subsidies and Competition: Evidence from Medicare Advantage Before and After the Affordable Care Act,” Working Paper, January 12, 2023 (“Pelech and Song, Pricing and Pass-Through in Response to Subsidies and Competition”), p. 4, available at [https://hcp.hms.harvard.edu/sites/default/files/assets/users/Working Papers/Pricing_Pass-through_MA_1-12-23.pdf](https://hcp.hms.harvard.edu/sites/default/files/assets/users/Working%20Papers/Pricing_Pass-through_MA_1-12-23.pdf) (“High benchmarks, combined with the new bidding mechanism, also changed how insurers allocated resources between enrollee benefits and premiums. Because benchmarks were high, few insurers charged additional premiums beyond the standard Medicare premium paid by all beneficiaries, and instead competed by providing additional covered benefits and reduced cost sharing.”).

³³³ Marika Cabral, et al., “Do Larger Health Insurance Subsidies Benefit Patients or Producers? Evidence from Medicare Arbitrage,” *American Economic Review*, 108(8), 2018 (“Cabral et al., Evidence from Medicare Arbitrage”), pp. 2048–2087 at pp. 2049, 2063–2068, 2085. The authors also describe that decreased payments might result in an increase in premiums or less generous benefits (“Naturally, the lines of argument are reversed when a reduction in payments is proposed.”).

³³⁴ Duggan et al., Who Benefits when the Government Pays More, p. 62.

in benchmarks, and the associated decrease in payments to plans, are associated with a decrease in the rebates offered to prospective enrollees.³³⁵

187. Finally, evidence in the current matter is also consistent with this academic research. In particular, Melissa Sedor, Vice President of Finance of Medicare & Retirement for UnitedHealthcare, provided testimony related to UnitedHealth's MA bids.³³⁶ Ms. Sedor testified that UnitedHealth, following discussion with CMS in 2014, discontinued its claim verification process, which she testified typically led UnitedHealth to delete diagnosis codes associated with their MA plan enrollees.³³⁷ Ms. Sedor testified that the discontinuation of claims verification led to an increase in risks scores for its MA plans and, as a result, to an increase in the payments received by its MA plans.³³⁸ As part of the MA bid process for payment years 2015 and later, however, UnitedHealth used most of the increase in payments to reduce MA plan enrollee premiums or to offer supplemental benefits to MA plan enrollees.³³⁹ That is, when UnitedHealth received more payments from CMS for its MA plans, it reduced the cost sharing faced by its MA plan enrollees and provided additional benefits to those enrollees. For example, for payment year 2015, UnitedHealth estimated that changing the claims verification process resulted in an expected increase in payments of \$140 million, but that roughly \$135 million of that was reinvested back into health plans, with lower premiums and better Part D benefits.³⁴⁰

³³⁵ Pelech and Song, Pricing and Pass-Through in Response to Subsidies and Competition, pp. 5–6 (“For each dollar decrease in the benchmark post-ACA, plans reduced their bids by roughly the same amount—57 cents on average—while passing through an average cut of 26 cents in rebates to beneficiaries. Within this change in rebates, plans reduced cost-sharing and covered benefits by about twice as much on the margin after the ACA as they had increased those buy-downs and coverage before the ACA – perhaps suggesting that insurers allocate cuts towards plan characteristics that are less salient to beneficiaries.”)

³³⁶ Sedor Deposition, p. 19:14–18.

³³⁷ Sedor Deposition, p. 32:1–10 (“Q. [...] And I'm not going to ask you what the claims verification program did or how it worked. But in general, it tended to delete more codes than it added; is that correct? [...] THE WITNESS: The claims verification process generally resulted in deleting of codes. [...] Q. And hence lower risk scores? A. Yes.”), p. 35:10–22.

³³⁸ Sedor Deposition, pp. 32:19–33:8 (“Q. [...] Did the cancellation of the claims verification program affect United's bids? A. Yes, it did. Q. How so? A. When the claims verification process ceased, we were towards the end of pricing for 2015, and the cessation of that process resulted in the 2014 risk scores being higher, which went into the bids, which they then would have projected to also have a higher risk score in 2015. As a result of that higher risk score in 2015, we were able to change our bids around and pass that benefit back to the member by lowering the premiums we received from the members or by adding supplemental benefits to those bids.”).

³³⁹ Sedor Deposition, pp. 33:18–34:3 (“Q. Okay. So the thing that happened was the bid amount stayed the same, the risk score went up, and that money was redistributed to things like supplemental benefits? A. Correct. Q. Or lowering— A. Or lower premiums. Q. And when you say ‘premiums’ in this context, you mean collected from the beneficiaries, not CMS? A. Yes.”).

³⁴⁰ Sedor Deposition, pp. 46:8–48:13, Exhibit 732.

B. If Payments to MA Plans Decline, Some MA Plans Would Reduce the Quality of Benefits Provided

188. In addition to increasing bids and enrollee cost sharing to account for reduced payments, some MA plans would reduce their costs by reducing the quality of the experience enrollees have with their plan. For example, managed care plans, such as MA plans, rely on a network of health care providers and negotiate rates with these providers to help manage costs.³⁴¹ MA plans may reduce the quality of their network as a cost-saving measure when the payments they receive decline, for example by relying more on lower-quality providers.

189. Historical evidence from proposed payment cuts to Medicare Advantage in the last decade supports this conclusion. In 2014, proposed decreases to payments to Medicare Advantage plans were rolled back due to pressure from insurers and lawmakers, who claimed that the cuts would hurt seniors by increasing costs or limiting their provider networks.³⁴² This is consistent with declining payments to MA plans having a negative impact on the quality of plans provided and the patient experience.

190. Academic research confirms these points, as does the evidence in this matter. As discussed above, Cabral and coauthors (2018) find that an increase in payments to private plans increased the generosity of MA plans, and they similarly note that a decrease in payments may result in less generous benefits.³⁴³ As also discussed above, UnitedHealth increased supplemental benefits to its MA plan enrollees when payments to its MA plans from CMS increased.³⁴⁴

³⁴¹ See ¶ 35.

³⁴² Caroline Humer and David Morgan, “U.S. Government Rolls Back Proposed Medicare Advantage Cut,” *Reuters*, April 7, 2014, available at <https://www.reuters.com/article/us-usa-healthcare-medicare/u-s-government-rolls-back-proposed-medicare-advantage-cut-idINBREA361R520140407> (“‘In many parts of the country, including New York, Medicare Advantage works very well. They’ve shouldered their share already and this proposed cut would have been disproportionate, hurting seniors who would lose doctors or pay more. We’re glad the administration heeded our call and reversed the policy,’ Democratic Senator Charles Schumer said in a statement.”).

³⁴³ Cabral et al., *Evidence from Medicare Arbitrage*, pp. 2048–2087 at pp. 2049, 2063–2068, 2085.

³⁴⁴ Sedor Deposition, pp. 32:1–34:2.

C. If Payments to MA Plans Decrease, Some MA Plans Would Exit the Market, Reducing the Number of Options Available to Consumers

191. If MA plans were to receive less in payments from CMS, some MA plans would cease to provide MA insurance (in certain, or even all, counties). In this case, Medicare beneficiaries in the affected counties would face reduced choice in Medicare insurance products.

192. Historical evidence confirms that when MA plans receive less payments, some plans exit. For example, the BBA capped payments to MA plans. Specifically, in 1997, the BBA limited plans' reimbursements to be at most 2 percent higher than the prior year's reimbursement,³⁴⁵ yet between 1999 and 2003, overall Medicare expenditures per enrollee grew between 4.2 and 9.0 percent per year, meaning that many plans were not able to fully cover their costs.³⁴⁶ Plans responded to these reimbursement caps by "reduc[ing] the number of covered services, such as prescription drug coverage, and rais[ing] their cost-sharing requirements."³⁴⁷ In addition, some plans withdrew from certain counties and enrollment in Part C started to decline in 1999. The number of MA contracts fell from 264 to 154 within the first two years following the full implementation of the BBA caps.³⁴⁸ Between 1999 and 2003, more than two million beneficiaries were involuntarily disenrolled from the MA plans that withdrew.³⁴⁹

193. A 2006 report to CMS indicated that following the implementation of the MMA in 2003 and the associated increase in payments in 2004, the number of MA plans available increased by approximately 62 percent in 2005.³⁵⁰ The conclusions of this report to CMS are consistent with other academic work that has studied plan entry in response to increased payments to MA plans.³⁵¹ For example, Duggan et al. (2016) find that relative to comparable counties, those with

³⁴⁵ McGuire et al., *Economic History of Medicare Part C*, pp. 289–332 at pp. 306, 309.

³⁴⁶ See Workpaper 1. Medicare expenditure data available at NHE2021.xlsx when accessing "National Health Expenditures by type of service and source of funds, CY 1960-2021 (ZIP)" at "Historical," *Centers for Medicare & Medicaid Services*, available at <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical>. Medicare enrollment data available at Medicare_Enrollment_Trend_by_State_1985_2012.xlsx when accessing "Historical Enrollment Data (ZIP)" at "CMS Program Statistics," *Centers for Medicare & Medicaid Services*, available at <https://data.cms.gov/collection/cms-program-statistics>.

³⁴⁷ McGuire et al., *Economic History of Medicare Part C*, pp. 289–332 at p. 310.

³⁴⁸ Pope et al., *Impact of Increased Financial Incentives to Medicare Advantage Plans*, pp. 29–30.

³⁴⁹ McGuire et al., *Economic History of Medicare Part C*, pp. 289–332 at p. 310.

³⁵⁰ Pope et al., *Impact of Increased Financial Incentives to Medicare Advantage Plans*, pp. 11, 29–30.

³⁵¹ Duggan et al., *Who Benefits when the Government Pays More*, pp. 50–67 at p. 50 ("Our results demonstrate that the additional reimbursement leads more private firms to enter this market."). I note that other papers—including Cabral et al., *Evidence from Medicare Arbitrage*, pp. 2048–2087 at pp. 2070–2071—have found more muted responses in terms of entry in response to changes in reimbursement rates. They observe no evidence of increased

a 10.5 percent higher reimbursement floor (due to being located in a metropolitan statistical area with a population of 250,000 or more) had an average of 1.8 more MA insurers.³⁵²

194. If MA plans were to exit, Medicare beneficiaries would be less likely to choose an MA plan, as they would consequently have fewer MA plan options from which to choose. As a result, a decline in reimbursements to MA plans will not only reduce plan availability; it would also be expected to reduce total enrollment in MA. Between 1999 and 2004, enrollment in MA fell from 6.9 million (18 percent of all Medicare enrollees) to 5.3 million (13 percent of all enrollees).³⁵³ The timing of this decline directly followed the capped growth in MA reimbursement under the BBA, up through the point where plans were able to re-contract under the more generous terms of the MMA.³⁵⁴ Following the passage of the MMA and the subsequent increase in plan entry, the share of beneficiaries enrolled in MA continued to grow from 2003 to present day.³⁵⁵

195. The academic literature also shows that MA plan enrollment responds to plan reimbursement. Duggan et al. (2016) also find that average share of Medicare enrollees electing MA plans was 13.1 percentage points higher in counties where plans were reimbursed an amount 10.5 percent higher than in other counties.³⁵⁶ In a separate paper, Duggan et al. (2018) find that an additional \$100 per person, per month in MA reimbursement is associated with a 5.1 percent increase in the share of Medicare recipients enrolled in MA.³⁵⁷ Curto et al. (2021) use data from 2006-2011 to estimate an equilibrium model of optimal bidding in the context of MA. They estimate that an increase of \$100 in the risk-adjustment benchmark would increase the share of Medicare beneficiaries enrolled in MA by approximately 10 percentage points, and

payments increasing either the number of counties with at least one plan or the number of plans per county more generally. In regards to the former, the authors attribute this to the small additional revenue that could have been earned by insurers entering zero-plan counties that received more payments.

³⁵² Duggan et al., Who Benefits when the Government Pays More, pp. 50–67 at p. 51.

³⁵³ The total number of Medicare enrollees calculated as the total number of Medicare beneficiaries enrolled in Part A and/or Part B. Freed et al., A Dozen Facts About Medicare Advantage in 2020; Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends.

³⁵⁴ Pope et al., Impact of Increased Financial Incentives to Medicare Advantage Plans, p. 2.

³⁵⁵ Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends; Freed et al., A Dozen Facts About Medicare Advantage in 2020.

³⁵⁶ Duggan et al., Who Benefits when the Government Pays More, pp. 50–67 at p. 51.

³⁵⁷ Mark Duggan, et al., “The Consequences of Health Care Privatization: Evidence from Medicare Advantage Exits,” *American Economic Journal: Economic Policy*, 10(1), 2018, pp. 153–186 at p. 181 (“Consistent with the existing literature (Afendulis, Chernew, Kessler 2013; Cawley, Chernew, and McLaughlin 2005; Pope et al. 2006) we find that an additional \$100, per person month, in MA reimbursement (or about a 20 percent increase, relative to average reimbursement) is associated with a 5.1 percent increase in the share of nationwide Medicare recipients in MA.”).

that conversely, reducing the benchmark decreases the MA enrollment share as well as consumer surplus.³⁵⁸

D. Correctly Estimating the Change in Government Payments to UnitedHealth, If UnitedHealth Were Required to Identify and Delete Unsupported Codes, Requires Accounting for Behavioral Responses from MA Plans

196. As I discuss in Sections X.A–C, economic theory and historical evidence indicate that MA plans would alter their behavior were they required to identify and delete unsupported diagnosis codes. As a matter of economics, then, any credible estimate of the change in government payments to an MA plan that was required to identify and delete unsupported codes would need to account for changes in the behavior of MA plans and of Medicare beneficiaries. Failure to do so would ignore the full ramifications of a policy requiring MA plans to identify and delete unsupported codes and would ignore the potential for the government (and enrollees) to pay more due to higher bids (and higher cost sharing, in the case of enrollees).

Executed this 29th of September, 2023



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³⁵⁸ Curto et al., Can health insurance competition work? Evidence from Medicare Advantage, p. 599, Table 3.

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Work Experience

The Trione Director, Stanford Institute for Economic Policy Research (SIEPR), 2015 - present.

The Wayne and Jodi Cooperman Professor of Economics, Stanford University, 2014 – present.

Senior Fellow, Stanford Institute for Economic Policy Research, 2014 - present.

Chair, Department of Business Economics and Public Policy, the Wharton School, University of Pennsylvania, 2012 – 2014.

Rowan Family Foundation Professor, Wharton School, University of Pennsylvania, 2012 - 14.

Faculty Director, Penn Wharton Public Policy Initiative, 2012 – 2014.

Professor, Department of Business Economics and Public Policy, Department of Health Care Management, the Wharton School, University of Pennsylvania, 2011 – 2014.

Professor, University of Maryland, Department of Economics, 2007 - 2011.

Senior Economist, Council of Economic Advisers, Executive Office of the President, 2009 - 2010.

Associate Professor, University of Maryland, Department of Economics, 2003 – 2007.

Visiting Fellow, Brookings Institution, 2006 – 2007.

Assistant Professor, University of Chicago, Department of Economics, 1999 – 2003.

Visiting Assistant Professor, MIT, Department of Economics, 2001 – 2002.

Teaching Fellow, Harvard University, Department of Economics, 1996 - 1998.

Research Assistant, Harvard University, Department of Economics, 1994 - 1996.

Teaching Assistant, M.I.T. Department of Electrical Engineering and Computer Science, 1993-94.

Education

Ph.D., Economics, June 1999, Harvard University.

M.S., Electrical Engineering, June 1994, M.I.T.

B.S., Electrical Engineering, June 1992, M.I.T.

Journal Publications:

Mark Duggan. 2000. "Hospital Ownership and Public Medical Spending" *Quarterly Journal of Economics*, 115(4): 1343-1374.

Mark Duggan. 2001. "More Guns, More Crime" *Journal of Political Economy*, 109(5): 1086-1114.

Mark Duggan. 2002. "Hospital Market Structure and the Behavior of Not-for-Profit Hospitals" *RAND Journal of Economics*, 33(3): 433-446.

Mark Duggan and Steven Levitt. 2002. "Winning Isn't Everything: Corruption in Sumo Wrestling" *American Economic Review*, 92(5): 1594-1605.

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Other Publications:

Mark Duggan. 2003. "Guns and Suicide: Correlation or Causation?" in *Evaluating Gun Policy*, edited by Philip Cook and Jens Ludwig, Brookings Institution Press.

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Mark Duggan. 2020. "Economic Policy in a Biden Administration." SIEPR Policy Brief. December.

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Working Papers

"The Impact of Privatization: Evidence from the Hospital Sector." (with Atul Gupta, Emilie Jackson, and Zachary Templeton) reject-and-resubmit at *Quarterly Journal of Economics*.

“Why Does the Inflation Reduction Act Exclude expensive Cancer Treatments in Price Negotiations?”
revise and resubmit at *Journal of Clinical Oncology: Oncology Practice*.

“Heterogeneity in the Impact of Privatizing Social Insurance: Evidence from California’s Medicaid
Program” (with Craig Garthwaite, Gina Li, and Adelina Wang).

“Do CEOs Know Best? Evidence from China.” (with Nicholas Bloom, Hong Cheng, Hongbin Li, and
Franklin Qian).

Popular Press Articles

“Pandemic Unemployment Will Soon Bring Tax Hikes.” (with Andrew Johnston). *Wall Street Journal*.
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Congressional Testimony

“Ensuring Success for the Social Security Disability Insurance Program and its Beneficiaries”
testimony before the Joint Economic Committee, November 4, 2015.

“The Coming Crisis: Social Security Disability Insurance Trust Fund Insolvency” testimony before the
Senate Budget Committee, February 11, 2015.

“The Rise in SSDI Enrollment, the Impact on the Labor Market, and the Need for Reform,” testimony
before the Social Security Subcommittee of the U.S. House Committee on Ways and Means,
June 19, 2013.

Research Grants

Emerson Collective. The Impact of the Medicare Program on the Price, Utilization, and Development
of Cancer Treatments. 2021-2023.

Social Security Administration. The Minimum Wage and Social Security Disability Insurance. 2019-
2020 (with Gopi Shah Goda).

Social Security Administration. The Effect of the Delayed Retirement Credit on Social Security Claiming and Employment. 2019-2020.

Washington Center for Equitable Growth. The Effects of Industry Consolidation on Government Procurement: The Case of DoD. 2017-2018.

Social Security Administration. Are Veterans' and Social Security Disability Benefits, Old Age Benefits, and Earnings Complements or Substitutes? 2016-17 (with Courtney Coile).

Laura and John Arnold Foundation. Strengthening Economic Policy Relevant Research at SIEPR. 2016-2019.

Alfred P. Sloan Foundation. The Labor Market Effects of the Affordable Care Act. 2016-2020 (with Gopi Shah Goda).

Alfred P. Sloan Foundation. The Labor Market Effects of the VA's Disability Compensation Program. 2015-2019 (with Courtney Coile).

National Institute on Aging. P01 AG00584 Project 7: Disability Programs, Health, and Work at Older Ages around the World. Co-Investigator (PI: David Wise). 2011-2015.

Social Security Administration. Public Health Expenditures on the Working Age Disabled: Assessing Medicare and Medicaid Utilization of SSDI and SSI Recipients. Co-principal investigator (Co-PIs: David Autor and Amitabh Chandra), 2008-2010.

Social Security Administration. How Has the Growth of the Disability Compensation program affected the SSI and OASDI Programs? Co- principal investigator (Co-PI: David Autor), 2007– 2008.

National Science Foundation. Government Procurement of Pharmaceuticals. 0518858. Co-Principal investigator (PI: Fiona Scott Morton), 2005 – 2011.

Social Security Administration. #10-P-98363-1-04. How Does the Design of Social Security Affect Work and Retirement Decisions? Disability Insurance and Labor Supply Forecasts. Co-Principal investigator (Co-PI: David Autor), 2006 – 2007.

National Institute of Child Health and Development. The Impact of Child SSI Enrollment. R03HD050441. Principal Investigator (Co-PI: Melissa Kearney), 2005 – 2008.

Robert Wood Johnson Foundation. The Effect of HMO Contracting on Government Spending and Health Care Quality. Principal Investigator, 2002 – 2004.

Sandell Center for Retirement Research. The Rise in the Disability Rolls and the Decline in Unemployment. Co-principal investigator (Co-PI: David Autor), 2001 – 2002.

Professional Activities

American Economic Association 2022 Annual Meeting Program Committee, 2020 – 2022.

Program Area Coordinator, Econometric Society World Congress, 2020.

Chair, Bay Area Council Economic Institute, 2019 - present.

Member of Committee to select Editor of *American Economic Journal: Economic Policy*, 2018.

Affiliated Expert, Cornerstone Research, 2015 – present.

Advisory Board, Nuna Health, 2015 – 2019.

National Institutes of Health, Health and Retirement Study Data Monitoring Committee, 2014 - 2020.

American Economic Association, Committee on Government Relations, 2013 – 2017.

National Bureau of Economic Research IRB Committee, 2012 – 2015.

U.S. Bureau of Economic Analysis, Health Experts Advisory Group, 2012 – 2016.

Leonard Davis Institute, Senior Fellow, 2011 – 2014.

Social Security Advisory Board, Technical Panel on Assumption and Methods, 2010 – 2011.

Food and Drug Administration, Special Government Employee, 2011.

Advisory Board Member, McKinsey Center for U.S. Health System Reform, 2010 - 2012.

Research Associate, National Bureau of Economic Research, 2007–present.

Faculty Research Fellow, National Bureau of Economic Research, 2000-2007

Research Associate, Maryland Population Research Center, 2003-2011.

Co-organizer (with Amy Finkelstein) of NBER Public Economics Program meeting, Spring 2007.

Organizer of NBER Health Care meeting, Autumn 2007.

Member of Committee to Select Editor of *American Economic Journal: Applied Economics*, 2006-07.

Member of Social Security Administration's Technical Advisory Panel for Modeling the Effect of Social Security Reform on the SSDI Program, 2004-05.

Program Committee Member for the Econometric Society's 2005 World Congress.

Co-organizer (with Steven Levitt) of NBER Universities' Research Conference "The Economic Analysis of Government Expenditure Programs," 2002.

Member of American Economic Association, American Society of Health Economists, and National Academy of Social Insurance.

Fellowships and Awards

Stanford University Economics Department Distinguished Faculty Teaching Award, 2021-2022.

National Institute for Health Care Management Research Award (with Fiona Scott Morton), 2011.

ASHEcon Medal awarded once every two years to "Economist Age 40 and under who has Made the Most Significant Contributions to the Field of Health Economics", 2010.

Raymond Vernon Prize (with Melissa Kearney) for Best Article in the *Journal of Policy Analysis and Management*, 2007.

University of Maryland Undergraduate Student Teaching Award, 2006.

University of Maryland Graduate Student Teaching Award, 2005, 2006.

Alfred P. Sloan Foundation Research Fellow, 2004 - 2006.

Journal of Political Economy Griliches Award, Honorable Mention, 2002.

University of Chicago Faculty Appreciation Award, 2000 (awarded by economics Ph.D students)

Alfred P. Sloan Foundation Doctoral Dissertation Fellowship, 1998-99.

Harvard's Derek Bok Center Award for Excellence in Undergraduate Teaching, 1997 and 1998.

NBER Not-for-Profit Fellowship, 1997-98.

Harvard University Positive Political Economy Fellowship, 1996-97.

Harvard University Economics Department Fellowship, 1994-98.

Harvard University Albert J. Lynch Fellowship, 1994-98.

M.I.T. Frederick Hennie Award for Excellence in Undergraduate Teaching, 1994.

William T. Grant Foundation Fellowship, 1993-94.

Tau Beta Pi, 1991.

Editorial and Referee Service

Board of Editors, *Journal of Policy Analysis and Management*, 2021 – present.

Board of Editors, *American Economic Journal: Economic Policy*, 2007-2012, 2015 – 2021.

Co-Editor, *American Economic Journal: Economic Policy*, 2012 – 2015.

Co-Editor, *Journal of Public Economics*, 2010-2013.

Associate Editor, *Journal of Public Economics*, 2007-2010.

Referee for: *American Economic Journal: Applied Economics*, *American Economic Journal: Economic Policy*, *American Economic Review*, *B.E. Journals in Economic Analysis and Policy*, *Demography*, *Econometrica*, *Economic Inquiry*, *Economic Journal*, *Economics Letters*, *European Economic Review*, *Health Affairs*, *Health Economics*, *Health Services Research*, *Industrial and Labor Relations Review*, *Journal of the American Medical Association*, *Journal of Applied Econometrics*, *Journal of Development Economics*, *Journal of Economics and Management Strategy*, *Journal of Economic Literature*, *Journal of the European Economic Association*, *Journal of Health Economics*, *Journal of Human Resources*, *Journal of Labor Economics*, *Journal of Law and Economics*, *Journal of Legal Studies*, *Journal of Policy Analysis and Management*, *Journal of Political Economy*, *Journal of Public Economics*, *Labour Economics*, *National Institute of Health*, *National Science Foundation*, *Quarterly Journal of Economics*, *Review of Economics and Statistics*, *Review of Economic Studies*, *Review of Industrial Organization*, *Southern Economic Journal*.

Stanford University Service

Senate of the Academic Council, 2016 – 2018, 2023 - present.

COVID-19 Vaccine Governance Committee, 2021.

Sustainability Blueprint Advisory Committee, 2020 – 2021.

Human-Centered AI Design Team, 2018 - 2019.

Precision and Population Health Design Team, 2018 - 2019.

Faculty Athletic Fellow, Stanford Cross-Country and Track and Field Teams, 2016 - present.

Stanford Fellows program, 2016 – 2018.

Faculty Advisory Board, Haas Center for Public Service, 2015 – 2021.

Executive Committee Chair, Public Policy Program, 2015 – present.

Pre-Major Advisor, 2015 – 2021.

University of Pennsylvania Service

Member of Executive Committee, Leonard Davis Institute for Health Economics, 2012-14.

Penn Fellow (one of 8 faculty selected university-wide), 2011-13.

Chair of Business and Public Policy Department's Junior Recruiting Committee, 2011-12.

Member of Wharton Personnel Committee, 2011-12.

University of Maryland Service

Member of Economics Department Executive Committee, 2004-06, 2008-09.

Chair of Economics Department Junior Recruiting Committee, 2004-05, 2007-08.

Member of Economics Department Junior Recruiting Committee, 2004-06, 2007-08.

Member of Economics Department Senior Recruiting Committee, 2006-07, 2008-09.

Member of Economics Department Salary Committee, 2006-09.

Presentations:

2020-2023: ASSA Annual Meetings, Bocconi, Boston University / Harvard / MIT, University of California at Berkeley, University of California at Irvine (scheduled), University of Chicago, Collegio Carlo Alberto, NBER, University of Pennsylvania, Tsinghua University, New York University, University of Virginia (scheduled).

2016-2020: University of Arizona, ASSA Annual Meetings, Brigham Young University, University of California at Irvine, University of California at Los Angeles, University of Chicago, City University of New York, Columbia University, Federal Reserve Bank of Chicago, Federal Reserve Bank of Dallas, Federal Reserve Bank of New York, Harvard University, Johns Hopkins University, University of Maryland, Michigan State, NBER, Northwestern University, University of Southern California, Texas A&M.

2013-2015: Arizona State University, ASSA Annual Meetings, Brookings Institution, Brown University, University of California at Berkeley, University of California at Los Angeles, University of California at Santa Barbara, Columbia University, Congressional Budget Office, Duke University, Federal Reserve Board of Governors, University of Illinois at Urbana-Champaign, M.I.T., University of Minnesota, NBER, University of Oregon, Princeton University, RAND, Stanford University.

2010-2012: ASSA Annual Meetings, Boston University, Brown University, University of California at Berkeley, University of Chicago, Columbia University, Cornell University, Harvard University, University of Illinois at Chicago, Institute for Fiscal Studies, Johns Hopkins University, London School of Economics, M.I.T., National Tax Association, NBER, Northwestern University, Princeton University, Renaissance Technologies, University

of Pennsylvania (Wharton), Rice University, University of Southern California, Stanford University, Warwick University, Yale University.

- 2007-2009: American Enterprise Institute, American Society of Health Economists, American University, ASSA Annual Meetings, Brown University, Bureau of Economic Analysis, Centers for Medicare and Medicaid Services, Columbia University, Dartmouth College, Duke University, Georgetown University, Georgia State, Harvard University, University of Houston, University of Illinois at Urbana-Champaign, NBER, RAND, Stanford University, Syracuse University, University of Houston, University of Maryland, U.S. Department of Veterans Affairs.
- 2006-2007: ASSA Annual Meetings, Brigham Young University, Brookings Institution, University of California at Berkeley, CINP 2006 Chicago Congress, Federal Trade Commission, Free University of Amsterdam, Harvard University (KSG), University of Illinois at Chicago, NBER, National Center of Health Statistics, University of Pittsburgh / Carnegie Mellon, Population Association of America, Social Security Administration, Southern Economic Association, Yale University.
- 2005-2006: American Society of Health Economists, Boston University, Brookings Institution, University of California at Berkeley, Georgetown University, George Washington University, NBER-CCER Conference in Beijing, University of North Carolina at Chapel Hill, University of Pennsylvania (Wharton), Population Association of America, Princeton University, University of Rochester, Stanford Graduate School of Business, Washington University.
- 2004-2005: Centers for Medicare and Medicaid Services, Cornell University, Federal Trade Commission, Harvard University, MIT, University of Michigan, HEC Montreal, NBER, Northwestern University (Kellogg), RAND, Stanford University, SUNY-Buffalo, Urban Institute, World Bank, Yale School of Public Health.
- 2003-2004: ASSA Annual Meetings, Baruch College, Brookings Institution, Case Western Reserve University, University of Chicago, Columbia University, George Mason University, NBER, University of Pennsylvania (Wharton), Social Security Administration, University of Virginia.
- 2002-2003: University of British Columbia, Brown University, University of California at San Diego, Case Western Reserve University, University of Chicago GSB, University of Colorado at Denver, Columbia University, Harvard University, NBER, Princeton University, University of Texas at Austin, University of Wisconsin at Madison.
- 1998-2002: ASSA Annual Meetings, University of California at Berkeley, University of California at Los Angeles, University of Chicago, Duke University, Harvard University, Mathematica, MIT, University of Michigan, NBER, Northwestern University, Princeton University, Stanford University, University of Wisconsin at Madison.

University of Chicago Ph.D. Advisees (with first job placement)

Rodrigo Garcia-Verdu, 2000, Mexico Central Bank
Rena Rosenberg, 2000, McKinsey and Company
Joseph Doyle, 2001, M.I.T. Sloan School
Ming-Jen Lin, 2001, National Taiwan University
Deborah Healy, 2002, U.S. Department of Justice
Grecia Marrufo, 2002, Stanford post-doctoral fellowship
Raphael de Coninck, 2003, NYU post-doctoral fellowship
Damien de Walque, 2003, World Bank
Chris Rohlfs, 2006, Syracuse University

University of Maryland Ph.D. Advisees (with first job placement, ** indicates Chair or Co-Chair)

Jennifer Goodwin, 2004, Duke post-doctoral fellowship
Rubiana Chamarbagwala, 2005, Indiana University
Julian Cristia, 2006, Congressional Budget Office
Beomsoo Kim, 2006, University of North Carolina at Greensboro
Gaobo Pang, 2006, Watson Wyatt
Heng Wei, 2006, Price Waterhouse Coopers
Alex Whalley, 2006, University of California at Merced
Janet Hao, 2007, Conference Board
Scott Imberman **, 2007, University of Houston
Emily Owens, 2007, Cornell University, Public Policy and Management
Perry Singleton **, 2007, Syracuse University
Aparajita Goyal **, 2008, World Bank
Melissa Powell McInerney, 2008, College of William and Mary
Melinda Sandler, 2008, North Carolina State University
Meltem Daysal, 2009, Tillburg University
Craig Garthwaite **, 2009, Northwestern University (Kellogg)
Tamara Hayford **, 2009, Congressional Budget Office
Jessica Hennessey, 2009, Furman University
Yeon Soo Kim, 2010, Korea Development Institute
Lingsheng Meng **, 2010, Tsinghua University
Quynh Nguyen, 2010, World Bank
Li Tang, 2010, Inter-American Development Bank
Abby Alpert **, 2011, RAND
Diether Beuermann **, 2011, IADB
Keith Kranker **, 2011, Mathematica
Timothy Moore, 2012, George Washington University

University of Pennsylvania Ph.D. Advisees (with first job placement, ** indicates Chair or Co-Chair)

Adam Isen, 2013, U.S. Department of the Treasury
Jillian Popadak, 2014, Duke University (Fuqua)

Daniel Sacks, 2014, Indiana University (Kelley)
Victoria Perez, 2015, Indiana University (SPEA)
Boris Vabson **, 2016, Nuna Health
Andrew Johnston **, 2016, University of California at Merced

Stanford Ph.D. Advisees (with first job placement, ** indicates Chair or Co-Chair)

Joe Orsini, 2016, Nuna Health
Pietro Tebaldi, 2016, University of Chicago
Monica Bhole, 2017, Pandora
Atul Gupta, 2017, University of Pennsylvania (Wharton)
Kevin Nguyen, 2017, Amazon
Ian Hoffman, 2018, Cornerstone Research
Cristos Makridis, 2018, Council of Economic Advisers
Daniel Bennett, 2019, Analysis Group
Yiwei Chen, 2019, Quantco
Audrey Guo **, 2019, Santa Clara University
Rodrigo Carril **, 2020, Pompeu Fabra University
Yiqun Chen, 2020, University of Illinois at Chicago
Sarah Eichmeyer, 2020, University of Munich
Emilie Jackson **, 2020, Michigan State University
Adelina Wang **, 2020, NBER Post-Doctoral Fellowship
Sookyo Jeong **, 2021, Lyft
Hui Ding **, 2022, Fudan University
Gina Li **, 2023, Federal Reserve Board

Popular Press Coverage

Boston Globe, Business Week, CNN, Christian Science Monitor, Economist, Financial Times, The Hill, Houston Chronicle, Los Angeles Times, NPR, New York Times, San Francisco Chronicle, Wall Street Journal, and others.

Prior Testimony of Mark G. Duggan, Ph.D.

Testimony Since 2019

Amgen Inc., Amgen Manufacturing Limited, and Amgen USA, Inc. v. Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S., United States District Court for the District of Delaware, Case No. 1:14-cv-01317. Deposed on November 1, 2018. Hearing Testimony on June 21, 2019.

Washtenaw County Employees' Retirement System v. Walgreen Co., Gregory D. Wasson, and Wade Miquelon, United States District Court for the Northern District of Illinois, Eastern Division, Case No. 1:15-cv-03187. Expert reports submitted November 11, 2020 and December 15, 2020. Deposed on February 11, 2021.

In Re: National Prescription Opiate Litigation: State of Washington v. McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation, State of Washington, King County Superior Court, Case No. 19-2-06975-9. Expert reports submitted January 11, 2021, April 19, 2021, July 11, 2021, and October 8, 2021. Deposed on July 13, 2021.

County of Dallas v. Purdue Pharma L.P., et al., District Court, 116th Judicial District, Dallas County, TX, Cause No. 2018-CI-77098. Expert report submitted July 30, 2021. Deposed on September 14, 2021.

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Industry Reports	
"Eliminating the FFS Adjuster from the RADV Methodology May Affect Plan Payment," <i>Avalere Health</i> , available at https://avalere.com/wp-content/uploads/2019/03/20190318-FFS-Adjuster-Analysis-Final-.pdf	March 2019
"Employer Health Benefits: 2021 Annual Survey," <i>Kaiser Family Foundation</i> , available at https://files.kff.org/attachment/Report-Employer-Health-Benefits-2021-Annual-Survey.pdf	November 2021
"Medicare Advantage: A Policy Primer," <i>Commonwealth Fund</i> , available at https://www.commonwealthfund.org/publications/explainer/2022/may/medicare-advantage-policy-primer	May 3, 2022
"The Facts About Medicare Spending," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/interactive/medicare-spending	June 2023
"Total Number of Medicare Beneficiaries by Type of Coverage," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries	2019
Claire Noel-Miller, "Medicare Beneficiaries' Out-of-Pocket Spending for Health Care," <i>AARP Public Policy Institute</i> , available at https://www.aarp.org/content/dam/aarp/ppi/2021/12/medicare-beneficiaries-out-of-pocket-health-care-spending.doi.10.26419-2Fppi.00105.002.pdf	December 2021
Gregory Pope, et al., "Impact of Increased Financial Incentives to Medicare Advantage Plans: Final Report," <i>RTI International</i> , available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/Pope.pdf	September 2006
Gretchen Jacobson, et al., "A Dozen Facts About Medicare Advantage," <i>Kaiser Family Foundation</i> , available at https://web.archive.org/web/20181129174017/https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/	November 13, 2018
Gretchen Jacobson, et al., "Medicare Advantage Hospital Networks: How Much Do They Vary?," <i>Kaiser Family Foundation</i> , available at http://files.kff.org/attachment/Report-Medicare-Advantage-Hospital-Networks-How-Much-Do-They-Vary	June 20, 2016
Gretchen Jacobson, et al., "Medicare Advantage: How Robust Are Plans' Physician Networks?," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/report/medicare-advantage-how-robust-are-plans-physician-networks/	October 5, 2017
Meredith Freed, et al., "A Dozen Facts About Medicare Advantage in 2020," <i>Kaiser Family Foundation</i> , available at https://web.archive.org/web/20201210075019/https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020	April 22, 2020
Jared Ortaliza, et al., "How Do Health Expenditures Vary Across the Population," <i>Peterson-KFF Health System Tracker</i> , available at https://www.healthsystemtracker.org/chart-collection/health-expenditures-vary-across-population/	November 12, 2021
Jeannie Fuglesten Biniek, et al., "Spending on Medicare Advantage Quality Bonus Payments Will Reach at Least \$12.8 Billion in 2023," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/spending-on-medicare-advantage-quality-bonus-payments-will-reach-at-least-12-8-billion-in-2023/	August 9, 2023
John Wennberg, et al., "Tracking the Care of Patients with Severe Chronic Illness: The Dartmouth Atlas of Health Care 2008," <i>The Dartmouth Institute for Health Policy and Clinical Practice</i> , available at https://data.dartmouthatlas.org/downloads/atlas/2008_Chronic_Care_Atlas.pdf	2008
Julia Lambert, "Actuarial Report on Medicare Advantage FFS Adjuster," <i>Wakely</i>	August 28, 2019
Juliette Cubanski and Anthony Damico, "Key Facts About Medicare Part D Enrollment and Costs in 2023," KFF, available at https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-and-costs-in-2023	June 7, 2023

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Juliette Cubanski, et al., "A Primer on Medicare: Key Facts about the Medicare Program and the People it Covers," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/report-section/a-primer-on-medicare-how-does-medicare-pay-providers-in-traditional-medicare/	March 20, 2015
Letter from Matthew Eyles (AHIP) to Seema Verma (CMS), "RE: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 ('Proposed Rule')", available at https://ahiporg-production.s3.amazonaws.com/documents/AHIP_RADV_comments_FINAL_8_27.pdf	August 27, 2019
Matthew Rae, et al., "Patient Cost-Sharing in Marketplace Plans, 2016," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/health-costs/issue-brief/patient-cost-sharing-in-marketplace-plans-2016	November 13, 2015
Meredith Freed, et al., "Medicare Advantage 2023 Spotlight: First Look," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/	November 10, 2022
Meredith Freed, et al., "Medicare Advantage in 2022: Premiums, Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings," <i>Kaiser Family Foundation</i> , available at https://web.archive.org/web/20230211090856/https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings	August 25, 2022
Nancy Ochieng, et al., "Medicare Advantage in 2023: Enrollment Update and Key Trends," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/	August 9, 2023
Nancy Ochieng, et al., "Medicare Advantage in 2023: Premiums: Out-of-Pocket Limits, Cost Sharing, Supplemental Benefits, Prior Authorization, and Star Ratings," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/	August 9, 2023
Rob Pipich, "Medicare Advantage RADV FFS adjuster: White paper," <i>Milliman White Paper</i> , available at https://assets.milliman.com/ektron/Medicare_Advantage_RADV_FFS_adjuster_8-23-2019.pdf	August 23, 2019
Robin Rudowitz, et al., "10 Things to Know about Medicaid," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid	June 30, 2023
Wyatt Koma, et al., "Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/	April 24, 2020
Wyatt Koma, et al., "FAQs on Medicare Coverage of Telehealth," <i>Kaiser Family Foundation</i> , available at https://www.kff.org/medicare/issue-brief/faqs-on-medicare-coverage-of-telehealth/	May 23, 2022

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"2023 Medicare Advantage and Part D Advance Notice Fact Sheet," <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/newsroom/fact-sheets/2023-medicare-advantage-and-part-d-advance-notice-fact-sheet	February 2, 2022
"2023 Medicare Parts A & B Premiums and Deductibles 2023 Medicare Part D Income-Related Monthly Adjustment Amounts," <i>Centers for Medicare & Medicaid Services</i> , available at	September 27, 2022

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https://www.cms.gov/newsroom/fact-sheets/2023-medicare-parts-b-premiums-and-deductibles-2023-medicare-part-d-income-related-monthly	
“Actuarial Bid Training: Introduction to Bidding” available at Introduction to Bidding.pdf when accessing “Actuarial Bid Training (ZIP)” at “Actuarial Bid Training,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/actuarial-bid-training	September 6, 2023
“Acute Inpatient PPS,” <i>Centers for Medicare & Medicaid Services</i> , https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps	September 6, 2023
“Addendum to the Fee-For-Service Adjuster Study,” <i>Centers for Medicare & Medicaid Services</i> , available at Addendum to the Fee-for-Service Adjuster Study.pdf when accessing “RADV Provision CMS 4185-N4 Data Release June 2019” at “Medicare Risk Adjustment Data Validation Program Resources,” <i>Centers for Medicare & Medicaid Services</i> , September 6, 2023, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources	June 2019
“Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf	March 28, 2003
“Advance Notice of Methodological Changes for Calendar Year (CY) 2005 Medicare Advantage (MA) Payment Rates,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/advance2005.pdf	March 26, 2004
“Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/advance2006.pdf	February 18, 2005
“Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2011.pdf	February 19, 2010
“Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part1.pdf	December 27, 2017
“Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf	January 30, 2019
“Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/files/document/2023-advance-notice.pdf	February 2, 2022
“Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2010.pdf	February 20, 2009
“Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.cms.gov/files/document/2021-advance-notice-part-ii.pdf	February 5, 2020
“Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies, and 2018 Call Letter,” <i>Centers for Medicare & Medicaid Services</i> , available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advance2018_119.pdf	February 1, 2017
“Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model,” <i>Centers for Medicare & Medicaid</i>	December 20, 2018

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EXHIBIT D-57

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al,

Defendants.

Case No. 16-cv-08697 FMO

**EXPERT REPORT OF CRAIG GARTHWAITE
SEPTEMBER 29, 2023**

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I. INTRODUCTION AND QUALIFICATIONS

A. Qualifications

1. My name is Craig Garthwaite. I am the Herman Smith Research Professor in Hospital and Health Services and a tenured Professor of Strategy at the Kellogg School of Management, Northwestern University. I am also the Director of the Program on Healthcare at Kellogg, and I organize Kellogg's healthcare business curriculum. At Kellogg, I teach courses in health care strategy, the economics of strategy, and value creation in biopharmaceuticals.
2. I am a Research Associate at the National Bureau of Economic Research, and a Faculty Associate at the Institute for Policy Research at Northwestern University. I received a Ph.D. in Economics from the University of Maryland at College Park, a Master's in Public Policy from the Gerald R. Ford School of Public Policy at the University of Michigan, and a B.A. in Political Science from the University of Michigan.
3. Prior to my graduate studies, I was an Economist at Public Sector Consultants in Lansing, Michigan, and the Director of Research and Chief Economist at the Employment Policies Institute in Washington, DC.
4. My research focuses on a variety of issues, including the potential impacts of health policy and the changing health care market on the operations of private health firms such as hospitals and insurers. In my academic research, I have worked with a variety of large and complex datasets, including insurer claims datasets,¹ hospital discharge datasets,² and hospital financial reports.³ My research has been published in journals such as the *Quarterly Journal of Economics*, the *American Economic Review*, the *Review of Economics and Statistics*, the *Journal of Health Economics*, the *New England Journal of Medicine*, the *Annals of Internal Medicine*, and *Health Affairs*, and has been profiled in

¹ Craig Garthwaite, David Dranove, and Christopher Ody, "The Economic Downturn And Its Lingering Effects Reduced Medicare Spending Growth By \$4 Billion In 2009–12," *Health Affairs*, Vol. 34, No. 8, August 2015, pp. 1368-1375, <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0100>.

² Mark Duggan, Craig Garthwaite, and Adelina Yanyue Wang, "Heterogeneity in the Impact of Privatizing Social Health Insurance: Evidence from California's Medicaid Program," *NBER Working Paper Series*, No. 28944, June 2021.

³ Craig Garthwaite, Christopher Ody, and Amanda Starc, "Endogenous Quality Investments in the U.S. Hospital Market," *Journal of Health Economics*, Vol. 84, No. 102636, May 14, 2022.

media outlets such as *The New York Times*, *The Wall Street Journal*, and *The Washington Post*. I have testified before the United States House of Representatives and the United States Senate on matters related to health care markets, prescription drugs, and health care reform.

5. A copy of my Curriculum Vitae, including a list of all publications I have authored in the last ten years, is attached as **Appendix A**. A list of my prior testimony from the last four years is attached as **Appendix B**.

B. Assignment

6. The United States of America (“United States”) and Relator Benjamin Poehling (together, “Plaintiffs”) allege that, in relation to their Medicare Advantage and Medicare Advantage prescription drug plans, UnitedHealth Group Inc. and its subsidiaries (collectively, “Defendants”) knowingly and improperly avoided or decreased an obligation to repay risk adjustment payments to the Medicare program administered by the Centers for Medicare and Medicaid Services (“CMS”) by retaining risk adjustment payments to which they were not entitled.⁴
7. I have been engaged by counsel for Plaintiffs to provide expert testimony in this matter. Specifically, I have been asked to (1) identify diagnosis codes from service years 2008 through 2016 that Defendants submitted to CMS for risk adjustment payments covering payment years 2009 through 2017, where Defendants reviewed the medical records associated with those diagnosis codes as part of their Chart Review Program and did not find support for the diagnosis codes, and those diagnosis codes affected payment; (2) calculate the financial impact on Defendants’ Medicare Advantage and Medicare Part D risk adjustment payments that would have resulted had Defendants deleted the diagnosis codes I identified;⁵ and (3) determine the number of beneficiaries in each payment year for

⁴ United States’ Amended Complaint-In-Partial-Intervention and Demand for Jury Trial, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 MWF (SSx), November 17, 2017 (“US vs UHG Amended Complaint”).

⁵ I was also asked to separately calculate the portion of this impact that is associated with diagnosis codes reviewed by Defendants in Second Level Review as part of the Chart Review Program.

whom Defendants would have received reduced risk adjustment payments from CMS had Defendants deleted the diagnosis codes I identified.

8. I have also been asked to separately calculate the financial impact on Defendants' Medicare Advantage and Medicare Part D risk adjustment payments resulting from their failure to delete the diagnosis codes included on two spreadsheets produced by Defendants, which contain diagnosis codes that Defendants identified as having been included in their Claims Verification program but not having completed all the steps of the program (hereinafter referred to as "Defendants' CV Pipeline Lists").
9. For my work on this case, I am being compensated at my standard hourly billing rate of \$900. Staff at Analysis Group, a consulting firm, worked under my direction and helped me prepare my report. I also receive compensation from Analysis Group based on its collected staff billings for its support of me in this matter. Neither my compensation in this matter nor my compensation from Analysis Group is in any way contingent or based on the content of my opinions or the outcome of this or any other matter.
10. I have reviewed documents, data, testimony, and other materials provided through discovery or obtained from public sources. The documents, data, testimony, and other materials that I have relied upon as a basis for my opinions are listed in **Appendix C**.
11. **Appendix D** contains more detailed descriptions of the data I relied upon and the methods I used for my analyses, as well as illustrative examples of the data and methods.
12. My opinions are based on the research and analyses that I undertook during this period and the information available to me as of the date of this report. Should additional relevant materials including documents, data, testimony, declarations or reports of other experts, or other information be made available to me, I may adjust or supplement my opinions as appropriate.

II. SUMMARY OF OPINIONS

13. I have identified in **Attachment 1** a set of diagnosis codes that Defendants submitted to CMS for risk adjustment purposes. According to my analysis, Defendants reviewed the medical records that were the source of these diagnosis codes as part of their Chart Review Program and their review found no support for these diagnosis codes or their associated

Hierarchical Condition Categories or Rx Hierarchical Condition Categories. In addition, I found no other instances of these diagnosis codes nor did I find other diagnosis codes associated with the same Hierarchical Condition Categories or Rx Hierarchical Condition Categories that Defendants may have submitted for that beneficiary in the same year.⁶ I have calculated that the risk adjustment payments Defendants received from CMS would have been reduced if Defendants had deleted these diagnosis codes.

14. I have concluded that:

- i. The total financial impact on Defendants' Medicare Advantage and Medicare Part D risk adjustment payments resulting from Defendants' failure to delete the diagnosis codes in **Attachment 1** is \$2,135,252,375 for payment years 2009-2017.
- ii. The total number of affected beneficiaries counted year-by-year across payment years 2009-2017 is 1,132,418.⁷
- iii. The total financial impact on Defendants' Medicare Advantage and Medicare Part D risk adjustment payments resulting from Defendants' failure to delete the diagnosis codes listed in Defendants' CV Pipeline Lists is \$188,402,348.

III. BACKGROUND

15. In this section, I provide a description of Medicare Advantage, which is based on my professional understanding and my review of the documents cited herein. My intent is to provide background and context relevant to understanding the analyses I have performed.

⁶ Specifically, the diagnosis codes in **Attachment 1** do not share an HCC with any other submitted diagnosis code, do not share an HCC with any other risk adjustment-eligible but unsubmitted diagnosis code, *and* do not map to an HCC recorded in the Claims Verification program, as further explained in Section **VI.E**.

⁷ Each beneficiary is counted once for each payment year in which their risk adjustment payments are affected. If a beneficiary's Medicare Advantage and Medicare Part D risk adjustment payments are affected in a single year, that beneficiary is counted only once in that year.

A. Medicare Overview

16. Medicare provides health insurance for people aged 65 or older, younger people with a disability, end-stage renal disease, or amyotrophic lateral sclerosis, and certain railroad retirement beneficiaries.⁸
17. Medicare beneficiaries have the option to enroll in “Traditional Medicare,” which is largely administered by CMS,⁹ or “Medicare Advantage,” which is administered by commercial insurers known as Medicare Advantage Organizations (“MAOs”).¹⁰
18. Traditional Medicare includes two types of coverage, called “Parts.” **Part A** generally covers inpatient care in hospitals, care in nursing facilities, care in hospice facilities, and home health care.¹¹ **Part B** generally covers outpatient services from doctors and other health care providers, durable medical equipment, and other preventative services.¹² Under Traditional Medicare, healthcare providers submit claims for services to CMS for payment by CMS on a claim-by-claim basis (sometimes called “fee-for-service”).¹³ Traditional Medicare beneficiaries may also purchase prescription drug coverage under Medicare Part D.
19. Medicare Advantage, or **Part C**, is an alternative to Traditional Medicare through which MAOs offer Medicare-approved plans that bundle coverage normally provided by CMS in Part A and Part B to beneficiaries enrolled in Part C. MAOs may also offer plans that include prescription drug coverage under Medicare **Part D**.¹⁴ A Medicare Advantage plan that includes Part D coverage is called a Medicare Advantage Prescription Drug (“MA-

⁸ 42 USC § 426 et seq; 42 CFR § 406.5; 42 CFR § 406.10; 42 CFR § 406.11; 42 CFR § 406.12; 42 CFR § 406.13.

⁹ Gabrielle Clerveau, Nancy Ochieng, Juliette Cubanski, and Tricia Neuman, “A Snapshot of Sources of Coverage Among Medicare Beneficiaries,” Henry J. Kaiser Family Foundation, August 14, 2023, <https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/>, accessed September 28, 2023; 42 USC § 1395c et seq.

¹⁰ “Medicare Advantage Promoting Interoperability Programs,” Centers for Medicare & Medicaid Services, September 6, 2023, <https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/medicare-advantage>, accessed September 28, 2023; 42 USC § 1395w et seq.

¹¹ 42 USC § 1395c.

¹² *Ibid.*

¹³ 42 USC § 1395c et seq.

¹⁴ 42 USC § 1395w et seq.

PD”) plan.¹⁵ MAOs can, and generally do, operate a large number of Medicare Advantage plans.

20. Under Medicare Advantage, beneficiaries and/or their healthcare providers submit claims to Medicare Advantage plans and, instead of receiving payment from CMS on a “fee-for-service” basis, receive payment from the MAO.¹⁶ MAOs that participate in the Medicare Advantage program receive monthly premium payments for each beneficiary enrolled in their plans.¹⁷ These “per member per month” payments are calculated in accordance with a method for determining anticipated medical costs, called risk adjustment.¹⁸

B. Risk Adjustment for Medicare Advantage

i. Payments to Medicare Advantage Plans

21. Under Part C, each MAO receives per member per month payments from CMS for each beneficiary enrolled in its Medicare Advantage plans.
22. The per member per month payments that MAOs receive from CMS are calculated as a plan-specific “bid,” or base rate,¹⁹ which is adjusted based on geography but otherwise the same for every beneficiary in the plan, multiplied by a risk score, which is beneficiary-specific and calculated based on the beneficiary’s health status and demographics, such as age and sex.²⁰ The base rate is meant to reflect the average cost of coverage for a beneficiary in the plan.²¹ The risk score is designed to broadly account for anticipated

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ 42 USC § 1395w-23(a)(1)(C); 42 CFR § 422 et seq.

¹⁸ 42 USC § 1395w-23(a)(1)(C); 42 CFR § 422 et seq.

¹⁹ Each MAO plan submits bids to CMS indicating the premium amount that would be required to cover an average beneficiary’s expenses. There is a maximum premium CMS will pay for an average beneficiary based on geography (the “benchmark”). If a plan’s bid falls below the benchmark, it receives a rebate. If the plan’s bid exceeds the benchmark, the plan collects that difference from its beneficiaries. See 42 USC § 1395w-23(a)(1)(B); *Ibid.*(b)(1)(B).

²⁰ Other factors, such as the congressionally mandated coding adjustment (see *Ibid.*(a)(1)(C)(ii)) and the normalization factor (see 42 CFR § 422.308(a)) also affect the amount CMS pays MAOs.

²¹ See 42 USC § 1395w-24 et seq; 42 CFR § 422.254 et seq.

differences in the cost of coverage between beneficiaries.²² In general, CMS pays MAOs higher per member per month amounts to cover beneficiaries who are expected to incur more medical costs because of their poor health status.

23. CMS calculates the risk score using the CMS Hierarchical Condition Category Risk Adjustment Model (“CMS HCC Model”),²³ which assigns weighted numeric values to various factors that affect the expected costs to cover a beneficiary, including health status and demographics (e.g., sex, age, disability, whether institutionalized, and whether enrolled in Medicaid).²⁴ CMS makes publicly available on its website computer programs for calculating risk scores.²⁵ These programs take beneficiary health status information and demographics as inputs, and automatically calculate a risk score for each beneficiary based on the weighted numeric values assigned to the various factors in the CMS HCC Model.
24. The health status portion of a beneficiary’s risk score depends upon the medical diagnosis codes that an MAO submits to CMS for that beneficiary. CMS requires MAOs to submit beneficiary diagnosis codes using the International Classification of Diseases (“ICD”) system established by the World Health Organization.^{26, 27}

²² Tamara Beth Hayford and Alice Levy Burns, “Medicare Advantage Enrollment and Beneficiary Risk Scores: Difference-in-Differences Analyses Show Increases for All Enrollees On Account of Market-Wide Changes,” *The Journal of Health Care Organization, Provision, and Financing*, Vol. 55, No. I-II, June 22, 2018, p. 2.

²³ 42 USC § 1395w-23(a)(1)(C); 42 CFR §§ 422.300 - 422.308.

²⁴ “CMS Manual System Transmittal 118,” Department of Health & Human Services and Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R118MCM.pdf>, accessed June 30, 2022 (“In order to use the risk adjustment model to calculate risk scores for payment, CMS creates a relative factor for each demographic factor and HCC in the model.”).

²⁵ “Medicare risk adjustment information,” Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment>, downloaded on June 16, 2023.

²⁶ During the time period at issue in this matter, diagnosis codes were coded using the ICD-9-CM coding system until the Centers for Disease Control and Prevention fully transitioned diagnosis codes to the ICD-10-CM coding system on October 1, 2015. See “Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 7, 2014, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/announcement2015.pdf>, accessed September 14, 2023 Section N.

²⁷ “CMS Manual System Transmittal 118,” Department of Health & Human Services and Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R118MCM.pdf>, accessed June 30, 2022, p. 4.

25. Each year, CMS calculates a new risk score for each beneficiary based on diagnosis codes documented for that beneficiary in the previous year.²⁸ For example, the health status component of a beneficiary's final risk score used for payment in 2011 (the "payment year") is determined only by the diagnosis codes documented during medical encounters with their providers in 2010 (the "service year"). Diagnosis codes from encounters that occurred outside of the service year do not affect the calculation of the beneficiary's final risk score for the associated payment year.
26. During payment years 2009-2017 (corresponding to service years 2008-2016), which is the time period at issue in this matter, CMS had specific rules governing MAO submissions of diagnosis code data (also called "risk adjustment data"). For example, diagnosis codes used to determine payments for a particular payment year (*e.g.*, 2011) must be supported by the beneficiary's medical records and must generally result from face-to-face encounters²⁹ between beneficiaries and providers with an acceptable specialty³⁰ that occurred during the corresponding service year (*e.g.*, 2010). Furthermore, for every date of service (*e.g.*, a medical encounter that took place on January 1, 2010) included within a medical record ("Chart") and used as the basis for submission of a given diagnosis code, the Chart must be signed and include the provider's credentials.³¹ In this Report, I refer to encounters that meet CMS' rules as risk adjustment-eligible encounters, and I refer to the diagnosis codes associated with these encounters as risk adjustment-eligible diagnosis codes.
27. The CMS HCC Model maps some, but not all, diagnosis codes to one of 70 or 79 (depending on the time period)³² Hierarchical Condition Categories ("HCCs"), which

²⁸ 42 CFR § 422.304 et seq.

²⁹ For example, labs and diagnostic radiology encounters are not considered valid sources for diagnosis codes used to determine payment. See *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide*, Centers for Medicare & Medicaid Services, January 1, 2008, <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>, accessed September 5, 2023, at Section 3.2.3. There are limited exceptions to the face-to-face requirements, such as diagnoses made by pathologists. See also 42 CFR 422.310(d)(1); 45 CFR 162.1002(c)(2) and (c)(3).

³⁰ A list of acceptable physician specialties is found in *Ibid.*, at Table 3H.

³¹ *Ibid.* at Section 7.2.4.2.

³² For service years 2008-2012, CMS used version 12 of the CMS HCC Risk Adjustment Model, which included 70 HCCs. Starting with service year 2013, CMS began phasing in version 22 of the model, which included 79 HCCs. Full implementation of version 22 began with service year 2016. See "Announcement of Calendar Year

represent groups of diagnosis codes that define major health conditions.³³ For example, diagnosis code 25000, *Diabetes mellitus without mention of complications*, diagnosis code 24900, *Secondary diabetes mellitus without mention of complication, not stated as uncontrolled, or unspecified*, and diagnosis code 25003, *Diabetes mellitus without mention of complication, type I, uncontrolled - as a primary diagnosis code* all map to HCC 19, *Diabetes without complications*.³⁴

28. If an MAO does not submit any diagnosis codes for a particular beneficiary during the service year, the beneficiary's risk score for the payment year is based solely on the beneficiary's demographic factors. For example, in service year 2010, a beneficiary who is female, 65 years old, not disabled, not institutionalized, and not dually enrolled in Medicaid would have a demographic factor of 0.298.³⁵ If the MAO did not report any diagnosis codes for this beneficiary in service year 2010, the associated per member per month payment in payment year 2011 would be 29.8% of the plan's base rate. Thus, if the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$29.80 for this beneficiary.
29. If an MAO submits a diagnosis code for a beneficiary mapping to an HCC, the CMS HCC Model incorporates that HCC into its calculation of the beneficiary's risk score. For

(CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 1, 2013, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/announcement2014.pdf>, accessed September 14, 2023 at Table 5; *Report to Congress: Risk Adjustment in Medicare Advantage*, Centers for Medicare & Medicaid Services, December 2021, <https://www.cms.gov/files/document/report-congress-risk-adjustment-medicare-advantage-december-2021.pdf>, accessed June 30, 2022, at 7. CMS determines which diagnosis codes map to which HCCs each year.

³³ In the CMS HCC Model, diagnosis codes are grouped with other clinically similar diagnosis codes and the diagnosis groupings are mapped to condition categories based on similar clinical characteristics and severity, and cost implications. Hierarchies are imposed on the condition categories included in the model (then called “Hierarchical Condition Categories or “HCCs”). “CMS Manual System Transmittal 118,” Department of Health & Human Services and Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R118MCM.pdf>, accessed June 30, 2022, at § 70.1.

³⁴ The illustrative examples presented in my Report and in **Appendix D** use ICD-9 codes, but the same concepts apply to ICD-10 diagnosis codes.

³⁵ The factors presented in the examples in my Report are from CMS’ “Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies,” Centers for Medicare & Medicaid Services, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023 at Table 1-4.

example, assume that the beneficiary described above had only one risk adjustment-eligible medical encounter in 2010, with Provider A, and that Provider A reported diagnosis code 25000 to the MAO for this encounter. Assume that in turn, the MAO submitted this diagnosis code to CMS. As noted above, diagnosis code 25000 maps to HCC 19, *Diabetes without complication*, which is assigned a factor of 0.181. When the demographic risk factor (0.298) and HCC 19 risk factor (0.181) are combined, the resulting total risk score for this beneficiary would be 0.479.³⁶ If the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$47.90 for this beneficiary.

30. Some HCCs are strictly additive, such that multiple diagnosis codes mapping to different HCCs will have a numerical value assigned to each HCC and each HCC will be included in the risk score and payment calculation. For example, consider Beneficiary 1 in **Exhibit 1** below. Assume that she has the same demographic factor as the hypothetical beneficiary described above (0.298) but that Provider A reported two diagnosis codes for her based on the 1/1/2010 medical encounter. In this hypothetical, Provider A reported diagnosis codes 25000 and 82100, which map to HCC 19, *Diabetes without complication* and HCC 158, *Hip fracture/dislocation*, respectively. HCC 19 is assigned a factor of 0.181 and HCC 158 is assigned a factor of 0.450, resulting in a total risk score of 0.929 for this beneficiary.³⁷ If the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$92.90 for this beneficiary.

³⁶ $0.479 = 0.298 \text{ demographic factor} + 0.181 \text{ HCC 19 factor}.$

³⁷ $0.929 = 0.298 \text{ demographic factor} + 0.181 \text{ HCC 19 factor} + 0.450 \text{ HCC 158 factor}.$

Exhibit 1
Risk Score Calculation for Hypothetical Beneficiary 1

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
1	1/1/2010	A	Claims	25000	19	0.181
1	1/1/2010	A	Claims	82100	158	0.450
Demographic Factor						0.298
Total Risk Score						0.929
x Base Rate						\$100
Per Member Per Month Payment						\$92.90

31. If an MAO submits multiple diagnosis codes mapping to the same HCC for a beneficiary, the beneficiary's risk score does not depend on which specific diagnosis code was reported. Nor does the risk score depend on how many times a particular diagnosis code is reported within a service year.
32. This principle can be observed in **Exhibit 2** below. Like Beneficiary 1, Beneficiary 2 had her first encounter in 2010 with Provider A on 1/1/2010. Again, Provider A reported diagnosis codes 25000 and 82100, which map to HCC 19 and HCC 158, respectively. Beneficiary 2 then had three subsequent encounters with Provider A in the same year, for which Provider A only reported diagnosis code 25001. Diagnosis code 25001, like diagnosis code 25000, maps to HCC 19. In service year 2010, Beneficiary 2 has the same two distinct HCCs as Beneficiary 1 (HCC 19 and HCC 158). As a result, despite having a greater number of submitted diagnosis codes, Beneficiary 2 has the same risk score as Beneficiary 1 (0.929). Likewise, if the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$92.90 for this beneficiary.³⁸

³⁸ 0.929 = 0.298 demographic factor + 0.181 HCC 19 factor + 0.450 HCC 158 factor.

Exhibit 2
Risk Score Calculation for Hypothetical Beneficiary 2

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
2	1/1/2010	A	Claims	25000	19	0.181
2	1/1/2010	A	Claims	82100	158	0.450
2	4/1/2010	A	Claims	25001	19	0.181
2	5/1/2010	A	Claims	25001	19	0.181
2	6/1/2010	A	Claims	25001	19	0.181
2	7/1/2010	A	Claims	25001	19	0.181

Distinct HCCs	HCC Factor
19	0.181
158	0.450
Demographic Factor	0.298
Total Risk Score	0.929
x Base Rate	\$100
Per Member Per Month Payment	\$92.90

33. While some HCCs are strictly additive, certain HCCs represent more or less severe cases of the same condition or related conditions, and these are not strictly additive.³⁹ In these cases, the model utilizes a hierarchy such that only the most severe case of the condition is included in the risk score. For example, HCCs 15 through 19 are related to diabetes and defined by CMS as belonging to a single hierarchy.⁴⁰ If a beneficiary has a diagnosis code mapping to HCC 15 and a different diagnosis code mapping to HCC 19, only the more severe condition will be used for calculating that beneficiary's risk score.⁴¹ Within a hierarchy, more severe conditions map to lower HCCs,⁴² so in this example, HCC 15 would be included in the beneficiary's risk score and HCC 19 would not.

³⁹ "Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies," Centers for Medicare & Medicaid Services, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023.

⁴⁰ The five diabetes-related HCCs are defined as follows: Diabetes with renal or peripheral circulatory manifestation (HCC 15), Diabetes with neurologic or other specified manifestation (HCC 16), Diabetes with acute complications (HCC 17), Diabetes with ophthalmologic or unspecified manifestation (HCC 18), and Diabetes without complication (HCC 19); *Ibid.* at Table 1-4.

⁴¹ *Ibid.* at Table 1-4.

⁴² *Ibid.* at Table 1-4. The relative factor for HCC 19 for a non-institutionalized beneficiary is 0.181 and the relative factor for HCC 15 for that same beneficiary would be 0.608.

34. Consider Beneficiary 3 in **Exhibit 3** below. As with Beneficiary 1 and Beneficiary 2, this beneficiary has a demographic factor of 0.298 and had her first encounter in 2010 with Provider A on 1/1/2010. Again, Provider A reported diagnosis codes 25000 and 82100, which map to HCC 19 and HCC 158, respectively. If this were Beneficiary 3's only encounter during this service year, then she would have the same risk score as Beneficiary 1 and Beneficiary 2. However, Beneficiary 3 had one subsequent encounter with Provider A, for which Provider A reported diagnosis code 25040. Diagnosis code 25040 maps to HCC 15, which is a more severe condition in the same disease hierarchy as HCC 19.⁴³ For the purpose of risk adjustment, HCC 15 is included in Beneficiary 3's risk score and HCC 19 is not (HCC 19 is effectively subsumed by HCC 15). HCC 15 is assigned a factor of 0.608 and HCC 158 is assigned a factor of 0.450, resulting in a total risk score of 1.356 for Beneficiary 3.⁴⁴ If the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$135.60 for this beneficiary.

Exhibit 3
Risk Score Calculation for Hypothetical Beneficiary 3 (Hierarchy)

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
3	1/1/2010	A	Claims	25000	19	0.181
3	1/1/2010	A	Claims	82100	158	0.450
3	4/1/2010	A	Claims	25040	15	0.608

Distinct HCCs	HCC Factor
15	0.608
158	0.450
Demographic Factor	0.298
Total Risk Score	1.356
x Base Rate	\$100
Per Member Per Month Payment	\$135.60

35. The CMS HCC Model also accounts for anticipated costs associated with disease interactions, such that a risk score may be impacted if a beneficiary has a combination of

⁴³ *Ibid.* at Table 1-4.

⁴⁴ $1.356 = 0.298 \text{ demographic factor} + 0.608 \text{ HCC 15 factor} + 0.450 \text{ HCC 158 factor}$.

certain HCCs. In these cases, the beneficiary may receive an additional increase in their risk score.⁴⁵

36. To illustrate, consider Beneficiary 4 in **Exhibit 4** below. As with Beneficiaries 1, 2, and 3, this beneficiary has a demographic factor of 0.298 and had her first encounter in 2010 with Provider A on 1/1/2010. In this hypothetical, Provider A reported diagnosis codes 25000 and 436, which map to HCC 19, *Diabetes without complication*, and HCC 96, *Ischemic or unspecified stroke*, respectively. CMS applies a disease interaction factor for the combination of HCC 19 and HCC 96, which will increase this beneficiary's risk score by 0.149.⁴⁶ To calculate the risk score for Beneficiary 4, CMS totals the value of HCC 19 (which is assigned a factor of 0.181), HCC 96 (which is assigned a factor of 0.303), and the disease interaction factor (which is assigned a factor of 0.149), thereby resulting in a total risk score of 0.931 for this beneficiary.⁴⁷ If the base rate for this beneficiary's plan is \$100, then CMS would pay the MAO a risk adjusted per member per month payment of \$93.10 for this beneficiary.

⁴⁵ "Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies," Centers for Medicare & Medicaid Services, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023 at Table 1-4. CMS also applies a disabled/disease interaction factor if a beneficiary qualifies for disability status and has a combination of certain co-existing conditions, as reflected in the HCCs assigned to the beneficiary that result in a lift to the beneficiary's risk score. For the purposes of the examples included here, assume that the beneficiary does not qualify for disability status. "Medicare Managed Care Manual Chapter 7 - Risk Adjustment," Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf>, accessed October 15, 2022 at § 70.2.7; "Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies," Centers for Medicare & Medicaid Services, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023, p. 29.

⁴⁶ "Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies," Centers for Medicare & Medicaid Services, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023 at Table 1-4.

⁴⁷ $0.931 = 0.298 \text{ demographic factor} + 0.181 \text{ HCC 19 factor} + 0.303 \text{ HCC 96 factor} + 0.149 \text{ interaction factor for HCC 19 and HCC 96.}$

Exhibit 4
Risk Score Calculation for Hypothetical Beneficiary 4 (Disease Interactions)

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
4	1/1/2010	A	Claims	25000	19	0.181
4	1/1/2010	A	Claims	436	96	0.303
Demographic Factor						0.298
Disease Interaction Factor						0.149
Total Risk Score						0.931
x Base Rate						\$100
Per Member Per Month Payment						\$93.10

ii. Payments to MA-PD Plans

37. Risk adjustment is also a component of how CMS makes payments under Part D to MA-PD plans. The per member per month payment that CMS pays MA-PD plans for each beneficiary is based on a base rate, multiplied by a risk score.
38. The Part D risk score is calculated in a similar manner to the risk score for Part C and, as is true in Part C, is affected by the submission of diagnosis codes that map to Rx Hierarchical Condition Categories (“RxHCCs”) included within the CMS RxHCC Risk Adjustment Model (“CMS RxHCC Model”). The construction and use of RxHCCs is similar to the construction and use of HCCs. As with Part C, CMS makes publicly available on their website computer programs for calculating Part D risk scores based on the beneficiary diagnosis codes and demographics that are inputs to the program.⁴⁸
39. Many diagnosis codes map to both an HCC and an RxHCC, meaning that submission of such codes may impact payments under both models. Some diagnosis codes only map to an HCC or only map to an RxHCC and will only impact payments under the corresponding model. The same CMS rules discussed in the context of Part C above also apply to Part D: risk scores are calculated anew each year and are based only on diagnosis codes supported

⁴⁸ “Medicare risk adjustment information,” Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment>, downloaded on June 16, 2023.

by the beneficiary's medical records and, generally, resulting from face-to-face medical encounters with providers of certain specialties.⁴⁹

40. Part D payments from CMS to MA-PDs cover approximately 75% of the average total cost of prescription drug benefits, and beneficiary premiums cover the remainder.⁵⁰ CMS' portion of the payment is referred to as the "direct subsidy," and the beneficiary's portion is referred to as the "beneficiary premium."⁵¹ Like CMS' payment, the beneficiary's portion of the payment also depends on the risk score that CMS calculates based on diagnosis codes submitted to CMS for the beneficiary.
41. Additionally, unlike Part C, CMS applies "risk corridors" to Part D payments. Risk corridors are designed to reduce the risk that MAOs take on in providing prescription drug benefits to beneficiaries enrolled in MA-PD Plans.⁵² Risk corridors function at the plan level rather than at a beneficiary level. If an MAO's actual costs across all beneficiaries enrolled in a plan are higher than the expected costs, CMS will make additional payments to the MAO to help cover those costs. Conversely, if actual costs are lower than expected, the MAO must share those profits with CMS.
42. The expected costs for a given plan, referred to as the "target" amount, are set just below the amount the MAO receives to cover the beneficiaries in the plan, which includes CMS' portion of the payment (the direct subsidy) plus the beneficiaries' portion (the beneficiary premium), as MAOs are expected to incur some administrative costs in covering the

⁴⁹ 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide, Centers for Medicare & Medicaid Services, January 1, 2008, <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>, accessed September 5, 2023, pp. 62–63, 76.

⁵⁰ "Part D Payment System," Medicare Payment Advisory Commission, November 2021, https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partd_final_sec.pdf, accessed August 29, 2022.

⁵¹ 42 CFR § 423.329(a); 42 CFR § 423.286; "CMS Releases 2024 Projected Medicare Part D Premium and Bid Information," Centers for Medicare & Medicaid Services, July 31, 2023, <https://www.cms.gov/newsroom/fact-sheets/cms-releases-2024-projected-medicare-part-d-premium-and-bid-information>, accessed September 28, 2023.

⁵² *Sharing Risk in Medicare Part D Chapter 6*, Medpac, June 2015, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf, accessed September 26, 2023.

beneficiary.⁵³ If an MAO's actual costs for a given plan are less than 5% below the target amount, the MAO keeps all of those excess profits. Profits that the MAO earns based on costs that are between 5% and 10% below the target amount must be shared equally with CMS. For any profits the MAO earns based on costs that are more than 10% below the target, the majority (80%) must be returned to CMS. Conversely, the same tiers of risk sharing apply if the MAO incurs losses. The MAO must absorb all losses until their costs exceed the target amount by 5%. Losses associated with costs between 5% and 10% above the target amount are shared equally with CMS, and losses based on costs exceeding 10% above the target amount are largely borne by CMS (80%).

43. The diagnosis codes that MAOs submit to CMS for use in risk adjustment determine CMS' payment to MAOs, and these payments in turn are used to calculate the target amount for each MA-PD. The size of the gap between this target amount and the plan's actual costs may then result in an additional transfer of payment between MAOs and CMS under the risk corridors. In this way, under Part D, the diagnosis codes that MAOs submit for beneficiaries have an additional impact on payments which does not apply under Part C.

IV. DEFENDANTS' RISK ADJUSTMENT-RELATED PROGRAMS

44. In this section, I provide a description of certain programs Defendants implemented related to Medicare Advantage risk adjustment, which is based on my professional understanding and my review of the testimony and documents cited. My intent is to provide background and context relevant to understanding the analyses I have performed.
45. MAOs submit diagnosis code data for beneficiaries enrolled in their plans to CMS for use in risk adjustment.⁵⁴ Some of this data originates from provider-reported encounters, which providers report to MAOs as claims for reimbursement.⁵⁵ MAOs may also supplement this data with additional diagnosis codes that are supported by the beneficiary's medical records

⁵³ 42 CFR § 423.336(a)(2).

⁵⁴ 42 CFR § 422.310(a)-(b).

⁵⁵ *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide*, Centers for Medicare & Medicaid Services, January 1, 2008, <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>, accessed September 5, 2023, Section 3.2.1 – 3.2.3.

from the relevant service year, but that may not have already been reported on the provider's claim.⁵⁶

46. For the years at issue in this matter, Defendants conducted retrospective reviews of their Medicare Advantage beneficiaries' medical records, also known as "Charts," to identify diagnosis codes that were supported by those Charts.⁵⁷ Defendants' primary program for conducting these reviews, the Chart Review Program, was implemented for every payment year at issue in this matter. For some of these years, Defendants also implemented an additional program called Claims Verification.

A. Defendants' Chart Review Program

47. In the Chart Review Program, Defendants, either themselves or through a third-party vendor,⁵⁸ identified and collected Charts from certain providers who had reported encounters with beneficiaries to Defendants, and for which Defendants had submitted diagnosis codes to CMS.⁵⁹ The collected Charts could include information about only one encounter for a beneficiary from the relevant service year or multiple encounters from that year.⁶⁰ Some of the collected Charts included information about encounters with multiple

⁵⁶ *Ibid.* Section 3.2.4.

⁵⁷ Deposition of Kathleen O. Baker 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, Case No. 2:16-cv-08697-FMO-SS, May 30, 2023 ("Baker Deposition Volume 1"), 33:10–20 ("Q. Okay. So broadly speaking, what is Optum's retrospective chart review program? A. Optum's retrospective chart review program is a program where we submit a more complete health status from medical records collected on a member for appropriate payment from CMS. Q. Okay. So what is the purpose of Optum's chart review program? A. To submit more complete health statuses to CMS on risk adjustment members.").

⁵⁸ *Ibid.*, 137:1–9 ("Q. Okay. So let's go back to our hypothetical patient, Mary, who's seeing doctors at Vanderbilt Health. So -- and we're -- I'm focused now on the 2008 and 2009 dates of service. Can you just -- what was the name of one of the coding vendors that you used at the time? A. TCS, The Coding Source.").

⁵⁹ *Ibid.*, 65:5–68:9 ("In the retrieval process itself, if it went to a -- a vendor for retrieval, for instance, it could be something along the lines of when you send the chart over -- you know, a chart is a member-provider combination where the provider is based upon -- is selected from a location, for instance. ... And then as you're retrieving the chart, what the vendor will do is they'll call up the provider. They'll do some sort of provider verification, like asking are there X number of providers and their ID there to make sure they've got the right area. Then they'll go through a member verification to say hey, do you have these members with this information. ... And then once we get validation from there, typically we either fax or we would secure E-mail the complete list of the members. And then, based upon the number, we'd work with them to schedule either on site or they could themselves decide to send us the charts").

⁶⁰ *Ibid.*, 35:1–15 ("So in my personal opinion, when I say more complete health status, it's the recognition that there's -- we may not ever be able to submit 100 percent of a person's medical status, but it's -- in context of the retrospective chart review program, it's being able to say based upon a chart that we have on a member, knowing that a member may have multiple charts from different providers that contain different providers

providers.⁶¹ Certified medical record coders (“Coders”) reviewed the collected Charts to identify and code medical conditions that were documented by physicians in the Charts.⁶²

48. Defendants’ Chart Review Program, which began prior to the first year I was asked to analyze for this matter, grew during the time period at issue. **Exhibit 5** shows the number of beneficiaries enrolled in Defendants’ Medicare Advantage plans,⁶³ according to their annual public filings, along with the number of beneficiaries and service dates that were reviewed in Defendants’ Chart Review Program for the years at issue in this matter, according to Defendants’ data.

within those charts on different dates of services that we're, you know, attempting for one of those charts to provide information.”); *Ibid.*, 222:1–2. (“A chart could contain multiple dates of services.”).

⁶¹ *Ibid.*, 119:13–120:2 (“Q. Okay. So as a result of Optum's consolidation process for that retrieval -- retrieval provider ID, was it possible to collect charts for members that included encounters with multiple providers? ... THE WITNESS: So after we -- after we released the charts to the retrieval vendor and they did their consolidation and they did their validation and we retrieved the chart under that method, it could include multiple providers.”).

⁶² *Ibid.*, 187:17–188:4 (“Q. And did you believe that the coders hired by Optum for the 2008-2016 date of service chart reviews were among the best in -- available in the business? ... THE WITNESS: We required that our coders be certified coders. And then from there, we provided them training on risk adjustment coding.”); Deposition of Kathleen O. Baker 30(b)(6) *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, Case No. 2:16-cv-08697-FMO-SS, May 31, 2023 (“Baker Deposition Volume 2”), 420:7–422:22 (“Q. Okay. And then going forward for subsequent date of service years, so date of -- dates of service 2013, 2014, 2015 and 2016, were coders consistently instructed to record all RxHCCs? ... THE WITNESS: They were asked to code all HCCs and RxHCCs that they could identify in the chart according to their ability, according to the chart difficulty levels.”); Deposition of Melissa Sedor 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 29, 2023 (“Sedor Deposition”), 184:17–20 (“The chart review is looking at the medical record to determine which diagnosis the doctor or provider had documented in that medical record.”).

⁶³ *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide*, Centers for Medicare & Medicaid Services, January 1, 2008, <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>, accessed September 5, 2023, p. 168 (“During medical record review, the certified coder checks for the following: [t]he service was provided by an acceptable risk adjustment provider type and physician specialty ... [d]iagnoses supported by medical record submission.”).

Exhibit 5
Defendants' Medicare Advantage Beneficiaries⁶⁴ and
Beneficiaries and Service Dates Reviewed in Defendants' Chart Review Program
Service Years 2008–2016

Service Year	Defendants' Medicare Advantage Beneficiaries <i>based on 10-K filings</i>	Beneficiaries Reviewed	Beneficiary Service Dates Reviewed
	[A]	[B]	[C]
2008	1,495,000	540,037	1,962,873
2009	1,790,000	811,013	3,437,735
2010	2,005,000	1,040,460	5,150,626
2011	2,165,000	1,172,337	6,641,373
2012	2,565,000	1,291,814	7,255,206
2013	2,990,000	1,568,691	8,780,321
2014	3,005,000	1,901,809	11,949,263
2015	3,235,000	2,059,941	14,476,590
2016	3,630,000	2,212,997	16,412,551

49. While the number of beneficiaries enrolled in Defendants' Medicare Advantage plans grew by 143% from service year 2008 to 2016, the number of beneficiaries reviewed in Defendants' Chart Review Program grew by 310% and the number of service dates

⁶⁴ UnitedHealth Group Incorporated Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2010, filed February 10, 2011, <https://www.sec.gov/Archives/edgar/data/731766/000119312511030615/d10k.htm>, accessed September 29, 2023 p. 43; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2011, filed February 8, 2012, <https://www.sec.gov/Archives/edgar/data/731766/000073176612000009/unh2011123110k.htm>, accessed September 29, 2023 p. 37; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2012, filed February 6, 2013, <https://www.sec.gov/Archives/edgar/data/731766/000073176613000005/unh2012123110-k.htm>, accessed September 29, 2023 p. 39; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2013, filed February 12, 2014, <https://www.sec.gov/Archives/edgar/data/731766/000073176614000008/unh2013123110-k.htm>, accessed September 29, 2023 p. 36; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2014, filed February 10, 2015, <https://www.sec.gov/Archives/edgar/data/731766/000073176615000007/unh2014123110-k.htm>, accessed September 29, 2023 p. 35; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2015, filed February 9, 2016, <https://www.sec.gov/Archives/edgar/data/731766/000073176616000058/unh2015123110-k.htm>, accessed September 29, 2023 p. 33; UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2016, filed February 8, 2017, <https://www.sec.gov/Archives/edgar/data/731766/000073176617000009/unh2016123110-k.htm>, accessed September 29, 2023 p. 32.

reviewed grew by more than 736%.⁶⁵ In 2008, approximately 36% of the beneficiaries enrolled in Defendants' Medicare Advantage plans had a Chart reviewed in Defendants' Chart Review Program. By 2016, Defendants Chart Review Program included over 60% of Defendants' beneficiaries.⁶⁶

50. The Chart Review Program generally conducted reviews in a "blind" fashion,⁶⁷ meaning that the Coder did not know which diagnosis codes the provider had initially reported (and Defendants had submitted to CMS) for the encounter or encounters documented in the Chart under review.⁶⁸ In blind reviews, Defendants instructed their Coders to record all diagnosis codes eligible for risk adjustment that they determined were supported by the beneficiary's Chart.⁶⁹
51. For service years 2014-2016, Defendants also conducted a step in the Chart Review Program called "Second Level Review," where a *second* blind review was conducted for some Charts.⁷⁰ Based on Defendants' data, approximately 73% of the Charts reviewed in these years underwent a Second Level Review.⁷¹

⁶⁵ These calculations are based on the change in the number of beneficiaries (or beneficiary service dates) reviewed from 2008 to 2016, divided by the number of beneficiaries (or beneficiary service dates) reviewed in 2008, as shown in **Exhibit 5**.

⁶⁶ These calculations are based on the number of beneficiaries Defendants reviewed in the Chart Review Program [B], divided by the number of Defendants' Medicare Advantage beneficiaries [A] as shown in **Exhibit 5**.

⁶⁷ Baker Deposition Volume 1, 298:17–22 ("Q. Okay. Okay. So aside from the charts marked with the recode flag discussed here, Optum coded charts for UnitedHealthcare's chart review program using blind coding for the 2008 to 2016 dates of service, correct? A. Yes.").

⁶⁸ *Ibid.*, 260:1–260:16 ("[I]n blind coding a coder's given no additional information, other than the image of the chart to -- to code to the best of their ability.").

⁶⁹ *Ibid.*, 197:1–203:9 ("Q. And Optum also instructed its coders that the medical record had to support the diagnosis code selected, correct? ... THE WITNESS: We, as part of our QA process, would check to make sure that the code that the coder coded from the chart was supported appropriately within the medical record. But, again, that doesn't mean that they were 100 percent complete in what was coding from that chart.").

⁷⁰ *Ibid.*, 351:4–354:3 ("A. We would send charts to second-level review based upon the information that we saw where again, depending upon the coder's experience -- the complexity of the chart, the type of chart, if it was EMR or if it was handwritten -- that we would send it to second-level review."); 359:16–360:8 ("Q. Okay. So then if we're trying to figure out which one of Mary's chart reviews is first-time coding versus second-level review, would you determine that by looking at the dates that the chart was coded on? ... THE WITNESS: When we assigned a chart, we assigned it, like, in a work list. ... Q. Okay. A. And the work list would be this is work list 1LR. Then we would assign it, this is work list 2LR.").

⁷¹ See **Appendix D, Section III.A.ii.c** for an explanation of how I identified Charts that underwent a Second Level Review.

52. While most Chart Review Program reviews were blind, there were limited exceptions. In particular, in a project known as the “Recode Project,” Defendants gave Coders information about diagnosis codes previously submitted to CMS for the beneficiary, a type of review known as “informed coding.”⁷² In these instances, Defendants instructed Coders that it was not necessary to record diagnosis codes that had already been submitted for that year, since each distinct HCC only counts once per year toward a beneficiary’s risk score.⁷³ Based on Defendants’ data,⁷⁴ approximately 33% of the Charts reviewed in service years 2011 and 2012 were subject to informed coding.⁷⁵
53. Defendants analyzed diagnosis codes reported by providers and Chart Review Program results and identified the new diagnosis codes (*i.e.*, diagnosis codes not previously reported by the provider and not previously submitted by Defendants to CMS) that their Coders found as being documented in the Chart, and submitted those diagnosis codes to CMS for additional risk adjustment payments.⁷⁶ Defendants’ submission of these diagnosis codes, called “adds,” generally resulted in increases in beneficiaries’ risk scores and thus increases in CMS’ payments to Defendants to cover these beneficiaries. Defendants estimated that for payment years 2010-2015, the adds generated by their Chart Review Program resulted in over \$3.5 billion in additional risk adjustment payments made by CMS to Defendants.⁷⁷

⁷² Baker Deposition Volume 1, 263:14–264:11 (“A. I mean, I would maybe also just continue that further informed coding, as UnitedHealth uses the term to respond to this interrogatory was not specific to the rendering provider or date of service as the charts reviewed during chart review could contain information from multiple providers and multiple dates of services across different data collection years and different provider encounters.”).

⁷³ *Ibid.*, 285:6–14 (“Q. Okay. And those directions included a direction to only code each HCC once per year? A. Um-hmm. And I believe we also said do not – you do not need to code every RxHCC.”).

⁷⁴ Recode reviews were only conducted for services years 2011 and 2012. *Ibid.*, 268:9–269:11 and 298:6–15; UnitedHealth’s First Supplemental Responses and Objections to Plaintiff United States’ Sixth Set of Interrogatories, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, CASE NO. CV 16-08697 (SSx), July 19, 2022 (“UnitedHealth’s First Supplemental Responses and Objections to Plaintiff United States’ Sixth Set of Interrogatories”).

⁷⁵ See **Appendix D, Section III.A.iii** for an explanation of how I identified informed coded Charts. Defendants also identified a small number of informed coded Charts outside of these years. These represent less than 0.5% of Charts in service years 2013-2016.

⁷⁶ Sedor Deposition, 181:8–22 (“So I would say that the chart review process identified all HCCs, and then a separate process that was not part of the chart review program itself but was part of the submission process would identify which of those codes from a chart review were new and unique for submission.”).

⁷⁷ Production of Responses and Documents Responsive to CR / CV Interrogatories 1(F),1(J), 1(K) and Document Requests 4(C)(iii)(t), 4(C)(vii)(i), 5, and 6(D), December 21, 2015, p. 5.

54. While Defendants submitted the new diagnosis codes that were found to be supported in the Chart Review Program but were not previously reported by providers, they did not, as part of the Chart Review Program, generally⁷⁸ delete, investigate, or even flag diagnosis codes that were previously reported by a provider and submitted by Defendants to CMS but were *not* found to be supported in the Chart Review Program.⁷⁹

B. Defendants' Claims Verification Program

55. From 2010 through April 2014, Defendants conducted a program called "Claims Verification" or "CV," which involved the re-review of some Charts from the Chart Review Program for service years 2009-2012.⁸⁰ According to Defendants, CV utilized Charts previously reviewed in the Chart Review Program to determine if there were any provider-reported diagnosis codes that had been submitted to CMS, but were not supported by the Chart.⁸¹
56. The CV program applied only to a subset of Charts that had been reviewed in the Chart Review Program. For example, a Chart was only eligible for inclusion in the CV program if it was associated with what Defendants called an "exclusive HCC."⁸² An exclusive HCC is an HCC that is exclusive to one provider in the service year, and was not found to be

⁷⁸ For two years, Defendants investigated some of these diagnosis codes and, in some instances, deleted them, as further discussed in **Section IV.B**.

⁷⁹ Sedor Deposition, 249:16–251:16 ("Q. But you didn't do anything in particular with respect to the charts that had gone through chart review, right, to make sure that anything that the coders did not find as supported to try to validate any of those codes; correct? ... THE WITNESS: Correct. ... Q. And I would say by definition, if you didn't have that type of process, then you were not submitting deletes that would have -- that would have resulted; correct? ... THE WITNESS: Correct. Without a program to identify the deletes, we would not have been submitting deletes.").

⁸⁰ Production of Responses and Documents Responsive to CR / CV Interrogatories 1(F),1(J), 1(K) and Document Requests 4(C)(iii)(t), 4(C)(vii)(i), 5, and 6(D), December 21, 2015, p. 7 ("... the Claims Verification program continually evolved between 2010 and 2014 ..."); Deposition of Jon H. Bird 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 22, 2023 ("Bird Deposition Volume 1"), 102:21–103:21.

⁸¹ Sedor Deposition, 115:9–18 ("What [the CV] program did was to, when a medical record was looked at for chart review purposes to identify diagnosis codes that were not on the claim, it would also utilize those medical records to compare against the claim submitted by the provider to see if there were any codes submitted on the claim that were not supported by the medical records.").

⁸² Bird Deposition Volume 1, 109:1–18 ("[An exclusive HCC] would be an HCC or diagnoses that mapped to an HCC and that HCC is submitted by one and only one provider.").

supported by the review of that provider's Chart in the Chart Review Program.⁸³ Put differently, an exclusive HCC is one that was included in a beneficiary's record solely on the basis of a diagnosis code (or diagnosis codes) reported by one provider in the service year, but Defendants' Coders in the Chart Review Program identified no diagnosis codes mapping to that HCC in the review of that provider's Chart.⁸⁴ According to Defendants' data, 53% of the Charts that went through the Chart Review Program in service years 2011 and 2012⁸⁵ were excluded from the CV program because they did not include an exclusive HCC.⁸⁶ Defendants had various other reasons for excluding Charts from CV.⁸⁷ According to Defendants' data, for service years 2011 and 2012 only 16% of the Charts reviewed in the Chart Review Program were re-reviewed in the CV program.

57. In the CV program, Defendants often had multiple Coders re-review Charts to look for support for a diagnosis code mapping to the same HCC as the diagnosis code that was reported by the provider but was not found to be supported by Coders in the Chart Review

⁸³ "Exhibit 712-5 of Bird Deposition," MARA2076620 ("Charts will only be eligible for CV if the provider linked to the chart reported at least one exclusive HCC or exclusive RXHCC in a claim. An Exclusive HCC is defined as an HCC reported only in a claim by the linked provider during the data collection period."); Bird Deposition Volume 1, 102:15–20 ("Q. Can you explain what the claims verification program is? A. It was a program that we operated during a certain time frame that identified and reviewed exclusive HCCs that were submitted by providers that were part of the chart review program.").

⁸⁴ For example, suppose two providers submitted diagnosis codes mapping to HCC 15 for a beneficiary from two distinct encounters in a given service year. Further suppose that both of these encounters were reviewed in Defendants' Chart Review Program and that the Coders found no supporting diagnosis codes in the Charts corresponding to either encounter. HCC 15 would not be considered an exclusive HCC for the beneficiary and not eligible for the CV program because it was associated with diagnosis codes submitted by two providers in the service year. In contrast, if only one provider had submitted a diagnosis code mapping to HCC 15 for this beneficiary, HCC 15 would have been eligible for the CV program.

⁸⁵ Defendants have not produced data related to the CV program for service years 2009-2010. The CV program was in pilot phases and thus limited in scope in these years. Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2010 DOS, May 2, 2016, pp. 5–6.

⁸⁶ Defendants have indicated a reason for each Chart's exclusion from the CV program in two datasets, MARA2157340 and MARA2152921. This count of Charts excluded from the CV program because they did not meet the exclusive HCC criteria includes two reasons: 1) "[Chart IDs] with no exclusive HCC's present in claims" and 2) "Exclusive HCC not related to chart provider." Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016, p. 8.

⁸⁷ Defendants also excluded Charts associated with new enrollees, and Charts whose image was no longer available in their systems. Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016, p. 8.

Program.⁸⁸ These re-reviews were conducted by Coders employed by Defendants and third-party vendors engaged by Defendants.⁸⁹

58. Diagnosis codes that were still not found to be supported by the Chart in accordance with CMS guidelines after completing the re-reviews in the CV process were submitted as “deletes” to CMS.⁹⁰ If any CV Coder reported finding support for a diagnosis code mapping to the relevant HCC in any of the re-reviews, Defendants did not submit a delete to CMS for that diagnosis code.⁹¹
59. Defendants terminated the CV program in mid-2014.⁹² At the time that CV was terminated, Defendants had already identified a set of diagnosis codes associated with 2011 and 2012 services years that they had submitted to CMS based on a provider-reported claim but for which they found no support in the Chart Review Program. This set of diagnosis codes included 74,722 diagnosis codes associated with service year 2011 and 78,875 diagnosis codes associated with service year 2012.⁹³ Of these 153,597 diagnosis codes, Defendants

⁸⁸ Bird Deposition Volume 1, 311:2–22 (“And in this document -- or in this section it refers to RADV expert level review. Do you see that? A. I do see that. Q. And does that refer to external coders from your vendor, iCodify? A. iCodify was one of the vendors used. I don't know if it was exclusively used, but iCodify was one of the entities that did expert level review. Q. And when you say expert level review this is the review step that happens after the CVA analysis; is that right? A. CV analyst. Q. CV analyst? A. Correct. Q. And sometimes it's expert level review. Here it says RADV expert level review. But those refer to the same thing? A. Correct.”).

⁸⁹ *Ibid.*

⁹⁰ Sedor Deposition, 116:17–117:4 (“And then if you identified diagnosis codes through claims verification that had not been identified in the chart review, then you would delete -- you deleted those codes through the process that's depicted here. You'd submit the deletes to CMS; is that right? ... THE WITNESS: If through the claims verification process we obtained knowledge that that code was not supported in the medical record it would be submitted as a delete through the process depicted on the screen.”); Bird Deposition Volume 1, 119:12–120:10 (“[I]n terms of the main components that are listed here, outside of it being part of the chart review program, diagnoses were reviewed and they were -- to determine if supported, and deletes were processed.”).

⁹¹ Bird Deposition Volume 1, 232:6–13.

⁹² *Ibid.*, 104:7–105:11 (“Q. And so is that your testimony as the designee for UnitedHealthcare and Optum, that the suspension of CV went into place on April 18, 2014, and the termination of CV went into place on May 27, 2014? A. Yeah, my testimony is on or around April 18th is when I saw notification of delete processing, and I believe the program was also suspended on or around that date. And yeah, based upon the -- we have the exhibit in here which is Steve Nelson's email or memorandum to Scott Theisen. He indicates in there that the decision was made to terminate on May 27th, and then that memorandum was dated with notification to Scott and others that was on June 11th.”).

⁹³ MARA2164481 and MARA2160501.

identified only 800 codes that had not already been re-reviewed by one Coder in the CV program.⁹⁴

60. In general, the deletion of diagnosis codes results in a reduction in risk adjustment payments MAOs receive from CMS, because a deletion may result in the removal of an HCC, the removal of that HCC's factor from the risk score, and thus a lower payment for the beneficiary. During the CV program, Defendants accrued reductions in revenue to cover the reduction in risk adjustment payments from CMS that they expected the deletes might have.⁹⁵ At the time CV was terminated, Defendants were able to release the accrued reductions.⁹⁶ Defendants' estimate that these released funds total \$26 million for service year 2011 and \$166.7 million for service year 2012.⁹⁷

C. Example Calculations of Changes to Risk Scores Resulting from Submissions of Adds and Deletes

61. In this section, I provide example calculations of how risk scores might change due to the submission of adds and deletes resulting from Defendants' risk adjustment programs.
62. As an example, consider again hypothetical Beneficiary 4 presented in **Exhibit 4** above, whose provider-reported diagnosis codes 25000 and 436. Now suppose that in Defendants' Chart Review Program, a Coder reviewed the Chart from the 1/1/2010 encounter with Provider A, and that Coder identified support for diagnosis codes 25000 and 82100 in the Chart. However, the Coder did not find support for diagnosis code 436.

⁹⁴ Of the 78,875 diagnosis codes associated with service year 2012, Defendants have indicated in the spreadsheet that 800 had been reviewed in the Chart Review Program but not yet re-reviewed by any Coder in the Claims Verification program. For service year 2011, no such indicator exists in Defendants' spreadsheet.

⁹⁵ Sedor Deposition, 193:23–194:17 (“Q. I see. Now, you're here to talk about the claims verification roll forward schedules for certain quarters in 2013 and 2014. How did you use the roll forward schedules? A. The roll forward schedule was created on our entire risk adjustment receivable account which is at times, depending on the time of year, could be a very large account. Within that risk adjustment receivable account we're accruing for the midyear reconciliation, the final reconciliation. We have reserves against it for possible deletes that we're paying out. So across our entire Medicare Advantage business, that balance can be pretty large. So the roll forward is actually detailing that entire RAF receivable account and then breaking it down into subcategories of what is in that account based on the supporting schedules that add up to those balances.”).

⁹⁶ *Ibid.*, 217:22–218:2 (“Q. Okay. Why did you release the reserves for claims verification in 2014? ... THE WITNESS: The reserves were released because the program was discontinued.”).

⁹⁷ *Ibid.*, 210:1–211:21 and 212:5–214:8 ([For service year 2012] “Q. Okay. Because the total would have been 166.7? A. Across -- the total negative revenue would have been 166.7 across all of 2013 and Q1 of 2014.”) ([For service year 2011] (“So therefore our entire P&L activity was a favorable 26 million.”)).

63. For the purposes of this example calculation, assume that this beneficiary's Chart Review Program results were used to identify adds but not deletes. In this case, diagnosis code 82100 would have been added to this beneficiary's records, and diagnosis 436 would not have been deleted.

Exhibit 6
Beneficiary Diagnosis Codes if Chart Review Data Only Used for Adds

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
4	1/1/2010	A	Claims+Chart Review	25000	19	0.181
4	1/1/2010	A	Claims	436	96	0.303
4	1/1/2010	A	Chart Review	82100	158	0.450

Distinct HCCs	HCC Factor
19	0.181
96	0.303
158	0.450
Demographic Factor	0.298
Disease Interaction Factor	0.149
Total Risk Score	1.381
x Base Rate	\$100
Per Member Per Month Payment	\$138.10

64. In **Exhibit 6**, diagnosis codes 25000, 436, and 82100 are in HCC 19, HCC 96, and HCC 158, respectively. In the CMS HCC Model, HCC 19 is assigned a factor of 0.181, HCC 96 is assigned a factor of 0.303, and HCC 158 is assigned a factor of 0.450. After accounting for demographic factors and the disease interaction between HCC 19 and HCC 96, the use of Chart Review Program data results in a total risk score of 1.381 for this beneficiary.⁹⁸ If the base rate payment for this beneficiary's plan is \$100, then CMS would pay Defendants a risk adjustment per member per month payment of \$138.10 for this beneficiary, or \$45 more than if Defendants had not added diagnosis code 82100.⁹⁹

⁹⁸ $1.381 = 0.298 \text{ demographic factor} + 0.181 \text{ HCC 19 factor} + 0.303 \text{ HCC 96 factor} + 0.450 \text{ HCC 158 factor} + 0.149 \text{ interaction factor for HCC 19 and HCC 96}$.

⁹⁹ My assignment is not to calculate the value of adds from the Chart Review Program. I include this example to demonstrate how risk scores and per member per month payments are impacted by the submission of additional diagnosis codes.

65. Now reconsider the example from **Exhibit 6** if this beneficiary's Chart Review Program results were used to identify deletes as well as adds. Diagnosis code 82100 would have been added to the list of diagnosis codes submitted to CMS, *and* diagnosis 436 would have been reported to CMS as a delete. CMS increases the risk score by the value of HCC 158 and removes the risk score lift caused by the prior submission of HCC 96. Because HCC 19 and HCC 96 are no longer co-existing conditions assigned to this beneficiary, CMS also removes the risk score lift caused by the disease interaction factor.

Exhibit 7
Beneficiary Diagnosis Codes if Chart Review Data Used for Adds and Deletes

Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
4	1/1/2010	A	Claims+Chart Review	25000	19	0.181
4	1/1/2010	A	Claims	436	96	0.303
4	1/1/2010	A	Chart Review	82100	158	0.450

Distinct HCCs	HCC Factor
19	0.181
158	0.450
Demographic Factor	0.298
Disease Interaction Factor	0.149
Total Risk Score	0.929
x Base Rate	\$100
Per Member Per Month Payment	\$92.90

66. As shown in **Exhibit 7**, diagnosis codes 25000, 436, and 82100 map to HCC 19, HCC 96, and HCC 158, respectively, which are assigned factors of 0.181, 0.303, and 0.450, respectively. However, deleting diagnosis code 436 now excludes HCC 96 from the beneficiary's risk score calculation, reducing the total risk score from 1.381 to 0.929. If the base rate payment for this beneficiary's plan is \$100, then CMS would pay Defendants a risk adjustment per member per month payment of \$92.90 for this beneficiary, or \$45.20 less in per member per month payments than if Defendants had only added diagnosis code 82100 and not deleted diagnosis code 436.
67. The presence of other diagnosis information submitted to CMS for a beneficiary can mean that some deletes may not have had financial impact. Continuing with the example from **Exhibit 7**, suppose that the beneficiary had a second encounter in that service year, this time with Provider B on 2/1/2010. Further suppose that Provider B reported that the

beneficiary had diagnosis code 43491, which maps to HCC 96. In this example, even though the Coder did not find support for diagnosis code 436 in the Chart associated with Provider A's encounter with the beneficiary on 1/1/2010, HCC 96 nevertheless would be preserved in the beneficiary's risk score calculation because on 2/1/2010, Provider B reported diagnosis 43491, which also maps to HCC 96.

Exhibit 8						
Beneficiary Diagnosis Codes if Chart Review Data Used for Adds and Deletes						
Beneficiary	Date	Provider	Source	Diagnosis	HCC	HCC Factor
4	1/1/2010	A	Claims+Chart Review	25000	19	0.181
4	1/1/2010	A	Claims	436	96	0.303
4	1/1/2010	A	Chart Review	82100	158	0.450
4	2/1/2010	B	Claims	43491	96	0.303

Distinct HCCs	HCC Factor
19	0.181
158	0.450
96	0.303
Demographic Factor	0.298
Disease Interaction Factor	0.149
Total Risk Score	1.381
x Base Rate	\$100
Per Member Per Month Payment	\$138.10

68. The HCC factors for **Exhibit 8** are the same as those for Exhibit 6, resulting in the same total risk score of 1.381 for this beneficiary, implying the same per member per month payment of \$138.10 at a base rate of \$100. In this hypothetical, the use of Chart Review Program results to delete a diagnosis code does not affect the ultimate payment, because it does not impact the list of HCCs that CMS uses to calculate the payment for the beneficiary.

D. Defendants' Risk Adjustment Systems and Submission of Diagnosis Codes

i. Defendants' Risk Adjustment Systems

69. Defendants maintained databases to store diagnosis codes associated with their Medicare Advantage beneficiaries in order to submit them to CMS each year. Defendants pooled, validated, and filtered diagnosis codes from various sources into two final databases, hereinafter referred to collectively as "Defendants' Risk Adjustment Databases."

70. One of these databases, the Ingenix Risk Adjustment Data System (“IRADS”), was in use for all years at issue in this matter.¹⁰⁰ The other database, the Encounter Data Processing System (“EDPS”), was used from service year 2014 onwards.¹⁰¹
71. Defendants’ Risk Adjustment Databases generally tracked the source(s) of each diagnosis code.¹⁰² Many of the diagnosis codes in Defendants’ Risk Adjustment Databases came from one of two sources:
- i. **Provider-reported claims data.** When providers submit claim and encounter data to Defendants, they include diagnosis codes in the submission. Defendants passed diagnosis codes from these provider-reported claims into their Risk Adjustment Databases.¹⁰³
 - ii. **Defendants’ Chart Review Program data.** Defendants maintained data sets that contained the results of the Chart Review Program (“Chart Review Databases”).¹⁰⁴ Defendants passed diagnosis codes from their Chart Review Databases into their Risk Adjustment Databases.
72. Some of the diagnosis codes in Defendants’ Risk Adjustment Databases came from other sources and programs. For example, if a Chart was included in the CV program and the

¹⁰⁰ Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 6, 2023 (“Cannon Deposition Volume 1”), 59:22–60:5 (“Q. Okay. IRADS. What is IRADS used for? A. IRADS is a database within Optum that is used to house information related to Medicare Advantage beneficiaries. Q. And how long has -- or actually, was IRADS used for data that was being housed for dates of service 2008 through 2016? A. Yes, it would have stored data at that time frame.”); Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 7, 2023 (“Cannon Deposition Volume 2”), 353:5–353:23 (“Q. And my question for you is: Is there another system by which you use to submit that same type of data to CMS through the systems that we’ve mentioned that is outside of IRADS? ... THE WITNESS: The EDPS system also submits data to CMS for Medicare Advantage beneficiaries. BY MS. GLOVER: Q. Okay. Outside of EDPS and IRADS, are there any systems that you use to submit data to CMS for the beneficiaries enrolled in UnitedHealthcare’s plans? ... THE WITNESS: I believe IRADS and EDPS are the two systems that submit data for Medicare Advantage beneficiaries to CMS.”).

¹⁰¹ See **Section IV.D.i** for an explanation of why Defendants maintained two separate systems. While both databases served the same function for Defendants, they each have unique data elements and structures.

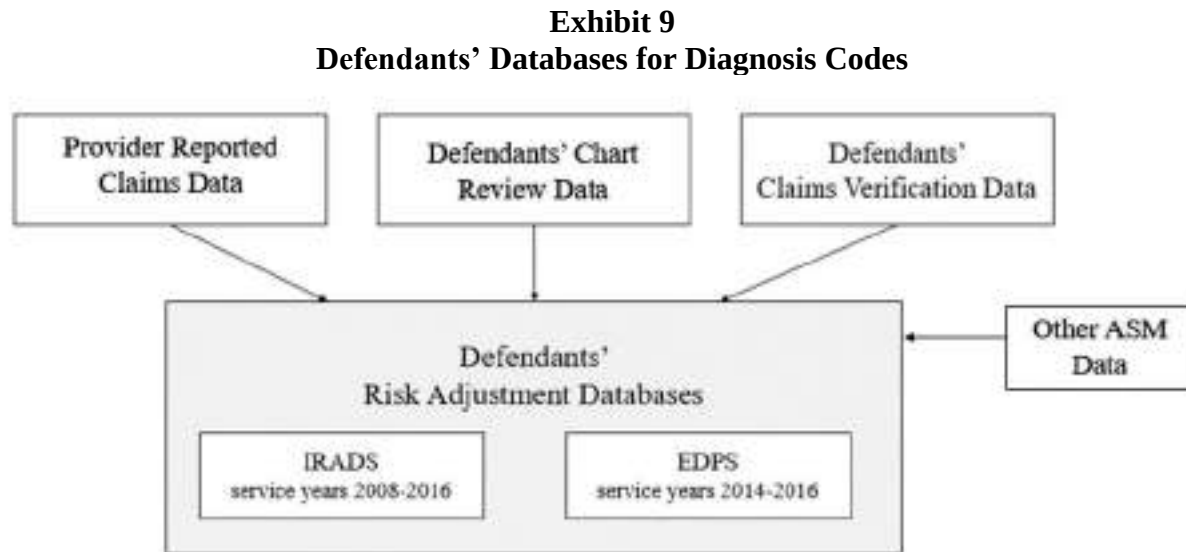
¹⁰² Cannon Deposition Volume 2, 353:5–353:23 Defendants produced EDPS data in two separate tables, one containing provider-report claims data and one containing data from other sources, including records from the Chart Review Program. In the data containing encounters from other sources, it is not clear how to distinguish records from the Chart Review Program from records from other sources.

¹⁰³ See **Appendix D, Section III.B** for a description of provider-reported claims data.

¹⁰⁴ See **Appendix D, Section III.A** for a description of Defendants’ chart review data.

CV Coder found support for an additional diagnosis code that was not previously reported by a provider or any Coders in the Chart Review Program, that diagnosis code might be added to Defendants' Risk Adjustment Databases.¹⁰⁵ A variety of other programs, such as provider attestations and hospital abstracts, also contributed diagnosis codes through what Defendants referred to as Alternative Submission Mechanism ("ASM").¹⁰⁶

73. The relationship between these databases is summarized in **Exhibit 9**.



ii. Defendants' Submission of Diagnosis Codes for Risk Adjustment

74. Defendants determined which diagnosis codes in their Risk Adjustment Databases could be submitted to CMS based on CMS requirements.¹⁰⁷ For example, was Defendants' policy not to submit diagnosis codes associated with Charts reviewed in the Chart Review

¹⁰⁵ Bird Deposition Volume 1, 167:13–168:9.

¹⁰⁶ *Ingenix Risk Adjustment Data System ("IRADS")*, UnitedHealth Group, December 16, 2014, p. 5. Production of Responses to Questions re: Document Request 4(C) – July 26th Letter, Attachment A, Sections B3, H, I, and J, September 23, 2016 September 23, 2016

¹⁰⁷ Defendants identified a specific set of conditions under which they would not submit diagnosis codes identified in the Chart Review Program. In particular, Defendants indicated that it was their policy not to submit diagnosis codes identified in the Chart Review Program if the Chart was not signed by a provider. Production of Responses and Documents Responsive to CR / CV Interrogatories 1(F), 1(J), 1(K) and Document Requests 4(C)(iii)(t), 4(C)(vii)(i), 5, and 6(D), December 21, 2015; Production of Responses to Questions re: Chart Reviewed File 4(C)(iv) – Chart Error & Omission Codes and Chart Reviewed File 4(C)(v) – Diagnosis Error & Omission Codes, December 1, 2016.

Program where the Coder noted that the Chart had not been signed by the provider.¹⁰⁸ As discussed in **Section III.B**, this is consistent with CMS policy regarding what constitutes a risk adjustment-eligible diagnosis code.

75. Defendants' Risk Adjustment Databases track whether each diagnosis code was submitted to CMS, and if so, CMS' response to the submission (*e.g.*, whether CMS accepted the diagnosis code for use in risk adjustment).
76. Just as Defendants maintained two risk adjustment systems during the at-issue time period, so did CMS, which I collectively refer to as "CMS' Risk Adjustment Databases."¹⁰⁹ For the entire time period at issue, Defendants' submitted diagnosis codes from their IRADS database to CMS' Risk Adjustment Processing System ("RAPS").^{110, 111} For service years 2014–2016, Defendants also submitted diagnosis codes from their EDPS database to the "CMS EDPS" database.¹¹² Two Risk Adjustment Databases were maintained by both Defendants and CMS starting in service year 2014 because this is when CMS began requiring MAOs to submit a broader set of information associated with beneficiaries

¹⁰⁸ Sedor Deposition, 125:3–20 ("Q. Okay. Did you ever delete diagnosis codes because they were missing a signature or a credential? . . . THE WITNESS: Yes. If we submitted something from a medical record that did not have a signature and we were not able to achieve or obtain some kind of attestation from that provider to tell us that was in fact their medical record, then we would have submitted a delete for it. Q. Okay. And do you now if you actually made deletes on that basis? A. Yes, we did.") and 168:13-20 ("Additionally, as we've discussed, charts or medical records need to have a provider signature and credentials. There could have been times where we submitted a code through our chart review process and then realized that they did not have the proper signature and credentials and then had to submit a closed period delete for that original submission.").

¹⁰⁹ These CMS Risk Adjustment Databases were used for Part C and Part D, such that MAOs could submit a diagnosis code just once for use in both risk score calculations.

¹¹⁰ *Ingenix Risk Adjustment Data System ("IRADS")*, UnitedHealth Group, December 16, 2014, p. 8; Cannon Deposition Volume 2 353:21–23 ("I believe IRADS and EDPS are the two systems that submit data for Medicare Advantage beneficiaries to CMS.")

¹¹¹ Each RAPS submission must include the following information, also referred to as a "cluster": the Medicare beneficiary's identification number; the date(s) of the medical encounter (the physician office visit, hospital outpatient visit, or hospital inpatient stay); the type of provider (inpatient, outpatient, or physician); and the diagnosis code(s) reported by the provider for the encounter. *2008 Risk Adjustment Data Technical Assistance For Medicare Advantage Organizations Participant Guide*, Centers for Medicare & Medicaid Services, January 1, 2008, <https://www.hhs.gov/guidance/document/2008-risk-adjustment-data-technical-assistance-medicare-advantage-organizations>, accessed September 5, 2023, at Section 4.6.

¹¹² Each CMS EDPS submission includes, at least, the information included in RAPS submissions as well as other information relating to the encounter.

enrolled in Medicare Advantage and MA-PD Plans.¹¹³ During service years 2014–2016, the new CMS EDPS database was phased in, while the RAPS database was phased out.

77. In service year 2014, all diagnosis codes submitted to both RAPS and CMS EDPS counted for a given beneficiary's total risk score. It did not matter to which system a diagnosis code was submitted or whether it was submitted to only one system or both. CMS credited all diagnosis codes submitted to either system and calculated a single, total risk score.
78. In service years 2015 and 2016, CMS calculated two separate risk scores for each beneficiary using diagnosis codes submitted to RAPS and CMS EDPS. CMS then blended the RAPS risk score and the CMS EDPS risk score to calculate the final risk score used for payment.¹¹⁴ In 2015, the blend was 90% RAPS and 10% CMS EDPS. In 2016, the blend was 75% RAPS and 25% CMS EDPS.¹¹⁵ For example, for service year 2016, if the diagnosis codes submitted to the RAPS system resulted in a risk score of 1.1, and the diagnosis codes submitted to CMS EDPS system resulted in a risk score of 0.9, the final risk score used for payment would be 1.05 (*i.e.*, 1.1 multiplied by 0.75 plus 0.9 multiplied by 0.25).¹¹⁶
79. Both of CMS' Risk Adjustment Databases allow MAOs to delete previously submitted diagnosis codes. While CMS imposes a deadline for MAOs to submit adds, it allows submission of deletes after that deadline.¹¹⁷ In the event that MAOs submit deletes after

¹¹³ "Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," Centers for Medicare & Medicaid Services, February 21, 2014, <https://www.cms.gov/medicare/health-plans/medicareadvgtgspcratestats/downloads/advance2015.pdf>, accessed September 28, 2023, p. 28.

¹¹⁴ *Risk Adjustment for EDS & RAPS User Group*, Centers for Medicare & Medicaid Services, November 17, 2016, [https://www.csscooperations.com/internet/cssc3 nsf/files/RA_Slides_111716_5CR_111816.pdf/\\$File/RA_Slides_111716_5CR_111816.pdf](https://www.csscooperations.com/internet/cssc3 nsf/files/RA_Slides_111716_5CR_111816.pdf/$File/RA_Slides_111716_5CR_111816.pdf), accessed September 28, 2023, p. 56.

¹¹⁵ *Ibid.*, p. 56.

¹¹⁶ $(75\% \text{ RAPS} * 1.1 \text{ RAPS Risk Score}) + (25\% \text{ CMS EDPS} * 0.9 \text{ CMS EDPS Risk Score}) = 1.05 \text{ Weighted Risk Score}$.

¹¹⁷ 42 CFR § 422.310(g)(2)(ii).

the deadline, CMS effectively retroactively adjusts the per member per month payments that it previously paid the plan.^{118, 119}

E. Matching Provider-Reported Encounters to Chart Review Records

80. Defendants' Risk Adjustment Databases contain diagnosis codes from multiple sources, as discussed in **Section IV.D.i**. The same encounter may be associated with multiple sets of diagnosis codes, with variations in the diagnosis codes contained in each set. For example, an encounter in Defendants' Risk Adjustment Databases may be associated with (1) diagnosis codes reported by the provider; and (2) diagnosis codes identified as supported in the Chart Review Program. In order to compare the diagnosis codes reported by the provider and the diagnosis codes identified as supported in the Chart Review Program for a given encounter, I needed to address two issues arising from the structure of Defendants' databases.
81. First, provider-reported encounters in Defendants' Risk Adjustment Databases do not contain encounter identifiers that allow direct linkage to Chart Review Program results in Defendants' Risk Adjustment Databases or to Chart Review Program results in Defendants' Chart Review Databases. Because of this way in which Defendants structured these databases, connecting a provider-reported encounter to the Chart Review Program Coder's results for that same encounter necessitates taking additional analytic steps.
82. Second, Defendants' databases do not consistently track provider information associated with records from the Chart Review Program. In particular, for records from the Chart Review Program in IRADS, the provider identified on the record was typically a "dummy" identifier such as 1099999, which bore no relationship to the actual provider who had the

¹¹⁸ Sedor Deposition, 79:9–14 (“Q. Okay. And when you say their processing closed period deletes, that is because you can’t submit additional codes after the final submission deadline, but I think as you testified earlier you can submit deletes; right? A. Correct. Q. Okay. And functionally, what the rerun does is it’s a rerun of that final reconciliation; is that right? A. Yes. Q. Okay. So functionally, it’s retroactively adjusting the per member per month payments that the plan received for a given beneficiary in a given payment year; right? A. Yes, that’s correct.”).

¹¹⁹ During the CV program, it was Defendants’ practice to submit “closed period” deletes. “Exhibit 712-5 of Bird Deposition,” MARA2076620 (“Because of the nature of the CV process, closed period deletes are to be expected each year. This is because chart review is conducted up until the final sweep and the CV process occurs after the chart review is completed.”).

face-to-face encounter with the beneficiary.¹²⁰ Additionally, testimony and documents explain that the provider identifiers in Defendants' Chart Review Databases also do not always reflect the actual provider who had the face-to-face encounter with the beneficiary.¹²¹ This is a result of Defendants' process for collecting Charts in the Chart Review Program, which sometimes grouped providers together under a single provider identifier.¹²²

83. Because of these issues, comparing the diagnosis codes on a provider-reported encounter to diagnosis codes identified in the Chart Review Program for that same encounter required that I develop methods of carefully matching these encounters, which are described in **Section VI.A.ii** and in **Appendix D, Section III.B.i**.

V. METHOD OVERVIEW

84. As noted above, I have been asked to identify diagnosis codes that Defendants submitted to CMS and for which Defendants did not find support in their Chart Review Program. To be clear, my assignment was not to identify all diagnosis codes that Defendants submitted to CMS for which there may not be support. My assignment was limited to only diagnosis codes associated with Charts that Defendants reviewed in the Chart Review Program. As illustrated by **Exhibit 5** in **Section IV.A** above, which shows the number of Medicare Advantage beneficiaries listed in Defendants' annual public filings, not all of Defendants'

¹²⁰ In Defendants' EDPS data, it is not clear how to distinguish records from the Chart Review Program from records from other sources.

¹²¹ "Exhibit 712-5 of Bird Deposition," MARA2076620 ("... providers are rolled up at the location level (based on address) and, we currently only capture the main (header) provider in ChartSync."); Bird Deposition Volume 1, 259:21–260:25 ("... there was a lack of -- because a lot of these claim systems came together through acquisition, there could be duplicative IDs across systems and the addition of things like, you know, a suffix, prefix to try and make it unique ... So do you see a complete match in terms of what appears in the chart review system with what you see in IRADS? Probably not. But through these processes of crosswalk and enrichment, that's how the match was achieved. Q. Okay. And so it was considered a match even if the data element wasn't identical if you could, through the process of enrichment, remove a suffix or add a leading zero or do something of that nature that satisfied you that it was the same provider on both sides; is that right? ... THE WITNESS: It would be sufficient to move to the next stage of the process.").

¹²² Production of Responses to Questions re: Document Request 4(C) – July 26th Letter, Attachment A, Sections A1, B2, B5, B6, C1, E, F, & K, August 26, 2016 B2, B5, B6, C1, E, F, & K, August 26, 2016, p. 5 ("... information from other providers (outside of the retrieval provider) may have been present and subsequently coded from the chart"); Baker Deposition Volume 1, 65:5–68:22, 110:3–128:21 ("[T]he chart that included the encounters with potentially multiple providers would all be -- would be assigned one retrieval provider ID, correct? A. It would be assigned one retrieval provider ID for that specific member-provider group location, but that member could have seen, you know, five different doctors.").

beneficiaries were included in the Chart Review Program. My analysis pertains only to beneficiaries with Charts reviewed in the Chart Review Program.

85. To identify the list of diagnosis codes that Defendants submitted to CMS for which Defendants did not find support in their Chart Review Program, my analysis proceeds, for each beneficiary in each year, in six steps.¹²³

- i. First, I match provider-reported encounters in Defendants' Risk Adjustment Databases to data from the Chart Review Program in order to identify a list of encounters that Defendants reviewed in their Chart Review Program ("Reviewed Encounters").
- ii. Second, I identify the diagnosis codes that Defendants' Coders determined were supported by the beneficiary's Charts upon their review of those Charts ("Supported Diagnosis Codes").
- iii. Third, I identify the diagnosis codes that were submitted to CMS from these encounters and used to calculate risk scores ("Submitted Diagnosis Codes").
- iv. Fourth, I compare these Submitted Diagnosis Codes to the Supported Diagnosis Codes to identify a list of "Potential Deletes." A diagnosis code is considered a Potential Delete if it is a Submitted Diagnosis Code from a Reviewed Encounter but *not* a Supported Diagnosis Code for a chart review corresponding to the same Reviewed Encounter.
- v. Fifth, I classify diagnosis codes on the list of Potential Deletes according to the presence of other relevant diagnosis codes in Defendants' data that map to the same HCC.
- vi. Sixth, I use this classification and additional criteria to create a final list of "Deletes" that is composed of some, but not all, of the diagnosis codes on the Potential Deletes list.

¹²³ The method summarized herein provides an overview of the analytical steps I have undertaken. Further technical detail is provided in **Appendix D**, which along with the programs I have provided can be used to replicate my results.

86. I then calculate the financial impact of these Deletes on the Part C and Part D payments that Defendants received from CMS. My financial analysis proceeds in three steps.
- i. First, I calculate a revised risk score for each beneficiary, using the diagnosis codes that would have remained had Defendants submitted the Deletes to CMS.
 - ii. Second, I compare the revised risk score to the risk score used to calculate CMS' actual payment to Defendants, in order to calculate a change in risk score. As part of this step, I ensure I can replicate the calculation of the actual risk score for the beneficiaries on the Deletes list and filter out a small number of beneficiaries for whom I am unable to exactly replicate the risk score calculated by CMS.
 - iii. Third, I use the change in risk score to calculate the change in payment, which reflects the amount by which Defendants' risk adjustment payments would have been reduced had they submitted the Deletes to CMS.
87. I then count the number of beneficiaries per year whose risk adjustment payments would have been reduced had Defendants submitted the Deletes to CMS.
88. Finally, I was instructed to separately quantify the financial impact associated with the diagnosis codes on Defendants' CV Pipeline Lists.
89. The remainder of this report explains this analysis in greater detail.

VI. METHOD FOR IDENTIFYING DELETES

A. Identification of Reviewed Encounters

90. To identify Reviewed Encounters, I use data from two sources: Defendants' Risk Adjustment Databases and Defendants' Chart Review Databases.

i. Identification of Encounters in Chart Review Data

91. When Defendants' Coders reviewed a Chart in the Chart Review Program, the diagnosis codes that Coders found to be supported in the Chart were recorded in Defendants' Chart Review Databases. In general, the diagnosis codes found to be supported in the Chart were also passed into Defendants' Risk Adjustment Databases with an indicator that the record originated from the Chart Review Program. To identify the encounters reviewed in the Chart Review Program, I rely on both of these sources. I cannot exclusively rely on

Defendants' Risk Adjustment Databases for two reasons. First, in some cases, the Coder identified no risk adjustment-eligible diagnosis codes on the Chart, and so no information about that review is recorded in Defendants' Risk Adjustment Databases, but the existence of that review is recorded in Defendants' Chart Review Databases. Second, in EDPS, Defendants' Risk Adjustment Database that was used for service years 2014-2016, there is no clear indicator for whether each record originated from the Chart Review Program, and thus I cannot rely on such records to identify encounters reviewed in the Chart Review Program. For these reasons, to identify the full set of encounters that were reviewed in the Chart Review Program, I supplement the data from the Chart Review Program in Defendants' Risk Adjustment Databases with the data in Defendants' Chart Review Databases.

92. As discussed in **Section IV.A**, in Defendants' Chart Review Program, 65% of Charts for 2014-2016 service years were reviewed by a second blind Coder in Second Level Review. Defendants' Chart Review Databases for service years 2014-2016 contain an indicator to identify these Charts. When creating the list of Reviewed Encounters, I include an indicator for whether each encounter was identified in Defendants' Chart Review Databases as originating from a Chart that went through Second Level Review.¹²⁴
93. See **Appendix D, Section III.A.ii** for details on my use of Defendants' Chart Review Databases to identify encounters reviewed in the Chart Review Program, and identification of encounters subject to Second Level Review.

ii. Matching Encounters from Chart Review Data to Provider-Reported Encounters

94. Having generated a list of encounters that were reviewed in the Chart Review Program, I then match these encounters to their corresponding provider-reported encounters in Defendants' Risk Adjustment Databases. I must match these encounters in order to later compare the diagnosis codes found to be supported in the Chart Review Program to the diagnosis codes reported by the provider for the same encounter. I apply the same method

¹²⁴ Of the \$997,051,302 total financial impact for Part C and Part D in service years 2014-2016 shown in **Exhibit 10**, \$799,407,848 is associated with diagnosis codes submitted by Defendants to CMS associated with Charts that were reviewed in Defendants' Second Level Review program.

to match records from the Chart Review Program to each of Defendants' Risk Adjustment Databases, IRADS and EDPS.

95. As discussed in **Section IV.E**, Defendants' Risk Adjustment Databases do not assign a unique encounter identifier to each encounter and do not consistently track provider information associated with each record. For these reasons, I employ two methodologies for matching encounters reviewed in the Chart Review Program to their associated encounters reported by providers.
96. The first method matches the beneficiary identifier, date of service, and provider identifier associated with the provider-reported encounter in Defendants' Risk Adjustment Databases with the beneficiary identifier, date of service, and provider identifier associated with the Chart in Defendants' Chart Review Databases.¹²⁵ If these data elements match, I conclude that the provider-reported encounter in Defendants' Risk Adjustment Databases must be a Reviewed Encounter. See **Appendix D, Section III.C.i** for a detailed description and example of this method for identifying Reviewed Encounters.
97. The second method of matching applies when all provider-reported diagnosis codes for a given beneficiary on a particular service date were reported by a single provider. I am able to ascertain whether a single provider reported all diagnosis codes on a given service date by counting the unique provider identifiers across all entries where Defendants' Risk Adjustment Databases indicate the encounter originated from a provider submission (and not another one of Defendants' Risk Adjustment programs, *i.e.*, Chart Review or CV). If Defendants' Risk Adjustment Databases indicate a single provider for all provider-reported diagnosis codes on a given service date, and Defendants' data also shows that a Chart with that service date was reviewed in the Chart Review Program, I conclude that the provider-reported encounter in Defendants' Risk Adjustment Databases must be a Reviewed

¹²⁵ I rely on the records from the Chart Review Program in Defendants' Chart Review Databases for this matching method, as opposed to the chart review data in Defendants' Risk Adjustment Database, as provider identifier information was not always passed from Defendants' Chart Review Databases to Defendants' Risk Adjustment Databases.

Encounter.¹²⁶ See **Appendix D, Section III.C.ii** for a detailed description and example of this method for identifying Reviewed Encounters.

98. With these matching methods, I am able determine which provider-reported encounters in Defendants' Risk Adjustment Databases are Reviewed Encounters.¹²⁷
99. In some cases, I am able to match a provider-reported encounter to a corresponding record from the Chart Review Program using one or both of these methods, but I nevertheless do not include that encounter in the final list of Reviewed Encounters. For example, if it is not clear that the provider-reported encounter is risk adjustment-eligible (*e.g.*, it is not a face-to-face encounter with an acceptable provider specialty), I exclude it even if it clearly matches to an encounter reviewed in the Chart Review Program. See **Appendix D, Section III.B.i** for details on how I identify provider-reported, risk adjustment-eligible encounters.
100. I also exclude from the final list of Reviewed Encounters all encounters for which the data from the Chart Review Program is potentially incomplete because the Coder was "informed." As discussed in **Section IV.A**, informed Coders were made aware of which diagnosis codes were already submitted to CMS for that beneficiary, and so, to avoid duplication, may not have recorded those diagnosis codes, resulting in an incomplete record of their findings. Therefore, I exclude the encounters on these Charts from the list of Reviewed Encounters.¹²⁸ See **Appendix D, Section III.A.iii** for details on my identification encounters subject to informed coding.
101. Some encounters from the Chart Review Program were not matched to a provider-reported encounter in Defendants' Risk Adjustment Databases using these methods. Of the 76

¹²⁶ The provider identifiers in the Reviewed Encounters identified under this second method do not always match the provider identifiers in their corresponding record from the Chart Review Program. This is an expected result, as Defendants have explained that that is because the chart review data does not always reflect the actual provider in the face-to-face encounter with the beneficiary. See **Section IV.E**.

¹²⁷ Of the \$2,135,252,375 total financial impact for Part C and Part D shown in **Exhibit 10**, \$1,382,953,493 is associated with only method one.

¹²⁸ Defendants produced data to identify the specific Charts that underwent informed coding, and I have excluded from the list of Reviewed Encounters every encounter associated with a Chart that Defendants' data identified as informed coded. Defendants have indicated that a small number of additional Charts were subject to informed coding during a pilot project that was operational for only one month in 2013. Should Defendants produce data identifying these, I may update my analyses to exclude them. Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016.

million beneficiary service dates in Defendants' Chart Review Databases for the at-issue service years, I was not able to identify a corresponding provider-reported encounter with the same service date in either of Defendants' Risk Adjustment Databases for approximately 16%. While these records from the Chart Review Program may correspond to a provider-reported encounter in Defendants' Risk Adjustment Database, they were not matched under either of my two methods. It is therefore possible that the final list of Reviewed Encounters undercounts the actual number of provider-reported encounters that Defendants reviewed in the Chart Review Program.

B. Identification of Supported Diagnosis Codes

102. After identifying Reviewed Encounters, I compare the diagnosis codes reported by the provider to the diagnosis codes found to be supported in the Chart Review Program. If a diagnosis code was reported by the provider and was found to be supported in the Chart Review Program (either in the initial review or the Second Level Review), I consider the diagnosis code to be a Supported Diagnosis Code. See **Appendix D, Section IV** for a detailed description of how I identify Supported Diagnosis Codes.

C. Identification of Submitted Diagnosis Codes

103. Next, I analyze Defendants' Risk Adjustment Databases to identify the diagnosis codes from Reviewed Encounters that Defendants submitted to CMS. Each of Defendants' Risk Adjustment Databases, IRADS and EDPS, contains fields that indicate whether each instance of a diagnosis code was submitted to, and accepted by, CMS. See **Appendix D, Section V** for details on how I identify these diagnosis codes.

D. Identification of Potential Deletes

104. To identify Potential Deletes, I identify all diagnosis codes that are Submitted Diagnosis Codes but not Supported Diagnosis Codes (*i.e.*, all diagnosis codes from Reviewed Encounters that were submitted to CMS but were not found to be supported in the Chart Review Program).
105. For example, if diagnosis code 436, *Acute, but ill-defined, cerebrovascular disease*, was reported by a provider and submitted to CMS, it would be on the Submitted Diagnosis Codes list. If the provider encounter that was the source of this code was matched to a

Chart Review encounter, but the Chart Reviewer did not find support for diagnosis code 436, then diagnosis code 436 would not be on the Supported Diagnosis Codes list. Comparison of the Submitted Diagnosis Codes to the Supported Diagnosis Codes would therefore identify diagnosis code 436 as a Potential Delete. It remains to be determined, however, whether 436 should be on the final Deletes list.

E. Classification of Potential Deletes

106. Next, I use three criteria related to HCC-mapping to classify the diagnosis codes on my list of Potential Deletes.¹²⁹ These criteria, which are not mutually exclusive, assess whether diagnosis codes on my list of Potential Deletes map to the same HCC as other diagnosis codes (or, in the instance of Claims Verification, other recorded HCCs) in Defendants' databases. Only Potential Deletes that do not meet any of these criteria are included in the final Deletes list.

i. Potential Deletes Sharing HCCs with Other Submitted Diagnosis Codes

107. For the first criterion, I assess whether the diagnosis code, if deleted, would have an effect on the beneficiary's risk score and in turn, a financial impact on the risk adjustment payments Defendants received from CMS. A diagnosis code would not affect the beneficiary's risk score when deleted if it maps to the same HCC as another diagnosis code that is *not* on the Potential Deletes list and that was submitted to CMS for the beneficiary in the relevant year.¹³⁰ In this case, deleting the diagnosis code would not result in a deletion of the HCC for the beneficiary, and thus it would not impact financial payments from CMS, as it is the HCC that is relevant to the beneficiary's risk score, as explained in **Section III.B** above. For example, suppose diagnosis code 436, which maps to HCC 96, appears on the Potential Deletes list for a beneficiary. If diagnosis code 43491, which also maps to HCC 96, was also submitted for the beneficiary that year and does *not* appear on the Potential Deletes list, the deletion of diagnosis code 436 would have no effect on the beneficiary's risk score. I consider diagnosis codes on the Potential Deletes list that share an HCC with another submitted diagnosis code *not* on the Potential Deletes list to meet this first criterion.

¹²⁹ While I refer to HCCs in this section, the same concepts and methods apply to RxHCCs for my Part D analysis.

¹³⁰ For ease of exposition, I use the phrase "submitted to CMS" in this section to refer to diagnosis codes that were both submitted to CMS by Defendants' and accepted by CMS.

108. To assess whether diagnosis codes on the Potential Deletes list meet this criterion, I examine the full set of diagnosis codes submitted to CMS for the beneficiary in the year. I identify these diagnosis codes in IRADS and EDPS following the method described in **Section VI.D** above, but do not limit to those associated with Reviewed Encounters or even provider-reported encounters. Diagnosis codes relevant to this assessment, like diagnosis code 43491 above, include diagnosis codes submitted from provider-reported, risk adjustment-eligible encounters, that I do not identify as Reviewed Encounters.¹³¹ I also examine submitted diagnosis codes associated with other encounter types, including Chart Review encounters, in Defendants' Risk Adjustment Databases.

ii. Potential Deletes Sharing HCCs with Other Unsubmitted Diagnosis Codes

109. The second criterion is similar to the first criterion in that I again assess whether the diagnosis code on the Potential Deletes list map to the same HCC as another diagnosis code in Defendants' databases. However, in contrast to the first criterion, the other diagnosis codes I examine for this second criterion are risk adjustment-eligible but were *not* submitted to CMS for the beneficiary in the relevant year. Since Potential Deletes only include codes submitted to CMS, these unsubmitted diagnosis codes would, by definition, not be on the Potential Deletes list. Continuing with the above example, I would consider diagnosis code 436 to meet this criterion – but not the first criterion – if diagnosis code 43491 was also observed in Defendants' databases as a risk adjustment-eligible diagnosis code, but had not been submitted to CMS.¹³² In this case, the deletion of diagnosis code 436 could affect the beneficiary's risk score, depending on whether any other diagnosis codes, also mapping to HCC 96, were submitted to CMS that year. I consider diagnosis codes on the Potential Deletes list that share an HCC with another unsubmitted diagnosis code that is *not* on the Potential Deletes list to meet this second criterion.

¹³¹ In addition to encounters that were not reviewed by Defendants, this set of encounters may include certain encounters that *were* reviewed as part of Defendants' Chart Review Program, but which I do not identify as Reviewed Encounters using either of my two methodologies.

¹³² An instance of a diagnosis code may not have been submitted to CMS if it was a duplicate of a diagnosis code that Defendants already submitted for a beneficiary in the service year. Instances of diagnosis codes outside of Defendants' Risk Adjustment Databases are by definition unsubmitted.

110. To assess whether diagnosis codes on the Potential Deletes list meet this criterion, I examine four types of unsubmitted diagnosis codes within and outside of Defendants' Risk Adjustment Databases:
- i. Diagnosis codes associated with chart review encounters in Defendants' Risk Adjustment Databases;
 - ii. Diagnosis codes associated with provider-reported, risk adjustment-eligible encounters in Defendants' Risk Adjustment Databases;
 - iii. Diagnosis codes from Defendants' Chart Review Databases that do not appear in Defendants' Risk Adjustment Databases; and
 - iv. Diagnosis codes from Defendants' Provider-reported Claims databases that do not appear in Defendants' Risk Adjustment Databases.¹³³
111. First, I examine unsubmitted diagnosis codes associated with chart review encounters in Defendants' Risk Adjustment Databases. Diagnosis codes associated with these encounters may be unsubmitted as a result of Defendants' policy to not submit duplicate diagnosis codes for a beneficiary.¹³⁴
112. Second, I examine unsubmitted diagnosis codes associated with provider-reported, risk adjustment-eligible encounters in Defendants' Risk Adjustment Databases, including but not limited to those I identify as Reviewed Encounters. Diagnosis codes associated with provider-reported, risk adjustment-eligible encounters may be unsubmitted for the same reason that chart review encounters in Defendants' Risk Adjustment Databases were not submitted.
113. Third, I examine diagnosis codes from Defendants' Chart Review Databases that do not appear in Defendants' Risk Adjustment Databases. The absence of these codes in Defendants' Risk Adjustment Databases necessarily makes them unsubmitted. I rely on Defendants' Chart Review Databases to identify these diagnosis codes. In general, Defendants passed all diagnosis codes that were identified in the Chart Review Program

¹³³ Out of caution, I do not apply a risk adjustment-eligible requirement to these diagnosis codes.

¹³⁴ Bird Deposition Volume 1, 194:25–196:10.

into their Risk Adjustment Databases. However, Defendants held some diagnosis codes back and did not transmit them from their Chart Review Databases to their Risk Adjustment Databases. Regardless, I consider *all* diagnosis codes found by *any* of the Coders in my assessment, regardless of whether they were transmitted from Defendants' Chart Review Databases to its Risk Adjustment Databases.¹³⁵ The only diagnosis codes in this category which I do not consider are diagnosis codes which are not risk adjustment-eligible. As discussed in **Section IV.D**, Defendants had internal policies that governed which diagnosis code from Chart Review were submitted for risk adjustment through their Risk Adjustment Databases. In particular, Defendants had a policy not to submit diagnosis codes associated with unsigned Charts, as these diagnosis codes were not considered risk adjustment-eligible.^{136, 137} Consistent with Defendants' policy, I do not examine these codes in my assessment of this criterion.¹³⁸

114. Fourth, I examine diagnosis codes from Defendants' Provider-reported Claims databases that do not appear in Defendants' Risk Adjustment Databases. Like the third category, the absence of these diagnosis codes in Defendants' Risk Adjustment Databases necessarily means that these diagnosis codes were unsubmitted. I examine these diagnosis codes because deposition testimony in this matter has indicated that, for a period of time, some diagnosis codes reported by providers may not have been added to IRADS due to a technical issue.¹³⁹

¹³⁵ I include diagnosis codes associated with informed coded Charts as well.

¹³⁶ Bird Deposition Volume 1, 217:9–221:19 (“Q. And if a chart was assigned one of those EO codes, the HCCs associated with that chart review were not included in the comparison list; right? A. At this point, correct.”).

¹³⁷ Defendants identified a specific set of “error and omission” codes which, when associated with a Chart or diagnosis code in chart review, would prevent transmission of those results to Defendants' Risk Adjustment Databases. Production of Responses to Questions re: Chart Reviewed File 4(C)(iv) – Chart Error & Omission Codes and Chart Reviewed File 4(C)(v) – Diagnosis Error & Omission Codes, December 1, 2016, p. 2.

¹³⁸ If these diagnosis codes were examined in this step, the total financial impact for Part C and Part D would be reduced to \$2,070,024,611.

¹³⁹ Deposition of Marybeth Meyer, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. 16-08697 FMO, June 7, 2022 (“Meyer Deposition”), 232:19–234:5 (“Well, the focus on the data issues really came with the implementation of the Encounter Data System. That was also one of the ways where we identified that the data being submitted to Optum and then being submitted to CMS via the new encounter data submitted system was -- had gaps in it.”).

115. See **Appendix D, Section VII.A** for more details regarding these categories of unsubmitted diagnosis codes.

iii. Potential Deletes Mapping to HCCs Recorded in Claims Verification

The third criterion relates to Defendants' Claims Verification program and therefore applies only to diagnosis codes on the Potential Deletes list with dates of service in 2011 and 2012. In particular, I assess whether any of these diagnosis codes map to an HCC that was found to be supported as part of the Claims Verification program. As discussed above in **Section IV.B**, the Claims Verification program identified support for diagnosis codes at the HCC level. To identify these HCCs, I use data in Defendants' Risk Adjustment Databases, as well as other data produced by Defendants that houses CV results. I consider diagnosis codes on the Potential Deletes list which share an HCC with one of these CV-recorded HCCs to meet this third criterion.

F. Identification of Deletes

116. I identify as Deletes those diagnosis codes from the Potential Deletes list which did not meet *any* of the three criteria above. In other words, I identify Deletes as those diagnosis codes on the Potential Deletes list that do not share an HCC with any other submitted diagnosis code, do not share an HCC with any other risk adjustment-eligible but unsubmitted diagnosis code, *and* do not map to an HCC recorded in the Claims Verification program.¹⁴⁰ I also require that Deletes satisfy several additional checks, discussed below.
117. The first check pertains to service years 2014-2016, when both of Defendants' Risk Adjustment Databases – IRADS and EDPS – were in use. In these years, I identify Potential Deletes separately for each database, based on information in that database, as well as data

¹⁴⁰ Testimony indicates that this method also follows Defendants' practice during the operation of the CV program. Specifically, it is my understanding that Defendants would delete an HCC if a diagnosis code in that HCC was not supported by the medical record, and there were no other diagnosis codes in that HCC that were supported by the medical record. See Deposition of Rebecca Martin, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. 16-08697 FMO, August 5, 2022 ("Martin Deposition"), 79:12–80:11 ("Q. And if it is the only diagnosis code that maps to the risk adjustment -- risk adjusting HCC, there's no other ones that can be submitted or take its place, is it your understanding that a diagnosis that's not supported by medical record documentation needs to be deleted? ... THE WITNESS: In the context of what you just described where it is the only diagnosis code that supports the HCC, there's no other X19 or other risk adjusting transaction that would otherwise support the HCC and we learn that the HCC is no longer supported or that there's something about the medical record that cannot support the condition, then yes, there would be an expectation that upon learning of that information, we would delete the code.").

external to both of Defendants' Risk Adjustment Databases. I use the same method to identify Potential Deletes for each database, which was specifically designed to limit false positives. However, the structural differences between the two databases introduce the possibility that a given diagnosis code, which is submitted to and accepted by CMS in both systems, meets one or more of the criteria from **Section VI.E** in one system but none of the criteria from **Section VI.E** in the other system. Out of an abundance of caution, I do not consider such diagnosis code to be a Delete in either system.

118. I also do not consider as Deletes any of the following:¹⁴¹

- i. Diagnosis codes that did not impact risk adjustment payments for the beneficiary, including diagnosis codes for newly enrolled beneficiaries;¹⁴²
- ii. Diagnosis codes associated with beneficiaries who were not enrolled in a Medicare Advantage plan (or in the case of Part D, a MA-PD plan) for the whole year;
- iii. Diagnosis codes associated with beneficiaries who were not enrolled in Defendants' plans during the year; and
- iv. Diagnosis codes associated with beneficiaries with end stage renal disease, whose risk adjustment payments are not determined by the CMS HCC Model or the CMS RxHCC Model.

119. My final list of Deletes can be found in **Attachment 1**.^{143, 144}

¹⁴¹ See **Appendix D, Section VIII** for a description of how I identify the referenced groups of beneficiaries.

¹⁴² Sedor Deposition, 90:13–17 (“Not all risk scores are calculated using HCCs if the person is newly aged into Medicare and is only 65. I believe for the first year of their enrollment they are not getting a risk score based on any HCCs.”).

¹⁴³ There is a separate list for each year at issue in this matter. There are also separate lists for each of Defendants' Risk Adjustment Databases. Each list contains columns indicating whether the diagnosis code is a Delete under each CMS model.

¹⁴⁴ As explained in **Section VII** below, the final Deletes list is limited to beneficiaries for whom I can perfectly replicate actual risk scores. The final Deletes list for Part D additionally excludes diagnosis codes which only impact Part D risk scores and which are associated with beneficiaries enrolled in MA-PD plans for which changes in risk corridor payments fully offset changes in direct subsidy payments.

VII. CALCULATING FINANCIAL IMPACT OF DEFENDANTS' FAILURE TO SUBMIT DELETES

120. I rely on data and publicly available computer programs from CMS to calculate the amount of risk adjustment payments that Defendants retained for the Deletes.¹⁴⁵ I proceed as follows.
121. First, I calculate a revised risk score for each beneficiary, based on a list of diagnosis codes that does *not* include diagnosis codes on the Deletes list.
122. Second, I compare the revised risk score to the actual risk score that was used by CMS in order to calculate the actual per member per month payment for that beneficiary (*i.e.*, the risk score that was calculated based on diagnosis codes that Defendants submitted to CMS, which includes the diagnosis codes on the Deletes list). I calculate the change in risk score as the actual risk score used by CMS to calculate the payment, minus the revised risk score. As part of this step, I ensure I can replicate actual risk scores calculated by CMS for beneficiaries on the Deletes list and filter out a small number of beneficiaries for whom I am unable to do so.
123. Third, I use the change in risk score to calculate a change in the per member per month payment for each beneficiary. I then aggregate across all beneficiaries to calculate the amount of risk adjustment payments that Defendants retained for the Deletes across all years.
124. I perform these steps for Part C and for Part D separately, and then aggregate the results to calculate the amount of risk adjustment payments that Defendants retained for the Deletes for Part C and Part D combined.

A. Revised Risk Scores

125. To calculate a revised risk score for each beneficiary, I begin with a list of unique diagnosis codes that Defendants submitted to CMS based on the data in their Risk Adjustment Databases, and I remove the diagnosis codes that appear on the Deletes list. Then, using CMS' Risk Adjustment Database I identify and add to this list all diagnosis codes that other

¹⁴⁵ "Medicare risk adjustment information," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment>, downloaded on June 16, 2023.

MAOs submitted to CMS for the beneficiary in the relevant service year (these may exist if the beneficiary switched plans mid-year).¹⁴⁶ I input this list of diagnosis codes into the publicly available CMS HCC Model and CMS RxHCC Model computer programs discussed in **Section III.B**, which calculate the beneficiary's risk score.¹⁴⁷

126. As discussed in **Section III.B**, these computer programs require information on the beneficiary's demographics.¹⁴⁸ I rely on a CMS-produced database called MARx ("Medicare Advantage Prescription Drug System"), as well as other data produced by CMS to obtain information on the beneficiary's demographics and input that into CMS' computer program along with the list of diagnosis codes.
127. See **Appendix D, Section IX.A** for detailed information about how I identify diagnosis codes that Defendants submitted to CMS, how I identify diagnosis codes that other MAOs submitted to CMS, how I identify beneficiary demographic information in MARx, and how I use the CMS HCC Model and CMS RxHCC Model computer programs to calculate a risk score for each beneficiary and how I replicate the additional adjustments CMS applies to calculate a final risk score.
128. I calculate a Part C revised risk score and as relevant, a Part D revised risk score for each beneficiary in each year.

B. Changes in Risk Scores

129. Having calculated a revised risk score for each beneficiary based on the list of diagnosis codes that does not include the diagnosis codes on the Deletes list, I subtract each revised risk score from the actual risk score that was used by CMS in order to calculate the actual

¹⁴⁶ Some beneficiaries may also have switched mid-year from or to a Traditional Medicare plan. I do not have data on those diagnosis codes and therefore drop these beneficiaries from my analyses and do not calculate any financial impact associated with them.

¹⁴⁷ As discussed in **Section IV.D**, for service year 2014, submitted diagnosis codes were pooled from CMS' two Risk Adjustment Databases to calculate a single risk score. Therefore, for service year 2014, I pool diagnosis codes from both databases to input into CMS' models. For service years 2015 and 2016, when two separate risk scores were calculated and then weighted, I perform this step twice, once using diagnosis codes submitted by Defendants from IRADS and diagnosis codes submitted by other MAOs from RAPS, and once using diagnosis codes submitted by Defendants from EDPS and diagnosis codes submitted by other MAOs from CMS EDPS.

¹⁴⁸ "Medicare risk adjustment information," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment>, downloaded on June 16, 2023.

per member per month payment for that beneficiary (*i.e.*, the risk score that was calculated based on diagnosis codes that Defendants submitted to CMS, which includes the diagnosis codes on the Deletes list). The actual risk score that was used by CMS to calculate each beneficiary's actual payment can be derived from CMS' MARx database.¹⁴⁹ See **Appendix D, Section IX.B** for detailed information on how I derived the actual risk score that was used by CMS for payment.

130. By subtracting the revised risk score from the actual risk score that was used by CMS for payment, I obtain a change in risk score for each beneficiary. This represents the change in risk score that would have occurred had Defendants submitted the diagnosis codes identified on the Deletes list as deletes to CMS. I calculate a Part C change in risk score and a Part D change in risk score for each beneficiary in each year.
131. As a confirmatory step, for each beneficiary, I also rerun CMS' computer programs using the full set of diagnosis codes that Defendants and other MAOs submitted to CMS, and the demographic information from MARx, to ensure that I can replicate exactly the MARx-derived risk score that was actually used by CMS to calculate payments. This ensures that the change in risk score that I calculate for each beneficiary is entirely attributable to the change in the list of diagnosis codes input into CMS' computer programs (*i.e.*, entirely due to Defendants' failure to submit the Deletes), and not some other inaccuracies in demographic data in MARx or missing diagnosis codes from other MAOs. I am able to exactly replicate approximately 98% of the actual risk scores used by CMS for payment.¹⁵⁰ I conservatively remove from my analysis any beneficiary whose risk score I was not able to perfectly replicate, such that these beneficiaries are not included in the final list of Deletes or my quantification of financial impact of the Deletes. See **Appendix D, Section IX** for detailed information on how I replicated risk scores.

¹⁴⁹ Sedor Deposition, 97:4–12 (“The MARX system is a CMS system that they utilize to generate the payments on a monthly basis.”).

¹⁵⁰ This reflects the number of beneficiary months in which I am able to replicate Part C risk scores across all years, using the diagnosis codes in IRADS/RAPS or diagnosis codes in EDPS/CMS EDPS. I exclude from this calculation beneficiaries who were not enrolled in one of Defendants' plans for the entirety of the year, as well as beneficiaries who were enrolled in Traditional Medicare at any point during the year. It also excludes beneficiaries who are not on either the CMS HCC Model or the CMS RxHCC model, such as beneficiaries with end stage renal disease or on hospice or newly enrolled in Medicare.

C. Changes in Payment for Part C

132. Having calculated a change in each beneficiary's Part C risk score that is attributable to Deletes, I multiply it by the plan's base rate to calculate a change in payment. The base rate for plans is generally available in the MARx database, but in some cases, it is not. In cases where the plan base rate is not available in the MARx database, I derive it using other variables that are available. See **Appendix D, Section IX.C** for details on how I derive the base rate when it is not available.
133. Across all beneficiaries and years, I calculate an aggregated Part C change in payments of \$2,109,423,348. This represents the total amount by which Defendants' Part C risk adjustment payments from CMS would have been reduced had Defendants submitted the diagnosis codes identified on the Deletes list as deletes to CMS.

D. Changes in Payment for Part D

134. Similar to Part C, having calculated a change in each beneficiary's Part D risk score that is attributable to Deletes, I multiply it by the plan's base rate to calculate a change in payment. As discussed above in **Section III.B**, under Part D, the base rate includes two elements, both of which are determined by the beneficiary's risk score: the direct subsidy, paid by CMS, and the beneficiary premium, paid by the beneficiary. I separately calculate the change in CMS' payment and the change in beneficiary payments based on the change in risk score. Across all of Defendants plans in all years of my analysis, I calculate the change in beneficiary payments to be \$28,927,661. In other words, had Defendants submitted the diagnosis codes on the Deletes list, beneficiaries on Defendants' plans would have, in aggregate, paid \$28,927,661 less in premiums. Because this cost was not covered by CMS, it is not subject to the risk corridors payments discussed in **Section III.B.ii**. It is also not included in my final calculations of the financial impact of Defendants' failure to submit Deletes, as my assignment was to assess the financial impact to CMS, not beneficiaries on Defendants plans.
135. For the CMS portion of Part D payments, as a final step, I calculate the change in payment that results from the application of risk corridors. I calculate this change at the plan level, rather than the beneficiary level consistent with how CMS calculates risk corridors. As described in **Section III.B.ii**, the size of the gap between a plan's target spending and actual

spending affects the profit sharing between MAOs and CMS. As a plan's target spending amount depends on risk adjustment payments, a change to risk adjustment payments may impact this profit sharing. I therefore calculate a change in risk corridor payments for each of Defendants' Part D plans based on their calculated change in risk adjustment payments, including both the change in direct subsidies and the change in beneficiary premiums. I then calculate each plan's change in Part D payments from CMS as the change in their direct subsidy payments less the change in their risk corridor payments. For some plans, the change in risk corridor payments offsets the entire change in direct subsidy payments, and I remove beneficiaries associated with those plans from the Deletes list as explained below in **Section VII.E**. See **Appendix D, Section IX.D** for a detailed description of how I calculate changes in Part D payments, including these risk corridor payments.

136. Across all beneficiaries and years, after accounting for risk corridors, I calculate an aggregated Part D change in CMS payments of \$25,829,027.¹⁵¹ This represents the total amount by which Defendants' Part D risk adjustment payments from CMS would have been reduced had Defendants submitted the diagnosis codes identified on the Deletes list as deletes to CMS.

E. Total Financial Impact of Defendants' Failure to Submit Deletes

137. I calculate the amount that was retained by Defendants by not deleting the diagnosis codes identified as Deletes in my analysis by summing the Part C and Part D payment amounts calculated above. **Exhibit 10** shows these amounts by year. See **Attachment 2** for a list of these amounts by year and contract. See **Attachment 3** for a list of these amounts by beneficiary, year, and contract.¹⁵²

¹⁵¹ Prior to the application of risk corridors, this amounts to \$67,445,692.

¹⁵² There is a separate list for each year at issue in this matter. Because risk corridors are applied at the plan level rather than the beneficiary level, the Part D amounts in these lists do not account for risk corridor payments.

Exhibit 10
Total Financial Impact of Defendants' Failure to Submit Deletes

Service Year	Part C	Part D	Total
2008	\$82,582,771	\$1,997,923	\$84,580,694
2009	\$147,171,500	\$3,001,475	\$150,172,975
2010	\$331,821,261	\$6,781,677	\$338,602,938
2011	\$100,694,304	\$1,595,961	\$102,290,264
2012	\$214,581,077	\$2,512,619	\$217,093,696
2013	\$242,617,635	\$2,842,871	\$245,460,506
2014	\$272,202,891	\$1,214,241	\$273,417,133
2015	\$322,034,749	\$2,507,514	\$324,542,263
2016	\$395,717,161	\$3,374,745	\$399,091,906
TOTAL	\$2,109,423,348	\$25,829,027	\$2,135,252,375

VIII. CALCULATING THE NUMBER OF BENEFICIARIES YEAR-BY-YEAR FOR WHOM DEFENDANTS WOULD HAVE RECEIVED REDUCED RISK ADJUSTMENT PAYMENTS FROM CMS

138. As stated above, I was also asked to calculate the number of beneficiaries in each payment year for whom Defendants would have received reduced risk adjustment payments from CMS had they submitted the Deletes.
139. Because I have already calculated the total amount that was retained by Defendants by not deleting the diagnosis codes identified as Deletes across all beneficiaries, determining the total number of impacted beneficiaries is straightforward. For each year, I sum the total number of unique beneficiaries who have at least one Delete, as reflected in **Attachment 1**.
140. Individual beneficiaries are counted once per year if they have a change in their risk score for Part C and/or Part D. Thus, a beneficiary enrolled in an MA-PD plan who has a change in both their Part C risk score and Part D risk score would be counted once not twice. I make one exception to this counting rule, which pertains to beneficiaries enrolled in MA-PD plans for which changes in risk corridor payments fully offset changes in direct subsidy payments for Part D. These beneficiaries are only counted if they have a change in their Part C risk score, as the changes in their Part D risk scores do not impact Part D payments due to the risk corridors.

141. For payment years 2009-2017, the total number of beneficiaries counted year-by-year where the beneficiary's risk score would have changed *and* for whom Defendants would have received reduced risk adjustment payments, either under Part C or Part D or both, had Defendants submitted the Deletes is 1,132,418. **Exhibit 11** shows the number of beneficiaries by year.

Exhibit 11
Total Beneficiaries Resulting in a Payment Change Due to
Defendants' Failure to Submit Deletes

Service Year	Part C	Part D	Total
2008	24,579	58,012	66,013
2009	44,549	102,395	116,115
2010	98,171	154,091	187,372
2011	32,418	59,046	70,832
2012	70,663	78,282	107,894
2013	90,731	95,960	134,036
2014	104,298	96,640	144,945
2015	107,152	64,628	135,361
2016	134,592	82,555	169,850
TOTAL	707,153	791,609	1,132,418

Note: total counts do not equal the sum of counts for Part C and Part D for the reasons described in Paragraph 140.

IX. CALCULATING FINANCIAL IMPACT OF DELETING DIAGNOSIS CODES ON DEFENDANTS' CV PIPELINE LISTS

142. As stated above, I was also asked to separately calculate the financial impact on Defendants' Medicare Advantage and Medicare Part D risk adjustment payments resulting from their failure to delete the diagnosis codes on Defendants' CV Pipeline Lists.¹⁵³
143. One of these lists includes "2011 [service date] encounters in RAPS for which the multi-stage CV process was begun but not completed" at the time Defendants terminated their CV program.¹⁵⁴ The other list "includes a complete list of all identified 2012 [service date]

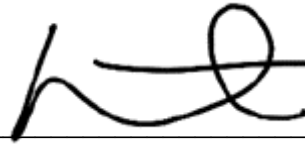
¹⁵³ MARA2164481; MARA2160501.

¹⁵⁴ Production of Replacement File for MARA2117116, September 30, 2016, p. 1.

In Process CV Encounters or CV Cancelled Deletes with Part C financial impact.”¹⁵⁵ The second list includes approximately 800 encounters that “were not reviewed by any coder as part of the CV process.”¹⁵⁶

144. Had Defendants deleted the diagnosis codes on these lists, the risk adjustment payments Defendants received from CMS would have been reduced by \$36,032,222 in 2011 and \$152,370,126 in 2012 for Part C and Part D, or \$188,402,348 in aggregate across the two years.¹⁵⁷

Signed on September 29, 2023.

A handwritten signature in black ink, appearing to read 'CG', is written above a horizontal line.

Craig Garthwaite

¹⁵⁵ Response to Follow Up Questions on March 18, 2016 Letter re: 2012 DOS Encounters Identified for CV Review, May 27, 2016, p. 1.

¹⁵⁶ *Ibid.*, p. 2.

¹⁵⁷ The value associated with the 800 diagnosis codes on the 2012 service date list that Defendants identified as not reviewed by any coded as part of the CV process are associated with \$955,195 of this total.

APPENDIX A
CRAIG GARTHWAITE

Strategy Department
Kellogg School of Management, Northwestern University
2211 Campus Drive, Evanston, IL 60208
Email: c-garthwaite@kellogg.northwestern.edu

APPOINTMENTS

Kellogg School of Management, Northwestern University
Professor of Strategy, 2020 - Present
Herman R. Smith Research Professor in Hospital and Health Services, 2017-Present
Director, Program on Healthcare at Kellogg, 2016 - Present
Associate Professor of Strategy (with tenure), 2016 – 2020
Assistant Professor of Strategy, 2010 - 2016
Senior Lecturer and Donald P. Jacobs Scholar in Management and Strategy, 2009 - 2010

National Bureau of Economic Research
Research Associate, 2016-Present
Faculty Research Fellow, 2011-2016

Institute for Policy Research, Northwestern University
Faculty Associate, 2015 - Present

EDUCATION

Ph.D. Economics, University of Maryland at College Park, 2009
M.A. Economics, University of Maryland at College Park, 2008
M.P.P Gerald R. Ford School of Public Policy at the University of Michigan, 2001
B.A. Political Science, cum laude, University of Michigan, 2000

PUBLIC SERVICE

Member, Aspen Economic Strategy Group (2021 – Present)

Member, Congressional Budget Office Panel of Healthcare Advisers (2020 – Present)

Member, Congressional Budget Office Technical Review Panel for the Health Insurance Simulation Model (2018-2020)

Member, Health Affairs Council on Spending and Value (2018-2023)

Testimony, United States House of Representatives, 2018

- House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law: “Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS Health and Aetna”

Testimony, United States House of Representatives, 2019

- House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law: “Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets”

Testimony, United States Senate, 2019

- Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy, and Consumer Rights: “Your Doctor/Pharmacist/Insurer Will See You Now: Competitive Implications of Vertical Consolidation in the Healthcare Industry”

Testimony, United States House of Representatives, 2019

- House Education and Labor Committee, Subcommittee on Health, Education, Labor and Pensions: “Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency”

Testimony, United States House of Representatives, 2021

- House Oversight and Reform Committee “Unsustainable Drug Prices (Part III)”

Testimony, United States Senate, 2022

- Senate Committee on Commerce, Science, and Transportation’s Consumer Protection, Product Safety, and Data Security Subcommittee: “Ensuring Fairness and Transparency in the Market for Prescription Drugs”

Testimony, United States Senate, 2023

- Senate Committee on Health, Education, Labor, and Pensions: “Taxpayers paid billions for it: So why is Moderna considering quadrupling the price of the COVID vaccine?”

ACADEMIC PUBLICATIONS

“The Impact of Early Discharge Laws on the Health of Newborns,” (with William Evans and Heng Wei), *Journal of Health Economics*, 2008, 27(4): 843-870.

“The Economic Benefits of Pharmaceutical Innovations: The Case of Cox-2 Inhibitors,” *American Economic Journal: Applied Economics*, 2012, 4(3): 116-137.

“Empirical Evidence on the Value of Pharmaceuticals,” (with Mark Duggan), in *The [Oxford] Handbook of the Economics of the Biopharmaceutical Industry*: Oxford University Press: Oxford, 2012: 463-492.

“The Doctor Might See You Now: The Supply Side Effects of Public Health Insurance Expansions.” *American Economic Journal: Economic Policy* 2012, 4(3): 190-217.

“Heterogeneity in the Benefits of Greater Treatment Intensity” (with William Evans), *The Review of Economics and Statistics*, 2012, 94(3): 635-649.

“Can Celebrity Endorsements Affect Political Outcomes: Evidence from the 2008 US Democratic Presidential Primary,” (with Tim Moore), *The Journal of Law, Economics, and Organizations*, 2013, 29(2): 355-384.

“Demand Spillovers, Combative Advertising, and Celebrity Endorsements,” *American*

Economic Journal: Applied Economics, 2014, 6(2): 76-104.

“Giving Mom a Break: The Effect of Higher EITC Payments on Maternal Health” (with William Evans), *American Economic Journal: Economic Policy*, 2014, 6(2): 258-290.

“Public Health Insurance, Labor Supply, and Employment Lock,” (with Tal Gross and Matthew Notowidigdo), *Quarterly Journal of Economics*, 2014, 129(2): 653-696.

“Health Spending Slowdown Is Mostly Due to Economic Factors, Not Structural Change in the Health Care Sector” (with David Dranove and Christopher Ody), *Health Affairs*, 2014, 33(8): 1399-1406.

“The Economic Downturn and its Lingering Effects Reduced Medicare Spending Growth by \$4 Billion In 2009–12,” (with David Dranove and Christopher Ody), *Health Affairs*, 2015, 34(8): 1368-1375.

“Investment Subsidies and the Adoption of Electronic Medical Records in Hospitals.” (with David Dranove, Chris Ody, and Bingyang Li), *Journal of Health Economics*, 2015, 44: 309-19.

“The Market Impacts of Product Patents in Developing Countries,” (with Mark Duggan and Aparajita Goyal), *American Economic Review*, 2016, 106(1): 99-135

“The Black/White Educational Gap, Stalled Progress, and the Long Term Consequences of the Emergence of Crack Markets,” (with William Evans and Timothy J. Moore), *The Review of Economics and Statistics*, 2016, 98(5): 832-847.

“Affordable Care Act’s Medicaid Expansion Led to Substantial Decreases in Uncompensated Care but Levels and Many Hospitals Remain High,” (with David Dranove and Christopher Ody), *Health Affairs*, 2016, 35(8): 1471-1479.

“How do Hospitals Respond to Negative Financial Shocks? The Impact of the 2008 Stock Market Crash (with David Dranove and Christopher Ody),” *The RAND Journal of Economics*, 2017, 48(2): 485–525.

“Insurance Expansion and Hospital Emergency Department Access: Evidence from the Affordable Care Act,” (with John Graves, Tal Gross, and Matthew Notowidigdo), *Annals of Internal Medicine*, Feb 7 2017, 166(3):172-179

“Success and Failure in the Insurance Exchanges (with John Graves),” *New England Journal of Medicine*, March 9, 2017, 376(10):907-910

“The Economics of Indication Based Pricing (with Amitabh Chandra),” *New England Journal of Medicine*, July 2017, 377(2):103-106.

“Hospitals as Insurers of Last Resort,” (with Tal Gross and Matthew Notowidigdo), *American Economic Journal: Applied Economics*, 2018, 10(1): 1-39.

“The CVS–Aetna Merger: Another Large Bet on the Changing U.S. Health Care Landscape,” (with Austin Frakt), *Annals of Internal Medicine*, January 9, 2018.

“The Orphan Drug Act at 35: Observations and an Outlook for the Twenty-First Century,” (with Nicholas Bagley, Benjamin Berger, Amitabh Chandra, and Ariel D. Stern) in *Innovation Policy and the Economy*, 2018, Volume 19, pages 97-137, National Bureau of Economic Research, Inc.

“Characterizing the Drug Development Pipeline for Precision Medicine, (with Chandra, Amitabh, Garthwaite, Craig and Stern, Ariel Dora Stern), *Economic Dimensions of Personalized and Precision Medicine*, 2018, National Bureau of Economic Research, Inc.

“It’s Time to Reform the Orphan Drug Act,” (with Nicholas Bagley, Amitabh Chandra, and Ariel D. Stern), *NEJM Catalyst*, Dec 19, 2018.

“Economic Principles for Medicare Reform (with Amitabh Chandra),” *ANNALS of the American Academy of Political and Social Science*, 2019, 686(1): 63-92.

“All Medicaid Expansions Are Not Created Equal: The Geography and Targeting of the Affordable Care Act,” *Brookings Papers on Economic Activity*, Fall 2019 (with John Graves, Tal Gross, Zeynal Karaca, Victoria Marone, and Matthew Notowidigdo)

“The Economics of Medicare for All,” book chapter in *Maintaining the Strength of American Capitalism* published by the *Aspen Economic Strategy Group*, eds. Melissa Kearney and Amy Ganz, December 2019.

“Insurance access and demand response: Price and welfare implications,” (with David Dranove and David Besanko), *Journal of Health Economics*, 2020, 73.

“The Economics of Medical Procedure Innovation,” (with David Dranove, Christopher Heard, and Bingxiao Wu), *Journal of Health Economics*, January 2022, Vol. 81.

Guns and Violence: The Enduring Impact of Crack Cocaine Markets on Young Black Males, (with Bill Evans and Timothy J. Moore), *Journal of Public Economics*, February 2022, vol. 206.

“Endogenous Quality Investments in the US Hospital Market,” (with Chris Ody and Amanda Starc), *Journal of Health Economics*, July 2022, 84:10236.

“Does consumer demand pull scientifically novel drug innovation?,” (with David Dranove and Manuel Hermosilla), *RAND Journal of Economics*, August 18 2022, Vol. 53 Issue 3.

“The Returns to Medical Inventions,” (with David Dranove and Bingxiao Wu), *The Journal of Law & Economics*, November 2022, Vol 65 Num. S2.

“Expected Profits and The Scientific Novelty of Innovation,” NBER Working Paper #27093, (with David Dranove and Manuel Hermosilla), forthcoming, *RAND Journal of Economics*

WORKING PAPERS

“Regulatory Approval and Expanded Market Size,” NBER Working Paper #28889 (with Amitabh Chandra and Benjamin Berger)

“Who Profits From Amateurism: Rent-Sharing in Modern College Sports,” NBER Working Paper #27734 (with Jordan Keener Matthew J. Notowidigdo Nicole F. Ozminkowski), *revise and resubmit, American Economic Journal: Applied Economics*

“The Impact of Private Contracting on Healthcare for the Old and Sick: Evidence from California’s Medicaid Program” (with Mark Duggan and Adelina Wang)

“Reinsuring the Insurers of Last Resort” (with Chris Ody and David Dranove)

“The Opportunities and Limitations of Monopsony Power in Healthcare: Evidence from the United States and Canada,” July 2019 (with Jillian Chown, David Dranove, and Jordan Keener)

“Artificial Intelligence, the Evolution of the Healthcare Value Chain, and the Future of the Physician,” NBER Working Paper #30607 (with David Dranove)

OTHER PUBLICATIONS

The Impact of the ACA’s Medicaid Expansion on Hospitals’ Uncompensated Care Burden and the Potential Effects of Repeal (with David Dranove and Christopher Ody), *Commonwealth Fund Issue Brief*, May 2017.

“A Floor and Trade Proposal for Hospital Charity Care,” The Hamilton Project working paper.

CASES

Wildcat Physical Therapy (with Dylan Duffy), 2019

Evaluating Vertical Integration at AB-Inbev Across the Globe (with Sarit Markovich, Eugenio Gomez A Latorre, and Andrea Meyer), 2018, Kellogg 5-118-002)

Consumer Cost Sharing in Health Insurance (with Chris Ody), 2018

Quality Provision in the Nursing Home Industry (with Chris Ody), 2017

Renal Care in the United States, 2020

Sovaldi: Pricing a Breakthrough Drug (with Meghan Busse), 2015

The Global Aircraft Manufacturing Industry, 2002-2011 (with Jen Brown), 2012. Kellogg Case #5-312-505.

Starbucks: A Story of Growth, (with Jen Brown and Meghan Busse), 2011. Kellogg Case #5-211-259.

PERMANENT WORKING PAPERS

Pharmaceutical Profits and the Social Value of Innovation, NBER Working Paper #20212, (with David Dranove and Manuel Hermosilla)

“The Effect of In-Utero Conditions on Long Term Health: Evidence from the 1918 Spanish Flu Pandemic,” April 2008 (First Draft, July 2007).

TEACHING

Core Business Strategy (STRT 431), Kellogg School of Management, 2009-Present
Foundations of Strategy, Kellogg-HKUST EMBA, 2016-Present
Strategy Frameworks Kellogg EMBA, 2017-Present
Healthcare Strategy (STRT 443), Kellogg School of Management, 2017-Present
Healthcare Strategy (STRTX 945), Kellogg School of Management EMBA, 2017-Present
Value Creation and Capture in Biopharmaceuticals (HCAK 960), 2022 - Present

HONORS AND AWARDS

Sidney J. Levy Teaching Award for Electives, 2021
Kellogg Chairs' Core Course Teaching Award, 2019
Lavengood Professor of the Year Finalist, 2019
Lavengood Professor of the Year Finalist, 2018
Kellogg Faculty Impact Award, Healthcare Strategy, 2018
Sidney J. Levy Teaching Award for Electives, 2017
Poets and Quants 40 Best Under 40 Professors, 2015
Kellogg Faculty Impact Teaching Award, Business Strategy, 2012
Kellogg Faculty Impact Teaching Award, Business Strategy, 2012
Kellogg Chairs' Core Course Teaching Award, 2011
International Institute of Public Finance (IIPF) Young Economists Award, 2011
Kellogg Faculty Impact Teaching Award, Business Strategy, 2010
University of Maryland Third Year Paper Fellowship

INVITED PRESENTATIONS

2008: University of Notre Dame
2009: Chicago Booth Graduate School of Business
2010: University of Wisconsin-Madison, Dartmouth College, University of Notre Dame
2011: AEA Annual Meeting, University of Illinois-Chicago, Olin Business School at Washington University, Harris School of Public Policy at the University of Chicago, Indiana University SPEA, National Tax Association Annual Meeting, AcademyHealth Research Insights Meeting
2012: AEA Annual Meeting (Presenter and Discussant), Society of Labor Economists Annual Meeting, NBER Summer Institute, University of Illinois Urbana-Champaign, University of California-Davis, Columbia University

- 2013: University of Chicago Health Economics Workshop, University of British Columbia, University of California-San Diego, University of Kentucky, Texas A&M University, Wharton School of the University of Pennsylvania, University of Maryland, Brookings Institution, UC-Davis Poverty Center
- 2014: AEA Annual Meeting, Northwestern Law School, RAND Corporation, Rice University/University of Houston, HDMS User Forum, Bates/White Life Science Conference, Vanderbilt University, University of Michigan RWJF Scholars, Northwestern University Economics Department
- 2015: AEA Annual Meeting, Stanford University, University of California-Irvine, MIT/BU Health Economics Seminar, Syracuse University, NBER Summer Institute, UT-Austin, University of Maryland
- 2016: Harris School of Public Policy at the University of Chicago, Owen School of Management, Vanderbilt University.
- 2017: National Tax Association Annual Meeting
- 2018: University of Georgia, Auburn University, Harvard University, Boston University, American Enterprise Institute, University of Southern California
- 2019: American Medical Association, Ohio State University, University of Louisville, Emory University, Aspen Ideas Festival, Aspen Economic Strategy Group, University of Utah, Aspen Ideas Festival, Aspen Ideas Health Festival, Aspen Economic Strategy Group
- 2020: Harris School of Public Policy at the University of Chicago
- 2022: The Wharton School

ACADEMIC ACTIVITIES

Co-Editor, *Journal of Public Economics*, (2016 – 2020)

Reviewer: *American Economic Review*, *Quarterly Journal of Economics*; *Journal of Political Economy*; *Econometrica*; *Review of Economic Studies*; *New England Journal of Medicine*, *The Journal of Public Economics*; *American Economic Journal: Economic Policy*; *Health Affairs*; *The Review of Economics and Statistics*; *The Journal of Industrial Economics*; *The Journal of Health Economics*; *The Journal of Human Resources*; *Journal of Policy Analysis and Management*; *International Journal of Industrial Organization*; *Health Economics*; *Social Science and Medicine*; *Economic Inquiry*

PAST EMPLOYMENT

Employment Policies Institute, Washington, DC
Director of Research and Chief Economist, 2003-2005
Public Sector Consultants, Lansing, MI
Economist, 2002-2003

OUTSIDE ACTIVITIES

Affiliated Consultant, Analysis Group (2018-Present)
Consultant for Wal-Mart Inc. (2019-2020)
Eli Lilly Advisory Board (2020)
Janssen Advisory Board (2021 - Present)

Speaking engagements for Allergan, Alexion, Digestive Health Professionals Association
National Pharmaceutical Council, Wisconsin Association of Health Plans, Great American
Insurance.

APPENDIX B
EXPERT CONSULTING AND TESTIMONY

1. (Presentation) Marshfield Clinic Zoning Appeal, Oneida County Planning and Development committee, Oneida County, WI, December 14, 2017 (on behalf of appellant).
2. (Deposition testimony) *In Re: United States of America ex rel. Frank M. Rembert and Michael R. Paradise vs. Bozeman Health Deaconess Hospital D/B/A Bozeman Health and Deaconess-Intercity Imaging, LLC. D/B/A Advanced Medical Imaging*, United States District Court, District of Montana, Butte Division, Case No. 2:15-cv-00080-SHE, December 11, 2015 (on behalf of Relators).
3. (Testimony) Before the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, February 27, 2018.
4. (Testimony) Before the House Judiciary Committee, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, March 7, 2019.
5. (Deposition testimony) *In Re: National Prescription Opiate Litigation*, United States District Court, Northern District of Ohio, Eastern Division, MDL No. 2804 Case No 17-MD-2804, June 7, 2019 and July 14, 2021 (on behalf of Defendant CVS).
6. (Testimony) Before the Senate Judiciary Committee, Subcommittee on Antitrust, Competition Policy, and Consumer Rights, June 12, 2019.
7. (Testimony) Before the United States House of Representatives, House Education and Labor Committee, Subcommittee on Health, Education, Labor and Pensions, September 26, 2019.
8. (Testimony) Before the House Oversight and Reform Committee, May 18, 2021.
9. (Deposition testimony) *State of Florida, Office of the Attorney General, Department of Legal Affairs v. Purdue Pharma L.P. et al.*, in the Circuit Court of the Sixth Judicial Circuit in for Pasco County, Florida, Case No. 2018-CA-001438, December 13, 2021 (on behalf of Defendant CVS).
10. (Testimony) Before the Senate Committee on Commerce, Science, and Transportation's Consumer Protection, Product Safety, and Data Security Subcommittee, May 5, 2022.
11. (Testimony) Before the Senate Committee on Health, Education, Labor, and Pensions, March 22, 2023.

APPENDIX C
MATERIALS RELIED UPON

Legal Documents

42 CFR § 406.10.
42 CFR § 406.11.
42 CFR § 406.12.
42 CFR § 406.13.
42 CFR § 406.5.
42 CFR § 422 et seq.
42 CFR § 422.254 et seq.
42 CFR § 422.304 et seq.
42 CFR § 422.308(a).
42 CFR § 422.310(a)-(b).
42 CFR § 422.310(g)(2)(ii).
42 CFR § 423.286.
42 CFR § 423.329(a).
42 CFR § 423.336(a)(2).
42 CFR §§ 422.300 - 422.308.
42 USC § 1395c et seq.
42 USC § 1395c.
42 USC § 1395w et seq.
42 USC § 1395w-23.
42 USC § 1395w-24 et seq.
42 USC § 426 et seq.
Chart Sync and Medical Record Manager, UnitedHealth Group, December 16, 2014.
Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 6, 2023.
Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 7, 2023.
Deposition of Jon H. Bird 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 22, 2023.
Deposition of Kathleen O. Baker 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, Case No. 2:16-cv-08697-FMO-SS, May 30, 2023.
Deposition of Kathleen O. Baker 30(b)(6) *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, Case No. 2:16-cv-08697-FMO-SS, May 31, 2023.
Deposition of Marybeth Meyer, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. 16-08697 FMO, June 7, 2022.
Deposition of Melissa Sedor 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 29, 2023.
Deposition of Rebecca Martin, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. 16-08697 FMO, August 5, 2022.
Ingenix Risk Adjustment Data System ("IRADS"), UnitedHealth Group, December 16, 2014.
Production of Replacement File for MARA2117116, September 30, 2016.
Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2010 DOS, May 2, 2016.

Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016.

Production of Responses and Documents Responsive to CR / CV Interrogatories 1(F), 1(J), 1(K) and Document Requests 4(C)(iii)(t), 4(C)(vii)(i), 5, and 6(D), December 21, 2015.

Production of Responses and Documents Responsive to CR / CV Interrogatory 1(F) and Document Requests 4(C)(iv)(n) and 4(C)(vii)(i), March 31, 2016.

Production of Responses to Questions re: Chart Reviewed File 4(C)(iv) – Chart Error & Omission Codes and Chart Reviewed File 4(C)(v) – Diagnosis Error & Omission Codes, December 1, 2016.

Production of Responses to Questions re: Document Request 4(C) – July 26th Letter, Attachment A, Sections A1, B2, B5, B6, C1, E, F, & K, August 26, 2016.

Production of Responses to Questions re: Document Request 4(C) – July 26th Letter, Attachment A, Sections B3, H, I, and J, September 23, 2016.

Response to Follow Up Questions on March 18, 2016 Letter re: 2012 DOS Encounters Identified for CV Review, May 27, 2016.

United States' Amended Complaint-In-Partial-Intervention and Demand for Jury Trial, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 MWF (SSx), November 17, 2017.

UnitedHealth's First Supplemental Responses and Objections to Plaintiff United States' Sixth Set of Interrogatories, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, CASE NO. CV 16-08697 (SSx), July 19, 2022.

Financial Documents

UnitedHealth Group Incorporated Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2010, filed February 10, 2011, <https://www.sec.gov/Archives/edgar/data/731766/000119312511030615/d10k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2011, filed February 8, 2012, <https://www.sec.gov/Archives/edgar/data/731766/000073176612000009/unh2011123110k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2012, filed February 6, 2013, <https://www.sec.gov/Archives/edgar/data/731766/000073176613000005/unh2012123110-k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2013, filed February 12, 2014, <https://www.sec.gov/Archives/edgar/data/731766/000073176614000008/unh2013123110-k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2014, filed February 10, 2015, <https://www.sec.gov/Archives/edgar/data/731766/000073176615000007/unh2014123110-k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2015, filed February 9, 2016, <https://www.sec.gov/Archives/edgar/data/731766/000073176616000058/unh2015123110-k.htm>, accessed September 29, 2023.

UnitedHealth Group Incorporated, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the Fiscal Year Ended December 31, 2016, filed February 8, 2017, <https://www.sec.gov/Archives/edgar/data/731766/000073176617000009/unh2016123110-k.htm>, accessed September 29, 2023.

Public Documents

“2006-2011 Model Software/ICD-9-CM Mappings,” *Centers for Medicare & Medicaid Services*, <https://www.cms.gov/medicare/health-plans/medicareadvtgsspecratestats/risk-adjustors-items/risk2006-2011>, accessed September 25, 2023.

“Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” *Centers for Medicare & Medicaid Services*, February 20, 2009, <https://www.cms.gov/medicare/health-plans/medicareadvtgsspecratestats/downloads/advance2010.pdf>, accessed September 26, 2023.

“Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter,” *Centers for Medicare & Medicaid Services*, February 15, 2013, <https://www.cms.gov/medicare/health-plans/medicareadvtgsspecratestats/downloads/advance2014.pdf>, accessed September 29, 2023.

“Advance Notice of Methodological Changes for Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter,” *Centers for Medicare & Medicaid Services*, February 21, 2014, <https://www.cms.gov/medicare/health-plans/medicareadvtgsspecratestats/downloads/advance2015.pdf>, accessed September 28, 2023.

“Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies,” *Centers for Medicare & Medicaid Services*, April 2, 2007, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/announcement2008.pdf>, accessed September 5, 2023.

- “Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 1, 2013, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/announcement2014.pdf>, accessed September 14, 2023.
- “Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 7, 2014, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/announcement2015.pdf>, accessed September 14, 2023.
- “Announcement of the August 2019 Software Release,” Centers for Medicare & Medicaid Services, July 29, 2019, <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelphdesk/Downloads/Announcement-of-the-August-2019-Software-Release.pdf>, accessed September 29, 2023.
- “Announcements and Documents,” *Centers for Medicare & Medicaid Services*, September 6, 2023, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents>, accessed September 29, 2023.
- “Apply for Medicare Part D Extra Help program,” *The United States Social Security Administration*, <https://www.ssa.gov/medicare/part-d-extra-help>, accessed September 29, 2023.
- “CMS Manual System Transmittal 118,” *Department of Health & Human Services and Centers for Medicare & Medicaid Services*, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R118MCM.pdf>, accessed June 30, 2022.
- “CMS Releases 2024 Projected Medicare Part D Premium and Bid Information,” *Centers for Medicare & Medicaid Services*, July 31, 2023, <https://www.cms.gov/newsroom/fact-sheets/cms-releases-2024-projected-medicare-part-d-premium-and-bid-information>, accessed September 28, 2023.
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I. OVERVIEW

1. This appendix explains in detail the methods I used for the analyses in my report. It includes descriptions of the data sources I relied upon and illustrative examples.
2. The code produced with this report implements every stage of my analysis, from the initial loading of data produced by Defendants and CMS to the creation of the final output that forms the basis of my opinions. It was prepared under my direction by staff at Analysis Group. Every detail of my analysis is therefore exactly specified in the code.¹ Accordingly, my method can be reviewed, in its entirety, by anyone with knowledge of the SAS language² and SQL.³
3. As discussed in my Summary of Opinions,⁴ my analysis begins by identifying a set of diagnosis codes for each beneficiary that were (i) submitted by Defendants to CMS for risk adjustment purposes; (ii) used in the calculation of the risk adjustment payments Defendants received from CMS for that beneficiary; (iii) sourced from medical records reviewed by Defendants as part of their Chart Review Program; (iv) not found to be supported by Defendants during the Chart Review Program; and (v) not associated with HCCs for which other instances of diagnosis codes mapping to the same HCC could have been submitted by Defendants for that beneficiary in the same year. After identifying this set of diagnosis codes, I analyze the impact of Defendants' failure to delete them, including the financial impact on Defendants' risk adjustment payments for Medicare Advantage and

¹ Any perceived discrepancies between the analytic code itself and a written description of it (in this Appendix or in my Report) should be resolved by inspection of the code, since the code is the definitive description of my method.

² SAS, the principal programming language used for my analytic code, is a standard language designed for statistical computing and data analysis. "Why SAS," SAS, 2023, https://www.sas.com/en_us/company-information/why-sas.html, accessed September 25, 2023. It is the language chosen by CMS to implement its risk adjustment program. See, for example, "2006-2011 Model Software/ICD-9-CM Mappings," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/risk2006-2011>, accessed September 25, 2023.

³ In addition to native SAS commands, my analytic code contains SQL code embedded within SAS "proc sql" procedures. SQL is a ubiquitous programming language used to create, modify, and analyze databases in many industries, including but not limited to health care. Natassha Selvaraj, "What is SQL Used For? 7 Top SQL Uses," Datacamp, October 2022, <https://www.datacamp.com/blog/what-is-sql-used-for>, accessed September 25, 2023.

⁴ **Report, Section II.**

Medicare Part D and the total number of affected beneficiaries year-by-year for payment years 2009–2017. I use the same analytic code to calculate the financial impact on Defendants’ risk adjustment payments resulting from Defendants’ failure to delete the set of diagnosis codes in Defendants’ CV Pipeline Lists. The only difference between the two analyses is that the second analysis uses the diagnosis codes found on the CV Pipeline Lists, rather than the set of diagnosis codes identified in my review of Defendants’ databases, as the input to the financial impact analysis.

II. IDENTIFICATION OF UNIQUE BENEFICIARIES

4. Defendants’ risk adjustment payments for Medicare Advantage and Medicare Part D are beneficiary-specific. Each year, payments depend upon a beneficiary’s diagnosis codes in the prior year as well as beneficiary-level demographic factors. I therefore conduct my analysis at the beneficiary-year level.⁵
5. Since the analysis is done per beneficiary and per year, correctly identifying the data associated with each beneficiary in each year is a necessary preliminary step. Treating data associated with one beneficiary as data associated with multiple beneficiaries, or treating data associated with multiple beneficiaries as if it belonged to a single beneficiary, could lead to incorrect conclusions.
6. During the time period in question, CMS (and therefore Defendants) chiefly identified beneficiaries using HICNs (“Health Insurance Claim Numbers”). HICNs are assigned based on a beneficiary’s Social Security Number (“SSN”) as well as the reason a beneficiary qualifies for Medicare, and since the reason for qualification can change, a single beneficiary can have multiple HICNs over time, even in the same year.⁶ CMS later

⁵ The only exception to this principle is the application of Medicare Part D risk corridors, which are analyzed at the plan-year level and pertain only to the calculation of payments. The identification of Deletes and risk score impact in both Part C and Part D is strictly isolated on a per-beneficiary, per-year basis.

⁶ Stephanie Ellen, “Definition of Medicare HIC Number,” Sapling, <https://www.sapling.com/7890627/definition-medicare-hic-number>, accessed September 25, 2023.

transitioned from HICNs to MBIs (“Medicare Beneficiary Identifiers”), which are randomly generated and not linked to SSNs or eligibility.⁷

7. In order to correctly associate data from Defendants and CMS with unique beneficiaries in each year, I use data provided by CMS which maps HICNs and MBIs to an internal CMS identifier called BENE_SK, which is intended as a unique, unchanging identifier for each beneficiary.^{8,9} I use this mapping to create a crosswalk between all values of HICNs and MBIs and their corresponding unique BENE_SK values.¹⁰ To avoid cases where beneficiary identity may be in doubt, I exclude from my analysis approximately 0.01% of HICNs and MBIs because they map to multiple BENE_SKs or no BENE_SKs.

III. IDENTIFICATION OF REVIEWED ENCOUNTERS

8. As discussed in my **Report, Section VI.A**, I identify provider-reported encounters reviewed as part of Defendants’ Chart Review Program (*i.e.*, Reviewed Encounters) using data from Defendants’ Chart Review Databases and Defendants’ Risk Adjustment Databases.

A. Identification of Encounters in Chart Review Data

9. As shown in **Exhibit 9** in my Report, Defendants’ Risk Adjustment Databases contain data from multiple sources, including but not limited to Defendants’ Provider-Reported Claims Databases and Defendants’ Chart Review Databases. However, not all information from these databases is reflected in Defendants’ Risk Adjustment Databases. I therefore create a list of encounters that were reviewed in the Chart Review Program by supplementing the

⁷ “Understanding the Medicare Beneficiary Identifier (MBI) Format,” Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/new-medicare-card/understanding-the-mbi.pdf>, accessed September 25, 2023.

⁸ CMS files USBP009429489-498, USBP009429500-01, USBP009429503.

⁹ “Data Dictionary for CJR Baseline, Monthly, Target Price, and Reconciliation Reports,” U.S. Department of Health & Human Services, December 21, 2018, <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cjr%20data%20dictionary%2012%2021%2018.html>, accessed September 25, 2023.

¹⁰ To reduce the presence of personal identifiable information during my analysis and in intermediate results, I assign each BENE_SK to an anonymized identifier at the beginning of my analysis, and I use this ANONYMOUS_SK as the beneficiary identifier until remapping it to BENE_SK and HICN at the end of my analysis.

chart review data in Defendants' Risk Adjustment Databases with additional data which can only be found in Defendants' Chart Review Databases.

i. Chart Review Data in Defendants' Risk Adjustment Databases

10. IRADS, Defendants' Risk Adjustment Database that was used during the entire time period at issue in this matter, contains a field called SUB_SOURCE_CD, which generally indicates the source of data for each encounter. For encounter data that originated from Defendants' Chart Review Databases, the SUB_SOURCE_CD is "CHARTAUDIT." I consider CHARTAUDIT data to represent records of encounters that were reviewed in Defendants' Chart Review Program.¹¹
11. Defendants' data production of EDPS, Defendants' Risk Adjustment Database that was used for service dates in 2014–2016, includes separate tables for data originating from provider-reported encounters and alternative sources, including but not limited to, records from the Chart Review Program. I have not identified an equivalent field within the EDPS alternative sources data that allows the immediate identification of records originating from the Chart Review Program. For this reason, I do not use data from the Chart Review Program contained within EDPS to identify encounters for inclusion in the list of encounters reviewed in Defendants' Chart Review Program. Instead, I rely exclusively on data contained within Defendants' Chart Review Databases, discussed in the next section.

ii. Chart Review Data in Defendants' Chart Review Databases

12. I supplement the list of encounters that I identified above using data from the Chart Review Program in Defendants' Risk Adjustment Databases with encounters from Defendants' Chart Review Databases. As explained in my **Report, Section VI.A.i**, the principle reason I do this when analyzing the IRADS database is that Defendants' Risk Adjustment Databases do not contain the CHARTAUDIT encounters described above where Defendants' Coders (or a third-party vendor employed by the Defendant) observed no risk

¹¹ Defendants produced data for mapping Chart IDs from chart review data to corresponding IRADS 'CHARTAUDIT' data. MARA2157336; MARA2152917. See also Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 7, 2023 ("Cannon Deposition Volume 2"), 391:15–19 ("And so if you look in IRADS, I think it eventually got to the point where if you looked at that ASM, it should be – let's put it this way, it should be assigned something related to chart review or chart or chart audit.").

adjustment-eligible diagnosis codes for a particular encounter on the Chart, but the encounter was still reviewed by Defendants. For EDPS, I do this because I have not identified a direct equivalent of a CHARTAUDIT encounter (as discussed above).

13. During the at-issue period, Defendants' Chart Review Program was carried out by their own Coders as well as various third-party vendors. The systems used to conduct the Chart Review Program also changed over time. For service dates in 2008 and 2009, Defendants used multiple vendors and loaded the data collected and submitted by individual vendors directly into IRADS. As a result, results from the Chart Review Program results recorded during these years were produced in a set of over 1,000 files from five different vendors, which I collectively refer to as "vendor files." From service year 2010 forward, Defendants relied on their own Coders as well as some third-party vendors to review Charts, but they consolidated the results of these reviews into central databases. For service dates in 2010–2013, Defendants consolidated data from the Chart Review Program into a single database called ChartSync.¹² For service dates in 2014–2016, data from the Chart Review Program were recorded in two systems known as Medical Record Manager ("MRM") and Epsilon. According to deposition testimony, MRM was the primary system used to record results from the Chart Review Program, while Epsilon was a secondary system used to prepare such data for transmission into Defendants' Risk Adjustment Databases.¹³ I therefore rely on MRM for service dates in 2014–2016. In the following sub-sections, I describe these three categories of data from the Chart Review Program: vendor files, ChartSync, and MRM. From each of these sources, I identify encounters recorded by Coders in the Chart

¹² *Chart Sync and Medical Record Manager*, UnitedHealth Group, December 16, 2014, pp. 4, 10. There is also some ChartSync data for service dates in 2009, and very little for service dates in 2008, which I use to supplement the data in the vendor files; Deposition of Biggs T. Cannon, III 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 6, 2023 ("Cannon Deposition Volume 1") 37:11–14 ("Generally speaking, the ChartSync system was a database or a tool that was used to capture chart information related to the review of medical charts for Medicare Advantage beneficiaries"), 44:25–45:1 ("ChartSync was used for chart review.").

¹³ Cannon Deposition Volume 1, 54:5–23 ("Q. What is Epsilon used for? A. Epsilon is more of a staging area. So it can store results related to those programs. Q. Oh, okay. What do you mean by staging program? A. So it's another database that just houses the results and can be used as just an additional area to house results and potentially analyze data from. Q. Okay. I guess different from -- does MRM also store results? A. Yes. Q. What's the difference, then, between MRM and Epsilon insofar as the use of it for the chart review program is concerned? ... THE WITNESS: I believe MRM is more of a front end where people doing chart review can actually conduct the review.").

Review Program as unique combinations of the following fields: beneficiary identifier, start date of service, end date of service, and provider identifier. The availability of provider identifiers differs by source and by year, as discussed below.

a) Vendor Files

14. My analysis of the “vendor files” used for service dates in 2008 and 2009 begins by classifying each file according to the specific vendor. The five vendors are TCS, Mediconnect, Outcomes, Pi, and ECS. I classify files by their Bates stamp using the correspondence below, which I derived based on underlying file names and consistency in data fields across files:¹⁴

Exhibit A

Vendor File Classification	
Vendor	Bates Range
TCS	MAPL002077000-MAPL002078102
Outcomes	MAPL002078103-MAPL002078719
Mediconnect	MAPL002078720-MAPL002078749
Pi	MAPL002078750-MAPL002078751
ECS	MAPL002078752-MAPL002078763

15. I process data from the five different vendors and create a single consolidated dataset with fields relevant to my analysis. These fields include beneficiary identifiers (first name, last name, date of birth, member ID, and sometimes, HICN) as well as information about the medical encounter (provider identifier, service date, and diagnosis code). I standardize the formats and names of these fields across files to facilitate consolidation into a single dataset. As part of this process, I convert certain invalid values (such as a service date of “99/99/99”) to blank values. I also remove spaces from fields containing beneficiary first and last names (*e.g.*, converting “MARY ANNE” to “MARYANNE”) and ensure that

¹⁴ Produced file names were provided in 2018_0917 - 2008 - 2009 DOS Production Tracker_P6000706.xlsx. For each vendor, up to 18 files were provided with names following the format “Vendor_[Name]_FileType[N]” (*e.g.*, MAPL002078746 is named “Vendor_Mediconnect_FileType2”). I classify other files based on data field alignment with these “FileType” files. For example, the data fields in MAPL002078720 (“named UHC_FinalCompletes_20090419.txt”) align with those in MAPL002078746, suggesting that MAPL002078720 is a Mediconnect file following the FileType2 format.

diagnosis codes are normalized to the common format used elsewhere in Defendants' databases.

16. While the vendor files do contain some information on the provider associated with the Reviewed Encounter, the provider identifiers in these files are inconsistently formatted. For this reason, I do not rely on provider identifiers when I identify Reviewed Encounters by matching provider-reported encounters to encounters from the Chart Review Program, as described in **Section III.C** below. This reflects my cautious choice to minimize the chance of identifying a false encounter match, which could lead to incorrect conclusions about whether chart review recorded the diagnosis codes associated with the provider-reported encounter. This approach likely means that some provider-reported encounters reviewed in Defendants' Chart Review Program for service years 2008 and 2009 will not be matched and will therefore not contribute any diagnosis codes to the Deletes list even though they were reported by providers and not found in the Chart Review Program.
17. A key difference between the vendor file types is the information provided to identify unique beneficiaries. While TCS, Mediconnect, and Outcomes files have a field corresponding to the HICN described above, this field is blank for the majority of observations, and the Pi and ECS files do not have a HICN field. I therefore rely on other member identifiers, including numeric or alphanumeric member ID variables, names, and dates of birth – which are populated for the majority (and, in some instances, 100%) of observations in each dataset – to identify unique beneficiaries within the files. I map a BENE_SK to each vendor file observation using a crosswalk I created using the IRADS member data for 2008-2009 dates of service¹⁵ and the BENE_SK crosswalk described above in **Section II**. The IRADS member data include the HICN field, as well as fields for name, date of birth, and a member ID.
18. I use the following approach to map a BENE_SK to each vendor file observation. If a HICN is provided in the vendor file observation, I directly map the BENE_SK to the provided HICN.¹⁶ If a HICN is not provided, I identify a set of potential BENE_SK

¹⁵ MAPL002079150.

¹⁶ While certain vendor file types have dedicated HICN fields, I have also observed HICN values in member ID fields. I therefore use both the dedicated HICN field and the member ID field in this step.

matches using name, date of birth, and if needed, member ID. If name and date of birth are both provided, I use them both to identify potential matches in the IRADS member data. If either name or date of birth is unavailable *or* if no potential matches sharing both name and date of birth are found, I identify potential matches based on matches between member ID (which is never missing in the vendor files) and either date of birth *or* name.

19. When identifying potential matches using these other fields, I require exact matches for name and date of birth. However, I consider there to be a member ID match even when one member ID is contained within the other, as I have observed many instances in which this occurs for beneficiaries who can be conclusively identified by name, date of birth and BENE_SK.¹⁷ For example, I would consider a member ID of 000039570212 to match a member ID of 00039570212. Since this containment logic only applies in cases where there is also a match on name or date of birth, I consider it unlikely to generate false matches.
20. After using these rules to identify potential matches for each vendor file observation, I classify observations according to the number of potential matches: no potential matches, a single match, and more than one match. I map observations with a single match to the corresponding BENE_SK because there does not seem to be any possible ambiguity about their identity. I exclude observations with no matches. I also exclude observations with multiple matches to avoid the risks that would be associated with a false match. These “unmapped observations” represent beneficiaries for whom I potentially have incomplete chart review data. I therefore exclude from my analysis, for service dates in 2008 and 2009, all BENE_SKs with a member ID match to these observations. Ultimately, I am able to map a BENE_SK to 98.7% of observations in the vendor files. The 1.3% of unmatched observations translates to approximately 22,000 unique BENE_SKs, which I exclude from my analysis of service year 2008–2009 data. I exclude these beneficiaries out of caution, despite the possibility that certain provider-reported encounters associated with these beneficiaries were reviewed in Defendants’ Chart Review Program and that certain

¹⁷ Among approximately 892,000 unique and populated combinations of first name, last name and date of birth in the IRADS member data for 2008–2009, which all map to the same BENE_SK, 66% are associated with multiple member ID variables. Among those associated with multiple member ID variables, 29% are associated with at least two member IDs where one is contained within the other.

diagnosis codes from those Reviewed Encounters were submitted to and accepted by CMS but unsupported by the review.

b) ChartSync

21. For service years 2009 through 2013 (and, to a much lesser extent, 2008), Defendants collected and stored chart review data in a system called ChartSync.¹⁸ Unlike the vendor files, ChartSync consistently recorded the beneficiary's HICN, which I map to a BENE_SK. It also consistently recorded for each encounter a unique provider identifier that Defendants used to identify providers across its data systems, which I refer to as the "Provider ID" field.^{19, 20} The BENE_SK, the Provider ID and the service dates are used together to create a list of encounters reviewed in the Chart Review Program. I exclude from this list a small number (2%) of encounters for which the CHART_STATUS field indicates that the review may not have been complete or for which there is any indication that the record is associated with a program other than chart review.²¹

c) MRM

22. For service dates in 2014 through 2016, Defendants collected and stored chart review data in a system called MRM.²² Similar to ChartSync, MRM consistently recorded the beneficiary's HICN, which I map to a BENE_SK, as well as the service dates and Provider ID²³ associated with each encounter. MRM also recorded the National Provider Identifier

¹⁸ *Chart Sync and Medical Record Manager*, UnitedHealth Group, December 16, 2014, pp. 4, 10; Cannon Deposition Volume 1, 37:11–14 (“Generally speaking, the ChartSync system was a database or a tool that was used to capture chart information related to the review of medical charts for Medicare Advantage beneficiaries”) and 44:25–45:1 (“ChartSync was used for chart review.”).

¹⁹ In ChartSync, the Provider ID field is called CHART_PROVIDER_NBR.

²⁰ For service year 2013, approximately 27% of the unique Provider IDs appear to be populated with a federal taxpayer identification number, rather than Defendants' Provider ID. I do not apply my second method of matching to these encounters.

²¹ Defendants identified five “error and omission” codes that Defendants did not use in the Chart Review Program (D14, D28, C07, C08, C30). I exclude from the list of chart review encounters any encounters that have diagnosis codes associated with these five “error and omission” codes. Production of Responses and Documents Responsive to CR / CV Interrogatory 1(F) and Document Requests 4(C)(iv)(n) and 4(C)(vii)(i), March 31, 2016, p. 2.

²² Cannon Deposition Volume 1, 50:4–10. (“Q. Okay. And was MRM used as a repository for chart review results for 2014 to 2016 data of service? ... THE WITNESS: I believe it captured chart review results at that time frame. That sounds about right, yes.”).

²³ In MRM, the Provider ID field is called SOURCE_SYSTEM_PROV_ID.

(“NPI”) associated with each encounter.^{24, 25} For service dates 2014-2016, I use Provider IDs *and* NPIs in the lists of encounters reviewed in the Chart Review Program. As discussed in my **Report, Section VI.A.ii**, the first method I use to identify Reviewed Encounters relies on identifying a match between provider identifiers in Defendants’ Risk Adjustment Databases and chart review data. The provider identifier that is predominant in IRADS is Provider ID. However, Provider IDs are not present in EDPS, which uses NPI as the provider identifier. Thus, to apply the first method, I rely on Provider IDs to match IRADS records to chart review and I rely on NPI to match EDPS records to chart review. For this reason, there are effectively two lists of chart review encounters for these years: 1) a list of BENE_SK, service dates, and Provider IDs for matching to IRADS, and 2) a list of BENE_SK, service dates, and NPIs for matching to EDPS.²⁶ As with ChartSync, I exclude from both of these lists encounters for which the status field indicates that the review may not have been complete or for which there is any indication that the record is associated with a program other than chart review (11%).²⁷

²⁴ National Provider Identifiers (“NPIs”) are unique 10-digit numeric identifiers assigned to health care providers by CMS as part of its National Plan and Provider Enumeration System (NPPES). Unlike other identifiers, which may be specific to a given practice location or time period, a provider’s NPI will remain the same even if the provider changes his/her name, address, or area of specialization. Health care organizations, such as health plans, physician offices, and hospitals, are required to use NPIs in administrative and financial transactions. *NPI: What You Need to Know*, Centers for Medicare & Medicaid Services, March 2022, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/NPI-What-You-Need-To-Know.pdf>, accessed September 25, 2023.

²⁵ In MRM, the NPI field that is consistently populated across 2014-2016 is called PROV_NPI. In addition, there is a second NPI field in MRM called REND_PROV_NPI, which is only populated in service year 2016 for just under half of records). I use both of these fields when matching chart review records to EDPS, such that if either one matches the NPI information in EDPS, it is considered a match and thus a Reviewed Encounter.

²⁶ To avoid any potential incorrect match to EDPS, I exclude NPIs that are associated with groups of providers, rather than individual providers, according to a publicly available CMS dataset. This excludes the possibility of my second matching method matching a provider-reported EDPS encounter with Provider A to a chart review encounter with Provider B, if Provider A and B share an NPI because they are in the same group. The publicly available CMS dataset that I rely on to identify individual and group NPIs is called the “National Plan and Provider Enumeration System (NPPES) Downloadable File,” and it contains deactivated as well as active NPIs. “NPPES NPI Registry,” Centers for Medicare & Medicaid Services, <https://npiregistry.cms.hhs.gov/search>, accessed September 25, 2023.

²⁷ For this exclusion in MRM, I rely on the same list of five “error and omission” codes discussed in **FN 21** for ChartSync, and to determine the chart status I rely on the GCM_BUS_FUNC_STATUS field. MRM also contains a field called GCM_PROGRAM_NAME, which I use to exclude all Charts associated with a program other than the Chart Review Program (as indicated by the value ‘CR’ in this field).

23. MRM, unlike ChartSync or the vendor files, directly indicates whether each Chart went through Second Level Review.²⁸ I identify each encounter associated with a Second Level Review and separately quantify the financial impact of Defendants' failure to delete unsupported diagnosis codes associated with these encounters.

iii. Identification of Informed-Coded Charts

24. As discussed in the Report, I exclude from the list of chart review encounters used to identify Reviewed Encounters all encounters associated with Charts for which the chart review data is potentially unreliable or incomplete due to the Coder being informed about diagnosis codes previously submitted to CMS for that beneficiary in that year. To identify informed coded Charts, I rely on the lists of Chart IDs that Defendants identified as being subject to informed coding.^{29, 30}

B. Identification of Provider-Reported, Risk Adjustment-Eligible Encounters in Defendants' Risk Adjustment Databases

25. Defendants' Chart Review Program reviewed certain Charts associated with provider-reported, risk adjustment-eligible encounters. To assess the correspondence between diagnosis codes recorded by Defendants' Coders during Chart Review and diagnosis codes submitted by providers for those encounters reviewed during Chart Review, I must first identify provider-reported, risk adjustment-eligible encounters in each of Defendants' Risk Adjustment Databases, as discussed in **Section III.B.**³¹

²⁸ Charts that went through Second Level Review in MRM appear twice in the data, with a value of "Coding" in the GCM_BUSS_FUNC_NAME field for the first review and "SLR" for the Second Level Review.

²⁹ MARA2117127; MARA2117128; Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016. This document identifies: (1) charts that were subject to informed coding as a result of the Recode Project that occurred in project year 2012; and (2) charts that were reviewed by iCodify which were coded using informed coding.

³⁰ In addition to the list of Chart IDs produced by Defendants, I also rely on a crosswalk Defendants produced for mapping Chart IDs to IRADS 'CHARTAUDIT' encounters, so that I can identify and exclude these encounters in IRADS as well. MARA2157336; MARA2152917.

³¹ While it is possible that some encounters that are not eligible for use in risk adjustment were reviewed in Defendants' Chart Review Program, these encounters are not relevant to my analysis, because they are not allowed to affect payment amounts from CMS to Defendants. I therefore exclude these encounters from my analyses.

i. Identification of Provider-Reported Encounters

26. The SUB_SOURCE_CD field in IRADS, mentioned above in **Section III.A.i**, can be used to identify whether an encounter originated from a Provider-Reported Claims Databases, and if so, which Provider-Reported Claims Database. I rely on this field to identify provider-reported encounters in IRADS.³²
27. As discussed in **Section III.A.i**, in EDPS, provider-reported encounters are stored in a separate table from encounters from alternative sources, so they are easy to identify. However, unlike IRADS, EDPS can contain multiple versions of a single provider-reported encounter. For example, it is possible for a provider-reported encounter to be submitted by the provider and later corrected or deleted.³³ I therefore identify the most recent version of each provider-submitted encounter using a combination of fields.

ii. Identification of Risk Adjustment-Eligible Encounters

28. In IRADS, Defendants attached error messages to encounters that were not eligible for use in risk adjustment.³⁴ Some of the most common error messages in IRADS are “Lab services are excluded,” “Provider specialties are excluded,” and “Diagnostic Radiology Services are excluded.”³⁵ IRADS encounter error information also contains a variable called ACTIVE_FLG which indicates whether the error message in question was “active.” I

³² The Provider-Reported Claims Databases evolved over time.

³³ Each edit to a provider-reported encounter in EDPS is associated with a unique identifier in a field called MED_CLM_SK. A provider-reported encounter that was never altered in EDPS is associated with a single MED_CLM_SK, whereas a provider-reported encounter that was edited multiple times would include a unique MED_CLM_SK for each edit. Edits can include adding diagnosis codes to the encounter, as well as correcting or deleting diagnosis codes, and the PRCS_STS_NM field indicates the edit type (e.g., “Original,” “Correction,” “Delete”). EDPS also includes a field called PRNT_MED_CLM_SK, which indicates the “parent” MED_CLM_SK to which corrections and deletions are tied. First, I identify a set of voided versions by creating a list of the “parent” claims (PRNT_MED_CLM_SKs) associated with deletions and correction that were accepted by CMS. I rely on the PRCS_STS_NM field to identify whether a claim is a correction or a delete. If CMS accepted a deletion or correction, it implies the associated “parent” claim is now void. I remove these voided versions of the claim. I then limit the remaining claims to those accepted by CMS. I rely on the PRCS_ST_NM field to determine whether CMS accepted each version of the claim. This field takes on values such as “CMS Accepted” and “CMS Rejected.”

³⁴ In IRADS, the ERROR_KEY field contains a numerical value which can be mapped to an ERROR_MSG field which contains the meaning of each numerical value.

³⁵ As discussed in my **Report, Section III.B.i**, only face-to-face encounters with providers from certain specialties are considered eligible for risk adjustment.

identify risk adjustment-eligible encounters as encounters that are not associated with an active error message.³⁶

29. In EDPS, risk adjustment-eligible encounters are identified based on the type of bill (“TOB”) codes³⁷ and Current Procedural Terminology/Healthcare Common Procedure Coding System (“CPT/HCPCS”) codes³⁸ associated with the encounter. CMS uses the TOB code to determine whether an encounter reflects services provided by a facility that is an acceptable source of risk adjustment diagnosis codes.³⁹ Institutional inpatient and institutional outpatient claim types are mapped to acceptable TOB codes as determined by CMS.⁴⁰ CPT/HCPCS codes are used in healthcare billing for coding medical services, procedures, and supplies. For example, CPT code 99212 represents an office visit or other outpatient visit for an established patient (as opposed to a new patient) lasting between 10 and 19 minutes.⁴¹ For each service year, CMS publishes a list of CPT/HCPCS code that it considers eligible for use in risk adjustment. Per CMS guidelines, as long as one service associated with the encounter is risk adjustment-eligible, all diagnosis codes associated with the encounter are risk adjustment-eligible.⁴² I use these two types of codes to identify

³⁶ To determine whether an encounter is associated with an error message, I consider only the error messages that are active for that encounter (i.e., the ACTIVE_FLG is equal to “Y”). While I observe that Defendants generally did not submit to CMS diagnosis codes on encounters with an active error message, in a small number of cases, even though the encounter is associated with an active error message, Defendants appear to have submitted at least some of the diagnosis codes on the encounter to CMS. In these cases, I consider the encounter risk adjustment-eligible, despite the error message.

³⁷ EDPS does not contain a field that reflects the TOB associated with each encounter. However, CMS produced three datasets that contain TOBs for each encounter in EDPS (USBP009429419-21), which I rely on to identify TOBs.

³⁸ EDPS contains a field called BILL_PRCDR_CD, which contains the CPT/HCPCS code associated with each service associated with the encounter.

³⁹ Cheri Rice, “Final Encounter Data Diagnosis Filtering Logic,” Centers for Medicare & Medicaid Services, December 22, 2015, [https://www.csscooperations.com/internet/cssc3 nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/\\$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf](https://www.csscooperations.com/internet/cssc3 nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf), accessed October 15, 2022, pp. 3–5.

⁴⁰ *Ibid.*, pp. 3–5.

⁴¹ “CPT code 99212: Established patient office visit, 10-19 minutes,” American Medical Association, <https://www.ama-assn.org/practice-management/cpt/cpt-code-99212-established-patient-office-visit-10-19-minutes>, accessed September 25, 2023.

⁴² Cheri Rice, “Final Encounter Data Diagnosis Filtering Logic,” Centers for Medicare & Medicaid Services, December 22, 2015, [https://www.csscooperations.com/internet/cssc3 nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/\\$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf](https://www.csscooperations.com/internet/cssc3 nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf)

risk adjustment-eligible encounters among three risk adjustment-eligible provider types (institutional inpatient, institutional outpatient, and professional encounters) following the CMS Final Encounter Data Diagnosis Filtering Logic.⁴³

C. Matching Encounters from Chart Review Data to Provider-Reported Encounters

30. Defendants' Chart Review Program did not review all provider-reported, risk adjustment-eligible encounters. As discussed in my **Report, Section IV.A**, chart review was only performed on a subset of Charts. Making the further determination that the Chart associated with a given provider-reported, risk adjustment-eligible encounter was reviewed involves matching these encounters to encounters in chart review data.
31. I employ two matching methods to identify which provider-reported, risk adjustment-eligible encounters in Defendants' Risk Adjustment Database represent Reviewed Encounters. If either method is satisfied, I consider the encounter to have been reviewed. I use both methods in both of Defendants' Risk Adjustment Databases.

i. Provider Identifier Match

32. My first matching method applies in cases where there is an exact date of service match and a provider identifier match between a provider-reported, risk adjustment-eligible encounter and a chart review record.
33. To determine if there is an exact date of service match, I look for records in Defendants' chart review data that have start and end dates that exactly correspond to the start and end dates of provider-reported encounters. If the start and end dates are not identical,

2012%2022%2015.pdf, accessed October 15, 2022; "Medicare Risk Adjustment Eligible CPT/HCPCS Codes," *ibid.*, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/cpt-hcpcs>, accessed September 18, 2023.

⁴³ Cheri Rice, "Final Encounter Data Diagnosis Filtering Logic," Centers for Medicare & Medicaid Services, December 22, 2015, [https://www.csscooperations.com/internet/cssc3nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/\\$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf](https://www.csscooperations.com/internet/cssc3nsf/files/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf/$File/Final%20Industry%20Memo%20Medicare%20Filtering%20Logic%202012%2022%2015.pdf), accessed October 15, 2022; "Medicare Risk Adjustment Eligible CPT/HCPCS Codes," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/cpt-hcpcs>, accessed September 18, 2023. Institutional inpatient encounters and institutional outpatient encounters are identified using TOB codes found in Tables 1 and 2 of the CMS Final Encounter Data Diagnosis Filtering Logic, respectively. Institutional outpatient encounters and professional encounters are limited to those with risk adjustment-eligible CPT/HCPCS codes found in the risk adjustment-eligible CPT/HCPCS Code list published annually by CMS.

encounters are not matched, even if the provider-reported encounter's date range contains, is contained within, or otherwise overlaps with the chart review record's date range.

34. If I have found an exact service date match, I then determine if there is a provider identifier match by comparing the provider identifier on the provider-reported encounter in Defendants' Risk Adjustment Databases to the provider identifier that Defendants associated with a given Chart for collection purposes in their Chart Review Program. For matching IRADS provider-reported encounters to chart review, I rely on Provider ID. However, because the format of Provider ID differs in IRADS and Chart Review Databases, I leverage a crosswalk created and used by Defendants⁴⁴ called SAS_ALL_PROVIDERS to reconcile Provider IDs.⁴⁵ I use this table to evaluate correspondence between Provider IDs in Defendants' Risk Adjustment Databases with Provider IDs in Defendants' Chart Review Databases.⁴⁶ For matching EDPS provider-reported encounters to chart review, I rely on NPI.⁴⁷
35. To demonstrate this method, consider the hypothetical presented in **Exhibit B** below. Because the beneficiary, dates of service and provider identifiers match for the January 1, 2010 encounter, I conclude that the chart reviewed with Chart ID 123abc-45de was associated with encounter 0000A00001, making encounter 0000A00001 a Reviewed Encounter. Similarly, I conclude that the chart reviewed with Chart ID 678fab-90c was associated with encounter 0000A00002, making encounter 0000A00002 a Reviewed Encounter. I would not consider encounter 0000A00003 to be a Reviewed Encounter under

⁴⁴ Cannon Deposition Volume 1, 99:7–9 (“I think data elements from the SAS_All_Providers table could be used in ChartSync to help to identify providers.”).

⁴⁵ MAPL003292389 (“All_Providers program collects provider and provider_group related data from different sources and consolidates all this data into one record per provider_id.”).

⁴⁶ Deposition of Jon H. Bird 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 22, 2023 (“Bird Deposition Volume 1”), 262:2–263:10.

⁴⁷ As described above in **Section III.A ii.c**, I limit my use of NPIs to only those associated with individual providers. To perform this matching, I rely on two fields in MRM (PROV_NPI and REND_PROV_NPI), and the rendering and billing providers recorded in the NPI and PROV_TYPE fields in EDPS.

this method because while the beneficiary and dates of service match to the chart review encounter, the provider identifiers do not match.⁴⁸

Exhibit B
Provider-Reported Encounters

Beneficiary	Encounter	Start Date	End Date	Provider	Source
123456789A	0000A00001	1/1/2010	1/1/2010	000000123	Claims
123456789A	0000A00002	3/1/2010	3/1/2010	000000456	Claims
123456789A	0000A00003	3/1/2010	3/1/2010	000000789	Claims

Chart Review Encounters

Beneficiary	Chart ID	Start Date	End Date	Provider
123456789A	123abc-45de	1/1/2010	1/1/2010	000000123
123456789A	678fab-90c	3/1/2010	3/1/2010	000000456

36. As illustrated by the above hypothetical, this method of matching allows for the identification of Reviewed Encounters on dates of service where a beneficiary sees multiple providers if and only if there is a provider match between one of the provider-reported encounters and the chart review encounter. If a beneficiary sees multiple providers on a date of service and none of these providers match to the provider associated with a chart review encounter for that same beneficiary on that same date of service, as would be the case if the provider identifier for the chart review on March 1, 2010 above were an identifier other than 456 (e.g., 731 or 198), I would not consider any of the provider-reported encounters to be Reviewed Encounters. I apply this limit out of caution, despite the possibility that one of these provider-reported encounters does correspond to the chart review encounter.

ii. Single Provider on Date of Service

37. The second method of matching identifies Reviewed Encounters when there is only one provider identifier associated with all provider-reported, risk-adjustment eligible encounters in Defendants' Risk Adjustment Databases for a beneficiary on a particular date of service and an encounter for that beneficiary on that date of service is observed in chart

⁴⁸ While I would not identify encounter 0000A00003 as a Reviewed Encounter, I would still consider diagnosis codes associated with encounter 0000A00003 in constructing the final Deletes list. I elaborate upon how I do this in Section VIII.

review. In this case, I conclude that the Chart associated with the provider-reported encounter(s) was reviewed in the Chart Review Program., regardless of whether there is a provider identifier match. If Defendants' Risk Adjustment Databases indicate that the beneficiary only saw one provider on a given date of service, and there is a Chart associated with that beneficiary and date of service, the Chart must be associated with that same provider.

38. As explained in my **Report, Section IV.E**, there are valid reasons why the provider identifier may differ between a provider-reported encounter and the chart review record of that encounter. Chart review records may include “dummy” provider identifiers or provider identifiers corresponding to a provider related to but different from the true provider who had the face-to-face encounter with the beneficiary and who is typically the provider identified in provider-reported encounters. For example, a related provider may be another provider practicing in the same office or location as the provider who had the face-to-face encounter with the beneficiary.
39. When determining whether only one provider identifier is associated with a particular date of service in Defendants' Risk Adjustment Databases for a given beneficiary, I consider provider identifiers associated with both single-day encounters (*i.e.*, encounters where the start and end dates are the same) and multi-day encounters (*i.e.*, encounters where the end date is after the start date). This means that for a given date of service, I count the number of distinct providers across both single-day encounters taking place on that date and multi-day encounters where the service date range includes that date. As discussed in **Section III.A**, I use Provider ID as the provider identifier in IRADS and NPI as the provider identifier in EDPS. I therefore use Provider ID to count providers on each date of service in IRADS and I use NPI to count providers on each date of service in EDPS.⁴⁹
40. As I explain in my **Report, Section VI.E** and discuss further in **Section VI.A.iv** below, deposition testimony indicates that a technical issue may have impacted transmission of data from certain Provider-Reported Claims Databases to IRADS during the at-issue

⁴⁹ Each encounter in EDPS can be associated with a rendering provider and a billing provider. To select a provider identifier for use in counting, I choose the field that is populated with an individual NPI, according to the NPES data discussed in **FN 24** above. In the rare case that both fields are populated with an individual NPI, I give preference to the rendering provider NPI.

period.⁵⁰ I therefore also check the Provider-Reported Claims Databases to ensure that there is just one provider associated with the date of service in those databases before I match a provider-reported encounter from IRADS to chart review using this method.

41. To demonstrate this method of matching, reconsider the hypothetical shown in **Exhibit B** above. Based on the provider identifiers in the provider-reported encounter data, this beneficiary saw one provider on January 1, 2010 (Provider 123) and two providers on March 1, 2010 (Providers 456 and 789). Because only one provider identifier is associated with January 1, 2010 and we observe a chart review record associated with that exact date, I would conclude under this method that the chart reviewed with Chart ID 123abc-45de was associated with provider-reported encounter 0000A00001, making encounter 0000A00001 a Reviewed Encounter.
42. In this example, the provider identifiers on the provider-reported encounter and the chart review record match exactly (both are Provider 123). However, if the provider identifier in chart review for the January 1, 2010 encounter were Provider 999, encounter 0000A00001 would still be considered a Reviewed Encounter under my second method, because only one provider was seen on January 1, 2010 and there is a chart review record for January 1, 2010.
43. In contrast, neither encounter 0000A00002 nor encounter 0000A00003 would be considered a Reviewed Encounter under my second method. While these two encounters take place on a date of service that is observed in Defendants' chart review data, they are associated with different providers (*i.e.*, the provider count is two for that beneficiary-date of service combination) and it is unclear which encounter was reviewed without

⁵⁰ Deposition of Marybeth Meyer, *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. 16-08697 FMO, June 7, 2022 ("Meyer Deposition"), 232:19–233:10 ("Well, the focus on the data issues really came with the implementation of the Encounter Data System. That was also one of the ways where we identified that the data being submitted to Optum and then being submitted to CMS via the new encounter data submitted system was -- had gaps in it. And the Encounter Data System, we started submitting data to CMS in -- was 2012 dates of service. I think it was mid-- early to mid-2013 EDS data started to go to CMS, and CMS did not move to EDS as a primary -- as the only source of risk adjustment calculation until dates of service. So I would say from the 2012 dates of service all the way through the 2021 dates of service, there was a lot of activity on improving the completeness of the date of submissions."). I perform this check when matching IRADS provider-reported encounters to chart review only. I do not perform a similar check when matching EDPS provider-reported encounters to chart review as the deposition testimony indicated the technical issue was specific to IRADS.

additionally comparing provider identifiers. However, since one of the provider identifiers (456) does match exactly, 0000A00002 would be considered reviewed under my first method.

IV. IDENTIFICATION OF SUPPORTED DIAGNOSIS CODES

44. After identifying provider-reported encounters in Defendants' Risk Adjustment Databases that were reviewed in Defendants' Chart Review Program (*i.e.*, Reviewed Encounters), I check whether the diagnosis codes from those provider-reported encounters were supported by the chart review. I consider an instance of a given diagnosis code from a provider-reported encounter to be supported if, and only if, the same diagnosis code is included in the chart review record of that encounter in Defendants' Risk Adjustment Databases.⁵¹ Otherwise, I consider that particular diagnosis code instance to be unsupported.
45. As an example, consider the reviewed encounter on January 1, 2010 for Beneficiary 123456789A discussed above (encounter number 0000A00001). Since I determined that this provider-reported encounter was a Reviewed Encounter, I next determine whether its associated diagnosis codes were identified in Defendants' Chart Review Program by looking to the corresponding chart review data in Defendants' Risk Adjustment Database. **Exhibit C** shows that diagnosis codes 25000, 43491, and 5569 were reported by the provider. However, only diagnosis codes 25000 and 43411 were identified by Defendants in their Chart Review Program. I therefore consider diagnosis 25000 to be supported and diagnosis codes 43491 and 5569 to be unsupported.⁵² If my method had *not* determined that encounter number 0000A00001 was a Reviewed Encounter, I would of course not find any diagnosis codes unsupported in this case.

⁵¹ I perform this comparison in IRADS using encounters with a SUB_SOURCE_CD value of "CHARTAUDIT." As noted above, EDPS does not contain an analogous field to identify records originating from Defendants' Chart Review Databases. I therefore rely on Defendants' Chart Review Databases directly for EDPS.

⁵² While I do not consider diagnosis code 43491 to be supported, I check for other diagnosis codes mapping to the same HCC as an unsupported diagnosis code – such as diagnosis code 43411 in this hypothetical – before I classify an unsupported diagnosis such as 43491 as a Delete.

Exhibit C
Provider-Reported Diagnosis Codes

Beneficiary	Encounter	Start Date	End Date	Provider	Source	Diagnosis	HCC
123456789A	0000A00001	1/1/2010	1/1/2010	000000123	Claims	25000	19
123456789A	0000A00001	1/1/2010	1/1/2010	000000123	Claims	43491	96
123456789A	0000A00001	1/1/2010	1/1/2010	000000123	Claims	5569	33

Chart Review Diagnosis Codes

Beneficiary	Chart ID	Start Date	End Date	Provider	Source	Diagnosis	HCC
123456789A	123abc-45de	1/1/2010	1/1/2010	000000123	Chart Review	25000	19
123456789A	123abc-45de	1/1/2010	1/1/2010	000000123	Chart Review	43411	96

V. IDENTIFICATION OF SUBMITTED DIAGNOSIS CODES

46. As explained in my **Report, Section VI.C**, both of Defendants' Risk Adjustment Databases, IRADS and EDPS, contain fields that indicate whether each diagnosis code was submitted to, and accepted by, CMS. Diagnosis codes submitted by Defendants to CMS were maintained by CMS in parallel risk adjustment databases to IRADS and EDPS, known as RAPS and CMS EDPS, respectively. In this section, I describe how I identify submitted diagnosis codes among those diagnosis codes associated with Reviewed Encounters.⁵³
47. During the at-issue period, it was Defendants' policy not to submit some duplicate diagnosis codes from IRADS to RAPS if the same diagnosis code had already been submitted for a given beneficiary for the same service year.⁵⁴ In these cases, diagnosis

⁵³ To confirm I am correctly identifying submitted diagnosis codes, I replicate the risk scores that CMS calculates for each beneficiary using the list of submitted diagnosis codes that I identify. As discussed in **Section IX.B**, I am able to replicate 98% of beneficiary Part C risk scores recorded by CMS and 95% of Part D risk scores.

⁵⁴ Bird Deposition Volume 1, 194:6 – 196:10 (“So there’s other codes that CMS would – so a true duplicate, then you were not supposed to submit to CMS. They didn’t want to get multiple versions of the same code submitted. This was a process that was implemented internally. And legend has it that at the request of CMS – I don’t know exactly what the source was – to limit the amount of data that they were receiving where only one member diagnosis combination per six months should be submitted for risk adjustment purposes.”); Deposition of Melissa Sedor 30(b)(6), *United States of America, ex rel. Benjamin Poehling v. UnitedHealth Group, Inc., et al.*, No. CV 16-08697 FMO, June 29, 2023 (“Sedor Deposition”), 101:6–23 (“Q. And in RAPS, CMS had a

codes would be flagged in IRADS as not submitted even though they were eligible for use in risk adjustment. Therefore, in IRADS, even when an encounter is eligible for use in risk adjustment, not every risk-adjustment eligible diagnosis code associated with that encounter was necessarily submitted to and accepted by CMS. To identify submitted and accepted diagnosis codes in IRADS, I rely on two fields, which reflect the “state” of the diagnosis code (*i.e.*, whether it was submitted by Defendants to CMS)⁵⁵ and the “status” of the diagnosis code (*i.e.*, whether it was accepted by CMS).^{56, 57} If a diagnosis code associated with a Reviewed Encounter is associated with a state of “CMS Response Processed” and a status of “RAPS Accepted,” I consider that diagnosis code to have been submitted by Defendants and accepted by CMS.

48. CMS EDPS processing was not similarly limited. CMS guidance to MAOs was to submit all diagnosis codes associated with risk adjustment-eligible encounters, regardless of whether the diagnosis code had already been submitted with another encounter in the same year. As discussed in **Section III.B.i**, I rely on a combination of fields in EDPS to determine the most recent accepted version of each provider-reported encounter. Consistent with CMS guidance, I consider all diagnosis codes associated with the most recent accepted version of these encounters to be submitted to and accepted by CMS.

VI. IDENTIFICATION OF POTENTIAL DELETES

49. As explained in my **Report, Section VI.D**, I identify Potential Deletes in two steps. I first create a list of all diagnosis codes that are Submitted Diagnosis Codes but not Supported Diagnosis Codes (*i.e.*, all diagnosis codes from Reviewed Encounters that were submitted

policy that you couldn’t have more than 5 percent duplicate diagnosis clusters; right? A. Yes. ... Our business practice was to submit one and not two.”).

⁵⁵ To obtain the “state” of each diagnosis code, I use the REC_STATE_KEY in IRADS, which contains a numerical value from 1 to 10, and map that a meaning using a crosswalk produced by Defendants. MARA2083697.

⁵⁶ To obtain the “status” of each diagnosis code, I rely on the REC_STATUS_KEY in IRADS, which contains a numerical value from 1 to 13, and map that a meaning using a crosswalk produced by Defendants. MARA2083698.

⁵⁷ Cannon Deposition Volume 1, 301:1–304:2 (“Is there a way to tell from the data whether those specific diagnosis codes were in fact submitted to CMS and accepted by RAPS? THE WITNESS: A potential way is to utilize the Rec_State and Rec_Status_Key. The best way to do that is really to utilize the RAPS return data from CMS.”). As discussed below, I also look for diagnosis codes in the finalized CMS data, which should correspond to the RAPS return data.

to CMS but were not supported by chart review). I then remove from this list any diagnosis codes where the Coder in the Chart Review Program found support for a different diagnosis that maps to the same HCC.⁵⁸ I therefore consider the provider-reported diagnosis code to be indirectly supported by the Chart Review if the diagnosis code reported by the provider and the diagnosis code recorded by the Coder in chart review map to the same HCC.

50. To illustrate this, consider the example of Beneficiary 123456789A's encounter on January 1, 2010 in **Exhibit C** above. While the chart review of this encounter did not find support for diagnosis code 43491, it did find support for diagnosis code 43411. Both diagnosis code 43491 and diagnosis code 43411 map to HCC 96. I would therefore *not* include diagnosis code 43491 on the list of Potential Deletes.⁵⁹ I would, however, include diagnosis code 5569 from the provider-reported encounter on the list of Potential Deletes, as the Coder in chart review did not record any diagnosis mapping to the same HCC (33).

VII. CLASSIFICATION OF POTENTIAL DELETES

51. As discussed in my **Report, Section VI.E**, I classify diagnosis codes on my list of Potential Deletes as meeting certain HCC-related criteria, which I then use to identify the Deletes list. Specifically, I assess whether diagnosis codes on my list of Potential Deletes map to the same HCCs as other diagnosis codes observed in Defendants' databases, which do not appear on the list of Potential Deletes, or to HCCs, which were recorded in Defendants' Claims Verification Program. For the former, I distinguish between other diagnosis codes that were submitted to CMS and other diagnosis codes that were not submitted to CMS. As explained in my **Report, Section VI.E**, I make this distinction because deleting a diagnosis code that maps to the same HCC as another *submitted* diagnosis code would have no impact on a beneficiary's risk score or payment, while deleting a diagnosis code that only maps to the same HCC as another *unsubmitted* code (or one that does not map to the same HCC as any other diagnosis code) would impact the beneficiary's risk score, and in turn, the risk adjustment payments.

⁵⁸ See **Report, Section III.B** for a discussion of how multiple diagnosis codes can map to the same HCC.

⁵⁹ I would also exclude diagnosis code 25000 from the list of Potential Deletes, as it is directly supported by the chart review record.

52. I discuss below the different data sources I use to examine these other submitted and other unsubmitted diagnosis codes. The first two data sources include both submitted and unsubmitted codes, while the others include only unsubmitted codes. I additionally discuss the Claims Verification data, which I also use as a basis for classifying diagnosis codes on my Potential Deletes list.

A. Data Sources

i. Chart Review Encounters in Defendants' Risk Adjustment Databases

53. I examine submitted and unsubmitted diagnosis codes associated with Chart Review encounters in Defendants' Risk Adjustment Databases. As discussed in **Section III.A.i** above, Chart Review records in IRADS are indicated with 'CHARTAUDIT' in the SUB_SOURCE_CD field. As I have not identified an equivalent field in EDPS to identify Chart Review records, I instead examine the broader set of all non-provider-reported diagnosis codes that are associated with risk adjustment-eligible encounters in EDPS, including but not limited to encounters originating from Chart Review.⁶⁰ For both IRADS and EDPS, I follow the method described in **Section V** above to identify submitted versus unsubmitted diagnosis codes from these encounters.

ii. Unreviewed Risk Adjustment-Eligible Encounters

54. I examine submitted and unsubmitted diagnosis codes associated with risk adjustment-eligible encounters in Defendants' Risk Adjustment Databases that I do not identify as Reviewed Encounters using either of the matching methods described in **Section III.C**.
55. For IRADS, I examine all diagnosis codes associated with provider-reported, risk adjustment-eligible encounters (the identification of which is described in **Section III.B**), which were not matched to Chart Review records using either matching method, either because the encounter was not reviewed or because it was reviewed but there was misalignment in the fields used for matching. I also examine a small number of additional risk adjustment-eligible diagnosis codes associated with encounters in IRADS that did not originate from provider-reported claims or from the Chart Review Program, according to

⁶⁰ I describe in **Section III.B.ii** the method I use to identify the final accepted version of risk-adjustment eligible provider-reported encounters in EDPS. I apply these same methods to identify the final accepted version of risk-adjustment eligible non-provider-reported encounters in EDPS.

the SUB_SOURCE_CD.⁶¹ As discussed in **Section V**, Defendants' practice in IRADS was to not submit duplicate diagnosis codes, even if those diagnosis codes were associated with a risk adjustment-eligible encounter. I choose to examine these unsubmitted diagnosis codes given the possibility that Defendants would have submitted them had they been the only instances of those diagnosis codes.^{62, 63}

56. For EDPS, I examine all diagnosis codes associated with provider-reported, risk adjustment-eligible encounters (the identification of which is described in **Section III.B.ii**), which were not matched to chart review records using either matching method.
57. For both IRADS and EDPS, I follow the method described in **Section V** above to identify submitted versus unsubmitted diagnosis codes from these encounters. In my examination of these diagnosis codes in both systems, I do not consider any diagnosis codes associated with these encounters, which were deleted by Defendants.

iii. Additional Chart Review Data

58. I examine diagnosis codes from Defendants' Chart Review Databases that do not appear in Defendants' Risk Adjustment Databases. These diagnosis codes are necessarily unsubmitted. I consider all such diagnosis codes, with the exception of diagnosis codes that Defendants have indicated they purposefully did not pass into their Risk Adjustment Databases. Defendants identified a set of 21 "error and omission" codes which, when associated with a diagnosis code in chart review data, would "block" the submission of that diagnosis code to its Risk Adjustment Databases.⁶⁴ I do not consider instances of diagnosis

⁶¹ These additional values for SUB_SOURCE_CD, including DIRECT and HOUSECALL, represent 6.3% of encounters in IRADS.

⁶² I do this because Defendants did not necessarily submit a previously unsubmitted instance of a given diagnosis code when a submitted instance of that diagnosis code was found to be unsupported. Sedor Deposition, 104:1–11 ("So if we had -- if the same member saw the same provider three times and got diagnosed with diabetes, we would only submit that one time and save the other two in the database. If at some point we found out that the one we chose to submit was no longer supported but we still had two others that were supported, then we chose to net those out because ultimately the impact to your risk score is still the same. You could still support that that member had diabetes for that date of service year.").

⁶³ The only exceptions are by state code, status code, and their associated descriptions are: 10-11, CMS Response Processed / Delete; 3-1, Front End Error / Front End Error; 4-4, Excluded / Excluded by User.

⁶⁴ The diagnosis codes that Defendants identified take on the following values: C01, C02, C03, C04, C05, C06, D01, D02, D03, D05, D06, D07, D09, D11, D12, D13, D14, D19, D20, D27 and D28. Production of Responses to Questions re: Chart Reviewed File 4(C)(iv) – Chart Error & Omission Codes and Chart Reviewed File 4(C)(v) – Diagnosis Error & Omission Codes, December 1, 2016, p. 2.

codes associated with these error and omission codes unless there is at least one instance of the same diagnosis code for a beneficiary within the service year that does not include one of these error and omission codes.

iv. Defendants' Provider-Reported Claims Databases

59. I examine diagnosis codes from Defendants' Provider-Reported Claims databases that do not appear in Defendants' Risk Adjustment Databases.
60. As shown in **Exhibit 9** in my Report, information from Defendants' Provider-Reported Claims databases that is relevant to risk adjustment generally was passed into Defendants' Risk Adjustment Databases. However, due to testimony from a witness in this matter regarding a potential technical issue with this transmission during the at-issue period, I examine diagnosis codes that may not have been transmitted from these systems in my classification of Potential Deletes.
61. The witness did not specify with certainty the time period over which the transmission process was affected, nor did the witness specify which of multiple Provider-Reported Claims systems were impacted.⁶⁵ I therefore processed data from several of the largest Provider-Reported Claims systems in an effort to identify diagnosis codes that may not have been properly transmitted to IRADS. I refer to these claims systems by the following names, as recorded in the MEMBER_SOURCE_CD field in IRADS: COSMOS, NICE, FACETSRV, FACETSCSP, and SNFCT. Together, these systems represent 96.8% of diagnosis codes associated with provider-reported encounters in IRADS from service dates 2008–2016. While many diagnosis codes present in these Provider-Reported Claims databases may not have been transmitted to IRADS for a valid reason other than the technical issue (*e.g.*, the claim is for an encounter that is not risk adjustment-eligible), I

⁶⁵ The witness mentioned COSMOS and FACETS as examples of impacted systems but could not confirm that these were the only impacted systems. Meyer Deposition, 196:9–197:9 (“A. There is multiple claim -- claim processing systems. There’s -- there’s Facets; there’s Cosmos. Those are the two big claim processing systems that process Medicare Advantage claims. ... They included information that Optum did not have. They did not receive that information in their data feeds. Q. Any other system besides Facets and Best [sic]? A. I think there were other claims processing systems. There’s been a lot of, you know, company acquisitions where you get their claim processing system and then it gets merged. I can’t think of other system names. ... Q. Was this additional data that you’re referring to not in IRADS? A. Correct. It’s not in IRADS.”).

identify and examine a broad set of diagnosis codes in these databases that were not transmitted to IRADS. I describe my process for identifying these diagnosis codes below.

62. Across the Provider-Reported Claims databases, the following information is available for a given medical claim: beneficiary information (*e.g.*, ID number, first name, last name, date of birth), provider information (*e.g.*, provider identifier, specialty, name, address), dates of service, diagnosis codes, and procedure codes.
63. In processing the data from each Provider-Reported Claims database, I first identify the variables that would enable me to match beneficiaries and encounters to IRADS (including dates of service, provider identifiers, and diagnosis codes). For each database and year, I then take the following steps to generate a list of diagnosis codes that may not have been transmitted to IRADS due to the technical issue mentioned above. First, I identify all beneficiaries associated with the particular claims database in IRADS that year using the MEMBER_SOURCE_CD field and limit the Provider-Reported Claims data to data associated with these beneficiaries. Second, I identify the encounters in the Provider-Reported Claims data for which there is an encounter match to IRADS.⁶⁶ For *matched* encounters, I then identify those diagnosis codes associated with the encounter in the Provider-Reported Claims database, which are not observed in IRADS as part of the same encounter.⁶⁷ For *unmatched* encounters, I identify those diagnosis codes associated with the encounter in the Provider-Reported Claims database, which were not observed in IRADS under the same dates of service and provider. In a third and final step, I generate for each beneficiary and year a list of unique diagnosis codes for examination based on the diagnosis codes identified in the second step.

⁶⁶ I match encounters using member identifiers, encounter identifiers, and dates of service. In this step, I limit provider-reported encounters in IRADS to those where the MEMBER_SOURCE_CD corresponds to the claims system being analyzed. In the largest Provider-Reported Claims database, COSMOS, I find that up to 13% of encounters have no match in IRADS and up to 0.5% of diagnosis codes from matched encounters are not observed in IRADS, depending on the year. For unmatched encounters, I find that up to 29% of diagnosis codes are not observed in IRADS under the same dates of service and provider, depending on the year.

⁶⁷ I identify unobserved diagnosis codes from observed encounters, as well as diagnosis codes observed in unobserved encounters given deposition testimony that the technical issue impacted entire claims as well as certain diagnosis codes on claims. Meyer Deposition, 200:15–17 (“[T]hey had been missing claims. They had been missing diagnosis codes on claims.”).

v. Data from Defendants' Claims Verification Program

64. I examine HCCs that were recorded in the Claims Verification program. To the extent that Claims Verification Coders identified HCCs supported by a Chart, and that had not already been identified by a Chart Review Coder, I consider such HCCs in my examination. Diagnosis codes mapping to HCCs that originated from CV are present in IRADS, as well as in separate CV datasets produced by Defendants, and I use both of these sources to identify diagnosis codes and HCCs recorded in the CV program. In IRADS, these are associated with a SUB_SOURCE_CD of 'CVADD'. In Defendants' CV datasets, I identify supported diagnosis codes and HCCs as those confirmed by either the initial CV Coder or the second, "expert" CV coder, as identified in the fields CV_REVIEW_CODED and CV_EXPERT_REVIEW_CODED. I also examine diagnosis codes and HCCs with a "disposition code" that indicates support was found for the medical condition the CV Coder was looking for.⁶⁸

VIII. IDENTIFICATION OF DELETES

65. As explained in my **Report, Section VI.F**, I identify Deletes as those diagnosis codes from the Potential Deletes list which did not meet *any* of the three criteria defined in my **Report, Section VI.E**. Deletes therefore represent diagnosis codes that do not share an HCC with any other submitted diagnosis code, do not share an HCC with any other risk adjustment-eligible but unsubmitted diagnosis code, and do not map to an HCC recorded in the Claims Verification program.
66. In addition, I require that Deletes satisfy several additional checks. Specifically, I do not consider as Deletes any of the following:
- i. Diagnosis codes that did not impact risk adjustment payments for the beneficiary, including diagnosis codes for newly enrolled beneficiaries;⁶⁹
 - ii. Diagnosis codes associated with beneficiaries who were not enrolled in a Medicare Advantage plan (or in the case of Part D, a MA-PD plan) for the whole year;

⁶⁸ These disposition codes include CVD02 (HCC and RxHCC on Chart) and CVD03 (Higher HCC and RxHCC on Chart). Production of Responses and Documents Responsive to CR / CV Interrogatories 1(A), 1(E), 3(A)-(B), 3(E), 3(H), 3(M), and 6 and Document Requests 4(C)(iv)(n) and 5, January 29, 2016, p. 6.

⁶⁹ I identify new enrollees using the RAF type, as discussed in **Section IX.A.v**.

- iii. Diagnosis codes associated with beneficiaries who were not enrolled in Defendants' plans during the year; and
 - iv. Diagnosis codes associated with beneficiaries with end stage renal disease, whose risk adjustment payments are not determined by the CMS HCC Model or the CMS RxHCC Model.⁷⁰
67. For checks (ii) and (iii), I identify beneficiaries enrolled in Defendants' plans for at least one month of the year using a list of plan identifiers and dates produced by Defendants.⁷¹
68. The final Deletes list is additionally limited to beneficiaries for whom I can perfectly replicate actual risk scores, as described in **Section IX.B** below. The final Deletes list for Part D additionally excludes diagnosis codes which only impact Part D risk scores and which are associated with beneficiaries enrolled in MA-PD plans for which changes in risk corridor payments fully offset changes in direct subsidy payments.

IX. CALCULATION OF FINANCIAL IMPACT OF DELETES

69. As explained in my **Report, Section III.B**, Defendants received risk adjustment payments from CMS based on their beneficiaries' risk scores, based on beneficiary demographics and diagnosis codes MAOs submit to CMS. Risk scores are fundamental to my calculation of the financial impact of Defendants' failure to delete the diagnosis codes I identify as Deletes.
70. The financial impact of Defendants' failure to submit the Deletes is equal to the amount of risk adjustment payments that Defendants retained, which were associated with these Deletes. I calculate this amount in three steps. First, I calculate a revised risk score for each beneficiary using a list of diagnosis codes that excludes diagnosis codes on the Deletes list. Second, I calculate the change in risk score as the difference between this revised risk score and the actual risk score that CMS used to determine risk adjustment payments to Defendants. As part of this step, I ensure I can replicate the actual risk score for each

⁷⁰ I identify beneficiaries with end stage renal disease using the RAF type, as discussed in **Section IX.A.v**.

⁷¹ Defendants produced lists of their plan numbers, identified by CONTRACT_NBR, which do not include stand-alone prescription drug plans. My analysis therefore only includes Medicare Advantage Part C plans and Medicare Advantage plans with both Part C and Part D coverage. To limit to months in which a beneficiary was covered by a Defendants' plan I limit to months that fall between FROM_DT and THRU_DT. I do not include plans where CONTRACT_DESC is "INVALID CONTRACT NUMBER" or IS_BAD is equal to 1.

beneficiary in each year. Third, I use the change in each beneficiary's risk score to calculate an implied change in per member per month payments for each beneficiary. The calculated change in payments represents the payments retained by Defendants for the Deletes.

A. Revised Risk Scores

71. For each beneficiary and year, I calculate risk scores using CMS' risk adjustment model software, which is publicly available on the CMS website.⁷² The software, which includes SAS macros and formats corresponding to different risk scoring models, is released every year for the upcoming payment year. Each yearly release includes the CMS HCC Model⁷³ and the CMS RxHCC Model, among others.⁷⁴ The CMS HCC Model is used to calculate risk scores and payments for the majority of Part C beneficiaries, while the CMS RxHCC Model is used to calculate risk scores and payments for Part D.

i. Model Inputs

72. The CMS HCC Model software and CMS RxHCC Model software both require two main inputs for each beneficiary: beneficiary diagnosis codes and beneficiary demographics. The beneficiary demographics used by the model are the beneficiary's sex, date of birth, Medicaid status, and original reason for enrollment in Medicare ("OREC").⁷⁵

⁷² "Medicare risk adjustment information," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors>, downloaded on June 16, 2023.

⁷³ For some years at issue in this matter, there are two CMS HCC Models. As explained in my **Report, Section III.B**, the CMS Model assigns a numeric value to various factors that affect the expected costs to cover a beneficiary, including health status and demographics. The version of the model corresponds with its calibration, which is the process by which those factors that affect the expected costs to cover a beneficiary are assigned the numeric coefficient that contributes to a beneficiary's risk score. From payment year 2009 to 2013 scores were calculated using version 12 of the CMS HCC Model. In payment year 2014 model was recalibrated, which correspond with version 22 of the CMS HCC Model.

⁷⁴ The software also includes programs to calculate risk scores for beneficiaries whose payments are determined by other models, such as beneficiaries with end stage renal disease ("ESRD"). "Medicare risk adjustment information," Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors>. Some beneficiaries also have a "frailty" adjustor, which mandated that capitated payments for beneficiaries enrolled in the Program of All-Inclusive Care for the Elderly (PACE) be adjusted for the comparative frailty of PACE enrollees. I exclude ESRD and PACE beneficiaries from my analysis. Additionally, I exclude beneficiaries for whom I do not have sufficient data to complete my analyses, including new enrollees, beneficiaries in the data for less than 12 months in a year, and beneficiaries with no populated payment amount.

⁷⁵ The original reasons for enrollment in Medicare include old age, disability, ESRD, or both disability and ESRD.

73. To identify the diagnosis codes relevant to beneficiaries' revised risk scores, I begin with a list of unique diagnosis codes that Defendants submitted to CMS. I identify these diagnosis codes using the method described in **Section V**, but I include all risk adjustment-eligible encounters in the service year rather than just Reviewed Encounters. I then remove from this list all diagnosis codes on the Deletes list. Finally, I add to this list any diagnosis codes that plans *not* administered by Defendants submitted to CMS for the beneficiary in the relevant service year. (These may exist if the beneficiary switched plans mid-year.) These additional diagnosis codes appear in the RAPS and CMS EDPS databases with submission information linked to plans that are not associated with Defendants.⁷⁶
74. I obtain beneficiary demographic information from multiple datasets produced by CMS. I obtain each beneficiary's gender and date of birth from data produced by CMS with information on beneficiaries.⁷⁷ I use Risk Adjustment System ("RAS") data to determine whether the beneficiary is enrolled in Medicaid.⁷⁸ Finally, I use MARx ("Medicare Advantage Prescription Drug System") data to obtain information on the beneficiary's original reason for enrolling in Medicare.

ii. Raw Risk Scores

75. The CMS model software uses a list of diagnosis codes and demographics for each beneficiary to determine which HCCs and RxHCCs contribute to that beneficiary's risk score. Within a given population segment (discussed further below), every HCC or RxHCC

⁷⁶ To identify plans that are not administered by Defendants, I again rely on the list of plans produced by Defendants, described in **Section VIII** above. As discussed in **Section III.B**, EDPS, unlike IRADS, can contain multiple versions of a single encounter. The same is true for CMS EDPS. In CMS EDPS, I use the same method to identify the most recent accepted version of each encounter as I do in EDPS. Also similar to EDPS, in CMS EDPS I identify risk-adjustment eligible encounters using TOB and CPT/HCPCS codes, following the CMS Final Encounter Data Diagnosis Filtering Logic as described in **Section III.B**.

⁷⁷ The beneficiary's age is calculated by CMS software as of February 1 of the payment year based on his or her date of birth, in the BENE_BRTH_DT field. The beneficiary's gender is determined based on the BENE_SEX_CD field.

⁷⁸ The fields indicating whether the beneficiary is enrolled in Medicaid are BENE_MD CD_MALE_DSBLD_SW, BENE_MD CD_MALE_AGED_SW, BENE_MD CD_FEML_DSBLD_SW, and BENE_MD CD_FEML_AGED_SW.

is assigned an HCC or RxHCC factor that quantifies its additive contribution to the beneficiary's total risk score.⁷⁹

76. The CMS HCC Model software generates multiple risk scores for each beneficiary corresponding to certain population segments. For payment years prior to 2011, the CMS HCC Model generates risk scores for three population segments: Community, Institutional, and New Enrollee.⁸⁰ Starting in payment year 2011, the CMS HCC Model includes a fourth segment for new enrollees in Medicare special needs plans, and starting in payment year 2016, the Community segment of the CMS HCC Model is split into six sub-categories based on Medicaid and Medicare eligibility.⁸¹
77. For payment years 2009 and 2010, the CMS RxHCC Model generates a base risk score, which is then scaled with a multiplier for beneficiaries belonging to four population segments characterized by income, institutional status, and low-income subsidy eligibility.⁸² Starting in payment year 2011, the CMS RxHCC Model generates segment-specific risk scores for eight population segments characterized by income, institutional status, and Medicare eligibility.⁸³

iii. Risk Score Adjustment

78. I make two adjustments to the risk scores that are output by the CMS HCC and CMS RxHCC Model software, which are consistent with adjustments performed by CMS.

⁷⁹ As discussed in my **Report, Section III.B** some combinations of HCCs also increase the risk score by a disease interaction factor.

⁸⁰ Community refers to a beneficiary who is not institutionalized or who is institutionalized for less than 90 days in the year. Institutional refers to a beneficiary who is institutionalized in a place such as a nursing home for more than 90 days in the year. "Medicare Managed Care Manual Chapter 7 - Risk Adjustment," Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf>, accessed October 15, 2022, p. 11.

⁸¹ These included six segments defined by three types of Medicaid Eligibility (Full Benefits, Partial Benefits, and Non-Dual) and two types of Medicare Eligibility (aged and disabled).

⁸² These segments include Low Income (partial), Low income (full), Long Term Institutional (aged), and Long Term Institutional (disabled). I identify long term institutional status and low-income status using the fields BENE_PTD_LTI_CD and BENE_PTD_LOW_INCM_STUS_IND in MARx, respectively.

⁸³ These segments include Aged, non-low income; Aged, low income; Disabled, non-low income; Disabled, low income; Institutional; New Enrollee, non-low income; New Enrollee, low income; and New Enrollee, institutional.

79. The first adjustment is applied to both CMS HCC and CMS RxHCC Model risk scores and involves dividing all risk scores by a normalization factor. CMS performs this adjustment to ensure that, despite variation in average expenditures for Traditional Medicare beneficiaries over time, a beneficiary's expected expenditure continues to equal that beneficiary's risk score times the expenditure of the average Traditional Medicare beneficiary in the payment year.⁸⁴ The annual normalization factor is calculated by CMS separately for each model by fitting a trend to a sliding window of five years of data. Every year, the dataset used to calculate the normalization factor is updated by dropping the oldest year in the dataset and adding a new year.⁸⁵ In accordance with CMS calculations, I divide each beneficiary's risk scores for Part C and Part D by the relevant normalization factors.⁸⁶
80. The second adjustment applies only to risk scores generated by the CMS HCC Model starting in plan year 2010. It accounts for differences in diagnostic coding practices between Medicare Advantage and Traditional Medicare plans. I make this adjustment by multiplying relevant risk scores by a quantity equal to one minus a coding intensity adjustment factor, which is released annually by CMS.⁸⁷

⁸⁴ "Because average predicted FFS risk scores increase after the model calibration year due to coding and population changes, CMS applies a normalization factor to adjust beneficiaries' risk scores so that the average risk score is 1.0 in subsequent years." "Medicare Managed Care Manual Chapter 7 - Risk Adjustment," Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf>, accessed October 15, 2022, p. 32.

⁸⁵ *Ibid.* p. 32 ("The normalization factor is calculated by first using the model to predict risk scores for the FFS population over a number of years. Next, CMS estimates the annual average trend in the risk scores over these years. This annual trend is then compounded by the number of years between the model denominator year and the payment year to produce the normalization factor for the payment year.").

⁸⁶ For Part C, the normalization factors range from 0.988-1.034, depending on the service year. For Part D, the normalization factors range from 0.980-1.015, depending on the service year. "Announcements and Documents," Centers for Medicare & Medicaid Services, September 6, 2023, <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents>, accessed September 29, 2023.

⁸⁷ Specifically, I multiply the normalized risk score by (1 – the coding intensity adjustment factor). For more details on how the coding adjustment factor is calculated, see "Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," Centers for Medicare & Medicaid Services, February 20, 2009, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/advance2010.pdf>, accessed September 26, 2023, pp. 9–11.

81. When applying these adjustments, I follow CMS practices for rounding, which is to round to the third decimal place after each risk score calculation step.⁸⁸

iv. Risk Score Weighting

82. After applying the adjustments described above, I follow CMS practice by combining certain pairs of risk scores into a single blended risk score.
83. The first combination of risk scores stems from the fact that there were two versions of the HCC CMS Model software – version 12 and version 22 – during the at-issue period.⁸⁹ Version 12 was used for payment years 2009-2013, version 22 was used for payment years 2016-2017, and both versions were used in payment years 2014-2015. The CMS HCC Model therefore generates separate risk scores for each version in payment years 2014-2015. For each beneficiary and population segment, I calculate a single risk score as a weighted combination of the version 12 and version 22 risk scores. In payment year 2014, version 12 is weighted at 25% and version 22 is weighted at 75%.⁹⁰ In payment year 2015, version 12 is weighted at 67% and version 22 is weighted at 33%.⁹¹
84. The second combination of risk scores stems from Defendants’ and CMS’ use of two Risk Adjustment Databases in payment years 2015-2017 (service years 2014-2016). As discussed in my **Report, Section IV.D**, all diagnosis codes present in either of the two CMS databases (RAPS and CMS EDPS) are pooled and counted in payment year 2015,

⁸⁸ *Risk Adjustment for EDS & RAPS User Group*, Centers for Medicare & Medicaid Services, August 15, 2019, [https://www.csscooperations.com/internet/csscw3_files/nsf/F/CSSC081519_RAWebSlides_5CR_082019.pdf/\\$FILE/081519_RAWebSlides_5CR_082019.pdf](https://www.csscooperations.com/internet/csscw3_files/nsf/F/CSSC081519_RAWebSlides_5CR_082019.pdf/$FILE/081519_RAWebSlides_5CR_082019.pdf), accessed September 25, 2023, p. 11.

⁸⁹ “Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter,” Centers for Medicare & Medicaid Services, February 15, 2013, <https://www.cms.gov/medicare/health-plans/medicareadvgtgspeccratestats/downloads/advance2014.pdf>, accessed September 29, 2023, pp. 16, 63. Although there were two versions of the RxHCC software during the at-issue years, the model transitioned directly from version 3 to version 5 in payment year 2016 and did not require blending.

⁹⁰ “Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 1, 2013, <https://www.cms.gov/medicare/health-plans/medicareadvgtgspeccratestats/downloads/announcement2014.pdf>, accessed September 14, 2023, p. 2.

⁹¹ “Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Centers for Medicare & Medicaid Services, April 7, 2014, <https://www.cms.gov/medicare/health-plans/medicareadvgtgspeccratestats/downloads/announcement2015.pdf>, accessed September 14, 2023, p. 2.

but risk scores are calculated separately for RAPS and CMS EDPS in payment years 2016 and 2017. I therefore input a list of all beneficiary diagnosis codes submitted across both systems to the CMS HCC and CMS RxHCC Model software in payment year 2015. In payment years 2016 and 2017, I follow CMS practice and calculate a single blended risk score for each segment by weighting the RAPS risk score at 90% and the CMS EDPS risk score at 10% in payment year 2016 and weighting the RAPS risk score at 75% and the EDPS risk score at 25% in payment year 2017.⁹²

85. When applying these adjustments, I again follow CMS stated practices for rounding with one exception. When calculating blended RAPS and CMS EDPS risk scores in payment year 2016, I truncate scores rather than rounding them in order to replicate the risk scores as calculated by CMS that year.⁹³

v. Risk Score Selection

86. After completing the adjustment and weighting steps described above, I select the appropriate Part C and/or Part D risk scores for each beneficiary, according to their demographics and benefit type(s).
87. For each beneficiary with Part C benefits, I select a risk score for each month based on the beneficiary's model segment in that month. A beneficiary's Risk Adjustment Factor ("RAF") type, either alone or in combination with the beneficiary's age, indicates the model segment used by CMS to calculate the beneficiary's final risk score.⁹⁴ I identify each

⁹² *Risk Adjustment for EDS & RAPS User Group*, Centers for Medicare & Medicaid Services, November 17, 2016, [https://www.csscooperations.com/internet/cssc3_nsf/files/RA_Slides_111716_5CR_111816.pdf/\\$File/RA_Slides_111716_5CR_111816.pdf](https://www.csscooperations.com/internet/cssc3_nsf/files/RA_Slides_111716_5CR_111816.pdf/$File/RA_Slides_111716_5CR_111816.pdf), accessed September 28, 2023, p. 56.

⁹³ CMS identified an error and subsequently corrected it, however, this error is observable in the data produced by CMS. See "Risk Adjustment for EDS and RAPS User Group," CMS, August 15, 2019, available at *Risk Adjustment for EDS & RAPS User Group*, Centers for Medicare & Medicaid Services, August 15, 2019, [https://www.csscooperations.com/internet/csscw3_files_nsf/F/CSSC081519_RAWebSlides_5CR_082019.pdf/\\$FILE/081519_RAWebSlides_5CR_082019.pdf](https://www.csscooperations.com/internet/csscw3_files_nsf/F/CSSC081519_RAWebSlides_5CR_082019.pdf/$FILE/081519_RAWebSlides_5CR_082019.pdf), accessed September 25, 2023 at slide 11 ("CMS received questions describing instances where plan calculated risk scores differ at the third decimal place from CMS calculated risk scores (i.e., those shown on the monthly membership reports (MMR)). We discovered a technical issue in the way rounding was applied in the risk scores calculations and have corrected the issue. As we indicated in prior webinars, when validating risk scores plans should round at the third decimal place after each risk score calculation step.").

⁹⁴ For payment years 2009-2016, I select the community score (SCORE_COMMUNITY) for beneficiaries with RAF type 'C' and the institutional score (SCORE_INSTITUTIONAL) for beneficiaries with RAF type 'I'. For payment year 2017, when CMS introduced more granularity to the CMS HCC model segments, I follow CMS

beneficiary's RAF types using the BENE_RAF_TYPE_CD field in the MARx data. As this field may be retroactively updated in the MARx data to accommodate mid-year demographic changes, I follow CMS guidance in selecting the correct value for each beneficiary in each month.⁹⁵

88. In payment years 2010 – 2017, for each beneficiary with Part D benefits, I select a Part D risk score for each month based on the beneficiary's model segment. In payment years 2009 and 2010, I apply a multiplier to a single base score based on the beneficiary's model segment. A beneficiary's Long Term Institutional and Low-Income Status, either alone or in combination with the beneficiary's age, indicates the model segment used by CMS to calculate the beneficiary's final risk score.⁹⁶ I identify each beneficiary's Long Term Institutional Status and Low-Income Status using the BENE_PTD_LTI_CD and BENE_PTD_LOW_INCM_STUS_IND fields in the MARx data.⁹⁷

B. Changes in Risk Scores

89. After identifying revised risk scores for all beneficiaries, I calculate changes in risk scores as the difference between the revised risk scores and the actual risk scores that CMS used to calculate per beneficiary per month risk adjustment payments. For my analysis, I obtain the actual risk scores used by CMS from MARx data.⁹⁸ These risk scores represent the final risk score, after adjustments and weighting.

guidance in selecting the relevant risk score. "Announcement of the August 2019 Software Release," Centers for Medicare & Medicaid Services, July 29, 2019, <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Downloads/Announcement-of-the-August-2019-Software-Release.pdf>, accessed September 29, 2023, p. 2.

⁹⁵ To identify the RAF type ultimately used to determine a beneficiary's risk score and associated monthly payment, I identify instances of retroactive updates to the RAF type and replace the RAF type in any prior months in that payment year with the updated RAF type.

⁹⁶ Similar to Part C, I follow CMS guidance in identifying each beneficiary's model segment and calculating the relevant risk score. "Medicare Managed Care Manual Chapter 7 - Risk Adjustment," Centers for Medicare & Medicaid Services, September 19, 2014, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf>, accessed October 15, 2022, p. 26.

⁹⁷ See **FN 95** for a description of how I identify relevant values of these fields given MARx retroactive adjustments.

⁹⁸ I identify the actual risk score used by CMS in MARx using the same approach used to identify the beneficiary's RAF type, as described in **FN 95**.

90. As discussed in my **Report, Section VII.B**, as a confirmatory step, I ensure that I can replicate the risk score recorded in MARx for each beneficiary by following the steps outlined in **Section IX.A**, but using the full set of risk adjustment-eligible diagnosis codes that Defendants and other plans submitted to CMS. In months where a beneficiary is covered by Defendants, I am able to replicate 98% of the beneficiary Part C risk scores recorded in MARx and 95% of the Part D risk scores.⁹⁹ I exclude from my analysis any beneficiary for whom I cannot exactly replicate exactly the MARx risk score in the relevant year.¹⁰⁰ I exclude these beneficiaries to eliminate the possibility that the revised risk scores I calculate for the beneficiary are in any way inaccurate. As discussed in my **Report, Section VII.B**, I apply this exclusion by removing diagnosis codes for these beneficiaries from the final Deletes list in the year, meaning these beneficiaries have no financial impact and do not contribute to the affected beneficiary counts.

C. Changes in Payment for Part C

91. After calculating changes in Part C risk scores, I calculate corresponding changes in risk adjustment payments. To do so, I multiply changes in risk scores for each beneficiary and month by the beneficiary's plan's base rate.
92. I derive the base rate using the MARx data using two elements: the monthly contract rate and a "Medicare as a Secondary Payor" reduction amount.^{101, 102} Similar to a beneficiary's RAF types and risk scores, plan base rates may be updated retroactively. I account for this

⁹⁹ This calculation does not include the beneficiaries I have excluded for the reasons discussed in **Section X**.

¹⁰⁰ The only exception is that for payment years 2016 and 2017, I still include 0.7% of beneficiary months in my analysis of Part C if I am able to replicate either their "raw" RAPS risk score or their "raw" CMS EDPS risk score, but not both. CMS' RAS data contain "raw" risk scores for each beneficiary. For these beneficiaries, I recalculate a revised risk score using the method described in **Section IX.A**, using (i) the actual "raw" risk score for the system where I cannot replicate the score; and (ii) the revised risk score I calculate for the system where I can replicate the score.

¹⁰¹ Similar to RAF types and risk scores, I identify the relevant values of these variables. Contract rates for Part C are associated with MARx variables BENE_PTA_CNTRCT_RATE_AMT and BENE_PTB_CNTRCT_RATE_AMT. *Plan Communication User Guide for Medicare Advantage Prescription Drug Plans*, Centers for Medicare & Medicaid Services, August 30, 2019, <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelppdesk/Downloads/Plan-Communication-User-Guide-v132-August-30-2019.pdf>, accessed September 25, 2023, section 6.

¹⁰² "When MSP status applies, the risk-adjusted portion of the Part C Payment is reduced to account for the coverage that the employer provides for Working Aged or Working Disabled beneficiaries, or that the health Plan provides for beneficiaries with ESRD." *Ibid.*, pp. 6-11.

and identify the actual base rates used by CMS using a similar approach, except that adjustment amounts have to be allocated evenly over the months to which the adjustment applies.¹⁰³

93. In some cases, the contract rate is not directly available in the MARx data and I derive it from other fields available in the MARx data. Specifically, I calculate the contract rate by dividing the portion of the risk adjustment payment that depends on the risk score by the actual risk score.¹⁰⁴ This method does not introduce uncertainty about the contract rate because the contract rate has a simple algebraic relationship to other quantities which are populated. I have confirmed that when I perform this calculation for contracts where the contract rate is available in the MARx data, my result always matches the stated contract rate.

D. Changes in Payment for Part D

94. I begin my approach for calculating changes in risk adjustment payments for Part D by multiplying changes in Part D risk scores for each beneficiary and month by the beneficiary's plan's base rate.
95. The base rate for Part D plans is also available in the MARx data. Like the Part C base rate, includes two elements: the direct subsidy and the beneficiary premium.¹⁰⁵ However, in Part C, both elements represent payments from CMS, and in Part D only the direct subsidy element is paid by CMS (the beneficiary premium is, as the name suggests, paid by the

¹⁰³ I apply retroactive adjustments to the MSP reduction amount in MARx by identifying instances of retroactive adjustments and reallocating payments to the relevant months. I identify the months over which to reallocate payments using BENE_PMT_ADJSTMNT_MSA_STRT_DT and BENE_PMT_ADJSTMNT_MSA_END_DT and calculate the final monthly payment amount by dividing the adjustment amount (BENE_PTA_MSP_RDCTN_ADJSTMT_AMT and BENE_PTB_MSP_RDCTN_ADJSTMT_AMT) by the number of months over which the adjustment applies (BENE_PTA_PMT_ADJSTMT_MOS_CNT and BENE_PTB_PMT_ADJSTMT_MOS_CNT).

¹⁰⁴ For the purpose of an analysis of repayments I am only concerned with the part of the payment that is a function of the risk score, since I am concerned with the financial impact of Defendants' failure to delete certain diagnosis codes and the resulting impact on risk scores. In addition to the MSP reduction amount, the portion of the payment that is a function of the risk score is identified by the following variables in MARx, which are also subject to the same reshaping as the MSP reduction amount: BENE_PTA_RISK_ADJSTMT_AMT and BENE_PTB_RISK_ADJSTMT_AMT.

¹⁰⁵ The direct subsidy and beneficiary Part D premium are derived from BENE_PTD_DRCT_SBSYD_PMT_AMT and BENE_PTD_BASIC_PRM_AMT in MARx and are adjusted for incremental updates using the method previously described.

beneficiary).¹⁰⁶ I therefore quantify changes in payments separately for payments Defendants received from CMS through direct subsidies and payments Defendants received from beneficiaries through beneficiary premiums.

96. I further adjust these changes in payments for the Part D program's risk corridors. The risk corridors are a symmetric risk-sharing mechanism between CMS and Part D plan sponsors, such as Defendants. They are symmetric in that they limit each plan's losses as well as profits. If a plan's spending in a year is much higher than anticipated, CMS provides the plan with additional payments. If a plan's spending in a year is much lower than anticipated, the plan returns a share of the prospective payments it received from CMS (*i.e.*, direct subsidy payments). Risk corridors are calculated using a statutory formula as part of a reconciliation process, which occurs six months after the end of each benefit year.¹⁰⁷
97. To account for risk corridors in my analysis of changes in Part D payments, I rely on Payment and Reconciliation System ("PRS") data from CMS.¹⁰⁸ For each plan and year, I recalculate the risk corridor payment using a revised measure of the plan's target amount, upon which the risk corridor payment is based.¹⁰⁹ For each plan and year, I calculate a revised target amount by subtracting the plan's total change in risk adjustment payments from the actual target amount that is in the PRS data, while adjusting for the administrative cost ratio. I then use this revised target amount to recalculate the plan's risk corridor payments with the formula used by CMS in its reconciliation process.
98. After calculating each plan's revised risk corridor payments, I calculate each plan's change in Part D payments from CMS as the change in their direct subsidy payments less their change in risk corridor payments. In doing so, I identify plans for which the change in risk

¹⁰⁶ "Apply for Medicare Part D Extra Help program," The United States Social Security Administration, <https://www.ssa.gov/medicare/part-d-extra-help>, accessed September 29, 2023.

¹⁰⁷ *Sharing Risk in Medicare Part D Chapter 6*, Medpac, June 2015, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-6-sharing-risk-in-medicare-part-d-june-2015-report-.pdf, accessed September 26, 2023.

¹⁰⁸ CMS reopens their reconciliations after four years and recalculates risk corridors to update payment calculations based on post-deadline submissions from MAOs.

¹⁰⁹ The target amount, identified by PRS variable TA, reflects the total amount paid to the plan for Part D less administrative costs and can be calculated as the sum of the total direct subsidy paid and the total beneficiary basic premium amount paid, times one minus the administrative cost ratio, which is the ratio of administrative costs to total costs for the Basic Benefit. USBP009865191.

corridor payments offsets the entire change in direct subsidy payments, as such plans would not have retained any Part D payments associated with Deletes.

X. FINANCIAL IMPACT OF DELETING DIAGNOSIS CODES ON DEFENDANTS' CV PIPELINE LISTS

99. I separately calculate the financial impact on Defendants' Medicare Advantage and Medicare Part D premium payments resulting from their failure to delete the diagnosis codes on Defendants' CV Pipeline Lists, as discussed in my **Report, Section VIII**.
100. For this calculation, I run the CMS software on all submitted diagnosis codes, minus any diagnosis codes on the Defendants' CV Pipeline Lists. This analysis does not rely on the Deletes list. As a final step, I make the same beneficiary exclusions as I do when calculating the financial impact of Deletes, discussed in **Section VIII**.

EXHIBIT D-58 INTENTIONALLY BLANK

EXHIBIT D-59

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al,

Defendants.

Case No. 16-cv-08697 FMO

**ERRATA TO
EXPERT REPORT OF CRAIG GARTHWAITE
MARCH 11, 2024**

1. I submitted a report in this matter on September 29, 2023, an initial errata on October 4, 2023, and a subsequent errata on January 5, 2024. On January 29, 2024, Mr. M. Timothy Renjilian submitted a rebuttal report to my report (the “Renjilian Rebuttal Report”). Since that time, my team and I have investigated two points that Mr. Renjilian raised in his rebuttal report that relate to **Attachment 1** to my report.
2. First, in footnote 32, the Renjilian Rebuttal Report stated that a number of member-dx-DOS combinations on my deletes list do not appear in CMS’ RAPS data. The Renjilian Rebuttal Report states that for each of these diagnosis codes, there is another instance of the same diagnosis code for that same member – but on another date of service for the member in the same service year – which was submitted to RAPS; thus, “the inclusion of the 46,149 diagnosis codes in the Deletes did not affect Dr. Garthwaite’s financial impact calculations.” I agree with these statements. The inclusion of these diagnosis codes also did not affect the counts of beneficiaries with financial impact in my report. However, the inclusion of these specific instances of these diagnosis codes that do not appear in RAPS was inadvertent, and I have removed these instances from the version of **Attachment 1** submitted with this errata.
3. Second, in paragraph 57, the Renjilian Rebuttal Report states: “The version of the Garthwaite Deletes from the January 5, 2024 Errata contained the same number of IRADS diagnosis codes but 36% fewer EDPS diagnosis codes than the October 4, 2023 Errata version,” and “there are more than 1,200 members across service years 2014–2016 for whom Dr. Garthwaite identified an alleged Part C overpayment but who do not have any diagnosis codes in the January 5, 2024 Errata version of the Garthwaite Deletes.” In the process of revising **Attachment 1** produced on January 5, 2024, I inadvertently dropped from the list of EDPS deletes the diagnosis codes and beneficiaries that the Renjilian Rebuttal Report is referring to. This issue has been corrected in the version of **Attachment 1** submitted with this errata.
4. My team and I identified two additional issues that resulted in a small overinclusion of diagnosis codes and beneficiaries on **Attachment 1**.
5. The first issue resulted in an overinclusion of diagnosis codes in the final two years of my analysis. As discussed in my report, I exclude from my analysis a small number of

beneficiaries for whom I cannot replicate exactly the MARx risk score in the relevant year.¹ As noted in my report, in the final two years, I am sometimes able to replicate the MARx risk score from either RAPS or CMS EDPS, but not both, and in those cases, I include in my analysis only the deletes and financial impact associated with the system in which I was able to replicate the MARx risk score.² However, in these instances, the January 5, 2024 version of **Attachment 1** included both the IRADS and EDPS deletes for these beneficiaries, even if the risk score could only be replicated in one system and thus no financial impact was included in my analysis for the other system (and removing these diagnosis codes from **Attachment 1** therefore has no effect on my financial impact calculations). This resulted in the overinclusion of approximately 1,000 bene-dx-DOS on the IRADS deletes list and 4,000 bene-dx-DOS on the EDPS deletes list. I have removed these diagnosis codes from the version of **Attachment 1** submitted with this errata.³

6. The second issue resulted in the inclusion of 9 beneficiaries on **Attachment 1** for whom I ultimately did not calculate any financial impact. While I identified deletes for each of these beneficiaries, CMS' MARx payment data indicated that Defendants did not receive net positive payments from CMS for these beneficiaries for the months that were included in my analyses, and thus I excluded these beneficiaries from the figures and exhibits in my report, and from Attachments 2 and 3. I have now also removed these 9 beneficiaries from the version of **Attachment 1** submitted with this errata.
7. I here submit a revised version of **Attachment 1** and a revised version of the computer code for **Attachment 1**, reflecting the issues discussed above.

¹ See my Report, Appendix D, ¶ 90. ("In months where a beneficiary is covered by Defendants, I am able to replicate 98% of the beneficiary Part C risk scores recorded in MARx and 95% of the Part D risk scores. I exclude from my analysis any beneficiary for whom I cannot exactly replicate exactly the MARx risk score in the relevant year.")

² See my Report, Appendix D, footnote 100. ("For payment years 2016 and 2017, I still include 0.7% of beneficiary months in my analysis of Part C if I am able to replicate either their 'raw' RAPS risk score or their 'raw' CMS EDPS risk score, but not both.")

³ The removal of these diagnosis codes does not change the number of unique beneficiaries on **Attachment 1** because each of these beneficiaries does have financial impact, but, out of caution, my calculations only included their financial impact in one system because I was not able to replicate exactly their MARx risk score in the other system.

8. Finally, as my team and I engaged in revising **Attachment 1** as described above, we identified two additional issues that have a de minimis effect on the figures, exhibits, and attachments to my report. In an effort to provide full transparency, these two issues are described below.
9. The first issue is related to risk score rounding and resulted in an overinclusion of 10 beneficiaries and an associated \$85 in financial impact in the final two years of my analysis.⁴ In my calculations, each of these beneficiaries had IRADS deletes and thus a change in their RAPS risk score, but they had no EDPS deletes. However, in my calculations, the CMS EDPS risk score change was calculated as the change in the beneficiary's blended risk score, less the change in their RAPS risk score, which resulted in the appearance of a small change in their CMS EDPS risk score despite the lack of EDPS deletes. Due to the way risk scores were rounded, the change in the blended risk score for these beneficiaries was calculated as 0.001 higher than the change in their IRADS risk score, resulting in a calculation of the change in their CMS EDPS risk score as 0.001.⁵ However, these beneficiaries did not actually have EDPS deletes and thus their CMS EDPS risk score change should be 0.000; they only appear to have 0.001 change because of these rounding differences. While these 10 beneficiaries did not appear on EDPS **Attachment 1**, because there were no deletes in that system to include, they were incorrectly included in beneficiary counts that appear in the figures, exhibits, and other attachments to my report. Due to the de minimis nature of this issue, I have not updated the figures, exhibits, and attachments to my report to account for them.
10. The second issue relates to beneficiaries for which a negative financial impact is calculated. In Attachment 3, there are a total of 3 beneficiaries with a negative value in the Part C financial impact field and a total of 8,396 beneficiaries with a negative value in the Part D financial impact field. The net effect of including these beneficiaries is to reduce the total financial impact calculation in my report. While I identified deletes for each of these beneficiaries, CMS' MARx payment data indicated that on net, Defendants paid more to

⁴ Two of these beneficiaries are associated with service year 2015 and eight are associated with service year 2016.

⁵ For example, the beneficiary's blended risk score change would be 1.002, and their RAPS risk score change would be 1.001, resulting in a calculated CMS EDPS risk score change of 0.001.

CMS than they received from CMS for these beneficiaries in the months that were included in my analyses.⁶ Part of my assignment in this matter was to determine the number of beneficiaries for whom Defendants would have received reduced risk adjustment payments from CMS had Defendants deleted the diagnosis codes I identified. Therefore, these beneficiaries should have been excluded from the final count of beneficiaries in my report. Correcting this issue would result in a reduction in the final count of beneficiaries from 1,154,197 to 1,148,038, which is a reduction of 6,159 or 0.5%. Due to the de minimis nature of this issue, I have not updated the figures, exhibits, and attachments to my report to account for them.

Signed on March 11, 2024.

A handwritten signature in black ink, appearing to read 'Craig Garthwaite', written over a horizontal line.

Craig Garthwaite

⁶ For some of these beneficiaries, there are months with positive payments from CMS to Defendants, but these months were excluded from my analysis (for example, because I could not replicate exactly the risk score in that month). These reason that this issue disproportionately affects Part D is that CMS' payment to Defendants under Part D depends in part on the size of the beneficiary premium, and for many of these beneficiaries, the beneficiary premium was high enough to result in a net negative payment from CMS to Defendants.

EXHIBIT D-60

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al,

Defendants.

Case No. 16-cv-08697 FMO

**EXPERT REPORT OF MELVIN J. INGBER, PHD
JANUARY 29, 2024**

EXPERT REPORT OF MELVIN J. INGBER

January 26, 2024

Qualifications

I am currently a consultant on health services payment, risk adjustment and quality issues. I have been asked to provide a rebuttal to expert reports particularly addressing diagnosis codes in Traditional Medicare (TM) deemed unsupported by medical records and their effect on the CMS-HCC risk adjustment model and payment to MA plans. In particular, I am rebutting specific opinions offered by UnitedHealthcare's experts Mark Duggan, Julia Lambert, and Michael P. Salve.

From July 1, 2006 through April 7, 2023, I was a Principal Scientist at RTI International, specializing in health economics, health care payment, and quality measures. At RTI, I served as a project director, analyst, or consultant on numerous projects, many listed in the appended résumé. Topic areas covered included risk adjustment modeling for spending on medical services, prescription drugs, and quality measures; post-acute care (PAC) assessments, episodes, and payment systems; frailty measures; an evaluation of the Centers for Medicare & Medicaid Services (CMS) initiative to reduce avoidable admissions of nursing home residents; and the statistical design for adjusting the data in the Home Health Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.

Particularly related to the subject matter of this rebuttal expert report, while at RTI, I was able to continue working on the risk adjustment models being used by CMS for Part C and Part D payment. I was the project director for this work for a few years and senior analyst for the following years at RTI. I was deeply involved in the decision-making related to grouping ICD-9 and ICD-10 codes into HCCs. I also was involved in deciding which provider types would be considered best sources for diagnoses. A major process shift was the need to use reported procedure types rather than provider types when MA encounter data became a source of diagnoses. (Encounters do not have specialty indicators for physicians.) I worked on the same decision-making for the ACA Health Exchange risk adjuster system when RTI received that contract. In addition, I developed a demographically-based risk adjustment system for new enrollees joining MA C-SNPs. These are Special Needs Plans for beneficiaries with existing chronic conditions. The demographic system is for C-SNP enrollees who do not have full prior year Medicare or MA claims records but are reported by a C-SNP to have a known qualifying condition; they have higher costs than typical new enrollees.

Another related area I worked on was the adjustment for beneficiary frailty that CMS applies to certain MA plans and PACE plans because they enroll a relatively large proportion of people with functional deficits.¹ This was an add-on to the base risk adjustment models.

Prior to working at RTI, I was an economist at CMS for more than 15 years and was the director of CMS's Division of Payment Research for more than 5 years. As division director, I supervised intra- and extramural research and demonstration evaluations, particularly those related to payment for TM and MA, including refinement and reform of payment for hospitals, PAC, and geographic adjustment of physician payment. Pay-for-performance issues were also an area of study. I was a frequent consultant on other CMS research projects for technical and operational issues.

Focusing on the topic of the subject matter of this rebuttal expert report, I was the lead government analyst for the research and development of risk adjuster systems for Medicare enrollees in MA plans and for the Medicare Part D program^{2,3,4}. This was the multi-year work to investigate the characteristics, advantages and disadvantages, of candidate risk adjustment systems for a future managed care payment system, ultimately called Medicare Advantage. A brief outline of this work is below.

I was the project officer for grants and contracts for risk adjustment system development for Part C and Part D. For Part C, I managed grants (in the form of cooperative agreements) and contracts with researchers at Johns Hopkins School of Public Health, Boston University, Health Economics Research, RTI International, University of California at San Diego, Kaiser Permanente Center for Health Research, and studied the work of 3M. I evaluated the application of their proposed systems to Medicare and advised on making changes to test the effects of modifications. I also made recommendations to HCFA (renamed CMS) as to the characteristics of each system. Some of these systems were proprietary, *e.g.*, the ACGs from Johns Hopkins and the CRGs from 3M. I recommended one of the nonproprietary systems that had great transparency as to how it created the risk factor values. Although they all had reasonable predictive power, some had risk groups constructed in a complex manner. It was my recommendation (agreed to by others) that the transition to a clinical from a demographic model

¹ Kautter, J., Ingber, M.J., & Pope, G.C. (2008). Medicare Risk Adjustment for the Frail Elderly. *Health Care Financing Review*, 30, 83 - 93.

² Ash, A. S., Ellis, R. P., Pope, G., Ayanian, J. Z., Bates, D. W., Burstin, H., Iezzoni, L. I., & Ingber, M. J. (2000). Using diagnoses to describe populations and predict costs. *Health Care Financing Review*, 21(3), 7-28.

³ Pope, G. C., Ellis, R. P., Ash, A. S., Liu, C. F., Ayanian, J. Z., Bates, D. W., Burstin, H., Iezzoni, L. I., & Ingber, M. J. (2000). Principal inpatient diagnostic group model for Medicare risk adjustment. *Health Care Financing Review*, 21(3), 93-119

⁴ Ingber, M. J. (2000). Implementation of risk adjustment for Medicare. *Health Care Financing Review*, 21(3), 119-126.

would need transparency to be accepted. I did recommend what would be the RTI HCC system as transparent and nonproprietary and amenable to CMS' desired changes. That is the risk adjustment model that has been utilized in the MA program since 2004 and is (with developments over time) the model used today⁵.

I also used the HCC system as the basis of the CMS internally developed risk adjuster model for beneficiaries with End-Stage Renal Disease (ESRD). Using the RTI HCC code mappings, I led the development at CMS of the system of risk adjustment for beneficiaries 1) on dialysis, 2) having a kidney transplant, and 3) the post kidney-transplant period. The segments of risk adjusted payments and risk adjustment differed from what had been used in the prior AAPCC ESRD system. This model formulation was then further developed by RTI.⁶

For the Part D prescription drug risk adjustment model, I led the development internally at CMS to build a model using a complex substitution of Blue Cross Blue Shield and Medicaid drug data for nonexistent Medicare drug data.⁷ RTI would later develop similar models using actual Medicare drug data. The Part D model was implemented in 2006.

I have not testified as an expert prior to this case, but was deposed as a fact witness in connection with this matter in June 2022.

My fuller résumé is attached as Appendix A of this report.

For my work on this matter, I am being compensated at the rate of \$200.00 per hour. The content of my opinions is in no way influenced by my compensation in this matter, nor is my compensation in any way contingent or based on the content of my opinions or the outcome of this, or any other matter.

In the process of preparing this report, I reviewed a variety of documents, CMS publications, and other related material, including documents and depositions produced in this matter. A complete list of the documents I relied upon in forming my opinions is attached as Appendix B.

A list of all publications that I have authored in the previous 10 years is part of my résumé in Appendix A.

My work in this matter is ongoing. I reserve the right to update my opinions as additional information becomes available.

⁵ A risk adjustment model based on hospital diagnoses was used from 2000 until 2004. This was the PIP-DCG model. Plan payments from these models phased-in averages of demographic and risk models until 2008.

⁶ Robst, J., Levy, J. M., & Ingber, M. J. (2007). Diagnosis-based risk adjustment for Medicare prescription drug plan payments. *Health Care Financing Review*, 28(4), 15–30

⁷ Levy, J. M., Robst, J., & Ingber, M. J. (2006). Risk adjustment system for the Medicare capitated ESRD program. *Health Care Financing Review*, 27(4), 53–70

Background and Summary of Opinions

In this report I will describe the place and characteristics of the risk adjustment model in payment for MA plans. The history of Medicare managed care and the nature of payment to MA plans is relevant to understanding what the payment system does and does not do, and how the statistical estimation of the current risk adjustment models affects and does not affect payment to MA plans. In particular, I will describe the different effects of patterns of diagnosis coding in the creation of the risk adjustment model and in the use of it in determining MA plan payments.

Summary of Opinions

Mark Duggan's and Julia Lambert's opinions are based on the view that the presence of unsupported codes in TM data used in the risk adjustment model to estimate the expenditures for the HCCs for MA enrollees results in systematic underpayment for MA plans that have unsupported codes removed from their risk adjustment submissions. This view is incorrect because average relative risk scores produced by the model are not systematically affected by unsupported codes in the TM data and the related changes that occur in the computation of county rates. As I explain more fully below, the presence of unsupported codes in TM data has a mixed effect on group risk scores generated by the model and does not have the unidirectional affect that the presence of unsupported codes has in the MA data. The model uses millions of codes from TM data, and the model compensates for the effect of some unsupported codes on group risk scores by allocating costs to other risk factors used to generate the risk scores. By sharp contrast, an unsupported code submitted by an MA plan increases payment to the MA plan – there is no averaging out to compensate for the effect of the unsupported code as there is when unsupported codes in TM data are used in calibrating the model. It should be mentioned here that CMS audits of MA plan data (RADV audits) that disallow unsupported codes submitted by MA plans also allow for the addition of codes that may have been omitted. The TM data used for model calibration typically has more unreported supportable diagnosis codes than MA data because payment is based more on procedures than diagnoses. The non-unidirectional effect of the unsupported and unreported codes is shown in Exhibit 1.

Similarly, Michael Salve's opinion compares error rates for TM data to error rates found for some UnitedHealth MA submissions, but Salve ignores the fact that error rates in the TM and MA data do not lead to parallel effects on payment. Errors in TM data do not cause systematic over-or-under-payments. Errors in MA data do. Even if there were a 31% error rate in the TM data used to calibrate the model, and even if some of UnitedHealth's MA submissions had a 13% error rate, that does not mean UnitedHealth was underpaid, nor that UnitedHealth can keep payments for unsupported codes until its error rate equals 31% (or any other percentage).

An important ignored aspect of the difference between building the estimated model using TM data and using the model when making payments is the important role the risk scores from the TM model play in determining the county or (benchmark) payment rates. The county rates are

constructed by the CMS Office of the Actuary using the TM payment data. For the county rate the average spending in each county is converted to the spending on the person with a 1.0 risk score. The average risk score for beneficiaries in a given location is rarely 1.0, but varies with the characteristics of the population. The conversion to get the county rate is:

Eq. 1

$$\text{County rate} = (\text{average spending in county}) / \text{risk score of county}.$$

If the county average risk score is lower than 1.0, e.g., 0.8, the normalization to a rate for a 1.0 person is higher than the average spending in the county; a higher risk score lowers the rate. .

If one accepts that a large number of unsupported codes are in the TM data and that, as a result and on average, the risk factor values are low, then the risk scores for the full population are low. As the effect on the HCCs varies in magnitude and direction the average risk score for each county might be lower or higher than it would be without unsupported codes. As a result, the county spending could be divided by a low risk score resulting in a higher county rate or a lower risk score resulting in a lower rate. The population illness profiled in each county in each year is not the same as the population used to estimate the model and the rates of unsupported (and missing) codes vary. This means that lower risk scores do not necessarily result in lower payment to MA plans even if there are unsupported codes in the TM data.

As I will explain below, a brief summary of my specific opinions are:

Opinion 1: In the CMS-HCC risk adjustment model, average relative risk scores of MA enrollees are not strongly and systematically affected by the presence of unsupported codes in the TM data. Any presence of unsupported codes in TM data has a mixed effect on group risk scores and does not have the one directional affect that unsupported codes have when submitted by MA plans for payment. Instead, due to the statistical process of model estimation, the relative weight of factors may shift due to the presence of unsupported codes in the TM data, but average payments for large groups would stay consistent and accurately compensate MA plans for the risk they bare, particularly for larger insurers with diverse enrollees.

Opinion 2: The effect of errors in TM calibration data are not comparable to the effect of errors in MA data or underpayment of plans. Some unsupported diagnosis codes may be present or deleted but when the model is calibrated the total Medicare expenditures used in the calibration do not change. This means that while the removal of an unsupported diagnosis code from a given HCC has the potential to impact the coefficient for that HCC, the costs associated with the beneficiary with the unsupported HCC will simply shift to another HCC or demographic factor and the resulting predicted payments from CMS for the MA population as a whole will be about the same as they were with a model utilizing unsupported codes in the calibration process. Likewise, the payments to MA organizations with representative plans (*i.e.*, plans that include beneficiaries with a wide variety of conditions and demographics) will not necessarily

substantively change or will change in a *de minimis* way, despite the removal of unsupported codes from the calibration data. Only if there was a very large misrepresentation of the morbidity of the population would there be a substantive distortion in the risk scores.

Opinion 3:

The average change in risk scores resulting from large numbers of unsupported codes that might be in the TM data is variably offset when the county rates are created by CMS each year. The hypothetical lowered HCC risk factors (and, ultimately, lower person risk scores) could result in increased county rates in some cases. These increased county rates are used to pay MA plans and the impact of risk scores potentially lowered by the presence of unsupported codes in the model is offset.

Definitions

There are a few terms that I use with regularity throughout this report. For ease of reference, I am including here the meaning of those terms, as well as specific context for their use in instances where that may be helpful:

- Risk factor: The term risk factors may be the person characteristics used to estimate the costs of medical care for people or the values of the effects of the characteristics. It is usually clear when the characteristic itself or its effect is being referred to. Although applied to individuals, they are used to profile groups of people so as to determine the amounts Medicare would pay MA plans for their enrollees. The risk factor effects are usually estimated in dollar terms but converted to relative factors in application, as noted below. A person may be characterized by a single risk factor in a simple demographic-only model, or the sum of the person's risk factors in the richer models, such as the HCC and RxHCC models currently used.
 - Demographic (risk) factor: These are the risk factors associated with person characteristics not associated with clinical conditions per say, but with related characteristics, such as age, sex, and eligibility for Medicaid.
 - Clinical (risk) factor: These are factors related to the clinical characteristics of people. They are based on diagnosis codes on medical claims (and medical records when plans add these) and aggregated into clinically and cost similar groups, e.g., diabetes, various cancer types, various cardiac conditions, etc.
- Relative risk factor: The risk factor magnitudes are currently estimated using claims data from TM that have both diagnoses and provider payment amounts. The factors are in dollar terms. These absolute dollars are national average values for the factors and not suitable for payment in every geographic region and in a future year. The dollar amounts do reflect the relative sizes of the risk factors, however. The dollar factors are divided by the Medicare population average dollars per person to create relative factors that are used to adjust average Medicare payments in smaller geographic areas.

- Risk scores: Risk scores are the sum of the relative risk factors for each person that are used to predict the cost of care for a person with those characteristics. Average risk scores are used in describing groups as well.
- Relative cost: A relative cost may refer to the total estimated cost of a person or group of people based on the applicable risk factors for the individuals in the group. These costs are either from the dollars estimated by the risk model or the costs predicted after the risk scores are converted to payment amounts.
- Dollar coefficient: The term coefficient is the magnitude of the dollar risk factor as estimated by the statistical model. When mathematical formulas are used to predicted risk, the effect sizes of the factors in the formula are called coefficients in math terminology. Statistical software used to estimate the factor magnitudes use this term.

Brief history of managed care in Medicare⁸

The history of managed care in Medicare is meaningful as it indicates how average payments for groups are the goal of the payment to risk plans. As can be seen, models for demographically-defined groups would pay well for groups of people with typical ranges of health for their age and sex. The risk adjuster clinical groupings were needed because research showed the enrollees of many risk plans were healthier than average TM beneficiaries for their demographics. Below I describe how the clinical information was added to account for favorable or unfavorable health selection of enrollees.

Managed care in Medicare was present as early as 1965. Payment for these plans, some of which are still functioning today, was based on cost of the plan to provide services. The early cost plans did not have to serve all comers and were mostly employer or union based. These plans, based on reported costs, were not “risk” plans, a type of plan that is paid a premium determined by formulas that estimate the expected cost to treat plan enrollees and not the actual costs incurred by the plans determined after the fact.

In the 1970s, there was evolution in the definition of what standards a Medicare HMO would have to meet and there was also the introduction of the prepaid method. The concept of risk sharing was introduced, initially with plans reporting costs to be compared with a Medicare expected cost. Savings relative to the expected cost would be shared with the government. The expected cost is the first form of risk adjustment for managed care and was a classic actuarial method based on demographic factors. The adjusted annual per capita cost (AAPCC)⁹ was computed by accounting for age, sex, institutional status, dual eligibility for Medicaid and later

⁸ For a fuller description of history see: Zarabozo C. (2000). Milestones in Medicare Managed Care. Health care financing review, 22(1), 61–67.

⁹ <https://www.cms.gov/newsroom/fact-sheets/federal-payment-methodology-medicare-health-plans>

whether Medicare was a primary payer.¹⁰ The base payments and adjustment were estimated using Medicare payments for the vast majority of Medicare beneficiaries in the standard fee-for-service program that paid providers for individual services. That part of the program is currently often referred to as Traditional Medicare (TM). This method was later applied to the initial full risk program in which payments were fixed at 95 percent of the full AAPCC amount.

There was an AAPCC computed for each county based on the TM costs in the county, with adjustment for the varied demographic factors of each county. An important feature, carried over to full risk adjustment, is the form the demographic risk adjusters take. The AAPCC adjustment factors are based on the ratio of the costs of each demographic group to the national costs. The AAPCC adjustment factors are not expressed as costs, but as relative factors (demographic scores). The formula for assigning a payment for an individual enrolled in a plan was:

$$\text{Payment} = (0.95) \times (\text{County Per Capita Costs} / \text{Avg. County Demographic Score}) \times \text{Enrollee Demographic Score}$$

Examples of the scores that would be applied to the AAPCC county rates in 1999 are:

1999 DEMOGRAPHIC COST FACTORS - AGED¹¹

PART	SEX	AGE	INSTITUTIONALIZED	NON-INSTITUTIONALIZED		
				MEDICAID	NONMEDICAID	WORKING AGED
A	MALE	65-69	1.75	1.15	0.65	0.4
		70-74	2.25	1.5	0.85	0.45
		75-79	2.25	1.95	1.05	0.7
		80-84	2.25	2.35	1.2	0.8
		85+	2.25	2.6	1.35	0.9
	FEMALE	65-69	1.45	0.8	0.55	0.35
		70-74	1.8	1.05	0.7	0.45
		75-79	2.1	1.45	0.85	0.55
		80-84	2.1	1.7	1.05	0.7
		85+	2.1	2.1	1.2	0.8
B	MALE	65-69	1.6	1.1	0.8	0.45
		70-74	1.8	1.35	0.95	0.65
		75-79	1.95	1.55	1.1	0.8
		80-84	1.95	1.7	1.15	0.9
		85+	1.95	1.7	1.15	1

¹⁰ For simplicity the similar but separate set of AAPCCs for beneficiaries with end-stage renal disease will not be discussed here.

¹¹ <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/downloads/ratebook1999.zip>

FEMALE	65-69	1.5	1.05	0.7	0.4
	70-74	1.65	1.15	0.85	0.55
	75-79	1.65	1.25	0.95	0.7
	80-84	1.65	1.25	0.95	0.75
	85+	1.65	1.25	1	0.85

Because there are two trust funds that are used to pay for Medicare services, there are actually separate demographic risk factors for Part A (inpatient care), and Part B (outpatient care). Note that these demographic risk factors are used to multiply the average county rate to produce a payment, which is an average for that demographic group. Note also that they increase with age, creating higher payments for those groups that cost more to the program, so they are true risk adjusters, but based on differences in average risk for relatively large groupings containing individual beneficiaries with very varied costs.

I will first focus on the changes in the risk adjuster component and not the other aspects of county per capita costs, which are both determined by the risk adjusters and also have been modified over time for policy reasons not directly related to risk.

How well the demographic adjuster worked and need for improvement

In the early period of capitated (full risk) plans, enrollment in this part of the Medicare Program was relatively low with relatively few plans. Plans were expected to enroll populations that were similar to the overall Medicare program and, as in most insurance, average payments to plans would be good enough to meet the needed revenues at the plan level. The demographic risk adjusters may not predict the spending for individuals very well, but predictive power at the group level is much better. Prediction errors for individuals tend to average out. This “law of large numbers” principal is used in the more detailed forms of risk adjustment as well.

The demographic risk adjusters were observed to have weakness that resulted in producing Medicare payments to the MA Plans that were too high for the actual enrollment. Many studies showed that plans were targeting for enrollment healthier than average Medicare beneficiaries. The financial incentive for plans to attempt to select healthier than average enrollees is clearly present, as is the tendency of sicker beneficiaries to stay with current providers. Studies of the matter are in my Reliance Materials, Appendix B. A summary statement of such findings was presented in the United States General Accounting Office¹² (GAO) testimony to the Subcommittee on Health, Committee on Ways and Means, House of Representatives, in 1977.¹³

We are pleased to be here today to discuss the rates Medicare pays health maintenance organizations (HMO) in its risk contract program, Medicare’s

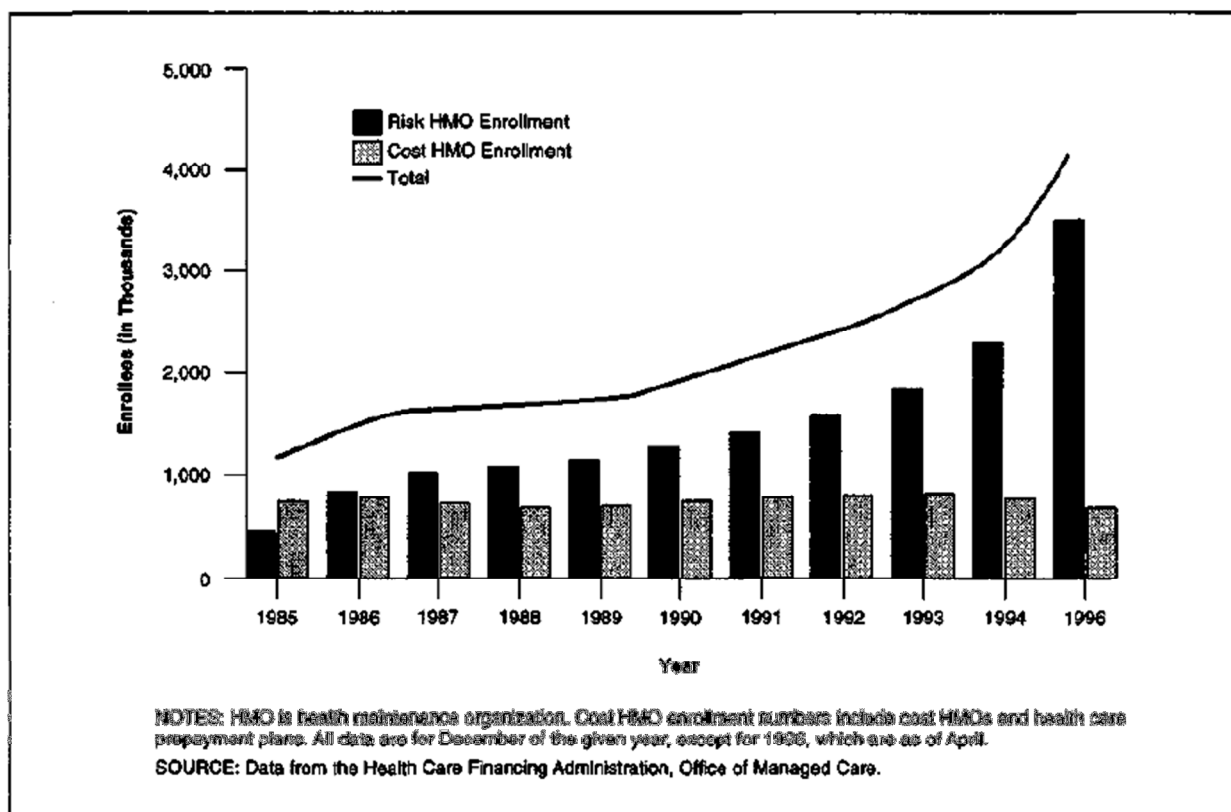
¹² More recent name is United States Government Accountability Office.

¹³ <https://www.gao.gov/assets/t-hehs-97-78.pdf>

principal managed care option. As you know, Medicare's method for paying risk contract HMOs was designed to save the program 5 percent of the costs for beneficiaries who enroll in HMOs. However, 10 years of research on Medicare's costs under HMOs has found that the program's rate-setting method results in excess payments to HMOs because HMO enrollees would have cost Medicare less if they had stayed in the fee-for-service sector. Recently, the Physician Payment Review Commission (PPRC) estimated that annual excess payments to HMOs nationwide could total \$2 billion.

This issue for the program became more serious financially over time as enrollment in capitated risk plans grew.

Medicare HMO Enrollment 1985 – 1996¹⁴



Well before the implementation of clinical risk factors being added to the risk adjuster formula, researchers were working on such formulations. A major obstacle was getting the required information into the risk adjuster system. There was a significant amount of claims-based information available to Medicare for the great number of beneficiaries in TM, allowing a more clinically-based risk model to be built using that TM data. On the other hand, there was little

¹⁴ Zarabozo C. (2000). Milestones in Medicare Managed Care. Health care financing review, 22(1), 61–67.

information available on the managed care enrollees, not enough to allow assignment of risk to plan enrollees. (Much of the limited information on plan enrollees that could be used in research came from the Medicare Current Beneficiary Survey, which collects information more directly from a statistical sample of beneficiaries.)

CMS, then named Health Care Financing Administration (HCFA), was researching risk models using various types of clinical information starting in the early 1990s. Studies were done on formulations by researchers at Johns Hopkins, Boston University, University of California San Diego, 3M and Health Economics Research (merged into RTI). In common, was the use of diagnosis data to profile the cost risk of Medicare beneficiaries and, ultimately, health plan enrollees.

Plans being overpaid was one of the issues that resulted in Congress passing sections of the Balanced Budget Act of 1997 (Pub. L. 105-33), which mandated:¹⁵

“(3) Establishment of risk adjustment factors.--

“(A) Report.--The Secretary shall develop, and submit to Congress by not later than March 1, 1999, a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status. Such report shall include an evaluation of such method by an outside, independent actuary of the actuarial soundness of the proposal.

“(B) Data collection.--In order to carry out this paragraph, the Secretary shall require Medicare+Choice organizations (and eligible organizations with risk-sharing contracts under section 1876) to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary deems necessary for periods beginning on or after July 1, 1998. The Secretary may not require an organization to submit such data before January 1, 1998.

“(C) Initial implementation.--The Secretary shall first provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payments by no later than January 1, 2000.

“(D) Uniform application to all types of plans.--Subject to section 1859(e)(4), the methodology shall be applied uniformly without regard to the type of plan.

The Medicare+Choice Program evolved into the Medicare Advantage Program. Because of data limitations, the diagnosis data for payment year 2000 were only from hospital inpatient services. (This transition model was called the PIP-DCG model.) Data from other provider types were

¹⁵Public Law No. 105-33 Sec. 1853(a)(3)

used for the period starting payment year 2004 after a method for data submission was developed. The two versions of clinical risk adjustment were phased in slowly, starting at 10 percent of payment in 2000 with the rest based on the demographic model. The 2004 model, called the HCC model, has continued with various improvements to this day.

How the HCC model uses diagnoses to produce risk factors

An essential aspect of the HCC models is that the diagnoses (from the TM data) included in the model are used to predict relative costs of conditions in the following year. In effect, they profile the MA enrollees as they are expected to cost in the payment year starting after the medical profile is created from the immediately preceding year. This means some acute events in the diagnosis year have lower costs predicted for the following year. The model is termed prospective.

In producing the HCC risk models, full data, with diagnoses and payments, are needed. CMS uses TM claims as the source for the data. The types of claims from TM to be used as reliable sources of diagnoses include hospital inpatient and outpatient and most physician claims. Alternatively, claims from laboratory tests and radiology are not used, as they will, for example, report diagnoses that ordering physicians particularly want evaluated. Such claims however would report disease codes, even if the test for the condition is negative.

For clarity, I will use terminology from this point in the report distinguishing the persons in Medicare TM and in MA plans. All the people entitled to Medicare are beneficiaries. However, I will use the term beneficiaries for those in TM; I will use the term enrollees for those enrolled in MA plans. Thus, beneficiary data are used to determine the relative risk factor magnitudes and enrollee data are used to assign which factors are applied to each MA plan enrollee.

For the early years of risk adjustment, MA plans had been submitting enrollee diagnoses that were extracted from claims submitted to them by providers. CMS instructed MA plans which sources to use, which were the same ones used in the TM data. Reporting a diagnosis once during a year was deemed sufficient for the diagnosis to be considered to be included in an enrollee profile. This was termed the Risk Adjustment Processing System (RAPS) data. Since 2012 MA plans have been required to submit fuller extracts from provider claims, with more detail, including payments to their providers. These claim-like records are referred to as Encounter Data. This data stream is the Encounter Data System (EDS). Use of these Encounter Data has been phased in, supplementing the prior RAPS records. Recently, only encounter records are used to profile MA enrollees.

The MA Encounter Data diagnoses are used to assign risk factors to enrollees. They have not as yet been used to calibrate the relative risk factors associated with clinical conditions, as reliability of all the data elements, including payments, is being evaluated. Rather, the model risk adjustment factors come from relative costs for beneficiaries in TM. The TM model does not

determine which or how many MA enrollees are assigned clinical risk factors. The MA encounter records determine that.

The HCC risk model is an equation that sums up the effects of many risk factors. Demographic relative factor amounts are supplemented by the relative factor amounts associated with medical conditions. A simplified form of the equation is

Total risk score = relative factor for a demographic factor + relative factor for medical condition 1 + relative factor for medical condition 2 ... + relative factor medical condition n.

Any one person might have a demographic factor and only a few or none of the medical conditions in their score.

Because there are so many combinations of medical conditions and demographic types, a statistical method is used to estimate the average relative cost effect of each of the factors. Ordinary least squares regression is the method used to determine the best estimate of costs associated with all the risk factors in the model.¹⁶ The data used are those characterizing all the TM beneficiaries appropriate to be in risk plans; millions of beneficiaries go into the estimation.

Before describing the characteristics of this method, it is useful to understand how the clinical conditions are included in the model. Diagnoses in medical claims in the U.S. have the form of codes in the 10th version of the International Classification of diseases – Clinical Modification (ICD-10-CM) (Prior to October 1, 2015, the U.S. used ICD-9-CM). There are more than 70,000 disease codes in the system. A small example is:

E11.34 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy

One of the following 7th characters is to be assigned to codes in subcategory E11.34 to designate laterality of the disease:

- 1 - right eye
- 2 - left eye
- 3 - bilateral
- 9 - unspecified eye

E11.341 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema

E11.349 Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema

In order to have enough people to get reliable estimates of the cost of diseases it is necessary to group conditions that are clinically related and reasonably close in costs. The process does not produce a precise cost estimate for every narrowly defined medical condition, but does produce

¹⁶ Ordinary least squares (OLS) computes the values of average relative factor costs that minimize the sum of the squared errors of prediction for the model beneficiaries. Squares of negatives are positive, so this basically sums the error magnitudes. The OLS method produces the sum of 0 for the offsetting positive and negative errors.

an average cost for people with conditions within a range of related conditions. Diseases that are related but differ by severity, as indicated by cost, are assigned different condition categories. The resulting groups, formed after much clinical discussion and statistical cost estimation, are called Hierarchical Condition Categories (HCCs). Some HCCs are not included in the model because numbers of patients are too small, expected costs are low, coding of the condition is considered too variable and discretionary, or the diagnosis is a symptom or test finding without definitive cause. The guidelines for the included and excluded condition categories are described in the 2021 Report to Congress on the model.¹⁷ For example, the code for the common cold (J00) is not included in the model because the value of the risk factor is very low, especially for the payment year following, and the prevalence is so high it does not distinguish populations. Similarly treated is acute pharyngitis (J02), sore throat. Codes for conditions with low frequency but high costs must be added to groups with higher frequency to accurately predict the costs on average for the group.

Next, I will explain how the data are entered into the estimating model, what the factors actually mean, and how imperfect data affect the model results.

Estimating the HCC risk model

The HCC risk adjuster model does not produce a unique category for every possible combination of demographics and HCCs. Instead, it treats the risk factors as additive in creating a risk score for a person. The equation that is used has the simplified form:

Eq. 2

$$\text{Actual beneficiary cost} = a_1 \times \text{age/sex group}_1 + a_2 \times \text{age/sex group}_2 + \dots + a_n \times \text{age/sex group}_n + b_1 \times \text{HCC1} + b_2 \times \text{HCC2} + \dots + b_m \times \text{HCCm} + \text{random error}$$

Each beneficiary in the model population has data that are used to indicate whether they have the characteristics that are risk factors in the model equation. Each beneficiary has a total cost of treatment during the year and belongs to some age/sex group. For a female age 72, the variable for the age/sex group including females 70 – 74 is set to a value of 1; all the other age/sex group characteristics are set to a value of 0. For the HCC disease categories, a healthy beneficiary would have all the HCC characteristic values set to 0. A beneficiary with diseases included as important risk factors would have each of the HCCs assigned a value of 1 for the conditions that medical providers that are accepted sources of diagnoses have coded in that beneficiary's medical claims.

The coefficients of the equation (Eq. 2), the letters a and b, are estimated average costs of each of the risk factors computed by the statistical process that uses information from the millions of beneficiaries to produce the estimates for a model that predicts all the costs of the population,

¹⁷ <https://www.cms.gov/files/document/report-congress-risk-adjustment-medicare-advantage-december-2021.pdf>

based on much more information than just demographic characteristics. Although the model is estimated using payments in dollars, the average dollar risk score of each factor is divided by the population average spending per person to create relative risk factors. Summing the relative factors for an individual yields the person's risk score. With so many possible demographic and HCC combinations, the relative score that will be used to assign a payment for a person has a much wider range than the purely demographic scores. A person with no model HCC will have a score based on a model demographic factor and a resulting score usually less than 1.0 (average). Some HCCs will add a small amount to the score, perhaps 0.1; others may add 10 or more. This creates payment ranges more sensitive to differences in plan enrollee characteristics. A sample of relative risk factors for the characteristics in the model is shown in the table on page 17.

The process of estimating the HCC model produces a risk score of 1.0 as the average beneficiary score using the data for the population for that year. Because the model is expressed in relative scores and not actual dollars, it may be applied to future years. Average treatment patterns do not change rapidly. However, coding patterns have been observed to change, as do updates in the ICD-10 codes. The result is that the TM population, which has an average risk score of 1.0 in the calibration year, may have a higher score when the model is applied to the following year, 1.05, for example. Because the payment system is always based on the TM population having an average of 1.0, the model scores are normalized back to 1.0 by dividing the HCC scores by 1.05 in this example. This is needed to create the correct average county rates used as the basis for converting risk scores to payment. This is often referred to as the fee-for-service normalization factor, and is in the MA yearly payment announcements published by CMS.

Among the causes for the upward "creep" in risk scores is the medical profession having their consciousness raised about screening and reporting particular medical conditions. An example of such "collective" behavior is that, for a few years, there was an observed increase in coding of kidney disease. A more recent example relates to the increased adoption by some healthcare systems of electronic medical record software that reminds providers of codes they might add to a billing record based on data in the system. Some of these systems intentionally focus on codes in the HCCs. For example, the Epic system used by certain medical providers allows for a module added for just that purpose.

2024 CMS-HCC Model Relative Factors for Continuing Enrollees,¹⁸ excerpt

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Female								
0-34 Years		-	0.238	-	0.346	-	0.454	0.948
35-44 Years		-	0.288	-	0.332	-	0.420	0.810
45-54 Years		-	0.340	-	0.384	-	0.404	1.031
55-59 Years		-	0.385	-	0.421	-	0.424	0.949
60-64 Years		-	0.436	-	0.502	-	0.414	0.881
65-69 Years		0.330	-	0.435	-	0.365	-	1.188
70-74 Years		0.395	-	0.506	-	0.423	-	1.119
75-79 Years		0.465	-	0.596	-	0.485	-	0.965
80-84 Years		0.524	-	0.665	-	0.544	-	0.862
85-89 Years		0.624	-	0.775	-	0.618	-	0.750
90-94 Years		0.737	-	0.869	-	0.738	-	0.627
95 Years or Over		0.742	-	0.877	-	0.835	-	0.481
Male								
0-34 Years		-	0.106	-	0.191	-	0.306	0.826
35-44 Years		-	0.154	-	0.204	-	0.261	0.719
45-54 Years		-	0.215	-	0.293	-	0.300	0.991
55-59 Years		-	0.283	-	0.410	-	0.353	0.989
60-64 Years		-	0.345	-	0.504	-	0.374	0.917
65-69 Years		0.332	-	0.531	-	0.375	-	1.275
70-74 Years		0.396	-	0.626	-	0.417	-	1.224
75-79 Years		0.502	-	0.714	-	0.498	-	1.319
80-84 Years		0.571	-	0.789	-	0.565	-	1.238
85-89 Years		0.664	-	0.907	-	0.615	-	1.135
90-94 Years		0.800	-	0.993	-	0.712	-	0.946
95 Years or Over		0.896	-	1.058	-	0.904	-	0.825
Medicaid and Originally Disabled Interactions								
Originally Disabled, Female		0.228	-	0.160	-	0.103	-	-
Originally Disabled, Male		0.135	-	0.158	-	0.075	-	-
Medicaid		-	-	-	-	-	-	0.130

continued

Note: FB means full benefit; PB means partial benefit

¹⁸ <https://www.cms.gov/files/document/2024-announcement-pdf.pdf>

Variable	Description Label	Community, NonDual, Aged	Community, NonDual, Disabled	Community, FBDual, Aged	Community, FBDual, Disabled	Community, PBDual, Aged	Community, PBDual, Disabled	Institutional
Disease Coefficients								
HCC1	HIV/AIDS	0.301	0.213	0.397	0.237	0.196	0.109	1.322
HCC2	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	0.500	0.598	0.649	0.780	0.447	0.591	0.605
HCC6	Opportunistic Infections	0.381	0.763	0.588	0.833	0.518	0.685	0.728
HCC17	Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic	4.209	3.995	3.896	4.235	3.946	4.103	1.952
HCC18	Cancer Metastatic to Bone, Other and Unspecified Metastatic Cancer; Acute Leukemia Except Myeloid	2.341	2.486	2.277	2.537	2.166	2.403	1.110
HCC19	Myelodysplastic Syndromes, Multiple Myeloma, and Other Cancers	1.798	1.989	1.563	1.661	1.520	1.554	0.957
HCC20	Lung and Other Severe Cancers	1.136	0.978	1.166	1.173	1.214	1.067	0.672
HCC21	Lymphoma and Other Cancers	0.671	0.540	0.654	0.739	0.627	0.618	0.493
HCC22	Bladder, Colorectal, and Other Cancers	0.363	0.366	0.382	0.409	0.410	0.351	0.314
HCC23	Prostate, Breast, and Other Cancers and Tumors	0.186	0.233	0.196	0.218	0.203	0.237	0.197
HCC35	Pancreas Transplant Status	0.949	1.393	1.117	0.573	1.117	2.740	1.106
HCC36	Diabetes with Severe Acute Complications	0.166	0.191	0.186	0.235	0.166	0.210	0.280
HCC37	Diabetes with Chronic Complications	0.166	0.191	0.186	0.235	0.166	0.210	0.280
HCC38	Diabetes with Glycemic, Unspecified, or No Complications	0.166	0.191	0.186	0.235	0.166	0.210	0.280
HCC48	Morbid Obesity	0.186	0.144	0.300	0.178	0.164	0.118	0.442
HCC49	Specified Lysosomal Storage Disorders	9.256	13.778	2.833	6.399	3.269	7.771	1.528

...

Note that to create even better distinctions in the risk modeling, there are actually seven separate risk models, distinguishing people with different levels of dual eligibility for Medicaid and nursing home institutionalization status. One can see that for a given HCC, the relative risk factors differ across the models for the subpopulations.

No model can predict perfectly for individuals because all the information about every possible coded condition and severity of the condition is not included in the model, nor is it available. The process of statistical estimation is to get the best combinations of estimated weights to predict for the whole population and to predict well for subgroups of the population that differ in health as well as demographic characteristics. Getting the predictions good for groups as large as MA plans and not for individuals or small groups of individuals is the goal for insurance purposes. Insurance of all kinds depends on getting good estimates of the risk of groups of covered entities, people in the case of Medicare. This works for the insured and insurer. If the exact future cost of an insured entity were known, the premium would be that cost, and the insured entity would have no benefit from buying insurance. Setting premiums for a group means each insured entity is covered for worst cases, but paying for the average case in the group. The plan revenue is the average for the group. The data for health insurance always show that the insurer is underpaid for some of the insured and overpaid for others, as compared to each insured's actual costs. The HCC risk adjusters get better average estimates for narrower subgroups than demographic adjusters, and even better averages across the full plan enrollment. There is always some risk of unexpected costs or savings for the plan, but reserves and reinsurance is part of the business.

Data quality and the effect on the risk factors

The diagnosis data describing the beneficiaries in the model are determined by TM physicians and professional coders who interpret physician written diagnoses, using ICD-10-CM. Given the large number of TM claims feeding into the model, overcoding (diagnosis codes not supported by the beneficiary's medical records) and under-reporting of diagnoses (diagnosis codes that are supported by the beneficiary's medical records, but are not coded for that beneficiary) may, and likely do occur. We observe the average of coding practices by providers in TM. What is seen in the claims used to estimate the HCC model is the average coding pattern of diagnoses across accepted provider sources. The HCCs describing a patient are those reported on any of accepted claim types for that patient. It does not matter how many times a condition is coded through the year or whether more than one ICD-10 code in an HCC is reported. A diagnosis falling within one of the model HCCs will be captured in the model by setting that HCC marker equal to 1.

How the Model Works

Coding variation, or errors, have a minor effect on the risk scores estimated in the HCC modeling process, as will be discussed. There may be codes on claims that are unsupported by the medical record. While these errors are present on both TM claims and MA claims, they have very different consequences when they occur in the TM data used for estimation in the model vs.

occurring in data submitted by MA plans for payment. Because such unsupported codes can occur in both data sets, it is important to consider the consequences of these errors and any appropriate reaction to the errors. As will be seen below, the consequences of such unsupported codes in TM estimation data is not of the same magnitude as the consequence of unsupported codes in the MA encounters—which is substantive and always increases payments to the MA plans.

The entire Medicare population exhibits varied constellations of medical conditions. The way the model works is that for any one HCC reported for a person there may be a few, many or no other HCCs reported. The total patient costs for that beneficiary will be spread over all the HCCs and demographic factors the beneficiary has, to varying degrees for that person. Inclusion of more or fewer diagnoses for a person does not affect the total costs reported on claims. The statistical process employed in the model uses information from all the beneficiaries to come up with estimates of the average costs associated with each of the risk factors to best predict the total spending, using those markers for risk. Spending related to conditions not explicitly included in the model is not lost. The costs are often captured by demographic factors, age/sex, with greater effect if the conditions are more frequent in a particular age group, increasing the estimated factor for the group. They also may be similarly captured by included model HCCs that frequently co-occur with the conditions not explicitly in the model. The statistical process assigns costs to the risk factors that *best* explain the cost profile of the population. “Best” in this type of model means the estimated set of risk factors minimizes the sum of the square of the errors in predicting the actual costs of individuals in the model population. The squares of errors are always positive numbers, even if the error is a negative number. The average error (not squared) for the population modeled is 0 using the OLS method described. It is important to understand that pursuant to this model, individuals’ actual costs may not be predicted with very high precision, but the costs of groups of beneficiaries are much more precise because errors for the individuals average out.

The Effect on the Risk Scores in the Model of Having a Valid Diagnosis Omitted for some of the Beneficiaries or an Unsupported Diagnosis being Incorrectly Included for a Beneficiary

In this discussion the presentation is not intended to say that the ideal situation for data used for calibration and the data submitted for payment should not have the same characteristics. Ideally if a population were coded by the TM practitioners they would have the same codes as those in the data submitted by MA plans. This discussion will show that the effect of having unsupported codes or excluding them from the MA data is entirely different from the effects of such code changes in the data used to calibrate the model. More coding—whether supported or unsupported—in MA always increases payment. More coding—whether supported or unsupported—in the TM calibration data changes the relative risk factor levels to some degree. Some factors may increase and others decrease.

The costs to be explained by the model that were reported by a provider for a beneficiary for whom a valid diagnosis (HCC) was not submitted or for whom an unsupported diagnosis (HCC) was submitted are not changed by the reported presence or absence of the diagnosis.¹⁹ The particular HCC in question is exhibited by hundreds, thousands or even millions of others. The average estimated cost for that particular HCC is affected in a minor way by the presence or exclusion of an unsupported code. At a population level, the effect of an unsupported code has mixed effects on factors but the average population risk score is 1.0. Net payment effects vary when the model is estimated with and without the code and vary at the payment phase because the county rates are also changed.

In Exhibit 1, I demonstrate the concept described above by using a small, hypothetical model (meaning that the impact of changes will be more dramatic than in the CMS HCC model because Exhibit 1 includes a smaller set of diseases and beneficiaries than the CMS HCC model). The exhibit shows the effects of removing codes deemed unsupported and adding codes that were deemed supported but not originally reported. I generated Exhibit 1 in Excel on a small fictitious data set similar in form to TM model data. The data have total costs and a set of HCCs for each person. Exhibit 1 has a model similar to Eq. 2, with some data indicated as unsupported for some people. The Descriptions tab in the exhibit has greater detail than is described here. On the “(1) with unsupported codes” tab, I show an initial model, which includes a certain number of HCC markers defined as unsupported. On the “(2) supported codes only” sheet, I show the same model, but I have removed the unsupported HCCs (turning those HCC marker values from “1” to “0”). The costs associated with the unsupported HCCs remain with the individual person but are redistributed to other HCCs and demographic factors in the second iteration of the Exhibit 1 model (i.e., they are not removed from the model). On the tab “(3) Supported+unsubmitted” HCCs that are simulated to be supported, but not reported, have their markers changed from “0” to “1”. The “Differences” tab in the workbook compares the relative risk factors in the three models and creates person risk scores for people with different profiles of HCCs. The result is that going through the process of doing an HCC audit on the simulated TM data, removing the HCCs with unsupported diagnosis codes, has some relative factors decreasing and some increasing in the “audited” version. Changes when unsubmitted codes are added are also shown. Looking at the total risk scores for a few people profiled, it shows that the scores do not all go up or down as HCCs are removed or added. The code changes and simulated people were chosen with no knowledge of what the results would be. Also, as indicated in the exhibit, the settings of initial set of HCCs were done randomly and the addition of unsupported codes done without knowledge of the consequences. The final examples shown in the Difference tab demonstrate

¹⁹ The data used to estimate a model must be pulled at some point in time. Any audits done before the pull that denied some of a provider’s claims would have been done. Any effects of audits in the future are not known. Denial of a claim removes both that claim’s diagnoses and payment. (The diagnoses may appear on other claims.) Although the effect on the audited provider might be substantive, given the volume of claims in the data across so many providers, the effect on average estimated costs of a condition and the total cost of the population would not be substantive.

how the 1.0 risk score is identical under all Exhibit 1 models. So, regardless of any observed fluctuations in risk scores for individuals (with some going up and some going down), at a population level adding or subtracting codes does not have a unidirectional effect on risk scores for individuals or subgroups.

Lambert and Duggan suggest that United would be inappropriately underpaid if it is required to repay CMS for unsupported diagnosis codes it has submitted and for which it has been paid if its payments were determined through application of the CMS HCC model and the model TM data included an equal or greater number of unsupported diagnosis codes that were not removed from the data. There are multiple reasons this result is not always substantive or true when payment is made. First, the TM unsupported codes are akin to the unsupported codes accounted for in my example in Exhibit 1—meaning unsupported codes in TM will have varied impacts at the HCC and group levels. And as I will describe below, unsupported diagnosis codes submitted by MA Plans in Part C will have direct positive impact on the payments MA Plans receive. Essentially, Lambert’s and Duggan’s analysis is misleading because it fails to recognize the different impacts unsupported codes have in the TM data versus the MA data. The effect of added unsupported codes in MA data when a TM estimated model is being applied to determine payment to the MA is quite different and increases payments; there is no averaging out or redistribution of costs to other HCCs or demographic factors.

Further, Lambert and Duggan ignore another piece of correcting model calibration data—accounting for codes that are supported by the medical record but have not been submitted by providers in TM (“unsubmitted codes”). Neither Lambert nor Duggan substantively address the issue of unsubmitted codes in the TM data. Just as removing unsupported codes in the TM data would have some effect on the specific HCC average scores, so would the adding of missing, but supportable codes. I demonstrate this in Exhibit 1 on the “(3) Supported+unsubmitted” tab, where I exclude the same unsupported codes as were excluded on the “(2) supported codes only” tab but I add HCCs that I assume were supported by the medical record but were not submitted in the initial data. In the “Differences” sheet, I include a comparison of the three different hypothetical Exhibit 1 models. As was true with removing the unsupported HCCs, including additional supported HCCs changes the relative factors. Some risk scores go up and some risk scores go down but, at a population level, the model still predicts the same overall payments. As Exhibit 1 demonstrates, including unsubmitted codes in the TM calibration data has a varied and not directionally consistent impact on the relative risk factors, i.e., the relative factors may go up or down. I will show that changes in risk scores that do occur if coding errors are very frequent are inconsistent when the payment amounts are computed

The effect of coding variation when the model is used for payment

When an unsupported diagnosis that triggers a model HCC is reported in MA encounter data, it increases the risk score of that enrollee, unambiguously. The average score for the MA enrollees and payment to the MA plan is increased by a fixed amount, dependent on the size of the risk

factors and the local ratebook amount for the location of the plan. Submitting unsupported diagnoses at the payment stage has a one-way effect on payment; it increases payment. And, importantly, these codes do not represent higher intensity of coding, but a payment for diagnoses for a condition that is wrongly associated with that plan's enrollee. There is no model-based justification for the extra cost paid resulting from the reporting of an unsupported code not to be refunded to the payer, the Medicare program. But, as shown in the section above, an unsupported code in the TM data does not have a similarly unidirectional impact on payment – and may not have any impact on payment at all. There is, therefore a stark difference between the impact of an unsupported code reported by a TM provider on behalf of a TM beneficiary (moderated by the statistical process that determines estimated risk scores based on averages of many risk factors for many beneficiaries as well as the redistribution of costs to other factors in the model) and the impact of an unsupported code reported by an MA plan for one of its enrollees (the MA plan is paid the entire amount estimated for the cost of the unsupported HCC, despite it being incorrectly associated with its enrollee).

Likewise, in MA, the incentives are to capture codes not on claims (and, as noted, there is software that can be utilized to do so) because, as explained above, MA plans are paid directly and unidirectionally (more) for every diagnosis submitted. Some MA plans may schedule additional visits – like home health assessment visits – during which the MA plan gathers diagnosis codes that may not be gathered for a TM beneficiary. While the TM data has some rate of missing as well as unsupported codes that may raise some risk factors and lower other risk factors, the same incentives to capture all supported claims do not exist for TM providers, as they are not directly paid for diagnosis codes. (For most services, procedures reported determine payment.) Presumably therefore, the rate of missing codes in MA is smaller than that in the TM data. The high intensity of coding in MA, with the medical records being an accepted source, as well as provider claims, means the proportion of omitted codes is much lower in MA. MA starts with an advantage of higher intensity of supported codes. The TM data may have more unsupported codes (that rate, however, is unknown) but it likely has a larger balance of supported, but unreported codes because there is little incentive to code everything in the medical record on TM claims. As demonstrated in Exhibit 1, both unsupported and unsubmitted codes in the calibration data can have impact – some going up and some going down – on Relative Factors, but, at a population level, will not impact payment as directly as such codes in the MA data. Unsupported codes on the MA side will absolutely impact payments to MA plans.

One other offsetting factor must be considered that occurs even if there are unsupported diagnoses in the TM calibration data. If there is some net reduction of risk factors because of large numbers of unsupported codes the lower scores that result can increase the county rates used for payment. As shown above in Eq. 1, the county rate is a county spending amount divided by the average risk score for the county. If the average risk score for a county were lowered by unsupported codes the smaller average risk score in the denominator of the equation results in

increased payment to the plan. The MA plan would have its risk scores for people in such a county paid at a higher county rate.

Summary Rebuttal to Specific Comments in Lambert report

In Julia Lambert's report, starting at page 11, the concept of actuarial soundness in coding of data by TM and plans is discussed. Ideally, data consistency is the desired situation. But the data reporting processes differ in the calibration and payment phases. The inconsistency of the effects of making adjustments at the payment phase and at the calibration phase should be accounted for. The problem, as described by Julia Lambert, is that the disallowance of unsupported diagnoses by CMS is not done in the TM claims as well. The other error type, adjusting for supported but unreported codes will be discussed below. Importantly, even with Lambert concentrating on the errors in the TM data, she wholly fails to address the completely different effects that unsupported diagnoses have on estimation (in the TM data) and payment (to the MA plans). Because the modeling process inherently has to attribute costs to one or more of the risk factors in the model (the sum of the error is 0) the effect of having errors in TM data associated with unsupported diagnoses is to alter the risk factor of the HCC involved and alter other risk factors for HCCs or demographics in varying directions. With the effects in varying directions unsubmitted and unsupported codes may ultimately minimize or cancel out impacts on the relative risk factors. The estimates of individual coefficients are impacted slightly by having these errors present in the TM data. What is not captured in one risk factor is added to whole demographic groups in the estimation population, or related medical conditions. The process of model estimation is to get good estimates of the relative risk factors based on typical coding. Changes in one factor are compensated for by changes in others. But, the effect of removing unsupported codes in MA data is not parallel to removing such codes in the modeling process. Including unsupported codes in the modeling data will move the relative factors slightly; while including unsupported codes at the MA payment stage can add thousands of dollars to payments to MA plans for the enrollees associated with those unsupported codes. Julia Lambert ignores this distinction.

On page 26 of her report, Lambert claims that her analysis shows that, in removing unsupported diagnosis codes from the model, "1) the average dollar coefficients increase, 2) the average relative values of the model increase, 3) the resulting risk scores to the MAOs also increase as a result when applying the revised relative values to existing MAO data, and 4) results do not change even if expenditures from unsupported diagnoses are removed."

"An equivalent, and perhaps more important, conclusion of the analysis is that the unsupported diagnosis codes in the TM data result in reduced relative values on average in the current risk adjustment model from what they would have been had CMS developed the model on only supported codes. That is, unsupported HCCs in the TM data dilute the average relative values currently used in MA payment."

But Lambert neglects to assess how the county rates will be adjusted for any on-average reduction of relative values of the model that could exist because of the presence of unsupported codes. As I state above and in Opinion 3, the average change in risk scores resulting from large numbers of unsupported codes that might be in the TM data is offset variably when the county rates are calculated by CMS. The hypothetical lowered risk factors (and, thereby, risk scores) could result in increased county rates depending on the medical profile of the beneficiaries for the year of data the model is being applied. The payment results are mixed. This part of the payment determination ignores the opposite effects on risk factor values caused by the data not reported by TM providers in typical coding.

Additionally, Lambert discusses CMS Part D payment for prescription drugs in the same context of unsupported codes. She points out that CMS has not applied the removal of unsupported MA diagnosis codes to that model. This does, in fact, suggest that CMS should be doing so. However, there is another difference, not noted by Lambert, in the modeling data for Part D. She states that TM data alone are used for the modeling. In fact, MA as well as TM data are included in the costs and claims for all Medicare beneficiaries. For Part C, costs reported on MA encounter data have not been yet deemed accurate enough for use to calibrate models. There are plans that are reporting values of 0 for payment for all or a large proportion of medical encounters. The cost data for drugs are in Prescription Drug Event datasets for both standalone plans (PDPs) and MA drug plans (MAPDs) — TM and MA beneficiaries. The plan payments to pharmacies and the plan liability are considered accurate. The coding patterns of diagnoses are being averaged, and the average, not solely TM, is what is used to estimate the risk factors for drug spending for the drug HCCs, called RxHCCs. However, in the payment phase it actually is proper to exclude unsupported codes. As with Part C, the model estimation data containing some unsupported codes (whether from TM or MA) will have minimal impact on the risk factors—possibly increasing or possibly decreasing for some groups. However, unsupported diagnosis codes that are submitted for payment when the Part D model is applied will result in a windfall for the MA-PD plan.

Returning to the issue of supported, but unreported, diagnoses, Lambert puts it into the discussion of the statutorily mandated Coding Intensity Adjuster (CIA) starting on page 15. The CIA is a statistical adjustment based on analyses separate from the consideration of auditing claims and encounters when payments are in the computation phase. She does not discuss the underlying reasons for differences in incentives for coding in TM and MA. It is my understanding, and observation, that MA plans “mine” their data to reduce the degree of supported, but unreported codes as well as engage in other activities that lead to increased coding.

Aside from the issue of unsupported diagnosis codes that raise MA enrollees’ risk scores, is the effort MA plans make to increase supportable diagnoses that might not be reported in the typical coding pattern. There are seminars on optimal coding practices with the risk models as the target

for optimization. One of the practices has been to give financial incentives to providers that increase the risk scores of their managed care patients. (I have personally attended such a meeting with testimonials from a physician group that was rewarded for more intense coding than they typically had done.) There are many companies offering assistance in improving coding of HCCs and software like the Epic system add-ons mentioned above. The increased intensity is not for unsupported codes, but to be sure supported codes are coded on claims at a level that would otherwise be lower if coded with the same incentives as a TM provider has.

An example of coding practice as it differs from traditional practice is given in the advice by American Health Information Management Association (AHIMA), which is describing reasonable practices specifically for HCC payment.²⁰

There are two important aspects of HCC coding:

1. Analyzing health record documentation to identify reportable conditions
2. Accurately assigning ICD-10-CM codes to these conditions

ICD-10-CM coding for HCC reporting is different from traditional ICD-10-CM coding because the intent is to report all conditions that affect the individual's health status concurrently across the continuum of care. Similar to traditional coding practices—used for reimbursement, statistics, and research—all the conditions for a particular episode of care (inpatient admission, clinic visit, same-day surgery, etc.) are reported. In HCC coding, the risk adjustment coding professional codes all conditions for the episode of care like traditional coding. However, continuous review of the health record documentation throughout the year is necessary to ensure all conditions have been considered and abstracted by the end of the year.

As described by Lambert, CMS is by law required to develop a correction factor for this level of coding intensity. It is now 5.9 percent. This factor assumes the codes are supportable and does not intend to correct for unsupported codes.

Summary Rebuttal to Specific Comments in Duggan report

First, Mark Duggan mischaracterizes the import of the CIA in the same way as does Julia Lambert. Starting on page 50 of his expert report, Duggan describes the reasons that plans should collect very complete diagnoses for their enrollees from sources, including medical records. Reporting this highly complete diagnosis set is unquestionably more intense than the reporting done on TM claims. For purposes of this discussion, however, just as was the case with Julia Lambert, it is important to recognize that the CIA is designed to address a separate issue from the existence of potentially unsupported codes in the MA data that has been submitted to CMS. Rather, it is intended to address the increased intensity of diagnoses submission

²⁰ Watson, M. M. (2018). Documentation and coding practices for risk adjustment and hierarchical condition categories.

compared to TM. There is a difference between the presence of a diagnosis in the medical record and whether that code would be usually reported on claims (the source of TM data). Claims are supposed to report diagnoses relevant to care of the patient. Some diagnoses are under control or so mild that there are no treatment costs associated with them. They would not warrant reporting in the TM claims. Using the medical records as a source increases coding intensity.

Second, while Duggan provides much detail about the benchmark, which is the newer version of the AAPCC county rates that are multiplied by relative risk scores, his statement on page 57, paragraph 120, is an overstatement of the relevant issue.

... because the model relies on FFS Medicare enrollees to predict expenditures that are associated with each HCC for MA enrollees, it implicitly assumes that, for each HCC, the relative cost to treat enrollees is the same in FFS Medicare and MA plans. This assumption is only true when the distribution of unsupported diagnosis codes (and thus HCCs) is identical in FFS Medicare and MA plans. Thus, the model is unlikely to accurately predict expenditures for MA enrollees unless the distribution of unsupported diagnosis codes (and thus HCCs) is identical in the FFS Medicare and MA populations (so that the incremental cost of an HCC is the same across the two populations).

I disagree with the argument that follows starting in paragraph 121, for reasons I have described above. As I have discussed, the effect of unsupported codes is very different in the estimation of the relative risk factors from the effect in payment to MA plans. In payment, unsupported codes directly increase payments. In the estimation for relative risk factors, because all the beneficiary costs used in the model estimation are accounted for, irrespective of the presence of the unsupported codes, the unsupported codes have only small effects on the average estimated risk factors. Some go up and some go down, and the net effect on large group risk scores is much smaller than the effect on risk scores in the payment phase. If the result of an unsupported code for a beneficiary is to reduce a relative factor, the value for everyone in the same demographic group or some related HCC would be slightly increased. Conversely, an unsupported code submitted for an MA enrollee will result in hundreds or thousands of dollars in additional payments for that enrollee because the added HCC marker adds an amount related to its risk factor. This means that any direct comparison of error rates in TM data to MA data is not valid.

While it is true that the risk score for a TM person could vary somewhat related to the presence of an unsupported code in a particular HCC, the effect would depend on the full constellation of HCCs the person is coded for. Some of that person's HCC factors could be affected oppositely. In addition, and significantly, the purpose of the HCC model is to pay properly at the group level. It is not just one person or HCC factor that is affected by the presence of the unsupported code, but all beneficiaries in the model, with varied patterns of HCCs that are affected in varied ways.

I also disagree with Duggan's statement on page 59 of his report that "removing diagnosis codes for FFS Medicare enrollees would not change the benchmark against which plans bid." In fact, the benchmark (which is the county rate) could be higher lower in different counties and year of application of the model. Payments are not always reduced by lower scores if base rates increase.

Summary Rebuttal to Specific Comments in Salve report

Salve concentrates on determining the error rate in the TM data and comparing it to the error rate determined in other studies for MA data, as if the two rates are equivalent in consequences. Even if one accepts the “unsubstantiated” TM error rate of 31.6% cited on page 6 of his report, and further accepts the 13.3% error rate cited for UnitedHealth on page 47 of his report, Salve does not follow through on the consequences to the model risk scores when the model is re-estimated on the data with the unsupported codes removed. Rather, he seemingly simply – and without any analysis or recognition of how the model estimation works – compares the whole number percentages of the two error rates he describes, finding 31.6% to be higher than 13.3% (a fact that is obviously accurate, but without accounting for differences in impact on risk scores). He describes the regression model, but does not address how the process adjusts the risk factor values to properly predict at the group level. Differences in error rates in the TM and MA data do not lead to parallel effects on payment. Errors in TM do not cause systematic over- or under-payments. Errors in MA data do – they cause over-payment.

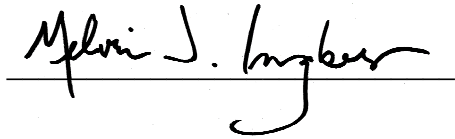
Summary

Although both of the Lambert and Duggan expert reports discuss the CMS-HCC payment system in detail, neither addresses the issue of how the presence of unsupported data actually affects the HCC model relative factors and how it impacts the total risk factors for individuals and for larger groups. Salve similarly ignores the impact unsupported codes have on model calibration and, instead, compares two percentages that should not be compared per se. I opine that the OLS regression compensates strongly for the unsupported codes. Not excluding unsupported codes at the payment phase would create much greater errors than having unsupported codes in the calibration data. Unsupported codes in MA always increase payments. Such codes in the TM data have varied effects on payments, not unidirectional. It is an important distinction to recognize that the model creates relative risk factors; it does not assign payments. The average relative risk score for a large group is not affected greatly by the presence of unsupported diagnosis codes in the TM data, and the impact that is created is small and does not go in only one direction. Conversely, the effect of unsupported diagnoses in the MA data is to systematically raise payments for every person assigned such a diagnosis.

Going back to the original AAPCC method I described above, plans were paid on demographic factors only, with no clinical data, and the large groups that were HMOs were adequately paid, with most studies indicating overpayment because of favorable selection of enrollees in those demographic groups. Those demographic factors did not vary by clinical subgroup. The HCC model uses clinical information to produce better averages for smaller groups. The issue raised by Lambert, Duggan, and Salve is whether the presence of some unsupported codes **in the data used for estimation** results in systematic underpayment for plans that have their unsupported codes removed. It does not because the unsupported codes in TM do not have the same effect as

unsupported codes in MA plans and because there are offsets by group when county rates are set and by data year.

Executed the 26th day of January 2024

A handwritten signature in black ink, reading "Melvin J. Ingber", is written over a horizontal line.

Melvin J. Ingber, PhD

MELVIN J. INGBER

Summary of Professional Experience

Melvin J. Ingber is currently a consultant on health services payment, risk adjustment and quality issues.

Previously he was a principal scientist at RTI International, specializing in health economics, health care payment, and quality measures. At RTI, he served as a project director, analyst, or consultant on numerous projects, some of which are listed below. Topic areas covered included risk adjustment modeling for spending on medical services, prescription drugs, and quality measures; post-acute care (PAC) assessments, episodes, and payment systems; frailty measures; an evaluation of the Centers for Medicare & Medicaid Services (CMS) initiative to reduce avoidable admissions of nursing home residents; and the statistical design for adjusting the data in the Home Health Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.

Dr. Ingber was an economist at CMS for more than 15 years and was director of CMS's Division of Payment Research for more than 5 years. As division director, he supervised intra- and extramural research and demonstration evaluations, particularly those related to payment, including refinement and reform of payment for hospitals, PAC, and geographic adjustment of physician payment. Pay-for-performance issues were also an area of study. He was a frequent consultant on other CMS research projects for technical and operational issues.

Dr. Ingber was the lead government analyst for the research and development of risk adjuster systems for the Medicare Part D program and for Medicare enrollees in HMOs. He continued that work at RTI while expanding into other areas.

Education

PhD, Economics, State University of New York at Stony Brook, Stony Brook, NY, 1985.

MS, Physics, Cornell University, Ithaca, NY, 1965.

BS, Physics, Queens College, City University of New York, Flushing, NY, 1962.

Selected Project Experience

RTI

Site-Neutral Payment Systems for Post-Acute Care Settings (2014 to 2015, 2017 to 2022)—*Senior Analyst*. In this project, measures for risk-adjusted admission and readmission rates for beneficiaries in ACOs were being developed. The measures are being developed for ACOs, treating them as responsible parties.

Evaluation of the Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents (2012 to 2021)—*Project Director*. Directed a team in a multifaceted project to evaluate the effects of a CMS initiative on many measures, including admissions, emergency department visits, costs, and quality measures. The project included long-term care residents in more than 120 nursing homes in seven states. Comparison groups were selected and tracked. Primary and secondary data collection was required covering Medicare and Medicaid services. A second phase of this Initiative, concentrating on six medical conditions, was evaluated. This phase added a payment incentive to the first phase and a second arm that had payment incentives only.

Development of Post-discharge Readmission Measures for IRFs, LTCHs, and SNFs (2012 to 2023)—*Task Leader*. Directed the development of risk-adjusted measures of all-cause unplanned readmissions

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during the 30 days after discharge from an inpatient rehabilitation facility (IRF) or long-term care hospital (LTCH) to a lower level of care. This involved model development, determination of planned readmissions, validation of measures, and presentation to the National Quality Forum. This work was expanded to readmission measures for SNFs, discharge to community measures for all these facility types, and Medicare spending per beneficiary for episodes of care starting with a PAC stay.

Part C&D Risk Adjustment Model Research, Development and Maintenance for Medicare Advantage and Prescription Drug Plans (2007 to 2023)—*Project Director/Senior Analyst*. Directed a team in a multitask project to maintain and improve risk adjustment methods for Medicare capitated plans. This included refining the ICD-9-CM diagnosis grouper, re-estimating models over time using newer data, including the Medicare Part D prescription drug data, updating the groupers with new diagnosis codes, and improving models using additional predictors. The project also includes adapting all the models, aged/disabled, institutionalized, end-stage renal disease (ESRD), and Part D drug, to ICD-10-CM diagnosis codes. Recent work included expanding the modeling to the mandated federal ACA health exchange plans, accounting for multiple benefit structures.

Risk Adjustment Model Research, Development and Maintenance for ACA Health Exchange Plans (2011 to 2023)—*Senior Analyst*. Worked on development of models for ACA plans, methods of filtering claims for acceptability of diagnoses, addition of drug categories, nonlinear models.

Chronically Critically Ill Patient Payment Recommendations (2010 to 2014)—*Senior Analyst and Project Director*. A study to identify the chronically critically ill and medically complex (CCI/MC) patients for payment reform in short- and long-stay acute hospitals (LTCHs). CCI/MC patient profiles and potential payment alternatives were developed in both settings. Simulations of impacts of changes to LTCH payment required by law were run under various behavioral scenarios.

National Implementation of the Home Health CAHPS (2008 to 2011)—*Statistical Consultant*. Developed the sampling design and modeling for estimation of effects of survey mode and patient characteristics on responses of home health patients to the patient survey of perceptions of care. The adjustments derived will be applied to the national implementation of the survey.

Development of Post-acute Care Episodes (2007 to 2014)—*Senior Analyst*. This was a series of projects to define episodes of PAC appropriate for bundled payment, to create predictive models for payments and costs using Consumer Assessment and Record Evaluation (CARE) assessment data and to extrapolate the model nationally.

Post-Acute Care Payment Reform Demonstration (2007 to 2012)—*Associate Project Director*. Assisted in coordinating demonstration, collecting data from a new PAC assessment instrument (CARE) and care resource report and supervising analysis of the data to create new payment systems for Medicare post-acute care providers—LTCHs, IRFs, skilled nursing facilities, and home health agencies.

Medicare Part D Program Evaluation (2007 to 2011)—*Project Director*. Directed team in evaluating the effect of the new drug program on non-drug Medicare services. The goal was to determine if the program changed utilization and expenditures on other services. Other aspects were the effects in the Medicare Advantage program and the effects particularly on beneficiaries with chronic diseases. Adherence to drug regimens in the subsidized and unsubsidized enrollees were studied and the effects of adherence were determined.

Physician Group Practice Demonstration (2006 to 2013)—*Analyst*. Worked with team to conduct and evaluate a Medicare demonstration in which large group practices were rewarded for reducing expenditure growth for an assigned treated population compared to other practices in their service area. All measures of change were measured after accounting for changes in population morbidity.

Development of Patient Assessment Instrument for Medicare Post-Acute Care (2006 to 2010)—*Scientific Advisor/Analyst*. Worked with team to develop new web-based patient assessment instrument

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and data analysis to evaluate the predictive power of the assessment tool. The new instrument, CARE, has been used to develop new PAC payment methods.

Development of Frailty Adjuster for Medicare Advantage Payment System (2006)—*Analyst*. Developed models to predict the number of activities of daily living difficulties that would be reported by beneficiaries in surveys, using demographic, clinical, and county characteristics from the census; and a similar model to predict the frailty factors needed to adjust predicted costs. Models were developed using survey data and applied to develop adjusters for all counties in the Medicare Advantage ratebook.

Professional Experience

2023 to present. Independent consultant

2006 to 2023. RTI International, Division for Health Services and Social Policy Research, Washington, DC.

Principal Scientist.

1990 to 2006. Centers for Medicare & Medicaid Services (CMS), Office of Research, Development and Information, Baltimore, MD.

Director, *Division of Payment Research* (2000 to 2006).

Economist (1990 to 2006).

1984 to 1990. University of Texas at Dallas, Department of Economics and Political Economy, School of Social Sciences, Dallas, TX.

Assistant Professor.

Professional Service

Panel member, National Institutes of Health State of the Science Committee on Prevention of Fecal and Urinary Incontinence, 2007

Books, Book Chapters, and Monographs

Coomer, N. M., Ingber, M., Coats, L. A., & Morley, M. (2017). *Using Medicare cost reports to calculate costs for post-acute care claims*. Research Triangle Park, NC: RTI Press.
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Ingber, M. J. (2002). Implementation of risk adjustment for Medicare. In C W. Wrightson, Jr. (Ed.), *Financial strategy for managed care organizations*. Chicago, IL: Health Administration Press.

Ingber, M. J. (1999). The current state of risk adjustment technology for capitation. In N. Goldfield (Ed.), *Physician profiling and risk adjustment* (2nd ed.). New York, NY: Aspen Publishers, Inc.

Peer-Reviewed Journal Articles

Feng, Z., Vadnais, A., Huber, B., Deutsch, A., Li, Q., Bercaw, L., Ingber, M. J., Segelman, M., Khatutsky, G., Sroczynski, N., & Xu, L., (2023). Hospital Transfer Rates among Long-Stay Nursing Home Residents: Variation by Day of the Week. *Journal of the American Medical Directors Association*. <https://doi.org/10.1016/j.jamda.2023.06.018>

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- Deutsch, A., Palmer, L., Neumann, H., Potelle, J., Ignaczak, M., McMullen, T., & Ingber, M. J. (2023). Characteristics and outcomes of Medicare patients treated in inpatient rehabilitation facilities: 2013-2018. *Rehabilitation Nursing Journal*, 48(3), 109-121.
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- Deutsch, A. F., McMullen, T., Vaughan, M., Palmer, L. A. M., Kwon, M. S., & Ingber, M. J. (2022). The change in self-care score quality measure for inpatient rehabilitation facilities: Exclusion criteria and the risk-adjustment model. *Archives of Physical Medicine and Rehabilitation*.
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- Daras, L. C., Ingber, M. J., Carichner, J., Barch, D., Deutsch, A., Smith, L. M., ... Andress, J. (2018). Evaluating hospital readmission rates after discharge from inpatient rehabilitation. *Archives of Physical Medicine and Rehabilitation*, 99(6), 1049-1059. <https://doi.org/10.1016/j.apmr.2017.07.008>
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- Feng, Z., Ingber, M. J., Segelman, M., Zheng, N. T., Wang, J. M., Vadnais, A., Coomer N. M., & Khatutsky, G. (2018). Nursing facilities can reduce avoidable hospitalizations without increasing mortality risk for residents. *Health Affairs (Project Hope)*, 37(10), 1640-1646. <https://doi.org/10.1377/hlthaff.2018.0379>
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- Friedman, H., He, F., Daras, L. C., Ingber, M. J., Evans, R., & Levitt, A. (2019). *Evaluating the relationship between post-acute care providers' performance on post-discharge potentially preventable hospital readmission measures and other quality measures*. Poster session presented at AcademyHealth Annual Research Meeting 2019, Washington, DC, United States.
- Daras, L. C., Pardasaney, P. K., He, F., Morley, M. A., DiBello, M. V., Li, Q., & Ingber, M. J. (2018). *National data on Medicare claims-based measures used in the skilled nursing facility quality reporting program*. Gerontological Society of America's Annual Scientific Meeting, Boston, MA, United States.
- Daras, L. C., Vadnais, A. J., Karwaski, C., Zhang Pogue, Y., DiBello, M. V., Shah, A. R., ... Poyer, J. (2019). *The skilled nursing facility value-based purchasing program highlights from program year one*. Academy Health, Washington, DC, United States.
- Marino, M., Pardasaney, P. K., Blackmon, B. D., Ingber, M. J., Broyles, I. H., Levitt, A. F., & McMullen, T. (2019). *Variation in post-acute care discharge to community rates by social risk factors*. Poster session presented at Academy Health Annual Research Meeting, Washington, DC.
- Pardasaney, P. K., Marino, M., Ingber, M. J., He, F., Broyles, I. H., Levitt, A. F., & McMullen, T. (2019). *Reliability and validity of the discharge to community measures in the Centers for Medicare & Medicaid Services' (CMS) post-acute care quality reporting programs*. Academy Health Annual Research Meeting, Washington, DC.
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EXHIBIT D-61

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

**UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,**

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO (SSx)

**EXPERT REPORT OF
DANIEL KESSLER, Ph.D.
SEPTEMBER 29, 2023**

CONFIDENTIAL

(Contains Attorneys' Eyes Only Information As Designated)

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I. Qualifications

1. I am a tenured professor at Stanford Law School and the Stanford Graduate School of Business; a professor (by courtesy) at the Stanford School of Medicine; a Senior Fellow at Stanford's Hoover Institution and its Institute for Economic Policy Research; and a Research Associate at the National Bureau of Economic Research, the country's leading nonprofit, nonpartisan economic research organization. I teach a University-wide course in health care finance and regulation at Stanford. I have also taught courses in health policy at the Wharton School of the University of Pennsylvania and Harvard Law School. I have served as a consultant to the U.S. Federal Trade Commission, hospitals, health systems, and insurers. I currently serve on Stanford's Committee on Faculty and Staff Human Resources, which oversees the University's health insurance plans and reports to its Chief Financial Officer. I obtained a J.D. from Stanford Law School in 1993 and a Ph.D. in economics from MIT in 1994, specializing in law-and-economics and health economics.

2. I study the empirical effects of health policy. I have published numerous books and papers in peer-reviewed journals on health economics, health insurance, and regulation. I served as the principal investigator for a grant from the U.S. National Institutes of Health to study how Medicare reimbursement policy should account for hospital integration and as an investigator for a grant from the U.S. Agency for Healthcare Research and Quality to study how physician organizational choices affect the cost and quality of care. I have also received grant support from the U.S. National Science Foundation, the California Health Care Foundation, and the American Cancer Society. In addition, my recent research is directly relevant to this case. I have published several peer-reviewed papers on how CMS should regulate and pay Medicare Advantage plans, how risk-adjustment data should be collected, and on the effects of Medicare Advantage on medical treatments and mortality. My full curriculum vitae is attached as Appendix A. It also summarizes my expert testimony over the last four years.

3. My compensation for work on this matter is \$900 per hour. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. My compensation in this matter is not contingent or based in any way on the content of my opinion or the outcome of this or any other matter.

4. I hold the opinions I express in this report to a reasonable degree of certainty in the field of economics.

II. Assignment and Summary of Opinions

5. I offer six main opinions. My first opinion, discussed in § III, is that attempting to achieve “payment neutrality” between Medicare Advantage (MA) and Fee-For-Service Medicare (FFS) creates incentives for differences in coding between the sectors. This occurs because attempting to achieve payment neutrality – that is, payments for MA enrollees to equal what they would be expected to cost in FFS – requires the Centers for Medicare and Medicaid Services (CMS) to pay MA plans on the basis of their enrollees’ health. But paying plans on the basis of their enrollees’ health creates a dilemma – it gives plans an incentive to find and report as many diagnoses as possible so as to increase the reported morbidity of their enrollees. This incentive is absent in FFS, which pays providers on the basis of the procedures that they perform, not on the basis of the diagnoses that they code. Thus, payment neutrality creates a differential incentive for “coding intensity” in MA versus FFS – that is, the coding of diagnoses conditional on a patient’s true medical condition.

6. My second opinion, discussed in § IV, is that differences in coding intensity between the sectors can be due to either present unsupported codes (“overcoding”) or absent supported codes (“undercoding”) in either MA or FFS. In § IV, I explain how increases in present unsupported codes increase a sector’s coding intensity, as do decreases in absent supported codes. More present unsupported codes in claims data imply that the claims data overstate the severity of patients’ true medical conditions; more absent supported codes imply that the claims data understate severity.

7. My third opinion, discussed in § V, is that the Coding Intensity Adjustment (CIA, also known as the Coding Pattern Adjustment) does not and has never identified whether differences in coding between the sectors are due to differences in the rates of either present unsupported or absent supported codes. The CIA was created by CMS in order to make payments to MA plans account for differences in coding intensity between MA and FFS. In § V, I review public and confidential documents that show that the CIA does not and has never distinguished whether the differences in coding intensity between MA and FFS for which it accounts arise from differences in present unsupported or absent supported codes.

8. My fourth opinion, discussed in § VI, is that CMS has already recovered payments to MA plans in aggregate due to MA-FFS differences in unsupported codes, if the CIA achieves its stated goal. Because the CIA does not identify whether differences in coding intensity are due to supported or unsupported codes, if it accounts for all of the differences in coding intensity between MA and FFS, then CMS has necessarily already recovered payments to MA plans in aggregate due to MA-FFS differences in unsupported codes. In § VI, I also explain several corollaries to this proposition, including the following:

- a. Any removal of unsupported codes from MA plan data in the aggregate would allow CMS to recover twice for the removed unsupported codes, causing MA plans to receive less than their intended payments and, thus, to be “underpaid”;
- b. In order to know whether CMS has “overpaid” any particular plan due to that plan’s level of unsupported codes, it is necessary to determine how much the particular plan’s coding intensity deviates from the industry average and in what direction; and
- c. Unless a plan knows how much its own coding intensity deviates from the industry average and in what direction, it cannot know whether it is “overpaid” or “underpaid.”

9. My fifth opinion, discussed in § VII, is that CMS must conduct chart (also known as medical record) reviews to determine whether and to what extent it has already recovered payments due to unsupported codes, if the CIA is too low. If the CIA is too low, then CMS has not fully recovered payments to MA plans due to coding intensity differences, even after adjusting for the CIA. These unrecovered payments, however, can be from more present unsupported codes in MA versus FFS, or fewer absent supported codes in MA versus FFS. Unless MA-FFS differences in absent supported codes account for all of the CIA, some of the CIA must compensate CMS for MA-FFS differences in present unsupported codes. If this is true, then there is no way to determine how much CMS has already recovered for present unsupported codes without knowing the relative rates of absent supported and present unsupported codes in MA and FFS – which would require medical record reviews. In § VII, I explain several corollaries to this proposition, including that deleting unsupported codes (or even a subset of unsupported codes) from a particular MA plan’s

data could bring payments to the plan closer to or farther from payment based on CMS's payment model.

10. My sixth opinion, discussed in § VIII, is that the regulatory process would be the economically efficient means to address remaining MA-FFS differences in coding intensity, if the CIA is too low. The regulatory process increases clarity and predictability, which reduces policy uncertainty, and thereby increases investment and employment in firms in the health care sector. If the CIA is too low, the most efficient way to address remaining MA-FFS differences in coding intensity would be to increase the CIA explicitly through the regulatory process by which it was determined in the first place. If the CIA is too low, and there is some reason not to address remaining MA-FFS differences by increasing the CIA, then the regulatory process would again be the economically efficient means to consider alternative approaches (such as Mandatory Two-Sided Review, which would require that MA plans evaluate *all* the diagnoses on any claim subjected to a medical record review – not just the absent supported diagnoses – and delete any diagnoses not supported by the chart) to addressing remaining MA-FFS differences in coding intensity. I also show that my opinion is consistent with CMS's historical treatment of Mandatory Two-Sided Review.

III. Attempting to Achieve “Payment Neutrality” Between Medicare Advantage and Fee-For-Service Creates Incentives For Differences in Coding Between the Sectors

11. The Medicare program offers beneficiaries two ways to obtain health insurance coverage: FFS and MA. FFS, sometimes called “traditional” Medicare, pays physicians and other providers based on the services they supply, such as office visits and procedures. All services are classified according to the Healthcare Common Procedure Coding System (HCPCS), which contains codes for over 7,000 different services. Each service is associated with a payment rate, based on the amount of work required to provide the service and the expenses in providing it, that the provider would be expected to incur.¹ The MA program makes a fixed payment per enrollee per month to an MA plan, which then contracts with providers for services for the plan's participants.² In doing

¹ See MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 95–96 (June 2019).

² See Centers for Medicare & Medicaid Services, Report to Congress: Risk Adjustment in Medicare Advantage 3 (Dec. 2021), <https://www.cms.gov/files/document/report-congress-risk-adjustment-medicare-advantage-december-2021.pdf>.

so, the MA program seeks to give plans incentives to manage their enrollees care to be lower cost and/or higher quality than it would have been in FFS.³

12. Most Medicare policy analysts start from the principle that payments to MA plans should achieve “payment neutrality,” sometimes also described as “financial neutrality” or a “level playing field”⁴ with FFS. The Medicare Payment Advisory Commission, or MedPAC, is an independent congressional agency established by the Balanced Budget Act of 1997 to advise the U.S. Congress on the Medicare program, including payments to health plans participating in Medicare Advantage.⁵ MedPAC defines payment neutrality as requiring payments for MA enrollees to equal what they would be expected to cost in FFS Medicare.⁶ MedPAC has for many years supported the principle of payment neutrality,⁷ as has my own research.⁸ According to MedPAC, “an underlying rationale for this policy is that it encourages beneficiaries to enroll in whichever sector (MA or FFS) is more efficient in their local health care market.”⁹

13. To achieve payment neutrality, CMS must pay MA plans on the basis of their enrollees’ health. MA plans report their enrollees’ health to CMS in the form of diagnosis codes and other enrollee characteristics. If MA plans enroll beneficiaries who are healthier (and therefore likely to be lower cost) than those in FFS, then payment neutrality would require CMS to pay the plans less than the average cost of FFS enrollees; but if MA plans enroll beneficiaries who are sicker than those in FFS, then payment neutrality would require CMS to pay the plans more than the average cost of FFS enrollees. The process of determining how much less or more CMS should pay MA plans than the average cost of FFS enrollees is called “risk adjustment.”

14. But paying plans on the basis of their enrollees’ health creates a dilemma – it gives plans an incentive to find and report as many diagnoses as possible so as to increase the reported morbidity of their enrollees.¹⁰ This incentive is absent in FFS, which pays providers on the basis

³ Thomas McGuire, Joseph Newhouse, & Anna Sinaiko, *An Economic History of Medicare Part C*, 89(2) *Milbank Quarterly* 289, 289 (2011).

⁴ Jacob Glazer & Thomas G. McGuire, *Paying Medicare Advantage Plans: To Level or Tilt the Playing Field*, 56 *J. Health Econ.* 281, 281 (2017).

⁵ See *What We Do*, MedPAC, <https://www.medpac.gov/what-we-do>.

⁶ See MedPAC, Report to the Congress: Medicare and the Health Care Delivery System 97 (June 2019).

⁷ See *id.* at 261.

⁸ See Gary E. Bacher, Michael E. Chernew, Daniel P. Kessler, Stephen M. Weiner, *Regulatory Neutrality Is Essential To Establishing a Level Playing Field For Accountable Care Organizations*, 32(8) *Health Affairs* 1426 (2013).

⁹ MedPac, Issues for Risk Adjustment in Medicare Advantage 97 (June 2012).

¹⁰ Richard Kronick & Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4(2) *Medicare & Medicaid Research Review* E2–3 (2014).

of the procedures that they perform, not on the basis of the diagnoses that they code. Thus payment neutrality creates a differential incentive for “coding intensity” in MA versus FFS – that is, the coding of diagnoses conditional on a patient’s true medical condition.¹¹

IV. Differences in Coding Between the Sectors Can Be Due to Either Present Unsupported or Absent Supported Codes in Either MA or FFS

15. MA-FFS coding intensity differences can arise from type I and type II errors. Type I errors, also known as overcoding, refer to the presence of “unsupported” codes – codes that are recorded on the claims-based data, but do not reflect a patient’s true medical condition. Type II errors, also known as undercoding, refer to the absence of “supported” codes – codes that are not recorded on the claims-based data, but do reflect a patient’s true medical condition.

16. Because both MA and FFS data may include both type I and type II errors, MA-FFS coding intensity differences can arise from four sources: the presence of unsupported codes in MA, the absence of supported codes in MA, the presence of unsupported codes in FFS, and the absence of supported codes in FFS. The frequency in MA and FFS of present unsupported codes and absent supported codes – and therefore the sources of coding intensity differences between the sectors – are empirical questions.

17. The direction and magnitude of the difference in coding intensity between MA and FFS depends on the frequency of present unsupported and absent supported codes in the two sectors. For example:

- a. If MA contains the same number of present unsupported codes than FFS but the fewer absent supported codes, then MA would have greater coding intensity than FFS.
- b. MA might still have greater coding intensity than FFS, even if it contains fewer present unsupported codes, if MA also contains many fewer absent supported codes.
- c. Alternatively, if MA contains fewer present unsupported codes than FFS, and the same number of absent supported codes, then MA would have lesser coding intensity than FFS.

¹¹ I use the term “true medical condition” to refer to the patient’s medical condition as documented in the patient’s medical record.

- d. MA could have the same coding intensity as FFS, even if it has fewer present unsupported codes, as long as it also has fewer absent unsupported codes.

18. A stylized example makes this point clear. For simplicity, assume that every diagnosis code has the same effect on a patient's expected cost. In this example, the coding intensity of a sector (MA or FFS) would be equal to the number of present unsupported codes less the number of absent supported codes. Exhibit 1 reports the number of present unsupported and absent supported codes for the average patient in MA and FFS under four different hypothetical scenarios, which correspond (respectively) to ¶¶ 17.a – 17.d.

19. In scenario a, the average patient in MA has 10 present unsupported and no absent supported codes, whereas the average patient in FFS has 10 present unsupported and 5 absent supported codes. In this scenario, MA has greater coding intensity than FFS. MA also has greater coding intensity than FFS in scenario b, in which the average patient has 8 present unsupported codes and no absent supported codes, as compared to 10 present unsupported and 5 absent supported codes in FFS. By contrast, in scenario c, MA has lesser coding intensity than FFS: the average patient in MA has 5 present unsupported and 5 absent supported codes, as compared to 10 present unsupported and 5 absent supported codes in FFS. In scenario d, MA has the same coding intensity as FFS. Even though the numbers of present unsupported and absent supported codes in MA are not the same as the numbers in FFS, the difference in each sector between the numbers of present unsupported and absent supported codes – which determines the sector's coding intensity – are the same.

Exhibit 1: Coding intensity in MA and FFS in Four Hypothetical Scenarios

Scenario	MA average patient		FFS average patient
a	10 present unsupported 0 absent supported Coding intensity $10 = 10 - 0$	More intense ←	10 present unsupported 5 absent supported Coding intensity $5 = 10 - 5$
b	8 present unsupported 0 absent supported Coding intensity $8 = 8 - 0$	More intense ←	10 present unsupported 5 absent supported Coding intensity $5 = 10 - 5$
c	5 present unsupported 5 absent supported Coding intensity $0 = 5 - 5$	More intense →	10 present unsupported 5 absent supported Coding intensity $5 = 10 - 5$
d	8 present unsupported 3 absent supported Coding intensity $5 = 8 - 3$	Equally intense =	10 present unsupported 5 absent supported Coding intensity $5 = 10 - 5$

20. The existence of a difference in coding intensity between MA and FFS does not imply that MA coding less closely reflects a patient's true medical condition than FFS, or vice versa. Define the extent to which a sector reflects a patient's true medical condition as the average total error rate in the sector, i.e., the sum of the number of present unsupported and absent supported codes. For example:

- a. MA could have greater coding intensity than FFS if MA perfectly reflected a patient's true medical condition (i.e., did not have an error rate) when FFS imperfectly reflected a patient's true medical condition due to absent supported codes.
- b. Greater coding intensity in MA could be consistent with MA coding less closely reflecting a patient's true medical condition (i.e., had an error rate), if MA's greater coding intensity were due to a greater number of present unsupported codes and the same number of absent supported codes as FFS.

- c. Greater coding intensity in MA could also be consistent with MA and FFS equally imperfectly reflecting a patient's true medical condition (i.e., both MA and FFS had error rates), depending on the source of the imperfections in the two sectors.

21. A stylized example makes this point clear. For simplicity, again assume that every diagnosis code has the same effect on a patient's expected cost. Exhibit 2 reports the number of present unsupported and absent supported codes for the average patient in MA and FFS under three different hypothetical scenarios, which correspond (respectively) to ¶¶ 20.a – 20.c.

Exhibit 2: Coding Intensity Differences Do Not Indicate Which Sector's Coding Most Closely Reflects Patients' True Medical Condition

Scenario	MA average patient		FFS average patient
a. MA perfectly reflects true medical condition, FFS imperfectly	0 present unsupported 0 absent supported Coding intensity 0 = 0 - 0	More intense ←	0 present unsupported 5 absent supported Coding intensity -5 = 0 - 5
b. MA imperfectly reflects true medical condition, FFS perfectly	5 present unsupported 0 absent supported Coding intensity 5 = 5 - 0	More intense ←	0 present unsupported 0 absent supported Coding intensity 0 = 0 - 0
c. MA and FFS reflect medical condition equally imperfectly	10 present unsupported 5 absent supported Coding intensity 5 = 10 - 5	More intense ←	5 present unsupported 10 absent supported Coding intensity -5 = 5 - 10

22. In scenario a, the average patient in MA has no present unsupported and no absent supported codes, so it perfectly reflects the patient's true medical condition; the average patient in FFS has no present unsupported and 5 absent supported codes, so it imperfectly reflects the patient's true medical condition. In this scenario, MA has greater coding intensity than FFS. In scenario b, the average patient in MA has 5 present unsupported codes and no absent supported codes, so it imperfectly reflects the patient's true medical condition. In this scenario, MA has greater coding intensity than FFS. In scenario c, the average patient in MA has 5 present unsupported codes and no absent unsupported codes, so it imperfectly reflects the patient's true medical condition; the average patient in FFS has no present unsupported and no absent supported codes, so it perfectly reflects the patient's true medical condition. In this scenario, MA still has

greater coding intensity than FFS. Scenario c shows that even if both MA and FFS reflect the average patient's medical condition equally imperfectly – that is, by making 15 coding errors – MA can have greater coding intensity than FFS. Simply reversing the hypothetical shows that MA can also have lesser coding intensity than FFS, even if both MA and FFS reflect the patient's true medical condition equally imperfectly.

V. The Coding Intensity Adjustment Does Not and Has Never Identified Whether Differences in Coding Between the Sectors Are Due to Differences in Supported or Unsupported Codes

A. Background on the Coding Intensity Adjustment

23. Federal law requires CMS to publish annually a “Rate Announcement” no later than April 6 that explains how payments to MA plans will change in the following calendar year (also known as the “Payment Year”).¹² Federal law also requires CMS to publish annually an “Advance Notice” draft of its “Rate Announcement” no later than February 15 to enable public comment on any changes to MA plan payment that will be specified in its subsequent “Rate Announcement.”¹³ In many (but not all) years, CMS publishes some comments that it receives on the year's Advance Notice, along with its responses to the comments, as part of its Rate Announcement. Thus the 2008-2018 set of Advance Notices and Rate Announcements provide a complete history of all changes to MA plan payment policy for that period, including the adoption of a CIA.¹⁴ Through CMS's responses to comments on the Advance Notices, the Rate Announcements also in many years explain the reasoning behind and details about changes to MA plan payment, including the CIA.¹⁵

24. The CIA was created by CMS in response to the Deficit Reduction Act of 2005 (DRA 2005). DRA 2005 added § 1853(k)(2)(B)(iv)(III) to the Social Security Act, requiring risk adjustment to account for “differences in coding patterns between [MA] plans and providers under ... parts A and B to the extent that the Secretary has identified such differences.”¹⁶ In its 2008 and 2009 Advance Notices and Rate Announcements, CMS described and reported results from studies

¹² 42 U.S.C. 1395w-23 § 1853(b)(1)-(b)(2).

¹³ *Id.*

¹⁴ I assign each Advance Notice and Rate Announcement to the Payment Year to which the Advance Notice or Rate Announcement applies.

¹⁵ *See, e.g.*, Rate Announcement, April 4, 2011 at 37.

¹⁶ 42 U.S.C. 1395w-23 § 1853(k)(2)(B)(iv)(III).

“designed to assess the degree of coding patterns (sic) differences that may be identified between FFS and MA and the extent to which any differences could be appropriately addressed by an adjustment to the CMS-HCC risk scores.”¹⁷ In those years, CMS declined to adopt a CIA.¹⁸ In the 2010 Rate Announcement, CMS adopted a CIA, and has retained a CIA for all of the subsequent years.¹⁹

25. As I explain below, these Advance Notices and Rate Announcements, along with internal CMS documents, show that the CIA does not and has never identified whether differences in coding between MA and FFS are due to differences in supported or unsupported codes.²⁰ In particular:

- a. According to CMS, the DRA 2005 did not require CMS to identify the source of MA-FFS differences in coding (§ V.B);
- b. CMS did not identify the source of coding differences in its preliminary studies of a CIA (§ V.C);
- c. CMS did not identify the source of coding differences in the methodology it used in 2009 to calculate the CIA for 2010 (§ V.D);
- d. CMS did not identify the source of coding differences in its implementation of the CIA after 2010 (§ V.E); and
- e. Changes to the specification of the CIA that CMS considered after 2010 did not identify the source of coding differences (§ V.F).

26. This is not surprising. CMS’s calculation of the CIA does not and has never relied on medical record reviews. Without medical record reviews from both MA and FFS, it is impossible to determine the extent to which claims-based differences in MA-FFS enrollee health are due to differences in the volume of supported versus unsupported codes. To determine the extent to which claims-based differences in MA-FFS enrollee health were due to one source of coding error or the other requires knowledge of the scope of that type of error in both MA and FFS.

¹⁷ Advance Notice, February 16, 2007 at 8; *see* Advance Notice, February 22, 2008 at 10–14.

¹⁸ *See* Rate Announcement, April 2, 2007 at 17; Rate Announcement, April 7, 2008 at 18.

¹⁹ *See* Rate Announcement, April 6, 2009 at 19; *see e.g.*, Rate Announcement, April 2, 2012 at 25 (addressing comments related to the CIA).

²⁰ *See also* Sean Creighton Deposition (“Creighton Dep.”), October 4, 2022, at 101:15–102:1 (“Q: And so it's fair to say that as part of calculating the coding intensity adjustment, CMS made no attempt to distinguish between supported and unsupported codes in the Fee-for-Service population or in the MA population; correct? A: That is correct.”).

B. According to CMS, the Deficit Reduction Act of 2005 Did Not Require CMS To Identify the Source of Coding Differences When It Directed CMS To Adopt a Coding Intensity Adjustment

27. CMS first adopted a CIA in its 2010 Rate Announcement. In that Rate Announcement, CMS responded to comments on that year's Advance Notice. One response to comments stated that:

As documented in the 2009 Announcement, CMS believes that the statutory language in the DRA provision at issue provides for a payment adjustment if CMS establishes that there are “differences in coding patterns between [MA] plans and providers under part A and B”...This means that MA organizations are coding “accurately” when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, “differences” in coding patterns, **regardless of the source** [emphasis added], would make the MA plan coding “inaccurate” for purposes of implementing risk adjustment.²¹

28. As I explain in ¶ 16, there are four sources of differences in coding patterns: the presence of unsupported codes in MA, the absence of supported codes in MA, the presence of unsupported codes in FFS, and the absence of supported codes in FFS. According to CMS, any of these four sources of differences in coding could make MA organizations coding “inaccurate” for purposes of implementing risk adjustment – and thereby support the adoption of a CIA.

C. CMS Did Not Identify the Source of Coding Differences In Its Preliminary Studies of a Coding Intensity Adjustment

29. Prior to adopting a CIA in the 2010 Rate Announcement, CMS described and reported results from studies “designed to assess the degree of coding patterns (sic) differences that may be identified between FFS and MA and the extent to which any differences could be appropriately addressed by an adjustment to the CMS-HCC risk scores.”²² These preliminary studies did not identify which of the four sources underlaid coding pattern differences between the sectors.

²¹ Rate Announcement, April 6, 2009 at 20.

²² Advance Notice, February 16, 2007 at 8.

30. In its 2008 Rate Announcement, CMS described two studies that it conducted to assess the extent of coding differences.²³ The first study compared the extent to which MA and FFS consistently identified beneficiaries with ongoing, chronic conditions from year-to-year. It found no notable differences between the consistency with which MA and FFS identified ongoing, chronic conditions. It concluded that the consistency with which MA and FFS identified ongoing, chronic conditions was therefore not a source of MA-FFS coding differences.

31. The second study compared the risk score trends in MA versus FFS. It found that, over the 2004-2006 period, MA risk scores increased faster than FFS risk scores. To further investigate the source of this difference in trends, the study separately compared the trends in risk scores for three groups of enrollees: “joiners” (enrollees who enter MA versus those who enter FFS), “leavers” (enrollees who exit MA versus FFS), and “stayers” (enrollees who remain in MA versus FFS). It found two dynamics that explained the difference in trends.

32. The first dynamic was changes in enrollment patterns in MA versus FFS: the risk scores of joiners and leavers. The study found that more high-risk-score enrollees entered MA than FFS, and more high-risk-score enrollees exited FFS than MA. According to CMS, “with FFS losing higher risk beneficiaries than MA, and with MA enrolling higher risk beneficiaries than FFS, MA risk scores were pushed up at a faster rate than risk scores in FFS.”²⁴ According to CMS, “[w]e would not want to adjust payment for such factors [as different enrollment patterns in MA versus FFS] since they are unrelated to coding patterns.”²⁵

33. The second dynamic was changes in risk scores in enrollees who remained in MA and FFS: the risk scores of stayers. The study found that part of this difference was due to “changes in the demographic characteristics of enrollees (such as aging into brackets with higher relative factors or obtaining Medicaid eligibility)”²⁶ and that “[w]e would not want to adjust payment for such factors [as changes in demographic characteristics] since they are unrelated to coding patterns.”²⁷ The study also found that “part of the differential increase in risk scores is due to the increase in the disease component of MA stayers’ risk scores”²⁸ but that “we have not been able to measure

²³ See Rate Announcement, April 2, 2007 at 16–17. The description of the studies in the following paragraphs follows closely the language in this Rate Announcement.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

the possible causes of this differential.”²⁹ The study concluded that “[g]iven that we [CMS] cannot yet definitively attribute the difference in MA and FFS risk scores to underlying coding patterns [sic] differences, we will not make a coding intensity adjustment to MA payment for 2008.”³⁰

In its 2009 Advance Notice, CMS described additional research into the possible causes of the differential increase in the disease component of MA stayers’ risk scores. According to CMS, “[a]lthough CMS cannot definitely determine whether ‘catch up’ to FFS coding occurred or not, CMS recognizes that plans may have experienced some catch up, particularly during initial years of operation.”³¹ In a subsection titled “More complete coding,” CMS concluded that “[w]e do not assume that the coding pattern differences that we found in our study are the result of improper coding. As discussed above, CMS understands that MA plans have made efforts to identify enrollees’ conditions and may be coding more completely than FFS.”³² This means that the additional research described in the 2009 Advance Notice did not identify the extent to which MA-FFS differences in coding patterns were caused by the relatively greater absence of supported codes in FFS (catch up) or by the relatively greater presence of unsupported codes in MA.

34. CMS affirmed this conclusion in its 2009 Rate Announcement, in which it again decided not to make a coding intensity adjustment:

In the Advance Notice, we identified differences between the risk scores of MA and FFS Medicare enrollees. However, we did not have available comprehensive information from medical records to support our hypothesis that risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees.³³

²⁹ *Id.*

³⁰ *Id.*

³¹ Advance Notice, February 22, 2008 at 12. CMS defines “catch-up” in its 2008 Rate Announcement as “MA plans increasing their coding to ‘catch up’ to the level of FFS” and contrasts catch-up with “coding patterns that exceed FFS.” Rate Announcement, April 2, 2007 at 17.

³² Advance Notice, February 22, 2008 at 12.

³³ Rate Announcement, April 7, 2008 at 18.

D. CMS Did Not Identify the Source of Coding Differences In Its Initial Implementation of a Coding Intensity Adjustment in 2010

35. In its 2010 Advance Notice, CMS concluded that “there exists a difference in coding patterns between MA and FFS”³⁴ and expressed its intention “to apply a coding pattern difference adjustment in 2010.”³⁵ In its 2010 Rate Announcement, CMS established a CIA of 3.41 percent. Nowhere in the Advance Notice or Rate Announcement does CMS do any of the following:

- a. Report results from medical record reviews;
- b. Quantify the extent to which the 3.41 percent difference is due to a relatively greater absence of supported codes in FFS, a relatively greater presence of unsupported codes in MA, or some combination of the two; or
- c. Identify whether any of the difference is due to any unsupported codes in MA at all.

36. Indeed, as I explain in ¶ 27, in its 2010 Rate Announcement CMS explicitly states that it understands that “‘differences’ in coding patterns, regardless of the source, would make the MA plan coding ‘inaccurate’ for purposes of implementing risk adjustment”³⁶ and that “[a]s discussed above, the MA coding pattern difference adjustment is not adjusting for coding that is incorrect, but for coding that differs from FFS and is therefore inaccurate for payment.”³⁷

37. CMS’s statement that “the MA coding pattern difference adjustment is not adjusting for coding that is incorrect, but for coding that differs from FFS” is consistent with the method that CMS used to calculate the CIA. In particular, according to the 2010 Advance Notice (as modified by the 2010 Rate Announcement) CMS calculated the CIA as follows:

- a. Create “stayer” cohorts of MA and FFS beneficiaries for 2004-05, 2005-06, and 2006-07;
- b. Calculate the difference in disease score growth for each MA and FFS cohort, and then subtract the FFS disease score growth from the MA disease score growth;³⁸
- c. Calculate the average annual difference in MA-FFS disease score growth (which CMS determined to be 1.75 percent);

³⁴ Advance Notice, February 20, 2009 at 8.

³⁵ *Id.* at 9.

³⁶ Rate Announcement, April 6, 2009 at 20.

³⁷ *Id.* at 26.

³⁸ See Appendix B for a general description of how CMS calculates disease scores.

- d. Multiply the average annual difference in MA-FFS disease score growth by the MA enrollment duration factor (EDF), which is the average length of time that beneficiaries enrolled in an MA plan in January 2009 had been enrolled in an MA plan since January 2006. According to CMS, the product of the annual average difference in MA-FFS disease score growth and the EDF “is an estimate of how much lower [MA] risk scores would be in 2010 if they rose at the same rate as FFS risk scores over the period 2007-2010.”³⁹ CMS determined the EDF to be 2.45, so it determined that the product of the annual average difference in MA-FFS disease score growth and the EDF was 4.16 percent ($= 1.75 \text{ percent} \times 2.38$); and
- e. Multiply by the percent of MA enrollees who are stayers in January 2009 (which CMS determined to be 81.8 percent) to allow the application of the CIA to all MA enrollees’ risk scores.⁴⁰

38. In its 2010 Rate Announcement, CMS set the CIA to be 3.41 percent $\approx 4.16 \text{ percent} \times 0.818$.⁴¹

E. CMS Did Not Identify the Source of Coding Differences In Its Implementation of Coding Intensity Adjustments After 2010

39. Exhibit 3 reports the CIAs for 2011-2018. Exhibit 3 shows that, after the 2010 Rate Announcement, CMS set the CIA at the same level for 2011-2013, increasing it in 2014-2018 to the statutory minima specified by the American Taxpayer Relief of 2012.⁴² In no year’s Advance Notice or Rate Announcement did CMS provide any calculations to support its decision.

40. Because CMS did not identify the source of coding differences in its initial implementation of a CIA in 2010; in every year from 2010-2018 CMS set the CIA at either the 2010 level or the statutory minimum; and in no year after 2010 did CMS provide any calculations to support its decision in any Advance Notice or Rate Announcement, I conclude that CMS did not identify the source of coding differences in its implementation of coding intensity adjustments after 2010.

³⁹ Rate Announcement, April 6, 2009 at 22.

⁴⁰ See Advance Notice, February 20, 2009 at 10; Rate Announcement, April 6, 2009 at 19.

⁴¹ See Rate Announcement, April 6, 2009 at 19.

⁴² See Kronick & Welch, *supra* note 10, at E4.

Exhibit 3: CMS Offered No Basis For the Magnitude of the CIA After 2010

Year	CIA	Statutory Minimum	Basis for Calculation of CIA In Advance Notice or Rate Announcement
2011	3.41%		None
2012	3.41%		None
2013	3.41%		None
2014	4.91%	4.91%	None
2015	5.16%	5.16%	None
2016	5.41%	5.41%	None
2017	5.66%	5.66%	None
2018	5.91%	5.91%	None

F. Changes to the Specification of the CIA that CMS Considered After 2010 Did Not Identify the Source of Coding Differences

41. CMS considered at least three studies after 2010 that proposed changes to the way that it calculated the CIA. None of these studies identified the source of coding differences between the sectors:

In 2011, CMS considered GAO’s argument that CMS’s calculation of the 2010 CIA of 3.41 percent likely resulted in excess payments to MA plans.⁴³ The GAO study proposed several steps to improve the accuracy of CMS’s calculation of the CIA including “accounting for additional beneficiary characteristics, including the most current data available, identifying and accounting for all years of coding differences that could affect the payment year for which an adjustment is made, and incorporating the trend of the impact of coding differences on risk scores.”⁴⁴

⁴³ GAO, Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices, GAO-12-51, at 2 (January 2012).

⁴⁴ *Id.* at 14.

- a. In 2012, CMS conducted an internal analysis that showed how the CIA would change using different cohort years, a longer EDF, a different risk adjustment model, and a different MA stayer percentage. None of these variants affect the underlying method established in the 2010 Advance Notice and Rate Announcement (which did not identify the source of coding differences, see § V.C) so none of them identify the source of coding differences.⁴⁵
- b. In 2014, CMS considered an ASPE analysis that concluded that “most of this [differential MA risk score growth] appears to result from the plans identifying more diagnoses in a population that is no sicker than before”⁴⁶ but provides no evidence beyond its citation to a prepublication version of a study later published in the Medicare and Medicaid Research Review (MMRR).⁴⁷ This study, in turn identifies the differential trend in MA coding intensity by assuming that “in the absence of coding intensity efforts, the risk score for a given MA beneficiary would increase, on average, at the same rate as the risk score for an otherwise similar FFS beneficiary from one year to the next.”⁴⁸ For the reasons discussed in § V.D, this approach does not identify whether increases in coding intensity are due to supported or unsupported codes.

VI. If the Coding Intensity Adjustment Achieves Its Stated Goal, CMS Has Already Recovered Payments to MA Plans in Aggregate Due to MA-FFS Differences in Unsupported Codes

42. Because the CIA does not identify whether differences in coding patters are due to supported or unsupported codes, if it achieves its stated goal and accounts for “differences in coding patterns between [MA] plans and providers under ... parts A and B,”⁴⁹ then CMS has necessarily already recovered payments to MA plans in aggregate due to MA-FFS differences in unsupported codes. Because the CIA does not identify whether differences in coding patterns

⁴⁵ See USBP052417595 (AEO).

⁴⁶ See USBP001836865 (AEO).

⁴⁷ See Kronick & Welch, *supra* note 10.

⁴⁸ *Id.* at E6.

⁴⁹ 42 U.S.C. 1395w-23 § 1853(k)(2)(B)(iv)(III).

are due to supported or unsupported codes, if it accounts for “differences in coding patterns between [MA] plans and providers under ... parts a and b,” then it must account for the net impact of all of the four sources of differences in ¶ 16.⁵⁰ If it accounts for all of the four sources of differences in ¶ 16, then all differences due to coding intensity would be removed from MA-FFS differences in payments in aggregate – including differences in unsupported codes. I refer to the payments to MA plans in aggregate, after risk adjustment and the application of the CIA (excluding rebates and beneficiary premiums) as the “intended payments.”⁵¹

A. Any Removal of Unsupported Codes from MA Plans in Aggregate Would Result in Underpayment to Plans by Allowing CMS to Recover Twice

43. After adjusting for the CIA, any removal of unsupported codes from MA plan data in aggregate (i) would reduce payments to MA plans in aggregate below the intended payments, (ii) is inconsistent with the attempt to achieve payment neutrality, and (iii) would allow CMS to recover twice for the removed unsupported codes.⁵² A stylized example shows how this follows directly from ¶ 42. For simplicity, assume that every diagnosis code has the same effect on a patient’s expected cost, equal to an effect of 0.01 on the patient’s risk score. Consider an extended version of the hypothetical scenario a from Exhibit 1, in which the average patient in MA has 110 codes (with 10 present unsupported and no absent supported codes), whereas the average patient in FFS has 100 codes (with 10 present unsupported and 5 absent supported codes). By construction, the average patient in MA has a risk score of 1.1 ($= 110 \times 0.01$); the average patient

⁵⁰ See, e.g., Creighton Dep., October 4, 2022, at 99:9–15 (“Q. Got it. Now, ultimately the coding intensity adjustment attempts to account for all the differences in coding patterns between the Medicare Advantage population and the Fee-for-Service population; correct? A. Correct.”) Sean Creighton was the division director responsible for preparing the annual advance notice, which is the governing document for payment to MA and Part D plans for the forthcoming year.”). Mr. Creighton reported to the director of the Medicare Plan Payment Group. See Creighton Dep., March 23, 2022, at 33:13–34:10.

⁵¹ See Creighton Dep., March 23, 2022, at 119:21–120:14 (“Q. And you go on to write: ‘This would result in the MA plan coding “accurately” reflecting the fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, “differences” in coding patterns, regardless of the source, would make the MA plan coding “inaccurate” for purposes of implementing risk adjustment.’ And I take it that’s part of the effort to respond to this question about accurate versus inaccurate. Correct? A. Yeah. It’s really saying that in this context, differences in coding patterns result in inaccurate payments. And by ‘inaccurate,’ what is actually meant is essentially payments that would – either you could say violate actuarial equivalence at a high level, but in a more real sense that result in different payment than was intended.”).

⁵² This proposition holds even if there are no MA-FFS differences in unsupported codes. In this case, CMS would have no economic rationale for recovering for unsupported codes in MA plans in aggregate in the first instance, so any removal of unsupported codes from MA plans in aggregate would allow CMS to recover for the removed unsupported codes when it had no economic rationale to do so.

in FFS has a risk score of 1.0 ($= 100 \times 0.01$). Because the coding intensity of MA is 10 ($= 10$ present unsupported – 0 absent supported codes), whereas the coding intensity of FFS is 5 ($= 10$ present unsupported – 5 absent supported codes), the average MA risk score after adjusting for MA-FFS differences in coding intensity is 1.05 ($= [110 - (10 - 5)] \times 0.01$). The average MA risk score of 1.05 after adjusting for differences in coding intensity reflects the fact that the average MA patient has 5 more “true medical conditions” than the average FFS patient. The intended payment would therefore be \$1.05 per dollar of expected FFS spending. Because the average MA risk score after adjusting for MA-FFS differences in coding intensity is 1.05, the CIA must be 4.55 percent ($\approx 1 - [1.05 / 1.1]$, since $1.1 \times [1 - \text{CIA}] = 1.05$).⁵³

44. If CMS required deletion of any of the present unsupported codes from MA plan data in aggregate without changing the CIA, then it would reduce the average MA risk score after adjusting for the CIA below 1.05. This means that CMS would reduce payments to MA plans below the intended payment, effectively allowing CMS to recover twice for the removed unsupported codes and resulting in the MA plans being “underpaid.” This result would be inconsistent with the attempt to achieve payment neutrality, and would be inconsistent with payment neutrality itself if CMS’s estimate of the effect of a diagnosis code on a patient’s expected cost were correct.

45. For example, suppose that CMS required an MA plan with average coding intensity from the scenario above to delete 5 of the 10 present unsupported codes from its data. This would make the coding intensity of the MA plan ($5 = 5$ present unsupported – 0 absent supported codes) equal to the coding intensity of FFS ($5 = 10$ present unsupported – 5 absent supported codes). It would not change the fact that the average MA patient has 5 more “true medical conditions” than the average FFS patient; would not change the average MA risk score after adjusting for MA-FFS differences in coding intensity from 1.05 ($= [105 - (5 - 5)] \times 0.01$); and would not change the intended payment of \$1.05 per dollar of expected FFS spending. Yet, if the old CIA of 4.55 percent were imposed, it would reduce the average MA risk score after adjusting for the CIA to approximately 1 ($\approx 1.05 \times [1 - 0.0455]$). The problem is that the CIA was calculated based on the presence of the 5 unsupported codes that CMS, after calculating the CIA, required the MA plans to remove.

⁵³ See USBP000161652 at 39.

46. The example also demonstrates that the presence of unsupported codes in MA plan data is insufficient to establish that CMS has paid more than the intended payments—i.e., that CMS has “overpaid” the average MA plan.⁵⁴ With a CIA of 4.55%, the average plan would be neither overpaid nor underpaid despite the fact that it had 10 present unsupported codes.

B. Other Implications of CMS Having Already Recovered Payments to MA Plans In Aggregate Due to MA-FFS Differences in Unsupported Codes

47. Five corollaries also follow from ¶ 42. Consider the example from ¶ 43, adding to it the specific characteristics of three equally-sized MA plans, A, B, and C. Consistent with the example above, assume that the average patient in each MA plan has 110 codes, giving each MA plan an average risk score of 1.10 ($= 110 \times 0.01$). Also continue to assume a CIA of 4.55 percent, so that the average MA risk score after adjustment for the CIA in each plan would continue to be 1.05.

48. Additionally, assume that the average patient in A has 15 present unsupported and no absent supported codes, in B has 10 present unsupported and no absent supported codes, and in C has 5 present unsupported and no absent supported codes. Although the CIA of 4.55 percent adjusts for MA-FFS differences in coding intensity *in aggregate*, it does not adjust for plan-specific differences in coding intensity. In particular, the CIA does not fully adjust for the level of unsupported codes in A, which has a coding intensity of 15 and so should receive \$1 per dollar of expected FFS spending based on CMS’s risk-adjustment model, after fully adjusting for the level of unsupported codes in that plan. The difference between plan A’s and FFS coding intensity is 10 ($= 15 - 5$), exactly offsetting the difference in codes between A and FFS ($= 110 - 100$). As CMS would have paid A \$1.05 per dollar of expected FFS spending, after adjusting for the CIA, CMS has therefore not fully recovered payments from A due to its level of unsupported codes – A has been “overpaid.” By contrast, CMS has fully recovered payments from B and C due to their levels of unsupported codes. In particular, the CIA exactly adjusts for the level of unsupported codes in B, which has a coding intensity of 10 (which equals the industry average); the CIA actually over-adjusts for the level of unsupported codes in C, which has a coding intensity of 5

⁵⁴ See also Anne Hornsby 30(b)(6) Deposition (“Hornsby 30(b)(6) Dep.”), May 19, 2023, at 111:15–21 (“Q. Okay. But for the purposes of MA plan payments, the determination of whether or not the payments were equitable or overpaid or underpaid requires an analysis of the different level of coding between the diagnoses and fee-for-service data or the Medicare Advantage data? A. Yes.”).

(which is less than the industry average). Despite having unsupported codes in their data, plans B and C would not be “overpaid” in this scenario.

49. This example demonstrates five corollaries. First, in order to determine whether CMS has “overpaid” any particular plan due to that plan’s level of unsupported codes, it is necessary to know how much the particular plan’s coding intensity deviates from the industry average and in what direction. Moreover, unless a plan knew how much its own coding intensity deviates from the industry average and in what direction, it cannot know whether it is “overpaid” or “underpaid.”⁵⁵ A plan with a given coding intensity would be “overpaid” if its coding intensity is greater than the industry average, but would be “underpaid” if its coding intensity is less than the industry average. I am not aware of any data or information that would allow United to have calculated the extent to which its coding intensity would have exceeded (or differed from) the industry average, which means I am unaware of how United could have determined whether it was overpaid or underpaid.

50. Second, the presence of unsupported codes in any particular plan’s data is insufficient to establish that CMS has “overpaid” or “underpaid” it. Correct calculation of the presence and extent of “overpayment” must also account for the plan’s level of absent supported codes and the industry average level of present unsupported and absent supported codes.

51. Third, if all differences in coding intensity are removed from MA-FFS differences in payments in aggregate, then differences in coding intensity due to MA plans’ review of claims to add (otherwise absent) supported codes but not to delete (otherwise present) unsupported codes are necessarily also removed from MA-FFS differences in payments in aggregate.

52. Fourth, if differences in coding intensity due to MA plans’ review of claims to add (otherwise absent) supported codes but not to delete (otherwise present) unsupported codes are removed from MA-FFS differences in payments in aggregate, then any additional reductions in payments to MA plans in aggregate for either of these reasons would necessarily reduce payments to MA plans in aggregate below the intended payments. As a result, MA plans in this scenario would be “underpaid.”

⁵⁵ Alternatively, if a plan knew its own coding intensity and the coding intensity of FFS (along with the CIA), it could back out the industry average MA coding intensity.

53. Fifth, because the intended payments attempt to achieve MA-FFS payment neutrality⁵⁶ – that is, payments for MA enrollees equal to what they would be expected to cost in FFS – additional reductions in payments to MA plans in aggregate (after the application of the CIA) for MA-FFS differences in coding intensity due to MA plans’ review of claims to add (otherwise absent) supported codes but not to delete (otherwise present) unsupported codes is inconsistent with the attempt to achieve payment neutrality.⁵⁷

VII. If the Coding Intensity Adjustment Is Too Low, CMS Must Conduct Medical Record Reviews To Determine Whether and To What Extent It Has Already Recovered Payments Due to Unsupported Codes

54. If the CIA is too low to account for “differences in coding patterns between [MA] plans and providers under ... parts A and B,”⁵⁸ then CMS has not fully recovered payments to MA plans due to coding intensity differences, even after adjusting for the CIA.⁵⁹ These unrecovered payments can be from two sources: from fewer absent supported codes in MA relative to FFS, or more present unsupported codes in MA relative to FFS. Unless MA-FFS differences in absent supported codes account for all of the CIA, some of the CIA must compensate CMS for MA-FFS differences in present unsupported codes. If this is true, then there is no way to determine how

⁵⁶ See Creighton Dep., March 23, 2022, at 106:17–107:11 (“Q. Sorry about that, Mr. Creighton. So what I was asking you in layman's terms, how would you describe that proposition that MA plans have a differential rate of increase in coding relative to fee-for-service? A. As we've discussed, the incentive for MA plans is to more comprehensively and accurately collect and report data on the conditions, health conditions, and specifically the diagnosis of their members. You know, over time what that leads to is a different pattern or accelerated rate of coding relative to fee-for-service. So what -- and that is what coding intensity refers to. So a coding intensity adjustment is a way of saying, okay, we understand that incentive exists, we're going to measure it, make a payment adjustment for it so that the standard of actuarial equivalence or comparability between fee-for-service and MA is maintained in payment.”).

⁵⁷ If the intended payment actually achieves payment neutrality, then additional reductions in payments to MA plans in aggregate (after the application of the CIA) for MA-FFS differences in coding intensity due to MA plans’ review of claims to add (otherwise absent) supported codes but not to delete (otherwise present) unsupported codes is inconsistent with payment neutrality.

⁵⁸ 42 U.S.C. 1395w-23 § 1853(k)(2)(B)(iv)(III). Because of the absence of medical record reviews, it is not known definitively whether the CIA accounts for “differences in coding patterns between [MA] plans and providers under ... parts A and B,” is too low to do so, or too high to do so. CMS acknowledged this in its 2009 Rate Announcement: “We did not have available comprehensive information from medical records to support our hypothesis that risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees.” Rate Announcement, April 7, 2008 at 18. The average annual difference in MA-FFS risk score growth inflated by the EDF – the basis on which CMS has set the CIA – is *only an approximation* of the extent to which claims-data-based differences in MA-FFS risk score growth represent differences in coding intensity and can only be determined by comparing the diagnoses recorded in each sector’s claims data to matching medical records.

⁵⁹ In order to be as favorable to CMS as possible, the analysis in this section assumes that CMS should recover for MA-FFS differences in coding intensity, after adjusting for the CIA, even though it was mandated to have set the CIA to have done so in the first instance. If CMS’s failure to meet its mandate were to preclude it from seeking recovery from MA plans attributable to “differences in coding patterns between [MA] plans and providers under ... parts A and B” in aggregate, then it should recover nothing for such differences in aggregate if the CIA is too low.

much CMS has already recovered for present unsupported codes without knowing the relative rates of absent supported and present unsupported codes in MA and FFS – which would require medical record reviews.

55. Several corollaries follow from ¶ 54. First, removing unsupported codes from MA plan data in aggregate could bring payments to MA plans closer to or farther from the intended payments, depending on the relative rates of absent supported and present unsupported codes in MA and FFS. To determine whether removing unsupported codes from MA plan data in aggregate would bring payments to plans closer to the intended payments would require knowing the relative rates of absent supported and present unsupported codes in MA and FFS – which would require medical record reviews.

56. A stylized example makes this point clear. In the example, assume the following:

- a. Every diagnosis code has the same effect on a patient's expected cost, equal to an effect of 0.01 on the patient's risk score;
- b. The average patient in MA has 110 codes, whereas the average patient in FFS has 100 codes; and
- c. The CIA is set to be 4.55 percent.

As a consequence, the average MA risk score after adjusting for the CIA would be 1.05 ($= [1.1 \times (1 - 0.0455)]$).

57. Exhibit 4 reports the number of present unsupported and absent supported codes for the average patient in MA and FFS under two different hypothetical scenarios. In scenario a, the average patient in MA has 2 present unsupported and no absent supported codes, whereas the average patient in FFS has 2 present unsupported and 7 absent supported codes. In this scenario, MA has greater coding intensity than FFS ($2 > -5$). MA has the same greater coding intensity than FFS in scenario b. In both scenarios, the CIA is set too low (4.55 percent $<$ 6.36 percent).

Exhibit 4: Coding intensity in MA and FFS in Two Hypothetical Scenarios

Scenario	MA average patient	FFS average patient	CIA Should Be
a	2 present unsupported 0 absent supported Coding intensity $2 = 2 - 0$	2 present unsupported 7 absent supported Coding intensity $-5 = 2 - 7$	6.36 percent ⁶⁰
b	6 present unsupported 4 absent supported Coding intensity $2 = 6 - 4$	5 present unsupported 10 absent supported Coding intensity $-5 = 5 - 10$	6.36 percent

58. In the example, removing unsupported codes from MA plan data in aggregate would bring payments to MA plans closer to the intended payments in scenario a, but farther from the intended payments in scenario b. In scenario a, deleting the 2 unsupported codes from the average MA patient would bring the intended payments to the approximately correct amount. Deleting these 2 unsupported codes would bring the average MA risk score after adjusting for the CIA to approximately 1.03 ($\approx ([110 - 2] \times 0.01 \times [1 - 0.0454])$), which would be correct.⁶¹ In scenario b, however, deleting the 6 unsupported codes from the average MA patient would bring the intended payments below the correct amount. Deleting these 6 unsupported codes would bring the average MA risk score after adjusting for the CIA to approximately 0.99 ($\approx ([110 - 6] \times 0.01 \times [1 - 0.0454])$) – approximately 0.04 less than it should be, as compared to the base case in which the average MA risk score after adjusting for the CIA is 0.02 greater ($= 1.05 - 1.03$) than the correct risk score.⁶²

59. The example highlights why removing unsupported codes from MA plan data, after adjusting for the CIA but without considering the relative rates of absent supported and present

⁶⁰ Because the coding intensity of MA is 2 ($= 2$ present unsupported $- 0$ absent supported codes), whereas the coding intensity of FFS is -5 ($= 2$ present unsupported $- 7$ absent supported codes), the average MA risk score after adjusting for MA-FFS differences in coding intensity is 1.03 ($= [110 - (2 - [-5])] \times 0.01$). The average MA risk score of 1.03 after adjusting for coding intensity reflects the fact that the average MA patient has 3 more “true medical conditions” than the average FFS patient. Because the average MA risk score after adjusting for MA-FFS differences in coding intensity is 1.03, the CIA must be 6.36 percent ($\approx 1 - [1.03 / 1.1]$, since $1.1 \times [1 - \text{CIA}] = 1.03$). See USBP000161652 at 39.

⁶¹ See *id.*

⁶² Scenario b also shows that removing a subset of unsupported codes can also bring payments to MA plans farther from the intended payments. Instead of deleting all 6 unsupported codes, suppose that only 5 were deleted. Deleting these 5 unsupported codes would bring the average MA risk score after adjusting for the CIA to approximately 1.0 ($\approx ([110 - 5] \times 0.01 \times [1 - 0.0454])$) – approximately 0.03 less than it should be.

unsupported codes in MA and FFS, is arbitrary.⁶³ If the number of unsupported codes in MA plan data happens to be small relative to the magnitude of the gap between the actual and the correct CIA, then removing the unsupported codes could bring payments to MA plans closer to the intended payment. But if the number of unsupported codes in MA plan data happens to be large relative to the gap between the actual and the correct CIA, then removing the unsupported codes could cause payments to MA plans to diverge from intended payments even more than they would have, were the unsupported codes left unremoved.

60. Second, removing unsupported codes from any particular MA plan's data could bring payments to the plan closer to or farther from those based on CMS's risk-adjustment model. To determine whether removing unsupported codes from any particular MA plan's data would bring payments to it closer to or farther from this amount would require knowing both the relative rates of absent supported and present unsupported codes in aggregate and how much the particular plan's rates of absent supported and present unsupported codes deviate from the industry average and in what direction.

61. Consider scenario b in the example from ¶¶ 56-58, adding to it the specific characteristics of three equally-sized MA plans, A, B, and C. Assume that the average patient in A has 6 present unsupported and no absent supported codes, in B has 6 present unsupported and 4 absent supported codes, and in C has 6 present unsupported and 8 absent supported codes.⁶⁴ Removing unsupported codes from A would bring payments to it approximately to those based on CMS's risk-adjustment model, after adjusting for the CIA. By construction, the CIA is set to be 4.55 percent; so the

⁶³ Moreover, even if CMS considered the rates in MA and FFS of absent supported and present unsupported codes – which it did not – the amount of additional recovery that it should receive for MA-FFS differences in *present unsupported codes alone* would depend on how much of the CIA should be allocated to compensating CMS for MA-FFS differences in absent supported versus present unsupported codes. Because there is no intrinsic basis for this allocation, calculating the amount of additional recovery that CMS should receive for MA-FFS differences in present unsupported codes alone would require an extrinsically-imposed rule. In scenario b, if the CIA should be allocated first to compensating CMS for MA-FFS differences in absent supported codes, then CMS should receive an additional \$0.01 per dollar of FFS spending for MA-FFS differences in present unsupported codes alone (since the CIA of 4.55 percent fails to fully compensate CMS even for MA-FFS differences in absent supported codes, it should receive full additional compensation for all MA-FFS differences in present unsupported codes). But if the CIA should be allocated proportionately to compensating CMS for MA-FFS differences in absent supported versus present unsupported codes, then CMS should receive only an additional \$0.00286 per dollar of FFS spending ($= \$0.01 - \$0.00714 = \$0.01 - (\$0.01 \times [1 / 7] \times 0.05)$), since 1/7 of the CIA of 5 percent should be allocated to compensating CMS for MA-FFS differences in present unsupported codes and 6/7 should be allocated to compensating CMS for MA-FFS differences in absent supported codes).

⁶⁴ The average number of present unsupported codes is 6 and of absent supported codes is 4 in MA in aggregate, consistent with scenario b.

average risk score in A after adjusting for the CIA (but before removing the unsupported codes) would be 1.05; and the average risk score in A after removing unsupported codes from A and adjusting for the CIA would be approximately 0.99 ($\approx ([110 - 6] \times 0.01 \times [1 - 0.0454])$). This is approximately correct, given that the average patient in A would have one fewer “true medical conditions” than the average FFS patient (110 codes with 6 unsupported and 0 absent supported codes implying 104 true medical conditions in A, versus 100 codes with 2 unsupported and 7 absent supported implying 105 true medical conditions in FFS).

62. For C, removing unsupported codes brings payment to the plan below those based on CMS’s risk-adjustment model, after adjusting for the CIA. Deleting C’s 6 unsupported codes would bring the average risk score in C after adjusting for the CIA to 0.99, just as it did for A. However, because C has a coding intensity of -2 (6 present unsupported and 8 unsupported codes), it should receive \$1.07 per dollar of expected FFS spending based on CMS’s risk-adjustment model, after fully adjusting for the level of unsupported codes in that plan – not \$0.99. The average patient in C would have seven more “true medical conditions” than the average FFS patient (110 codes with 6 unsupported and 8 absent supported codes implying 112 true medical conditions in C, versus 100 codes with 2 unsupported and 7 absent supported implying 105 true medical conditions in FFS).

VIII. If the Coding Intensity Adjustment Is Too Low, the Regulatory Process Would Be the Economically Efficient Means To Address Remaining MA-FFS Differences in Coding Intensity

63. As I explain in § VI, if the CIA achieves its stated goal, then CMS has already recovered for all MA-FFS differences in coding intensity, so no additional policies are necessary to address MA-FFS differences in coding intensity.

64. Mandatory Two-Sided Review is one means to address MA-FFS differences in coding intensity. Mandatory Two-Sided Review would require that MA plans evaluate *all* the diagnoses on any claim subjected to a medical record review – not just the absent supported diagnoses – and delete any diagnoses not supported by the chart. Given a particular value for the CIA, Mandatory Two-Sided Review would tend to decrease payments to plans in aggregate just as would increasing the CIA.

65. If the CIA achieves its stated goal, then Mandatory Two-Sided Review would not only be unnecessary but also push the CIA farther from achieving its stated goal. If the CIA achieves its

stated goal, any policy like Mandatory Two-Sided Review that would have the same effect as increasing the CIA effectively would make the CIA greater than it needed to be and result in MA plans being underpaid in the aggregate.

66. If the CIA is too low, then Mandatory Two-Sided Review could address the MA-FFS coding differences that remain. However, even if the CIA is too low, Mandatory Two-Sided Review may or may not bring the CIA closer to achieving its stated goal. If the CIA is too low, and Mandatory Two-Sided Review reduces payments to MA plans by exactly the amount of the MA-FFS difference in coding intensity that remains after accounting for the CIA, then it would bring the CIA closer to achieving its stated goal. But if Mandatory Two-Sided Review reduces payments to MA plans by more than the MA-FFS difference in coding intensity that remains after accounting for the CIA, then it may not bring the CIA closer to achieving its stated goal. If Mandatory Two-Sided Review reduces payments to MA plans by more than the MA-FFS difference in coding intensity that remains after accounting for the CIA, then that would result in “underpayments” to MA plans. Even if the government is agnostic as to whether plans are overpaid or underpaid, adding Mandatory Two-Sided Review on top of the CIA would bring the CIA closer to achieving its stated goal only if the magnitude of the difference that remains after accounting for the CIA before Mandatory Two-Sided review is greater than the magnitude of the difference that exists after accounting for the CIA and Mandatory Two-Sided Review. Put another way, if the CIA underestimates the average MA-FFS difference in coding intensity, then requiring Mandatory Two-Sided Review could overshoot the mark by more than the original error from underestimation of the CIA, adding a greater inaccuracy to payments than existed in the first place based on any misestimation of the CIA.

67. If the CIA is too low, then the regulatory process would be the economically efficient means to address remaining MA-FFS differences in coding intensity. If the CIA is too low, the efficient way to address remaining MA-FFS differences in coding intensity would be to increase the CIA explicitly through the regulatory process by which it was determined in the first place, discussed in detail above in § V of this report. If the CIA is too low, and there is some reason not to address remaining MA-FFS differences by increasing the CIA, then the regulatory process would be the economically efficient means to consider alternative approaches (such as Mandatory Two-Sided Review) to addressing remaining MA-FFS differences in coding intensity.

68. In § VIII.A - VIII.C, I explain why the regulatory process would be the economically efficient means to consider alternative approaches (such as Mandatory Two-Sided Review) to addressing remaining MA-FFS differences in coding intensity if the CIA is too low, and there is some reason not to address remaining MA-FFS differences by increasing the CIA:

- a. In § VIII.A, I explain why the regulatory process provides clarity and predictability, and in turn reduced policy uncertainty;
- b. In § VIII.B, I explain why reduced policy uncertainty increases investment and employment in markets for health care; and
- c. In § VIII.C, I show that CMS originally sought to use the regulatory process to impose Mandatory Two-Sided Review, which is consistent with my opinion that the regulatory process would be the efficient means to evaluate it.

A. The Regulatory Process Increases Clarity and Predictability, Thereby Decreasing Policy Uncertainty

69. MA plans are obliged to attest that their risk adjustment data “[b]ased on best knowledge, information, and belief . . . [is] accurate, complete, and truthful.”⁶⁵ The language in the Risk Adjustment chapter of the 2011 Medicare Managed Care Manual states that MA plans must “[e]nsure the accuracy and integrity of risk adjustment data submitted to CMS.”⁶⁶ But CMS has elsewhere made clear that the requirement that plans certify accuracy based on “best knowledge, information, and belief,” reflects “recognition of the fact that [MA] organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce.”⁶⁷

70. The term “accuracy” has more than one definition. On one hand, according to CMS’s 30(b)(6) witness, “accuracy of diagnosis data means it’s documented in the medical record.”⁶⁸ On the other hand, in its 2010 Rate Announcement, CMS defined “inaccurate for purposes of risk adjustment” as “differences in coding patterns [between MA and FFS], regardless of the source.”⁶⁹ As I explain in ¶ 66, Mandatory Two-Sided Review increases accuracy, as defined by CMS in its

⁶⁵ USBP009417534; MAPL002846682 at 7.

⁶⁶ Hornsby 30(b)(6) Dep., May 25, 2023, Exhibit 1080 at 4.

⁶⁷ Hornsby 30(b)(6) Dep., May 25, 2023, Exhibit 164 (Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pt. 422)).

⁶⁸ Hornsby 30(b)(6) Dep., May 25, 2023, at 167:8-9.

⁶⁹ Rate Announcement, April 6, 2009 at 20; *supra* ¶ 27.

2010 Rate Announcement, only if a) the CIA is too low and b) Mandatory Two-Sided Review reduces the magnitude of the difference in MA-FFS coding intensity that exists after accounting for the CIA and Mandatory Two-Sided review to less than the magnitude of the difference that remains after accounting for the CIA but before Mandatory Two-Sided Review.

CMS is aware that MA plans may not know which definition of “accuracy” to use to satisfy their obligation to submit accurate data.⁷⁰ The ambiguity of the term “accuracy” arises out of the fact that “accurate” for purposes of risk adjustment does not mean “accurate” in terms of reflecting the medical record correctly.⁷¹ And, as Ms. Hornsby testified, “CMS believes that [it] is the MAO’s responsibility to determine how it is they can truthfully certify to their risk adjustment data.”⁷²

71. I am not aware of any data or information that would allow United to have determined whether Mandatory Two-Sided Review increases accuracy, as defined by CMS in its 2010 Rate Announcement. As I explain in ¶ 49, I am not aware of any data or information that would allow United to have determined whether it was overpaid or underpaid. But if United could not have determined whether it was overpaid or underpaid, then it could not have determined whether Mandatory Two-Sided Review would have increased accuracy, as defined by CMS in its 2010 Rate Announcement.

72. I understand the following:

- a. The government's position in this case is that the general requirement that MA plans must warrant the “accuracy, completeness, and truthfulness” of their data also creates a specific obligation for MA plans to conduct Mandatory Two-Sided

⁷⁰ See Hornsby 30(b)(6) Dep., May 25, 2023, at 182:7-12 (“Q: So why did you want to propose a rule to address this instead of, you know, just enforcing the rules you already provided? A: There was a concern that MAOs did not understand accuracy.”).

⁷¹ See Rebecca Paul Deposition, April 13, 2022, at 156:9–157:7 (“A. And again, just to clarify the context of what this means, that differences in coding patterns between who is being paid and the data that the model is based on make the coding -- the result of the coding inaccurate, even if the coding -- even if the codes themselves are accurate. The word here, ‘inaccurate,’ is referencing to a level of the scores and the risk adjustment that would result from it, not some -- the sentence is accurate. Q. So is it your testimony, Ms. Paul, that there are circumstances where the coding is accurate, but the result of the coding is inaccurate? A. That they mean different things. Coding accurate, meaning based in the medical record. The inaccuracy that might result is the level of the score, and it’s a technical issue, not a -- it wasn’t documented issue. When we calculate risk scores, we make adjustments to them to offset different things before we produce risk scores that are used in payments. This is common. And so if we didn’t make such adjustments, the risk scores used in payment would not be the right ones.”).

⁷² See Hornsby 30(b)(6) Dep., May 25, 2023, at 167:20–168:4 (“Q: And -- and when you say ‘all requirements,’ you’ve never had a requirement that MAOs conduct a medical record review, have you? A: CMS has not put in writing a requirement to conduct medical record reviews. CMS believes that is the MAO’s responsibility to determine how it is they can truthfully certify to their risk adjustment data.”).

Review;⁷³ United disagrees with that position, and that United sought clarity from CMS in 2014 as to whether it was obligated to conduct Mandatory Two-Sided Review;⁷⁴

- b. CMS's position in this case appears to be that CMS, as a matter of policy, generally would not provide such clarity to MA plans that ask for it,⁷⁵ despite statements by the Department of Justice in another case suggesting that contractors with the government should make this sort of request.⁷⁶

I do not offer a legal opinion regarding MA plans' obligation to conduct Mandatory Two-Sided Review or the ambiguity of that obligation.

73. But to the extent that obligation is ambiguous, the regulatory process would increase clarity and predictability, especially if (as Ms. Hornsby testified) CMS generally would decline to answer plans' questions about ambiguities about plans' obligations. Indeed, Ms. Hornsby and Ms. Rice both suggest the regulatory process as a means to clarify MA plans' obligation to conduct Mandatory Two-Sided Review. In an email dated June 4, 2013, Ms. Hornsby states that Mandatory Two-Sided Review should be proposed as an official rule.⁷⁷ In an email dated October 26, 2015, Ms. Rice agrees that the regulatory process would reduce the ambiguity of MA plans' obligation to conduct Mandatory Two-Sided Review:

Our regs say that plans must use reasonable diligence to identify overpayments.

We have not yet defined what that means. We could through regulation, define

⁷³ See Hornsby 30(b)(6) Dep., May 25, 2023, at 67:15–72:21 (citing Hornsby 30(b)(6) Dep., May 25, 2023, Exhibit 164, Medicare Program; Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (proposed June 29, 2000) (to be codified at 42 C.F.R. pts. 417 and 422)).

⁷⁴ See Brian Thompson Deposition, March 1, 2022, at 55:10–61:2; 151:22–152:3; Steve Nelson Deposition, July 26, 2022, Exhibit 320 (MARA2157039 (AEO)).

⁷⁵ See *supra* note 74; Hornsby 30(b)(6) Dep., May 25, 2023, at 45:9–45:22, 80:2–16.

⁷⁶ According to the Brief for the United States in *United States Ex Rel. Tracy Schutte v. Supervalu, Inc.*, Nos. 21-1326 & 22-111, (a) “companies that seek funds from the government (particularly on a recurring basis) often have ready avenues for resolving ambiguity in payment rules” (p. 25 n. 4); (b) “When such avenues for clarification are readily available, a contractor’s failure to invoke those mechanisms while seeking public funds may be evidence of deliberate ignorance or recklessness under the FCA” (p. 25 n. 4); and (c) “The government therefore relies on its contracting partners to approach the inevitable ambiguities in good faith, following what they understand to be the best interpretation and seeking clarification when necessary.” (p. 32)

⁷⁷ See Hornsby 30(b)(6) Dep., May 25, 2023, Exhibit 1206 (USBP065879950) and 174:4–174:18 (“Q: All right. So let’s start with the email, the last paragraph. You – of the – of the first email on the page, which actually is from June 2013 and carries over to the – the second page of the document. So the last paragraph of that email says, “We really think we should do 6B requiring an MAO that conducts medical record review to look for both over- and underpayments.” Do you see that? A: Yes, I do. Q: Okay. And that’s a reference to the medical record review rule that was proposed in – in January of 2014; correct? A: Yes, that is.”).

specific steps a plan must take, at a minimum, to meet that requirement. For example, we could require them to self-audit (i.e., their own RADV audits). We could also revive the NPRM proposal we had that if a plan is checking a medical record for underpayments, they must also look for overpayments [Mandatory Two-Sided Review]. On the attestation language, we are working now to tighten it up. But without a reg change (as described above), we are limited in how high we set the bar.⁷⁸

74. In particular, the regulatory process could be used to determine the extent to which MA-FFS differences in coding intensity remain, after accounting for the CIA; propose specific ex ante rules governing how Mandatory Two-Sided Review would be implemented; and evaluate whether the proposed implementation of Mandatory Two-Sided Review brought the CIA closer to achieving its stated goal. By proposing the rule ex ante and with specificity, the regulatory process would improve clarity and predictability.⁷⁹ Improving clarity and predictability, in turn, would reduce the policy uncertainty that MA plans would otherwise face in seeking to comply with the law.

B. Reduced Policy Uncertainty Increases Investment and Employment in Firms In the Health Care Sector

75. Reduced policy uncertainty, in turn, increases investment and employment in firms in the health care sector. The inverse relationship between policy uncertainty on one hand, and investment and employment on the other hand, was observed in general by former Federal Reserve Chairman Benjamin Bernanke. In a study published in one of the leading peer-reviewed economics journals, Bernanke formalizes the intuition that uncertainty gives firms an incentive to

⁷⁸ Cheri Rice Deposition, August 3, 2022, Exhibit 1067 (USBP001891973). Ms. Rice was the Director of the Medicare Plan Payment Group from 2010-2017. *See id.* at 16:22–17:4.

⁷⁹ *See* Richard A. Posner, *Regulation (Agencies) versus Litigation (Courts): An Analytical Framework*, §§ 1.2.1–1.2.2, in Daniel P. Kessler, *Regulation vs. Litigation: Perspectives from Economics and Law*, Chapter 1, University of Chicago Press (2010); *see also* Sean Cavanaugh Deposition (“Cavanaugh Dep.”), February 17, 2022, at 144:24–145:4 (“Q. And one reason you would promulgate rules, or propose rules, is to set the requirements, give your interpretation of the statute, or clear up ambiguity in the rules and requirements for things like Medicare Advantage plans? A. Yes.”). Mr. Cavanaugh was the Director for the Center of Medicare, reporting to the Administrator of CMS. *See id.* at 23:12-23.

delay investment and hiring when investment projects are costly to undo or workers are costly to hire and fire.⁸⁰

76. More recent research shows that the relationship proposed by Bernanke exists empirically in markets for health care. A study in the same journal as Bernanke's original article develops new indices of economic policy uncertainty based on newspaper coverage of current events.⁸¹ One of these indices seeks to quantify economic policy uncertainty in the health care sector. This health care economic policy uncertainty index increases with the number of mentions of regulatory uncertainty in health care entitlement programs, which include Medicare and Medicaid.

77. The study matches its health care economic policy uncertainty index with data on individual government contracts with specific firms from the Federal Registry of Contracts and government health care spending to calculate the share of firm revenues derived from sales to the government. The study finds that, holding other factors constant, firms with greater exposure to government purchases experience reduced investment and employment growth when health care economic policy uncertainty increases.⁸²

C. CMS's Behavior Is Consistent With My Opinion That the Regulatory Process Is The Economically Efficient Means To Evaluate Two-Sided Review

78. Assuming that CMS considers economic efficiency to be desirable in determining its policy toward MA plans, CMS's behavior is consistent with my opinion that the regulatory process is the economically efficient means to consider Mandatory Two-Sided Review for MA plans:

- a. On January 10, 2014, CMS proposed Mandatory Two-Sided Review on MA plans through the rulemaking process. According to the proposed rule:

Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to

⁸⁰ See Ben S. Bernanke, *Irreversibility, Uncertainty and Cyclical Investment*, 97 Quarterly J. of Economics 85 (1983).

⁸¹ See Scott R. Baker, Nicholas Bloom, Steven J. Davis, *Measuring Economic Policy Uncertainty*, Quarterly J. of Economics (Mar. 10, 2016).

⁸² *Id.* at 3.

CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments.⁸³

- b. On May 23, 2014, at the direction of the Administrator of CMS, CMS declined to impose Mandatory Two-Sided Review on MA plans through the rulemaking process.⁸⁴ According to the final rule, “In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e) [imposing Mandatory Two-Sided Review].”⁸⁵
- c. I am not aware of any attempts by CMS to clearly specify that Mandatory Two-Sided Review is required for MA plans through an alternative process⁸⁶ such as subregulatory guidance.⁸⁷

⁸³ Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1,918, 2,000 (proposed Jan. 10, 2014) (to be codified at 42 C.F.R. pt. 422).

⁸⁴ See Cavanaugh Dep., February 17, 2022, at 151:8–15 (“Q. Whose ultimate decision was it not to finalize this rule? Who had that authority? A. I – I received my instructions on what to finalize and what not to finalize from the administrator’s office. Q. That would be the Secretary? Or the – or the administrator of CMS? A. The administrator of CMS.”).

⁸⁵ Federal Register, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29,844, 29, 925-26 (May 23, 2014) (to be codified at 42 C.F.R. pt. 422).

⁸⁶ See Cavanaugh Dep., February 17, 2022, at 155:16–23 (“Q. Sitting here today, you can’t identify any rule or regulation that created an affirmative obligation to audit the claims data submitted by providers, or to proactively review medical records, to ensure that the codes selected by providers were supported? A. I cannot. But I’m not an expert in the area and don’t work in that area.”). See also Hornsby 30(b)(6) Dep., May 25, 2023, Exhibit 1206-1 (USBP076134076) (“Under existing regulation, there is no requirement to counter the incentive for MA organizations to conduct medical record reviews only for the purpose of identifying underpayments.”).

⁸⁷ At some time in 2013 or 2014, I understand that CMS specified through subregulatory guidance that Affordable Care Act Marketplace plans perform Mandatory Two-Sided Review. See Creighton Dep., October 4, 2022, at 85:17–88:2 (“Q. I understand your objections. Let’s be clear here, in the contexts of an ACA health exchange, an ACA health plan, when that health plan undertook to do a chart review of claims that it received from a provider that – A. Right. Q. -- in doing fee-for-service, small f; correct? A. Yes. Q. If that ACA health plan undertook to do a chart review, for example, to look for additional diagnosis codes under this guidance from CMS, that health plan was required to evaluate all the diagnoses on the original claim and delete any diagnoses not supported by the chart; correct? A. That -- that is correct. Q. And this was guidance that was applicable only to the ACA health plans; correct? A. That is absolutely correct. Q. And on Page 2 Section 1 b, ‘Encounters in a Capitated Environment.’ A. (Indicating). Q. Do you see that? A. (Indicating). Q. All right. Again, CMS is directing the health plans in the ACA exchange space – A. (Indicating). Q. -- that if they were to undertake a chart review, a medical-record review, of claims submitted by providers in a capitated environment that chart review must also evaluate diagnoses on the original claim and delete any diagnoses not supported by the chart; correct. A. That is correct. Q. Okay. And, again, this was an obligation that was imposed, or a guidance that was imposed, solely upon the ACA health plans; correct? A. That’s correct. And if I might ask, what was of the date of this memo? Q. The note on the -- on the top... A. Okay. So sometime between -- sometime before April 30th, 2015. Okay. That’s fine. Q. I’ll represent to you that on the website it was dated June 2013. And if you look at the first answer it indicates that it’s a Notice of Benefit Payments for 2014. So it had to be promulgated at some point prior to 2014; correct? A. Generally speaking, yes. But their -- their timing on everything was so off then. But, yeah, generally, that would be correct. So sometime 2013 or ‘14.”).

Signed on the 28th of September, 2023, at Stanford, CA.



Dr. Daniel P. Kessler

I am not offering an opinion as to why CMS in fact took different approaches to Mandatory Two-Sided Review in Affordable Care Act Marketplace and MA plans or whether CMS could validly impose such an obligation on MA plans through subregulatory guidance. However, differences between the MA and Marketplace risk adjustment processes may explain the difference in CMS's approaches to them. MA risk adjustment uses FFS data to estimate the underlying model that is used to calculate MA risk adjustment payments. I understand that a number of plans, including United, objected on that basis to requiring MA plans to engage in reviews to identify and delete unsupported codes because FFS data also contained unsupported codes and CMS did not engage in similar reviews to identify and delete them from FFS data. *See* UHG Response to CMS's Request for Comment on RADV Contract-Level Payment Recovery Methodology, at 1-3. By contrast, Marketplace risk adjustment uses *Marketplace* plans' data to estimate the underlying model that is used to calculate Marketplace risk adjustment payments. *See* John Kautter, Gregory Pope, & Patricia Keenan, *Affordable Care Act Risk Adjustment: Overview, Context, and Challenges*, 4(3) Medicare & Medicaid Research Review E1 (2014) (describing ACA risk adjustment generally). Thus, there would be no *a priori* difference in unsupported codes between the data on which the underlying Marketplace risk adjustment model relies and the sector in which the risk adjustment payments would be made, making the objection above inapplicable.

APPENDIX A

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Education

Ph.D. Economics, Massachusetts Institute of Technology, 1994
J.D. Stanford Law School, 1993
B.A. Economics, Harvard University, 1988

Academic Positions

Professor, by courtesy, Stanford School of Medicine, Department of Medicine, Center for Primary Care and Outcomes Research, 2021-
Director of Research, Hoover Institution, 2019-
Senior Fellow, Stanford Institute for Economic Policy Research, 2016-
Professor, Stanford Law School, 2009-
Professor, by courtesy, Stanford School of Medicine, Department of Health Research and Policy, 2008-20
David S. and Ann M. Barlow Professor in Management, Graduate School of Business, Stanford University, 2007-10
Visiting Professor, Harvard Law School, 2007
Senior Fellow, Hoover Institution, Stanford University, 2006-
Professor, by courtesy, Stanford Law School, 2004-2009
Professor, Graduate School of Business, Stanford University, 2003-
Visiting Associate Professor, Wharton School, University of Pennsylvania, 2002-03
Associate Professor, Graduate School of Business, Stanford University, 1998-2003
Assistant Professor, Graduate School of Business, Stanford University, 1994-98

Awards, Fellowships, and Other University Affiliations

Affiliate, Stanford Center on Longevity, 2008-
Health Care Research Award, National Institute for Health Care Management Foundation, 2003
Fellow, Center for Advanced Study in the Behavioral Sciences, 2003-04
Graduate School of Business Trust Faculty Fellow, 2000-01
Affiliate, Center for Social Innovation, Stanford Graduate School of Business, 2000-
Research Associate, National Bureau of Economic Research, 1999-
Public Policy Advising Award, Stanford University, 1998
Kenneth J. Arrow Award for Best Paper in Health Economics, International Health Economics Association, 1997
Affiliate, Center for Health Policy, Stanford University, 1997-
Class of 1969 Faculty Scholar, Stanford Graduate School of Business, 1997-98
National Fellow, Hoover Institution, 1997-98
John M. Olin Faculty Fellow, 1996-97
Faculty Research Fellow, National Bureau of Economic Research, 1994-99

Academic Publications

- “The Responsiveness of Medicaid Spending to the Federal Subsidy,” with M. Kate Bundorf, *National Tax Journal* 75(4): 661-80 (2022).
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- *In re: National Prescription Opiate Litigation*, Case No. 1:17-MD-2804 (reports, deposition, and trial testimony).

APPENDIX B

CMS estimates the MA-FFS difference in disease score growth for a given cohort using a five-step process, *see* USBP000161652 at 39:

- a. Collect claims-based data on diagnoses (and demographic characteristics) from MA and FFS beneficiaries;
- b. Collect spending data from FFS beneficiaries for the calendar year subsequent to year in which diagnosis data were collected;
- c. Estimate a regression model of FFS spending data on demographic characteristics and FFS diagnosis data;
- d. Using the estimates from this model, predict what spending on the MA enrollee with the average set of demographic characteristics and diagnoses would have been, were the enrollee in FFS; and
- e. Calculate the difference between this value and the average spending of FFS enrollees, expressed as a percentage of the average spending of FFS enrollees.

EXHIBIT D-62

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

**UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,**

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO (SSx)

**EXPERT REPORT OF
JULIA LAMBERT, FSA, MAAA
SEPTEMBER 29, 2023**

CONFIDENTIAL

(Contains Attorneys' Eyes Only Information As Designated)

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INTRODUCTION

I have been retained by counsel on behalf of UnitedHealth Group, Inc. and its various related parties (“UHG”) to provide an expert opinion regarding the allegations in a lawsuit filed by Benjamin Poehling and the United States (“Government”).¹ UHG is a Medicare Advantage Organization (“MAO”). My opinion concerns the actuarial methods that the Centers for Medicare & Medicaid Services (“CMS”) uses to calculate payment to MAOs in the Medicare Advantage (“MA”) program and how the Government’s allegations compare to those methods and the Actuarial Standards of Practice (“ASOPs”).

The Government alleges that UHG has unlawfully retained overpayments from the MA program. This report reflects my opinion and associated support regarding actuarially sound payment in the MA program and whether the alleged amounts are overpayments.

Information regarding my background, qualifications, and compensation is included at the end of this report.

SUMMARY OF OPINIONS

ASOPs, promulgated by the Actuarial Standards Board, set forth the principles and procedures for sound actuarial practice in the United States. In order for a risk adjustment model to be actuarially sound, ASOP 45 specifically provides that the risk adjustment model should be applied in a manner reasonably consistent with how it was designed.²

Based on my experience as an actuary specializing in the MA program, the ASOPs, a review of various materials, CMS’s design of the MA payment model, and my calculations of alternative risk model calibrations, it is my opinion that MA and Part D risk-adjusted payment resulting from a MAO’s submission of unsupported diagnosis codes does not necessarily result in overpayments. Classifying all such payments as “overpayments” is actuarially inappropriate, because it ignores both the fundamentals of the MA rating program and how CMS developed the risk adjustment model.

My opinion is based on the following:

1. Based on my experience as an actuary and the ASOPs, actuarially sound risk-adjusted payment depends on applying the risk model in a manner reasonably consistent with how it was developed. That is, there must be “Data Consistency” between the data used to develop the model and the data it is applied to. The MA risk model was developed from Traditional Medicare (“TM”) data, which is largely unaudited, and contains diagnosis codes that are not supported in the medical record. As a result, the MA risk model distributes the cost of treating beneficiaries across demographic and medical conditions in

¹ See Compl., Doc. 171, *United States ex rel. Poehling v. UnitedHealth Group, Inc. et al.*, No. 16-cv-08697 (Nov. 11, 2017).

² American Academy of Actuaries, Actuarial Standard of Practice (“ASOP”) No. 45, <https://www.actuarialstandardsboard.org/asops/regulatory-filings-health-benefits-health-insurance-andentities-providing-health-benefits>.

the data, including conditions identified by diagnosis codes that are supported in the medical records and others that are not supported. This generally results in reducing the payment for any given code. However, that reduction per medical condition is offset (and the resulting payment may then be appropriate) by the fact that MAOs will be paid for some beneficiaries who do not have the medical condition supported (i.e., the unsupported codes). So long as the MAO's rate of unsupported codes is roughly the same as that used in the development of the MA risk model, the payment should be consistent and accurate. But if the MAO is paid only for conditions identified by diagnosis codes that are supported in the medical records—and as a result the rate of unsupported codes in the MAO's data is lower than in the TM data—then the MAO will be underpaid because the payment amounts were calculated based in part on unsupported codes in the TM data.

To abide by the ASOP 45, the MA risk model should be applied in a manner reasonably consistent with how it was designed. Removing MAO payments related to unsupported codes fundamentally changes the application of the risk model. Whether or not an MAO was overpaid cannot be determined solely by the presence of unsupported medical conditions in its data. Rather, an MAO is overpaid only if its level of unsupported diagnosis codes exceeds or is not reasonably consistent with the level of unsupported diagnosis codes in the TM data used to develop the risk model.

The Government has recognized the consistency principle in other programs where risk scores are similarly calculated for beneficiaries based on unsupported codes, including the Medicare standalone Part D Plan (“PDP”) program and individual and small group programs under the Affordable Care Act (“ACA”). Through the ACA, the Government created a national, comprehensive health insurance program where private insurers offer coverage to individuals and small businesses, and the Government subsidizes eligible members with premiums and cost-sharing assistance. The plan designs must meet certain coverage requirements, and premiums and coverage are not based on pre-existing conditions. In both the Medicare PDP and the ACA programs, the risk-adjusted payments made to MAOs and ACA insurers are calculated in part on diagnoses that are not supported in the medical record.

2. Reducing risk scores by removing unsupported codes for UHG payment—without regard for the unsupported code error rate in the TM data—could interfere with CMS's ability to establish equivalent risk scores for the same cohort regardless of program. Since 2005, CMS has upheld the principle that the same population, whether in the TM or MA program, should have the same risk scores, in order to ensure accurate payment. If the Government removes a significant amount of unsupported codes, it must test to ensure it has not invalidated this requirement.
3. Testing conducted under my supervision and detailed in Appendix I shows that the relative risk values in the MA model (the values assigned to each condition by the risk model) are already reduced as a result of a significant level of unsupported diagnosis codes in the TM data. Additional reduction to UHG payment through removing UHG payment related to unsupported diagnosis codes could result in an inappropriate, double reduction to payment.

4. A decision that retrospectively removes a significant amount of UHG revenue related to unsupported diagnosis codes would materially change the payment rules and nullify the actuarial certification UHG submitted with the filing of MA plan benefits and premiums. Almost all health insurance rate filings include an actuarial certification that guarantees an accurate and reasonable projection of the required revenue, based on projected expenses and margin under the proposed benefits. The Government, the insurer, and the beneficiaries rely on the certification as confirmation that the benefits and premium comply with applicable rules and that the coverage does not threaten the insurer's solvency. For MA filings, the Government mandates an additional certification provision where actuaries must certify that the required revenue reflect an *average risk profile*. This requirement for an average risk profile is essential for actuarially sound payment in the carefully constructed MA payment and risk adjusted program. If the Government succeeds in removing revenue related to unsupported diagnosis codes after the fact, it is retrospectively changing the definition of the average risk profile certified by the UHG actuaries. If the unsupported diagnoses are material, the submitted actuarial certification no longer holds, and the actuarial soundness of the program, which the Government relied on through the actuarial certification, would be undermined resulting in underpaying the MAO for the provided benefits.
5. All of the previous opinions except the second opinion are directly applicable to Part D payment for the combined medical and pharmacy program (the Medicare Advantage and Part D or "MAPD" program) plans as well. That is, it is my opinion that Part D risk-adjusted payment resulting from a MAO's submission of unsupported diagnosis codes does not necessarily result in overpayments. Classifying all such payments as "overpayments" is actuarially inappropriate, because it ignores both the fundamentals of the MA rating program and how CMS developed the risk adjustment model.

BACKGROUND OF THE MA PAYMENT SYSTEM

The following sections provide background information on the development of the risk model used for the MA program. Although the entire description is important, the key takeaways from this section include:

- 1) The risk adjustment model used for MA payment was developed using TM claim data and costs.
- 2) The TM claim data includes diagnosis codes that are unsupported in the claim records.
- 3) MA payment is based on actuarially certified bids that include a calculation of costs for an enrollee with a national average risk profile.
- 4) The definition of a national average risk profile is based on an average TM beneficiary with a 1.0 risk score that is calculated using the MA risk model.

Risk Adjustment, MA Bidding, Actuarial Certification, and MA Payment

The risk adjustment methodology for the MA program dates back to the Balanced Budget Act of 1997 (the “Act”). The Act provides that “the Secretary shall develop, and submit to Congress by not later than March 1, 1999, a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status. Such report shall include an evaluation of such method by an outside, independent actuary of the actuarial soundness of the proposal.”³

During the time relevant here (payment years 2009 through 2017 based on diagnosis years 2008 through 2016, or the “Review Period”), CMS paid capitation rates to MAOs based on projected medical and administrative expenses for the offered healthcare benefits as well as the margin levels sought by the MAO. The capitation rates for an average (1.0) beneficiary are required to be lower than or equal to the MA benchmark amounts, which CMS develops based on the per capita costs from the TM program.

The precise capitation amounts by county, the beneficiary premiums, and the benefits offered in any MA contract year are proposed by the MAO via a rate filing submitted to the Government in the year prior to the contract year. In addition to a description of the benefits, the rate filing includes a standardized worksheet called a Bid Pricing Tool (also referred to as the “BPT” or “bid”). Each BPT includes an actuarial calculation of the required revenue amount and beneficiary premium that the MAO needs to cover the proposed benefits, administrative expenses, and the target margin.

CMS requires a separate bid submission for each plan design and that each one be certified by a qualified actuary. The actuarial certification indicates, among other things, that:⁴

1. The bids are based on the “average revenue requirements in the payment area for a [Medicare Advantage and Medicare Part D] enrollee with a national average risk profile.”⁵
2. The pricing data and assumptions are reasonable for the benefits offered.
3. The bids were prepared in compliance with the current ASOPs.

The first certification item above refers to bids being based on an enrollee with a national average risk profile. That means that the calculations of the revenue and beneficiary premium are based on an average beneficiary in the TM program with a risk score of 1.0 (“a 1.0 beneficiary”) in the contract year. For MAOs to identify how their own beneficiaries’ average risk scores compare to a national average risk profile of 1.0, CMS provides various payment and risk adjustment information in advance of the bid deadline through advance and final rate notices.

Through these notices, MAOs receive details on how risk scores will be calculated, including CMS’s publication of its risk model, the relevant county level benchmarks, and the services the plan is required to cover during the following contract year. Using CMS’s published risk model,

³ 42 U.S.C. § 1395w-23(a)(3)(A).

⁴ Instructions for Completing the Medicare Advantage Bid Pricing Tools for Calendar Year 2017, p. 98.

⁵ *Id.*

MAOs compare the average risk scores of the beneficiaries expected to enroll in their MAO to an average beneficiary risk score of 1.0 to calculate the revenue requirement for that national average enrollee profile covered in the certification.

These bids are reviewed and approved by CMS before the start of the following contract year. In addition, approximately one third of the bids go through a rigorous audit procedure where an actuary hired by CMS reviews the calculations and checks the bid information, including the supporting data and assumptions for compliance with CMS's instructions, guidance, and regulations (called "Bid Audits"). These audits result in a written list of observations and findings that provide a foundation for improvement in future bid submissions, as well as potentially more formal consequences including fines and penalties for MAO with egregious results.

After CMS approves the bids and the contract year starts, the Government pays the MAO using this average revenue requirement based on the national average risk profile submitted in the bids. CMS generally pays MAOs for the medical portion of the benefits in two components:

- 1) A risk-adjusted capitation payment. This amount is to reimburse MAOs for covering the TM benefits for the population. It is calculated based on an individual risk score for each beneficiary that the MAO enrolls and multiplied by the revenue requirement for a national average enrollee (also called the "standardized bid amount").
- 2) A rebate amount. This amount is paid to MAOs that bid a revenue requirement below the county level benchmark. The rebate is calculated as a percentage of the difference between the risk-adjusted benchmark and the revenue requirement for covering TM benefits for the expected population. This rebate amount helps fund the MAO for any additional benefits beyond the basic TM benefit. The MAO cannot just keep the rebate as profit. Rather, it is required to offer supplemental benefits with a value (including benefit cost, administrative expense, and margin) at least as great as the rebates in the BPT.

The beneficiary's risk score is a relative amount (centered around 1.0) that reflects various risk factors that correlate with that beneficiary's expected healthcare costs, including demographic information like age and originally disabled factors, as well as diagnosed medical conditions. The risk score value is correlated to the expected healthcare costs of the beneficiary. More critical medical conditions and additional medical conditions usually mean higher expected costs and result in higher risk scores. A beneficiary risk score over 1.0 means the beneficiary has risks and expected costs that are higher than the average TM beneficiary. A risk score lower than 1.0 means the beneficiary has risks and expected costs that are lower than the average TM beneficiary. Because the risk score is multiplied by the standardized bid amount to get the risk-adjusted payment for each individual beneficiary, the application of the risk scores results in MAOs receiving a higher capitation amount for beneficiaries that are likely to incur high healthcare costs and a lower capitation amount for healthier beneficiaries expected to have lower healthcare costs.

The applicable MA risk adjustment model during the Review Period is called the CMS Hierarchical Condition Categories ("CMS-HCC") risk model. A similar Part D ("PD") model, used for the both the pharmacy offering of MAOs and the standalone PDP programs, is called the Prescription Drug Hierarchical Condition Category ("RxHCC") risk model. Standalone PDPs are

prescription drug plans offered by insurers where the Government pays a capitation rate for only pharmacy benefits. Beneficiaries in the standalone PDP program are generally enrolled in Part A and/or Part B of the TM program.

The MA and PD models are *prospective* risk adjustment systems. Prospective risk adjustment systems use diagnosis codes from the previous year (Year 1) to estimate relative risks in the current year (Year 2) for payment. Demographic factors are generally determined based on the same year as the payment.⁶ For example, for MAO beneficiaries in contract year 2017, each beneficiary's diagnoses from 2016 and demographic information from 2017 are used to estimate the beneficiary's risk score for 2017.

Development of the CMS-HCC Risk Model

The Government developed the CMS-HCC risk model using regression, a predictive analytic process. A regression process identifies which variables (medical conditions and demographic characteristics) are significant in predicting relative costs and also quantifies the amount of cost each variable contributes to the overall amount. For MA, like many other risk adjustment systems, the regression process is executed on historical data where both the Year 1 medical conditions and the Year 2 demographic information and costs are known. The costs from Year 2 are regressed against the medical condition and demographic variables to determine the relative contributions of each predictive variable to the costs in Year 2.

For the CMS-HCC risk model, the regression is performed on historical TM data where the TM paid claim amounts are used for costs and the diagnosis codes included on those claims submitted for payment are used to identify medical conditions. The diagnosis codes on the TM claims are largely unaudited. By "unaudited," I mean that the diagnosis codes used to identify medical conditions are used in the model as they are submitted by the providers to the Medicare program. CMS does not generally audit those TM diagnosis codes to confirm they are supported in the medical records.⁷ Therefore, some diagnosis codes in the TM data, which are used as the basis for the risk adjustment model, are not supported in medical records. CMS has acknowledged that not all diagnosis codes in the TM data are fully supported.⁸ As discussed below, the estimate of unsupported diagnosis codes in the TM data is significant.

As a first step in the model development, related diagnosis codes for medical conditions with similar costs are mapped to groupings of Condition Categories ("CCs"). Only diagnosis codes

⁶ In concurrent (as opposed to prospective) risk models, diagnosis codes and demographic information from the current year are used to estimate current risk scores, so there is no one-year lag between the diagnosis year and the payment year.

⁷ See Sean Creighton Deposition, Mar. 23, 2022, at 61:11–18 ("Q. But other than that, I think you testified a moment ago that the majority of the diagnosis codes that are submitted by providers are not audited, not reviewed by CMS for accuracy before being incorporated into the model. Is that accurate? A. There is certainly no medical record review."); Anne Hornsby 30(b)(6) Deposition, May 19, 2023, at 69:5–15 ("A. CMS understands that some diagnoses in the fee-for-service program are likely not supported by the medical record.").

⁸ See CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits - Technical Appendix*, at 6, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf> (showing the discrepancy rates in the CERT data).

from “risk-eligible” claims are used in mapping to Hierarchical Condition Categories (“HCCs”). In their evaluation of predictors of cost, CMS found that only diagnosis codes from certain types of claims were good cost predictors. Generally, diagnosis codes from laboratory and diagnostic claims were excluded when mapping diagnosis codes to CCs.

Each CC is evaluated to determine which CCs are the primary predictors of medical costs for the subsequent year. The CCs are mapped to HCCs to distinguish varying degrees of severity in the manifestation of a condition. For example, diabetes is a disease with multiple groupings of condition categories. Diabetes is divided into three levels of complications (diabetes without complications, diabetes with acute complications, and diabetes with chronic complications), where the related costs vary for these complication categories. The HCCs are defined to be hierarchical in nature so that a beneficiary that has multiple diagnosis codes that map to more than one of these diabetes categories will be limited to reflect only the most severe diabetes category. That is, a beneficiary with diabetes will only be assigned one condition category in the hierarchy of the diabetes condition categories.

In addition, demographic qualities are also studied to determine which age bands and demographic characteristics are predictive of costs. As you might expect, older ages correlate with higher costs. Exhibit A includes a list of the demographic and disease variables in the 2017 Community, Non-Dual, Aged MA Model for Continuing Enrollees. After CMS determines the HCC and demographic predictive variables, it then calculates the relative costs and relative values associated with each variable by performing the following:

1. Each TM beneficiary’s conditions and demographic characteristics (e.g., age, gender, original reason of entitlement) are determined based on diagnosis codes in Year 1 TM claims data and Year 2 enrollee information. Each beneficiary is assigned an array of “1” and “0” markers, indicating whether the beneficiary meets the demographic characteristics or has been diagnosed with the associated HCC condition. The HCCs for each beneficiary are denoted as “1” if the risk-eligible claims for that beneficiary contain any diagnosis codes that are mapped to that HCC. It only takes one diagnosis code from a risk-eligible claim to result in an HCC marker of “1.” If there are multiple providers that submit diagnosis codes on risk-eligible claims that all map to the same HCC, that HCC marker still reflects a value of “1,” the same as if only one risk-eligible claim included the diagnosis code.

Any demographic or HCC diagnoses that the beneficiary does not have are denoted as a “0”. This array of HCC and demographic markers is referred to as the beneficiary’s “risk profile.” Each beneficiary’s risk profile is linked to the beneficiary’s Year 2 costs.⁹ The risk profiles and costs together comprise the beneficiary input file dataset used by the regression to create the risk model.

Exhibit B contains an illustration of a beneficiary input dataset for the CMS 2017 Community, Non-Dual, Aged MA Model for Continuing Enrollees. In this Exhibit, Beneficiary “a” has Year 2 costs of \$11,403, is a female between 75 and 79 during Year 2,

⁹ Year 2 costs are beneficiary’s total expenditures incurred in Year 2 for TM benefits.

was not originally disabled, and had two conditions identified by HCC 170 (Hip Fracture/Dislocation) and HCC 173 (Complications of Specified Implanted Device or Graft).

2. CMS determines the marginal annual dollar costs associated with each HCC and demographic variable using a statistical regression analysis. Year 2 cost is the dependent variable, and the risk profiles reflect the independent variables of the regression. The regression allocates the TM costs from Year 2 to the demographic characteristics and the Year 1 HCCs. Marginal annual dollar costs associated with HCC and demographic variables are the output of the regressions and are commonly referred to as the “dollar coefficients.”

Exhibit A, Column (b) shows the dollar coefficients resulting from the regression on the Community, Non-Dual, Aged, Continuing Enrollees. For example, the regression analysis predicts:

- Being a female age 75-79 in Year 2, contributes \$4,111.23 of cost in Year 2.
- A diagnosis of HIV/Aids (HCC 1) in Year 1 contributes \$2,864.04 of cost in Year 2.
- A diagnosis of Septicemia (HCC 2) in Year 1 contributes an additional amount of \$4,183.18 of cost in Year 2.

With the dollar coefficients for each predictive variable produced by the regression, a predicted cost for each individual beneficiary can be calculated. The predicted cost for a beneficiary is the sum of the dollar coefficients where the beneficiary has predictive markers. For example, for a non-dual, aged, continuing enrollee living in the community who is female, age 77 and with a hip fracture and a traumatic amputation, the predicted cost would be \$10,392 as shown in the table below (using the dollar coefficients from Exhibit A).

Table 1 - Example of Predicted Cost for a Beneficiary

2017 CMS-HCC Model	
Community, Non-dual, Aged, Continuing Enrollee	
<u>Demographic Variable</u>	
(a) Female, 75-79 Years	\$4,111
<u>Condition Variables</u>	
(b) HCC 170 Hip Fracture/Dislocation	\$3,837
(c) HCC 173 Traumatic Amputations and Complications	<u>\$2,444</u>
(d) Total predicted cost (a) + (b) + (c)	\$10,392

3. Year 2 dollar coefficients are converted to relative values for each HCC and demographic variables by dividing the dollar coefficients associated with each variable by the *mean*

predicted expenditure across all TM beneficiaries. Unless a different denominator year is used, the *mean predicted expenditure* is the average of all predicted costs calculated by applying the dollar coefficients (output from the regression model) to the risk profiles determined in step one above. Of note, the mean predicted expenditure using the risk profiles of the beneficiary input file will match the average actual costs in the beneficiary input file.¹⁰ The schedule of relative values for each predictive variable constitutes the CMS-HCC risk model which CMS publishes in its annual rate notice.

Continuing with Exhibit A, the mean predicted expenditure for the 2017 CMS-HCC model was announced in the 2017 Final Rate Announcement to be \$9,185.29 for the denominator year.¹¹ By dividing each of the dollar coefficients in column (b) by \$9,185.29, the relative values (also called relative factors) for each variable are computed. For example, the relative value for HIV is calculated by dividing the HIV dollar coefficient of \$2,864.04 by the denominator of \$9,185.29 to get 0.312.

The entire set of relative values for the 2017 Community, Non-Dual, Aged MA Model for Continuing Enrollees are listed in the last column of Exhibit A.

The model's relative values can then be used to determine risk scores for each beneficiary in a payment year.

1. The risk score for each TM beneficiary can be determined by adding the relative values for the demographic characteristics and Year 1 HCCs applicable to that beneficiary. Beneficiaries who have more costly diagnoses and demographic characteristics will have a risk score greater than 1. For example, a beneficiary whose risk factors result in health care costs that are 30% greater than average would have a risk score of 1.3. On the other hand, beneficiaries with less costly diagnoses and demographic characteristics will have a risk score less than 1. For example, a beneficiary whose costs are 5% less than average will have a risk score of 0.95. By design, the average risk score calculated in this manner across all TM beneficiaries is always equal to 1.0 for Year 2, or the denominator year.

For example, a Medicare continuing enrollee living in the community that is non-dual and aged (i.e., non-disabled) that has a profile like the first beneficiary "a" in the beneficiary input file from Exhibit B will have a risk score of 1.132 using the relative values from Exhibit A. The relative values for each of the variables is added together to calculate the risk score as shown in the following table.

¹⁰ If a different denominator year is used, the mean predicted expenditure will not match the actual costs of the denominator year, but the average risk score for the denominator year will still equal 1.0.

¹¹ See 2017 Rate Announcement at 84 (Apr. 4, 2016).

Table 2 - Example of Raw Risk Score for a Beneficiary

2017 CMS-HCC Model	
Community, Non-dual, Aged, Continuing Enrollee	
<u>Demographic Variable</u>	<u>Relative Value</u>
(a) Female, 75-79 Years	0.448
<u>Condition Variables</u>	
(b) HCC 170 Hip Fracture/Dislocation	0.418
(c) HCC 173 Traumatic Amputations and Complications	0.266
(d) Raw Risk Score (a) + (b) + (c)	1.132

2. The CMS-HCC risk model's relative values are also used to calculate risk scores for the MA enrollees, with two additional adjustments:
 - a. Expected TM coding changes between the denominator year and the payment year used for MAO payment.
 - i. There is typically a lag of at least two to three years between the TM data used as the denominator year and the MAO payment year. During that time, coding or demographics can change and impact the average risk score of the TM population. This adjustment is intended to ensure that the average risk score across all TM beneficiaries remains 1.0 despite potential increased coding or demographic changes following the denominator year. This factor is called the Fee-For-Service ("FFS") Normalization Factor. MAO risk scores from the model are divided by this factor (which is usually greater than 1.0).
 - b. Differences in coding between the TM and the MA program.
 - i. The Coding Intensity Adjustment ("CIA"), sometimes called the "coding pattern adjustment," reduces the MAO risk scores to account for the perception that MAOs code more intensely than TM providers. In other words, a beneficiary may receive more numerous and intense HCCs in MA (where payment is based on such codes) than in TM where payment is generally based on procedures. The CIA aims to adjust the MAO risk scores down to a level of coding that is similar to the TM program. MAO risk scores from the CMS-HCC risk model are multiplied by $(1 - CIA)$, where the CIA is between 3% and 6% over the Review Period.

Continuing with our above example from Table 2 for 2017: the FFS Normalization Factor was 0.998 and the MA Coding Intensity Adjustment was 5.66%.¹² The beneficiary's final risk score would be 1.070 as calculated below.

¹² *Id.* at 3-4.

Table 3 - Example of Final Risk Score for a Beneficiary

2017 CMS-HCC Model	
Community, Non-dual, Aged, Continuing Enrollee	
<u>Demographic Variable</u>	
(a) Female, 75-79 Years	0.448
<u>Condition Variables</u>	
(b) HCC 170 Hip Fracture/Dislocation	0.418
(c) HCC 173 Traumatic Amputations and Complications	<u>0.266</u>
(d) Raw Risk Score (a) + (b) + (c)	1.132
<u>Additional Adjustments</u>	
(e) 2017 FFS Normalization Factor	0.998
(f) 2017 MA Coding Intensity Adjustment	5.66%
(g) Final 2017 Risk Score (d) / (e) * [1- (f)]	1.070

OPINION SUPPORT

- I. The actuarial soundness of payments to MAOs depends on Data Consistency between the development and application of the risk adjustment model. To comply with actuarial principles, UHG may be considered as overpaid only by comparing its level of unsupported codes with that in the TM data used to develop the risk adjustment model. Further, due to the presence of unsupported codes in the TM data used to calibrate the model, removing MA payments related to unsupported codes could introduce an inconsistency and result in payments that are not actuarially sound.**

Actuarially Sound Payment Requires that the Risk Adjustment Model be Developed and Applied to Reasonably Consistent Data.

The ASOPs, promulgated by the Actuarial Standards Board, set forth the principles and procedures for sound actuarial practice in the United States. ASOP 45 provides the actuarial standards for “quantifying differences in morbidity across organizations, populations, programs and time periods using commercial, publicly available or other health status based risk adjustment models or software products.”¹³ In the section addressing data, ASOP 45 provides that “the type of input

¹³ ASOP No. 45 § 1.2, The Use of Health Status Based Risk Adjustment Methodologies.

data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model.”¹⁴

This actuarial principle of “Data Consistency” is a cornerstone of risk adjustment development. Much of the model construction is devoted to testing this principle, as risk adjustment development almost always uses a different set of data than what the risk adjustment will be applied to. In most cases the time period of the development data is older than the application data, but the source of data can also vary. If significant inconsistencies exist that violate the actuarial principle between development and application data, adjustments to the risk adjustment model must be implemented to offset the differences and bring the development data and application data back into reasonable consistency.

For MA payment, CMS uses historical diagnosis codes and expenditures from the TM data to create the model and then applies the model to the MA program. Both the source and the time period of the development data is different than the MA data to which it is applied. In its testing of consistency between the datasets, CMS found significant differences in the diagnosis code patterns (violating the Data Consistency principle) that warranted adjustment. As a result, CMS implemented factors to account for the differences and correct for the inconsistencies, namely the FFS Normalization Factor and the CIA. The FFS Normalization factor accounts for the time difference between the two datasets, and the CIA accounts for the source difference between the two datasets. These factors are described in more detail later in this section of the report.¹⁵

In this lawsuit, the Government alleges that UHG has retained “overpayments” from CMS. The Government maintains that UHG’s risk scores are too high because some portion of its risk scores result from diagnosis codes that the Government claims were not supported in the medical record. The Government maintains that any payments resulting from these alleged unsupported codes constitute overpayments that should be returned to the Government.

The Government’s overpayment theory ignores the actuarial principle of Data Consistency that is at the center of CMS’s risk adjustment model. Accurate risk adjustment payment results when the data used to calculate risk adjustment payments (i.e., apply the relative values from the model) is reasonably consistent with the data used to set risk adjustment factors (i.e., develop the model’s relative values). This consistency standard applied to MA payment means that payment to an MA plan is accurate if it is based on MA data that contains the same level of unsupported diagnoses as in the TM data upon which the model was designed.

If the Government is able to define an “overpayment” as any payment arising from unsupported diagnosis codes, it will alter the level and pattern of supported and unsupported codes in the UHG data. As such, it may be introducing an unreasonable inconsistency between the TM data used in developing the model and the UHG data to which the risk adjustment model is applied. A significant inconsistency in the level of unsupported diagnosis codes between the TM data and UHG data used for payment would violate the actuarial principle of Data Consistency and would call the actuarial soundness of the payments into question. One cannot categorically classify any

¹⁴ ASOP No. 45 § 3.2, The Use of Health Status Based Risk Adjustment Methodologies.

¹⁵ See *infra* § I.

payment related to unsupported HCCs as overpayments without considering the amount of unsupported HCCs in the MAO data relative to the TM data.

The TM Data Used for MA Model Development has a Significant Amount of Unsupported Diagnosis Codes.

CMS has acknowledged that the MA risk model development includes unsupported diagnosis codes (and HCCs) from the TM data.¹⁶ Until now, it has been unclear how many HCCs in the TM data were unsupported. Using the data from discovery in this case, Dr. Michael Salve from Berkeley Research Group (“BRG”) has reported that the level of unsupported HCCs (those HCCs resulting from unsupported diagnosis) in the TM data is significant. Based on sampled 2013 TM charts, the level of unsupported HCCs in the 2013 diagnoses year varies by HCC, but overall is estimated to be between 28.0% and 35.1% at a 90% confidence level. That is, approximately 28.0% to 35.1% (31.6% on average) of the conditions (HCCs) identified for beneficiaries in the TM data and used for risk adjustment were not supported in the claim record. For ease of reference, we will refer to the overall level of unsupported HCCs in the TM data as a simple 31.6% HCC error rate.

Accurate Payment Results When Risk Adjustment is Applied to Both Supported and Unsupported HCCs.

The relative values for each HCC were calculated by CMS using TM data with a 31.6% error rate. Therefore, MAO payments will be accurate from an actuarial perspective only if those relative values are applied to data that also contains a level of unsupported diagnosis codes reasonably consistent with this 31.6% rate of unsupported HCCs, all else being similar.

To determine whether UHG has received accurate payment, one must study the HCC error rates of the UHG HCC data relative to TM HCC data. The approach used for testing differences of HCC error rates between the UHG and TM data includes not only the overall error rate, but also, among other things, testing of:

1. consistency of unsupported diagnosis codes across various cohorts,
2. the distribution of errors by HCCs, and
3. changes in the error rates over time.

While the exact nature of any such study is beyond the scope of this opinion, the 31.6% error rate is useful for illustrative purposes. To the extent that UHG was receiving payment for HCCs that had error rates significantly greater than 31.6%, the Government would be justified actuarially in making an adjustment to payment. To the extent that UHG has lower error rates, UHG may be underpaid.

The following three possible scenarios should be considered to determine whether UHG was paid accurately according to the development of the MA model:

¹⁶ See *supra* notes 7-8.

1. UHG's HCC error rate is materially above the TM error rate of 31.6%;
2. UHG's HCC error is reasonably consistent with the TM error rate of 31.6%; or
3. UHG's HCC error is materially below the TM error rate of 31.6%.

In Scenario 1, the Government likely could modify the risk scores and recoup the associated payment related to unsupported diagnosis codes to some degree while maintaining the actuarial soundness of the risk model. The Government would need to be careful, however, to not remove so many unsupported diagnosis codes that the HCC error rate of the resulting data would be reduced significantly below the 31.6% TM level. Such recoupment would violate the actuarial risk adjustment principle and could result in actuarially unsound payment, absent other mitigating factors.

In Scenario 2, the payment is accurate from an actuarial standpoint given the reasonably consistent rate of error. Any further reduction in risk scores by the Government that removes significant amounts of payment would likely violate the actuarial principle.

In Scenario 3, the Government likely would not be justified in reducing risk scores and payment related to unsupported codes any further. In fact, actuarial principles would indicate that, absent some other mitigating factor, the payment already made to UHG could be understated and violate actuarial principles of consistency.

To my knowledge, the Government has not performed any analysis of HCC error rates for either UHG's MA data as a whole or TM data to date. As a result, its allegations of overpayment ignore basic actuarial principles related to risk adjustment, and oversimplify the complexities of the MA payment system, resulting in an unsound conclusion. Regardless of the scenario above, the undisputed presence of unsupported codes in the TM data that was used to develop the MA risk adjustment model requires the Government to account for such unsupported codes in any assessment of overpayment to an MAO related to unsupported codes.

The Data Consistency Principle and Accurate Payment Must be Assessed in the Aggregate.

It cannot be determined whether any single payment or subset of payments is actuarially appropriate without considering the overall levels of supported and unsupported codes in both the UHG and TM data.

As is the case with many items in actuarial science and insurance topics, a larger cohort of beneficiaries must be considered to determine actuarial soundness. In many cases, it's the statistical variation in claims that necessitates a larger set of data be used. In this case, an unsupported code for an individual beneficiary may not be an overpayment because the model payments are calculated in part on unsupported diagnosis codes that help offset the underpayments for other supported codes. The rating system is designed to create accurate payment over a large cohort of beneficiaries.

Accordingly, the determination of the appropriateness and actuarial soundness of risk adjustment payments must be made in aggregate or on average for larger cohorts. That is, a single payment for an MA beneficiary that is based on an HCC from an unsupported diagnosis code cannot be

assessed as an overpayment in isolation. Evaluation of any single payment or subset of payments for actuarial soundness would be inconclusive.

CMS Maintains the Consistency Principle in MA Rate Setting.

CMS has recognized the consistency principle in multiple contexts in MA rate setting:

1. Coding Intensity Adjustment. CMS acknowledged the consistency principle when implementing the CIA.¹⁷ The CIA is applied to all MA risk scores to account for differences in the volume and pattern of diagnosis coding between the providers in the TM program and the MA program.¹⁸ That is, the CIA is an adjustment that accounts for the differences in sources between the development and application data. Because more robust diagnosis coding results in higher risk scores and higher revenue, MAOs have an incentive to document and submit more codes than providers in the TM program, who do not have the same incentives. Absent some offsetting adjustment, the MAO risk scores would be higher for a cohort of TM members in an MA setting compared to the TM setting. The intention of the CIA reduction to MA risk scores is to normalize or standardize the MA risk scores to a level of coding that is reasonably consistent with the TM program.¹⁹

The Deficit Reduction Act of 2005 (“DRA”) required CMS to perform an analysis of “differences in coding patterns between Medicare Advantage plans and providers under” the TM program and establish an adjustment to MA payments for Calendar Year (“CY”) 2008 – CY 2010 “to the extent that the Secretary has identified such differences.”²⁰ The DRA provides that in implementing the CIA factor: “In order to ensure payment accuracy, the Secretary should conduct an analysis of the differences.”²¹ The DRA and actuarial principles both agree that accurate MA payment requires consistency between the MA and the TM coding patterns.

Per the DRA, CMS has performed analyses to estimate the CIA, and implemented the following amounts for the payment years in the review period:²²

¹⁷ The Coding Intensity Adjustment is also sometimes called the “Coding Pattern Adjustment.”

¹⁸ See 2010 Rate Notice at 19 (Apr. 6, 2009).

¹⁹ See *id.* at 21.

²⁰ Deficit Reduction Act of 2005, 120 Stat. 50, Pub. L. 109-171 (Feb. 8, 2006), <https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf>.

²¹ *Id.*

²² These values are compiled from the applicable Rate Notices for the associated calendar years.

Table 4 – CIA Amounts

Payment Year	CIA
2009	n/a
2010	3.41%
2011	3.41%
2012	3.41%
2013	3.41%
2014	4.91%
2015	5.16%
2016	5.41%
2017	5.66%

In 2017, for example, risk scores were reduced by the CIA of 5.66%. That is, each beneficiary risk score was multiplied by 0.9434 (1-5.66%). The CIA reduced risk adjusted revenue for all MAOs, including UHG. Note that the CIA reduction amounts during these years were statutorily required minimums.

Through the CIA, CMS normalizes the risk adjustment model for additional coding that exists in MA data (application data) that is not present in the TM data (development data) and maintains the Data Consistency between the development and the application of the risk adjustment model.

2. FFS Normalization Factor. CMS also applies a normalization factor to account for the fact that the volume and pattern of coding varies within the TM program due to the timing differences between the year of data underlying the risk adjustment model development (denominator year) and the year of data to which the model is applied (payment year). CMS realizes that to the extent that the coding and demographic changes over time, the originally developed relative values may no longer maintain a 1.0 average. Therefore, CMS implemented an adjustment (usually a reduction) to the risk scores for the differences in coding between the denominator year and the payment year. The table below shows the timing difference and the associated FFS Normalization Factors for the Community, Non-Dual, Aged MA Model for Continuing beneficiaries during the Review Period. In each year, the beneficiary risk scores for all MAOs, including UHG, are divided by the FFS Normalization Factor to calculate the beneficiary risk score.²³

²³ All of the below values are taken from the Rate Notices for the applicable calendar years.

Table 5 - FFS Normalization Factors for the Community, Non-dual, Aged, Continuing Enrollee CMS-HCC Model

Payment Year	Denominator Year	Timing Difference	FFS Normalization Factor (to adjust for the timing difference)
2009	2007	2 years	1.030
2010	2007	3 years	1.041
2011	2007	4 years	1.058
2012	2007	5 years	1.079
2013	2011	2 years	1.028
2014*	2011/2012	3/2 years	1.041/1.026
2015*	2011/2012	4/3 years	0.992/0.978
2016	2012	4 years	0.992
2017	2015	2 years	0.998

*In 2014 and 2015, CMS used a blend of risk scores from the 2013 and 2014 HCC models. In 2014, the factors of 1.041 and 1.026 were used for the 2013 and 2014 HCC Models, respectively. In 2015, the factors of 0.992 and 0.978 were used for the 2013 and 2014 HCC Models, respectively.

In 2017, for example, risk scores were divided by the FFS normalization of 0.998, which increased the risk scores from what they otherwise would have been.

3. Provider Data Sources. CMS does not accept “prescription drug data or lab results” to support a diagnosis during its Risk Adjustment Data Validation (“RADV”) audits. These codes were not identified as predictors of cost, so were not included as valid or risk-eligible diagnosis codes supporting the HCCs in the development of the model. Including these diagnosis codes as valid indicators of conditions during payment years or part of RADV audits would violate the consistency principle. In describing the exclusion of this data, CMS explained that payment should be determined only “based upon supporting medical record documentation from provider data sources that are used to calibrate the model.”²⁴ This precisely illustrates the fundamental importance of using consistent data in the development and application of the risk adjustment model.

All of these examples show how CMS strives to abide by the Data Consistency principle in its risk adjustment methodology.

The Government Recognizes the Actuarial Principle of Data Consistency in Other Programs and Allows Risk Scores Based on Unsupported Diagnosis Codes.

In other programs where risk scores are similarly calculated for beneficiaries, the Government has recognized that actuarially sound payment depends on Data Consistency between the development and application of the payment model. Two programs worth explaining are the Part D program

²⁴ *Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 75 Fed. Reg. 19,678-01, 19,748 (Apr. 15, 2010) (as corrected on June 7, 2010).

and the ACA program. In these programs, the Government makes payments based on submitted diagnosis codes, and payments based on known unsupported diagnosis code submissions are not categorically deemed inaccurate.

A. Part D Program

The Part D program similarly uses a risk adjustment model for Medicare beneficiaries. This model is developed from and applied to Part D programs that operate both as part of the MAPD program as well as the standalone program (the PDP program). The MAPD beneficiaries are largely the same as the beneficiaries being scored under the MA program.²⁵ The PDP beneficiaries are generally those who receive medical coverage under the TM program.

When assigning Part D risk scores to beneficiaries, TM beneficiaries under PDP plans receive risk scores based on the medical diagnosis codes present in the FFS data underlying the TM beneficiaries. This FFS data are the same data that are used to develop the MA risk adjustment model, and therefore contain a significant amount of unsupported diagnosis codes. Also, similar to the MA program, actuaries submit Part D bids based on an average 1.0 beneficiary, but here the average is based over all MAPD and PDP beneficiaries.

Unlike the MA program, the Part D risk scores used to calculate payments to PDP sponsors are largely unaudited and not subject to any targeted validation of the underlying diagnosis codes. All supported and unsupported diagnoses from the TM FFS claims that get mapped to HCCs result in additional risk score and payment to the PDP plans. If the Government's theory that any unsupported diagnoses should not result in payment, this difference in eligible diagnoses would result in a profound difference in methodologies between Part D payments for a TM beneficiary in a PDP and Part D payments for a MA beneficiary receiving PD benefits who are in theory paid under the same rate-setting and risk adjustment system.

Consider the following scenario:

- Provider P is a cardiologist in the TM program as well as UHG's MAPD network.
- Suppose Samantha is enrolled in a stand-alone PDP plan of a UHG competitor.
- Suppose Martha is enrolled in UHG's MAPD plan.
- Suppose Martha and Samantha both have the same demographics and diagnosis codes from provider P during 2016.
- Because of similar diagnoses and demographics, Martha and Samantha should both have the same risk score.
- However, suppose Provider P does a poor job in substantiating the diagnosis codes for his patients, and so all of the cardiac diagnosis codes for both Martha and Samantha are unsupported in the medical records.

If only supported diagnosis codes are included in payment for MAPD plans, dramatic differences in Part D risk scores and payments between similarly situated beneficiaries in MAPD versus PDP

²⁵ Most MA beneficiaries select plans that include Part D coverage. However, some MA beneficiaries choose plans that are "MA-only" and do not include coverage for Part D.

would result. The premise being used in the allegations of this case would indicate that Martha's risk score should be reduced but that Samantha's risk score should not change.

If the Government believes that payment should only be made on supported diagnosis codes for both MAPD and PDP programs, then a series of illogical consequences would ensue, again calling into question the actuarial soundness of the Part D payment model and associated risk adjustment program:

1. CMS would need to identify and delete all diagnosis codes for PDP beneficiaries for unsupported diagnosis codes in the TM data. This would remove diagnosis codes that the model was developed on and would create an inconsistency between the development and application of the model.
2. Payments for PDP sponsors would be reduced for approximately 31.6% of HCCs.²⁶
3. The average risk score for the PD beneficiaries would no longer be 1.0 and would be significantly less than 1.0. The average of PD risk scores across all PDP and MAPD plans would also be less than 1.0.
4. This result contradicts the requirement that the average PD risk score across all beneficiaries is 1.0 and would be a material payment methodology change that would impact the offering of benefits and premiums in this market.

The point of the Part D payment example is to illustrate how CMS's position on unsupported diagnosis in the MA program, when applied to the Part D program, creates problematic results. If only the unsupported diagnoses in MA are overpayments, then similarly situated beneficiaries (Martha and Samantha) will have the different Part D risk scores, an irrational outcome. Alternatively, if all unsupported diagnoses in both the PD portions of MAPD and PDP payment are overpayments, then the national average risk profile in the Part D program will no longer have a risk score of 1.0, violating a core tenet of the RxHCC model. CMS cannot assume that accurate payment must only be on supported diagnosis codes and that certain unsupported diagnosis codes, along with the associated payment, be deleted from the MAPD program only. Their own PDP program has been operating alongside the Part D component of the MAPD program, making payments on submitted unsupported codes, for over a decade.

If CMS would abide by the Data Consistency principle, the coding underlying the PDP beneficiaries in the TM data would be reasonably consistent with the coding underlying the MAPD Part D risk scores, and no incongruities would result.

B. Individual and Small Group Marketplaces That are Part of the Affordable Care Act (ACA)

As part of the ACA, the Government introduced a new program of coverage for individuals and small groups starting in 2014 offered by private insurers (issuers). As part of the program,

²⁶ Although the RxHCC model does not include the exact same HCCs, many are the same and would produce a similar result. To get a revised overall estimate, a similar statistical analysis would need to be performed on the HCCs in the Rx-HCC model.

enrollees are charged premiums based on costs for an average enrollee (based on a 1.0 risk level). Using a risk adjustment system, each of the issuers' covered members is scored and premiums are transferred between issuers based on the relative aggregated risk of the issuers' members. Relative risk is calculated based on the plan liability risk score ("PLRS"), allowable rating factors, induced demand factors, actuarial value factors, and geographic rating factors. Those issuers that have members with a lower relative risk will transfer revenues to those issuers where the membership has a higher relative risk.

The PLRS is calculated at both a plan level and an enrollee level (the plan level being the weighted average of the enrollees in the plan). At the enrollee level, the PLRS (or risk score) is determined based on the Department of Health and Human Services (HHS) HCC ("HHS-HCC") model, which is developed using regression techniques similar to the CMS-HCC risk model. The HHS-HCC model for ACA was originally calculated based on an alternate set of data,²⁷ but once the ACA data became reliable, the HHS-HCC risk adjustment model was developed based on the historical data from the ACA program itself (beginning with payment year 2021). The HHS-HCC model has separate segments for each metal plan level, taking into account the fact that higher-AV plans will incur greater costs due to their more generous benefit designs. In addition, the HHS-HCC model generally consists of the following types of predictive variables: demographic, enrollment duration, cost sharing reduction level, hierarchical condition categories, and prescription drug categories.

The diagnostic classification system for the HHS HCCs is similar to the MA program in that submitted diagnosis codes are mapped to chronic conditions and those chronic conditions that are found to be predictive of costs are grouped into HCCs. In similar fashion to MA, a regression model takes a beneficiary input file (containing all the markers of the predictive variables by enrollee) and calculates the marginal dollar contributions for each HCC. These dollars are converted to relative values, which are then applied to the ACA members to calculate their risk scores (PLRS values). The ACA risk model also is similar to the MA model scheme in that it must define a 1.0 average member that is used for premium development.

For years 2014 through 2016, no adjustments to the risk scores were made for the level of unsupported diagnosis codes (substantiation failure rate) in the claim records. Beginning in 2017, a RADV program for the ACA was finalized. Per the ACA 2019 rate notice, "the goal for the HHS-operated risk adjustment program is to ensure that enrollees' diagnoses on paid claims reflect the appropriately assigned HCCs and were diagnosed by a licensed clinician."²⁸

This RADV program for the ACA adjusts risk scores for errors when an issuer's failure rate is statistically meaningfully different than other issuers. Failure rates are used in calculating the final error rate of an issuer.²⁹ Issuers where the failure rate does not meet this threshold of statistical

²⁷ MarketScan data was used in full or in part for payment years prior to 2021.

²⁸ *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019*, 83 Fed. Reg. 16,930, 16,943 (Apr. 17, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-04-17/pdf/2018-07355.pdf>.

²⁹ Failure rate refers to the non-validation rate of an HCC and is calculated as $1 - (\text{IVA HCC Count} / \text{EDGE HCC Count})$. Error rate is developed when an issuer has failure rates that are deemed outliers and is used to calculate the PLRS adjustment for the RADV transfer. The adjusted PLRS is calculated as $\text{PLRS} * (1 - \text{Error Rate})$.

significance receive a 0% error rate and therefore do not have their issuer PLRS or risk score adjusted. For every issuer, the substantiation failure rates are calculated based on a documented process where Independent Validation Auditors (“IVAs”) review the medical records for sampled members. The IVAs identify the sample and review medical records for each HCC in the sample and identify the level of unsupported HCCs. Based on the results of these audits for the 2017 benefit and 2018 benefit year RADV programs, “HHS aggregates all issuers’ failure rates and creates HCC groupings, national means, and 95% confidence intervals at 1.96 standard deviations for that benefit year of HHS-RADV.”³⁰ Those issuers where the failure rate is outside the 95% confidence failure rate are identified as statistically significant or ‘outliers.’ In the 2019, 2020, and 2021 benefit years, RADV program outliers were identified as those with failure rates outside of the 90% confidence failure rate interval. Outlier issuers with higher failure rates than the confidence interval have their risk scores adjusted downward using a prescribed formula. For outlier issuers who have lower failure rates than the confidence interval, risk scores may be adjusted upward. Beginning in the 2019 benefit year RADV program there is “modification to the error rate calculation in cases where a negative error rate outlier issuer also has a negative failure rate”.³¹ HHS described the formula by indicating that “statistically meaningful errors should be adjusted to the weighted mean failure rate of each HCC group.”³² That is, the issuers’ risk scores are reduced in aggregate so that the error rate reflects the average of the HCC group (still reflecting an average level of unsupported codes). “If the issuer is not an outlier, the issuer is determined to have a zero error rate.”³³ For those issuers who have amounts of substantiation errors in their diagnosis codes that do not meet the outlier threshold, no adjustment is made to the risk score, and the risk scores continue to reflect the unsupported diagnosis codes in the original issuer data.

After adjusting the risk scores for the outlier issuers, the payment transfer methodology that moves revenue from issuers with low relative risk members to issuers with high relative risk members are recalculated and adjusted. Because of this payment transfer mechanism, issuers receiving a 0% error rate may still have their transfer amounts adjusted if the market error rate is nonzero.

An additional point contrary to the MA risk adjustment system is the timing of the RADV methodology announcement for ACA. Because these RADV processes affect the overall 1.0 member and the premium development, the RADV processes and calculations were announced prior to the application year so that any adjustments to the premium development could be made. That is, if an issuer suspected that their risk scores would be adjusted down due to a high error rate, they could make an adjustment when calculating and filing the premiums for 1.0 member to ensure that the premiums were actuarially sound.

³⁰ CMS, 2019 RADV White Paper, at 15 (Dec. 6, 2019), <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.pdf>.

³¹ *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019*, 83 Fed. Reg. 16,930, 16,943 (Apr. 17, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-04-17/pdf/2018-07355.pdf>.

³² 83 Fed. Reg. at 16,944.

³³ CMS, 2019 RADV White Paper, at 15 (Dec. 6, 2019), <https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.pdf>.

Although some of the details of the ACA program are different than in MA risk adjustment, the ACA risk adjustment program supports multiple points made in this report:

1. The intended premium adjustments for unsupported codes were tested and announced prior to the rate filing, so actuaries' certifications of those rate filings would be consistent with the intended practices.
2. Risk scores calculated on unsupported diagnosis codes do not necessarily result in overpayments. Only those issuers that are determined as outliers as compared to the development data have risk scores recalculated. Accurate payment requires that some level of unsupported diagnosis codes be used to calculate risk scores.
3. Testing for unsupported codes and accurate payment is not determined for a subset of members or codes, but rather testing is statistically done to measure the aggregate level of unsupported codes. Adjustments are similarly made at an aggregate level.
4. In compliance with the actuarial principle of Data Consistency, only those risk scores that are substantially different than that used in the development of the model are adjusted. The adjustment that is made is to move those risk scores to the weighted mean failure rate of each HCC group, that is, the average failure rate across the data used to develop the model. The adjustment does not entirely remove the failure error rate by moving the errors to zero. Rather, the payments are adjusted only to reflect the average failure rate in the data, maintaining consistency of application and development risk adjustment data.
5. The entire ecosystem of payment must be considered when adjusting payments. HHS was careful in the development of the ACA RADV program so as to not disturb the rate ecosystem and actuarially sound rate process. Prior to the implementation in 2017, two beta years of results were tested and distributed to the issuers without impact to premium revenues. The process continued to be refined during that time. HHS indicated in 2013 and throughout subsequent years that "[t]he purpose of data validation for risk adjustment is to promote confidence in the budget neutral payment transfer methodology by ensuring the integrity and quality of data provided from issuers operating in state markets under the HHS-operated risk adjustment program."³⁴

II. Reducing risk scores by removing unsupported codes for UHG payment could interfere with CMS's goals for same risk score for same cohort regardless of program and thereby undermine payment accuracy.

The Government maintains that an accurate risk adjustment system in the MA program should be implemented in such a way that the same population, whether enrolled in TM or MA, should have the same risk score. That is, accurate payment depends on a risk adjustment system where the same population cohort should have the same risk score regardless of the program (MA versus TM) where they are enrolled. Furthermore, since the average beneficiary in the TM program has

³⁴ CMS, *Affordable Care Act (ACA) HHS-Operated Risk Adjustment Data Validation (RADV) Process White Paper*, at 6 (June 22, 2013), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_050718.pdf.

a risk score of 1.0, a similar beneficiary should have a risk score of 1.0 in the MA program. The references below support this long-standing principle:

1. The DRA directed the Secretary to “adjust the risk scores for differences in coding patterns between Medicare Advantage plans and providers under the original Medicare fee-for-service program under parts A and B to the extent that the Secretary has identified such differences.”³⁵ That is, if coding is different between MA and TM providers, CMS must correct the risk scores so that the ultimate risk scores are similar.
2. As a result of the DRA, CMS studied the coding pattern differences between MA and TM and published adjustments to account for the differences in coding patterns between MA and TM. As part of the 2010 Final Rate Notice, CMS stated:

Given the fact that the MA payment methodology is based on fee-for-service payments, and that the risk adjustment methodology is designed to compare the risk scores of MA plan enrollees to other plan enrollees and beneficiaries not enrolled in MA plans, for this comparison to be valid, MA plans must code the way Medicare Part A and B providers do in order for risk adjustments to be valid. This means that MA organizations are coding “accurately” when they are coding in a manner similar to fee-for-service coding used on the beneficiaries to whom MA plan enrollees are being compared. In this sense, “differences” in coding patterns, regardless of the source, would make the MA plan coding “inaccurate” for purposes of implementing risk adjustment.³⁶

This reading of the word “inaccurate” is supported by floor statements made by Senator Grassley, Congressman Barton, and Congressman Thomas. Senator Grassley made the following floor statement; the other two committee chairs made very similar statements:

Section 5301 and the joint statement which accompanied the conference report in the Senate requiring adjustments for differences in coding patterns is intended to include adjustments for coding that is inaccurate or incomplete *for the purpose of establishing risk scores that are consistent across both fee-for-service and Medicare Advantage settings*, even if such coding is accurate or complete for other purposes. This will ensure that the goal of risk adjustment—to pay plans accurately—is met.³⁷

3. In CMS’s publication in 2014 regarding measuring coding intensity, Kronick and Welch stated:

As noted, payment to MA plans is calibrated based on coding patterns in FFS. *If, for example, Jane Doe would have a risk score of 1.0 if she were in FFS, the*

³⁵ Deficit Reduction Act of 2005, 120 Stat. 50, Pub. L. 109-171 (Feb. 8, 2006), <https://www.govinfo.gov/content/pkg/PLAW-109publ171/pdf/PLAW-109publ171.pdf>.

³⁶ 2010 Final Rate Notice.

³⁷ 152 Cong. Rec. S438 (daily ed. Feb. 1, 2006) (statement of Sen. Charles Grassley) (emphasis added); *see also id.* at H46 (statement of Rep. Joseph Barton) (similar); *id.* at H54 (statement of Rep. William Thomas) (similar).

*implicit assumption in the design of the MA payment system is that she would have the same risk score of 1.0 if she were enrolled in MA. Alternatively, if the same Jane Doe had a risk score of 1.1 if enrolled in MA, then her plan would be overpaid. As we use the phrase, “coding intensity” is the difference between the scores that a group of beneficiaries would have if enrolled in MA and their scores in FFS [F]or the purposes of creating an equitable MA payment system, the relevant question is whether MA risk scores are systematically different than those risk scores would be in FFS Suppose, for example, that average expenditure per FFS beneficiary is \$10,000/ year, and that the average risk score for all FFS beneficiaries is 1.0. The goal of the payment system is to assure that—if all of those beneficiaries were to enroll in MA—the average payment to MA plans would be approximately \$10,000 per beneficiary The goal of the risk adjustment system is to assure that MA plans that enroll sicker-than-average beneficiaries are paid appropriately, but *not to increase payment for an average beneficiary*.³⁸*

The same would be true of risk adjustment in the opposite direction as well. That is, the goal of risk adjustment is also not to decrease payment for average beneficiary.

Should the Government succeed in removing certain HCCs (relative values) due to unsupported codes, and thus lower UHG’s risk scores and the related payment in this case, the government will be introducing an inconsistency in risk scores between the TM and the MA programs for the same population, assuming that coding intensity adjustment appropriately adjusts for intensity differences and all else is equal. In the TM data, the risk scores for any population cohort are calculated based on all available unsupported and supported diagnosis codes. However, this same population cohort, if enrolled in UHG, would not have any part of the risk score calculated on diagnoses that are known to be unsupported. As such, the risk scores for the same population cohort may be less in the MA program than in the TM program. Thus, the Government may be introducing a difference that violates the established and core tenet of same risk score for same cohort, regardless of the program.

III. Alternative calibrations of the CMS-HCC risk model based on simulating the removal of unsupported diagnosis codes provide evidence that unsupported codes in the TM data reduce dollar coefficients and relative values compared to risk models developed with only supported codes.

To understand the effects of unsupported codes on the MA risk adjustment model, I have simulated the removal of unsupported diagnosis codes in the TM data and studied the effects on the MA risk adjustment model.

³⁸ R. Kronick & W.P. Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Research Review (2014), https://www.cms.gov/mmrr/downloads/mmrr2014_004_02_a06.pdf (emphasis added).

CMS has also performed analyses to address how the MA model would change if unsupported diagnosis were removed from the development of the model.³⁹ CMS's work was in support of its analysis on whether an FFS Adjuster was needed in its application of penalty calculations for RADV. My disagreements with CMS's ultimate findings have been published in comments,⁴⁰ where I detailed how the flaws in CMS's methodologies led to erroneous conclusions.⁴¹ However, I agree with one of CMS's findings: in its development of the revised risk model, CMS confirmed that the dollar coefficients on average would increase when removing unsupported diagnosis codes.

I have revisited the risk adjustment development analysis based on revised data received as part of discovery for this case to further understand and test what would happen to MA payment should the MA risk adjustment model be based on only supported diagnosis codes. My additional work, which is fully documented in Appendix I, included the following process:

- The original 2017 model for the Community, Non-Dual, Aged, Continuing Enrollee cohort was first replicated based on the CMS provided beneficiary input file.
- Estimated HCC error rates based on statistically valid samples from the TM FFS data were obtained from another expert.
- A number of simulations of removing unsupported HCCs (based on the HCC error rates) from the beneficiary input file were tested to see how dollar coefficients and relative values varied. These simulations include:
 - Random on/off
 - Scalar Method
 - On/off by Number of Charts
 - Scalar Method by Number of Charts
- Revised relative values and dollar coefficients from the recalibrated risk models were compared to the original model.
- These revised relative values were applied to beneficiary risk profiles in the UHG Final Model Output Data Files to confirm impact at a contract level.

³⁹ See CMS: *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADVMethodology.pdf>; *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits*, (Oct. 26, 2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Executive-Summary.pdf>; *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits - Technical Appendix*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf>; *Addendum to the Fee-For-Service Adjuster Study*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/RADV-Provision-CMS-4185-N4-Data-Release-June-2019.zip>.

⁴⁰ Paper, UnitedHealth Group, "Actuarial Report on Medicare Advantage FFS Adjuster," (Aug. 28, 2019), <https://www.regulations.gov/document/CMS-2018-0133-0263>.

⁴¹ CMS initially concluded that there was no material impact to the risk adjustment model nor to MA payment resulting from developing the model based only on supported diagnosis codes. This conclusion was based on introducing a new and never-used-before "Inflated Post-Audit Risk Score" adjustment to offset the change in relative risk values and HCC beneficiary error rates that were incorrectly developed.

- Further testing was performed to understand how removing costs in addition to removing unsupported HCCs impacts relative values.

My analyses indicate that the impact to the MA risk adjustment model of removing unsupported diagnoses, regardless of the manner in which unsupported HCCs are removed, are consistent with those I previously disclosed to CMS in my published comments. Specifically: 1) the average dollar coefficients increase, 2) the average relative values of the model increase, 3) the resulting risk scores to the MAOs also increase as a result when applying the revised relative values to existing MAO data, and 4) results do not change even if expenditures from unsupported diagnoses are removed.

An equivalent, and perhaps more important, conclusion of the analysis is that the unsupported diagnosis codes in the TM data result in reduced relative values on average in the current risk adjustment model from what they would have been had CMS developed the model on only supported codes. That is, unsupported HCCs in the TM data dilute the average relative values currently used in MA payment.

Illustration Using a Simplified Risk Model

These conclusions can be illustrated with a simplified risk model with only one HCC. If the model is designed with supported and unsupported diagnoses (unaudited data), the payment for one diagnosis will be calculated based on costs associated with beneficiaries who have the diagnosis (supported codes) and some who do not (unsupported codes). The unsupported codes will dilute (reduce) the average cost and average relative value used for MA payment for that diagnosis. The risk adjustment model therefore will underpay MAOs for beneficiaries coded with the diagnosis; however, because MAOs will receive payment for beneficiaries who have the diagnosis (supported codes) and some who do not have it (unsupported codes), the MAOs will ultimately receive appropriate payment consistent with the model design if their rate of unsupported codes for this condition mirrors that of CMS. In other words, MAOs will generally be underpaid for all diagnoses, but will make up for this underpayment because they will also be paid for beneficiaries who do not have the supported diagnoses (unsupported codes).

In contrast, if the model were designed with only audited data, that is, only supported codes, then the payment for each diagnosis would be higher, but there will be fewer beneficiaries with those diagnoses because the audit will remove any unsupported codes. If the model is applied with that design, that is, by paying MAOs only on audited data, the MAOs will then be paid accurately because they will receive the higher payment but only for those beneficiaries who have the diagnosis supported and not for any unsupported codes.

This dynamic can be illustrated further with a numerical example. Assume a population of five beneficiaries with only one potential Diagnosis – Diagnosis X. The cost of treating beneficiaries with a supported Diagnosis X is always \$5 per beneficiary, the cost of treating someone without Diagnosis X supported is always \$0, and that there are four beneficiaries who have Diagnosis X supported and one who does not have the code supported. The total cost of treating these five beneficiaries is \$20 (\$5+\$5+\$5+\$5+\$0) and the average cost is \$4 (\$20/5). The presence of the unsupported code diluted the average cost of treating Diagnosis X from \$5 to \$4. Therefore,

MAOs are underpaid \$1 for every beneficiary with Diagnosis X. MAOs, however, will be adequately paid in the aggregate so long as they receive payment for unsupported codes and there is at least one unsupported beneficiary with Diagnosis X out of every five diagnosed. Put simply, receiving \$4 for five beneficiaries (lower payment applied to unaudited data) will be the same as receiving \$5 for four beneficiaries (higher payment for only audited data).

Inaccurate payment occurs when the model is applied in a manner inconsistent with its design. For example, if a model is based on unaudited data but payment is based only on audited data, MAOs will be underpaid because they will receive the diluted payment for each supported diagnosis and no payment for the unsupported codes to make up for those underpayments. Using the example above, if the model is applied solely to audited (supported) data, an MAO with five beneficiaries coded with Diagnosis X but only four with supported diagnoses would receive a total payment of \$16 (four payments of \$4 each) when its true cost was \$20 (four patients at \$5 each and one at \$0).

Because of these diluted relative values created from unsupported TM HCCs in the risk model development data, actuarially sound risk adjustment depends on applying the diluted relative values to a combination of both supported and unsupported HCCs in the MA data. That is, accurate payment depends on both supported codes and unsupported codes being present in the MA data in a similar pattern to what exist in the TM data used to build the model.

Using the simplified example above (which is designed to illustrate the overall average impact of unsupported codes on payment), in the MAO one out of every five beneficiaries coded with Diagnosis X was unsupported. If an MAO plan has the same one out of five (20%) error rate for Diagnosis X, it would be paid consistent with the design. If, however, it has a higher error rate for Diagnosis X, then it would be overpaid because it will be receiving the wrong and higher payment more than one out of every five times. Accordingly, if the MAO's error rate is lower than 20%, the MAO will be underpaid.

This again can be illustrated with a simplified example. If the MAO has six beneficiaries all coded as having Diagnosis X, it would receive \$24 (six times \$4). If only four of those are supported, the error rate would be 33%, which is higher than the 20% built into the model. Accordingly, the MAO would be overpaid because it received \$24 when its actual costs were \$20 (four times the actual cost of \$5 per beneficiary with two beneficiaries at \$0 cost). If all six beneficiaries had supported codes, the error rate would be 0% and thus lower than the 20% built into the model. Accordingly, the MAO would be underpaid because it would have received \$24 when its actual costs was \$30 (six times \$5 per beneficiary).

Removing the unsupported HCCs from the MA data, as the Government intends to do here, may effectively result in a double-reduction of MA payment due to unsupported codes—once via paying the MAOs on reduced relative values (resulting from including unsupported TM HCCs in the development of the MA model) and secondly by removing payment related to unsupported codes. In the example above, the first reduction is the fact that the payment for Diagnosis X is only \$4 due to including unsupported codes in the model design. The second reduction would be applying the model on audited data only and not paying the MAO for the fifth unsupported beneficiary. In short, because the relative values already build in a reduction that accounts for a

certain level of error in CMS's TM data, neither the Government nor UHG can know whether there is an overpayment in the UHG data without first accounting for the TM error rate. And if UHG's error rate is consistent with or lower than the rate in the TM data, then requiring UHG to delete unsupported codes may risk double-dipping against UHG.

Algebraic Proof of Result

The fact that all tested scenarios of the recalibrated risk models result in higher average relative values is not surprising. Basic algebra, along with the basic tenets of regression and risk adjustment, prove that the average relative value from any recalibrated model using fewer markers must be higher than average relative value from the original risk adjustment model.

Definitions

N = number of beneficiaries

T = number of relative values

$\vec{v}$ =

array of relative values for all demographic and HCC variables for original model = $(v_1, v_2, v_3 \dots v_T)$

$m_{tk} = 0$ or 1 ,

for variable t (ranging from 1 to T), and for beneficiary k (ranging from 1 to N)

Similarly for the recalibrated model:

$\vec{v}'$ =

array of relative values for all demographic and HCC variables for revised model with diagnoses and payment removed

m'_{tk} = markers 0 or 1 for recalibrated model for variable t and beneficiary k

It follows that:

$$\sum_{k=1}^N \sum_{t=1}^T m_{tk} = \text{number of markers in baseline model across all beneficiaries}$$

$$\sum_{k=1}^N \sum_{t=1}^T m'_{tk} = \text{number of markers in revised model across all beneficiaries}$$

And:

$$\bar{v} = \text{Average relative value for original model} = \frac{\sum_{k=1}^N \sum_{t=1}^T m_{tk} v_t}{\sum_{k=1}^N \sum_{t=1}^T m_{tk}}$$

$$\bar{v}' = \text{average relative value for revised model} = \frac{\sum_{k=1}^N \sum_{t=1}^T m'_{tk} v'_t}{\sum_{k=1}^N \sum_{t=1}^T m'_{tk}}$$

Basic tenets of risk adjustment indicate that the average risk score over the population for both the original model and the recalibrated model is 1.0. That is:

$$(a) \quad \frac{\sum_{k=1}^N \sum_{t=1}^T m_{tk} v_t}{N} = 1 \quad \text{AND} \quad \frac{\sum_{k=1}^N \sum_{t=1}^T m'_{tk} v'_t}{N} = 1$$

Multiplying both of these equations by number of beneficiaries ‘N’ provides the following equalities:

$$(b) \quad \sum_{k=1}^N \sum_{t=1}^T m_{tk} v_t = N \quad \text{AND} \quad \sum_{k=1}^N \sum_{t=1}^T m'_{tk} v'_t = N$$

Assume that the number of markers in the revised model is less than the number of markers in the original model. That is, some of the markers m'_{tk} change from 1 to 0 as a result of auditing the markers.

This means that the sum of all markers in the revised model using only supported codes is less than the sum of the markers in the original model:

$$(c) \quad \sum_{k=1}^N \sum_{t=1}^T m'_{tk} < \sum_{k=1}^N \sum_{t=1}^T m_{tk}$$

It follows algebraically that:

$$(d) \quad \frac{1}{\sum_{k=1}^N \sum_{t=1}^T m'_{tk}} > \frac{1}{\sum_{k=1}^N \sum_{t=1}^T m_{tk}}$$

We then can maintain the inequality in (d) by multiplying each side of the inequality by number of beneficiaries ‘N’:

$$(e) \quad \frac{N}{\sum_{k=1}^N \sum_{t=1}^T m'_{tk}} > \frac{N}{\sum_{k=1}^N \sum_{t=1}^T m_{tk}}$$

Using substitution, we can replace the N {using the equivalences in (b)} in the inequality. Now we have:

$$(f) \quad \frac{\sum_{k=1}^N \sum_{t=1}^T m'_{tk} v'_t}{\sum_{k=1}^N \sum_{t=1}^T m'_{tk}} > \frac{\sum_{k=1}^N \sum_{t=1}^T m_{tk} v_t}{\sum_{k=1}^N \sum_{t=1}^T m_{tk}}$$

This is the same as $\bar{v}' > \bar{v}$.

That is, the average relative value of the revised model is greater than the average relative value of the original model.

This proof holds regardless of what the expenditures are in the regression calculations or the magnitude of the HCC error rate.

IV. Retrospectively removing unsupported diagnosis codes and the associated revenue would materially change the assumed payment methodology relied on in the bid submission process, nullify the actuarial certification, and underpay MAOs for the benefits offered.

MAO payment rates, benefit plans, and beneficiary premiums are not unilaterally set by CMS. Rather, they are the result of the bid submission process in which MAOs and their actuaries must project the revenue requirement of providing the proposed benefits to an enrolled population in an actuarially sound manner. MA payment relies on this revenue requirement, along with individually calculated risk scores for the beneficiaries that enroll, to calculate the risk adjusted capitation provided to MAOs.

A lynchpin between the bid process and the payment process that ensures actuarially sound payment is the definition of a beneficiary with a “national average risk profile.” In fact, as part of the actuarial certification of MA bids, actuaries must attest that the bids are based on the average revenue requirements in the payment area for a MAPD enrollee with a national average risk profile. In order to certify to this requirement, the actuary must understand the contract year risk model in order to project the risk score for the MAO’s expected population.

An enrollee with a national average risk profile refers to an average TM beneficiary with a risk score of 1.0 (also called a “1.0 beneficiary”). Projecting the revenue for a national average risk profile inextricably links the bid to the risk adjustment model in the contract year. As I will show, MAOs must have a correct understanding of the national average risk profile and method for computing risk scores in order to accurately determine a benefit design, beneficiary premiums, and payment rates that are financially viable.

In practice, actuaries calculate the needed revenue for a 1.0 beneficiary through completion of the BPT worksheets using the following general steps:

1. Actuaries project the cost for beneficiaries they anticipate will enroll in the plan in the contract year. The anticipated enrollment generally reflects the membership that has historically enrolled in the plan along with any expected changes in that membership. In practice, the estimated cost is calculated by trending the historical medical costs of the MAO’s beneficiaries to the contract year, adjusting the costs to reflect the benefits being proposed, and adding in administrative expenses and margin.
2. Actuaries estimate the average contract year’s risk score for this anticipated enrollment. The anticipated enrollment almost never reflects a 1.0 beneficiary.
3. The Government’s standardized BPT worksheet uses prescribed calculations to adjust the amounts actuaries project in #1 to calculate the revenue requirement for the anticipated population for the TM benefit.

4. CMS's standardized BPT worksheet then divides the required revenue in #3 above by the estimated contract year's risk score in #2 to determine the revenue requirement for an enrollee with a national average risk profile (a 1.0 beneficiary). This revenue requirement is called the "Standardized A/B Bid" in the BPT and is the same amount that actuaries opine on in the certification of the BPTs.

When submitting the bids, actuaries must provide both the BPT worksheets along with required supporting documentation and an actuarial certification. The supporting documentation describes how the actuaries completed the worksheets concentrating on detail for the estimated cost (#1) and risk scores (#2) above.

Actuaries need a complete understanding of the contract year risk score development in order to estimate the risk score for the anticipated population (#2). This includes government rating methodologies and the CMS-HCC model descriptions, as well as operational changes in how the MAO and its providers intend to code diagnoses. The Government validates the importance of accurately projecting risk scores with the following requirements.

- The Social Security Act Section 1853 mandates advance notice to the MAOs by requiring that CMS provide notice of assumptions and risk adjustment methodology in the annual rate letter and notice of changes at least 45 days in advance of the bid submission. As part of the 21st Century Cures act, CMS provided even a longer period (more than 60 days) for review of proposed changes to the CMS-HCC risk model.⁴²
- The MA BPT instructions specify that risk scores be estimated based on the methodology as discussed in the Rate Announcement and reflect plan specific coding trend.⁴³ They indicate that the coding trend be based on historical year over year risk score changes. In addition, the instructions indicate "[i]f deviations from previous trend are expected in the payment year, provide justification for such changes in the supporting documentation."⁴⁴

The actuarial profession also endorses this idea. ASOP 8, which provides guidance to actuaries submitting regulatory rate filings, states "the actuary should adjust past experience for any known or expected changes that, in the actuary's professional judgment, are likely to materially affect expected future results."⁴⁵ For the MA bid process, this includes changes in the risk adjustment process and the national average bid profile.

During the Review Period, UHG actuaries disclosed the following in their supporting documentation of the projected risk scores:

⁴² As amended by the 21st Century Cures Act, section 1853(a)(1)(I)(iii) of the Social Security Act requires that CMS provide an opportunity for review of the proposed changes and a public comment period of at least 60 days for proposed changes under section 1853(a)(1)(I) to the Part C risk adjustment model.

⁴³ Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2015, at 45 (Apr. 8, 2014).

⁴⁴ Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2015, at 155 (Apr. 8, 2014).

⁴⁵ ASOP No. 8 § 3.2.5.

- In every year during the Review Period: “As part of the preparation of the bids, we did not attempt to validate any actual or projected risk scores through a review of applicable medical records or of the systems used to submit RAF data to CMS.”⁴⁶
- And starting with the BPT submissions in 2015: “We also adjusted projected risk scores to account for changes in our medical record review processes. Specifically, based on multiple conversations with CMS and CMS's treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process.”⁴⁷

Based on these disclosures, it is clear that UHG actuaries projected risk scores for contract years during the Review Period based on diagnosis codes that were not validated in medical records. Thus, UHG projections of risk scores are higher than they would have been had UHG accounted for the removal of unsupported codes from the population. For example, the projected average risk score of an unaudited population may be 1.05 but once unsupported codes are removed the projected risk score may decrease to 0.98. As a result, the average revenue requirement for an enrollee with a national average risk profile, as certified by the actuary, is lower than it would have been had their data been subject to such coding programs.

The actuaries set benefits and premiums based on this risk score projection and related assumptions, setting benefits on a CMS revenue amount that was higher than it would have been had the unsupported diagnosis codes been deleted. This resulted in additional supplemental benefits being offered by the plan. These assumptions were reviewed by CMS through Desk Reviews and Bid Audits. Ultimately, the UHG bid submissions, including the methodology used to set risk scores, were approved by CMS.

Below I further explain how the bid amounts and actual payments are linked to the projected risk score and the national average risk profile, and how any significant retrospective change to the risk score definitions (as are being contemplated in this case) can result in underpayments or overpayments of revenue.

MAO Payment Depends on the Required Revenue for the National Average Risk Profile Defined in the BPT.

“The Required Revenue for the National Average Risk Profile” directly affects the payment to the MAO and is an amount developed and submitted as part of the MAO bid. The Part C revenue that CMS pays MAOs for an enrolled member uses the formula:

[(Risk Score of the beneficiary) times (the Standardized A/B bid)] plus (the Rebate).

The “Standardized A/B Bid” (the 1.0 bid) in this formula is the Required Revenue for the National Average Risk Profile for covering the TM benefits. The formula shows that payment to MAOs is

⁴⁶ See UHG Bid Documentation for 2009-2016 (AEO).

⁴⁷ See UHG Bid Documentation for 2015-2016 (AEO).

not only dependent on the individual member's risk score, but also the amount of the Standardized A/B Bid and Rebate, which are both determined via the bid submission process.

To the extent the bid submission under/overestimates the required revenue for a national average risk profile, the MAO will be under/overpaid. CMS recognizes the significance of the 1.0 bid by requiring an actuarial certification stating that in accordance with Federal law, the bid(s) are based on the "average revenue requirements in the payment area for a Medicare Advantage/Prescription Drug enrollee with a national average risk profile."⁴⁸

The Required Revenue for the National Average Risk Profile Depends on an Accurate Projection of Risk Scores for the Expected Population.

Projecting an accurate 1.0 bid through bid submission depends on a thorough understanding of the MAO payment process, including how risk scores will be determined. The MAO's estimate of the Required Revenue for the National Average Risk Profile is derived in part from projected risk scores.

Table 6 below illustrates the major components of a BPT.

Table 6 - Major Components of a BPT

Description	PMPM [1]
a. Standardized A/B Benchmark (1.0)	\$952.38
b. Projected Average Risk Score for Plan Population	1.05
c. Plan A/B Benchmark (a*b)	\$1,000.00
d. Plan A/B Bid for Contract Year (for expected plan population)	\$900.00
e. Standardized A/B Bid (1.0 Bid) (d/b)	\$857.14
f. Savings (c-d)	\$100.00
g. Rebate/Amt Available for Supp Benefits (.75*f) [2]	\$75.00
h. Expected payment/required revenue for benefits provided (b*e+g)	\$975.00

[1] PMPM refers to Per Member Per Month amount.

[2] The rebate percentage can vary based on star rating of the plan. We are using 75% in this example.

The Standardized A/B Bid in Row e (which is certified as being based on the national average risk profile) is calculated by dividing (d. the Plan A/B Bid for the Contract year) by the (b. Projected Average risk score for the plan population).

Row d or the A/B Bid is the estimated costs for the MAO of offering the TM benefits, including administrative expense and margin requirements. This amount is normalized to reflect costs for a national average risk profile by dividing it by (b. Projected Risk Score). That is, since the Plan A/B Bid for a 1.05 average risk member is \$900, the Standardized A/B Bid (in row e) for a national average risk member is \$900/1.05 or \$857.14. As you will see in the following section, the

⁴⁸ Instructions for Completing the Medicare Advantage Bid Pricing Tools for Calendar Year 2017, at 98.

Standardized A/B Bid is the basis for risk adjusted payment in the contract year and must be accurate. Any misestimate will result in incorrect payment.

To appropriately identify the required revenue for a national average risk member, the Medicare actuary must accurately assign a risk score to the expected plan population (the 1.05 in this example). If the projected risk score (item b.) is too high, the standardized A/B bid will be understated. If the projected risk score (item b.) is too low, the standard A/B bid will be overstated. See the example below for an illustration.

Table 7 - Illustrations of Over- and Under-Estimating Risk Score

Description	Scenario		
	Baseline	A	B
		Over-estimate of Risk Score	Under- estimate of Risk Score
b. Projected Average Risk Score for Plan Population	1.05	1.1	1
d. Plan A/B Bid for Contract Year (for expected plan population)	\$900.00	\$900.00	\$900.00
e. Standardized A/B Bid (1.0 Bid) (d/b)	\$857.14	\$818.18	\$900.00
Result		Standardized bid too low	Standardized bid too high

During the Review Period for this case, UHG and its actuaries explained that the projected risk scores did not reflect validation of diagnosis codes in the medical record. This means that the projected risk score was higher than it would have been had it reflected the reductions in risk scores that result from identifying and removing unsupported codes. For example, an unaudited population may have an average risk score of 1.1, but an audit may reveal that on average .05 of the risk score arises from unsupported codes and thus the audited average risk score would be 1.05. As reflected in the chart above, the unaudited 1.1 average risk score results in a standardized bid of \$818.18 and the audited 1.05 average risk score would result in a higher standardized bid of \$857.14.

As a result, UHG bid lower than it would have based on the expectation that the data included unsupported codes. UHG expected the national average risk profile member with a 1.0 risk score to be paid in a manner consistent with how UHG calculated and certified its bid. If CMS retrospectively changes how risk scores are calculated by removing known diagnoses, that is a material change not contemplated in the bid submission or the actuarial certification.

MA Payment Depends on the Required Revenue for the National Average Risk Profile (the Standardized A/B Bid) Defined in the BPT.

The Standardized A/B Bid (e.) is then used for MA payment for each beneficiary enrolled in the plan. Continuing with the baseline illustration, Table 8 shows the plan payment for beneficiaries with various risk scores.

Table 8 - Illustrations of Plan Payment for Various Beneficiaries

Beneficiary	Contract Year Risk Score	Standardized A/B Bid (for Nat'l Average Profile) from BPT	Rebate	Plan Payment from CMS
	(a)	(b)	(c)	(a) * (b) + (c)
1	0.80	\$857.14	\$75.00	\$760.71
2	0.85	\$857.14	\$75.00	\$803.57
3	0.90	\$857.14	\$75.00	\$846.43
4	0.95	\$857.14	\$75.00	\$889.28
5	1.00	\$857.14	\$75.00	\$932.14
6	1.05	\$857.14	\$75.00	\$975.00
7	1.10	\$857.14	\$75.00	\$1,017.85
8	1.20	\$857.14	\$75.00	\$1,103.57

As you can see from the table, the filed Standardized A/B Bid Amount listed in column (b) is foundational to payment in the contract year. If it is misestimated, it will affect payment for every enrolled beneficiary.

Retrospectively Changing the Risk Score Methodology Invalidates the Actuarial Certification, Results in Underpayment and Ruins the Actuarially Sound Rating System.

Any significant change to the rating system from what was assumed in the rate filing will introduce financial risks and disrupt the actuarial soundness of the MA rating program. As part of the bid submission, MAOs promise to pay for claims incurred at a benefit level for individuals based on an understanding of the revenue they will receive. Significantly reducing the payments to MAOs without providing an opportunity to adjust the benefits or collect additional premiums will almost certainly result in financial risks. Significant changes could take multiple forms, including changes to the 1.0 bid, changes to how risk scores are calculated, or eligibility changes on who can enroll.

In this case, the Government is proposing to significantly change how UHG is paid for past contract years by changing the methodology of calculating the risk scores. Here, the Government has alleged that approximately 28 million codes are unsupported and that any HCCs and revenue resulting from these codes should be removed. This methodology is clearly at odds with the assumptions UHG actuaries made during the bidding process, as documented in the supporting documentation that indicated risk scores were not validated in the medical record.

Reducing the risk scores for unsupported diagnosis codes results in the risk-adjusted capitation amounts for the population to be understated relative to the methodology expected in the bid. The revenue that MAOs receive for covering the TM benefits would be less than what was certified to be needed based on assumptions in the bid. By effectively changing the method in which risk scores are calculated from what was assumed in the bids, the Government would be changing the definition of the enrollee with a national average profile. At this adjusted revenue amount, the MAO would be underpaid, not receiving enough revenue to cover its expenses and obligations. The change relative to what was bid invalidates the actuarial certification and ruins the actuarial sound payment system.

The table below illustrates how the standardized A/B Bid (row e) would have changed had UHG assumed in its bid that it would undertake coding activities to identify and delete unsupported codes. In this illustration, we have assumed the removal of unsupported codes would have reduced the projected average risk score (row b) by approximately 7% (from 1.05 to 0.98).

Table 9 - Development of Bids Under Alternate Scenarios

Description	Scenario	
	Original Bid (assuming plan does not anticipate coding activities to identify and remove unsupported codes)	Revised Bid (assuming plan anticipates coding activities to identify and remove unsupported diagnoses)
Illustrative development of submitted bid		
a. Standardized A/B Benchmark (1.0)	\$952.38	\$952.38
b. Projected Average Risk Score for Plan Population	1.05	0.98
c. Plan A/B Benchmark (a*b)	\$1,000.00	\$933.33
d. Plan A/B Bid for Contract Year (for expected plan population)	\$900.00	\$900.00
e. Standardized A/B Bid (1.0 Bid) (d/b)	\$857.14	\$918.37
f. Savings (c-d)	\$100.00	\$33.33
g. Rebate/Amt Available for Supp Benefits (.75*f)	\$75.00	\$25.00
h. Expected payment/required revenue for benefits provided (b*e+g)	\$975.00	\$925.00

In the first column, the table shows an original bid that requires benefits (including administrative expense and margin) worth \$975 be offered to beneficiaries. If, alternatively, the projected risk scores would be estimated based on the assumption that the plan would undertake coding activities to identify and remove unsupported codes, the revised bid requires only \$925 of benefits (including administrative expense and margin) be offered to beneficiaries. The changed risk score model also results in a change to the standardized A/B Bid, where the original bid had an \$857.14 figure and the revised bid reflects an increased standardized A/B bid of \$918.37. These amounts reflect costs

to cover the national average risk profile included in the certification. As you can see, the assumptions for the projected risk score directly impact amounts required to be certified by the actuary.

As a result of the revised bid, even though the expected population would have been the same as in the original bid, the amount of rebate available for supplemental benefits would have reduced from \$75 PMPM to \$25 PMPM. Total payment would reduce from \$975 to \$925, about \$50 PMPM. This illustration shows that for the same member premium, benefits would need to be reduced by about \$50 PMPM from what was originally offered, or the MAO would need to go back and collect the premiums equal to \$50 per month from every beneficiary in order satisfy the actuarial certification under the revised assumption.

See the table below for the illustration how payment resulting from these two bids would have varied.

Table 10 - Illustration of Variation in Payment Resulting from Alternate Bids

Description	Scenario	
	Original Bid (assuming plan does not anticipate implementing coding program to identify and remove unsupported codes)	Revised Bid (assuming plan anticipates implementing coding program to identify and remove unsupported codes)
Illustrative development of submitted bid		
a. Standardized A/B Benchmark (1.0)	\$952.38	\$952.38
b. Projected Average Risk Score for Plan Population	1.05	0.98
c. Plan A/B Benchmark (a*b)	\$1,000.00	\$933.33
d. Plan A/B Bid for Contract Year (for expected plan population)	\$900.00	\$900.00
e. Standardized A/B Bid (1.0 Bid) (d/b)	\$857.14	\$918.37
f. Savings (c-d)	\$100.00	\$33.33
g. Rebate/Amt Available for Supp Benefits (.75*f)	\$75.00	\$25.00
h. Expected payment/required revenue for benefits provided (b*e+g)	\$975.00	\$925.00
Payment Scenario I - assuming risk scores include unsupported diagnoses & population as expected in original bid		
i. Risk score of population (including unsupported diagnoses)	1.05	1.05
j. Payment based on all diagnoses for TM benefits (e*i)	\$900.00	\$964.29
k. Payment based on all diagnoses for offered benefits (e*i+g)	\$975.00	\$989.29
l. Overpayment/(Underpayment) (k-h)	\$0.00	\$64.29

Result:	Actuarially Sound and consistent with bidding assumptions	Overpayment, not consistent with bidding assumptions
Payment Scenario II - assuming risk scores do not include unsupported diagnoses & population as expected in original bid		
m. Risk score of population (excluding unsupported diagnoses)	0.98	0.98
n. PMPM Payment for TM benefits at adjusted risk score (e*m)	\$840.00	\$900.00
o. Difference from expected payment/required revenue (n-j)	(\$60.00)	(\$64.29)
p. PMPM Payment for offered benefits at adjusted risk score (n+g)	\$915.00	\$925.00
q. Overpayment/(Underpayment) (p-h)	(\$60.00)	\$0.00
Result:	Underpayment, not consistent with bidding assumptions	Actuarially Sound and consistent with bidding assumptions

This illustration shows several results:

- 1) Retrospectively changing the risk adjustment model to adjust risk scores for HCCs that are unsupported (Scenario II payment with the original bid) results in payments that are lower than what was projected. In this case, the benefits were set based on a projection of revenue that was \$60 PMPM higher than actual revenue collected (p-h in the original bid column). This underpayment is directly related to the misestimate of the Standardized A/B Bid amount. That is, the actuarially certified amount related to the national average risk profile was not correct and resulted in underpayment.
- 2) If the unsupported codes were removed from the projected risk scores at the time of bidding (Scenario II payment with a revised bid), the bid could be adjusted so that the ultimate payment matches what was anticipated (p=h in the revised bid column). However, in this example, the supplemental benefits provided to members as part of the rebates would have been based on \$50 PMPM less revenue (\$75 - \$25), which is the difference in rebates in row g between the two columns.
- 3) While CMS pays the same amount for TM benefits under either the original or revised bid (see row j in original bid versus row n in the revised bid), the effect of revising the bid for unsupported diagnosis on MA payment would simply reduce their rebate amount (from \$75 to \$25 in row g), which in turn would reduce the supplemental benefits they offer to their beneficiaries.

UHG projected risk scores without validating them in the medical record, and CMS accepted those bids under these assumptions. A decision now to remove a material amount of unsupported HCCs creates a retrospective change to the rating, disrupts the actuarially sound payment system, nullifies the actuarial certification, and results in underpayment to the MAO. The actuarial certification, which protects both the enrolled beneficiaries and the MAO from significant risk of insolvency, would no longer apply.

V. All of the previous opinions except the second opinion are directly applicable to Part D payment for MAPD plans as well.

It is my opinion that Part D risk-adjusted payment resulting from a MAO's submission of unsupported diagnosis codes does not necessarily result in overpayments. Classifying all such payments as "overpayments" is actuarially inappropriate, because it ignores both the fundamentals of the Part D rating program and how CMS developed the risk adjustment model.

Each opinion (except the second one⁴⁹) is applicable because the Part D RxHCC model is developed in a similar manner to the CMS-HCC model in that it is a prospective model using HCCs built in part based on the diagnosis codes present in the TM claims data. As such, the RxHCC risk model was built on data that included a significant amount of HCC errors. The actuarial principle of Data Consistency means that the Part D risk model should be applied to data that includes both supported and unsupported codes. Like in MA, any single Part D payment or subset of payments based on unsupported diagnosis codes cannot be determined to be an overpayment without considering the overall unsupported HCC rate in the UHG data compared to the data used to develop the model.

Although we have not empirically studied the RxHCC model for impacts related to auditing the underlying diagnosis codes, the mathematical proof that the average relative value increases under alternative risk models based on audited data that I set forth above also applies to Part D. That is, the current relative values in the RxHCC model are diluted based on the unsupported codes included in the development data of the RxHCC model. Any additional reduction to Part D payment may double-reduce the payment for unsupported codes.

Furthermore, the actuarial certifications of the Part D rate filings also require that actuaries opine that the bids are based on the average revenue requirements for a Medicare Part D enrollee with a national average risk profile.⁵⁰ UHG's bid documentation of projecting risk scores also applies to the Part D bid development, resulting in a bid that is lower than it would have been had the risk scores been projected based on only audited codes. Reducing UHG Part D payment for unsupported codes materially changes the assumed payment methodology relied on in the bid submission process, nullifies the Part D actuarial certification, and underpays MAOs for the benefits offered.

⁴⁹ To my knowledge, CMS has not maintained that the Part D risk score should be the same for the same cohort regardless of program (TM vs. MAPD) and the DRA does not apply to Part D risk scores.

⁵⁰ Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Calendar Year 2017, p. 66.

CONCLUSION

The MA and PD risk adjustment models used for MAPD payment include unsupported diagnosis codes in the development of the relative values of each HCC. Under the well-established actuarial principle that models should be applied consistent with their design, it is fundamentally incorrect to conclude that a payment to an MAO is an “overpayment” simply because a beneficiary’s diagnosis code is not supported by the medical records. Reducing risk scores and the associated payment for such unsupported diagnosis codes may introduce an unreasonable inconsistency between how the model was designed to calculate accurate payments and how it is being applied to MA data, ignoring the actuarial standards of ratemaking and the complexities of the risk adjustment system. Furthermore, removing known unsupported diagnosis codes in MA data without a similar adjustment in the TM data may introduce a variation in risk scores between the TM and MA programs for the same population cohort, resulting in inaccurate payment and potential underpayment.

The relative values are currently diluted as a result of including unsupported HCCs in the development of the models. Accurate payment depends on applying those diluted factors to both supported and unsupported codes in the MA data. Retrospectively removing payment related to unsupported diagnosis codes unfairly changes the payment rules of the carefully constructed MA rating system. UHG relied on those payment rules when developing and certifying its bids—which CMS itself approved.

DISCLOSURES, LIMITATIONS, AND QUALIFICATIONS

I am an employee of Wakely Consulting Group, LLC, an HMA Company (“Wakely”). Wakely was retained on behalf of UHG to provide an independent review and opinion of the allegations of the Complaint. Wakely is a premier actuarial consulting firm and, as such, has provided support to the majority of health insurers in the U.S. Past engagements with UHG include the following.

- Tool/product sales of:
 - o WACA (Wakely ACA Database),
 - o WRI (Wakely Risk Insights),
 - o WPM (Wakely Pricing Model),
 - o WNRAR (Wakely National Risk Adjustment Report),
 - o WMRAT (Wakely Medicare Repricing Analysis Tool), and
 - o RAPID-M (Identification of diagnoses discrepancies between sources – Medicare version)
- General consulting of Medicare Advantage topics
- Large Group Benchmarking
- ACA Pricing and Rate Filings
- Consulting on the FFS Adjuster

My personal affiliation with the prior work that Wakely has performed for UHG primarily includes the Paper, “*Actuarial Report on Medicare Advantage FFS Adjuster*,” written in response to the Proposed Rule for the 2020 Medicare Advantage (MA) Program and Prescription Drug Benefit Program.

This report reflects my professional judgment. I was supported in my work by a team of individuals at Wakely who worked at my direction. My conclusions and report are based on my interpretation of actuarially sound payment and the supporting analysis Wakely performed at my direction.

I am currently a Member of the American Academy of Actuaries and am in good standing as a Fellow with the Society of Actuaries.

Qualifications

I am a Principal and Senior Consulting Actuary of Wakely. As an actuarial consultant, I have helped clients with health analyses involving financial risk involving claims and revenue. My clients are primarily in the insurance and pharmaceutical industries and include Medicare Advantage and Part D plans, state and federal governments, and healthcare providers.

Much of my current work involves reviewing Wakely publications, client deliverables, and tool development for the firm. My direct consulting work primarily involves providing analyses regarding health policy for Medicare-eligible populations, including risk adjustment impacts in the Medicare Advantage and Part D programs, changes to the Medicare Advantage and Part D drug benefit, and the CMMI programs. These analyses include estimating the effects of policies on Federal spending and providing consultation on the feasibility of these programs and/or policy

changes. Done properly, feasibility studies include multi-year projections of revenues and costs and require a full understanding of both current and potential changes to the health care landscape across many spectrums: payer risk and solvency, current Medicare programs and offerings, network adequacy and requirements, provider reimbursement and contracting as well as member behavior and incentives.

Most of my career has been devoted to actuarial consulting, where my work has varied, but generally focused on MAPD programs – where actuarial certifications are required for annual rate submissions for both the medical and pharmacy plan designs. I began working for clients on Medicare rate submissions in 2000 and have signed the rate filings related to the Medicare medical and pharmacy benefits most every year since then. In addition to the rate filings, I also performed Part D reconciliations for many of the same MAOs where I certified the rate filings.

Over the years, I routinely presented the results of my financial estimates and analysis to insurers. I also presented on countless occasions to clients and have made numerous presentations to various audiences on a broad range of topics in health care.

I received a bachelor's degree from the University of Nebraska, a master's degree in mathematics from the University of Colorado, and a Fellowship of the Society of Actuaries. I also am a member of and in good standing with the Academy of Actuaries. A copy of my resume is attached as Appendix II to this report. My publications of the last ten years and the cases in which I have served as a testifying expert over the last four years are listed in my resume.

Reliance

In forming my opinions, I relied on various data and information. This data will be provided and is also referenced by citations in the body of my report.

Other

To prepare this report, Wakely is being compensated at a rate of \$840 per hour for my services. Other members of the Wakely team are being compensated at the hourly amounts ranging from \$170 to \$790. The amount of my compensation did not depend in any way on the conclusions that I reached in this report.

Respectfully,

A handwritten signature in blue ink that reads "Julia Lambert". The signature is cursive and fluid, with the first name "Julia" and last name "Lambert" clearly distinguishable.

Julia Lambert, FSA, MAAA
Principal and Senior Consulting Actuary

September 29, 2023

APPENDIX I

QUANTITATIVE ANALYSIS AND TESTING

The Centers for Medicare & Medicaid Services (“CMS”) uses a combination of both supported and unsupported diagnosis codes from the Traditional Medicare (“TM”) data when identifying and developing Hierarchical Condition Categories (“HCCs”) for its CMS-HCC model. A team at Wakely working at my direction has conducted quantitative and theoretical testing to analyze the impact of using only supported (or audited) codes on CMS-HCC model coefficients and relative values. This appendix discusses the technical aspects of the simulations and the results of those recalibration analyses.

OVERVIEW OF ANALYSES AND RESULTS

In assessing the impact of using only audited codes on the CMS-HCC model, the Wakely team first recreated the 2017 CMS-HCC model for the community (non-institutional), non-dual, aged continuing enrollees using CMS provided beneficiary input files. The Wakely team then simulated the removal of unsupported HCCs in the beneficiary input file using the following four methodologies:

1. On/Off
2. Scalar
3. On/Off by Number of Charts
4. Scalar by Number of Charts

Each method provides a different technique of removing HCC markers from the beneficiary input file. These four methods are described in more detail in the Methodology section below.

As described in the main report, HCC markers in the TM beneficiary input file are beneficiary-level attributes, where a value ‘1’ denotes the presence of at least one diagnosis code that maps to an HCC during the 12-month experience period (also referred to as diagnosis period). For example, HCC1 HIV/Aids has three diagnosis codes¹ (B20, N9735, and Z21) that map to it. A beneficiary will receive an HCC marker of ‘1’ if an acceptable provider includes one of those diagnoses on a TM claim it submits to CMS for payment.

The Wakely team also tested varying levels of HCC specific error rates. For each HCC, the HCC error rate is defined as a proportion of HCC markers that are not supported by any of the documentation included in the provider’s medical chart(s) (also called medical records) for that beneficiary. Because HCC markers are assigned at the beneficiary level, the HCC error rate can also be described as a beneficiary-level error rate. For example, suppose a beneficiary has five

¹ The 2017 v22 mapping of diagnosis codes to HIV/Aids included:

- B20 Human immunodeficiency virus disease
- N9735 Human immunodeficiency virus, type 2 as the cause of diseases classified elsewhere
- Z21 Asymptomatic human immunodeficiency virus infection status

<https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/risk-adjustors-items/risk2017>

acceptable providers that each include one of the HCC1 HIV/Aids diagnosis codes in the claims submitted for TM payment. Further, assume that only two of the five providers have adequate supporting documentation in the medical chart. The HCC marker for HIV/Aids for this beneficiary would be considered adequately supported even though three of the providers' diagnoses were not supported. The only way that this beneficiary's HCC marker would be considered an error is if all five providers' diagnoses were unsupported.

The range of error rates for each HCC is based on the results of a Coding Review² performed by FTI Consulting ("FTI") on a sample of HCCs for TM beneficiaries and a subsequent statistical analysis on those results. All error rates were developed by Dr. Michael Salve at Berkeley Research Group ("BRG") and provided to Wakely for this analysis.

Given the statistical nature of the sample and the lack of a full response rate for the sample, I identified four sets of HCC error rates for testing. Error rates (a-c) are provided at the HCC level while the last set of error rates (d) is provided at a more detailed level—by HCC and chart count level. The three sets of error rates by HCC included a best estimate of error rates and two alternative scenarios at lower levels of error rates. The last set of error rates by HCC and chart count is similar to error rate set (a), but is by HCC and chart count.

- a. Best estimate of HCC error rates. This best estimate of the HCC error rates reflects an adjustment for missing charts,³ is the highest level of errors by HCC (a-c) tested, and equates to an overall 31.6% error rate of unsupported HCCs in the TM data.⁴
- b. HCC error rates at a 95% confidence level. The error rates in this scenario reflect the same assumptions as the best estimate, but here there is 95% confidence that the actual HCC error rates are greater than those listed (versus a 50% confidence level in the best estimate HCC error rate in (a)). This error rate equates to an overall 20.0% rate of unsupported HCCs in the TM data.
- c. Assuming non-respondent charts validated. This scenario of error rates reflects the HCC error rates assuming that every non-respondent chart would have validated the HCC. This scenario is below a range that I would consider reasonable, at an overall 13.7% rate of unsupported codes, but was included for testing purposes.
- d. HCC error rates by number of charts. The last set of error rates by HCC and chart count includes error rates by HCC and chart count with an adjustment for missing charts.⁵ This error rate equates to an overall 37.7% rate of unsupported HCCs in the TM data.

² For a complete description of the FTI Coding Review process, please refer to Dr. Paul Isaacs' Expert Report.

³ The adjustment for missing charts was developed by controlling for the number of the missing charts in the logistic regression analysis. See Dr. Salve's Expert Report for more details.

⁴ This error rate (as well as all subsequent error rates in the report) is calculated as the average of error rates by HCC weighted by the number of HCC markers in the beneficiary input file, adjusted by the months of eligibility observed during CY 2014. Interaction HCC variables were excluded from the average.

⁵ See Dr. Salve's Expert Report for more details.

The last set of error rates by HCC and chart count reflect an observation that, in the sample Coding Review, error rates varied depending on the number of charts with at least one diagnosis that map to the HCC. Specifically, the number of charts containing a diagnosis for a given HCC was shown to be positively correlated with a supported HCC and inversely correlated with the HCC error rate. By “number of charts,” I mean the number of distinct acceptable medical providers (as identified by National Provider Identifier (“NPI”)) who code diagnoses that map to an HCC. In the HIV/Aids HCC1 example above of five medical providers each coding one of the HIV/Aids diagnoses, the chart count would be five. Note that chart count refers to the number of distinct providers that code the diagnoses, not the number of visits or claims.

In general, the results indicate that recalibrating the CMS-HCC model on a simulated audited dataset with a lower number of HCC risk markers resulted on average in higher HCC and demographic dollar coefficients and relative values. The testing results provide quantitative evidence of a reduction of the original CMS-HCC model relative values due to the presence of the unsupported HCCs in the TM data.

DATA SOURCES

The analysis relied on three sources of data:

1. Payment year (PY) 2017 CMS-HCC model development files,
2. HCC error rates, and
3. Chart counts underlying each HCC marker in the beneficiary input file.

Each of these data sources are described in more detail below.

CMS-HCC Model Development Files

The main file used in developing the PY2017 CMS-HCC risk adjustment model is the beneficiary input file, which includes HCC risk markers incurred during the calendar year (CY) 2013 experience year and CY 2014 payment year claims costs (expenditures). The data was limited to the subset of the community, non-dual, aged, continuing enrollee cohort of beneficiaries underlying the corresponding segment of the risk model.⁶ This group represents the largest segment of the total TM beneficiary population, or 20.5 million beneficiaries. Table 1 presents the distribution of the beneficiary cohort by age categories. Note that I have shown both a raw count of beneficiaries in 2014 as well as a member month weighted count of 2014 enrollees.⁷ For example, a member that was enrolled for only six months of the 2014 calendar year would be counted as 0.5 of a member.

⁶ Other segments of the CMS-HCC model include risk values for various combinations of ESRD, Institutional, Dual, Disabled and New Enrollees.

⁷ Since the model development logic applies a weighting to the beneficiary risk markers based on the months of eligibility observed during CY 2014, a similar adjustment was applied to the enrollment for this table.

Table 1 - Original FFS Enrollee Profile - Community, Non-Dual, Aged, Continuing Enrollee Cohort

Description	2013/2014 FFS Original, Counts of Beneficiaries (a)	2013/2014 FFS Adjusted (Monthly Weighted) Counts of Beneficiaries (b)	Distribution % based on column (b)
Female, age 65 to 69	2,694,009	2,611,640	13.3%
Female, age 70 to 74	2,802,919	2,723,393	13.9%
Female, age 75 to 79	2,182,743	2,108,981	10.8%
Female, age 80 to 84	1,702,503	1,625,706	8.3%
Female, age 85 to 89	1,237,811	1,155,534	5.9%
Female, age 90 to 94	595,617	534,174	2.7%
Female, age 95 and greater	184,628	157,589	0.8%
Male, age 65 to 69	2,427,735	2,346,616	12.0%
Male, age 70 to 74	2,435,134	2,359,118	12.0%
Male, age 75 to 79	1,806,453	1,739,454	8.9%
Male, age 80 to 84	1,268,526	1,204,256	6.1%
Male, age 85 to 89	768,952	711,317	3.6%
Male, age 90 to 94	297,326	263,118	1.3%
Male, age 95 and greater	61,701	51,307	0.3%
Total	20,466,057	19,592,203	100.0%

Additionally, I received the beneficiary level file for the denominator year corresponding to the 2017 CMS-HCC model. This file contains the 2014 HCCs and demographic information for each beneficiary who had eligibility in CY 2015.

HCC Error Rates

The second data source included various HCC specific error rates. These error rates are based on the results of a Coding Review for a sample of risk-eligible charts⁸ performed by FTI and a subsequent statistical analysis performed by BRG. FTI performed a Coding Review on a sample of 3,950 selected HCCs for TM beneficiaries (3,950 ‘HCC-beneficiary markers’). Lack of provider responses to requested charts⁹ created a meaningful limitation in calculating the HCC error rates. Based on the sample results and a subsequent statistical analysis they performed, BRG estimated various sets of HCC error rates.¹⁰ Each HCC error rate set reflects a different methodology to address the lack of provider responses to requested charts.

⁸ Risk eligible charts included claims that would be eligible for inclusion in the HCC risk adjustment and exclude claims for diagnostic services such as laboratory claims. See 2022-09-15 CONFIDENTIAL_2013 FFS SAMPLE REVIEW RESULTS.xlsx (AEO-CONTAINS PHI).

⁹ In the context of this analysis, a chart means all medical information on a beneficiary in a given year received from a single provider.

¹⁰ See Dr. Salve’s Expert Report for more details.

Using the results of the Coding Review sample, BRG performed a logistic regression model with stratification by HCC.¹¹ This model ignored selected HCC-beneficiary markers where no charts were provided (dropped from the analysis). This statistical model estimates the probability of HCC validation rates with the following set of control variables.

1. Total number of charts. The chart count for a specific HCC-beneficiary marker of '1' was defined as the number of unique providers that coded a diagnosis mapping to that HCC for the beneficiary during the diagnosis year. Only risk-eligible charts from distinct providers serving the beneficiary during the diagnosis year and coding a particular HCC were included in the chart count for that HCC.¹²
2. Total cost associated with the sampled beneficiary. This is the amount of the Year 2 costs, or 2014.
3. The number of missing charts. These are the number of charts that were requested as part of the sample but were not returned.
4. The presence of an observed HCC (either supported or unsupported).

Wakely reviewed the methodology used by BRG and was comfortable with the reasonability of the results. Wakely selected three sets (a-c) of the error rates by HCC and one set (d) of error rates by HCC and chart count for testing:

- a. Estimated error rates by HCC from the logistic regression controlling for the missing charts. These error rates were estimated by BRG based on the sample data where sampled HCC-beneficiary markers with partially missing charts that remained invalidated were adjusted. The adjustment increased the 0% validation up, (reducing the error rate) by assuming that some of the missing charts would have validated, had they been received. This adjustment was informed by BRG's logistic model.¹³

These rates reflect the midpoint of the confidence interval of error rates for each HCC with a 50% likelihood that the true HCC error is higher and a 50% likelihood that the true HCC error is less than this level. Because this is the mid-point of the statistical range and because the rates have been adjusted to remove the impact of unresponsive charts, I have labeled this as my "best estimate" of error rates.

The overall average level of error rates across all HCCs in the TM data at the beneficiary level is 31.6% using this scenario. The average error rate is calculated using the number of HCC risk markers and the beneficiaries' PY2014 member months as weights. The average error rate calculated using only the number of HCC risk markers (and not the

¹¹ For a complete description of BRG's development of error rates, please refer to Dr. Salve's Expert Report at § V.III.

¹² The number of distinct risk-eligible provider charts is defined as the number of distinct NPI codes found in the beneficiary's medical claims history who billed to at least one diagnosis code that is associated with the given HCC marker and where the provider's specialty code is risk-eligible. This association was provided to BRG by CMS's published mapping of diagnosis codes to HCCs.

¹³ See *supra* note 11.

beneficiaries' PY2014 member months as weights) produced the same average value to the three significant digits. For consistency, the same calculation is applied to all error rate scenarios described below.

- b. The lower bound of the 90% confidence interval of error rates estimated from the logistic regression controlling for missing charts. These error rates reflect the bottom end of the statistical range of error rates from set (a) where there is 95% confidence that each actual HCC error rate is greater than those listed. These error rates are on average lower than in set (a) and (d), and higher on average than in set (c).

The overall level of error rates across all HCCs in the TM data is 20.0% using this scenario.

Given that each actual HCC error rate is 95% likely to be above this level, I view this as an extremely conservative (low) estimate of the HCC error rate in the TM data.

- c. HCC error rate estimated from the audited sample where diagnoses from any non-respondent (not returned) charts were assumed to be fully supported and the corresponding HCC validated. As stated earlier, this scenario was included for testing purposes, but is below what I believe to be a reasonable estimate. Although some of the specific HCC error rates in this scenario are higher than in scenario (b), this scenario produced the lowest level of error rates (13.7%) on average across all HCCs.
- d. Error rates by HCC and by chart count estimated from the logistic regression controlling for missing charts. BRG's statistical analysis found that the probability of an HCC being unsupported (HCC error rate) was inversely correlated with the number of charts with diagnoses mapping to the HCC (i.e., the more risk-eligible, distinct providers that submit a diagnosis that maps to a particular HCC, the less likely the HCC will be in error). The logistic regression produced a probability of an HCC being valid conditional on the number of distinct provider charts found with a particular HCC-beneficiary marker. The conditional probabilities (or error rates) by HCC and chart count were provided by BRG and used in Wakely's testing. The adjustment for the missing charts refers to the assumption regarding the number of missing charts. Conditional probability was calculated assuming the number of missing charts is 0. Similar to error rate (a) by HCC, this adjustment increases the validation rate assuming that all charts were received (same as reducing the error rate assuming all charts were received). This conditional probability is useful for applying to data where all charts are available such as the beneficiary input file. The additional information about the number of charts that were missing allows the model to account for the additional probability of HCC validation among the missing charts. The average of the HCC error rates in this set was 37.7%.

The first three sets of the error rates by HCC are presented in **Exhibit A. HCC Error Rates Scenarios** and the fourth set of error rates by HCC and chart count combination are presented in **Exhibit B. HCC Error Rates by Number of Charts**.

Chart Counts underlying each HCC Marker in Beneficiary Input File

In order to apply error rates listed by HCC and chart count (error rate set (d) described above) to the beneficiary input file, information regarding how many charts contain diagnoses that map to each HCC-beneficiary marker in the beneficiary input file was needed. BRG also provided Wakely with a data set containing the number of distinct, risk-eligible, provider charts containing diagnoses mapping to each HCC-beneficiary marker in the original CMS-HCC beneficiary input file. This summary of chart counts for each HCC-beneficiary marker in the beneficiary input file was based on the underlying TM claim data files received as part of discovery. The BRG file contains 79 fields, one for each of the HCCs, for each beneficiary in the beneficiary input file. Each of the 79 fields contain the number of distinct risk-eligible provider charts for the given beneficiary ID mapping to that HCC. A detailed description of the data set and its development are included in the BRG report. For some HCC-beneficiary markers, no diagnoses mapping to that HCC were found in the TM claim data. Approximately 4.9% of beneficiaries with at least one HCC were missing a chart count.

TESTING METHODS AND RESULTS

First, I replicated the 2017 CMS-HCC model for the community, non-dual, aged, continuing enrollees using the beneficiary input file described above. Using linear regression where the PY2014 claim costs were the dependent variable and the 85 HCCs (including 79 HCCs and 6 interaction HCCs) and 16 demographic variables were the independent values, and using PY2014 member months as the enrollment weights, I reproduced the dollar coefficients and relative values indicated in the 2017 Rate notice.¹⁴ For the remainder of this appendix, I call this the original CMS-HCC model.

I conducted testing using four methodologies of removing HCC markers (simulating the removal of unsupported HCCs) to quantify the range of potential impacts of removing the unsupported portion of HCC risk markers on the CMS-HCC model relative values. The four methodologies are summarized in Table 2. For each methodology, error rate scenario, and iteration, I performed the same regression used to recreate the original CMS-HCC model to calculate a revised set of CMS-HCC model dollar coefficients. In each revision, a set of simulated unsupported markers were removed from the beneficiary input file. Revised relative values were then calculated for each scenario by dividing the revised dollar coefficients by the same denominator of \$9,185.29.¹⁵ I then compared the revised dollar coefficients and relative values to the original dollar coefficients and relative values. For the methods involving random reassignment of 1's to 0's HCC risk

¹⁴ The rate notice contained the relative values, which I matched by dividing the dollar coefficients by the average predicted value in the denominator file of \$9,185.29.

¹⁵ Wakely was not provided detailed information to fully replicate the denominator under audited marker circumstances. However, testing of the 2017 denominator file using similar discrepancy rates as those used in the regression indicates that the revised denominator would be within +/-0.5% of the original value of \$9,185.29. More information on this testing is presented in supporting reference materials.

markers, the resulting coefficients developed from ten random iterations were averaged. As a last step, I compared the risk scores under the revised models to the original model for a subset of the UHG beneficiaries.

Table 2 – Overview of Testing and Results

Methodology Name	Description	Error Rate Scenarios	Output	Output Exhibit
(1) On/Off	Random reassignment of 1's to 0's for each HCC risk markers based on HCC's error rate	Three sets of error rates by HCC (a-c)	30 sets of results from 10 random iterations for three sets error rates	Exhibit C, columns 3-14
(2) Scalar	Multiplying HCC risk markers by a (1 - error rate) scalar for the corresponding HCC	Three sets of error rates by HCC (a-c)	Three sets of results (one for each error rate set)	Exhibit C, columns 15-26
(3) On/Off by Number of Charts	Random reassignment of 1's to 0's for HCC risk markers based on error rates conditional on the number of charts	One set of error rates by HCC by chart count (d)	10 sets of results from 10 random iterations of error rates	Exhibit C, columns 27-30
(4) Scalar Method by Number of Charts	Replacing all 1's in each HCC risk markers by the (1 - error rate) for the HCC conditional on the number of charts	One set of error rates by HCC by chart count (d)	One set of results for the error rate set	Exhibit C, columns 31-34

For the first method, (1) On/Off, a portion of HCC risk markers coded as present ('1') are reassigned to not present ('0'). Using the three sets of error rates for each HCC, for a randomly selected subset of beneficiaries, HCC risk marker is changed from present ('1') to not present ('0'). For example, if 20,000 beneficiaries in the development data set had HCC1 coded as present ('1') and the corresponding error rate for HCC1 in the highest rate scenario was 0.20, for a random subset of 4,000 beneficiaries ($0.20 \times 20,000$), the HCC1 risk marker would be changed from present ('1') to not present ('0'), producing an overall 20% lower prevalence of HCC1 thereby simulating an audited set of markers. Since the approach involved a random reassignment of risk markers, we performed the random deletion ten times creating ten simulated beneficiary input files for each error rate scenario.

For the second method, (2) Scalar, all risk markers were proportionally reduced by a scalar for the corresponding HCC calculated as (1 - error rate for HCC). For example, if the error rate for HCC1 in the highest rate scenario was 0.20, the HCC1 risk markers would be recalculated as original HCC1 risk marker $\times$ (1 - 0.20) or 0.80, producing an overall 20% lower prevalence of HCC1

thereby simulating an audited set of markers. The original risk markers values remained at '0' for members without HCC1 coded and were revised to '0.80' for members with HCC1 coded.

For the third method, (3) On/Off by Number of Charts, a portion of HCC risk markers coded as present ('1') are also reassigned to not present ('0') based on the predicted error rates by HCC and chart count. I performed the random deletion of markers 10 times. In each simulation, the HCC risk marker is changed from present ('1') to not present ('0') conditional on the number of charts indicated for the beneficiary-HCC marker. For example, suppose 2,000 beneficiaries in the development data set had HCC1 coded as present ('1') and were coded in seven charts. Also assume one of the provided error rates for HCC1 with seven charts was 0.10. Then, for a random subset of 200 beneficiaries with seven charts indicating HCC1 ($0.10 \times 2,000$), the HCC1 risk marker would be set to not present ('0'), producing a 10% lower prevalence of HCC1 with seven charts, thereby simulating an audited set of markers. Again, since the approach involved a random reassignment of risk markers, we performed the random deletion ten times creating ten simulated beneficiary input files for the error rate scenario (d).

For the fourth method, (4) Scalar Method by Number of Charts, all risk markers were proportionally reduced by a scalar for the corresponding HCC calculated as $(1 - \text{error rate})$ for HCC, given number of charts. For example, if the error rate for HCC1 with seven charts was 0.10, the HCC1 risk markers for beneficiaries with seven charts would be recalculated as original HCC1 risk marker $\times (1 - 0.10)$ or 0.90, producing an overall 10% lower prevalence of HCC1 with seven charts, thereby simulating an audited set of markers. Note that the risk markers values in this methodology also would no longer be binary in nature. The HCC1 marker for members who were never coded would maintain '0', and the HCC1 marker for members who originally were coded as a '1' would be revised to a range values less than one, based on the number of charts present.

The average of the HCC error rates in the error set (d) was 37.7%, calculated as a weighted average by the number of simulated audited HCC risk markers (adjusted for partial CY2014 enrollment) using the error rates by chart count. Table 3 below presents an illustrative example of applying HCC error rates by chart count and calculating the overall average HCC error rate. The error rate for the specific HCC is based on the number of charts except for the HCCs where the chart count data was not available (the 4.9% of beneficiaries with no charts counts found in the TM data). In those cases, the HCC error rate from set (a) was used. **Exhibit C** columns 31 and 35 correspond to the reduction in risk markers based on the average HCC error rate corresponding to the illustrative error rate values of 0.046 for HCC1 and 0.281 for HCC6. The overall average error rate of 0.184 is calculated taking into account the partial enrollment in the Year 2 (CY2014), as well as the overall prevalence of HCC1 and HCC6.

Table 3 - Illustration of Average Error Rate Calculation for Error Rate Set (d)

Beneficiary	HCC Risk Marker	Number of Charts for HCC	Error Rate by # Charts [1]	Months Enrolled in CY2014
A	HCC1 = 1	6	0.017	12
B	HCC1 = 1	10	0.002	8
C	HCC1 = 1	N/A [2]	0.124	9
A	HCC6 = 1	3	0.231	12
B	HCC6 = 1	N/A [2]	0.338	8
C	HCC6 = 1	8	0.016	9
D	HCC6 = 1	1	0.493	12
HCC1 Avg	Over 3 benes		0.046 [3]	0.806 [4]
HCC6 Avg	Over 4 benes		0.281 [5]	0.854 [6]
Overall Avg			0.184 [7]	

[1] The error rates by HCC set (a) are presented in **Exhibit A**. The error rates by HCC and chart counts set (d) are presented in **Exhibit B**.

[2] Note that for beneficiary-HCC combination where no chart data was available in the beneficiary input file, the average HCC error rate was used (from error set (a)).

[3] $0.046 = (0.017 \times 12 + 0.002 \times 8 + 0.124 \times 9) / (12 + 8 + 9)$

[4] 0.806 is the average of 12, 8, 9 months, or 9.67, divided by 12.

[5] $0.281 = (0.231 \times 12 + 0.338 \times 8 + 0.016 \times 9 + 0.493 \times 12) / (12 + 8 + 9 + 12)$

[6] 0.854 is the average of 12, 8, 9, 12 months, or 10.25, divided by 12.

[7] $0.184 = (0.046 \times 3 \times 0.806 + 0.281 \times 4 \times 0.854) / (3 \times 0.806 + 4 \times 0.854)$

The error rates by HCC and chart count were used to simulate a simplified two-step regression, where the probability of validation of the HCC markers is first predicted using a logistic regression and then those predicted probabilities of valid HCC markers are used as inputs into the linear regression that estimates the dollar coefficients of the CMS-HCC risk adjustment model. This two-step regression is referred to as “regression calibration” in depositions¹⁶ and discovery documents¹⁷ of this case. Because some of the results of regression calibration performed by CMS and received as part of discovery are directionally different, I wanted to test the results using this two-step regression approach. As discussed in the results section below, my results were directionally consistent in all testing.

¹⁶ Rebecca Paul Deposition, April 13, 2023, at 218:20-219:13 (AEO); Ilina Chaudhuri Deposition, August 10, 2023, at 185:5-186:22 (AEO).

¹⁷ Exhibit 1184-A to Rebecca Paul’s Deposition (AEO); Exhibit 1192-1 to Ilina Chaudhuri’s Deposition (AEO).

High-Level Results

Table 4a summarizes the original CMS-HCC and revised weighted average¹⁸ dollar coefficients for the original community, non-dual, aged, continuing enrollee model and the recalibrated models. Table 4b summarizes the original CMS-HCC and revised weighted average relative values corresponding to Table 4a. Table 5 summarizes the increase in weighted average relative values in each testing scenario. Each table shows the dollar coefficients for all risk markers, and the HCC and demographic markers, separately. Table 6 summarizes the number of demographic and HCC risk markers with a decrease and an increase in the relative values in each method and scenario tested. Based on these findings, the following conclusions can be drawn:

1. The CMS-HCC model development is impacted by the presence of the unsupported codes.
2. Testing showed that the dollar coefficients and relative values were higher on average for a risk model where the unsupported codes have been removed compared to a risk model based on both supported and unsupported codes. Said another way, the current relative values were lower on average than they would be if unsupported codes were removed.
3. If the risk adjustment model were revised to be based on only supported codes, such a model would have higher relative values for the majority of risk markers (over 90%), including the demographic risk markers as well as HCC risk markers, depending on the methodology.
4. The results were directionally similar when using the two-step regression approach.

Notably, the impact to the risk model for all of the various testing scenarios (even those where the error rates were at conservatively low levels) was material. While the chosen methodology of removing markers creates differences in how the demographic versus HCC dollar coefficients and relative values move, the average impact over all markers was consistent across all the methodologies when the same error rates are used. Even for those scenarios at the lowest error rates (listed as (b) and (c)), the impact to the average relative values and the dollar coefficients are 12.2% and 8.5% increases, respectively.¹⁹ For the best estimate error rate, the increase to the average relative values was 21.2%. In the deletion methods where the error rates from the chart counts were used to inform the level of removed markers, the impact to relative values was even higher, at 26.0%.

¹⁸ The weighting was based on the member month weighted number of risk markers in the TM data similar to column b in Table 1 for each HCC in the beneficiary input file for each regression. Note, the distribution of risk markers by HCC in this full data set is a different distribution than what was included in the sampled data of audited charts.

Table 4a - Weighted Average Coefficients by Method and Scenario

Scenario Description			Weighted Average Coefficient		
Deletion Method	Discrepancy Rate Used		All Risk Markers [1]	HCC Risk Markers [2]	Demog. Risk Markers [3]
Original CMS-HCC Model		N/A	\$3,365	\$2,954	\$3,971
1a	On/Off [4]	Best Est with adj	\$4,190	\$3,694	\$4,682
1b	On/Off [4]	Low end of the 90% Confidence Interval	\$3,844	\$3,381	\$4,384
1c	On/Off [4]	Non-respondent charts valid	\$3,681	\$3,238	\$4,241
2a	Scalar	Best Est with adj	\$4,190	\$4,411	\$3,972
2b	Scalar	Low end of the 90% Confidence Interval	\$3,844	\$3,733	\$3,973
2c	Scalar	Non-respondent charts valid	\$3,681	\$3,452	\$3,971
3d	On/Off by # of Charts [4]	By HCC by chart count	\$4,384	\$3,886	\$4,833
4d	Scalar by # of Charts	By HCC by chart count	\$4,384	\$4,746	\$4,057

Table 4b - Weighted Average Relative Values by Method and Scenario

Scenario Description			Weighted Average Coefficient		
Deletion Method	Discrepancy Rate Used		All Risk Markers [1]	HCC Risk Markers [2]	Demog. Risk Markers [3]
Original CMS-HCC Model		N/A	0.366	0.322	0.432
1a	On/Off [4]	Best Est with adj	0.456	0.402	0.510
1b	On/Off [4]	Low end of the 90% Confidence Interval	0.418	0.368	0.477
1c	On/Off [4]	Non-respondent charts valid	0.401	0.353	0.462
2a	Scalar	Best Est with adj	0.456	0.480	0.432
2b	Scalar	Low end of the 90% Confidence Interval	0.418	0.406	0.432
2c	Scalar	Non-respondent charts valid	0.401	0.376	0.432
3d	On/Off by # of Charts [4]	By HCC by chart count	0.477	0.423	0.526
4d	Scalar by # of Charts	By HCC by chart count	0.477	0.517	0.442

[1] Represents the average weighted by the risk markers resulting from each method for all demographic and HCC risk markers.

[2] Represents the average weighted by the risk markers resulting from each method for all HCC risk markers.

[3] Represents the average weighted by the risk markers resulting from each method for all demographic risk markers.

[4] Each of the weighted for these scenarios reflect the average of the ten regressions based on the random removal of markers.

Table 5 - Average Discrepancy Rate and Difference in Relative Values by Method and Scenario

Scenario Description			Average HCC Discrepancy Rate (Excl. Interaction HCCs) [1]	% Difference in Relative Values		
Deletion Method	Discrepancy Rate Used			All Risk Markers [2]	HCC Risk Markers [3]	Demog. Risk Markers [4]
1a	On/Off	Best Est with adj	31.6%	21.2%	24.2%	17.9%
1b	On/Off	Low end of the 90% Confidence Interval	20.0%	12.2%	13.9%	10.4%
1c	On/Off	Non-respondent charts valid	13.7%	8.5%	10.1%	6.8%
2a	Scalar	Best Est with adj	31.6%	21.2%	48.5%	0.0%
2b	Scalar	Low end of the 90% Confidence Interval	20.0%	12.2%	25.8%	0.0%
2c	Scalar	Non-respondent charts valid	13.7%	8.5%	17.3%	0.0%
3d	On/Off by # of Charts	By HCC by chart count	37.7%	26.0%	30.1%	21.7%
4d	Scalar by # of Charts	By HCC by chart count	37.7%	26.0%	59.2%	2.2%

[1] Represents the average rate of unsupported risk markers weighted by the revised risk markers (reduced) for non-interaction HCC risk markers.

[2] Represents the change in the average relative value weighted by the revised risk markers (reduced) for all HCC risk markers, relative to the original weighted average value in column [1] in Table 4b.

[3] Represents the change in the average relative value weighted by the revised risk markers (reduced) for all HCC risk markers, relative to the original weighted average value in column [2] in Table 4b.

[4] Represents the change in the average relative value weighted by the revised risk markers (reduced) for all demographic risk markers, relative to the original weighted average value in column [3] in Table 4b.

Table 6 - Directionality of Coefficient Changes by Method and Scenario

Scenario Description			# HCCs with Lower Rel Values [1]	# Demog. with Lower Rel Values [2]	# Markers with Higher Rel Values [3]
Deletion Method	Discrepancy Rate Used				
1a	On/Off	Best Est with adj	8	0	93
1b	On/Off	Low end of the 90% Confidence Interval	9	0	92
1c	On/Off	Non-respondent charts valid	8	0	93
2a	Scalar	Best Est with adj	0	6	95
2b	Scalar	Low end of the 90% Confidence Interval	0	3	98
2c	Scalar	Non-respondent charts valid	1	12	88
3d	On/Off by # of Charts	By HCC by chart count	5	0	96
4d	Scalar by # of Charts	By HCC by chart count	4	1	96

[1] Represents the count of unique HCC risk markers with lower relative values in the revised tested model compared to the original CMS-HCC model relative values for each HCC.

[2] Represents the count of unique demographic risk markers with lower relative values in the revised tested model compared to the original CMS-HCC model relative values for each demographic risk marker.

[3] Represents the count of unique all risk markers (HCCs and demographic) with higher relative values in the revised model compared to the original CMS-HCC model relative values.

In relaying this result of higher relative values of the revised model, it is important to note that the average relative factors can go up while maintaining the average risk score of 1.0 for the TM population. Because the total number of markers in the TM has gone down, the average number of markers *per beneficiary* has gone down as well by the same proportion. To further illustrate this point, consider the example in Table 7 below.

Table 7 - Illustration of Average Risk Score Under Revised Methodology

Description		Original	Revised (with unsupported diagnoses removed)
a	Number of Markers	99M	81M
b	Number of Beneficiaries	37M	37M
c	Average Number of Markers per Beneficiary (a/b)	2.676	2.189
d	Average Relative Value	0.373	0.457
e	Average Risk Score (c x d)	1.00	1.00

In the 2015 denominator file, suppose there are 99 million markers (including all demographic, HCC and interaction variables) on 37 million beneficiaries, or 2.676 markers per beneficiary²⁰. After removing markers for unsupported HCCs, suppose there is 81 million markers (19.2% less) over the same amount of beneficiaries, resulting in 2.189 markers per beneficiary (also 19.2% less).

The risk scores of the beneficiary population in both cases is 1.00:

- In the baseline example, the average relative value is 0.373. That is, $2.676 \times 0.373 = 1.00$
- In the revised scenario, where the relative values are only based on supported markers, the average relative value is 0.457. That is, $2.189 \times 0.457 = 1.00$

This simplified math concept illustrates how the average risk score can remain at 1.00 while the average value of the relative factors increases.

Impact on UHG MA Contract Experience in PY2017

Since the simulated audited data testing suggests that not every relative value increases and that a small number of variables would have lower relative values compared to the original data, the distribution of risk markers for a particular contract or set of members would matter to the overall calculated risk scores.

To analyze the overall impact of the revised relative values on UHG membership data, Wakely received model output reports distributed by CMS in the Final Yearly Model Output Data File, Part C data file format for UHG PY2017 MA contracts that contain the distribution of markers by beneficiary. Wakely calculated the original and revised risk scores for each beneficiary and summarized by contract using the original and revised relative values estimated in the methods and scenarios discussed above. The change in UHG risk scores between the original model (with lower average relative values) and the recalibrated models (with higher coefficients) is presented in Table 7. The table shows the range of the average changes in the risk scores by contract for non-ESRD, non-hospice, non-dual, aged, continuing enrollees. While the impact varied by contract, the revised risk adjustment model resulted in materially increased risk scores for all contracts with at least 300 beneficiaries in a contract for all tested scenarios. That is, the small number of HCC or demographic variables with lower coefficients did not have meaningful impacts when testing against the 2017 UHG data.

²⁰ All values referenced in this paragraph are illustrative; however, the conclusion does not depend on the precise numbers.

Table 8 - Impact on UHG MA Contract Experience by Method and Scenario

Scenario				
	Deletion Method	Discrepancy Rate Used	Average % Change in Risk Scores by Contract*	Range of Changes by Contract
1a	On/Off	Best Est with adj	20.4%	19.1% - 22.2%
1b	On/Off	Low end of the 90% Confidence Interval	11.9%	11.0% - 12.8%
1c	On/Off	Non-respondent charts valid	8.6%	7.9% - 9.4%
2a	Scalar	Best Est with adj	33.8%	27.8% - 42.0%
2b	Scalar	Low end of the 90% Confidence Interval	17.4%	14.3% - 21.5%
2c	Scalar	Non-respondent charts valid	11.1%	9.4% - 14.4%
3d	On/Off by # of Charts	By HCC by chart count	26.0%	24.5% - 27.0%
4d	Scalar by # of Charts	By HCC by chart count	42.0%	35.4% - 49.1%

*Testing includes only contracts with at least 300 beneficiaries. This is based on guidelines from The Office of the Actuary (OACT) for full risk score credibility as used in the bid pricing tools (BPTs).

The key results from Tables 5 and 8 (which are listed in blue font above) are repeated in Table 9 below.

Table 9 - Summary of Key Results

Scenario			Average Error Rate	Average Impact to Relative Risk Values	Average Impact to UHC Risk Scores
Deletion Method	Error Rate Used		(a)	(b)	(c)
1a	On/Off	Best Est with adj	31.6%	21.2%	20.4%
1b	On/Off	Low end of the 90% Confidence Interval	20.0%	12.2%	11.9%
1c	On/Off	Non-respondent charts valid	13.7%	8.5%	8.6%
2a	Scalar	Best Est with adj	31.6%	21.2%	33.8%
2b	Scalar	Low end of the 90% Confidence Interval	20.0%	12.2%	17.4%
2c	Scalar	Non-respondent charts valid	13.7%	8.5%	11.1%
3d	On/Off by # of Charts	By HCC by chart count with adj	37.7%	26.0%	26.0%
4d	Scalar by # of Charts	By HCC by chart count with adj	37.7%	26.0%	42.0%

This table shows that when removing HCC markers from the TM data due to unsupported HCC codes, larger HCC error rates (in column a) have larger impacts to the risk values (in column b), which in turn have directionally similar impacts on UHG risk scores (in column c). Put differently, the current UHG risk scores are reduced from what they otherwise would be if unsupported codes were removed in the development of the MA CMS-HCC risk score model. The larger the error rate in the data, the lower the current UHG risk scores are relative to revised data. By not accounting for the unsupported codes in the TM data, the current average relative risk factors are diluted on average by at least 7.8% [$1-1/(1+8.5\%)$], and likely diluted by much more than that. Our best estimate is that relative risk scores are diluted by 17.5% [$1-1/(1+21.2\%)$] using values from column (b). Using column (c), UHG risk scores are likely at least 7.9% [$1-1/(1+8.6\%)$] less than they would be had unsupported HCC codes been removed in the development of the risk adjustment model.

Removing Expenditures

The focus of the revised regression work so far discusses the simulations of removing unsupported HCC risk markers and recalibrating model coefficients and relative values, where the payment year costs were unchanged. To summarize, that work provides evidence that current relative values are lower on average than they would be should unsupported diagnoses be removed from the beneficiary input files.

In a 2018 Fee-For-Service (“FFS”) Adjuster study where CMS similarly removed HCC markers due to unsupported diagnoses and recalibrated the regression model based on the revised markers, the authors posit that diagnosis error in the TM claims may lead to payment error, and therefore

that TM payment year costs (also called expenditure data) should be adjusted for claims where the diagnoses are unsupported. Based on this assumption, the author accounts for the purportedly inflated expenditures via an “IPARS” adjustment, and then argues that such an adjustment reveals no material change to MA payment from their recalibration.²¹ The following analysis supports my opinion that removing expenditures is unwarranted, and even if expenditures were removed, the results would be the same as the previous testing shows. That is, the average relative values for recalibrated regression models where unsupported diagnoses are removed are higher on average than recalibrated regression models where both supported and unsupported diagnoses are included in the beneficiary input files, even if expenditures are removed in the development of the revised models.

1. The IPARs (Inflated Post-Audit Risk Score) adjustment is a faulty adjustment created in response to an incorrect application of the dollar coefficients from the regression calibration.

As detailed in my response to the CMS FFS Adjuster analysis,²² CMS made a mistake in their calibration. CMS incorrectly applied the higher dollar coefficients from their revised regression calibrations to the original and unaudited HCCs (in the original beneficiary input file). This application of the revised dollar coefficients to the original HCC markers resulted in a prediction that was higher than the actual TM expenditures. Because of this discrepancy, CMS felt it necessary to make the IPARs adjustment to the dollar coefficients, which ultimately undermined the conclusions of their analysis. The IPARs adjustment reduced the dollar coefficients by dividing them by a factor equal to (a contrived average predicted expenditure divided by the average cost of TM beneficiaries) where the contrived average predicted expenditure was calculated by applying the revised dollar coefficients to the original HCC markers.

Had CMS correctly applied the revised, higher dollar coefficients to their simulated, audited HCCs (the revised beneficiary input file), they would have seen that the predicted expenditures matched the actual TM expenditures and concluded that no IPARs adjustment was warranted. More information regarding my opinion is included in my response paper referenced above.

2. The prospective nature of the model removes the direct link between the expenditures and the unsupported HCCs used to develop the risk models.

The prospective nature of the CMS-HCC risk adjustment model entails using risk markers observed during the experience year (Year 1) to predict future costs incurred in the following calendar year (Year 2). As such, there is a one year difference between the unsupported HCCs and claim costs, and the association is not direct. Removing unsupported HCCs for claims in Year

²¹ See p. 5 of CMS, *Addendum to the Fee-For-Service Adjuster Study*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/RADV-Provision-CMS-4185-N4-Data-Release-June-2019.zip>. (“We performed this normalization because diagnoses cannot soundly be deleted in the CMS-HCC modeling context without making adjustments to account for the bias that the deletion procedure itself creates in expenditures.”).

²² Paper, UnitedHealth Group, “Actuarial Report on Medicare Advantage FFS Adjuster,” (Aug. 28, 2019), <https://www.regulations.gov/document/CMS-2018-0133-0263>.

1 could not possibly remove incurred costs during Year 2. They are not the same claims. Incurred claims may have an indirect relationship to the HCCs in the prior year, should the same or a different physician provide a similar service and code an unsupported HCCs in Year 2 in the same way that it was unsupported during Year 1. If expenditures in Year 2 are questioned as invalid for unsupported HCCs, a secondary audit of Year 2 diagnoses and their validity would be necessary in order to appropriately identify claims in Year 2 costs that have unsupported diagnoses.

3. The goal of MA risk adjustment is to use actual TM costs, which are not restated or audited for unsupported diagnoses.

Removing expenditures related to claims with unsupported diagnoses from actual TM incurred claims is fundamentally inconsistent with the core requirement of the MA risk adjustment model being based on the TM data costs. Removing costs from TM data for unsupported diagnoses would ultimately mean modifying costs that are to be the very basis of the relative factors. The point of the MA model is to create risk adjustment that adjusts the MA payments across beneficiaries in the same way that costs are incurred in the TM program.

To date, the TM data is largely unaudited and the TM claims have not been targeted to remove costs due to unsupported diagnoses. Doing so would require new audits that have not historically been performed and would likely change cost profiles from historical patterns.

4. Even if incurred costs were audited, most of TM costs are unaffected by unsupported diagnoses.

Payments for most claims, including outpatient claims, diagnostic lab and radiology claims, and physician claims are not dependent on specific diagnoses being on the claim. Even if unsupported diagnoses are found on these claims, the paid claims would be unaffected. Only Medicare inpatient claim payment is directly dependent on certain diagnosis codes. And even for inpatient claims where a diagnosis may be unsupported, other supported diagnoses on the inpatient claim could still result in partial or full payment. Therefore, unsupported diagnoses would have a potential impact on only the minority of TM costs.

5. Wakely testing indicates that the results of the analysis would be the same, regardless of removing expenditures.

Lastly, and perhaps most importantly, the testing²³ shows that even though the impact of dollar coefficients would be impacted by reductions in the expenditures, the directional impacts of the relative values would remain unchanged. Namely, if CMS were to adjust the beneficiary input file data by fully removing all unsupported diagnoses in Year 1 and adjust all expenditures due to unsupported diagnoses in Year 2 before running its regression, the average relative factors in the revised risk models would still *increase* compared to the original model.

The reason lies in the following risk adjustment principle: The average risk score for the calibration data set is 1.0.

²³ The results here are consistent with my original testing performed in response to CPI claims regarding reduced expenditure data. See also *id.* at Appendix III of my Actuarial Report in response to the CPI study.

Based on this principle, it algebraically follows that if the sum of indicated markers in the calibration dataset go down, the average relative value goes up regardless of how the payment amounts change. That algebraic proof is shown in the main report.

In addition, the analyses below establish the result to be true as an empirical matter by running recalibrated regression models where random amounts of expenditures are removed from the costs of the calibration dataset.²⁴ In all cases the answer is the same: Although the dollar coefficients of the revised regressions may change and can be reduced on average compared to the original dollar coefficients, the average revised relative values are never reduced compared to the original because the average predicted expenditure used in the normalization is also reduced.

My simulations show that if the revised dollar coefficients are normalized using this reduced predicted expenditure figure, the resulting revised relative factors would be similar to the revised relative factors and higher than the original relative factors, on a weighted average basis.

I modeled the reduction in expenditures using the following eight scenarios. Within Scenarios 1-4 and within Scenarios 5-8, I kept the revised risk profile markers the same and varied the manner in which expenditures were adjusted. Scenarios 1 through 4 present various reductions to expenditures along with the revised HCC markers matching the regression from 2a above. Scenarios 5-8 present various reductions to expenditures along with the first set of randomized HCC markers created for regression 1c.

Each scenario reflects performing a revised regression on beneficiary input files that simulate different expenditure reductions, calculating dollar coefficients for each regression. I then divided these dollar coefficients by the average predicted expenditure in the denominator file (hence also reflecting a parallel reduction in expenditures) to develop relative values. More descriptive information on these scenarios are in **Exhibit D** to the Appendix. Table 10 below provides a summary of the results.

The results are informative and provide empirical evidence that the average relative value increases in a similar manner regardless of how and if the expenditures are adjusted.

- Reducing expenditures in the calibration dataset results in the average dollar coefficients (column (a) in Table 10) that are generally lower than those without the reduction. The average dollar coefficient change is dependent on the amount of expenditures that are removed from the risk profiles. When proportionally more claim dollars than markers are removed from the revised risk profiles, the average dollar coefficient is reduced (as in Scenario 6 relative to the original model). When more markers are removed than costs, the average dollar coefficient increases (as in Scenario 3, relative to the original model).

The dollar coefficients, however, are divided by a lower average predicted cost (developed using the denominator dataset, column (c) in Table 10) when normalizing. The resulting

²⁴ Because we have not studied the expenditure impact of unsupported codes, we randomly reduced the expenditures with some high level constraints to evaluate the impact.

amounts in column (d) represent an average relative values for each of the recalibrated risk adjustment models.

- The average relative value (column (d) in Table 10), when weighting by the revised markers in the risk profiles of the denominator dataset, does not change within the scenarios 1-4 or within the scenarios 5-8, and is larger than the original average relative value in all scenarios.

Table 10 - Summary of Analysis Testing Changes in Expenditures

Description	Calibration Dataset	Expenditure Description	(a) Avg Dollar Coefficient *	(b) Avg Predicted Cost in Calibration Dataset	(c) Predicted Cost in Denominator Dataset	(d) Avg Relative Value (a) / (c)	(e) Avg Risk Score in Denominator Dataset
Original Model	Original Risk Profiles	Original Expenditures	\$3,365	\$8,968	\$9,185	0.366	1.000
Revision 2a	Scalar with Error (a)	No change	\$4,190	\$8,968	\$9,185	0.456	1.000
Scenario 1	Scalar with Error (a)	Reduce 20% of expenditures for all members	\$3,352	\$7,175	\$7,348	0.456	1.000
Scenario 2	Scalar with Error (a)	Reduce 30% of expenditures for all members	\$2,933	\$6,278	\$6,430	0.456	1.000
Scenario 3	Scalar with Error (a)	Reduce expenditures by an average of 90% for randomly selected 10% of members	\$3,813	\$8,160	\$8,358	0.456	1.000
Scenario 4	Scalar with Error (a)	Reduce expenditures by an average of 85% for randomly selected 15% of members	\$3,657	\$7,826	\$8,015	0.456	1.000
Revision 1c	One Set of On/Off with Error (b)	No change	\$3,681	\$8,968	\$9,185	0.401	1.000
Scenario 5	One Set of On/Off with Error (b)	Reduce 20% of expenditures for all members	\$2,945	\$7,175	\$7,348	0.401	1.000
Scenario 6	One Set of On/Off with Error (b)	Reduce 30% of expenditures for all members	\$2,577	\$6,278	\$6,430	0.401	1.000

Description	Calibration Dataset	Expenditure Description	(a) Avg Dollar Coefficient *	(b) Avg Predicted Cost in Calibration Dataset	(c) Predicted Cost in Denominator Dataset	(d) Avg Relative Value (a) / (c)	(e) Avg Risk Score in Denominator Dataset
Scenario 7	One Set of On/Off with Error (b)	Reduce expenditures by an average of 90% for randomly selected 10% of members	\$3,350	\$8,161	\$8,358	0.401	1.000
Scenario 8	One Set of On/Off with Error (b)	Reduce expenditures by an average of 85% for randomly selected 15% of members	\$3,212	\$7,824	\$8,013	0.401	1.000

* The average dollar coefficient reflects the weighted average across all risk markers from beneficiary input dataset.

EXHIBIT A

Data Associated with This Exhibit Will be Produced at a Later Date.

EXHIBIT B

Data Associated with This Exhibit Will be Produced at a Later Date.

EXHIBIT C

Data Associated with This Exhibit Will be Produced at a Later Date.

EXHIBIT D

Descriptions of Expenditure Testing Scenarios

Scenario 1 Methodology: For this testing, I relied on the 2013-2014 beneficiary input file that was modified using the deletion method and error rate corresponding to the scenario “2a Scalar,” which is described in the section “Testing Methods and Results.” 2014 expenditures for all beneficiaries were reduced by 20%. The regression to estimate CMS-HCC model dollar coefficients was rerun using the reduced expenditure amounts. A parallel process for risk marker deletion was performed on a subset of the denominator file consisting of community, non-dual, aged continuing enrollees. This revised subset of the denominator file was then used with the estimated dollar regression coefficients to calculate the reduction in the average predicted expenditures in the denominator file. This reduced denominator amount was used to calculate the revised relative values with the expenditure reduction.

Scenario 2 Methodology: Same as Scenario 1 but the expenditures were reduced by 30%.

Scenario 3 Methodology: For this testing, I also relied on the 2013-2014 beneficiary input file that was modified using the deletion method and error rate corresponding to the scenario “2a Scalar,” which is described in the section “Testing Methods and Results.” 2014 expenditures for a random set of 10% beneficiaries were reduced by a random amount (90% on average), and a regression to estimate CMS-HCC model dollar coefficients was rerun using the reduced expenditure amounts. A parallel process for risk marker deletion was performed on a subset of the denominator file consisting of community, non-dual, aged, continuing enrollees. This revised subset of the denominator file was then used with the estimated dollar regression coefficients to calculate the reduction in the average predicted expenditures in the denominator file. This reduced denominator amount was used to calculate the revised relative values with the expenditure reduction.

Scenario 4 Methodology: Same as Scenario 3 but with 2014 expenditures for a random set of 15% beneficiaries were reduced by random amount (85% on average).

Scenario 5 Methodology: For this testing, I relied on the 2013-2014 beneficiary input file that was modified using the deletion method and error rate corresponding to the scenario “1c On/Off,” which is described in the section “Testing Methods and Results.” 2014 expenditures for all beneficiaries were reduced by 20% and regression to estimate CMS-HCC model dollar coefficients was rerun using the reduced expenditure amounts. A parallel process for risk marker deletion was performed on a subset of the denominator file consisting of community, non-dual, aged, continuing enrollees. This revised subset of the denominator file was then used with the estimated dollar regression coefficients to calculate the reduction in the average predicted expenditures in the denominator file. This reduced denominator amount was used to calculate the revised relative values with the expenditure reduction.

Scenario 6 Methodology: Same as Scenario 5 but the expenditures were reduced by 30%.

Scenario 7 Methodology: For this testing, I relied on the 2013-2014 beneficiary input file that was modified using the deletion method and error rate corresponding to the scenario “1c On/Off,” which is described in the section “Testing Methods and Results.” 2014 expenditures for a random set of 10% beneficiaries were reduced by a random amount (90% on average), and a regression to estimate CMS-HCC model dollar coefficients was rerun using the reduced expenditure amounts. A parallel process for risk marker deletion was performed on a subset of the denominator file consisting of community, non-dual, aged, continuing enrollees. This revised subset of the denominator file was then used with the estimated dollar regression coefficients to calculate the reduction in the average predicted expenditures in the denominator file. This amount was used as a denominator to calculate the revised relative values with the expenditure reduction.

Scenario 8 Methodology: Same as Scenario 7 but with 2014 expenditures for a random set of 15% beneficiaries were reduced by a random amount (85% on average).

APPENDIX II

Julia Lambert Resume

Wakely Consulting Group, Tampa, CO

Principal and Senior Consulting Actuary

2008 – Current

- Oversight of firm's model development and training related to Medicare Advantage bid work.
- Has served as the lead actuary for several regional health plans in various states, where responsibilities include product design and rating, feasibility studies, rate certification, and valuation for Medicare, Medicaid, commercial group, and commercial individual products.
- Support reform analyses and policy implications of policy affecting Medicare beneficiaries.
- Performs expert witness work for various healthcare-related practice areas, including pharmacy programs, risk adjustment, and Medicare Advantage.
- Supported the state of Vermont in various projects including the evaluation of the Medicare-Medicaid Program (MMP) in support of their MMP application and performing cost estimates for the Medicare population as part of the single-payer proposal.
- Modeled impact of Medicaid eligibility expansion and pharmacy Carve-in/Carve-out analyses in Ohio on behalf of Association.
- Served as supporting actuary for SHOP exchange analyses for Illinois, Vermont, Delaware, and Rhode Island.
- Served as President of firm from 2015 through 2021.

Reden & Anders/Ingenix Consulting/now Optum Insight, Denver, CO

Managing Principal

2000 – 2008

- Appointed Medicare Actuarial Practice Leader responsible for the actuarial bidding process and Medicare strategy for the entire Reden & Anders actuarial practice.
- Provided strategic assistance on proposed and passed legislation. Advised client lobbyist on Medicare payment reform and been involved in discussions with MedPAC. This drove critical business decisions that had a significant impact on profitability.

- Developed feasibility studies for diverse products and services including Medicare, Medicaid, large group, and small group populations.
- Evaluated health care liabilities and complete actuarial opinions for financial statements.
- Actuarially certified large group and small group rate filings, Medicare bids, and small group rating methodologies.
- Forecasted revenues, costs, and financial profitability for diverse products and services.
- Established required rates and project costs for various products with an emphasis on Medicare Advantage plans.
- Determined risk targets, incentives, and capitation rates for provider contracts.
- Performed reimbursement analyses used for contract negotiations and establishing unit cost trends.
- Provider contracting analyses and negotiations: By comparing the differences in underlying demographics, health risks, unit costs, and utilization for the members associated with providers, carrier clients have been able to improve provider contracts through negotiations.
- Unit cost and utilization trend analyses: Created service reports that analyze unit cost and utilization by provider group, service category, and period, allowing the improvement of forecasts and expected outcomes.
- Underwriting and group pricing: Quantifying costs for large employers or carriers using detailed claims experience. Group renewals and new quotes, taking into account changes in plan designs, including high-deductible health plans, member cost-sharing, benefit maximums, and mandates.
- Facilitated the introduction of a new individual line of business by investigating competitor products, researching state regulations, generating scenario testing, integrating expected underwriting results, and establishing models to convey outcomes easily to the client.
- Reserve-setting: Oversee IBNR and lag adjustment expense reserve analyses for several clients.
- Forecasting and budgeting for health plans, implementing changes in risk scores. Deliver results to management determining participation in a particular line of business.

Leif Associates, Inc., Denver, CO

Consulting Actuary

1997-2000

- Provided large group underwriting assistance to HMOs.
- Prepared Colorado Annual Reports for HMOs, insurance companies, and dental carriers. These reports require that the rates/capitation amounts for all lines of business (including Medicaid and Medicare) be examined for appropriateness and adequacy of the claims experience, risk contracts, reinsurance, and administrative expenses of the company.
- Evaluated carrier compliance with applicable state and Federal small group law and regulations.
- Completed rate filings for HMOs, insurance companies, dental carriers, and mental health providers in various states.
- Completed reserve valuations for HMOs, self-funded employer health plans, employer trusts, mental health agencies, and state agencies.
- Studied the therapy needs of children with developmental delay and established projected costs of coverage.
- Established beginning claim costs used for establishing FAS 106 valuations for self-funded retiree medical plans.

Great-West Life, Englewood, CO

Assistant Actuarial Manager

1996 – 1997

- Supervised initial HMO rate filings in multiple states including pricing benefits and plan designs.
- Created and tested computer rating models for national health products.
- Responded to field questions regarding plan design, benefits, and pricing on newly released copay plans.
- Priced and coordinated release of PPO copay plans in hospital-only networks.
- Set POS targets for risk-sharing medical groups.

Physicians Mutual, Omaha, NE

Senior Actuarial Associate

1993 – 1996

- Designed and programmed the Agency Profitability Measurement System for life and health products.
- Designed and priced a new 10-year life product.
- Modeled profitability of all life policies for five years.
- Collected data and compiled information for the annual persistency study.
- Priced various optional health benefits.

University of Nebraska-Omaha, Omaha, NE

Mathematics Lecturer

1993 – 1996

- Taught Discrete Mathematics (logic, probability, statistics) and Linear Algebra to mathematics and computer science students.

EDUCATION

Master of Science, Mathematics, University of Colorado-Boulder, (1992)

Bachelor of Science, Magna Cum Laude, Secondary Education, University of Nebraska-Lincoln, (1989)

PROFESSIONAL DESIGNATIONS

Fellow, Society of Actuaries (FSA)

Member, American Academy of Actuaries (MAAA)

PROFESSIONAL AFFILIATIONS

Participant of Medicaid Certification Workgroup of the American Academy of Actuaries

Elected by peers to serve a three-year term on the Health Section Committee of the Society of Actuaries (SOA), in which she played a key role in Medicare Advantage education for the SOA. She also regularly speaks at webinars, seminars, and SOA meetings.

PUBLICATIONS IN LAST TEN YEARS (AUTHORED OR CO-AUTHORED)

Wakely White Paper, “*Wakely Summary of 2024 MA Advance Notice*,” Feb. 2022

Wakely White Paper, *“Issues in Part D Bids and Reconciliations that Lead to Overestimation of Cost,”* Nov. 2019

Wakely White Paper, *“Medicare Part D 2020: Where, Oh Where, Should My Pharmacy Rebates Go?,”* Mar. 2019

Paper, UnitedHealth Group, *“Actuarial Report on Medicare Advantage FFS Adjuster,”* Aug. 28, 2019 <https://www.regulations.gov/document/CMS-2018-0133-0263>

Wakely White Paper, *“MA Unleashed: CMS Issues Guidance on Newly Established Benefit Design Flexibility,”* May 2018

Paper, Office of the Assistant Secretary for Planning and Evaluation, *“Estimates of the Impact on Beneficiaries, CMS, and Drug Manufacturers in CY2020 of Eliminating Rebates for Reduced List Prices at Point-of-Sale for the Part D Program,”* Aug. 30, 2018

TESTIMONIES AND DEPOSITIONS IN LAST FOUR YEARS

United States of America and The State of Florida, ex rel., Amy Sanchez vs. Smart Pharmacy, Inc., Deposition taken March 29, 2022

PRESENTATIONS

Presentation, FRALL, *“Strategic Framework for the MAPD Bid Process,”* Jan. 25, 2015

Presentation, 2015 SOA Health Meeting, *“Payment Transfer Formula - the Mystery Revealed,”* June 16, 2015

Presentation, Health Plan Alliance, *“Payment Transfer Formula - the Mystery Revealed,”* Jan. 25, 2016

Presentation, 2016 SOA Health Meeting, *“Implications of the Encounter Data Processing System,”* June 15, 2016

Presentation, AHIP, *“Encounter Data Filtering,”* June 8, 2017

Presentation, Health Plan Alliance, *“2019 Rate Setting, Market Stabilization, and 1332 Waivers,”* Aug. 10, 2018

EXHIBIT D-63

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al,

Defendants.

Case No. 16-cv-08697 FMO (SSx)

UPDATED EXPERT REPORT OF PHILIP B. STARK
28 MARCH 2024

1. I am Distinguished Professor of Statistics at the University of California, Berkeley, where I am also a faculty member in the Graduate Program in Computational Data Science and Engineering; a co-investigator at the Berkeley Institute for Data Science; director of Berkeley Open Source Food; and affiliated faculty of the Simons Institute for the Theory of Computing, the Theoretical Astrophysics Center, and the Berkeley Food Institute. Previously, I was Associate Dean of Mathematical and Physical Sciences, Interim Regional Associate for the College of Chemistry and the Division of Mathematical and Physical Sciences, Chair of the Department of Statistics, and Director of the Statistical Computing Facility.

2. I have published more than two hundred articles and books. I have served on the editorial boards of archival journals in physical science, Applied Mathematics, Computer Science, and Statistics. I currently serve on three editorial boards. I have lectured at universities, professional societies, and government agencies in thirty countries. I was a Presidential Young Investigator and a Miller Research Professor. I received the U.C. Berkeley Chancellor's Award for Research in the Public Interest, the Leamer-Rosenthal Prize for Open Social Science, the IEEE Cybersecurity Award for Practice, a Velux/Villum Foundation Professorship, and the John Gideon Award for Election Integrity. I am a member of the Institute for Mathematical Statistics and the Bernoulli Society. I am a Fellow of the American Statistical Association, the Institute of Physics, and the Royal Astronomical Society. I am professionally accredited as a statistician by the American Statistical Association and as a physicist by the Institute of Physics.

3. I have consulted for many government agencies, including the U.S. Department of Justice, the U.S. Department of Agriculture, the U.S. Department of Commerce, the U.S. Department of Housing and Urban Development, the U.S. Department of Veterans Affairs, the Federal Trade Commission, the California Secretary of State, the California Attorney General, the California Highway Patrol, the Colorado Secretary of State, the Georgia Department of Law, the Illinois State Attorney, the New Hampshire Attorney General, and the New Hampshire Secretary of State. I currently serve on the Board of Advisors of the U.S. Election Assistance

Commission and its Voluntary Voting Systems Guidelines Committee. (The opinions expressed herein are, however, my own: I am not writing as a representative of any entity.)

4. I have testified before the U.S. House of Representatives Subcommittee on the Census; the State of California Senate Committee on Elections, Reapportionment and Constitutional Amendments; the State of California Assembly Committee on Elections and Redistricting; the State of California Senate Committee on Natural Resources; and the State of California Little Hoover Commission.

5. Methods I invented for auditing elections statistically are in law in approximately fifteen U.S. States.

6. I have been an expert witness or non-testifying expert in a variety of state and federal cases, for plaintiffs and for defendants, in criminal matters and a range of civil matters, including, *inter alia*: truth in advertising, antitrust, construction defects, consumer class actions, credit risk, disaster relief, elections, employment discrimination, environmental protection, equal protection, fairness in lending, federal legislation, First Amendment, import restrictions, insurance, intellectual property, jury selection, mortgage-backed securities, natural resources, product liability class actions, *qui tam*, risk assessment, toxic tort class actions, trade secrets, utilities, and wage and hour class actions.

7. I have been qualified as an expert on statistics in federal courts, including the Central District of California, the Northern District of Georgia, the District of Maryland, the Southern District of New York, and the Eastern District of Pennsylvania, as well as several state courts.

8. I have used statistics to address a wide range of questions in many fields.¹

¹ For example, I have used statistics to analyze the Big Bang, the interior structure of the Earth and Sun, earthquake risk, the reliability of clinical trials, the accuracy of election results, the accuracy of the U.S. Census, the risk of consumer credit default, food safety, the causes of geriatric hearing loss, the effectiveness of water treatment, sequestration of carbon in agricultural soils, the fragility of ecological food webs, risks to protected species, the effectiveness of Internet content filters, high-energy particle physics data, and the reliability of models of climate, among other things.

9. Since 1988, I have taught statistics at the University of California, Berkeley, one of the top two statistics departments in the world (see, e.g., QS World University Rankings, 2014) and the nation (US News and World Reports, 2018). I teach statistics regularly at the undergraduate and graduate levels. I have created five new statistics courses at Berkeley. I developed and taught U.C. Berkeley's first for-credit online course in any subject, which was among the first online courses approved for credit throughout the ten campuses of the University of California system. I also developed and co-taught online statistics courses to over 52,000 students, using an online textbook and interactive pedagogical materials I wrote and programmed.

10. Appendix 1 is my current *curriculum vitae*, which includes my publications for the last ten years and all cases in the last four years in which I gave deposition or trial testimony.

11. I am being compensated at the rate of \$1,800 per hour for my work in this matter. My compensation is not contingent upon the opinions I express nor upon the outcome of the litigation.

Assignment

12. I was asked to find the overlap between the list of diagnosis instances² identified by Mr. M. Timothy Renjilian in Opinions 2 and 3 of his expert report dated September 29, 2023, and subsequently updated on December 3, 2023 ("the Renjilian Report"), and the list of diagnosis instances included in the updated Final Deletes List from Dr. Craig Garthwaite's report dated March 11, 2024 ("the Garthwaite Report").

² I use the phrase "diagnosis instance" to refer to a unique record of a diagnosis code—that is, a diagnosis code associated with a particular from and through date of service, arising from a particular encounter with a particular provider. Mr. Renjilian uses the phrase "diagnosis code" to refer both to individual instances and to the underlying codes themselves. Mr. Renjilian notes this distinction (see e.g. Renjilian Report, at ¶139, in which he discusses "two instances of diagnosis code 571.5" belonging to a single member), but when he uses phrases like "67% of the diagnosis codes listed in the government's First Interrogatory Response," he is evidently counting *instances* of diagnosis codes. This is somewhat abstract, so here are some concrete numbers. Each of the 27,937,651 lines in the First Interrogatory Response has a unique combination of dx, hicn, fti_DosYr, dos_from, dos_thru, provider_nbr, and np_iрадstable. I call these *diagnosis instances* or *Dx instances* of which Mr. Renjilian identifies 18,849,686, or 67.47 percent, as belonging to his Opinion 2 (fti_Op2Total = 1). However, there are only 18,883,554 unique combinations of dx, hicn, and fti_DosYr in the First Interrogatory Response file, of which 12,107,495, or 64.12 percent, are identified as belonging to his Opinion 2. These are the *diagnosis codes* for each beneficiary in each year.

13. I was asked to analyze the rates at which CMS's RADV audit, discussed in Opinions 4, 5, and 7 in the Renjilian Report, found support for member-HCC-year combinations present in the First Interrogatory Response and identified in the Renjilian Report as having financial impact. I was also asked to determine whether the support rate associated with these combinations was statistically distinguishable from the support rates associated with RADV-reviewed member-HCC-year combinations not identified as having financial impact or not listed in the First Interrogatory Response at all.

14. I was asked to perform the two analyses described in the previous paragraph on the member-HCC-year combinations in the Garthwaite Final Deletes List.

15. I was asked to assess the overlap between the Garthwaite Final Deletes List and the CMS RADV audit and the statistical implications of the non-comprehensive nature of that overlap.

16. I was asked to review the statistical content of the expert report of Dr. Michael P. Salve, dated 29 September 2023 ("the Salve Report") including the sampling methodology and statistical models it employs.

Materials Relied Upon

17. The materials I relied upon in reaching my conclusions are listed in Appendix 2. Copies of some of those materials are provided as an electronic supplement to this report.

18. The computer programs I used to aggregate, load, and analyze data and to create the tables and figures in this report are provided as an electronic supplement to this report.

Opinions and Analysis

The Renjilian Report

I. **Opinions 2 and 3 of the Renjilian Report regarding the First Interrogatory Response (FIR) do not apply to the Garthwaite Final Deletes List, which contains a miniscule percentage of the diagnosis instances flagged in Opinion 2 and/or Opinion 3.**

(a) The Garthwaite Final Deletes List contains 2,087 of the diagnosis instances that Opinion 2 of the Renjilian report alleges are supported by other diagnosis instances at the HCC level. This overlap is very small: it comprises about 0.01 percent of the 18,849,686 diagnosis instances identified in Renjilian's Opinion 2 and about 0.11 percent of the 1,930,455 distinct diagnosis instances in the Garthwaite Final Deletes List.

(b) The Garthwaite Final Deletes List contains 5,922 of the diagnosis instances that Opinion 3 of the Renjilian report alleges would have no marginal effect on Part C or Part D Medicare Advantage payments to United if they were deleted. This overlap is also very small: it comprises approximately 0.03 percent of the 23,277,486 diagnosis instances identified in Renjilian's Opinion 3 and about 0.31 percent of the 1,930,455 distinct diagnosis instances in the Garthwaite Final Deletes List.

(c) The Garthwaite Final Deletes List contains 6,035 of the 23,491,048 diagnosis instances identified in Renjilian's Opinion 2 or Opinion 3 or both. This overlap is very small: It comprises about 0.03 percent of the diagnosis instances identified in Renjilian's Opinion 2 or Opinion 3 or both, and about 0.31 percent of the 1,930,455 distinct diagnosis instances in the Garthwaite Final Deletes List.

19. Opinion 2 of the Renjilian Report purports to identify and count, among the diagnosis instances listed in the FIR, those that were supported at the level of their associated HCC/RxHCC (or by an HCC/RxHCC above them in a hierarchy) by other diagnosis instances that were recorded by United reviewers but not found in the FIR list. I have not assessed whether any of Mr. Renjilian's factual claims about the diagnosis instances he flagged as belonging to Opinion 2 are correct.

20. Opinion 3 of the Renjilian Report purports to identify and count, among the diagnosis instances listed in the FIR, those that would have no impact on Part C or Part D

Medicare Advantage payments if they were deleted. I have not assessed whether any of Mr. Renjilian's factual claims about the diagnosis instances he flagged as belonging to Opinion 3 are correct.

21. I wrote computer programs to count the diagnosis instances identified in Opinion 2 and/or Opinion 3 of the Renjilian Report that are also present in Attachment 1 to Dr. Garthwaite's report, the "Final Deletes List." I understand from Dr. Garthwaite's report that the Final Deletes List includes diagnosis instances that satisfy all three of the following conditions:

(1) Dr. Garthwaite concluded that "[chart] review found no support for these diagnosis codes or their associated [HCCs] or [RxHCCs]", Garthwaite Report, at ¶13;

(2) Dr. Garthwaite "found no other instances of these diagnosis codes [or] diagnosis codes associated with the same [HCCs] or [RxHCCs] that Defendants may have submitted for that beneficiary in the same year", *Ibid.*;

(3) Dr. Garthwaite "calculated that the risk adjustment payments Defendants received from CMS would have been reduced if Defendants had deleted these diagnosis codes." *Ibid.*

22. Table 1 below shows the overlap between the diagnosis instances identified in Opinions 2 and 3 of the Renjilian Report and the diagnosis instances in the Garthwaite Final Deletes List.³

³ Mr. Renjilian's calculations are described in Appendix 1 of his report, a document with the filename "CONFIDENTIAL Appendix 1 - FTI FIR Table and Appendices Description.pdf," and the results of his putative identifications are in fields added to the file "FIR_2008_2016_FINAL FLAGS.txt" he produced with his report. Dr. Garthwaite's Final Deletes List is presented as a collection of twelve files produced with his report: attachment1_edps_2014.csv, attachment1_edps_2015.csv, attachment1_edps_2016.csv, attachment1_irads_2008.csv, attachment1_irads_2009.csv, attachment1_irads_2010.csv, attachment1_irads_2011.csv, attachment1_irads_2012.csv, attachment1_irads_2013.csv, attachment1_irads_2014.csv, attachment1_irads_2015.csv, and attachment1_irads_2016.csv. Following Mr. Renjilian's approach, I did not analyze the three EDPS files and focused instead on the nine IRADS files. To calculate the numbers in Table 1, I used Python scripts to construct a SQLite database containing tables with Mr. Renjilian's results and Dr. Garthwaite's results. I then wrote Python scripts to generate SQL queries that matched diagnosis instances across the two tables using healthcare identification numbers, diagnoses, and dates of service. I ran the SQL queries and analyzed the results within a Jupyter notebook.

Table 1: Overlap of Dx instances in Renjilian’s Opinion 2 and 3 with the Garthwaite Final

Delete List			
Renjilian Opinion	Renjilian count in FIR	Count in Garthwaite Final Deletes List	Percentage of Garthwaite Final Deletes List Dx Instances
Neither Opinion 2 nor 3	4,446,603	1,907,463	98.81
Opinions 2 and/or 3	23,491,048	6,035	0.31
<i>o/w Opinion 2 only</i>	213,562	113	<0.01
<i>o/w Opinion 3 only</i>	4,641,362	3,948	0.20
<i>o/w both Opinions 2 and 3</i>	18,636,124	1,974	0.10
New Instances in FDL	n/a	16,957	0.88
Total Dx Instances	27,937,651	1,930,455	100.0%

II. Opinion 4 of the Renjilian Report is based on all diagnosis instances in the FIR, even though Opinion 3 of the Renjilian Report had flagged a large percentage of those diagnosis instances as having no financial impact if deleted. RADV found support for those (inconsequential) diagnosis instances at a much higher rate (approximately 96 percent) than the instances that have financial impact if deleted according to Opinion 3 (approximately 60 percent). This difference in rates of support is large and highly statistically significant. Moreover, the overall rate at which RADV found support (approximately 88 percent) was substantially and statistically significantly higher than the rate at which RADV found support for those diagnosis instances in the FIR list identified in Renjilian’s Opinion 3 as having financial impact if deleted (approximately 59 percent). Thus, Renjilian’s Opinion 5 does not apply to those diagnosis instances in the FIR list that Renjilian identifies as having financial impact if deleted.

23. The CMS RADV audits analyzed in Opinion 4 of the Renjilian Report found support for member-HCC-year combinations contained in the FIR that are identified in the Renjilian Report as having financial impact if deleted (i.e., those covered by Renjilian’s Opinion 3) at a much lower rate than the overall 89% to 91% rate of RADV support stated in the

Renjilian Report.⁴ The conclusion of Opinion 5 of the Renjilian Report does not apply to these member-HCC-year combinations: according to Renjilian's work product, RADV found support for these combinations that had financial impact at a rate substantially lower than for the member-HCC-year combinations identified in Opinion 3: 61.3 percent versus 96.3 percent for those without financial impact for the V12 model, and 58.6 percent versus 96.2 percent for those without financial impact for the V22 model. These differences in the rates of support are highly statistically significant according to Fisher's exact test, with P-values below 0.0000001.⁵ In other words, there is a strong, statistically significant association between having financial impact (according to Renjilian's Opinion 3) and *not* having support in RADV.

24. To evaluate the rates at which RADV audits found support for member-HCC-years⁶ that Mr. Renjilian identified as having financial impact if deleted, I replicated and extended portions of Mr. Renjilian's analysis.

25. The first step was to construct a single "stacked" database table (as Mr. Renjilian calls it in paragraph 155 of his report) containing the data in the files produced by CMS.

26. Two fields⁷ in the "stacked" PFR data⁸ appear to indicate whether the medical record was submitted. The "Submission Status" field agreed with the other when both were present, and was always populated, so I used it to infer submission status. This agrees with the analysis described in paragraph 156(a) of the Renjilian Report.

27. Three fields⁹ in the "stacked" PFR data appear to indicate whether the submitted medical records were valid. I cross-tabulated the values of those fields and determined that

⁴ The Renjilian Report sometimes counts individual lines in FIR, which correspond to diagnosis instances ("Dx instances") rather than to member-HCC-year combinations, which I understand risk adjustments are based on. In this report, I generally focus on member-HCC-year combinations rather than on Dx instances. However, in discussing the Renjilian Report, the numbers I present may refer to Dx instances or to member-HCC-year combinations, as appropriate.

⁵ The rates differ across those groups by an amount that would be surprisingly large if the groups had been constructed by taking the pooled collection of member-HCC-year combinations and randomly splitting it into two groups of the respective sizes.

⁶ Mr. Renjilian refers to "member-HCC combinations" or, more concisely, "member-HCCs." The actual unit of analysis is member-HCC-year due to the annual nature of risk adjustment so I will refer to "member-HCC-years."

⁷ "Submission Status" and "submission_status."

⁸ Plan Feedback Report, See Renjilian Report at paragraph 153.

⁹ "Valid/Invalid MR", "Valid/Invalid MR (old)", and "Review Status".

“Valid/Invalid MR” agreed with the others whenever it was populated and one or more of the other fields was also present, but there were instances where “Valid/Invalid MR” was blank but “Valid/Invalid MR old” indicated “Valid.” I therefore treated the medical record as valid unless “Valid/Invalid MR” was “Invalid.” This follows the approach described in paragraph 156(b) of the Renjilian Report.

28. Five fields¹⁰ in the “stacked” PFR data appear to indicate whether support for the HCC was found. I cross-tabulated the values of those fields, which showed that the “Initial Findings” field was always present, was always populated, and had the same value as the other fields when they were present. Hence, I based the determination of whether support for the HCC was found on “Initial Findings.” This follows the approach described in paragraph 156(c) of the Renjilian Report.

29. Combining Dx instances corresponding to individual member-HCC-years and checking whether they were audited by RADV involves matching enrollees in the RADV data to the same enrollees in the FIR data. For contract years 2011 through 2013, I performed that process by looking for any match between the “HICN,” “RRHICN,” “MBI,” and “RRMBI” member identifiers provided in the PFR crosswalk¹¹ and the “hicn” and “hist_hicn” fields provided in the FIR¹². The crosswalk provided with the updated Renjilian Report for contract years 2014 and 2015 list¹³s only a single member identifier for each enrollee ID (“HICNBR”), so for those years I check that against both the “hicn” and “hist_hicn” fields in the FIR.

30. My results match the 2011–2013 counts in the left panel of Figure 15 of the Renjilian Report, which gives the number of member-HCC-years supported by RADV audits according to whether the audited member-HCC-year was or was not in the FIR.

¹⁰ “hcc_2013out”, “hcc_2014out”, “Initial Findings”, “Initial Findings (2014 HCCs)”, and “HCC_Initial_Finding”.

¹¹ MAPL010977189

¹² Renjilian Support Materials, “CONFIDENTIAL - UPDATED AS OF 12-03-23 - FTI First Interrogatory Response Table.txt”

¹³ Renjilian Support Material, “CON14 CON15 Member Mapping.xlsx”

31. RADV found support for a substantially smaller fraction of the member-HCC-years not identified in Opinion 3 of the Renjilian Report than it did for the member-HCC-years identified in Opinion 3. RADV found support for the member-HCC-years that (according to Opinion 3 of the Renjilian Report) have financial impact at a much lower rate than it found for member-HCC-years that do not have financial impact: 61.3 percent versus 96.3 percent for the V12 model, and 58.6 percent versus 96.2 percent for the V22 model. Thus, the comparison in paragraph 165 of the Renjilian Report is inapt and misleading. Previously submitted member-HCC-years that had not been identified by a United coder in Chart Review, *and* that were found—by Mr. Renjilian’s analysis—to have financial impact if deleted, were supported at a rate that was lower than other member-HCC-years examined by RADV.

32. I performed a statistical test known as Fisher’s Exact Test¹⁴ to assess whether the difference in the rates at which RADV found support could reasonably be ascribed to “the luck of the draw.” Fisher’s exact test compares the observed difference in rates between two groups to the distribution of differences that would arise if the two groups were formed by randomly partitioning their union into two groups of the observed sizes; it is based on the hypergeometric distribution. The null hypothesis for this test is that member-HCC-years in FIR that Renjilian did not flag in Opinion 3 and that were reviewed by RADV were like a random sample of all the member-HCC-years reviewed by RADV. The (two-sided) P-value for the tests was less than 0.0000001: it would be extremely unlikely to observe this difference in rates (61.3 percent versus 96.3 percent for the V12 model HCCs, and 58.6 percent versus 96.2 percent for the V22 model HCCs) if the grouping were random.

33. This shows that there is a strong, statistically significant association between a Dx instance having financial impact if deleted (according to Renjilian’s Opinion 3) and that instance *not* being supported by the RADV audit. Dx instances in the FIR list that Renjilian’s Opinion 3

¹⁴ See, e.g., See, e.g., Kaye, D. and Freedman, D.A., 2011. Handbook on Statistics, in *Reference Manual on Scientific Evidence*, 3rd Edition, Federal Judicial Center, at 255 (note 108) and 287. I used a two-sided test.

identifies as having financial impact are supported at a much lower rate than Dx instances in the FIR list that Renjilian identifies as having no financial impact.

Table 2: RADV Support for FIR Dx instances by value of Renjilian's Opinion 3 Flag

Model	years	RADV supported Op3=1	RADV unsupported Op3=1	percent supported	RADV supported Op3=0	RADV unsupported Op3=0	percent supported	P-value
V12	all	3,082	119	96.3	537	339	61.3	<0.0000001
	11–13	767	31	96.1	213	108	66.4	<0.0000001
	14–15	2,315	88	96.3	324	231	58.4	<0.0000001
V22	all	2,106	84	96.2	331	234	58.6	<0.0000001

34. In Opinion 5 and Figure 15, Renjilian counts member-HCC-year combinations and does not consider the impact of his Opinion 3 on his calculations. Indeed, Opinion 5 does not even mention Opinion 3. Opinion 7, however, *does* consider the impact of Opinion 3, and acknowledges that the RADV support rate is significantly lower for HCCs that Renjilian’s analysis says would have financial consequences if deleted. However, for unclear reasons, the findings in Opinion 7 involve diagnosis instances rather than member-HCC-years. (Oddly, he reports the overall member-HCC-year counts but not the member-HCC-year counts that he concludes have financial significance.)

35. My method for replicating Renjilian’s results using the flags he added to the FIR table yields an exact match for CY2011–13. This suggests that my findings may well be compatible with Renjilian’s own figures. Using the same method, I find that 213 out of 321 member-HCC-year combinations in CY2011–13 not excluded by Renjilian’s Opinion 3 were reviewed and supported in RADV (for a support rate of 66.4%).

36. However, in CY2014–15, there is a small discrepancy¹⁵ between Renjilian’s counts of member-HCC-years in FIR that were audited by RADV and my counts: I find two fewer member-HCCs supported than he does (4,795 instead of 4,797) and sixteen more member-

¹⁵ The simultaneous use of two HCC models (V12 and V22) in CY2014 and CY2015 makes counting member-HCC-year combinations less straightforward than it is in CY2011 through CY2013. My goal for this analysis is to match Renjilian’s methodology in his Figure 15 as closely as possible, even though his chosen approach of “count[ing] member-V12 HCC and member-V22 HCC combinations separately and add[ing] them together” might not be well-specified or appropriate. Renjilian Report at fn. 236.

HCCs unsupported than he does (594 instead of 578). This suggests that Renjilian might have reached slightly different results than I do when applying Opinion 3 to his CY2014–15 analysis. My determination in CY2014–15 is that 632 out of 1,079 member-HCC-year combinations in CY2014–15 not excluded by Renjilian’s Opinion 3 were reviewed and supported in RADV (for a support rate of 58.6%).

37. For the entire RADV period, I find 1,400 member-HCC-year combinations in FIR that were audited by RADV, of which RADV found support for 845, a rate of 60.4 percent. In contrast, Figure 15 of the Renjilian Report finds that for RADV overall, there were 55,730 member-HCC-year combinations and that RADV found that 48,911 of them had support, a rate of 87.8 percent. I performed Fisher’s Exact Test to assess the statistical significance of this difference in rates. The resulting P-value was less than 0.0000001; the difference is highly significant. Thus the claim in Renjilian’s Opinion 5 that the overall rate of support in RADV is approximately the same as the rate at which RADV found support for member-HCC-years in FIR does not apply to the subset of member-HCC-years that, according to Renjilian’s Opinion 3, would have financial consequences if deleted.

III. The overall rates at which member-HCC-year combinations are supported by RADV audits are substantially higher than the rates at which member-HCC-year combinations in the Garthwaite Final Deletes List were supported by RADV audits: for V12, roughly 83 percent for RADV overall versus 57 percent for the limited number of member-HCC-years in the Garthwaite Final Deletes list that were audited, and for V22, 79 percent versus 55 percent. These differences in rates are large and highly statistically significant. Thus, the claim in Opinion 5 that HCCs in FIR are supported at similar rates to those in RADV is not true for those diagnosis instances in the Garthwaite Final Deletes List: RADV finds a substantially lower rate of support for those.

38. I constructed a crosswalk from RADV enrollee identifiers to the Garthwaite Final Deletes List using a method similar to the one I used for the FIR (discussed above), except that

the Garthwaite Final Deletes List contains up to three member identifiers per line (“hic1,” “hic2,” and “hic3”). I merged repeated instances of a given HCC for each member for each year, separately for V12 and V22 HCCs, both for RADV and for the Garthwaite Final Deletes List. I considered a member-HCC-year combination to be supported by RADV if that HCC was supported for that member for that year in anywhere in the RADV data. After calculating the rates of support, I assessed whether the differences were statistically significant using Fisher’s Exact Test, as described in ¶32, *supra*.

39. For the V12 model, overall, RADV found support for 41,681 of 49,978 audited member-HCC-year combinations, a rate of 83.4 percent. In contrast, RADV found support for 263 of the 463 member-HCC-year V12 combinations it checked that are among the Garthwaite Final Deletes List, a rate of 56.8 percent. This difference in rates is large and highly statistically significant, with a P-value below 0.0000001.

40. For the V22 model, overall, RADV found support for 37,969 of 48,044 audited member-HCC-year combinations, a rate of 79.0 percent. In contrast, RADV found support for 161 of the 295 member-HCC-year V22 combinations on the Garthwaite Final Deletes List that it checked, a rate of 54.6 percent. This difference in rates is large and highly statistically significant, with a P-value below 0.0000001. This shows that there is a strong, statistically significant association between a member-HCC-year appearing in the Garthwaite Final Deletes List and that combination not being supported by the RADV audit. Combinations in the Garthwaite Final Deletes List are supported at a much lower rate than combinations in the RADV data.

IV. The RADV samples of individual HCCs are very small. When sample sizes are small, the uncertainty in estimated support rates for individual HCCs is so large that the estimates are not helpful, even if the RADV sample were a simple random

sample of HCCs—which it is not.¹⁶ For instance, for a sample of size 10 drawn uniformly at random from a large population, the width of a 95 percent confidence interval for the population rate ranges from about 31 percent (if the rate in the sample is 0 or 100 percent) to about 63 percent (if the rate in the sample is 50 percent). For a sample of size 30, the width of the interval ranges from about 12 percent (if the rate in the sample is 0 or 100 percent) to about 37 percent (if the rate in the sample is 50 percent). For the Garthwaite Final Deletes List, less than 19 percent of the total risk adjustment (the sum of the risk adjustments for all members for all years) for V12 and less than 8 percent of the total risk adjustment for V22 involves HCCs that were sampled at least 30 times in all by RADV. No V12 or V22 HCC was sampled 30 times or more in any year. HCC sample sizes for individual contracts (and plans) and individual years need to be adequate to estimate support rates for individual contracts, plans,¹⁷ and individual years, since the rate at which a given HCC is supported may vary.

41. Paragraph 158 of the Renjilian Report states, “Finally, in my experience, a sample of 1,891 codes would generally be considered quite robust for most evaluative purposes. Thus, the RADV audit results form an instructive basis on which to assess the First Interrogatory Response.” This is nonsense from a statistical perspective, for several reasons:

A. To construct unbiased estimates from random samples and to assess the accuracy of estimates based on random samples requires taking into account the statistical design of the sample, namely, the probability of selecting each subset of the population. I understand that as of 2012, the RADV sample is a random sample of enrollees, not of HCCs; that it is stratified by contract and may draw a different number

¹⁶ “Simple random sample” is a term of art. A simple random sample is a sample of a pre-specified size drawn from a population in such a way that every subset of that size has the same probability of being the sample. See ¶41A, *infra*, for reasons the RADV sample is not a simple random sample of enrollee-HCC-years.

¹⁷ I understand that RADV audits are “contract-level,” not plan-level or organization-level. I understand that during the relevant time period, CMS did not extrapolate from the RADV sample to contracts nor to all contracts operated by a given parent organization; and that starting in 2018, CMS will extrapolate RADV sample results to contracts but not to all contracts operated by a parent organization such as United Health Group.

of enrollees from different contracts and have different sampling fractions for different contracts; that it is stratified within contracts by risk score tercile; and that it excludes some enrollees. It is a stratified cluster sample of member-HCC-years within individual contracts, and the sampling frame differs from the population.¹⁸ It is not a simple random sample of member-HCC-years in the First Interrogatory Response. The sampling design must be taken into account to construct unbiased estimates from the sample and to quantify the uncertainties of those estimates.

B. “Robust” is also a term of art in statistics, but the use of that term in the Renjilian Report is not correct. An estimator (a function of the sample data used to estimate a parameter of the population) is robust if “small” violations of the distributional assumptions that justify the use of the estimator do not have a large impact on the accuracy of the estimator.¹⁹ “Robust” does not apply to sample sizes.

C. Whether the sample size is adequate depends on the design of the sample and the purpose to which the sample will be put. There is no such thing as a generically “adequate” sample size nor a sample size that provides an “instructive basis.”

D. I do not know whether the medical records reviewed by RADV were the same as the records reviewed by United’s chart review program when both examined the same member-HCC-year instance. It is possible that the records reviewed in United’s chart review program differ from those reviewed by RADV. To the extent that the records examined by the two programs differ, extrapolating RADV results to FIR or the Garthwaite Final Deletes List will have additional bias, beyond statistical bias relating to how the sample was drawn, no matter how large the sample is.

42. The discussion of the CMS RADV audit in the Renjilian Report does not consider HCCs separately: it only finds overall support rates pooled across HCCs. Other than a brief

¹⁸ See, e.g., Kaye, D. and Freedman, D.A., 2011. Handbook on Statistics, in *Reference Manual on Scientific Evidence*, 3rd Edition, Federal Judicial Center, at 292, 296.

¹⁹ See, e.g., Kaye, D. and Freedman, D.A., 2011. Handbook on Statistics, in *Reference Manual on Scientific Evidence*, 3rd Edition, Federal Judicial Center, at 295.

discussion of proportional similarity in paragraph 158, the cross-HCC support counts and rates that Mr. Renjilian presents treat all member-HCC-year or diagnosis instances as fungible.

43. Notably, while the Salve Report has serious statistical deficiencies as discussed below, it *does* point out that support varies significantly across HCCs and that stratification by HCC is important. *See* Salve Report at paragraphs 47 and 58 and Appendices D and E. The financial impact of different HCCs is in general different, so any variability in the rates of support across HCCs (or even variability of the rate of support for a given HCC across contracts and years) has financial implications, which the Renjilian Report ignores. Ignoring differences in rates of support across HCCs is misleading for several reasons.

44. First, under the CMS payment system, the mix of member-HCCs matters, not just the total number of HCCs.²⁰ There is no reason to assume that the RADV process examines or finds support for different HCCs at the same rate or finds support for the same HCC at the same rate in different years or for different contracts—indeed, there are reasons to assume the opposite.

45. Second, reporting only a pooled rate of support for all HCCs in the RADV data obscures the fact that the RADV sample is not a simple random sample of member-HCC-years and that the sample size for estimating the rates at which RADV finds support for individual HCCs overall, within individual years, and/or within particular contracts is often tiny. Indeed, two V12 HCCs in the Garthwaite Final Deletes List were not sampled at all by RADV. The sample sizes are smaller for comparisons limited to the relevant member-HCC-years (RADV overlap and support for member-HCC-year combinations present in the Garthwaite Final Deletes List). They are even smaller for HCCs within individual contract years. I understand that contract-years may be a more appropriate unit of analysis for financial issues than years without regard to contract, in part because RADV samples members from individual contracts.

²⁰ *See e.g.*, Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 4, 2011), at Table 9.

Moreover, I understand that contract-years may differ in characteristics that affect support rates overall and for individual HCCs (e.g., geography, providers, and patient demographics). I am not aware of any affirmative evidence that RADV finds support for HCCs in different contract-years at the same rates.

46. To make an unbiased estimate of the rate at which a particular HCC is supported by RADV in a particular period of time and/or for a particular contract and to quantify the uncertainty of any estimate (biased or not) requires knowledge of how the sample is drawn. The uncertainty will be large unless the sample size of that HCC from that period of time and/or contract is adequately large. I calculated the RADV sample sizes for each HCC-contract-year combination,²¹ separately for the V12 model HCCs and the V22 model HCCs. I also calculated the RADV sample sizes for higher levels of aggregation, including HCC-year combinations without regard to contract, HCC-contract combinations without regard to the year, and overall HCC sample sizes without regard to contract or year.

47. Because there are nearly 80 HCCs, many contracts, five years, and two risk models, there are thousands of HCC-contract-year combinations: 9,270 for model V12 and 4,157 for model V22. To summarize the sample sizes for such a large number of populations, I calculated the fraction of the “final deletes total risk score” (the total of the risk scores of the HCC-enrollee-years that, per Dr. Garthwaite’s analysis, should be deleted)²² represented by combinations that were sampled at least once, twice, ..., and at least 30 times, for each level of aggregation (all contracts in all years, each contract without regard to year, each year without regard to contract, and each contract in each year).

²¹ I understand that some contracts and plans merged or were renumbered in various years. To be conservative, I pooled the sample sizes for all contracts that were connected to each other according to CMS, even if only some plans moved from one of those contracts to another. See <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/plan-crosswalks> (last visited 27 January 2024).

²² To find the risk adjustment for each HCC under the V12 and V22 models, as appropriate, I downloaded the corresponding SAS code from CMS. <https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment> (last visited 24 January 2024) The “final deletes total risk score” that I computed does not account for interactions among HCCs nor for whether an HCC lower in the hierarchy of a deleted HCC would have been determined to be supported.

48. To calculate these summaries, first I calculated the “final deletes total risk score” for each level of aggregation, separately for V12 and V22. I repeated that calculation, omitting HCCs that RADV had not sampled at least once, at least twice, etc., up to at least 30 times at that level of aggregation (overall, per contract, per year, or per contract per year). The result of these calculations is in Figure 1, plotted separately for each contract year. The highest curve in each panel (blue, dots) is for aggregation across all contracts and all years; the second-highest (green, dots and dashes) is for aggregation within years across contracts; the third-highest (orange, dashes) is for aggregation within contracts across years; and the lowest (red, solid) is for aggregation within contracts and within years.

49. Figure 1 shows that roughly 20 percent of the final deletes total risk score is in HCCs that were sampled 20 times or more across all years and all contracts. Less than 30 percent of the final deletes total risk score is in HCCs that were sampled even once in the corresponding a contract-year, and in some instances (e.g., the V12 model in CY2011, 2012, and 2013), this figure is less than 10 percent. A vanishingly small fraction is in HCCs that were sampled at least five times in the corresponding contract-year. Because these sample sizes are so small, estimates of the population support rate based on the RADV sample would have very high uncertainty, regardless of how the RADV sample was drawn.

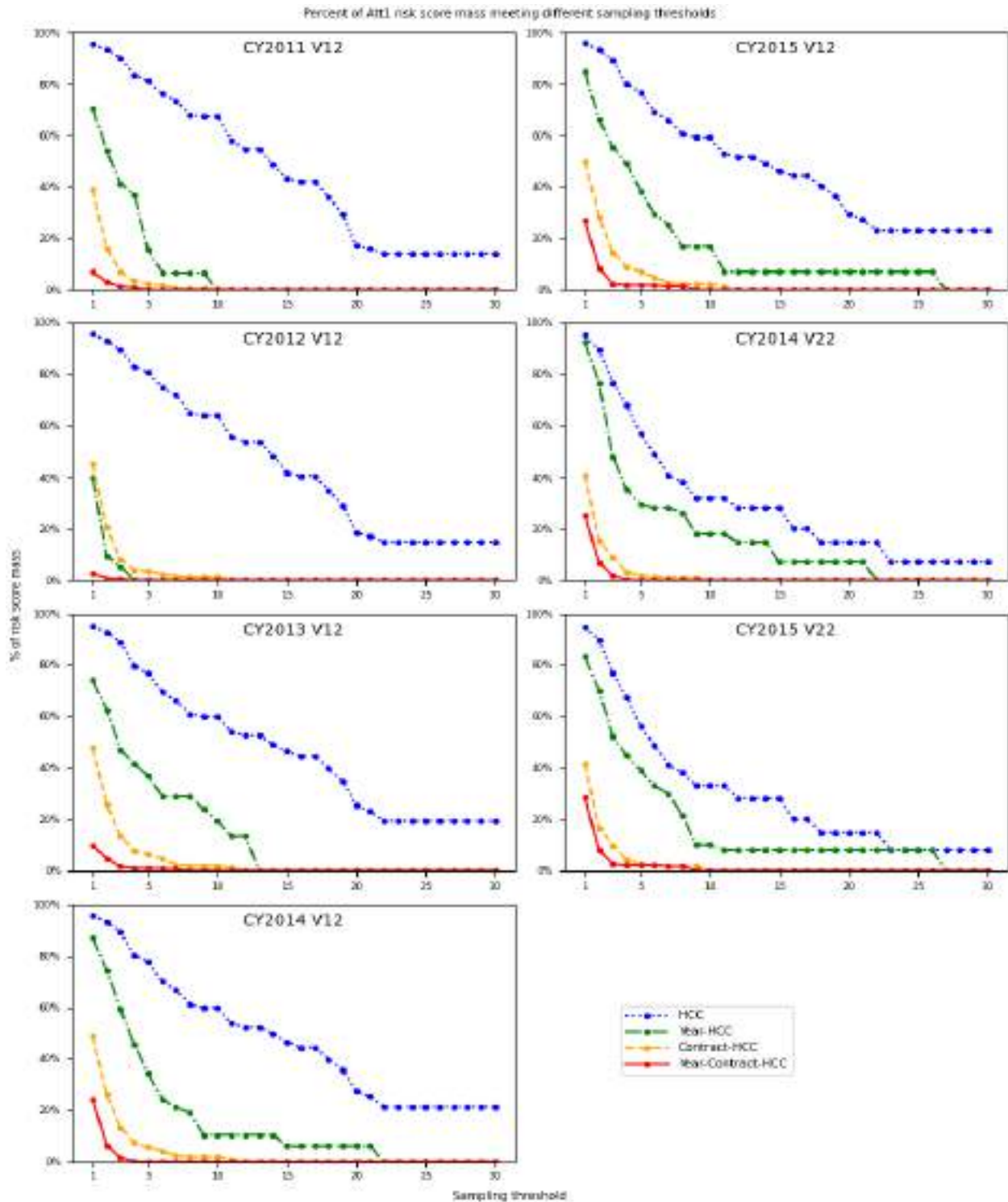
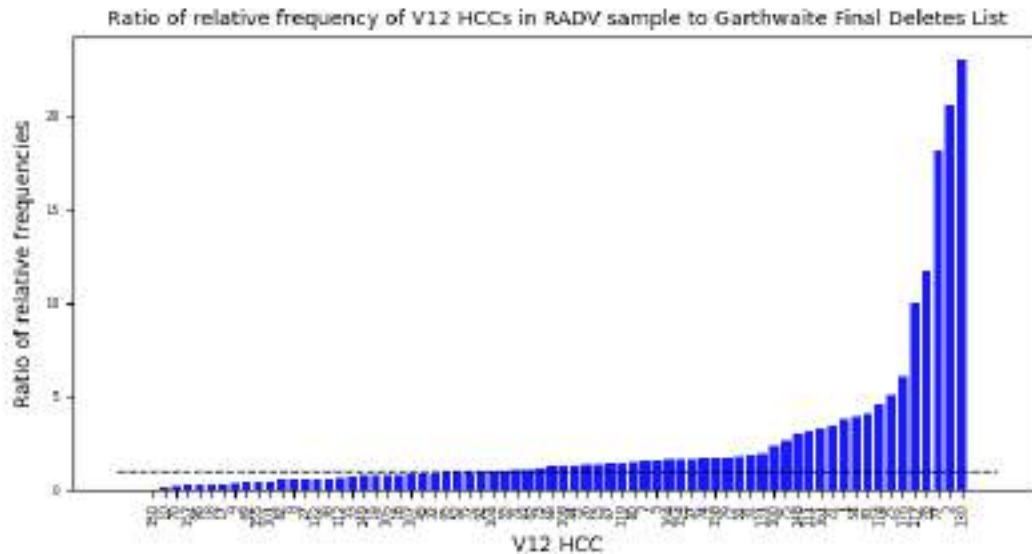


Figure 1: Percentage of the “final deletes total risk score” in groups of HCCs sampled at least 1, 2, ..., 30 times. HCC: samples per HCC without regard to year or contract. Year-HCC: samples per HCC per year. Contract-HCC: samples per contract. Year-Contract-HCC: samples per HCC per contract per year.



50. Figure 2 shows, for each HCC in the V12 model, the ratio of the relative frequency of the HCC in the RADV sample to its relative frequency in the Garthwaite Final Deletes List. Figure 3 shows, for each HCC in the V12 model, the ratio of the relative frequency of the HCC in the RADV sample to its relative frequency in the First Interrogatory Response (FIR). The ratios vary from 0 (for HCCs that were not sampled at all in RADV) to almost 29. If the sample were representative, all the ratios would be close to 1.

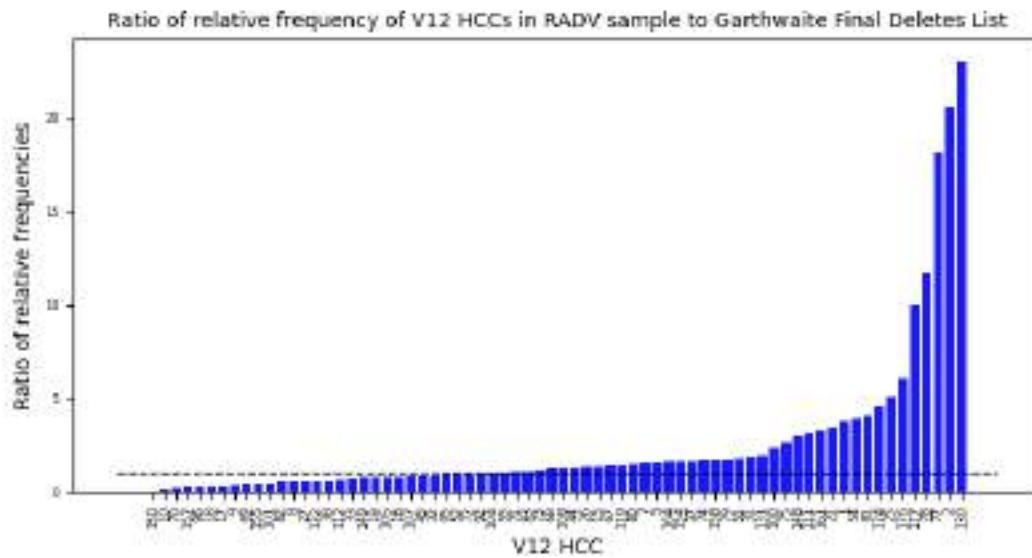


Figure 2: Ratio of relative frequencies of V12 HCCs in the RADV sample to their relative frequencies in the Garthwaite Final Deletes List, sorted by ratio. The dashed horizontal line corresponds to equal relative frequencies.

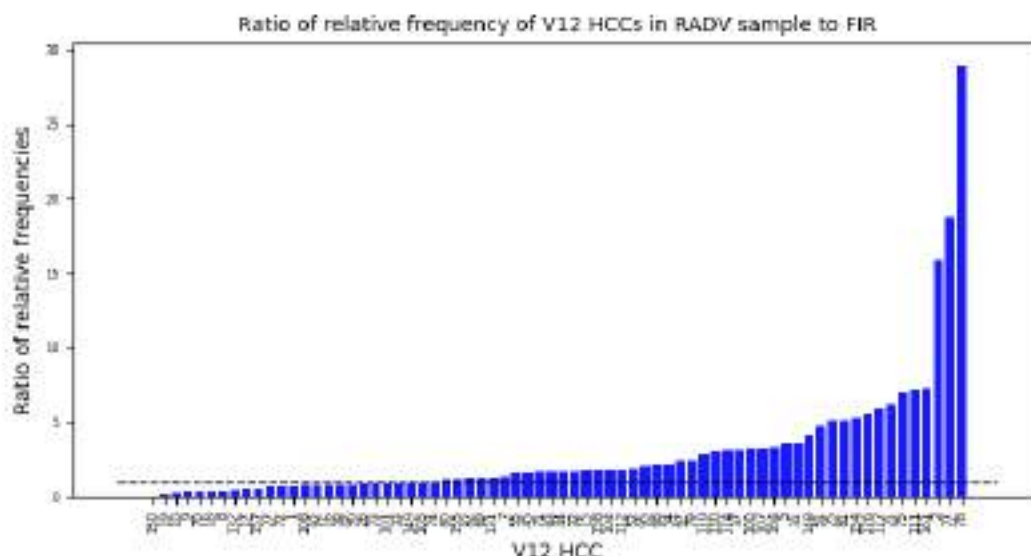


Figure 3: Ratio of relative frequencies of V12 HCCs in the RADV sample to their relative frequencies in the First Interrogatory Response (FIR), sorted by ratio. The dashed horizontal line corresponds to equal relative frequencies.

51. The large differences in relative frequencies of HCCs in the RADV sample versus their relative frequencies in the two populations in question suggest that if the RADV sample is a random sample at all, it is not a simple random sample from either of those populations. Indeed, for the hypotheses that the RADV HCCs are a simple random sample from populations with the same HCC frequencies as the Garthwaite Final Deletes List or from the First Interrogatory Response, chi-square tests based on the HCC frequencies yield P-values below 0.0000001: the V12 HCCs in the RADV sample are not representative of either of those populations. This is unsurprising given how the RADV sample is drawn.

52. Because the rate of support may vary by HCC (and by contract and by year), because the mix of HCCs differs so much between the RADV sample and the two populations in question, and because the RADV sample is not a simple random sample of member-HCC-years, extrapolating the overall rate of support in the RADV sample to the Garthwaite Final Deletes List or to the Dx instances in the FIR list may have considerable statistical bias. The design of the RADV sample needs to be taken into account, and an adjustment for the different mixes of HCCs is needed.

Summary of Opinions Regarding the Renjilian Report

53. In summary, the Renjilian Report's conclusions about the rate of diagnosis events that have no financial consequences (either because they are subject to Opinion 2 or Opinion 3) does not apply to the Garthwaite Final Deletes List, which contains very few diagnosis events flagged by Renjilian's Opinion 2 and/or Opinion 3. The rate at which RADV found support is much lower different for diagnosis instances in the FIR list with financial consequences (according to Renjilian Opinion 3) than it is for those without financial consequences. Yet the Renjilian Report ignores those differences, which undermine Opinion 5. The overall rate at which RADV found support is much higher than the rate at which it found support for member-HCC-years within the Garthwaite Final Deletes List: the raw RADV support rate should not be extrapolated to the Garthwaite Final Deletes List. (Moreover, the raw RADV support rate is not an unbiased estimate of the overall support rate for HCCs, because of how the RADV sample is drawn.) In addition, the Renjilian Report lumps together all HCCs, even though the deletion of different HCCs has different financial consequences and the rates at which RADV found support for different HCCs varies. The RADV sample size is very small (even zero) at the level of some individual HCCs, and smaller still if HCCs in different contracts and/or years are considered separately, which they should be if the rates of support differ across such groups and because the RADV sample is drawn separately from different contracts. The Renjilian Report treats the RADV sample as if it were a simple random sample from the relevant population of member-HCC-years, but it is not.

The Salve Report

V. The Salve Report did not draw a proper random sample of HCCs. It relied on a pseudo-random number generator that was inadequate for drawing samples of 50 HCCs from populations as large as those the samples were drawn from.

54. Most computers cannot generate truly random numbers. Instead, they use algorithms called *pseudo-random number generators* (PRNGs) to produce sequences of numbers that behave, to some degree of approximation, like truly random numbers. The degree of

approximation depends on details of the PRNG: some are better than others. Some are suitable for some purposes but not for others. The quality of PRNGs—how hard it is to tell that their output is not truly random—varies widely. A high-quality PRNG generally involves more complicated computations and is thus slower than lower quality PRNGs. When choosing among PRNGs, one should consider the purpose to which the pseudo-random numbers will be put. Some applications require higher quality PRNGs than others.

55. A PRNG generally operates as follows: starting from an initial *state* (related to a *seed*), the PRNG calculates an output (some number of pseudo-random bits) and updates its state to a new state. The *state space* is the set of possible states of the PRNG. The *period* is the number of outputs the PRNG can have before it starts to repeat itself. The period cannot be larger than the number of possible states.

56. Dr. Salve used the default PRNG in STATA, the Mersenne Twister, to draw samples of 50 members for each HCC. He used the Mersenne Twister to assign a pseudo-random number to each member-HCC pair, sorted the pairs within each HCC to put them in a pseudo-random order, then took the top 50 in each sorted list. Salve Report, at ¶60. I call that approach PIKK: permute indices and keep the top k .²³ The PIKK approach is like dealing a hand of cards: you can deal a hand of five random cards by shuffling the entire deck thoroughly to put the cards in a random order, then dealing the top five cards. It is crucial to shuffle thoroughly—well enough that every set of five cards is equally likely to be the top five cards in the deck.

57. PIKK works in theory with perfect random numbers, but it cannot work in practice with the particular PRNG that Salve used, for populations as large as the member-HCC population from which he sampled. Because of the size of its state space, the Mersenne Twister cannot construct every permutation of lists of more than 2,083 items,²⁴ but Dr. Salve tries to use

²³ See Stark, P.B., and K. Ottononi, 2018. Random Sampling: Practice Makes Imperfect. <https://arxiv.org/pdf/1810.10985.pdf> (last accessed 15 November 2023).

²⁴ The state space for the Mersenne Twister contains 19,937 bits. Two to the power 19,937, the number of possible states of the Mersenne Twister, is between 2,083 factorial (the number of orderings of 2,083 distinguishable items) and 2,084 factorial (the number of orderings of 2,084 distinguishable items). See Stark, P.B., and K. Ottononi, 2018. Random Sampling: Practice Makes Imperfect, <https://arxiv.org/pdf/1810.10985.pdf> (last visited 11 January 2024).

it to permute up to 3,100,061 things (for HCC 96). The ratio of the number of possible permutations of 3,100,061 things to the number of permutations that the Mersenne Twister can generate has more than 18 million digits before the decimal point. The Mersenne Twister is grossly underpowered for drawing samples from such large populations using PIKK. The PIKK approach using the Mersenne Twister cannot shuffle such a large deck (3,100,061 items) well at all.

58. Of the 79 HCCs in the dataset, 77 occur more than 2,083 times (only HCC 110 and HCC 166 have fewer occurrences). Dr. Salve's approach cannot in principle generate simple random samples of any of those 77 HCCs.

59. Dr. Salve could have drawn better random samples of HCCs in many different ways. To do so would require both a better PRNG (for instance, one based on cryptographic hash functions, as in the cryptorandom python package²⁵, which I co-wrote) and a better algorithm than PIKK for drawing random samples, such as the Fisher-Yates-Knuth-Durstenfeld method.

60. Because Dr. Salve's samples were not drawn in a way that ensures that each subset of 50 member HCC-pairs had the same chance of being selected from the data he had for each HCC, the estimates he computes are statistically biased to an unknown extent and in an unknown direction. The usual formulae for calculating uncertainties for statistical estimates do not apply to his results, because the samples were not drawn properly. There is no way to quantify the uncertainty in the estimates and conclusions he draws from the samples. In short, none of his statistical analyses is sound and none of the statistical conclusions he draws from the sample of HCCs is reliable, because the first step—drawing the sample—was done poorly.

61. The statistical tests in the Salve Report demonstrate that the sample of HCCs is not representative. The Salve Report misinterpreted the results of the tests it reported as supporting its conclusion that these samples were representative.

²⁵ See <https://github.com/statlab/cryptorandom> (last accessed 15 November 2023).

VI. The samples of HCCs in the Salve Report are not representative of the population from which they were drawn. The differences are large and statistically significant. The Salve Report misinterprets the results of the tests performed. Those tests were statistically weak, statistically inappropriate, and considered only two of many variables that could have been examined. In concluding that its test results showed no statistically significant difference between the member-HCC pairs sampled and the member-HCC pairs in the dataset from which it drew the sample, the Salve Report makes the basic logical error of conflating “weak evidence of a difference” with “affirmative evidence of no difference.”

62. Many of the Salve samples differ substantially from the populations from which they were drawn. For example, consider the cost variable, APAY_NonDual14. For nine HCC/sample-size combinations, the difference between the population mean and the sample mean *is larger than the population mean*. In one case, HCC 104, for the overall sample size 2,493 (the middle block in Table 3 below), the population mean is \$29,157 but the sample mean is \$123,310. This is a difference of \$94,153, more than three times the population mean! Table 3: Sample Means That Differ from Population Means by 50% or more, lists 35 combinations of HCC and sample size for which the difference between the APAY_NonDual14 for the Salve sample and the mean APAY_NonDual14 for the population is at least 50 percent of the population mean. The samples are hardly representative of the population in those examples.

Table 3: Sample Means That Differ from Population Means by 50% or more

HCC	Overall Sample Size	Population mean (\$)	Sample Mean (\$)	Difference (\$)	Relative difference (%)
18	3,950	20,077	7,400	12,677	63
19		12,845	5,217	7,627	59
34		26,265	49,411	23,146	88
73		33,180	79,084	45,904	138
74		23,964	46,463	22,499	94
104		29,157	65,856	36,699	126
161		26,960	48,395	21,435	80
162		40,282	15,502	24,780	62
170		29,253	77,236	47,983	164
176		30,970	57,924	26,954	87
12	2,493	12,103	5,911	6,192	51
18		20,077	9,433	10,643	53
19		12,845	5,259	7,586	59
34		26,265	60,593	34,328	131
39		33,718	14,497	19,220	57
73		33,180	87,128	53,949	163
75		25,309	38,697	13,388	53
77		19,683	31,874	12,191	62
99		32,938	53,667	20,730	63
104		29,157	123,310	94,153	323
161		26,960	50,106	23,146	86
162		40,282	14,624	25,658	64
170		29,253	106,703	77,450	265
189		35,661	58,105	22,444	63
11	2,370	17,143	7,769	9,374	55
18		20,077	5,745	14,331	71
19		12,845	4,236	8,609	67
23		22,573	10,570	12,003	53
34		26,265	67,511	41,246	157
73		33,180	61,409	28,229	85
99		32,938	55,753	22,815	69
134		56,550	87,606	31,056	55
162		40,282	17,265	23,017	57
170		29,253	112,056	82,803	283
176		30,970	47,149	16,178	52

63. Nonetheless, the Salve Report claims repeatedly that the samples are “representative” of the populations.²⁶ This erroneous conclusion is based on misinterpreting the

²⁶ “I confirmed via statistical tests that the beneficiaries associated with a particular sampled HCC marker (“sampled beneficiaries”) were statistically representative of the beneficiaries in the larger FFS calibration data

statistical tests Dr. Salve conducted,²⁷ as I shall explain. Not only are there large differences between many of the samples and the populations they were drawn from, those differences are statistically significant according to the tests reported in the Salve Report, which misinterpreted the results. Moreover, the statistical tests the Salve Report used are inappropriate and weak, and the Salve Report failed to examine all the fields in the data that were available.

64. The Salve Report only tested two variables (APAY_NonDual14 and WGT_NonDual14). Salve Report at ¶¶62–66. Many other facially relevant variables were available for Dr. Salve to examine. For instance, the Salve Report did not check whether the mix of plans in the sample was representative nor whether the mix of member ages was representative. Furthermore, there is no way to check whether the sample is representative with respect to support for HCCs, because that information is available only *after* inspecting the sampled medical records. If that information were available, there would be no reason to draw a sample.

65. The two particular tests used in the Salve Report to test representativeness, the Student-t test and the Kolmogorov-Smirnov test, are relatively weak (their *statistical power*, the probability that they detect a true difference, is relatively low), as I shall explain.

66. Student's t test is not appropriate for samples from populations that do not have a normal distribution (it can produce nominal P-values that are very different from its actual P-values), and it only tests for a difference in means, not other differences in the distributions.

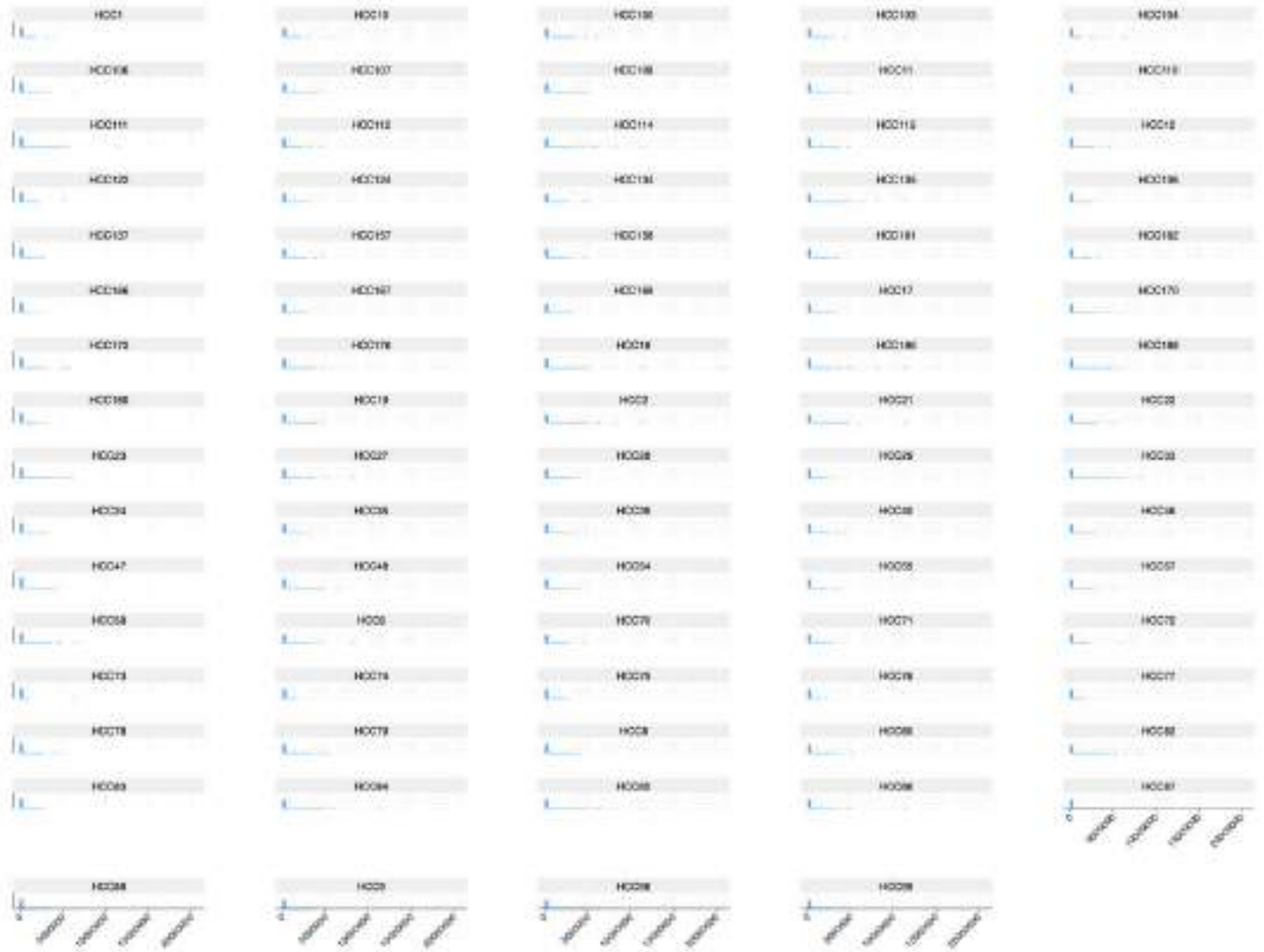
When population distributions are skewed, Student's t test tends to have only a small chance of

population who were identified as having that HCC in their health profile in the diagnosis year but who were not sampled ("**non-sampled beneficiaries**")." Salve Report, at ¶19.1 "For each of the 79 different HCCs, the 50 unique beneficiaries associated with the 50 sampled HCC markers are statistically representative of the population of beneficiaries who have that specific HCC marker." Salve Report, at ¶49. "Through these tests, I was able to ensure that the sampled beneficiaries (the beneficiaries associated with the sampled HCC markers) were statistically representative of the larger population of beneficiaries associated with those markers and that the estimates of the HCC error rates were accurate." Salve Report, at ¶64.

²⁷ Had the samples been drawn properly using an adequately powered PRNG and an appropriate sampling algorithm, there would be no point in conducting any test of representativeness: the possibility that the samples are not representative is automatically taken into account in appropriate methods for statistical inference. Indeed, if Dr. Salve had planned to draw new samples if his samples failed the tests, standard tests of significance and standard methods for computing confidence intervals using the resulting samples would not have been applicable. However, as described above, the samples were not random, and the tests in the Salve Report demonstrate that fact.

finding real differences. The cost figures, column APAY_NonDual14, are strongly skewed to the right for all HCCs, as shown in Figure 4: Histograms of Annualized Payments by HCC. A 2-sample permutation test would be more appropriate than the Student-t test.

Figure 4: Histograms of Annualized Payments by HCC



67. The Kolmogorov-Smirnov test is known to have little sensitivity to differences in the tails of distributions. The Stata documentation warns, “[i]n general, the Kolmogorov – Smirnov test (Kolmogorov 1933; Smirnov 1933; also see Conover [1999], 428 – 465) is not very

powerful against differences in the tails of distributions.”²⁸ (The “tails” of a distribution are the frequencies of large and small values.)

68. The Salve Report claims, “[f]or each of these statistical tests of representativeness, the null hypothesis being tested is that the sample is representative of the population.” Salve Report, at ¶67. That is incorrect. For the 1-sample Student-t test, the null hypothesis is that the parent population has a normal (“Gaussian”) distribution with a given mean and variance, and that the sample is a random sample from that population. For the Kolmogorov-Smirnov test, the null hypothesis is that the sample is a random sample from the population. “Representativeness” is not part of either null hypothesis.

69. The Salve Report misinterprets the number of “failed” tests, erroneously concluding that because relatively few tests gave results that were statistically significant at the 5 percent level, the data passed the suite of tests as a whole. In fact, the tests provide strong statistical evidence that the HCC sample is not random to an adequate degree of approximation—which is to be expected because the method used to draw HCC samples was inappropriate. I shall explain in detail why Salve’s conclusion that his samples are adequately random is incorrect.

70. The Salve Report states, “[t]he number of tests expected to pass will depend on the significance level and the number of tests performed. In this case, I conducted 316 tests at a 5% significance level, and therefore, I would expect approximately 16 tests (5% of 316) to produce a false positive result due to random chance. Therefore, approximately 300 tests (95%) should pass the statistical test by chance alone.” Salve Report, at ¶68. That statement is inside out. The correct statement is that if every null hypothesis were true, one would expect roughly 5 percent of the tests to produce yield results that are “statistically significant” at significance level 5 percent.²⁹

²⁸ Stata Corporation, “ksmirnov — Kolmogorov–Smirnov equality-of-distributions test,” at p4. <https://www.stata.com/manuals/rksmirnov.pdf> (last visited 26 November 2023).

²⁹ See, e.g., Kaye, D. and Freedman, D.A., 2011. Handbook on Statistics, in *Reference Manual on Scientific Evidence*, 3rd Edition, Federal Judicial Center, at pp. 249–257 and n. 100.

71. There are a variety of ways of “adjusting” P-values to account for the fact that many tests were performed. The simplest and most conservative is called the *Bonferroni adjustment* or *union bound*. It simply multiplies P-values by the number of tests that were performed. Dr. Salve ran 948 tests in all:

$$(79 \text{ HCCs}) * (3 \text{ sample sizes}) * (2 \text{ variables}) * (2 \text{ tests}) = 948.$$

72. The four smallest P-values among those 948 tests were 0.00000002058, 0.00000006436, 0.000002071, and 0.00001810. After the Bonferroni adjustment, they become 0.00001951, 0.00006101, 0.00196330, and 0.01715880: all remain substantially less than 5 percent, the threshold for statistical significance used in the Salve Report.³⁰ Hence, even though 948 tests were performed, the chance that *any* of them would have produced a small P-value as small as the smallest if the samples had been random is less than 0.002 percent. Similarly, the chance that any would have produced a P-value as small as the fourth-smallest is less than 1.72 percent. Thus, the tests Dr. Salve performed provide compelling statistical evidence that the samples were *not* approximately random. It is unsurprising that the samples failed the tests since they were drawn using an inadequate PRNG with an inappropriate sampling algorithm.

73. The Salve Report confuses ‘no statistical evidence of a difference’ with ‘statistical evidence of no difference.’ Viz, “[o]f the 316 tests conducted, 306 (97%) tests passed at the 5% significance level when conducted on the sample of 3,950 sampled and spare HCC markers. Similarly, 309 (98%) tests passed at the 5% significance level when conducted on the sample of 2,370 sampled HCC markers only. These results indicate that the samples are highly representative of the larger population and that the estimates of the HCC error rates are reliable.” Salve Report, at ¶69.

74. The ability of a statistical test to find a real difference generally increases as the sample size increases. By Dr. Salve’s faulty logic, if samples of size 5 gave larger P-values than the samples of size 50 he drew, those smaller samples would be *stronger* evidence that the

³⁰ If they were adjusted for only 316 tests, the number Dr. Salve focuses on (despite having performed at least 948 tests), the results would be even more significant.

samples were representative! In fact, a large P-value (or “insignificant” test result) is not evidence that the null hypothesis is true, merely the absence of evidence that the hypothesis is false. This is an elementary statistical error.³¹

75. Moreover, as explained above, if the samples were genuinely random the chance that any of the 948 P-values would be as small as 0.00000002058 is not greater than 0.002 percent, far less than 5 percent. The tests reported in the Salve Report thus provide strong statistical evidence that the samples were *not* in fact random samples. They do not provide affirmative evidence of representativeness, as the Salve Report claims.

76. Also, as explained above, the Salve Report stacked the deck by selecting inappropriate, weak tests and by testing only two of the available variables. Those two tests were unlikely to find real differences, because of the nature of the tests and (for Student’s t test) because of the extreme skewness of APAY_NonDual14—they have low *power*.

77. Finally, even if the sample sizes had been larger *and* the tests had been more powerful *and* the tests had not given such strong evidence that the sampling had gone wrong, that would not constitute affirmative evidence that the samples are representative with respect to the variable he draws conclusions about, namely, whether the HCC code has support.

VII. The Salve Report commits many basic statistical gaffes. In addition to the errors described above, the Salve Report misuses statistical terminology such as “statistically valid” and “statistically significant.” It uses complex approximate statistical methods in situations for which there are simple exact or conservative

³¹ This is addressed in Kaye, D.H., and D.A. Freedman, Reference Guide on Statistics, in National Research Council, 2011. *Federal Judicial Center Reference Manual on Scientific Evidence*, 3rd edition, at pp. 250–251: “p is not the probability of the null hypothesis given extreme data.”; also at fn. 99:

“(‘According to Dr. Howell, . . . a ‘P value’ of 0.30 . . . indicates that there is a thirty percent probability that the results of the . . . [s]tudy were merely due to chance alone.’). Such statements confuse the probability of the kind of outcome observed, which is computed under some model of chance, with the probability that chance is the explanation for the outcome—the “transposition fallacy.”

“Instances of the transposition fallacy in criminal cases are collected in David H. Kaye et al., *The New Wigmore: A Treatise on Evidence: Expert Evidence* §§ 12.8.2(b) & 14.1.2 (2d ed. 2011). In *McDaniel v. Brown*, 130 S. Ct. 665 (2010), for example, a DNA analyst suggested that a random match probability of 1/3,000,000 implied a .000033 probability that the DNA was not the source of the DNA found on the victim’s clothing. See David H. Kaye, “False But Highly Persuasive”: How Wrong Were the Probability Estimates in *McDaniel v. Brown*? 108 Mich. L. Rev. First Impressions 1 (2009).”

methods. It includes negative values in confidence intervals for quantities that cannot be negative. It reports narrower confidence intervals for quantities that involve additional unknowns. It interprets associations as if they were causal relationships, treating invented models with no theoretical or empirical support as if they were response schedules. It ignores uncertainties due to modeling assumptions. Its treatment of missing charts has no statistical foundation.

78. The Salve Report makes a number of basic statistical errors. For instance, paragraph 3 of the Salve Report states, “[m]y study began with drawing a statistically valid sample of HCC markers found in the 2013 HCC Dataset referenced above.” There is no such thing as “statistically valid sample” as a term of art in Statistics.³² Moreover, as discussed above, the sample was not drawn using an appropriate method, and it fails a number of statistical tests performed by Dr. Salve.

79. Similarly, Dr. Salve writes, “This sample size of 50 HCC markers per each HCC yielded enough HCC markers with collected Chart information such that 77 of the 79 HCC error rates were statistically significant at the 95% confidence level.” Salve Report, at ¶48. This is garbled in a number of ways, as I shall explain.

80. First, *any* nonzero rate is statistically significantly different from zero in this situation, because if the true population rate were zero, it would be impossible to observe even a single unsupported HCC in the sample. No statistical calculation is needed. In the samples the Salve Report relies on, every HCC except HCC 96 had at least one instance in which all requested, “risk-eligible” charts for a beneficiary were received, and yet none of those charts

³² Kaye and Freedman (2011) discuss statistical terms for describing samples in the context of discussing the misuse of ‘statistical significance’: “Many a sample has been praised for its statistical significance or blamed for its lack thereof. Technically, this makes little sense. Statistical significance is about the difference between observations and expectations. Significance therefore applies to statistics computed from the sample, but not to the sample itself, and certainly not to the size of the sample. Findings can be statistically significant. Differences can be statistically significant (supra Section IV.B.2). Estimates can be statistically significant (infra Section V.D.2). *By contrast, samples can be representative or unrepresentative. They can be chosen well or badly (supra Section II.B.1). They can be large enough to give reliable results or too small to bother with (supra Section IV.A.3). But samples cannot be “statistically significant,” if this technical phrase is to be used as statisticians use it.*” Kaye, D. and D.A. Freedman, 2011. Reference Guide on Statistics, in *Reference Manual on Scientific Evidence*, 3rd edition, Federal Judicial Center, at 252. (emphasis added).

provided support for the HCC at issue. Thus the raw data provide *certainty* (not merely statistical evidence) that the rate of unsupported HCCs in the population from which the sample was drawn is greater than zero for 78 of the 79 HCC codes, on the assumption that the chart reviews were accurate and that charts that were not requested would not have shown support. When data are incompatible with the null hypothesis, they are statistically significant. Dr. Salve's claim that two of the observed rates were not "statistically significant" is a basic statistical error.³³

81. Second, it is impossible for the rate of unsupported HCCs to be negative. Nonetheless, two of the confidence intervals for rates in the Salve Report include negative values: "[t]he 2 HCC error rates that were not statistically significant at the 95% confidence level were HCC 124 and HCC 189 with confidence interval lower bounds of -0.0088 and -0.0065, respectively." Salve Report, at note 25. Reporting negative lower endpoints for confidence intervals for rates of support, which cannot be negative, suggests that Dr. Salve used an inappropriate method to construct his confidence intervals or did not calculate or report the intervals correctly. If Dr. Salve used this same method to calculate confidence intervals for all HCCs, then there is reason to be skeptical of his conclusions for all HCCs, not only HCC 124 and HCC 189.

82. The method the Stata survey package³⁴ uses for constructing confidence intervals for rates cannot produce a negative lower endpoint. However, the method Stata uses to find confidence intervals for rates is not the best in this situation: it is approximate rather than exact.³⁵ Had the Salve samples actually been random, exact or conservative confidence intervals would be straightforward to calculate. See paragraphs 95–98, *infra*, for *pro forma* calculations of such confidence intervals.

Treatment of Charts That Were Not Retrieved

³³ See also paragraph 104, *infra*.

³⁴ <https://www.stata.com/manuals/svy.pdf> at pp148, 167ff (last accessed 15 November 2023)

³⁵ It is based on the normal approximation to the logit transform of the rate. <https://www.stata.com/manuals/svy.pdf> (last accessed 15 November 2023)

83. Some of the charts requested by Dr. Salve were not retrieved. Had all the requested charts been available, support for the HCC instances could not have decreased; it might have increased. However, it is impossible to know how many additional HCC instances would have been supported by the unretrieved charts.

84. Rather than accept the uncertainty in rates of support produced by these charts, the Salve Report purports to estimate the number of additional HCC instances the missing charts would have supported. The approach to estimating the number of HCC instances that would have found support involves making up a model for whether an HCC instance is supported. According to the (logistic regression) model Dr. Salve made up, whether an HCC instance has support is not an unknown fact (like whether a previously tossed coin landed showing heads or tails). Instead, it is random (like whether a yet-to-be-tossed coin *will* land heads or tails). According to the logistic regression, the “probability” that a given HCC instance has support in an unretrieved chart depends on the HCC, the number of charts requested, and the number of charts retrieved, and the value of APAY_NonDual14, according to a specific formula.

85. Logistic regression makes strong assumptions that have neither a theoretical nor an empirical basis here.³⁶ In the current context, logistic regression assumes that a given HCC-member pair has support if and only if a particular sum is greater than zero. In Dr. Salve’s model, that sum consists of a random variable with a logistic distribution, a constant that depends only on the particular HCC at issue, a second constant that is multiplied by the number of charts requested, a third constant that is multiplied by the number of charts that were unavailable, a fourth constant that is multiplied by both the number of charts requested and the number of charts unavailable, and a fifth constant that is multiplied by the value of APAY_NonDual14. Salve Report, at figure 4. The random variables are assumed to be independent and identically distributed across HCC-member pairs. These are very restrictive assumptions with no theoretical

³⁶ See, e.g., Freedman, D.A., 2009. *Statistical Models: Theory and Practice*, Cambridge University Press, at 121–128, 153–154.

basis in this application, nor any empirical basis to the best of my knowledge. The Salve Report provides none.

86. The Salve Report attempts to draw *causal inferences* using logistic regression to answer a hypothetical counterfactual question: had the unretrieved charts been retrieved, how many additional HCC-member pairs would have been supported?

87. That is entirely speculative. The Salve Report conflates observed associations (on average, HCC instances for which a larger fraction of requested charts were available were supported more often) with causal inference (if every requested chart for a particular HCC instance had been retrieved, would that HCC instance have been supported?)

88. The Salve Report also conflates rates (the fraction of HCC instances with various characteristics that were supported) with probabilities (the “likelihood” that a particular HCC instance is supported³⁷). A given chart either does or does not support a particular HCC instance. There is no “likelihood” or probability involved. There are *rates* at which HCCs with various characteristics are supported, but rates are not probabilities.³⁸

89. Fitting curves to data is unobjectionable. But using a fitted curve to (reliably) predict the effect of interventions—such as whether retrieving additional charts would find support—in general requires that the fitted curve be a *response schedule*. A response schedule is the rule Nature used to generate the data, not merely a pattern in the observed data.³⁹ Predicting the effect of a change to the system, such as retrieving additional charts, requires a response schedule (or a randomized controlled experiment, which was not undertaken).

90. It may be true that the rate of support for HCC instances for which more charts were retrieved is higher. It does not follow that one can reliably estimate how many additional

³⁷ Salve Report, at ¶¶ 86, 89, 94–96, 99, 100, 102–104.

³⁸ See, e.g., Stark, P.B., 2022. Pay No Attention to the Model Behind the Curtain, *Pure and Applied Geophysics*, 179, 4121–4145.

³⁹ For a discussion of response schedules and the assumptions that must be satisfied to draw causal inferences from regression, see Freedman, D.A., 2009. *Statistical Models: Theory and Practice*, Cambridge University Press, at 91–102.

HCC instances would have been supported had all the requested charts been retrieved, because the logistic regression model is not a response schedule.

91. To illustrate the fallacy of treating an observed relationship as if it were a response schedule, consider household size and household income. In the U.S., on average, larger household have higher household incomes.⁴⁰ The observed relationship does not mean that if a household of three adopts two children, its household income will increase, nor that if someone in the household gets a bonus, the household will grow. It certainly does not mean that one can reliably predict how much household income will increase if a household adopts two children. The response to a change, such as the response of income to increasing the size of a household, does not have any necessary connection to the population-level pattern in household income and household size.

92. There may be an association between the number of charts retrieved and finding support for an HCC instance. That does not mean that one can reliably predict whether a given HCC instance would have had support if every related chart had been retrieved. It does not even mean that one can reliably predict the fraction of HCC instances that would have had support if every requested chart had been retrieved. Association is not necessarily causation, and a curve fitted to data is not necessarily a response schedule. One cannot compensate for failing to collect adequate data by making up a model for the available data, generating fake data from that model, and pretending that the fake data can be substituted for the missing observations. Statistical technology cannot necessarily be substituted for shoe leather. In essence, that is what Salve's logistic regression model does.

93. Even when logistic regression is justified, it is fragile. Kennedy (2008, at p250), cited by the Salve Report,⁴¹ cautions “[u]nfortunately, logit and probit models are sensitive to misspecifications. In particular, in contrast to OLS in the classical linear regression (CLR)

⁴⁰ For 2022 U.S. Census Bureau Current Population Survey data, see Mean Size of Household by Income, All Races <https://www.census.gov/data/tables/time-series/demo/income-poverty/cps-hinc/hinc-01.html> (last visited 25 November 2023)

⁴¹ Salve Report, at note 62.

model, estimators will be inconsistent if an explanatory variable (even an orthogonal variable) is omitted or if there is heteroskedasticity.” A model is “misspecified” if it omits dependent variables upon which the outcome depends or if the functional dependence of the outcome on the dependent variables is different from what the model makes in. “Inconsistent” means that the estimates do not necessarily improve (according to a particular statistical measure⁴²) as the sample size grows. Setting aside the issue of whether having support is random or simply unknown, the logistic regression in the Salve Report might well be misspecified. For instance, the rate of support might depend on the healthcare provider, on geography, on the contract or plan, on the year, or on the specific diagnosis that led to the HCC. The Salve Report does not discuss performing tests of whether the model was correctly specified, nor any analyses of the sensitivity of the estimates to the model specification, nor even any uncertainty estimates for the predicted fraction of additional HCCs that would have been supported.

94. Even if the logistic regression model were justified and constituted a response schedule, the Salve Report does not take into account the uncertainty in the logistic regression in the reported uncertainties. Consider Appendix E of the Salve Report, which gives confidence intervals for the rates of unsupported HCCs in various scenarios. The scenario in the first table ignores the fact that some requested charts could not be retrieved. The scenario in the second table attempts to adjust for the unretrieved charts using the logistic regression model. The width of the 95 percent confidence interval for HCC 1 is 0.2632 before adjustment and 0.1879 after: the reported uncertainty is *smaller* after the adjustments than before the adjustments, even though the adjustment involves pulling a model out of thin air and fitting coefficients in the model to data. As a matter of logic, making additional unfounded assumptions cannot decrease the uncertainty.

⁴² An estimator of a parameter is *consistent* if, for every positive threshold, the probability that it differs from the true value of the parameter by more than that threshold approaches zero as the sample size increases.

Proper *Pro Forma* Confidence Intervals

95. I computed *pro forma* 95 percent confidence intervals for the rates of HCC support and for the overall rate of support across HCCs. The computations yield *pro forma* confidence intervals rather than *actual* confidence intervals because the calculations assume that Dr. Salve's samples were actual random samples, which they were not, as explained above. The intervals also assume that no chart that was not requested would have supported the HCCs.

96. The confidence intervals for HCC support are given in Appendix 3. To find the lower endpoint of the intervals, I assumed that missing charts would have shown support for the corresponding HCC. To find the upper endpoint of the intervals, I assumed that the missing charts would not have found support for the HCC. That treatment accounts for the potential bias from the charts that were requested but not retrieved. Unlike the intervals in the Salve Report, which are based on approximations, the statistical uncertainties I report for individual HCCs are exact, based on "inverting" hypergeometric hypothesis tests. The confidence interval for the overall rate of support for HCCs is based on inverting exact union-of-intersections tests.

97. The resulting *pro forma* intervals are substantially wider than the intervals in the Salve Report. For instance, the 95 percent confidence interval for HCC 1 goes from 2.2 percent to 58.7 percent, a range of 56.5 percent. In contrast, the Salve Report claims that after the "adjustments," there is 95 percent confidence that the rate is between 3.0 percent and 21.8 percent, a range of 18.8 percent. Salve Report at p62. The illusion of precision results from ignoring the uncertainty in the logistic regression adjustment and from using an approximate method for computing confidence intervals rather than an exact method.

98. The most common HCC in the dataset is 96, which occurred 3,100,061 times: it comprises more than 10 percent of the 30,398,333 HCC codes in the population from which Dr. Salve drew the sample. The Salve Report claims that a 95 percent confidence interval for the rate of support for HCC 96 is 3.4 percent to 21.9 percent, a range of 18.5 percent. Salve Report at 63. In fact, an exact *pro forma* 95 percent confidence interval is 0 to 58.8 percent, a range of 58.8 percent. Again, the Salve Report grossly overstates the precision of its results by ignoring the

uncertainty in the ad hoc logistic regression adjustments and using an approximate method to construct the confidence interval.

99. I calculated an exact *pro forma* confidence interval for the overall rate of HCC support, based on a “union of intersections” approach that relies on Fisher’s combining function for independent P-values. The exact *pro forma* confidence interval was 7.3 percent to 73.6 percent, a range of 66.3 percent. In contrast, Dr. Salve reports the interval of 27.4 percent to 35.8 percent, a range of 8.4 percent. Salve Report, at p54. Once again, the Salve Report grossly overstates the precision of its estimates by ignoring the uncertainty in the logistic regression adjustment and by using an approximate method rather than an exact or conservative method.

Summary of Errors in the Salve Report

100. The Salve Report did not draw samples of HCC instances properly: it used an inadequate pseudo-random number generator and an inappropriate algorithm for selecting samples using that generator. This produced a sample that was not random to an adequate degree of approximation and invalidates standard statistical methods for assessing uncertainty in estimates and inferences.

101. The Salve Report misinterprets the “representativeness” tests it conducted. The tests—which were statistically weak, inappropriate, and considered only two variables—nonetheless soundly reject the hypothesis that the samples were random, despite claims to the contrary in the Salve Report. Even though 948 tests were performed, had the samples been genuinely random, the chance of observing discrepancies in APAY_NonDual14 as large as were observed would be less than 0.002 percent, well below the 5 percent threshold for statistical significance used in the Salve Report. Thus, Dr. Salve’s assertion that the tests support his methodology is incorrect: the tests show that his statistical sampling methodology is broken.

102. The Salve Report commits numerous basic errors of statistics, including using inappropriate statistical tests and inappropriate methods for computing confidence intervals, misinterpreting large P-values as affirmative evidence that the null hypothesis is true, failing to account for the uncertainty in estimated parameters, treating a fitted curve as if it were a response

schedule, and conflating correlation with causation. These errors undermine many of the statistical conclusions in the Salve Report.

103. One of the texts cited in the Salve Report, Kennedy (2008), includes “The Ten Commandments of Applied Econometrics.” The Salve Report violates at least five of the ten commandments:

a. Rule 1 is “Use common sense and economic theory.” Common sense says that a negative rate of support for HCCs is silly, yet the Salve Report has negative lower confidence bounds for two such rates. Common sense says, “you don’t know what you don’t know,” but the Salve Report purports to estimate the fraction of HCCs that would have had support had all the requested charts been retrieved, without inspecting even a random sample of those charts. Common sense says that if your analysis involves untested, ungrounded assumptions, the uncertainty of your analysis increases. Yet the Salve Report gives shorter confidence intervals for rates that were “adjusted” using models with strong, ungrounded assumptions than it gives for rates without such uncertain adjustments.

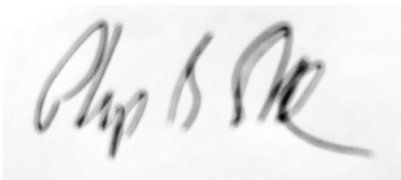
b. Rule 2 is “Avoid type III errors.” A type III error is to answer the wrong question. Logistic regression answers the wrong question. The Student-t tests, which assume that the population distribution is normal, answer the wrong question when used on samples from a population known to be non-normal. Arguably, confidence bounds for the overall rate of HCCs that are unsupported answer the wrong question, because they do not directly relate to changes in risk scores or payments to providers.

c. Rule 4 is “Inspect the data.” Had Dr. Salve inspected the APAY_NonDual14 data, it would have been obvious that Student’s t test was inappropriate because the population distributions are strongly skewed and hence non-normal. Had he looked at the differences between the population means and the sample means, it would have been obvious that the samples were not representative of the populations from which they were drawn.

d. Rule 5 is “Keep it sensibly simple.” The sensible, simple treatment of missing charts is to assume the worst (the “minimum error rate scenario”). It is neither simple nor sensible to make up a logistic regression model with no basis in theory or in the data, then to misinterpret a fitted curve (pulled from thin air) as if it were a response schedule (the “baseline with adjustment scenario”).

e. Rule 10 is “Report a sensitivity analysis.” Dr. Salve did not report a sensitivity analysis for his logistic regression model, nor did he take uncertainty in that model into account in his confidence intervals for the rates of support for the HCCs. He did not report any exploration of the sensitivity of the confidence intervals to the asymptotic approximations they ride on.

104. Because Dr. Salve’s sample was not random, there is no useful way to quantify the error in extrapolating from the sample to the population. The 31.6 percent number is meaningless, as are the so-called “confidence intervals.” And even if the estimated rate were meaningful, Mr. Salve does not explain whether or to what extent a rate of unsupported HCC instances translates to a change in risk scores or in dollars.



_____ Date: 28 March 2024

Philip B. Stark, Ph. D.

EXHIBIT D-64

**IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA EX REL.	§	
BENJAMIN POEHLING,	§	
	§	
	§	
Plaintiffs,	§	
	§	CASE NO.: CV 16-08697 (FMO SSx)
vs.	§	HON. FERNANDO MANZANO OLGUIN
	§	
UNITEDHEALTH GROUP, INC. ET AL.,	§	
	§	
	§	
Defendants.	§	
	§	

UPDATED EXPERT REPORT OF M. TIMOTHY RENJILIAN

December 3, 2023

CONFIDENTIAL, ATTORNEYS' EYES ONLY, & OUTSIDE COUNSEL EYES ONLY

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any financial impact on the government's payments to United plans. Second, with respect to the remaining diagnosis codes, the CMS CON11-13 RADV audits found support for 65.3% of the at-issue diagnosis codes that were (a) addressed in a CON11-13 RADV audit and (b) found to have financial impact based on Opinion 3. Combining these results with those of the CON14-15 RADV audits, the CMS CON11-15 RADV audits in total found support for 62.5% of the at-issue diagnosis codes that were (a) addressed in a CON11-15 RADV audit and (b) found to have financial impact based on Opinion 3. Thus, to the extent that the government's First Interrogatory Response is intended to be used as a basis for assessing either the pervasiveness or the dollar impact of improper diagnosis codes, it is biased and unreliable. .. 93

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I. QUALIFICATIONS

1. I am a Senior Managing Director with FTI Consulting, Inc. (“FTI”) and am based in Atlanta, Georgia. I am licensed as a Certified Public Accountant in Georgia. The primary focus of my work is (a) to conduct forensic accounting investigations of compliance and legal issues in the health care and life sciences industry, and (b) to provide consulting services related to operational, financial and compliance issues faced by health care and life sciences companies.

2. In an investigation context, I have worked on a wide range of matters involving potential financial and legal exposure related to billings made in connection with the provision of health care services. Among other things, these matters have involved audit and administrative adjustments; legal claims for recoupment of amounts paid; issues related to the preparation and presentation of Medicare cost reports; post-acquisition disputes; and alleged violations of applicable Federal and state laws. My role in such matters has included frequent interaction with corporate management and boards and with regulatory authorities and oversight organizations including, for example, the Department of Health and Human Services, the Department of Justice, and state Medicaid Fraud Control Units.

3. In my consulting role, my work has involved a variety of tasks related to operational issues, financial and accounting matters, auditing and monitoring activities, compliance programs, and evaluating and facilitating mergers and acquisitions.

4. My resume, including a list of all publications I have authored in the previous ten years and all cases in which I have testified as an expert at trial or by deposition in the previous four years, is included as Exhibit 1.

5. FTI is being paid \$695 per hour for my services in this case. In addition, other employees of FTI have worked under my direction in this matter. The billing rates for these individuals ranges from \$350 to \$625 per hour. Compensation for FTI’s services is not dependent on the outcome of this matter.

II. DESCRIPTION OF ENGAGEMENT

A. Scope of Work

6. I have been requested by Counsel for Defendant UnitedHealthcare and related entities (“United”) to review the government’s allegations that United knew it was overpaid, or recklessly disregarded an overpayment, each time United reviewed a Medicare beneficiary’s medical record and did not identify medical record support for a specific diagnosis code previously submitted to the Centers for Medicare & Medicaid Services (“CMS”) for the same beneficiary. My work has included, among other things, reviewing the government’s response to United’s first interrogatory in this matter, which requested that the government identify certain information related to each and every diagnosis code the government alleges United knowingly and improperly failed to delete or otherwise return to the Medicare Program as an overpayment.¹ In response to this interrogatory, the government provided data tables comprising approximately 28 million records of data representing diagnosis codes submitted by United for date of service years 2008 – 2016 that United allegedly improperly failed to delete. As part of my review of the government’s response, I have also reviewed relevant data maintained by United and produced in this matter and used it to evaluate the government’s response. Finally, based on this work, I have considered whether the government’s response to United’s first interrogatory constitutes an appropriate basis on which to calculate or evaluate potential damages in this case.

7. This report sets forth my opinions as of December 3, 2023.

B. Materials Relied Upon

8. A listing of the specific materials on which I have relied in forming the opinions expressed in this report is attached as Exhibit 2a and Exhibit 2b.

III. BACKGROUND

A. Summary of the Relevant Allegations

i. First Amended Complaint

¹ United’s First Interrogatory to the Government, dated January 3, 2020.

9. On November 17, 2017, the government filed the First Amended Complaint-in-Partial-Intervention in this case (the “First Amended Complaint” or “Complaint”). In the Complaint, the government alleges that, “for many years, the [United] Managing Defendants have conducted programs and engaged in other activities to increase the amount of risk adjustment payments from the Government to the Defendant [Medicare Advantage] Organizations.”² Specifically, the government alleges that United “conducted millions of medical record reviews as part of their revenue-generating national Chart Review Program, turned a blind eye to the negative results of those reviews showing hundreds of thousands of unsupported diagnoses that [United] had previously submitted to Medicare..., and knowingly and improperly avoided repaying Medicare for at least over a billion dollars in risk adjustment payments to which they were not entitled.”³

10. The government’s Complaint asserts that, since 2005, United conducted a large national Chart Review Program to increase risk adjustment payments received from the government by “collecting millions of medical records (also known as ‘charts’)⁴ from providers and then employing diagnosis coders (also known as ‘chart reviewers’) to review the medical records in order to mine them for diagnoses that the providers themselves did not report to the Defendant MA Organizations for the beneficiaries in their Plans. The [United] Managing Defendants then submitted these additional diagnosis codes (‘ADDS’) to the Government for billions of dollars of additional risk adjustment payments.”⁵

11. The Complaint goes on to allege that United “used the results of the chart reviews to only increase payments, *i.e.*, to submit additional diagnoses not reported by the providers.” At the same time, the Complaint asserts, United “systematically ignored the results of chart reviews that would have led to decreased payments, *i.e.*, results showing that diagnoses reported by providers to them and then submitted by them to the Government were not supported by the beneficiaries’ medical records.”⁶

² Complaint, para. 9.

³ *Id.*, para. 122.

⁴ Throughout my report, I will refer to “charts” and “medical records” interchangeably to mean the same thing.

⁵ Complaint, para. 10.

⁶ *Id.*, para. 11.

12. The government alleges that United “knowingly and improperly avoided comparing the diagnoses reported by the providers and submitted by them to the Government with the results of the coders’ chart reviews to identify those provider-reported diagnoses that were not supported by the beneficiaries’ medical records.”⁷ Moreover, the government contends that, if a coder performing a blinded chart review did not document a code that had been submitted, United “could and should have...withdrawn their prior submission of these unsupported diagnoses” and that if they had done so, the government “would not have made risk adjustment payments based on these unsupported diagnoses or, if it had already made the payments, it would have recovered them from [United].”⁸

13. While the government originally asserted six claims for relief, in light of a ruling on a motion to dismiss, I understand that this case now centers on the “reverse false claim” allegation from the First Claim for Relief. This specifically relates to the second portion of 31 U.S.C. § 3729(a)(1)(G), which states that it is a violation of the False Claims Act to knowingly conceal or knowingly and improperly avoid or decrease an “obligation to pay or transmit money or property to the Government.”⁹ The False Claims Act defines an “obligation” to include “an established duty, whether or not fixed, arising from...retention of any overpayment.”¹⁰ The government seeks to prove that United “knowingly and improperly failed to delete...invalid diagnoses that had been submitted to the Medicare Program for risk adjustment payments which were made by the Medicare Program to [United] or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses.”¹¹

ii. United’s First Interrogatory to the Government and Government’s Response

14. In January 2020, more than two years after the government filed its First Amended Complaint, United submitted its first interrogatory, “Interrogatory No. 1,” to the government. That interrogatory asked the government to “[i]dentify for date of service years 2008-2016 the Beneficiary...Date of Service, Diagnosis Code(s), CMS HCC(s) or RxHCC(s), and Provider...that

⁷ *Id.*, para. 12.

⁸ *Id.*, para. 12.

⁹ 31 U.S.C. §3729(a)(1)(G).

¹⁰ 31 U.S.C. §3729(b)(3).

¹¹ Complaint, para. 342.

corresponds to each and every diagnosis code [the government alleges United] ‘knowingly and improperly failed to delete...or otherwise return to the Medicare Program [as an] overpayment.’”¹²

15. The government responded to United’s Interrogatory No. 1 on February 3, 2020. After asserting objections to the interrogatory, the government responded that “although fact discovery is ongoing, and expert disclosures are not due until December 18, 2020, and that the United States reserves the right to supplement and/or amend this answer in full or in part as it learns new information and as expert analysis progresses, the United States alleges that UnitedHealth Defendants ‘knowingly and improperly failed to delete in the RAPS system the invalid diagnoses that had been submitted to the Medicare Program for risk adjustment payments which were made by the Medicare Program to them or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses’ for each and every Diagnosis Code that was known (as that term is defined by the False Claims Act) to be unsupported by medical records and that affected the amount of payment received by UnitedHealth from the Medicare Program.”¹³ The government then identified what it described as “representative examples” of such diagnosis codes and identified various documents from which the government claimed United could derive the information it sought.¹⁴

16. The parties disputed whether the government’s response to Interrogatory No. 1 was sufficient and whether the government was obligated to identify every diagnosis code the government contends United knowingly and improperly failed to delete or otherwise return to the Medicare Program as an overpayment. The parties brought their dispute to the Special Master during a May 21, 2020 conference, and the government then agreed to supplement its response. On June 8, 2020, the Special Master issued an order requiring the government to supplement its response to Interrogatory No. 1 by August 17, 2020 for date of service (“DOS”) years 2010 – 2013, by October 30, 2020 for DOS years 2008 – 2009, and by December 15, 2020 for DOS years 2014 – 2016.¹⁵

¹² United’s First Interrogatory to the Government, p. 6.

¹³ Government’s Responses and Objections to United’s First Set of Interrogatories to the Government, February 3, 2020, p. 8.

¹⁴ *Id.*, p. 9.

¹⁵ Order Re: Supplemental Response to Defendants’ Interrogatory No. 1, June 8, 2020.

17. In response to United’s Interrogatory No. 1, the government provided data tables comprising approximately 28 million¹⁶ line-item records of data representing allegedly unsupported diagnosis codes from DOS years 2008 – 2016 (“First Interrogatory Response”) that the government alleges led to overpayments that United should have returned. Each row of data in the First Interrogatory Response reflects a unique combination of Health Insurance Claim Number (or “HICN”, a unique Medicare member identifier), DOS, diagnosis code, corresponding HCC or RxHCC, and provider number.

18. All line-item records in the First Interrogatory Response are populated with a diagnosis code. However, not all records are populated with an HCC or RxHCC (HCCs and RxHCCs, and their importance to Medicare Advantage risk adjustment, are explained in Section B.ii. below). As summarized in Figure 1 below, only 41.9% of First Interrogatory Response records contain a diagnosis code mapping to an HCC, 89.2% contain a diagnosis code mapping to an RxHCC, and 3.2% contain a diagnosis code that does not map to either an HCC or an RxHCC.

Figure 1. First Interrogatory Response Records, by HCC or RxHCC.¹⁷

DOS Year	Total First Interrogatory Response Records					=A+C HCC Populated	=B+C RxHCC Populated
	A Only HCC	B Only RxHCC	C HCC and RxHCC	D Neither HCC nor RxHCC	Total		
2008	17,439	832,857	257,606	173,358	1,281,260	275,045	1,090,463
2009	36,432	1,688,573	539,470	408,597	2,673,072	575,902	2,228,043
2010	111,985	1,514,765	731,714	-	2,358,464	843,699	2,246,479
2011	111,841	1,413,035	621,985	-	2,146,861	733,826	2,035,020
2012	253,526	2,232,288	1,344,038	-	3,829,852	1,597,564	3,576,326
2013	336,255	2,505,401	1,589,395	-	4,431,051	1,925,650	4,094,796
2014	346,027	1,798,320	1,315,001	3,480	3,462,828	1,661,028	3,113,321
2015	393,363	1,626,036	1,243,242	145,801	3,408,442	1,636,605	2,869,278
2016	503,802	1,726,572	1,952,081	163,366	4,345,821	2,455,883	3,678,653
Total	2,110,670	15,337,847	9,594,532	894,602	27,937,651	11,705,202	24,932,379
%	7.6%	54.9%	34.3%	3.2%	100.0%	41.9%	89.2%

¹⁶ When I refer to the First Interrogatory Response data, I am referring specifically to the tables named: 2008dos.csv, 2009dos.csv, 2010DOS_Amended.csv, 2011DOS_Amended.csv, 2012DOS_Amended.csv, 2013DOS_Amended.csv, IRADS 2014dos.csv, IRADS 2015dos.csv, and IRADS 2016dos.csv. There are 27,937,651 records across these tables. The government produced IRADS and EDPS versions of the tables for the 2014 – 2016 DOS years. I relied upon the IRADS versions.

¹⁷ See Exhibit 3. These counts are based on my mappings of the diagnosis codes in the First Interrogatory Response to HCC(s) or RxHCC(s) based on the relevant diagnosis code mappings published by CMS for each payment year. They are not based on the HCC or RxHCC fields originally populated in the government’s list. The mapped HCC

19. These tables were provided across multiple data productions culminating in December 2020.¹⁸ In its initial production of the first of these tables in August 2020, the government “identifie[d] and incorporate[d] into its answer [to United’s First Interrogatory] the attached charts of Diagnosis Codes that [United] ‘knowingly and improperly failed to delete’ or ‘knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on such diagnoses.’”¹⁹ The First Interrogatory Response was described as the result of work through which the government:

...identified every diagnosis code that it contends UnitedHealth submitted to CMS to increase its risk adjustment payments, and then improperly failed to delete when UnitedHealth’s own reviewers found no support for the diagnosis code in the member’s medical records. For each diagnosis code on the United States’ list: (1) the diagnosis code was submitted by UnitedHealth to CMS and was required, by regulation, to be supported by an underlying medical record; (2) that medical record went through UnitedHealth’s medical record review program; and (3) UnitedHealth’s own reviewers did not find the diagnosis code to be supported by medical records. That is, each diagnosis code on the United States’ list is associated with a medical chart that UnitedHealth has already thoroughly reviewed, and in none of those reviews found support for the diagnosis code in question. However, UnitedHealth never deleted any of these diagnosis codes.²⁰

20. My understanding is that these tables comprise the government’s full list of allegedly at-issue diagnosis codes in this case. Beyond this description, I understand that the government has not explained in detail how the 28 million records in the First Interrogatory

and RxHCC values were almost always the same as the values populated in the First Interrogatory Response from DOS years 2008 – 2013 (<0.1% variation). For DOS years 2014 – 2016, these mapped values were different than the values populated in the First Interrogatory Response for approximately two-thirds of records. These differences are driven primarily by a large volume of the HCC and RxHCC fields in the First Interrogatory Response being blank or populated with “dummy” values (*i.e.*, 9999, 999, 8888) in these years.

¹⁸ Joint Stipulation Regarding Government’s Motion to Compel, dated April 29, 2021, p. 13.

¹⁹ Government’s First Interrogatory Response, dated August 17, 2020, p. 9.

²⁰ Joint Stipulation Regarding Government’s Motion to Compel, dated April 29, 2021, p. 8.

Response were identified – *e.g.*, what specific sources were queried, what assumptions were made – nor has it provided supporting data query scripts or workpapers.²¹ Also, the government has not quantified what the financial impact would have been had these codes actually been deleted from United’s risk adjustment submissions during the relevant years.

B. Background on the Medicare Advantage Program

i. The Medicare Program Coverage Components

21. Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease. Since its inception in 1965, Medicare has been administered directly by the Federal government and historically has had two parts: Medicare Part A (Hospital Insurance) and Medicare Part B (Medical Insurance).²² Medicare Part A covers inpatient hospital stays, skilled nursing care after a hospital stay, hospice care, and some home health care. Medicare Part B covers a portion of certain doctors’ visits, some home health care, medical equipment and supplies, certain outpatient services, and certain preventive services such as rehabilitation therapy, laboratory tests, and x-rays. Medicare Part B coverage requires that a monthly premium be paid to Medicare, along with a small deductible that must be reached before Medicare Part B begins paying for services.²³

22. Medicare Parts A and B (also called “original Medicare” coverage) are often referred to as “fee-for-service” (“FFS”) coverage as they (a) allow Medicare-eligible members to see any Medicare-approved doctor or hospital that accepts Medicare payment, and (b) provide payment to such doctors and hospitals on the basis of the specifically identified covered services actually provided.²⁴

23. Following the Balanced Budget Act of 1997, an additional Medicare coverage component was enacted: Medicare Part C (also known as “Medicare Advantage” or “MA”).²⁵

²¹ Deposition of Amanda Johnson, September 30, 2022, p. 27.

²² Klees, B. S., Eckstein, E. T., & Curtis, C. A. (2021, November 15). Office of the Actuary, Centers for Medicare & Medicaid Services, Department of Health and Human Services. *Brief Summaries of Medicare & Medicaid*, p. 8. (<https://www.cms.gov/files/document/brief-summaries-medicare-medicare-november-15-2021.pdf>).

²³ *Id.*, pp. 8 – 11.

²⁴ *Id.*, pp. 9 – 11

²⁵ *Id.*, p. 8. The Balanced Budget Act of 1997 created Part C as the “Medicare+Choice” program. It was later modified and renamed “Medicare Advantage” as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Medicare Part C addresses a type of Medicare health insurance plan offered by private insurance companies, called Medicare Advantage Organizations (“MAOs”), that contract with CMS to receive a “capitated” (i.e., fixed) payment per enrolled Medicare member per month²⁶ and then to provide those enrolled Medicare members with insurance coverage in lieu of their original Medicare Part A and Part B coverage.²⁷ By law, Medicare Advantage plans must cover at least the same health care services as original Medicare. However, as an incentive to join the plan, many Medicare Advantage plans cover services that are not covered by original Medicare, such as certain vision and dental care.²⁸

24. As noted above, original Medicare coverage pays health care providers for each covered service they furnish to eligible members. While Medicare sets the price it pays to health care providers, the volume of services (and, thus, the total spending by the program) remains largely uncontrolled. A key congressional objective of establishing the Medicare Part C program was to help restrain the growth of Medicare spending based on the belief that private MA plans, because of the fixed nature of the capitated payments they receive, have more incentive to control both (a) the price they pay to health care providers for services provided to their members, and (b) the quantity of such services provided.

25. Medicare Part D was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and adds prescription drug coverage to the original Medicare program.²⁹ Beginning in 2006, Part D provides subsidized access to prescription drug coverage on a voluntary basis, upon payment of a premium, to individuals entitled to Part A or enrolled in Part B, with premium and cost-sharing subsidies for low-income members.³⁰ Medicare Part D coverage plans are offered by insurance companies and other private companies approved by Medicare. Medicare Advantage plans may also offer prescription drug coverage so long as they follow the same rules as the Medicare Part D plans.³¹

²⁶ *Id.*, p. 19.

²⁷ *Id.*, p. 11.

²⁸ *Id.*, pp. 11-12.

²⁹ Klees, B. S., Eckstein, E. T., & Curtis, C. A. (2021, November 15). Office of the Actuary, Centers for Medicare & Medicaid Services, Department of Health and Human Services. *Brief Summaries of Medicare & Medicaid*, p. 8. (<https://www.cms.gov/files/document/brief-summaries-medicare-medicare-november-15-2021.pdf>).

³⁰ *Id.*, pp. 8-9.

³¹ *Id.*, p. 12.

ii. The CMS-HCC and CMS-RxHCC Models

26. As noted above, MAOs are compensated by CMS on a capitated basis. That is, they receive a monthly amount from CMS for each Medicare member enrolled with one of their MA plans. Under the Medicare Advantage program, the capitation payment received by the MAO can vary depending upon the health status of the member. In other words, while the payment for any given member is fixed, the payment amount across different members can vary based on the differing health statuses of the various members. This process of adjusting the payment based upon health status is referred to as “risk adjustment.”³²

27. Through its risk adjustment calculations, CMS alters future payments to MAOs based on the anticipated costs of particular MA member populations by taking into account information regarding MA members’ health statuses.³³ Payments are expected to be higher for populations of less healthy members, for example, in order to cover their higher expected costs of care.³⁴

28. CMS’s current risk adjustment payment methodology is the CMS-Hierarchical Condition Category (“HCC”) model. This model was first fully implemented for calendar year 2007.³⁵ Under the CMS-HCC model, CMS organizes clinically-related diagnosis codes into categories referred to as HCCs. HCCs are disease groupings consisting of diagnosis codes that are ranked based on disease severity and cost.³⁶ The diagnosis codes were initially based on the International Classification of Diseases, 9th Edition Clinical Modification (ICD-9-CM) coding, but were transitioned to the 10th Edition, or ICD-10, on October 1, 2015.³⁷

29. A separate risk adjustment model exists for Part D – the RxHCC model. This model is similar to the CMS-HCC risk adjustment model in its use of health status (demographics and diagnosis codes) to predict expenditures; however, it focuses on the expected Part D (*i.e.*, prescription drug) costs a plan will incur under the Medicare standard Part D benefit, rather than on the expected medical costs under Medicare Parts A and B. Different diseases are used to

³² 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide, p. 1-1.

³³ 73 Fed. Reg. 48279, at 48650 (Aug. 19, 2008).

³⁴ 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide, p. 1-4.

³⁵ 2013 Risk Adjustment Regional Technical Assistance Participant Guide, p. 6.

³⁶ *Id.*, p. 7.

³⁷ CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 6, 2015, p. 32.

estimate expected Part D drug costs than are used to predict expected Part A / B costs. Incremental costs associated with low-income (“LI”) and long-term institutional (“LTI”) members are also incorporated into the Rx-HCC model.³⁸

30. The CMS-HCC risk adjustment model was developed using enrollment and claims data from the original Medicare FFS program. The model is prospective, meaning diagnosis codes from the previous year, together with certain demographic information, are used to predict future costs and, thus, to set future capitation payment amounts.³⁹ In other words, the risk adjustment model uses MA member demographic and diagnostic data from a base year (also referred to as the “DOS year”) to calculate each MA member’s risk scores and capitation payment amounts for the following year (also referred to as the “payment year” or “calendar year”). For example, CMS used MA member demographic and diagnostic data for 2021 (the DOS year) to determine the risk scores used to adjust payments to MAOs in 2022 (the payment year).

31. According to the CMS 2012 Risk Adjustment Regional Technical Assistance Participant Guide, diagnosis codes included in risk adjustment data must be based on clinical medical record documentation from a face-to-face encounter, coded according to the applicable coding guidelines (ICD-9-CM or ICD-10), assigned based on dates of service within the data collection period, and submitted to the MAO from an acceptable source and acceptable provider type.⁴⁰ MAOs are responsible for ensuring that the data they collect comes from such acceptable provider types.⁴¹

32. For both inpatient and outpatient facilities, CMS has delineated between “covered” and “non-covered” facilities. This designation dictates what types of facilities are acceptable sources for risk adjustment data. For facilities designated as covered, MAOs may submit risk adjustment data, while facilities designated as non-covered may not submit risk adjustment data. For example, among inpatient facilities, covered facilities include short-term (general and specialty) hospitals, religious non-medical health care institutions, long-term hospitals, rehabilitation hospitals, children’s hospitals, psychiatric hospitals, and medical assistance facilities/critical access hospitals. Non-covered inpatient facilities include skilled nursing

³⁸ 2012 Risk Adjustment Regional Technical Assistance Participant Guide, p. 1-5.

³⁹ *Id.*, p. 1-2.

⁴⁰ *Id.*, pp. 2-5 – 2-7.

⁴¹ *Id.*, pp. 2-5 – 2-6.

facilities, intermediate care facilities, respite care, and hospice. Among outpatient facilities, covered facilities may include short-term (general and specialty) hospitals, community mental health centers, federally qualified health centers, long-term hospitals, children's hospitals, and rural health clinics. Non-covered outpatient facilities include free-standing ambulatory surgical centers ("ASCs"), home health care, and free-standing renal dialysis facilities.⁴²

33. In addition, for outpatient facilities, CMS has also designated certain types of services that are not acceptable sources of risk adjustment data. These "non-covered" services include laboratory, ambulance, durable medical equipment, prosthetics, orthotics, supplies, and radiology services.⁴³

34. For physicians, the collection of acceptable data for risk adjustment is based on the physician's specialty and must be the result of a face-to-face visit. Acceptable data includes data collected from both non-network and network physicians. Examples of acceptable physician specialty and/or provider types include, but are not necessarily limited to, general practice, general surgery, gastroenterology, neurology, obstetrics/gynecology, pathology, urology, nephrology, physical therapy, and nurse practitioner. CMS regularly updates its list of acceptable physician specialty and provider types for risk adjustment data and posts the guidance on its website.⁴⁴

35. Not all clinical diagnosis codes correspond to an HCC or RxHCC (*i.e.*, not all clinical diagnosis codes are risk-adjusting). To determine which HCCs or RxHCCs to assign to members under the CMS-HCC and CMS-RxHCC models, CMS requires MAOs to collect members' appropriate clinical diagnosis codes and then to submit that information to CMS through the Risk Adjustment Processing System ("RAPS").⁴⁵ CMS requires that even chronic conditions, which by definition are ones lasting one year or more, be submitted each year in order to be used for risk adjustment purposes.

36. CMS uses the diagnosis codes submitted by MAOs through RAPS to assign HCCs, and identify the related "interactions," for each member. Interactions are defined as "the combination of multiple diagnoses or disability that result in an extra relative factor added to the

⁴² *Id.*, pp. 2-5 – 2-6.

⁴³ *Id.*, p. 2-6.

⁴⁴ *Id.*, p. 2-7.

⁴⁵ 73 Fed. Reg. 48279, at 48650-48651 (Aug. 19, 2008). *See also* Risk Adjustment 101 Participant Guide: 2013 National Technical Assistance, CMS (Jul. 23, 2013), p. 11.

risk score evaluation.”⁴⁶ These HCCs and interactions are used to calculate the risk score for a member. Other items considered as part of the risk adjustment process are whether the member has (a) End-Stage Renal Disease (“ESRD”) status, or (b) has post-transplant status (also referred to as “Functioning Graft Status”). A payment adjustment factor is assigned for (a) each HCC supported by a diagnosis code submitted by an MAO, (b) the member’s ESRD status, and (c) the member’s Functioning Graft Status.⁴⁷

37. Multiple diagnosis codes submitted by an MAO may be assigned to the same HCC or RxHCC under the CMS-HCC and CMS-RxHCC models. Thus, even if multiple member diagnosis codes map to the same HCC or RxHCC, that HCC or RxHCC is counted only once for risk adjustment purposes for that member. Similarly, if one diagnosis code mapping to an HCC or RxHCC is deleted, but others still map to the same HCC or RxHCC, the payment adjustment factor based on that HCC or RxHCC will remain unchanged.⁴⁸ In this way, member risk adjustment scores are best thought of in terms of support at the “condition level” (*i.e.*, at the level of an HCC or RxHCC) rather than at the level of a discrete diagnosis code.

38. After all HCCs and RxHCCs are identified for a member, some HCCs or RxHCCs may be removed during the risk score calculation within the Risk Adjustment System (“RAS”)⁴⁹ based on a defined hierarchy. The process of removing HCCs and RxHCCs based on hierarchy ensures that only the most severe occurrence of a condition is included in the risk score calculation for each member.⁵⁰ For example, in 2013, four separate HCCs (7, 8, 9, 10) were part of a hierarchical disease group labeled “metastatic cancer and acute leukemia.”⁵¹ In this year, if a member had diagnosis codes mapping to both HCC 8 and 9, HCC 8 (the higher severity of the two) would supersede HCC 9 and be the only one considered in the member’s risk score. Therefore, not all diagnosis codes submitted by MAOs through RAPS are ultimately used in the

⁴⁶ 2012 Risk Adjustment Regional Technical Assistance Participant Guide, p 2-2.

⁴⁷ *Id.*, p. 1-3.

⁴⁸ *Id.*

⁴⁹ The Risk Adjustment System (“RAS”) is the processor that performs the calculation and sends the risk score to the payment system (MARx). See 2012 Risk Adjustment Regional Technical Assistance Participant Guide, p. 1-4.

⁵⁰ 2012 Risk Adjustment Regional Technical Assistance Participant Guide, p. 1-3.

⁵¹ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012.

calculation of a member's risk score. In addition, not all diagnosis codes submitted by MAOs impact the payment received by CMS.

39. MAOs can both add and delete diagnosis codes as part of their data submissions through RAPS. A specific data field called the "Delete Indicator" allows an MAO to delete a diagnosis code that has previously been stored in the RAPS database.⁵²

40. The risk adjustment model is run by CMS three times per year to calculate risk scores for all members with available data. The first run is used to calculate an initial risk score; the second to calculate a mid-year update; and the third is done at year end for "final reconciliation." Final reconciliation is used to complete the implementation of payments under risk adjustment, with CMS calculating the final risk adjustment factors and member status based on the full complement of data submitted by MAOs.⁵³

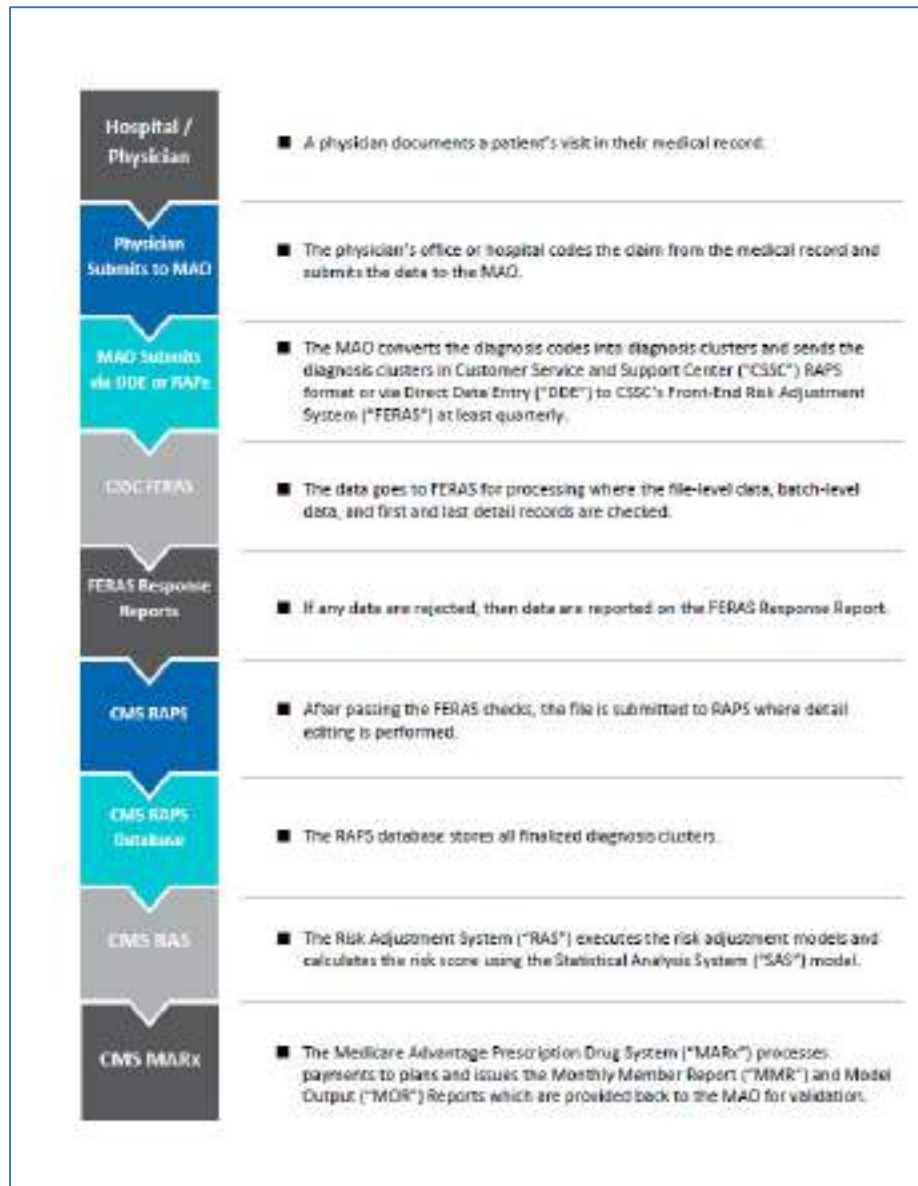
41. Figure 2 below, taken from the 2012 Risk Adjustment Regional Technical Assistance Participant Guide, provides an overview of the Risk Adjustment Data Flow as it pertains to physician-submitted codes.⁵⁴

⁵² 2008 Risk Adjustment Participant Guide, p. 4-9.

⁵³ *Id.*, p. 1-32.

⁵⁴ Effective January 1, 2022, CMS moved RAF calculation for payment year 2022 entirely from RAPS to EDPS (see CMS, *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, p. 6). Beginning in payment year 2015, CMS announced that payments for 2015 would be based upon a blending of RAPS and EDPS risk scores (see CMS, *Announcement of Calendar Year (CY) 2015 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 7, 2014, p. 2).

Figure 2. Physician-Originated Risk Adjustment Data Flow Overview.⁵⁵



iii. Risk Adjustment Data Validation Audits

42. CMS is required by law to validate the accuracy of payments made to MAOs, which includes validating both underpayments and overpayments.⁵⁶ Medicare Advantage Risk

⁵⁵ This overview is relevant to diagnosis codes submitted by physicians.

⁵⁶ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 1: "The Improper Payments Elimination and Recovery Act (IPERA) of 2010 requires CMS to validate the accuracy of the payments made to MA organizations and determine

Adjustment Data Validation (“RADV”) audits have been the primary tool for CMS to audit diagnosis codes that plans have submitted for payment under Medicare Part C and to recoup certain payments made. RADV audits are used by CMS to determine whether diagnosis codes submitted by MAOs can be validated by supporting medical record documentation. Diagnosis codes that cannot be validated contribute to a payment error rate.⁵⁷

43. CMS began conducting RADV audits in 2008 for the 2007 payment year. CMS annually selects MA contracts for RADV audits. An eligible MA contract includes any contract held by an MAO having received risk adjusted payments for any given calendar year being audited.⁵⁸ There are no specific rules outlining how CMS selects plans for audits, but CMS has cited that selection of contracts has been “based primarily on coding intensity, *i.e.*, the average change in the disease component of a contract’s risk scores compared to the average change in [Medicare fee-for-service] risk scores.”⁵⁹

44. To conduct RADV audits, CMS selects a set of MA contracts for each RADV audit cycle. During a RADV audit, CMS selects a sample of an MAO’s members and reviews the HCCs that were assigned based on the diagnosis codes submitted by the MAO to assess whether the diagnosis codes are supported by the applicable member medical records. Once members are selected for audit, the MAO is required to submit medical records to support all HCCs represented in the sampled members’ risk scores for the payment year.⁶⁰ Beginning with the RADV audits for the payment year 2011, CMS has allowed audited MA contracts to submit up to five records for each HCC being validated. Medical records may be from different providers for the same member and HCC under review.⁶¹ CMS allows an MAO to designate the medical record that it believes may substantiate the HCC under review as the “highest in priority.”⁶² All diagnosis codes are

the level of payment error.” The IPERA was enacted in 2010 and amended the Improper Payments Information Act of 2002. Both acts defined an improper payment as “any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements.”

⁵⁷ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 1.

⁵⁸ CMS, *Question and Answer Session – CY 2011 RADV Industry Training*, Updated March 20, 2014, p. 1.

⁵⁹ *Id.*

⁶⁰ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 3.

⁶¹ *Id.*

⁶² CMS, *Question and Answer Session – CY 2011 RADV Industry Training*, Updated March 20, 2014, p. 3.

abstracted from the medical record ranked highest in priority by the submitting MAO that supports the HCC under review.

45. CMS contracts with two independent contractors to perform the medical record reviews for a given MAO's RADV audit. The first contractor (the "Initial Validation Contractor") conducts the initial medical record review, and the second contractor (the "Second Validation Contractor") reviews all instances in which the Initial Validation Contractor believes a diagnosis code was not supported. Both contractors use certified coders in their respective reviews.⁶³ During their reviews, the coders also document any diagnosis codes that were supported but not previously submitted by the MAO.

46. After CMS completes a RADV audit, it calculates the contract's payment error based on the audit results. For each sampled member, the RADV-corrected risk score and corrected payment are calculated based on the HCCs that are supported by the RADV medical record review findings for the member. The correct payment is calculated considering both (a) the diagnosis codes that were previously submitted but not supported by medical record documentation during the RADV medical record review, and (b) any diagnosis codes that were not previously submitted but that were found to be supported by the medical record documentation during the RADV audit.⁶⁴ Member-level payment errors are defined as "the difference between the original payment and the RADV-corrected payment (per member per month)."⁶⁵ The overall payment error for each member may be either a net overpayment or a net underpayment.⁶⁶ Through its *Question and Answer Session – CY 2011 RADV Industry Training*, updated on March 20, 2014, CMS indicated that "recoveries based on extrapolation will begin with the calendar 2011 RADV audits;"⁶⁷ however, CMS recently released its Medicare Advantage Risk Adjustment Validation Final Rule stating that "CMS will extrapolate RADV findings beginning with payment year (PY) 2018 and will not extrapolate RADV audit findings for PYs 2011 through

⁶³ CMS, *Medicare Advantage Risk Adjustment Data Validation (RADV) Training, Contract-Level Industry-Wide Training Event*, January 29, 2019, pp. 42 – 48.

⁶⁴ United States Government Accountability Office ("GAO") Report to the Chairman, Committee on Ways and Means, House of Representatives, *Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments*, April 2016, pp. 2 – 4.

⁶⁵ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 3.

⁶⁶ *Id.*

⁶⁷ CMS, *Question and Answer Session – CY 2011 RADV Industry Training*, Updated March 20, 2014, p. 3.

2017.”⁶⁸ In other words, for RADV audits completed during the timeframe relevant to the government’s allegations, no RADV payment errors were extrapolated.

47. MAOs may pursue any or all of the following approaches to respond to payment adjustments arising from a RADV audit: (1) submit physician attestations for medical records with missing information; (2) appeal the auditors’ determinations arising from the medical record review; and (3) appeal the RADV payment error calculation. If an MAO chooses to appeal medical record review-related errors and/or the RADV payment error calculation, it has 60 days from the date of issuance of the RADV report to file a written request with CMS for the appeal. The request must include, specifically for each of the audited HCCs for which it is filing an appeal, the issues with which the MAO disagrees and the reasons for the disagreements. While MAOs may submit multiple medical records for each HCC during the primary audit process, as part of the appeal process, they can only choose a single medical record per HCC as the basis for an appeal.⁶⁹

iv. Medicare Part C Payment Error Rate

48. CMS annually submits to Congress an Agency Financial Report (“AFR”) that, among other things, reports the estimated amounts of improper payments made under Medicare Part C as well as a Part C Payment Error Rate. Per CMS, “Inaccurate or incomplete diagnosis data may lead CMS to disburse over-payments or under-payments to MA contracts. CMS conducts an annual Part C Improper Payment Measure (‘IPM’) activity, formerly known as National Risk Adjustment Data Validation (‘RADV’), to estimate the improper payments for the Medicare Part C Program due to unsubstantiated risk adjustment data.”⁷⁰

49. To calculate the Part C Payment Error Rate, Medicare selects a sample of Medicare Part C eligible members and reviews the relevant medical record documentation to substantiate the related CMS-HCC payments. As part of the review, “certified coders code the medical records, and the findings are used to recalculate risk scores for each sampled member. The difference

⁶⁸ Medicare and Medicaid Programs, *Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021*; 88 FR 6643, p. 6643.

⁶⁹ § 422.311(c) RADV audit dispute and appeal processes.

⁷⁰ CMS, *Medicare Part C Improper Payment Measure Program Background*: (<https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/medicare-part-c-ipm/program-background>).

between the payment risk scores and the recalculated risk scores is termed Risk Adjustment Error. Validation results from the sample are extrapolated to the broader Part C population to produce payment error estimates.”⁷¹

50. CMS calculates the Part C Payment Error Rates in two ways. First, it calculates a “net” error rate, which is based on offsetting overpayments and underpayments. Second, it calculates an error rate based on the gross payment errors (also called “Gross Improper Payments”). CMS defines “Gross Improper Payments” as the “absolute value of the sum of overpayments and underpayments.”⁷²

C. Summary of Relevant Data Sources

51. The section below provides a high-level overview of the key United data sources relevant to the analyses described in this report.

i. United Risk Adjustment Claims Data

52. United maintains significant amounts of information about the members enrolled in its MA plans. This includes the data that was submitted to CMS’s RAPS for the purposes of calculating MA risk adjustment payments. During the timeframe at issue in this case, much of this data resided in United’s Internal Risk Adjustment Data System (“IRADS”) or Encounter Data Processing System (“EDPS”).⁷³ These databases store large amounts of data pertaining to United’s MA plan members across numerous data tables – including, among other things, identifying information about those members, information about those members’ various healthcare encounters, information about the providers who interacted with those members in those encounters, and the diagnosis codes recorded by providers for each encounter. In addition, a significant amount of relevant member information necessary for risk adjustment was stored within United systems other than IRADS or EDPS, or contained within reports provided by CMS

⁷¹ *Id.*

⁷² CMS, *Medicare Part C Improper Payment Measure Program Error Rates and Findings*: (<https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/medicare-part-c-ipm>).

⁷³ IRADS contains diagnosis data relevant to this case for DOS years 2008 – 2016. EDPS contains diagnosis data relevant to this case for DOS years 2014 – 2016.

to United. These latter reports include the Monthly Member Report (“MMR”) and the Model Output Report (“MOR”).

53. The IRADS and EDPS data repositories are populated through several channels. This includes the submission of diagnosis codes from providers in connection with the treatment of members enrolled in United MA plans. In this context, providers submit claim and encounter data containing member diagnosis information in multiple formats, such as CMS-1500 claim forms (for professional physician claims) and UB-04 forms (for hospital claims). This inbound claims data is captured and maintained in several United claims adjudication systems. During the timeframe relevant to this case, these systems included: the Comprehensive Online Software Management and Operational Support System (“COSMOS”), a United claims adjudication and payment platform; the Newly Integrated Computer Environment (“NICE”), a claims processing platform relating to claims obtained through the PacifiCare acquisition; the Professional Encounter System (“PES”), an encounter reporting platform; the FACETS RV and FACETS Sierra systems, which contained claims data generally related to the West Coast, California, and Nevada markets; the FACETS CSP system, a Medicaid and community and state program claims and administrative platform; and PULSE, the legacy claims platform used by Oxford Health Plans that eventually migrated into COSMOS in 2012.⁷⁴ The encounter data from these multiple claims adjudication systems is aggregated, standardized, refined, and transmitted to IRADS. Among other things, this involves a filtering process to exclude diagnosis codes arising from ineligible encounters (so that only diagnosis codes from face-to-face visits with an acceptable provider type and specialty are included) and also a data standardization process to format the data so it can be successfully submitted to CMS’s RAPS.

54. IRADS and EDPS are also populated via submission through alternative channels such as the Alternate Submission Method (“ASM”), a process whereby diagnosis codes not captured through regular processes can be submitted for evaluation and possible submission to RAPS. ASM submissions can be necessary as a result of issues such as data errors, form limitations, or the identification of additional valid diagnosis codes through a chart review.

⁷⁴ Exhibit 703-2 to the 30(b)(6) Deposition of Biggs Cannon, dated 5/30/2023.

55. Included among the United Risk Adjustment Claims data are files that identify diagnosis codes that were initially submitted to RAPS by United but subsequently retroactively deleted after the diagnosis code was identified as not being applicable to that member in that year (the “Diagnosis Deletes Data”).⁷⁵ The Diagnosis Deletes Data contains key fields including HICN, From Date, Through Date, Diagnosis Code, and a Delete Indicator. Diagnosis codes can be deleted retroactively up to several years after the diagnosis code’s original submission. The Diagnosis Deletes Data I relied upon for the purposes of my report only includes deletions that were made up to the date(s) that these files were produced in this case.

56. For the purposes of my report, I define the “United Risk Adjustment Claims Data” as the data residing in any United database (including IRADS and EDPS), which: (a) maintains information about United MA plan members, their encounters, the providers associated with those encounters, and the diagnosis codes identified in those encounters (from any submission source); and (b) functioned as a repository from which diagnosis data was submitted to CMS’s RAPS for claims for MA risk adjustment reimbursement.

ii. United/Vendor Chart Review Data

57. During the timeframe at issue in this case, United and/or vendors working with United managed various chart review programs in which medical coders (independent of the providers or coders who originally identified and submitted diagnosis codes from a member’s encounter) reviewed member charts in an effort to identify diagnosis codes supported in the member’s charts. I refer collectively to the programs and efforts by United or third-party vendor coders to independently review member charts for purposes of identifying diagnosis codes supported by the charts as “Chart Review.”⁷⁶

58. During the timeframe relevant to this case, United’s Chart Review was offered by OptumInsight’s Clinical Performance and Compliance (“CPC”) business unit to MAO clients, including United’s Medicare & Retirement division. CPC used internal coders as well as coders

⁷⁵ Specifically, the Diagnosis Deletes Data includes: MARA2157342, MARA2152923, MARA2160498, MAPL003667107, MAPL000724834-MAPL000724836, MAPL005462874-MAPL005462875, and MAPL006427524-MAPL006427525.

⁷⁶ For clarity, my term “Chart Review” encompasses United’s Chart Review program, as well as the activities relating to the discrete “SUB_SOURCE_CD” pathways I relied upon in connection with the analyses discussed in Opinion 2 below.

from third-party vendors.⁷⁷ In almost all cases, the Chart Review coders performed “blind” reviews in which they were unaware of the diagnosis codes actually submitted by providers in connection with the charts subject to review.⁷⁸

59. The objective of United’s Chart Review process was to identify diagnosis codes supported in a member’s medical record to provide a more complete picture of the member’s overall health status.⁷⁹ Because the Chart Reviews were blind – meaning that the reviewers were only given the chart, and not any information about what diagnosis codes had previously been submitted or coded⁸⁰ – the failure to identify a diagnosis code during Chart Review that had previously been submitted or coded did not mean that the previous code was unsupported. It could mean, for example, that the Chart Review coder missed the code, or that a slightly different code was selected by the Chart Review coder as a result of the highly technical distinctions between certain codes.⁸¹

60. The data related to Chart Review was stored in various systems. During the timeframe relevant to this case, the data relating to United’s internal Chart Review efforts was stored in the ChartSync, Medical Record Manager (“MRM”), and Epsilon systems. The ChartSync system contains chart review data relevant to this case for DOS years 2008 – 2014. The

⁷⁷ During the timeframe relevant to this case, these third-party vendors included Outcomes (2005-2009); The Coding Source / Altegra Health (2005-2012); The Claremont Group (2007); Apogee (2008-2010); Mediconnect (2009-2010); Pi International (2009-present); iCodify (2009-present); Oncall Consulting (2012-2013); EMSI (2014-present); MedSave (2014-present); and RecordFlow (2014-present).

⁷⁸ See K. Baker 30(b)(6) Dep. Tr. 266:6-8: “We used informed coding in a very narrowly defined time frame.” I understand that in late 2012, United performed a Chart Review “recode project” wherein coders performed an additional review of charts from the 2011 DOS year and that in this project, Chart Review coders may have used an “informed coding” process. See K. Baker 30(b)(6) Dep. Tr. 268:3-270:5;281:9-282:3. In this process, the coder was provided with diagnosis codes previously coded or received from an acceptable data source across all providers associated with the member and/or non-United MA plan submissions for the member associated with the appropriate data collection period. See K. Baker 30(b)(6) Dep. Tr. 262:17-263:7. The informed coding information provided to coders was not specific to the rendering provider or date of service, as the charts reviewed could contain information from multiple providers and multiple dates of service across different data collection years and different provider encounters. See K. Baker 30(b)(6) Dep. Tr. 263:18-264:5. Beyond this 2012 recode project, an attempt was made in 2013 to use informed coding, but this effort was aborted because of data mapping challenges. Other than this, Chart Reviews were conducted blind during the time period at issue in this case. See K. Baker 30(b)(6) Dep. Tr. 266:18-267:10.

⁷⁹ K. Baker 30(b)(6) Dep. Tr. 33:17-34:16: “...Data can be submitted to CMS, you know, through various different channels, claims, encounter [sic]. And all of that data from different sources at different points in time, you know, potentially at different health plan memberships with different providers are consolidated by CMS to create a full health status. But that health status is never, ever fully complete. So with retrospective chart review, we’re trying to provide more complete health status for appropriate payment.”

⁸⁰ K. Baker 30(b)(6) Dep. Tr. 260:7-16.

⁸¹ K. Baker 30(b)(6) Dep. Tr. 36:12-37:20.

MRM and Epsilon systems contain chart review data relevant to this case for DOS years 2014 – 2016. When United used third-party vendors to perform chart reviews, the data related to those chart reviews was stored in the vendors’ systems. While the specific functionality and back-end data contents of these systems differ, generally speaking, they contain data about the results of the chart reviews that were performed – including, for example, information identifying the chart that was reviewed, the provider(s) associated with each chart, the results or outcomes of the chart review, and the diagnosis code(s) identified by the chart reviewer in connection with a given member’s chart.

61. For the purposes of my report, I define the “United/Vendor Chart Review Data” as the data residing in any United or vendor system or database (including ChartSync, MRM, Epsilon, and external chart review vendor data sources) that maintains information about chart reviews of United MA plan members, the results of the reviews, and the diagnosis codes identified by the reviews that were then included within the United Risk Adjustment Claims Data.

iii. Additional Reference Materials

62. Most of the data I relied upon for my report derived from productions of the United Risk Adjustment Claims Data and/or United/Vendor Chart Review Data, as further explained in the summary of relevant data requests and productions below. In some cases, I requested and obtained additional data from United that was useful to my analyses. This additional data included information used to identify the same member across time.

63. United maintains an internal data table providing a list of various identifiers for United members, including HICN and Medicare Beneficiary Identifier (“MBI”), as well as a “master ID” unique to the member.⁸² This table is called the “HICN-to-MBI Crosswalk.” In circumstances in which a unique member had multiple separate HICNs or MBIs, the master ID would still be the same for this member. United updates this internal table once per month. The table is limited to members with an MBI. During the monthly update process, if a new MBI is found and linked to an existing member, then a record is inserted into the table using the member’s existing master ID. If a new MBI is not linked to an existing member, then a new record is inserted

⁸² MBI replaced HICN as the unique identifier for Medicare members and became required for all Medicare transactions effective January 1, 2020.

with a new master ID.⁸³ The version of the table I relied upon for my analyses was generated by United in December 2019.

64. Additionally, the “Member” and “Member Audit” data tables, which were included as part of various productions of the United Risk Adjustment Claims Data,⁸⁴ contain lists of HICNs that crosswalk to a unique “Member Number” for members. As further described below in my report, I used a combination of the HICN-to-MBI Crosswalk and the Member and Member Audit data tables to create a consolidated resource to identify situations where unique members had more than one identifier over time. I refer to this data collectively as the “Related Member Identifier Data.”

D. Summary of Relevant Data Requests

65. A significant amount of data has been requested through discovery in this case at various points in time. The section below outlines the key data requests that led to the productions of data that I relied upon for my analyses.

i. Chart Review and Claims Verification Document Request 4C

66. In 2015, the government requested that United provide a significant amount of data relating to Chart Review for DOS years 2009 – 2012 (“Chart Review and Claims Verification Document Request 4C” or “DR4C”).⁸⁵ In DR4C, the government requested that United provide data related to “every member...associated with a chart subjected to Chart Review for Chart Reviews by any providers (including, but not limited to, FFS, capitated, physician and hospital providers) conducted by [United], by vendors paid in whole or in part by [United], or by the providers.”⁸⁶ For those members who had a chart subjected to Chart Review, the government requested that United provide: data tables with detailed information about the members (the “member file”); the providers visited by those members (the “provider file”); the diagnosis codes

⁸³ Information obtained via discussion with Caroline Le, Director of Medicare Risk Adjustment at Optum.

⁸⁴ Includes data produced in the DR4C, DR4C Supplemental, 2008 – 2009 & 2014 – 2016 DOS RFP, Verscend, Post Sweeps, and Supplemental Post Sweeps productions. (MAPL000724261, MAPL000724262, MAPL002079150, MAPL002079151, MAPL003667038, MAPL003667039, MAPL006427505, MAPL006427506, MAPL005462854, MAPL005462855, MAPL003292399, MAPL003292400).

⁸⁵ The government’s request was initially for data relating to DOS years 2009 – 2012, but the data ultimately produced in response was for DOS years 2010 – 2013.

⁸⁶ WideRight_Updated Requests 10-7-15.pdf.

belonging to those members (the “provider diagnoses” file); the members’ chart(s) subjected to Chart Review (the “CR reviewed charts” file); the diagnosis codes found by the chart reviewer(s) during the Chart Review process for charts subjected to Chart Review (the “CR diagnoses” file); and other data tables pertaining to those members.⁸⁷ The government requested information across all of United’s MA plans and from any database or system containing relevant information.

ii. In Process CV Encounter Request

67. In 2015, the government requested that United identify and provide data relating to 2011 and 2012 DOS encounters for which the multi-stage Claims Verification Program (“CV”) process was begun but not completed at the time United discontinued CV (“In Process CV Encounter Requests”). For those encounters, the government requested that United provide: “1. ProjectID (identifying the delete project as identified in the worksheet ‘12-13-2014 Data Set’), 2. PatientControlNumber, 3. HIC Number, 4. Provider Type, 5. From Date, 6. Through Date, 7. Diagnosis Code, 8. Plan Number, 9. The status of the code, e.g., whether it was submitted to RAPS and accepted. (or just confirm that all of them were submitted and accepted).”⁸⁸

iii. United States’ First Request for Production of Documents to Defendants

68. In October 2017, in the United States’ First Request for Production of Documents to Defendants (“Government’s First RFP”), the government requested that United provide data relating to chart reviews conducted as part of United’s Chart Review Program relating to medical encounters during DOS years 2005 through 2016.⁸⁹ Requests 35 – 36 of the Government’s First RFP requested data related to the charts that were reviewed as part of United’s Chart Review Program, as well as data related to each member for whom there was at least one chart subject to chart review during the requested timeframe (including, for example, all encounter and diagnosis data for those members, member identifying information, and provider identifying information for providers associated with those members’ encounters).⁹⁰ Request 38 of the Government’s First RFP requested documents relating to inputs to and outputs from United’s risk adjustment

⁸⁷ *Id.*

⁸⁸ See January 29, 2016 production letter (“2011 DOS Encounters Identified for CV Review”) from Latham & Watkins (excerpting October 30, 2015 Request).

⁸⁹ Plaintiff United States’ First Request for Production of Documents to Defendants, October 5, 2017.

⁹⁰ *Id.*

databases,⁹¹ and/or ad hoc processes conducted outside the formal risk adjustment databases, relating to any chart reviews.

E. Summary of Relevant Data Productions

69. United made multiple large productions of United Risk Adjustment Claims Data and United/Vendor Chart Review Data in response to the government's data requests. The productions upon which I relied are summarized in chronological order of production below.

i. In Process CV Encounter Production

70. In response to the In Process CV Encounter Requests, United compiled and produced several Excel spreadsheets identifying 2011 and 2012 DOS encounters in RAPS for which the multi-stage CV process was begun but not completed at the time United discontinued CV (the "In Process CV Code Data"). For 2011 DOS, these spreadsheets are Bates-stamped MARA2117116 and MARA2164481.⁹² For 2012 DOS, these spreadsheets are Bates-stamped MARA1298042, MARA2092181, and MARA2160501.⁹³ These productions were explained in greater detail in cover letters from United's Counsel, Latham & Watkins, at the time of production.⁹⁴

ii. Document Request 4C Production

71. In response to DR4C, in multiple iterations throughout 2016, United produced several large data tables containing information from the United Risk Adjustment Claims Data and United/Vendor Chart Review Data that was responsive to the government's requests for the DOS

⁹¹ This referred to any and all UHG or vendor databases relating to the submission of claims and diagnosis data in relation to UHG's risk adjustment programs.

⁹² See January 29, 2016 production letter ("2011 DOS Encounters Identified for CV Review") from Latham & Watkins; September 30, 2016 production letter ("Production of Replacement File for MARA2117116") from Latham & Watkins.

⁹³ See May 12, 2015 production letter ("2012 DOS Submissions Identified for Claims Verification") from Latham & Watkins; November 24, 2015 production letter ("2012 DOS Encounters Identified for CV Review") from Latham & Watkins; May 27, 2016 production letter ("Response to Follow Up Questions on March 18, 2016 Letter re: 2012 DOS Encounters Identified for CV Review") from Latham & Watkins.

⁹⁴ See May 12, 2015 production letter ("2012 DOS Submissions Identified for Claims Verification") from Latham & Watkins; November 24, 2015 production letter ("2012 DOS Encounters Identified for CV Review") from Latham & Watkins; See January 29, 2016 production letter ("2011 DOS Encounters Identified for CV Review") from Latham & Watkins; May 27, 2016 production letter ("Response to Follow Up Questions on March 18, 2016 Letter re: 2012 DOS Encounters Identified for CV Review") from Latham & Watkins; September 30, 2016 production letter ("Production of Replacement File for MARA2117116") from Latham & Watkins.

years 2010 – 2013 (the “DR4C Production”). In some cases, multiple tables were split out and produced in response to a single subcomponent of the DR4C request. These productions were explained in detail in cover letters from United’s Counsel, Latham & Watkins, at the time of production.⁹⁵

72. The DR4C tables that I relied upon for the analyses in my report include the following:

- a. DR4C.i. – “Member File” (for DOS years 2010 – 2013).⁹⁶ The “Member File” tables provide information about every member number associated with a chart subjected to Chart Review for any providers conducted by United, by vendors paid by United, or by the providers.⁹⁷
- b. DR4C.ii. – “Provider File” (for DOS years 2010 – 2013).⁹⁸ The “Provider File” tables provide information about providers visited by any members identified in the “Member File” tables (*i.e.*, rendering providers) and for all billing providers listed for these visits.⁹⁹
- c. DR4C.iii. – “Provider Diagnosis File” (for DOS years 2010 – 2013).¹⁰⁰ The “Provider Diagnosis File” tables provide information about every diagnosis code that exists in any United database – including, but not limited to,

⁹⁵ See February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins; April 15, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2011 DOS”) from Latham & Watkins; May 2, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2010 DOS”) from Latham & Watkins; June 29, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2013 DOS”) from Latham & Watkins.

⁹⁶ Includes Bates number MARA2160490 (DOS year 2010); MARA2157332 (DOS year 2011); MARA2152913 (DOS year 2012); and MARA2160687 (DOS year 2013).

⁹⁷ See, *e.g.*, February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins. Similar letters were produced for other DOS year productions.

⁹⁸ Includes Bates number MARA2160491 – MARA2160492 (DOS year 2010); MARA2157333 – MARA2157334 (DOS year 2011); MARA2152914 – MARA2152915 (DOS year 2012); and MARA2160688 – MARA2160689 (DOS year 2013).

⁹⁹ See, *e.g.*, February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins. Similar letters were produced for other DOS year productions.

¹⁰⁰ Includes Bates number MARA2160493 – MARA2160494 (DOS year 2010); MARA2157335 – MARA2157336 (DOS year 2011); MARA2152916 – MARA2152917 (DOS year 2012); and MARA2160690 – MARA2160691 (DOS year 2013).

diagnosis codes based on claims and encounters data or other types of data such as Patient Assessment Form (PAF) encounter record reviews – and that belong to any members listed in the “Member File” tables.¹⁰¹

- d. DR4C.iv. – “CR Reviewed Charts File” (for DOS years 2010 – 2013).¹⁰² The “CR Reviewed Charts File” tables provide information about every chart subjected to Chart Review.¹⁰³
- e. DR4C.v. – “CR Diagnoses File” (for DOS years 2010 – 2013).¹⁰⁴ The “CR Diagnoses File” tables provide information about diagnosis codes found by the chart reviewer or coder during the Chart Review process for every chart that went through the Chart Review process.¹⁰⁵
- f. DR4C “Deletes” file¹⁰⁶. This file lists diagnosis codes from the DR4C production that were subsequently retroactively deleted.

iii. Document Request 4C Supplemental Production

73. In June 2016, the government submitted a series of follow-up questions to United about the DR4C production. Among other things, the government requested that United provide data related to certain diagnosis codes in the DR4C data that were identified as “front end excluded” from RAPS.¹⁰⁷ In July 2016, United produced additional information responsive to this request (the “DR4C Supplemental Production”). This data, in documents Bates-stamped

¹⁰¹ See, e.g., February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins. Similar letters were produced for other DOS year productions.

¹⁰² Includes Bates number MARA2160495 (DOS year 2010); MARA2157337 (DOS year 2011); MARA2152918 (DOS year 2012); and MARA2160692 (DOS year 2013).

¹⁰³ See, e.g., February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins. Similar letters were produced for other DOS year productions.

¹⁰⁴ Includes Bates number MARA2160496 – MARA2160497 (DOS year 2010); MARA2157338 – MARA2157339 (DOS year 2011); MARA2152919 – MARA2152920 (DOS year 2012); and MARA2160693 – MARA2160694 (DOS year 2013).

¹⁰⁵ See, e.g., February 9, 2016 production letter (“Production of Responses and Documents Responsive to CR / CV Document Request 4(C) for 2012 DOS”) from Latham & Watkins. Similar letters were produced for other DOS year productions.

¹⁰⁶ MARA2160498.

¹⁰⁷ June 24, 2016 letter from Carol Lynn Wallack, Trial Attorney, Civil Division of the U.S. Department of Justice to Latham & Watkins.

MARA2160704 to MARA2160725, includes various tables from the United Risk Adjustment Claims Data from 2010 – 2013 that provide information about the errors associated with certain diagnosis codes and/or encounters.¹⁰⁸

iv. 2008 – 2009 and 2014 – 2016 DOS RFP Production

74. In April 2018, United produced data in response to requests 35, 36, and 38 of the Government’s First RFP for DOS years 2014 through 2016 (the “2014 – 2016 DOS RFP Production”). This included documents Bates-stamped MAPL001370197 to MAPL001370236.¹⁰⁹ Similar to the 2008 – 2009 DOS RFP Production described above, the 2014 – 2016 DOS RFP Production comprised numerous data tables broken out by DOS year and by the type of information requested. These include “member” tables, which provide information about the members relevant to the government’s requests; “diagnosis” tables, which provide information about those members’ diagnosis codes in the risk adjustment data during the timeframe; and so forth.

75. In September 2018, United produced data in response to requests 35, 36, and 38 of the Government’s First RFP for DOS years 2008 and 2009 (the “2008 – 2009 DOS RFP Production”). This included documents Bates-stamped MAPL002077000 to MAPL002079216, which comprised numerous data tables for these two DOS years, broken out by year and by the type of information requested, similar to the 2008 – 2009 DOS RFP Production.¹¹⁰

76. Broadly speaking, these productions were similar to the DR4C Production in that they provided member, provider, diagnosis code, diagnosis deletion, and chart review results information sourced from the United Risk Adjustment Claims Data and United/Vendor Chart Review Data for members who had charts subjected to chart reviews during the relevant timeframes.

v. SAS All Providers

¹⁰⁸ July 15, 2016 production letter (“Response to Provider Diagnosis File 4(C)(iii) Supplemental Data Requests”) from Latham & Watkins.

¹⁰⁹ June 15, 2018 production letter (“Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697”) from Latham & Watkins.

¹¹⁰ September 21, 2018 production letter (“Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697”) from Latham & Watkins.

77. In March 2019, in a supplemental response to requests 35 and 36 of the Government's First RFP, United produced a series of data tables providing detailed identifier and contact information for United providers. This includes first and last name, address, NPI, tax ID, and phone number. These tables, which are referred to as the "SAS All Providers" tables, are contained in the documents Bates-stamped MAPL003292331 to MAPL003292389.¹¹¹ The underlying data for the SAS All Providers tables comes from a repository maintained by OptumInsight populated with provider information submitted by OptumInsight's various customers. (OptumInsight provides Medicare Risk Adjustment services to United as well as non-United customers.)¹¹² The SAS All Providers repository contains raw provider details that were transmitted via a standardized, conforming file format that requires the population of certain data fields. Once that data is received and stored in the data repository, OptumInsight validates the data and combines it into a single master table. This data is refreshed monthly. I understand that the extracts produced in this case contain data from this repository for all United providers (*i.e.*, excluding providers submitted to OptumInsight from non-United customers).¹¹³ United produced more than 50 monthly SAS All Providers files.¹¹⁴

vi. Verscend Production

78. Subsequent to the 2008 – 2009 DOS RFP Production, United received additional chart review data from the vendor Verscend. This data included additional United members who were subject to chart review in 2008 – 2009 but who were not captured in the 2008 – 2009 DOS RFP Production. Because these members were responsive to the Government's First RFP, in March 2019, United supplemented the 2008 – 2009 DOS RFP Production with all responsive data for the new, incremental members identified in the Verscend data (the "Verscend Production"). This was captured in documents Bates-stamped MAPL003292457 and MAPL003292390 to MAPL003292416.¹¹⁵ This data is included within my definition of the United Risk Adjustment Claims Data and United/Vendor Chart Review Data.

¹¹¹ March 15, 2019 production letter ("Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697") from Latham & Watkins.

¹¹² MAPL003292389.

¹¹³ Information obtained via discussion with Caroline Le, Director of Medicare Risk Adjustment at Optum.

¹¹⁴ March 15, 2019 production letter ("Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697") from Latham & Watkins.

¹¹⁵ *Id.*

vii. July 2019 Supplemental Production

79. In July 2019, United identified and produced additional data from the United Risk Adjustment Claims Data and United/Vendor Chart Review Data that was responsive to DR4C and the Government's First RFP (the "July 2019 Supplemental Production"). The information responsive to DR4C related to DOS years 2010 and 2013, while the information responsive to requests 35, 36, and 38 of the Government's First RFP related to DOS years 2008, 2009, and 2014.¹¹⁶ This data was produced in the documents Bates-stamped MAPL003667028 to MAPL003667218.¹¹⁷

viii. Post Sweeps Production

80. In October 2019, United produced additional data from the United Risk Adjustment Claims Data and United/Vendor Chart Review Data that was responsive to the Government's First RFP relating to DOS years 2015 and 2016 (the "Post Sweeps Production")¹¹⁸. This data included diagnosis code submissions that were not included in the 2014 – 2016 DOS RFP Production.¹¹⁹ This data was produced in the documents Bates-stamped MAPL005462834 to MAPL005462902.¹²⁰

ix. Post Sweeps Supplemental Production

81. In December 2019, United produced supplemental data relating to the Post Sweeps Production (the "Post Sweeps Supplemental Production"). This included additional data from the United Risk Adjustment Claims Data and United/Vendor Chart Review Data that was responsive to the Government's First RFP relating to DOS years 2015 and 2016 that had not been included in

¹¹⁶ July 16, 2019 production letter ("Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697") from Latham & Watkins.

¹¹⁷ *Id.*

¹¹⁸ The "Post Sweeps Production" represents diagnosis codes added after CMS completes a sweep of RAPS for dates of service for a calendar year.

¹¹⁹ The 2014 – 2016 DOS RFP Production was generated prior to the final risk adjustment submission deadlines for DOS years 2015 and 2016.

¹²⁰ October 31, 2019 production letter ("Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697") from Latham & Watkins.

previous productions. This data was produced in the documents Bates-stamped MAPL006427492 to MAPL006427602.¹²¹

IV. SUMMARY OF OPINIONS

82. Based on the work I have performed to date, and as further detailed below, I have formed the following opinions:

- i. Opinion 1: The government's approach for identifying diagnosis codes that United allegedly improperly failed to delete or otherwise return as overpayments is flawed and overinclusive because millions of the diagnosis codes in the government's list are from providers whose charts do not appear to have undergone Chart Review and thus could not have resulted in the identification of unsupported diagnosis codes under the government's theory.
- ii. Opinion 2: The government's approach for identifying diagnosis codes that United allegedly improperly failed to delete or otherwise return as overpayments is flawed and overinclusive because it is mistakenly executed at the diagnosis code level rather than the condition (*i.e.*, HCC or RxHCC) level. In fact, for approximately 67% of the allegedly improper diagnosis codes in the government's list, United's Chart Review *confirmed* that the member had the condition corresponding to the diagnosis code at issue (or a more severe condition in the same hierarchy), meaning that there is no overpayment associated with the diagnosis code.
- iii. Opinion 3: The diagnosis codes listed in the government's First Interrogatory Response form an improper basis for evaluating potential overpayments because, in approximately 83% of cases, even if the diagnosis codes were incorrect, deleting those codes would not have impacted the Part C or Part D MA payments to United in the years at issue. There are a variety of reasons for this, including, but not limited to, the fact that (a) some diagnosis codes do not impact the risk adjustment process; (b) multiple diagnosis codes may support the same condition code; and (c) a higher level condition code may also be

¹²¹ December 6, 2019 production letter ("Re: United States ex rel. Poehling v. UnitedHealth Group, Inc., No. CV 16-08697") from Latham & Watkins.

supported, superseding any lower level condition code that may be found to be unsupported.

- iv. Opinion 4: The government's assertion that the diagnosis codes in the First Interrogatory Response are not supported is contradicted by CMS's own RADV auditors. In fact, CMS's coders found support for more than 89% of the First Interrogatory Response diagnosis codes mapping to member-HCC combinations that CMS reviewed as part of the CON11-13 RADV audits. This rate increases to 91% when also taking into account the results of the CON14-15 RADV audits.
- v. Opinion 5: Based on the results of CMS's RADV audits, the First Interrogatory Response codes were no more likely to be unsupported than any other codes submitted in connection with United plans reviewed by CMS's RADV audits.
- vi. Opinion 6: Contrary to the practice that it typically follows in identifying and quantifying overpayments resulting from diagnosis code errors in the risk adjustment process, the government here has chosen to focus solely on allegedly unsupported codes that were submitted to Medicare, rather than considering the net impact of both unsupported codes and codes that should have been, but were not, submitted. Even in cases where an MA plan sponsor has employed a chart review process like the one at issue here, there is a substantial possibility, as demonstrated in the government's own RADV audits, that there are additional appropriate codes that were missed and not submitted. In fact, the evidence in this matter indicates that such unsubmitted codes can outweigh any submitted codes that may lack proper support. Thus, to fully assess whether and to what extent a possible overpayment exists – even before considering whether any such overpayment was knowingly retained by United – it would be necessary to consider both the codes that may lack support as well as appropriate codes that were not submitted.
- vii. Opinion 7: If the results of CMS's CON11-13 RADV audits hold constant across all of the First Interrogatory Response codes at issue, then over 94% of the diagnosis codes identified in the government's list could not be overpayments. If the results of CMS's CON11-15 RADV audits hold constant across all of the First Interrogatory Response codes at issue, then approximately 94% of the diagnosis codes identified in the

government's list could not be overpayments. This is the result of two factors. First, as noted above, the analysis in Opinion 3 shows that approximately 83.3% of the diagnosis codes in the government's list do not have any financial impact on the government's payments to United plans. Second, with respect to the remaining diagnosis codes, the CMS CON11-13 RADV audits found support for 65.3% of the at-issue diagnosis codes that were (a) addressed in a CON11-13 RADV audit and (b) found to have financial impact based on Opinion 3. Combining these results with those of the CMS CON14-15 RADV audits, the CMS CON11-15 RADV audits in total found support for 62.5% of the at-issue diagnosis codes that were (a) addressed in a CON11-15 RADV audit and (b) found to have financial impact based on Opinion 3. Thus, to the extent that the government's First Interrogatory Response is intended to be used as a basis for assessing either the pervasiveness or the dollar impact of improper diagnosis codes, it is biased and unreliable.

V. **BASIS FOR OPINIONS**

A. **Opinion 1: The government's approach for identifying diagnosis codes that United allegedly improperly failed to delete or otherwise return as overpayments is flawed and overinclusive because millions of the diagnosis codes in the government's list are from providers whose charts do not appear to have undergone Chart Review and thus could not have resulted in the identification of unsupported diagnosis codes under the government's theory.**

i. **Overview**

83. Based on its own description, the government's First Interrogatory Response identified diagnosis codes with three conditions: "(1) the diagnosis code was submitted by UnitedHealth to CMS and was required, by regulation, to be supported by an underlying medical record; (2) *that medical record went through UnitedHealth's medical record review program*; and (3) UnitedHealth's own reviewers did not find the diagnosis code to be supported by medical records" (emphasis added).¹²² Based on this description, all diagnosis codes in the government's

¹²² Joint Stipulation Regarding Government's Motion to Compel, dated April 29, 2021, p 8.

First Interrogatory Response should have been related to charts reviewed through United's Chart Review in that year. However, many of the diagnosis codes in the government's First Interrogatory Response were submissions from providers whose charts do *not* appear to have been reviewed during that year.

84. The government has neither provided any detailed explanation about how they identified records that allegedly went through United's Chart Review nor provided a way to test or replicate their methodology. In comparing the government's list to the data that I understand to have been used in compiling the list, it appears that the government may have assumed a member's *entire* chart was reviewed by United if that member had one or more dates of service reflected in the United/Vendor Chart Review Data. This would be a critical error in the government's analysis to the extent that it does not recognize the *provider-specific* nature of Chart Review.

85. United's Chart Review process focused on the charts created by certain providers for a given member. In reality, members can see multiple providers on the same DOS. Consequently, there are cases in which the Chart Review would encompass charts only from some, but not all, of the providers seen by that member on that DOS. For example, assume John Doe saw Dr. Green, his general practitioner, and Dr. Red, his cardiologist, on the same day. On that day, Dr. Red recorded and submitted diagnosis code X, but Dr. Green did not. Also assume that only Dr. Green's chart underwent Chart Review; John Doe's records for the visit with Dr. Red were neither collected nor reviewed. In such a case, if the government reviewed John Doe's information in that year's Chart Review data, it would have seen that a diagnosis code X connected to this DOS was *not* identified in the Chart Review since the reviewer would not have had access to information related to the visit with Dr. Red. In such a circumstance, it appears that the government would erroneously assume that diagnosis code X was inappropriately submitted when, in actuality, diagnosis code X was submitted *by a provider whose charts were not reviewed* and, thus, would be outside the scope of the government's theory of liability.

86. To the extent that the government's First Interrogatory Response includes such diagnosis codes, they are inconsistent with the government's own description of its analysis and should be excluded from consideration in evaluating any alleged overpayments.

ii. Data Relied Upon

87. For the purposes of this analysis, in addition to the government's First Interrogatory Response data, I relied upon the following datasets:

- a. United/Vendor Chart Review Data. For this analysis, I used the United/Vendor Chart Review Data, which I understand contains data for every chart subjected to Chart Review during each given year.¹²³ While the specific structure and content of this data varies over time because it was generated in separate productions and sourced from separate systems, it has some key common characteristics relevant to my analysis. First, the data provides a unique "barcode" identifier, which is a unique serial code representing a unique member chart that was subjected to Chart Review.¹²⁴ Also, the data lists provider information associated with each unique chart. In some cases, this provider is only described in a single piece of information: a provider number.¹²⁵ In other cases, the provider's name, address, tax ID, and/or NPI was also available.¹²⁶ Notably, the United/Vendor Chart Review Data does not contain the actual charts that the coder(s) analyzed in Chart Review (*i.e.*, the progress notes, visit summaries, or other chart documentation the coder would have reviewed as a basis for his or her findings about the member's supportable diagnosis

¹²³ For DOS years 2008 – 2009, I relied upon the United/Vendor Chart Review Data produced in the 2008 – 2009 DOS RFP Production. This included data from ChartSync as well as from vendors working with United to perform chart reviews during this time – including vendors TCS, ECS, Pi, Mediconnect, and Outcomes. For DOS years 2010 – 2013, I relied upon the United/Vendor Chart Review Data produced in response to DR4C (the "CR Reviewed Charts File" tables), which provide information about every chart subjected to Chart Review for these DOS years. For DOS years 2010 and 2013, I relied upon a stacked combination of both the DR4C CR Reviewed Charts tables from the original DR4C productions for those years as well as the DR4C CR Reviewed Charts tables from the July 2019 Supplemental Production. For DOS years 2014 – 2016, I relied upon the United/Vendor Chart Review Data produced in the 2014 – 2016 DOS RFP Production, which included data from ChartSync, MRM, and Epsilon.

¹²⁴ All data from United's Chart Review system productions – *i.e.*, those from ChartSync, MRM, and Epsilon – contain barcodes. Some, but not all, data from the vendor productions contain barcodes.

¹²⁵ The Chart Data (DR4Civ) from the DR4C Production and DR4C Supplemental Productions for DOS years 2010 – 2013 only include a single provider number as the sole identifier for a provider within the chart data. This provider number is a numeric or alphanumeric code created and maintained internally within United's data systems; it does not convey the provider's name, address, or other external identifiers (such as NPI). The provider number can be linked to other data sources, further described below, which contain additional information about the provider, such as the name, address, NPI, and tax ID.

¹²⁶ The United/Vendor Chart Review Data produced in the 2008 – 2009 DOS RFP Production, July 2019 Supplemental Production, 2014 – 2016 DOS RFP Production, June 2018 Supplemental Production, and Post Sweeps Production contain provider identifiers in addition to just provider number, including provider name, address, NPI, and tax ID.

codes in that year). Further, the data is insufficient to determine whether the coder(s) had access to information in the member's chart beyond just the documentation pertaining to the provider listed in association with the chart. For example, if a unique chart was associated with unique provider X, and some or all of provider X's work was performed at practice location Y, the United/Vendor Chart Review Data does not indicate whether the coder(s) would have been able to review that member's charts for all activity performed by all providers at practice location Y, or just the activity relating to services performed by provider X.

- b. The Provider File (DR4Cii). The "Provider" tables contain information about providers visited by any members identified in the "Member File" tables (*i.e.*, rendering providers) and for all billing providers listed for these visits. This data includes provider identifiers including name, address, facility name, phone number, and provider source (e.g., COSMOS, NICE) that can be linked to provider numbers identified in the DR4Civ Chart Data.¹²⁷
- c. SAS All Providers data. The SAS All Providers data includes additional provider identifying information beyond just the United-internal provider number – such as provider name, address, tax ID, and NPI – for the providers listed in the United/Vendor Chart Review Data.
- d. Related Member Identifier Data. I used the Member, Member Audit, and HICN-to-MBI Crosswalk data to identify any related HICN(s) or MBIs for a unique United member.

iii. Methodology

88. To perform this analysis, I compared the member-provider combinations in the First Interrogatory Response to the United/Vendor Chart Review Data, which identifies provider

¹²⁷ For DOS years 2010 and 2013, I relied upon a combination of both the DR4C Provider tables from the original DR4C productions for those years as well as the DR4C provider tables from the July 2019 Supplemental Production to include all available provider identifiers and capture all potential provider matches for these years.

information related to reviewed charts. If the First Interrogatory Response data only includes diagnosis codes from charts that were part of the Chart Review process (as the government maintains), then, in any given year, each of the member-provider pairs from the First Interrogatory Response data should be reflected in the United/Vendor Chart Review Data. However, my analysis shows that this is not the case.

89. As an illustration, if there is a diagnosis code for member John Doe submitted by provider Dr. Green in the First Interrogatory Response data in DOS year 2012, and Dr. Green's chart for John Doe was reviewed as part of United's Chart Review program in that year, then Dr. Green's chart for John Doe – put another way, the “member-provider” combination of Dr. Green-John Doe – would be included in the United/Vendor Chart Review Data in that year. If a member-provider combination from the First Interrogatory Response data cannot be identified in the United/Vendor Chart Review Data, then there is no clear evidence to establish that diagnosis codes associated with that member-provider combination in that year were part of United's Chart Review in that year. Any such codes should not have been included in the government's list.

90. Executing this comparison is an intricate process because of the complexity of the relevant provider data across the various productions. The United/Vendor Chart Review Data is populated with inconsistent types and formats of provider identifying information across time because it was sourced from different upstream systems with varying structures and data parameters. This complexity has multiple dimensions. For example, the United/Vendor Chart Review data does not always contain the same types of provider identifying information.¹²⁸ Likewise, the United/Vendor Chart Review Data is not always formatted similarly across time. For example, provider numbers from certain underlying data sources sometimes contain alphabetic characters, while provider numbers from other sources do not.¹²⁹ Also, they can vary in terms of

¹²⁸ For example, the United/Vendor Chart Review Data in 2008 and 2009 – sourced from outside vendors ECS, TCS, Outcomes, and Mediconnect – does not uniformly identify a Provider NPI, an industry-standard identifier unique to a provider. Instead, in this time period, the data tended to provide identifiers such as Provider ID, Provider Name, and Provider Address. In more recent DOS years, the data captured in ChartSync, MRM, and Epsilon (including charts submitted by both United's internal chart reviewers as well as external vendors such as Pi Offshore, iCodify, and MedSave) includes NPIs and more comprehensive provider identifiers such as provider full name, address, and tax ID.

¹²⁹ For example, in the data from the Outcomes and Mediconnect Chart Review vendors, provider identifiers are numeric the majority of the time; in contrast, in the data from the PI, TCS, and ECS Chart Review vendors, provider identifiers are non-numeric the majority of the time. Note that, in the government's First Interrogatory Response, providers are identified by numeric provider numbers more than 90% of the time.

whether they include leading zeros – a practice that is a function of differing requirements across different systems. Another complexity arises from the fact that individual providers can have multiple provider numbers, addresses, and even NPIs across the relevant timeframe. All of these factors make the matching of providers and codes within the data very complicated and difficult, yet they all need to be considered to properly compare a unique provider from the United/Vendor Chart Review Data to the First Interrogatory Response.

91. Additionally, the United/Vendor Chart Review Data is further complicated by the nature of the provider identifier information itself. I understand that, in some cases, the provider identifier associated with a unique chart in the United/Vendor Chart Review Data could have been a consolidated identifier created for the purposes of retrieving chart(s) for a member from multiple providers at one location.¹³⁰ As a result, it is possible that the charts collected for some members included encounters with multiple providers.¹³¹ As an example of this, if a member was seeing multiple providers at a single facility, and United wanted to retrieve that member's records from across all those providers for Chart Review, United may have used the unique identifiers for just one of those providers to serve as the "retrieval" identifier for that entire facility. Consequently, if all of the providers' records were actually obtained, then they all may have been labeled with the same "retrieval" identifier, derived from just one of the providers, within the Chart Review system. Importantly, the United/Vendor Chart Review Data produced in this matter does not clearly indicate whether, or to what extent, multiple providers' charts were collected and reviewed in connection with the single provider identifier listed in the data. Moreover, I understand that, even if United intended to collect multiple providers' charts in connection with a single consolidated retrieval identifier, it may not actually have been able to collect them.¹³²

¹³⁰ K. Baker 30(b)(6) Dep. Tr. 65:5 – 68:9 describes the consolidation concept with respect to chart retrieval. *See also* K. Baker 30(b)(6) Dep. Tr. 117:18-118:6: "Q. Okay. So the retrieval provider information in ChartSync that is shown to the coder during retrospective chart review is retrieval provider information that is generated by Optum?...A: It is retrieval provider information that has been consolidated to avoid provider abrasion based upon the provider information that we had on hand."

¹³¹ K. Baker 30(b)(6) Dep. Tr. 119:13-120:2; 123:3-124:15.

¹³² K. Baker 30(b)(6) Dep. Tr. 120:8 – 121:6: "For example, you know, if it was a site...that had paper-based charts and we only went to...site 1 and it was a two-site one, we would only receive the part of the chart that was there for the doctors that saw there [sic]. But that doctor, let's say – call it Dr. A, could have been at site 1 on Monday, Wednesday, Friday but went to site 2 on...Tuesday and Thursday and we didn't have that component of the chart...And so it – the chart itself could have multiple information [sic], but we also wouldn't know for sure if it was complete."

92. The member-provider matching comparison is further complicated because of intricacies with unique *member* identifiers. Individual members can have multiple HICNs across time for various reasons.¹³³ In these cases, it is important to link those different HICNs together to ensure the comparison of member-provider combinations is at a unique member level.

93. To perform my analysis and ensure an accurate and comprehensive matching process, I began by creating consolidated lists of all the member-provider combinations and associated provider identifiers, where available, in the United/Vendor Chart Review Data across DOS years 2008 – 2016. These lists reflected the unique charts which were part of Chart Review for each member and the providers and accompanying provider identifier information¹³⁴ associated with those charts.

94. In creating these lists, I made efforts to clean and standardize the data where it was reasonably possible to systematically identify ways in which the data was inconsistent across time or between sources. For example, to link provider identifiers from the Provider table (DR4Cii) to the chart data (DR4Civ) in 2010, the chart provider number fields needed to be standardized. The Chart data contains an alphanumeric Chart Provider Number field, while DR4Cii contains a mostly numeric Provider Number field (similar to the provider numbers listed in the government’s First Interrogatory Response). For example, the provider “M.D., RAYMOND A. DURKIN” has a chart provider number of C_RAM_00250009593 in the chart data and a provider number of 00250009593 in the provider data. The provider data also contains the provider name, address, NPI, and tax ID, while the chart data contains the alphanumeric provider number as the sole provider identifier. To link these additional provider identifiers from the provider data to the chart data, the Chart Provider Number in the chart data must be standardized to exclude the “C_RAM_” prefix. I employed similar data standardization techniques across sources for other years to be

¹³³ For example, a change in marital status can cause a member’s HICN suffix to change from “B” for spouse to “D” for divorced spouse, widow, or widower.

¹³⁴ This included provider identifiers such as NPI, provider name, provider address, and provider tax ID that existed within the vendor chart data sources for DOS years 2008 – 2009 and the MRM, ChartSync, and Epsilon sources for DOS years 2014 – 2016. To capture provider identifiers for the DR4C 2010 – 2013 years (for which the chart data does not contain additional provider identifiers other than a provider number), I linked in provider identifiers (such as NPI, provider name, provider address, and tax ID) from the Provider Files (DR4Cii) to create a comprehensive member-provider list.

overly inclusive in matching member-provider combinations in United's chart data to member-provider combinations in the government's First Interrogatory Response.

95. Next, I pulled in additional identifying information from the SAS All Providers data to gather the names, addresses, tax IDs, and NPIs for the providers associated with the reviewed charts, as available. This was particularly important in years in which the only provider information given in the United/Vendor Chart Review Data was the provider number, such as in the DR4C productions for DOS years 2010 – 2013. As part of this, I extracted the SAS All Providers data across all DOS years – even in cases when the provider name, address, tax ID, and/or NPI was already provided in the United/Vendor Chart Review Data – to gather additional information to use in my analysis.¹³⁵

96. Next, I identified instances in which a unique member had more than one identifier. Identifying members with more than one HICN or MBI is important to ensure that the comparison of member-provider combinations between datasets is at a unique member level. To do this, I used the Related Member Identifier Data described above.¹³⁶ For example, member **First Last** with date of birth **mm/dd/yyyy** has a “master ID” of **12345678** and separate HICNs of **1111111A** and **2222222B**.¹³⁷ Using this method, I established a link between a given HICN and any “related HICNs” for the same unique member. I included this step to identify possible member-provider matches even in cases where a unique member may have been listed with one HICN in the First Interrogatory Response but another HICN in the United/Chart Review Data.

97. Then, I compared the member-provider combinations in the government's First Interrogatory Response data to the United/Vendor Chart Review Data using a variety of linking methods to attempt to find matches in a systematic way. The government's First Interrogatory Response includes data fields conveying the provider number, name, address, tax ID, and NPI for the provider who submitted each allegedly improper diagnosis code. Based on that structure, I

¹³⁵ In most cases, when the provider name, address, tax ID, or NPI was present in both the United/Vendor Chart Review Data and the SAS All Providers data, the common information was identical between the two datasets. Sometimes, the information was formatted differently between the two data sets.

¹³⁶ The HICN-to-MBI Crosswalk data provides a way to link member HICNs to a “master ID” that is completely unique to a member; similarly, the Member and Member Audit data provides a way to link member HICNs to a “Member Number”. While there is overlap between the HICN-to-MBI Crosswalk and Member/Member Audit data, each source also contains a distinct population of members and their related HICNs.

¹³⁷ All data examples highlighted **in green** are based on real data but have been anonymized in this report. The de-anonymized values for each example are provided in Exhibit 4.

searched for instances where the member-provider combination in the First Interrogatory Response could be found in the United/Vendor Chart Review Data on the basis of any of the following. In this methodology, I searched for matches on member HICNs as well as “related HICNs” based on the Related Member Identifier Data.

- The member + provider number from the First Interrogatory Response matched a member + provider number from the United/Vendor Chart Review Data
- The member + provider NPI from the First Interrogatory Response matched a member + NPI from the United/Vendor Chart Review Data (or SAS All Providers).
- The member + provider name + provider address from the First Interrogatory Response matched a member + provider name + provider address from the United/Vendor Chart Review Data (or SAS All Providers).
- The member + provider tax ID from the First Interrogatory Response matched a member + provider tax ID from the United/Vendor Chart Review Data (or SAS All Providers).
- I employed the above matching methods for all available data across all DOS years. In the DOS years 2008 – 2009, much of the United/Vendor Chart Review Data came from vendor systems (as opposed to United’s internal systems: ChartSync, MRM, or Epsilon). Because these vendor systems were structured differently and contained different information than United’s internal systems, I also employed additional matching methods in this period, including matching the member - provider last name + address combination in the vendor data to the member-provider last name + address combination in the First Interrogatory Response. To perform this matching exercise, I extracted the last name from the full name field for each source for comparison.¹³⁸

¹³⁸ For example, there are two records in the government’s First Interrogatory Response associated with HICN 3333333C and Provider Number 00080040163. Provider Number 00080040163 has a Provider Name “Bowles, M.D., Fred Kirk” and address of “1670 W Main St Ste 100” within the First Interrogatory Response. Within the Vendor Chart data, the same HICN 3333333C has a chart associated with the provider name “Bowles, Kirk” also at “1670 W Main St Ste 100”, the exact same address identified in the First Interrogatory Response. These records would not match on the basis of full name and address because the name was presented differently between the two data sources. Nevertheless, by extracting just the provider’s last name, I was able to identify a match on the basis of last name and address.

98. Any diagnosis codes relating to member-provider combinations from the government's First Interrogatory Response that are also found in the United/Vendor Chart Review Data are considered to be a "provider match," while any other diagnosis codes are ones where the provider does not match. As described above, my approach incorporated a large number of data points in an attempt to locate possible provider matches as exhaustively as possible. It also incorporated a variety of steps to control for instances of incomplete or inconsistently formatted data. These assumptions were designed to be systematic, replicable, reasonable, and to result in the identification of an over-inclusive, rather than under-inclusive, set of likely provider matches.

99. As an illustration of the potentially over-inclusive nature of my approach, my methodology sometimes results in the identification of a provider match only at the level of the provider's tax ID – an identifier that can be shared by multiple different providers (*e.g.*, different providers associated with the same physician practice). For approximately 4 million of the records in the government's First Interrogatory Response (14% of total), the member-provider combination can only be found in the United/Vendor Chart Review Data on the basis of the provider's tax ID.¹³⁹ For example, as shown in Figure 3 below, there are four diagnosis code records in the government's First Interrogatory Response for HICN 4444444D in DOS year 2015 from providers who share a tax ID of 421411630. Each of these diagnosis codes were submitted from a different provider, with different provider numbers and names: Matthew Gray (provider number 10003380), Mohammed Khalil (provider number 250007975), Laila Payvandi (provider number 250007981), and Susan Halter (provider number 250007970). In the United/Vendor Chart Review Data, the member has five unique chart review barcodes in this year. Of the providers listed in connection with these barcodes, only one (Matthew Gray) overlaps with the providers listed in the First Interrogatory Response based on the provider name and address or NPI. However, that provider has the tax ID of 421411630. Apparently on the basis of that connection alone, the government has assumed that the diagnosis codes from providers Khalil, Payvandi, and Halter can be associated with the chart review for which Matthew Gray was the listed provider. In such cases, the possible member-provider connection is tenuous, yet the government appears to have assumed that a provider's diagnosis code submission for a given member was part of Chart Review when the only supporting evidence that the chart was reviewed is that the member had a

¹³⁹ See Appendix X2.

chart for which some *other* provider with the same tax ID was listed in the United/Vendor Chart Review data.

Figure 3. Example: HICN 4444444D.

First Interrogatory Response
Member 4444444D - DOS Year 2015

dx	prov_name_sasall	provider_nbr	address_sasall	npi_sasall	tax_sasall
4011	GRAY, M.D., MATTHEW N.	10003380	1030 5TH AVE SE STE 1400 CEDAR RAPIDS IA 52403	1053398982	423411630
42842	HALTER, M.D., SUSAN M.	250007970	202 10TH ST SE STE 225 CEDAR RAPIDS IA 52403		423411630
41400	KHALIL, M.D., MOHAMMED E.	250007975	202 10TH ST SE STE 225 CEDAR RAPIDS IA 52403	1245273226	423411630
41401	PAYVANDI, M.D., LAILA A.	250007981	202 10TH ST SE STE 225 CEDAR RAPIDS IA 52403		423411630

United/Vendor Chart Review Data
Member 4444444D - DOS Year 2015

Barcode*	Chart_Provider_ID	Src_Prov_ID	Fullname	Address	NPI	Tax_ID
2b7474e7bb330...	C NEX 00010001380	C NEX 00010003380	GRAY, M.D., MATTHEW N.	1030 5TH AVE SE STE 1400 CEDAR RAPIDS IA 52403	1053398982	423411630
195270c902869...	C NEX 00010001380	C NEX 00050000616	STRAITHERS, M.D., ROBERT J.	202 10TH ST SE CEDAR RAPIDS IA 52403	1962738795	423462899
2b7474e7bb330...	C NEX 00050000616	C NEX 00270000620	BEEVERS, D.P.M., STEVEN W.	3053 CENTER POINT RD NE STE B CEDAR RAPIDS IA 52402	1630135122	423471231
2b7474e7bb340...	C NEX 00270000620	C NEX 00760000520	COWDEN, M.D., JOHN DAVID	1026 A AVE NE CEDAR RAPIDS IA 52402	1962665071	423504780

Source: [Chart Review Data]
*Truncated for space
Source: [SAS All Providers 2016_02]

100. As another example of the possible over-inclusions stemming from reliance on the provider's tax ID, in DOS year 2012, there is a provider included in the government's First Interrogatory Response, Southeast CT Nephrology Assoc PC (provider number 00310001688), which only matches to a provider in the United/Vendor Chart Review Data on a common tax ID. In the United/Vendor Chart Review Data, HICN 5555555E has four unique chart review barcodes in this year associated with three distinct providers: provider number 00360002827, provider number 00040026173, and provider number 00310001723. None of these is the provider listed in the government's First Interrogatory Response. One of them – provider 00310001723 – has the same tax ID (061397333) as listed for the *other* provider from the First Interrogatory Response. Thus, like the example in the paragraph above, the government apparently assumes that diagnosis codes from provider 00310001688 can be associated with the chart review for which provider 00310001723 was the listed provider based only on the shared tax ID of 061397333.

Figure 4. Example: HICN 5555555E.

First Interrogatory Response
Member 5555555E - DOS Year 2012

Dx*	prov_name_sasall	provider_nbr	address_sasall	tax_sasall
4011	SOUTHEAST CT NEPHROLOGY ASSOC PC	00310001688	88 NORWICH NEW LONDON TPKE UNCAVILLE CT 06382	061397333

United/Vendor Chart Review Data
Member 5555555E - DOS Year 2012

Barcode	Provider ID
31518975-0ef3...	C_NYC_00360002827
947b99e4-872d...	C_NYC_00360002827
a1e86542-2ccc...	C_NYC_00040026173
1588f7ac-8a0b...	C_NYC_00310001723

Source: [Chart Review Data]
*Truncated for visual

Provider ID	Tax
C_NYC_00360002827	030410597
C_NYC_00040026173	271094375
C_NYC_00310001723	061397333

Source: [SAS All Providers]

101. Beyond these issues related to the tax ID, there are other intricacies related to the identification of provider matches across the relevant time period that the government has not considered. For example, some records in the government's First Interrogatory Response lack various provider identifiers that would enable more accurate matching to the United/Vendor Chart Review Data.¹⁴⁰ Potential matches based solely on one matching field are less certain than those in which multiple fields match; nevertheless, I have included them as matches in my analysis. Also, I have observed that some individual providers are associated with multiple provider IDs, another wrinkle in the data that complicates the ability to make precise matches.¹⁴¹

102. Still, despite employing a methodology that is likely over-inclusive in identifying charts that may have undergone chart review, I found millions of instances in which the government's First Interrogatory Response appears to include encounters for which there is no discernible evidence showing that Chart Review was performed. Specifically, in 10% of the government's First Interrogatory Response records, I was unable to identify any form of member-

¹⁴⁰ For example, for a 2008 DOS year record in the government's First Interrogatory Response associated with HICN 6666666E, only two provider fields are populated: provider_nbr (10005732), and tax_ir (232211307). Per my analysis, this record solely matches on the provider ID for this member's chart. In the United/Vendor Chart Review Data, HICN 6666666E has a chart associated with 10005732. Because of this, I consider this record to be a provider match. However, the absence of name, address, NPI, and tax ID within the government's First Interrogatory Response complicates the ability to corroborate whether this was truly a provider whose chart went through Chart Review.

¹⁴¹ For example, in the government's First Interrogatory Response, in the 2014 DOS year, there are 117 records associated with three distinct provider numbers – 40012382, 40056008, and 40015189 – that, when linked to the SAS All Providers table, are associated with only one consistent provider name (Aanonsen, D.O., Deborah A.), address (11 Ralph Place Ste 314), tax ID (830438439), and NPI (1952395717). A single provider's association with each of the three aforementioned provider IDs complicates the member-provider matches in chart data.

provider match between the First Interrogatory Response and the United/Vendor Chart Review Data at all.

103. As one example of this phenomenon, there are seven diagnosis code records in the government's First Interrogatory Response for HICN 7777777G ("HICN A" for purposes of this example) and five diagnosis code records for HICN 8888888H ("HICN B" for purposes of this example) in DOS year 2012. Based on the Related HICN crosswalk sourced from the Member, Member Audit, and HICN-to-MBI Crosswalk data, both of these HICNs relate to the same member, who had a "master ID" of 23456789. In the government's First Interrogatory Response data, for the DOS year 2012, this member had 12 diagnosis codes associated with three providers, as follows:

- Six diagnosis code records associated with provider name "Quaranta, M.D., Joseph L." (based on the data field "prov_name_sasall"); provider number 00040007797 (from "provider_nbr"); NPI 1902860232 (from "npi_sasall"); tax ID 61562459 (from "tax_sasall"); and address of 960 Main St Branford CT 06405 (from "address_sasall").
- Two diagnosis code records associated with provider name "Price, M.D., Daniel Thomas" (based on the data field "prov_name_sasall"); provider number 00250005127 (from "provider_nbr"); tax ID 60982437 (from "tax_sasall"); and address of 2 Devine St Ste 1 North Haven CT 06473 (from "address_sasall"). The NPI field ("npi_sasall") was blank.
- Four diagnosis code records associated with provider "Toosy, M.D., Kaiser" (based on the data field "prov_name_sasall"); provider number 00480000536 (from "provider_nbr"); NPI 1215143953 (from "npi_sasall"); tax ID 201370225 (from "tax_sasall"); and address of 136 Sherman Ave Ste 504 New Haven CT 06511 (from "address_sasall").

Importantly, there are no charts involving this member and "Price, M.D., Daniel Thomas" in the United/Vendor Chart Review Data for DOS year 2012, even after considering the available additional provider identifying information in the way described above. Specifically, there are no records where either HICN A or HICN B is listed on a chart

review record with a provider number of 00250005127 or with any other provider number for which the information from the SAS All Providers data established some possible connection (i.e., where the provider name was “Price, M.D., Daniel Thomas”, address was “2 Devine St Ste 1 North Haven CT 06473”; or tax ID was 60982437.) There are only two providers listed in association with these HICNs in the United/Vendor Chart Review Data in this DOS year, and they match with the providers “Quaranta, M.D., Joseph L.” and “Toosy, M.D., Kaiser” listed above. On the basis of this, there does not appear to be any clear evidence that the two diagnosis codes associated with this member and “Price, M.D., Daniel Thomas” were subjected to Chart Review in this year. Consequently, these records could not have led to an overpayment under the government’s theory. This is shown in Figure 5 below.

Figure 5. Example: HICN 7777777G / 8888888H.

First Interrogatory Response
Member 7777777G / 8888888H - DOS Year 2012

Dx	prov_name_sasall	provider_nbr	mpi_sasall	tax_sasall	address_sasall
2720	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
2720	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
4011	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
4011	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
4928	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
4928	QUARANTA, M.D., JOSEPH L.	40007797	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
2720	PRICE, M.D., DANIEL THOMAS	250005127		60982437	2 DEVINE ST STE 1 NORTH HAVEN CT 06473
4011	PRICE, M.D., DANIEL THOMAS	250005127		60982437	2 DEVINE ST STE 1 NORTH HAVEN CT 06473
49120	TOOSY, M.D., KAISER	480000536	1215143953	201370225	136 SHERMAN AVE STE 504 NEW HAVEN CT 06511
49120	TOOSY, M.D., KAISER	480000536	1215143953	201370225	136 SHERMAN AVE STE 504 NEW HAVEN CT 06511
49120	TOOSY, M.D., KAISER	480000536	1215143953	201370225	136 SHERMAN AVE STE 504 NEW HAVEN CT 06511
49120	TOOSY, M.D., KAISER	480000536	1215143953	201370225	136 SHERMAN AVE STE 504 NEW HAVEN CT 06511

United/Vendor Chart Review Data
Member 7777777G / 8888888H - DOS Year 2012

Barcode*	Provider ID	Provider ID	Full Name	NPI	Tax	Address
9d0014c-c622...	C_PVS_00040007797	C_PVS_00040007797	QUARANTA, M.D., JOSEPH L.	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
90d0351a-0ef3...	C_PVS_00040007797	C_PVS_00040007797	QUARANTA, M.D., JOSEPH L.	1902860232	61562459	960 MAIN ST BRANFORD CT 06405
d8d140e8-bc1d...	C_PVS_00480000536	C_PVS_00480000536	TOOSY, M.D., KAISER	1215143953	201370225	136 SHERMAN AVE STE 504 NEW HAVEN CT 06511

Source: [Chart Review Data] Source: [SAS All Providers 2013_02]
*Truncated for visual

iv. Summary of Findings

104. Using the method described above, I calculated that, as a threshold matter, millions of diagnosis codes included in the government’s First Interrogatory Response – across all DOS years – relate to member-provider combinations for which I identified no evidence to indicate that

the diagnosis codes had been subject to Chart Review process in that year. In fact, in every year from 2008 through 2016, the government appears to have mistakenly included hundreds of thousands of diagnosis codes that do not appear to have gone through United's Chart Review. This indicates that the very foundation of the government's analysis is flawed and unreliable, even before considering any other factors which bear on the reasonableness or reliability of the government's proposed damages framework.

Figure 6. Standalone Impact of Provider Matching Analysis.¹⁴²

DOS Year	First Interrogatory Response Records		
	Total	No Provider Match	% of Total
2008	1,281,260	290,071	22.6%
2009	2,673,072	351,633	13.2%
2010	2,358,464	230,886	9.8%
2011	2,146,861	362,338	16.9%
2012	3,829,852	376,451	9.8%
2013	4,431,051	321,392	7.3%
2014	3,462,828	284,731	8.2%
2015	3,408,442	264,647	7.8%
2016	4,345,821	353,091	8.1%
Total	27,937,651	2,835,240	10.1%

B. Opinion 2: The government's approach for identifying diagnosis codes that United allegedly improperly failed to delete or otherwise return as overpayments is flawed and overinclusive because it is mistakenly executed at the diagnosis code level rather than the condition (i.e., HCC or RxHCC) level. In fact, for approximately 67% of the allegedly improper diagnosis codes in the government's list, United's Chart Review confirmed that the member had the condition corresponding to the diagnosis code at issue (or a more severe condition in the same hierarchy), meaning that there is no overpayment associated with the diagnosis code.

i. Overview

¹⁴² See Exhibit 5.

105. The government's First Interrogatory Response includes a list of diagnosis codes that it maintains United "knowingly and improperly failed to delete[.]" which thus means that United "knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on such diagnoses."¹⁴³ The government further asserts that "each diagnosis code on the United States' list is associated with a medical chart that UnitedHealth has already thoroughly reviewed, and in none of those reviews found support for the diagnosis code in question."¹⁴⁴ This characterization is misleading because my analysis demonstrates that in the case of approximately 67% of the diagnosis codes on the government's list, the chart reviewer in fact identified one or more diagnosis codes that map to the condition (or a more severe condition) at the HCC or RxHCC level, which drives the Medicare financial payment.

106. The diagnosis codes on the government's list are organized at the level of a unique combination of HICN, HCC or RxHCC, DOS, diagnosis code, and provider number. As explained above, diagnosis codes do not directly drive MA reimbursement or risk adjustment amounts. Instead, diagnosis codes map to HCCs (or RxHCCs); HCCs or RxHCCs impact member risk scores; and member risk scores in turn determine MA reimbursement for those members. A unique HCC or RxHCC can be, and often is, supported by multiple diagnosis codes and records. Here, it is important to note that the number of possible diagnosis codes is significantly higher than the number of possible HCCs and RxHCCs. As an illustration, for the 2017 payment year, nearly 10,000 unique diagnosis codes mapped to only 79 unique HCCs.¹⁴⁵ One of the reasons for this is the highly technical and descriptive discrepancies between separate diagnosis codes – such as two unique diagnosis codes for the same condition but on the right side of the body versus the left, or multiple unique diagnosis codes for the same condition but with different underlying causes.

107. To the extent that an HCC or RxHCC is associated with multiple diagnosis codes and records, and at least one such code/record is uncontested, then this means the HCC or RxHCC condition is uncontested – and there would be no overpayment associated with that HCC or

¹⁴³ Government's First Interrogatory Response, dated August 17, 2020, p. 3.

¹⁴⁴ Joint Stipulation Regarding Government's Motion to Compel, dated April 29, 2021, p. 2.

¹⁴⁵ More than 9,500 unique ICD-10-CM diagnosis codes mapped to just 79 unique HCC codes, with the number of unique diagnosis codes per HCC ranging from one to more than 800. Based on CMS's ICD-10 mappings file for the 2017 payment year at: (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/2017MidyearFinalICD-10-CMMappings.zip>).

RxHCC, even if another diagnosis code mapping to the same HCC or RxHCC was suspected of not being appropriately documented in a particular chart.

108. As explained in more detail below, for 67% of the diagnosis codes listed in the government's First Interrogatory Response, United's coders affirmatively identified in the medical record one or more diagnosis code(s) mapping to the same HCC or RxHCC condition, or a more severe HCC or RxHCC condition in the same hierarchy.

109. Importantly, none of the diagnosis codes I rely upon in this analysis were included in the government's list of purportedly problematic diagnosis codes, and the government has not alleged them to be improper. In other words, contrary to the government's theory, many of the allegedly improper diagnosis codes mapped to HCCs or RxHCCs for which support was identified for the HCC or RxHCC through United's Chart Review Program. As a result, the diagnosis codes from the government's First Interrogatory Response connected to those HCCs or RxHCCs could not have led to any MA overpayment.

ii. Data Relied Upon

110. For the purposes of this analysis, in addition to the government's First Interrogatory Response data, I relied upon the following datasets and key fields:

- a. Member-provider-diagnosis-level data from the United Risk Adjustment Claims Data. In this analysis, I principally used the United Risk Adjustment Claims Data, which contains every diagnosis code in any United database for members with a chart subjected to Chart Review during each given year.¹⁴⁶ These tables provide information about the diagnosis codes populated in United's data – including the associated member, provider, and

¹⁴⁶ For DOS years 2008 – 2009, I relied upon the “Encounter”, “Member”, “Member Audit”, “Diagnosis”, “Diagnosis Error”, “IR Error”, “Diagnosis Code”, and “Provider” tables from the 2008 – 2009 DOS RFP Production and the Verscend Production. For the 2009 DOS year, I also stacked the ChrtSupp 2009 Diagnosis table from the July 2019 Supplemental Production (MAPL003667043). For DOS years 2010 – 2013, I relied upon the DR4C Provider-Diagnosis datasets produced by United. For DOS years 2010 and 2013, I relied upon a stacked combination of both the DR4C Provider Diagnosis tables from the original DR4C productions for those years as well as the DR4C Provider Diagnosis tables from the July 2019 Supplemental Production. For DOS years 2014 – 2016, I relied upon the “Encounter”, “Member”, “Member Audit”, “Diagnosis”, “Diagnosis Code”, “Diagnosis Error”, and “Error” tables from the 2014 – 2016 DOS RFP Production and the Post Sweeps Production. For the 2015 and 2016 DOS year, I also used the data from the Supplemental Post Sweeps Production.

DOS; the pathway through which the diagnosis code was submitted (such as directly by a provider, or via Chart Review); whether the diagnosis code was submitted to and processed by RAPS; and, if some kind of error prevented the diagnosis code from being submitted to and processed by RAPS, the reason for that error. Though these tables came from separate productions, the fundamental components of the data relevant to my analysis are substantially similar – including the general structure of the tables (organized at the level of a member-provider-encounter-diagnosis combination) as well as the presence of the key data fields I relied upon as discussed below.

- b. HCC and RxHCC Mapping Data. For each diagnosis code in the United Risk Adjustment Claims Data, I joined in the HCC and/or RxHCC that mapped to the diagnosis code in that payment year based on publicly information available from CMS.
- c. Diagnosis Deletes Data. I joined the Diagnosis Deletes Data to the United Risk Adjustment Claims Data.¹⁴⁷
- d. Related Member Identifier Data. I used the Member, Member Audit, and HICN-to-MBI Crosswalk data to identify any related HICN(s) or MBIs for a unique United member.

iii. Methodology

111. To perform this analysis, I reviewed each of the HCCs and/or RxHCCs listed in the government's First Interrogatory Response to identify whether other diagnosis codes existed in the United Risk Adjustment Claims Data which (a) mapped to those HCCs or RxHCCs or more severe HCCs or RxHCC based on defined hierarchies from CMS; (b) had been subjected to Chart Review; (c) were submitted to and processed in RAPS (or, alternatively, not submitted to RAPS because of

¹⁴⁷ Specifically, I excluded from consideration in my analysis any diagnosis codes included in the Diagnosis Deletes Data. For DOS years 2010-2012, I joined the Diagnosis Deletes Data to the United Risk Adjustment Claims Data on Member-DOS-diagnosis code. For DOS years 2014-2016, I joined the Diagnosis Deletes Data to the United Risk Adjustment Claims Data on Member-DOS-diagnosis code-patient control number, which is equivalent to the encounter key in the United Risk Adjustment Claims Data.

being a potential duplicate submission, as further described below); (d) had not been subsequently deleted; and (e) were not alleged by the government to have been improperly submitted.

112. More specifically, no diagnosis code from the government's First Interrogatory Response would have led to an overpayment if the diagnosis code mapped to a unique member-HCC/RxHCC combination (*i.e.*, HICN+(HCC or RxHCC)) where that member-HCC/RxHCC combination was supported by one or more diagnosis codes in the United Risk Adjustment Claims Data that met the following conditions:

- a. *Sub Source Code Indicating the Diagnosis Code was Identified in Chart Review.* The "sub source code" field (displayed as "sub_source_cd") from the United Risk Adjustment Claims Data provides information about the source from which a diagnosis code was submitted, identifying the origination of the diagnosis code – e.g., provider encounters, hospital data, home health visits, etc.¹⁴⁸ I understand that the following "sub_source_cd" values indicate that the diagnosis code was identified via the review of a member's chart:¹⁴⁹
 - i. "CHARTAUDIT"¹⁵⁰ – This "sub_source_cd" value reflects that the diagnosis code was recorded as part of United's Chart Review program for professional encounters.
 - ii. "HOSABSTRACT" – This "sub_source_cd" value reflects that the diagnosis code was recorded as part of United's Chart Review program for hospital encounters.
 - iii. "PROGRAMDEV" – This "sub_source_cd" value reflects that a United coder determined the diagnosis code was

¹⁴⁸ See p. 15 of "WideRight_Updated Requests 10-7-15.pdf."

¹⁴⁹ These definitions are sourced from my discussions about the "sub_source_cd" field with Randy Myers, Director of Encounter Operations at OptumInsight, and Dylan Schulz, Director of Chart Review Record Submissions and Risk Adjustment and ASM Operations at Optum.

¹⁵⁰ Among the three "sub_source_cd" codes I relied upon in this analysis, "CHARTAUDIT" is the most common by a significant margin, reflecting more than 90% of the total volume of records relating to those three codes. See Appendix X4.

documented in a Patient Assessment Form (“PAF”) included within the patient’s medical record.

- b. *Diagnosis Code Not Deleted.* The diagnosis code was not included in the Diagnosis Deletes Data; and
- c. *Diagnosis Code either (a) Submitted to RAPS or (b) Not Submitted because it was a Duplicate.* In addition, at least one of the following two criteria are also met:
 - i. *Diagnosis Code Submitted to RAPS.* The diagnosis code was submitted to RAPS and processed by CMS. Specifically, this includes record where:
 - 1. The “record state” (“rec_state_key”) is “10” and the “record status” (“rec_status_key”) is “8”, indicating that a RAPS Return file was processed successfully and the associated diagnosis code was accepted by CMS without any errors, or:
 - 2. The “record state” (“rec_state_key”) is “10” and the “record status” (“rec_status_key”) is “10”, indicating that a RAPS Return file was processed successfully and the associated diagnosis code was accepted by CMS with warning codes. I understand from discussions with United that these warning codes are generated when CMS identifies the potential for submission of a certain volume of duplicate data and do not relate to a

warning about the validity of the submission itself.¹⁵¹

ii. *Diagnosis Code Not Submitted because it was a Duplicate .*

The diagnosis code was not submitted because of a certain type of technical error relating to duplicate data entry. In other words, the diagnosis code was not submitted to RAPS only because it was flagged as a potential duplicate diagnosis submission for that same member.¹⁵²

1. The “record state” (“rec_state_key”) is “4”, the “record status” (“rec_status_key”) is “2”, and the error code is either “X19” or “X46”. The “X19” error code occurs when the same member-diagnosis combination was submitted within the six month windows from January through June or July through December. The “X46” error code occurs when the same diagnosis for the same member on the same DOS was submitted, which can potentially cause a CMS “502” error¹⁵³ in the RAPS submission process.

113. As an example of this methodology, there are 23 line-item records in the government’s First Interrogatory Response for HICN 999999991 (a unique member) and HCC 7 (metastatic cancer and acute leukemia¹⁵⁴) in DOS year 2012.

¹⁵¹ This understanding is based on discussions with Randy Myers, Director of Encounter Operations at OptumInsight, and Dylan Schulz, Director of Chart Review Record Submissions and Risk Adjustment and ASM Operations at Optum.

¹⁵² Notably, in such cases, contrary to the government’s assertions, the United Chart Review did in fact find support for the questioned diagnosis code.

¹⁵³ A “502” error relates to the submission of duplicate diagnosis data for a unique member to RAPS. See ([https://www.csscoperations.com/internet/cssc3.nsf/files/RAPS_FERAS_Errors_Eff_01262018.pdf/\\$File/RAPS_FERAS_Errors_Eff_01262018.pdf](https://www.csscoperations.com/internet/cssc3.nsf/files/RAPS_FERAS_Errors_Eff_01262018.pdf/$File/RAPS_FERAS_Errors_Eff_01262018.pdf)).

¹⁵⁴ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, dated April 2, 2012.

- As shown in the data excerpt below, this unique member-HCC combination spans 23-line items because it is associated with five separate diagnosis codes, fourteen separate encounters, and four separate providers. The diagnosis codes were:¹⁵⁵
 - o ICD-9-CM code 1963 (secondary and unspecified malignant neoplasm of lymph nodes of axilla and upper limb);
 - o ICD-9-CM code 1970 (secondary malignant neoplasm of lung);
 - o ICD-9-CM code 1972 (secondary malignant neoplasm of pleura);
 - o ICD-9-CM code 1977 (malignant neoplasm of liver, secondary); and
 - o ICD-9-CM code 1985 (secondary malignant neoplasm of bone and bone marrow).

¹⁵⁵ ICD-9-CM Codebook – v32, FY2012 – FY2015.

Figure 7. Data excerpt: 2012 First Interrogatory Response table. (Sorted by dx, dos_from; not all fields shown).

hicn	dx	dx description*	hcc	rxhcc	dos_from	dos_thru	provider_nbr
9999999I	1963	Mal neo lymph-axilla/arm	7	11	**	**	174180004
9999999I	1963	Mal neo lymph-axilla/arm	7	11	**	**	174180004
9999999I	1970	Secondary malig neo lung	7	10	**	**	174180004
9999999I	1970	Secondary malig neo lung	7	10	**	**	174180004
9999999I	1970	Secondary malig neo lung	7	10	**	**	171040001
9999999I	1972	Second malig neo pleura	7	10	**	**	174180004
9999999I	1972	Second malig neo pleura	7	10	**	**	174180004
9999999I	1972	Second malig neo pleura	7	10	**	**	174180004
9999999I	1972	Second malig neo pleura	7	10	**	**	174180004
9999999I	1977	Second malig neo liver	7	10	**	**	174180004
9999999I	1977	Second malig neo liver	7	10	**	**	174180004
9999999I	1977	Second malig neo liver	7	10	**	**	174180004
9999999I	1977	Second malig neo liver	7	10	**	**	171040001
9999999I	1977	Second malig neo liver	7	10	**	**	171040001
9999999I	1977	Second malig neo liver	7	10	**	**	168730101
9999999I	1977	Second malig neo liver	7	10	**	**	168730101
9999999I	1985	Secondary malig neo bone	7	10	**	**	174180004
9999999I	1985	Secondary malig neo bone	7	10	**	**	174180004
9999999I	1985	Secondary malig neo bone	7	10	**	**	174180004
9999999I	1985	Secondary malig neo bone	7	10	**	**	171040001
9999999I	1985	Secondary malig neo bone	7	10	**	**	171040001
9999999I	1985	Secondary malig neo bone	7	10	**	**	168730101
9999999I	1985	Secondary malig neo bone	7	10	**	**	168730072

*Diagnosis description added by FTI for this example.

**Anonymized for report example.

- These are not the only diagnosis code records associated with this member-HCC combination in this year in United's data. In the larger 2012 DR4C Provider Diagnosis table, there are a total of 281 records for this same member-HCC combination, with multiple records across different encounter dates (and other variations¹⁵⁶), diagnosis codes, and providers. In total, there are nine unique

¹⁵⁶ Sometimes the same HICN-HCC-diagnosis-DOS-provider combination repeats across multiple rows, but with different submission timestamps.

diagnosis codes associated with this member-HCC combination in the 2012 DR4C Provider Diagnosis table.

- These 281 records include the 23 records from the government’s First Interrogatory Response for this member-HCC combination. However, they also include other records that meet the specific conditions for my analysis described above, meaning that they were confirmed by a coder in Chart Review based on the information in the member’s chart.
 - o First, there are ten line items (spanning three unique diagnosis codes: 1970, 1977, and 1985) where the “sub source code” indicates that the diagnosis was identified in Chart Review (CHARTAUDIT) and the “record state” is 10 (i.e., CMS RESPONSE PROCESSED), and “record status” is 8 (i.e., RAPS ACCEPTED), meaning the diagnosis codes were successfully received by CMS. These diagnosis codes, which were identified in the course of a chart review (as evidenced by the “sub source code”), support the HCC of 7 for this member in this year. An excerpt of these records is shown below.

Figure 8. Data excerpt: 2012 DR4C Provider Diagnosis Table. (Sorted by dx, new_min_dt; not all fields shown).

Source: DR4Cn; sorted by dx, new_min_dt

hic_nbr	diag_cd	dx_description*	hcc	rxhcc	new_min_dt	new_max_dt	sub_source_cd	rec_state_key	rec_status_key
99999991	1970	Secondary malign neo lung	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1977	Second malign neo liver	7	10	**	**	CHARTAUDIT	10	8
99999991	1985	Secondary malign neo bone	7	10	**	**	CHARTAUDIT	10	8
99999991	1985	Secondary malign neo bone	7	10	**	**	CHARTAUDIT	10	8

*Diagnosis description added by FTI for this example.

- o Second, there are 21 line items (spanning two unique diagnosis codes: 1977 and 1985) where the “sub source code” indicates that the diagnosis was identified in Chart Review (CHARTAUDIT) and the “record state” is “4” (i.e., Excluded) and the “record status” is “2” (i.e., Excluded on Front End)

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with an error code of X19, meaning the diagnosis code was technically flagged as being a potential duplicate of the same member-encounter from a recent submission.¹⁵⁷ These diagnosis codes, which were identified in the course of Chart Review (as evidenced by the “sub_source_cd”), also support the HCC of 7 for this member in this year. An excerpt of these records is shown below.

Figure 9. Data excerpt: 2012 DR4C Provider Diagnosis Table. (Sorted by dx, new_min_dt; not all fields shown).

[illegible]

*Diagnosis description added by FTI for this example.

114. In this example, this member-HCC combination would have been supported by the Chart Review findings reflected in the diagnosis codes identified above. The government has not alleged these diagnosis codes to be improper. Consequently, none of these 23 line items from the government's First Interrogatory Response associated with this member-HCC combination could have caused any Part C overpayment for this member-HCC combination in this year.

115. The flaws in the government's diagnosis code-level approach are further underscored by the often minor differences between unique diagnosis codes relating to the same

¹⁵⁷ I joined the error code information from the 2012 DR4C Supplemental Production to the 2012 DR4C Provider Diagnosis data to identify diagnosis codes with these error codes.

or similar clinical conditions. Put simply, many similar diagnosis codes map to the same HCCs and RxHCCs. This was true in the ICD-9 coding system, but it was exacerbated by the introduction of ICD-10 coding, which increased the number of possible diagnosis codes from 14,000 to more than 68,000 due to a desire for increased specificity in describing a patient's condition.¹⁵⁸ Minor coding distinctions often result in no difference to the member's HCC or RxHCC condition. For example, the government's First Interrogatory Response includes a line item for member 1010101J with diagnosis code E13.9 (other specified diabetes mellitus without complications¹⁵⁹) submitted on DOS A/2016. However, on the same DOS, that member also had a diagnosis code of E11.9 (type 2 diabetes mellitus without complications¹⁶⁰) as identified in Chart Review. Both E13.9 and E11.9 map to the same HCC 19 (diabetes without complications¹⁶¹), meaning there would be no change to this member's HCC condition for this year if the E13.9 had not been submitted. As another example, member 2020202K's diagnosis code of 296.30 (major depressive disorder, recurrent episode¹⁶²) on DOS A/2014 was included in the government's First Interrogatory Response. However, that same member had a separate submitted diagnosis code of 296.20 (major depressive disorder, single episode¹⁶³), which had been identified for the same DOS in Chart Review. These diagnosis codes map to the same HCC 55 (major depressive, bipolar, and paranoid disorders¹⁶⁴), meaning there would be no impact to the member's risk score, and thus no overpayment, if the diagnosis code 296.30 had been deleted.

116. I have observed several other similar examples following the same fact pattern as those above including:

- A member with diagnosis code 244.8 (other specified acquired hypothyroidism¹⁶⁵) identified in the First Interrogatory Response that also had diagnosis code 244.9 (unspecified

¹⁵⁸ International Classification of Diseases, (ICD-10-CM/PCS) Transition – Background, Centers for Disease Control and Prevention, available at: (https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm).

¹⁵⁹ ICD-10-CM Diagnosis Codebook – 2016.

¹⁶⁰ *Id.*

¹⁶¹ CMS, *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2016.

¹⁶² ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁶³ *Id.*

¹⁶⁴ CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

¹⁶⁵ ICD-9-CM Codebook – v32, FY2012 – FY2015.

acquired hypothyroidism¹⁶⁶) identified via Chart Review on the same DOS with both diagnosis codes mapping to RxHCC 42 (thyroid disorders¹⁶⁷).

- A member with diagnosis code 438.20 (late effects of cerebrovascular disease, hemiplegia affecting unspecified side¹⁶⁸) identified in the First Interrogatory Response that also had diagnosis code 342.90 (hemiplegia, unspecified, affecting unspecified side¹⁶⁹) submitted via Chart Review on a different DOS within the same year, with both diagnosis codes mapping to HCC 100 (Ischemic or unspecified stroke¹⁷⁰).

- A member with diagnosis code 303.93 (other and unspecified alcohol dependence, in remission¹⁷¹) identified in the First Interrogatory Response and diagnosis code 303.90 (other and unspecified alcohol dependence, continuous¹⁷²) submitted via Chart Review on the same DOS, with both diagnosis codes mapping to HCC 55 (drug/alcohol dependence¹⁷³).

- A member with diagnosis code 440.20 (unspecified atherosclerosis of native arteries of extremities, unspecified extremity¹⁷⁴) identified in the First Interrogatory Response and diagnosis code 440.21 (atherosclerosis of native arteries of the extremities with intermittent claudication¹⁷⁵) submitted via Chart Review on a different DOS within the same year, with both diagnosis codes mapping to HCC 108 (vascular disease¹⁷⁶).

iv. Summary of Findings

117. Using the method described above, I calculated that, on a standalone basis, 67% of the government's First Interrogatory Response diagnosis codes across all DOS years (18.8 million

¹⁶⁶ *Id.*

¹⁶⁷ CMS, *Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 6, 2015.

¹⁶⁸ ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁶⁹ *Id.*

¹⁷⁰ CMS, *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2011.

¹⁷¹ ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁷² *Id.*

¹⁷³ CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

¹⁷⁴ ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁷⁵ *Id.*

¹⁷⁶ CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

out of a total 28 million) relate to member-HCC/RxHCC combinations that are supported by other diagnosis codes identified through Chart Review. In other words, United's Chart Review identified other support for the conditions related to the diagnosis codes on the government's list, so those diagnosis codes therefore could not have led to any MA overpayment or the improper retention of an overpayment. The table below summarizes the number of such diagnosis codes in relation to the total First Interrogatory Response records for each DOS year.

Figure 10. Standalone Impact of Condition-Level Analysis.¹⁷⁷

DOS Year	First Interrogatory Response Records		
	Total	HCC/RxHCC Identified in Chart Review	% of Total
2008	1,281,260	560,823	43.8%
2009	2,673,072	1,034,645	38.7%
2010	2,358,464	1,179,454	50.0%
2011	2,146,861	1,314,358	61.2%
2012	3,829,852	2,966,984	77.5%
2013	4,431,051	3,170,820	71.6%
2014	3,462,828	2,644,678	76.4%
2015	3,408,442	2,565,556	75.3%
2016	4,345,821	3,412,368	78.5%
Total	27,937,651	18,849,686	67.5%

118. The above counts only include First Interrogatory Response records where my analysis shows that *all* condition codes related to the diagnosis code were supported by diagnosis codes identified in Chart Review (e.g., where only an HCC mapped to the diagnosis code and it was supported; where only an RxHCC mapped to the diagnosis code and it was supported; and/or where an HCC and RxHCC both mapped to the diagnosis code and were both supported). There are additional First Interrogatory Response records not included in this count that had both HCCs and RxHCCs and where either the HCC or RxHCC, but not both, was supported by my analysis. In total, 19.9 million First Interrogatory Response Records (71.2%) had at least one HCC or RxHCC supported by another diagnosis code identified in Chart Review.

¹⁷⁷ See Exhibit 6.

119. In short, the fact that a diagnosis code was not identified in Chart Review does not mean that there was an overpayment related to that code; it does not mean that the diagnosis code itself, or the condition code linked to that diagnosis code, was false; and it does not mean that United knew of the existence of an overpayment.

C. Opinion 3: The diagnosis codes listed in the government's First Interrogatory Response form an improper basis for evaluating potential overpayments because, in approximately 83% of cases, even if the diagnosis codes were incorrect, deleting those codes would not have impacted the Part C or Part D MA payments to United in the years at issue. There are a variety of reasons for this, including but not limited to the fact that (a) some diagnosis codes do not impact the risk adjustment process; (b) multiple diagnosis codes may support the same condition code; and (c) a higher level condition code may also be supported, superseding any lower level condition code that may be found to be unsupported.

i. Overview

120. The government contends that the diagnosis codes listed in its First Interrogatory Response constitute overpayments that United should have returned to the government by deleting those codes. However, in the overwhelming majority of cases – approximately 83.3% – the deletion of these diagnosis codes would have had no impact on those members' risk adjustment scores, and thus would have resulted in no financial impact to the government. An overpayment that does not exist cannot have been knowingly retained.

121. As discussed above, HCCs and RxHCCs impact a member's risk score, which is the factor in the MA risk adjustment model that determines the payment for a member. A unique HCC or RxHCC can be, and often is, supported by multiple diagnosis codes and charts. Examples of HCCs or RxHCCs with multiple sources of support include the following:¹⁷⁸

- An HCC can be supported by the same diagnosis code submitted from multiple different providers in the same year and/or on multiple encounters in that year. As

¹⁷⁸ The diagnosis code mappings illustrated in this hypothetical are based on CMS's ICD-10 mappings file for the 2017 payment year at: (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/2017MidyearFinalICD-10-CMMappings.zip>).

an illustration, a member may have had a diagnosis code of E08.22 (diabetes mellitus due to underlying condition with diabetic chronic kidney disease¹⁷⁹), mapping to HCC 18 (diabetes with chronic complications¹⁸⁰), submitted by Dr. John Doe from an encounter in January, and then the same diagnosis code of E08.22 submitted twice from Dr. Jane Doe from two separate encounters in April and June. These three diagnosis code submissions would come from three separate encounters across two separate providers and charts, and each independently would support the HCC. Deleting any one of these diagnosis codes would not affect the payment for the beneficiary as he or she would still have the same HCC.

- An HCC can be supported by different diagnosis codes that all map to the same HCC. As an illustration, a member may have had a diagnosis code of E08.22 (diabetes mellitus due to underlying condition with diabetic chronic kidney disease), mapping to HCC 18 (diabetes with chronic complications), submitted from Dr. John Doe from an encounter in January, as well as a diagnosis code of E08.29 (diabetes mellitus due to underlying condition with other diabetic kidney complication¹⁸¹), also mapping to HCC 18, submitted from Dr. John Doe at that same encounter.¹⁸² These two different diagnosis codes would each independently support the HCC. Deleting any one of these diagnosis codes would not affect the payment for the beneficiary as he or she would still have the same HCC.

122. To determine whether the deletion of the questioned diagnosis codes would have impacted reimbursement, I performed a “Simulated Deletion Analysis” to assess whether the deletion of the diagnosis codes in the government’s First Interrogatory Response would have resulted in a change to the HCCs or RxHCCs associated with a member, and thereby, have a financial impact.

ii. Overview of Simulated Deletion Analysis

¹⁷⁹ ICD-10-CM Diagnosis Codebook – 2016.

¹⁸⁰ CMS, *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2016.

¹⁸¹ ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁸² The diagnosis codes of E08.22 and E08.29 could have also been submitted from other providers and/or other encounters with Dr. John Doe. Assuming they were all valid diagnosis codes, the impact is the same.

123. My Simulated Deletion Analysis uses CMS-HCC Risk Adjustment Model software and CMS-RxHCC Risk Adjustment Model software to simulate the calculation of supportable HCCs and RxHCCs for the at-issue members in each year. For each payment year, CMS publishes a set of Statistical Analysis System (“SAS”) programs that can be used to intake information about members and diagnosis codes and, using that information, generate data about the supported HCC(s) and RxHCC(s) for each member in that year (the “CMS SAS Model”).¹⁸³ The CMS SAS Model requires “Person File” and “Diagnosis File” data inputs to run. The “Person File” includes key demographic data needed to calculate a member’s risk score. The “Diagnosis File” includes all diagnosis codes associated with a given member that were submitted and accepted by CMS in a given year. To perform the Simulated Deletion Analysis, I used the CMS SAS Model to identify the HCCs and RxHCCs for all members in the government’s First Interrogatory Response that would have been supported assuming none of the diagnosis codes from the First Interrogatory Response had been submitted (the “Delete Model”). By determining the HCCs and/or RxHCCs supported for each member without the diagnosis codes in the government’s First Interrogatory Response, I was able to assess whether deletion of the questioned diagnosis codes could have caused a change in risk score, and thus had a financial impact.

iii. Data Relied Upon

124. For the purposes of this analysis, in addition to the government’s First Interrogatory Response data, I relied upon the following datasets and key fields:

- a. Monthly Membership Report (“MMR”) datasets. MMR data is the basic accounting file containing member level payments, adjustments, and demographics for Medicare Advantage and Part D organizations.¹⁸⁴ For purposes of this analysis, I have chosen to rely on the December MMR file

¹⁸³ The CMS SAS Model software for payment years 2009-2017 is publicly available at: (<https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/risk-adjustment>). For my analysis, I used the CMS-HCC and CMS-RxHCC software for each year.

¹⁸⁴ MAPD Plan Communication User Guide Version 16.4.

as a proxy for year-end enrollment for each payment year to determine member-level demographics at year-end.¹⁸⁵

- b. Member-provider-diagnosis-level data from the United Risk Adjustment Claims Data. As described above in Opinion 2.
- c. HCC and RxHCC Mapping Data. For each diagnosis code in the United Risk Adjustment Claims Data, I joined in the HCC and/or RxHCC that mapped to the diagnosis code in that payment year based on publicly information available from CMS.
- d. Diagnosis Deletes Data. I joined the Diagnosis Deletes Data to the United Risk Adjustment Claims Data.
- e. Related Member Identifier Data. I used the Member, Member Audit, and HICN-to-MBI Crosswalk data to identify any related HICN(s) or MBIs for a unique United member.

iv. Methodology

125. I performed the following steps to prepare the files to input into the CMS SAS Model by payment year.

126. First, I created a “Person File” containing the key demographic data from the MMR data required to run the CMS SAS Model for every member in the government’s First Interrogatory Response *except* those for whom all diagnosis codes submitted in that year were the diagnosis codes in the First Interrogatory Response (the “Delete Model Person File”). This included the following fields: HICN, sex, date of birth (“DOB”), Medicaid status (“MCAID”),¹⁸⁶ New

¹⁸⁵ The CMS MAPD Plan Communication User Guide (“PCUG”) provides descriptions of the MMR fields. There were several PCUG versions effective during the time period in question. I have relied upon the following PCUG versions: Version 5.3, Version 6.3, Version 9.3, Version 10.1, and Version 16.4 to represent the payment years within the period of the government’s First Interrogatory Response.

¹⁸⁶ The MCAID field is designed to indicate whether a member has Medicaid status. For the Person File, I set MCAID to equal “0” (indicating the member did not have Medicaid) when the “Current Medicaid Status” field from the MMR data was “0” or “00 – No Medicaid Status.” Otherwise, I set MCAID to equal “1” (indicating the member did have Medicaid).

Medicare Enrollee with Medicaid (“NEMCAID”),¹⁸⁷ Original Reason for Entitlement (“OREC”),¹⁸⁸ and End-Stage Renal Disease Status (“ESRD”).¹⁸⁹ In other words, if a member in a year had diagnosis codes submitted that were included in the First Interrogatory Response as well as others that were not, the member would be included in the Delete Model Person File. On the contrary, if *every* diagnosis code for a member in a year was included in the First Interrogatory Response, the member would not be present in the Delete Model Person File.¹⁹⁰

127. Then, I created a “Diagnosis File” containing all diagnosis codes from the United Risk Adjustment Claims Data which were submitted to RAPS for each member in the Delete Model Person File *except* those that were included in the First Interrogatory Response (the “Delete Model Diagnosis File”). This was limited to instances where (i) the diagnosis code was submitted to RAPS successfully and the associated diagnosis code was accepted by CMS without any errors (*i.e.*, Record State = 10, Record Status = 8), or (ii) the return file was processed successfully, and the associated diagnosis code was accepted by CMS with warning codes (*i.e.*, Record State = 10, Record Status = 10). I also excluded any diagnosis codes which were listed in the Diagnosis Deletes Data.

128. Then, for each payment year relevant to this case, I ran the CMS SAS Model for the Delete Model. This generated the lists of HCCs and RxHCCs supported for each member from the First Interrogatory Response in each payment year based on the diagnosis codes actually submitted for that year *other than* the diagnosis codes from the government’s list. I compared the lists of supported HCCs and RxHCCs from the CMS SAS Model to the HCCs and RxHCCs on

¹⁸⁷ The NEMCAID field is designed to indicate whether a member is a new Medicare enrollee with Medicaid. For the Person File, I set NEMCAID to equal “1” if both: (a) the “Current Medicaid Status” field from the MMR data was anything other than “0” or “00 – No Medicaid Status”, and (b) the “RA Factor Type Code” from the MMR data was “E – New Enrollee”, “ED – New Enrollee Dialysis (ESRD)”, “E1 – New Enrollee Post Graft 4-9 (ESRD)”, or “E2 (New Enrollee Post Graft 10+ (ESRD)).”

¹⁸⁸ The OREC field is designed to indicate the original reason that the member was entitled to Medicare. This is a native field in the MMR data.

¹⁸⁹ The ESRD field is designed to indicate whether the member had End-Stage Renal Disease. For the Person File, I set ESRD to equal “1” if the “OREC” field from the MMR data was populated with “2 – Member insured due to ESRD.” Otherwise, I set the ESRD field to equal “0.”

¹⁹⁰ Approximately 15% of beneficiaries in the government’s list did not appear in the December MMR files and, thus, the demographic data associated with them was not available. This can occur, for example, because of death or change of plan by year-end. In order to run the CMS SAS Model, demographic information is required. Accordingly, when demographic data was unavailable, I identified the most common demographic statuses for the members *with* MMR demographic data and applied those to the members *without* demographic data. This convention does not impact the output of the CMS SAS Model for purposes of this analysis.

the First Interrogatory Response for these members.¹⁹¹ If an HCC or RxHCC from the government's First Interrogatory Response was still supported in the Delete Model, or supported by a higher severity HCC or RxHCC in the same hierarchy from the Delete Model, then I considered it to have no financial impact.¹⁹²

v. Summary of Findings

129. My Simulated Deletion Analysis shows that, in 83.3% of cases, the deletion of the diagnosis codes from the government's First Interrogatory Response would have had no impact on those members' risk adjustment scores, and thus would have had no financial impact to the government. There are many, often overlapping, reasons why the deletion of these codes would not have impacted risk adjustment scores. The output of the CMS SAS Model does not provide those reasons. Instead, it simply provides the HCCs/RxHCCs supported for each member based on the diagnostic and demographic data entered in the model. Thus, for example, if a member's HCC from the First Interrogatory Response was also supported in the Delete Model, the output from the CMS SAS Model would not explicitly identify the reason(s) why that HCC was supported in the Delete Model. Consequently, identifying the reason why any particular deletion did not impact the member's risk adjustment score requires detailed, individualized analysis. The below table summarizes the number of such diagnosis codes in relation to the total First Interrogatory Response records for each DOS year.

¹⁹¹ Here, I used the HCCs and RxHCCs mapped to the First Interrogatory Response diagnosis codes from the publicly available CMS data, as described earlier in my report, as opposed to the HCCs and RxHCCs natively populated in the data.

¹⁹² I also considered there to be no financial impact for any diagnosis codes relating to members who were listed as new enrollees for that payment year in the MMR data, because new enrollees' risk scores depend only on demographic data and do not consider diagnostic data. New enrollees are defined as members who had less than 12 months of Medicare Part B enrollment in the data collection year (*i.e.*, DOS year). See CMS, *Risk Adjustment Tips: New Enrollees*, January 2013.

Figure 11. Standalone Impact of Simulated Deletion Analysis.¹⁹³

DOS Year	First Interrogatory Response Records		% of Total
	Total	No Financial Impact	
2008	1,281,260	943,082	73.6%
2009	2,673,072	1,950,855	73.0%
2010	2,358,464	1,622,579	68.8%
2011	2,146,861	1,559,944	72.7%
2012	3,829,852	3,475,934	90.8%
2013	4,431,051	3,839,543	86.7%
2014	3,462,828	3,025,792	87.4%
2015	3,408,442	3,008,230	88.3%
2016	4,345,821	3,851,527	88.6%
Total	27,937,651	23,277,486	83.3%

130. The above counts only include First Interrogatory Response records where *none* of the condition codes related to the diagnosis code had a financial impact as per my Simulated Deletion Analysis (e.g., where only an HCC mapped to the diagnosis code and it was supported; where only an RxHCC mapped to the diagnosis code and it was supported; and/or where both an HCC and RxHCC mapped to the diagnosis code and both were supported). There are additional First Interrogatory Response records not included in this count that had both an HCC and RxHCC and where either the HCC or RxHCC, but not both, was supported by my analysis. In total, 23.7 million First Interrogatory Response Records (84.7%) had an HCC or RxHCC that was determined by my Simulated Deletion Analysis to have no financial impact.

131. Accordingly, while I have not quantified all of the various reasons why the deletion of diagnosis codes in the First Interrogatory Response failed to impact the related HCC(s)/RxHCC(s) and risk adjustment scores, I have analyzed and provided illustrative examples for many such scenarios below.

- vi. Example – Same HCC or RxHCC Supported by Diagnosis Code that was Identified by Chart Review.

¹⁹³ See Exhibit 7.

132. As discussed in Opinion 2 above, to a significant degree, I have found that a Chart Review coder identified one or more diagnosis codes that support the HCCs or RxHCCs mapping to allegedly at-issue diagnosis codes from the government's First Interrogatory Response. In these cases, deleting the diagnosis code(s) from the First Interrogatory Response would have had no financial impact to the government.

133. For example, the First Interrogatory Response includes two line items with the diagnosis code 493.91 (asthma, unspecified type, with status asthmaticus¹⁹⁴) for HICN 3030303L in DOS year 2011: one with DOS A/2011, and another with DOS B/2011. This diagnosis code maps to RxHCC 104 (chronic obstructive pulmonary disease and asthma¹⁹⁵). Notably, the United Risk Adjustment Claims Data in this year contains two records with a diagnosis code of 493.90 (asthma, unspecified type, unspecified¹⁹⁶), which also maps to RxHCC 104. One of these occurred on DOS A/2011, and the other on B/2011. These diagnosis codes had a "record state" of 10 and "record status" of 8 (meaning the diagnosis code was submitted to and accepted by RAPS) and a "sub_source_cd" of CHARTAUDIT (reflecting that the diagnosis code was identified in Chart Review). Further, in the United/Vendor Chart Review Data, these diagnosis codes are listed as ones identified in Chart Review for this member in this year. These diagnosis codes, which are not included in the government's First Interrogatory Response, support the RxHCC 104 for this member. As a result, deleting the two line items from the First Interrogatory Response would not have had a financial impact.

134. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 19.2 million (82%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.¹⁹⁷

vii. Example – Same Provider Submitted a Different Diagnosis Code Mapping to Same HCC or RxHCC.

¹⁹⁴ ICD-9-CM Codebook – v28 FY2011.

¹⁹⁵ CMS, *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2011.

¹⁹⁶ ICD-9-CM Codebook – v28 FY2011.

¹⁹⁷ See Exhibit 8. This amount is different than the number of codes impacted by the results of my analysis in Opinion 2. That is because my methodology in Opinion 2 includes diagnosis codes from the United Risk Adjustment Claims data with a "record state" of 4 and "record status" of 2 and the X19 or X46 error code. However, my analysis in Opinion 3 only includes diagnosis codes with a "record status" of 10 and a "record state" of 10 or 8.

135. As described above, many diagnosis codes can map to the same HCC and/or RxHCC. If multiple diagnosis codes map to the same HCC/RxHCC, then the presence of one appropriate diagnosis code is sufficient to support the HCC. If a diagnosis code from the First Interrogatory Response was deleted from the member's risk adjustment data in that year, the HCC associated with that diagnosis code would still be supported if there is another diagnosis code mapping to the same HCC for the same member. In many cases, deleting a diagnosis code from the government's First Interrogatory Response has no financial impact because another diagnosis about which no allegations have been raised was submitted by the same provider and supports the HCC related to that diagnosis code for that member in that year.

136. For example, the government's First Interrogatory Response includes two line items for diagnosis code 440.20 (unspecified atherosclerosis of native arteries of extremities, unspecified extremity¹⁹⁸) for member 4040404M – one from Dr. Cobrin on DOS A/2015, and another from the same provider on DOS B/2015. This diagnosis code maps to HCC 108 (vascular disease¹⁹⁹). In the United Risk Adjustment Claims Data for this member in this DOS year, there is a diagnosis code of 440.21 (atherosclerosis of native arteries of the extremities with intermittent claudication²⁰⁰) submitted by Dr. Cobrin on C/2015. This diagnosis code also maps to HCC 108. The diagnosis code of 440.21 on C/2015 from Dr. Cobrin is not part of the government's First Interrogatory Response, indicating that the government does not allege it should be deleted. As a result, the deletion of the 44020 diagnosis codes on A/2015 and B/2015 would have done nothing to impact this member's HCC of 108 in this year, meaning deleting these codes would have had no financial impact to the government.

137. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 4.5 million (19%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.²⁰¹

¹⁹⁸ ICD-9-CM Codebook – v32, FY2012 – FY2015.

¹⁹⁹ CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

²⁰⁰ ICD-9-CM Codebook – v32, FY2012 – FY2015.

²⁰¹ See Exhibit 8.

viii. Example – Higher HCC or RxHCC Supported by Other Diagnosis Code About Which No Allegations Have Been Raised.

138. As described above, the CMS-HCC model incorporates disease hierarchies such that the risk adjustment score depends only on the most severe manifestation of a disease. If another HCC in the disease hierarchy is reported for a member in that same year, the lower-severity HCC has no impact on payment for that member. In many cases, deleting a diagnosis code from the government's First Interrogatory Response has no financial impact because a higher HCC (or RxHCC) was supported by another diagnosis code about which no allegations have been raised for that member in that year.

139. For example, the government's First Interrogatory Response includes two line items for diagnosis code 571.5 (cirrhosis of liver without mention of alcohol²⁰²) for member 5050505N – one from Dr. Mesiya on DOS A/2012, and another from Dr. Diehl on DOS B/2012. This diagnosis code maps to HCC 26 (cirrhosis of liver²⁰³). In the United Risk Adjustment Claims Data for this member in this DOS year, there is a diagnosis code of 572.8 (other sequelae of chronic liver disease²⁰⁴) identified on B/2012. This diagnosis code, which is not included in the government's First Interrogatory Response, maps to HCC 25 (end-stage liver disease).²⁰⁵ This HCC 25 is a more severe HCC that supersedes HCC 26 for this member in this year. As a result, the deletion of the two instances of diagnosis code 571.5 from the government's First Interrogatory Response would have had no financial impact to the government, because this member's risk adjustment score was determined by the more severe HCC 25 supported by another diagnosis code about which the government has not raised an issue.

140. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 4.3 million (18%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.²⁰⁶

²⁰² ICD-9-CM Codebook – v32, FY2012 – FY2015.

²⁰³ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012.

²⁰⁴ ICD-9-CM Codebook – v32, FY2012 – FY2015.

²⁰⁵ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012.

²⁰⁶ See Exhibit 8.

ix. Example – Same Provider Submitted the Same Diagnosis Code on a Different DOS.

141. In some cases, a diagnosis code that appears in the government's First Interrogatory Response maps to an HCC or RxHCC that is supported by another submission of the diagnosis code from that provider on a different DOS that was not in the First Interrogatory Response. For example, the First Interrogatory Response includes one line item for HICN 6060606P containing diagnosis code 496 (chronic airway obstruction, not elsewhere classified²⁰⁷) for DOS A/2012 from provider Dr. Bhat; this maps to HCC 108 (chronic obstructive pulmonary disease²⁰⁸). Notably, the United Risk Adjustment Claims Data shows that the same diagnosis code of 496 was submitted by Dr. Bhat in connection with a separate encounter with a DOS of B/2012; this diagnosis code, as recorded for this date of service, was not included in the First Interrogatory Response. Because this diagnosis code supports HCC 108 for this beneficiary in 2012, deleting the allegedly improper diagnosis code from the First Interrogatory Response for member 6060606P would have had no impact on this member's HCC 108 in 2012, and thus there would have been no financial impact to the government.

142. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 7.5 million (32%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.²⁰⁹

x. Example – Different Provider Submitted a Diagnosis Code Mapping to the Same HCC/RxHCC.

143. In other cases, deleting diagnosis codes from the government's First Interrogatory Response causes no financial impact because a different provider submitted a diagnosis code that maps to the same HCC or RxHCC for that member in that year. For example, the government's First Interrogatory Response includes five line items for diagnosis code 25000 (type 2 diabetes mellitus without complication²¹⁰) submitted by Dr. Golomb (provider number 00010010292) for HICN 7070707Q, with DOS ranging from A/2015 – B/2015. Diagnosis code 25000 mapped to

²⁰⁷ ICD-9-CM Codebook – v32, FY2012 – FY2015.

²⁰⁸ CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012.

²⁰⁹ See Exhibit 8.

²¹⁰ ICD-9-CM Codebook – v32, FY2012 – FY2015.

HCC 19 (diabetes without complications²¹¹) in this year. However, the United Risk Adjustment Claims Data includes a diagnosis code of E11.9 (type 2 diabetes mellitus without complications²¹²) submitted by a different provider – Baptist Medical Center South, provider number 00500000056 – in connection with a DOS on C/2015. Diagnosis code E11.9 also maps to HCC 19. There are no records with a diagnosis code of E11.9 for this member in the government’s First Interrogatory Response in this year. Since diagnosis code E11.9 supports HCC 19, the deletion of the six 25000 diagnosis codes for this member in this year would have had no financial impact.

144. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 20.4 million (88%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.²¹³

xi. Example – Diagnosis Code Does Not Map to HCC or RxHCC.

145. As described above, not all diagnosis codes map to an HCC/RxHCC that risk adjusts. In many cases, deleting a diagnosis code from the government’s First Interrogatory Response has no financial impact because that diagnosis code was not one that mapped to an HCC or RxHCC in that payment year.

146. For example, the government’s First Interrogatory Response includes a line item for diagnosis code 305.1 (non-dependent tobacco use disorder²¹⁴) for member 8080808R submitted by Dr. Hoshiwara on DOS A/2008. At this time – i.e., the 2009 payment year – diagnosis code 305.1 did not map to any HCC or RxHCC. Indeed, even in the government First Interrogatory Response data, the “HCC” and “RxHCC” fields for this line item are blank. As a result, this diagnosis code would not have impacted this member’s risk score in that year.

147. The HCC and/or RxHCC was supported for reasons similar to this example for approximately 894,000 (4%) of the First Interrogatory Response diagnosis codes found to have no financial impact in my Simulated Deletion Analysis.²¹⁵

²¹¹ CMS, *Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 1, 2013.

²¹² ICD-10-CM Codebook, 2015.

²¹³ See Exhibit 8.

²¹⁴ ICD-9-CM Codebook, 2008.

²¹⁵ See Exhibit 8.

xii. Conclusion

148. As stated above, my Simulated Deletion Analysis shows that 23.3 million (83.3%) of the diagnosis codes in the government's First Interrogatory Response would have had no financial impact had they been deleted. Put another way, even if every code on the government's First Interrogatory Response was unsupported – which, as shown below, is contradicted by the results of CMS's own audits – then only 4.6 million (16.7%) could even potentially have resulted in overpayments because the rest did not impact payment at all. This once more indicates that (a) the fact that a diagnosis code was not identified in Chart Review cannot be assumed to indicate that an overpayment exists; and (b) the government's First Interrogatory Response is an inappropriate basis on which to evaluate potential overpayments.

149. In addition to evaluating whether there was an overpayment, I understand that it is also important to ascertain whether United had the requisite knowledge of any such overpayment. To conclude that United knew about the existence of an overpayment potentially related to an allegedly unsupported diagnosis code, one would first have to establish that the diagnosis code actually lacked support within the member's medical record. In a scenario where a diagnosis code was coded by a provider but not independently identified by a subsequent coder's review of the medical record as part of a Chart Review, it does not necessarily follow that the diagnosis code is unsupported. For example, the chart reviewer could have misinterpreted or overlooked information in the medical record that supported the diagnosis code. Likewise, different coders can reach different determinations based on their review of medical record documentation.²¹⁶ Coding is a complex and nuanced task, and there is no basis to believe that coders performing Chart Reviews were always perfectly correct and comprehensive in their determinations. If a diagnosis code was supported by the member's medical record – even if it was not identified by a coder in Chart Review – then there could be no overpayment stemming from that diagnosis code.

150. Even if a diagnosis code was definitively determined to be unsupported, multiple additional factors bear on whether that code would have caused an overpayment. As described above, an individual diagnosis code is not determinative of reimbursement in the risk adjustment calculation. Additional factors that would need to be investigated and considered would include:

²¹⁶ C. Kapustij 30(b)(6) Dep. Tr. at 118:8-119:2.

- a. *Whether other charts support the diagnosis code.* For example, the diagnosis code could be properly supported in the medical record from another provider who treated the member in that year. If the diagnosis code was properly supported by any medical records from providers for that member in that year, then the diagnosis code would be supported and could not have caused an overpayment.
- b. *Whether other properly submitted and supported diagnosis codes map to the same HCC or RxHCC as the diagnosis code at issue.* As described above, the condition code, not the diagnosis code, is the driving factor for the calculation of risk scores. Because of this, if the relevant HCC or RxHCC would still be supported by other diagnosis codes, then the diagnosis code at issue could not have caused an overpayment.
- c. *Whether the member's full set of medical records for the year support the submission of additional diagnosis codes which were not originally submitted that map to HCCs or RxHCCs that were not previously taken into account in determining the member's risk score.* To the extent this occurred, the impact of the additional HCC(s) or RxHCC(s) on the member's risk score would have to be considered and netted against any reductions in the risk score resulting from any unsupported diagnosis codes. Put another way, even if a submitted diagnosis code was found to be unsupported, and even if the deletion of that diagnosis code would have caused an HCC to be wholly unsupported, there still may not have been an overpayment if the medical record supported other unsubmitted diagnosis codes that mapped to other, additional HCC(s).
- d. *Whether the HCC or RxHCC mapping to the diagnosis at issue actually had an impact on the member's risk score.* Even if deleting the diagnosis code at issue would have rendered an HCC or RxHCC unsupported, the diagnosis code could not have led to an overpayment if that HCC or RxHCC was not one that impacted the member's risk score. For example, assume that a member had diagnosis code E11.9 (type 2 diabetes without complications)

coded by a provider. This diagnosis code maps to HCC 19 (diabetes without complications). Also assume that the E11.9 diagnosis code was found to be unsupported in the medical record and thus should have been deleted, and that the code was the only one mapping to HCC 19 for that member in that year. On its surface, that may suggest that HCC 19 improperly increased the member's risk score in that year, causing an overpayment. However, if the member was properly diagnosed with more serious diabetes complications in that year, and the member thus met the conditions for either HCC 18 (diabetes with chronic complications) or 17 (diabetes with acute complications), then the HCC 19 would not have impacted the member's risk score at all. Instead, the risk score would have depended on the more severe HCC 17 or 18.

151. An appropriate methodology for determining whether United knowingly retained an overpayment caused by an allegedly unsupported diagnosis code would require considering all of the complexities described above. It is not sufficient to merely compare and look for differences between the diagnosis codes submitted by United and of the diagnosis codes identified by United's Chart Review coders. To my understanding, the government has not undertaken this more comprehensive analysis.

D. Opinion 4: The government's assertion that the diagnosis codes in the First Interrogatory Response are not supported is contradicted by CMS's own RADV auditors. In fact, CMS's coders found support for more than 89% of the First Interrogatory Response diagnosis codes mapping to member-HCC combinations that CMS reviewed as part of the CON11-13 RADV audits. This rate increases to 91% when also taking into account the results of the CON14-15 RADV audits.

i. Overview

152. The government's First Interrogatory Response is comprised of diagnosis codes for which the government alleges that "(1) the diagnosis code was submitted by UnitedHealth to CMS and was required, by regulation, to be supported by an underlying medical record; (2) that medical record went through UnitedHealth's medical record review program; and (3) *UnitedHealth's own*

reviewers did not find the diagnosis code to be supported by medical records” (emphasis added).²¹⁷ As described above in my Opinions 1-3, the list of diagnosis codes included in the government’s First Interrogatory Response is significantly flawed for several reasons, including the extent to which it includes (i) diagnosis codes relating to providers who do not appear to have undergone Chart Review, as well as (ii) diagnosis codes that would not have impacted members’ risk scores or led to an overpayment if the codes were actually found to be unsupported by the medical records. In addition to these failings, the government’s First Interrogatory Response is also flawed in another important respect: it is premised on the unfounded assumption that a diagnosis code was unsupported any time a Chart Review coder failed to independently identify the diagnosis. In fact, I have obtained and reviewed evidence that, when CMS’s own RADV Validation Contractors reviewed the medical records for all 1,119 member-HCC combinations that were also included in the First Interrogatory Response as part of RADV Contract-Level audits²¹⁸ conducted on United plans for CY 2011, 2012, and 2013, the RADV Validation Contractors confirmed and validated those member-HCCs more than 89% of the time. When CMS’s RADV Validation Contractors reviewed the medical records for all 6,494 member-HCC combinations that were also included in the First Interrogatory Response as part of RADV Contract-Level audits conducted on United plans for CY 2011, 2012, 2013, 2014, and 2015, the RADV Validation Contractors confirmed and validated those member-HCCs 91% of the time.

153. I obtained and reviewed the Plan Feedback Report (“PFR”) results for a series of Contract-Level RADV audits performed by CMS pertaining to members enrolled in United plans, meeting criteria to be “RADV eligible”²¹⁹ from payment years 2011 – 2013 (the “CON11-13 PFR

²¹⁷ Joint Stipulation Regarding Government’s Motion to Compel, dated April 29, 2021, p 8.

²¹⁸ Per the *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Final Rule* at 42 CFR Part 22, “CMS conducts post-payment audits of MAO-submitted diagnosis data from a selection of MAOs for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees’ medical records. These audits are called contract-level Risk Adjustment Data Validation (RADV) program audits.”

²¹⁹ CMS set forth the criteria to determine member eligibility within the *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* released on February 24, 2012. Per CMS, a member is “RADV-eligible” if they meet the following criteria: (1) Enrolled in an MA contract (H-number, E-number, or R-number) in January of the payment year— based on CMS’s monthly member enrollment files; (2) Continuously enrolled in the same MA contract (as identified in step (1) above) from January of the data collection year through January of the payment year; (3) Non-End Stage Renal Disease (non-ESRD) status from January of the data collection year through January of the payment year; (4) Non-hospice status

Data”). I also obtained similar data for audits performed by CMS pertaining to payment years 2014 – 2015 (the “CON14-15 PFR Data”). Collectively, I refer to this as the “CON11-15 PFR Data.” I understand that this information was obtained by United from the CMS RADV Report Portal.²²⁰ For the members included in the data, the CON11-15 PFR Data indicates whether the member-HCC combinations selected by CMS for review as part of a RADV Contract-Level audit were found by CMS Validation Contractors to be valid and supported by the members’ medical record(s). Based on my review of the CON11-15 PFR Data, the data includes member-HCC combinations that were included in the government’s First Interrogatory Response in DOS years 2010-2014. For any member-HCC combinations that overlapped between the government’s First Interrogatory Response and the CON11-15 PFR Data (“overlapping member-HCC combinations”), I analyzed whether the CMS RADV audit validated the member-HCC combination. As detailed below, for the overlapping member-HCC combinations I identified, more than 89% (based on the CON11-13 PFR Data) and 91% (based on the CON11-15 PFR Data) were *validated* by CMS Validation Contractors.

ii. Data Relied On

154. For the purposes of this analysis, in addition to the government’s First Interrogatory Response data, I relied upon the following datasets and key fields:

- a. CMS Plan Feedback Report (PFR) Files RADV Results (“CON11-15 PFR Data”).²²¹ The CON11-13 PFR Data files included reports for fifteen total United MA contracts: four contracts from payment year 2011; five contracts from payment year 2012; and six contracts from payment year 2013. The CON14-15 PFR Data files included reports for 46 contracts from payment

from January of the data collection year through January of the payment year; (5) Enrolled in Medicare Part B coverage for all 12 months during the data collection year (*i.e.*, defined as full risk enrollees for risk adjusted payment); and (6) Had at least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection year that led to at least one CMS-Hierarchical Condition Category (HCC) assignment for the payment year.

²²⁰ The process for obtaining CON11, CON12, and CON13 PFR data is described in the “Appendix 6 – Plan Feedback Report” document from CMS (MAPL010977164). I understand that United obtained the PFR Data I relied upon for this analysis between approximately July 2019 and November 2023.

²²¹ MAPL010977147-189. The PFR files in the CON11-13 PFR Data include a disclaimer that “[t]he Plan Feedback Report results are preliminary and must not be viewed as final.” My understanding is that any final results pertaining to these reports have not been provided to United. Further, I am not aware that CMS has made any different determinations than the ones presented in this data.

year 2014 and 51 contracts from payment year 2015. These files provide results on the medical record review (“MRR”) process and preliminary MRR findings. They also provide key metrics related to the audited enrollees, audited CMS-HCC(s), and the top reasons for invalid medical records. The reports provide a detailed view of each medical record submission, including the submission date, validity status, invalid reason(s) if applicable, and initial preliminary coding determinations for MA organizations.²²²

- b. RADV Results Member Identifier Crosswalks: The CON11-13 RADV Results Member Identifier Crosswalk was created by United and contains the Enrollee ID (Enrollee_ID), contract number (Contract), payment year (Payment_Year), HICN (HICN), related HICN (RRHICN), MBI (MBI), and related MBI (RRMBI) for the 3,015 enrollees included in the CON11-13 PFR Data. This data provides an ability to link the member data from the CON11-13 PFR Data to the member data from the government’s First Interrogatory Response. The CON14-15 RADV Results Member Identifier Crosswalk was also created by United and contains the Enrollee ID and “HICNBR” for the enrollees included in the CON14-15 PFR Data.

- iii. Methodology

155. As the first step of my analysis, I consolidated the CON11-13 PFR Data by stacking together the four files for 2011, the five files for 2012, and the six files for 2013. Next, I used the RADV Results Member Identifier Crosswalk to identify all HICNs, related HICNs, MBIs and related MBIs for each member-HCC in the CON11-13 PFR Data. Because the “Enrollee ID” field in the CON11-13 PFR Data is masked, the RADV Results Member Identifier Crosswalk provides a link to identify all HICNs and MBIs for a given Enrollee ID.

156. Next, I linked each member-HCC from the CON11-13 PFR Data for each year to its corresponding member-HCC in the government’s First Interrogatory Response. Then, I aggregated the results across the DOS years 2010-2012. I counted the number of records in the

²²² MAPL010977164.

government's First Interrogatory Response for which (a) the member mapped to an HCC subject to a RADV audit in the CON11-13 PFR Data, and (b) the member-HCC combination was *validated* by CMS's Validation Contractors as documented in the RADV results. I considered any member-HCC from the government's First Interrogatory Response to be validated by the RADV results if it met the following criteria:

- a. The "Submission Status" field was populated with "Submitted", indicating that the member's medical record was submitted for the purposes of the RADV validation.²²³
- b. The submitted medical record was valid for the purposes of auditing the HCC. This was indicated by a lack of any "invalid" reason code in the "Valid/Invalid MR" field.²²⁴
- c. The "Initial Finding" field was populated with "HCC Found" or "HCC Found on another MR[.]" indicating that the audit validated the given enrollee/HCC combination.²²⁵ CMS will allow audited MA Organizations to submit up to five medical records per each audited CMS-HCC sampled per enrollee.²²⁶ CMS considers an HCC to be "supported" in the RADV results by the first medical record submitted by the plan which validates the HCC under review.²²⁷

157. As an example of my methodology, there is one encounter on DOS **A/2011** for HICN **9090909S** included in the government's First Interrogatory Response for DOS year 2011. During this encounter, HICN **9090909S** was diagnosed with ICD-9 code 434.91 (cerebral artery occlusion, unspecified with cerebral infarction²²⁸), which maps to HCC 96 (specified heart

²²³ MAPL010977164, p. 7.

²²⁴ MAPL010977164, pp. 7-8. Oppositely, when the field is not populated with "invalid", it is either blank or populated with "valid."

²²⁵ MAPL010977164, p. 8.

²²⁶ CMS, *CMS Question and Answer Section - CY 2011 RADV Industry Training*, March 20, 2014, p. 3 available at: (<https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvtrainingquestions.pdf>).

²²⁷ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012.

²²⁸ ICD-9-CM Codebook – v28 FY2011.

arrhythmias²²⁹). Based on the RADV Results Member Identifier Crosswalk, 9090909S maps to enrollee ID 112233_23, who was reviewed as part of the RADV review of contract R5287 as summarized in the CON12 PFR data. The CON12 PFR data shows that CMS reviewed five medical records for this member and validated HCC 96 in each medical record. Thus, CMS's own reviewers confirmed support at the condition level for HICN 9090909S's diagnosis code of 434.91 on A/2011. Consequently, it could not have resulted in an overpayment, nor could such a non-existent overpayment have been retained by United. The example below illustrates my comparison process.

Figure 12. First Interrogatory Response and RADV Results Comparison

First Interrogatory Response
Member 9090909S - HCC96 - DOS Year 2012

hcn	dx*	hcc	nhcc	dos_from	dos_thru	provider_nbr
777777G	43491	96	97	**	**	00050002184

Member Identifier Crosswalk
Member 9090909S - DOS Year 2012

HICN	RRHICN	MMI	RRMMI	Enrollee_ID	Contract	Payment Year
9090909S	9090909S	1A2284304-01	1A2284304-01	112233_23	R5287	2012

RADV Results
Member 777777G - CON12

Enrollee ID	Contract ID	Coversheet ID	Submitted	Valid/Invalid_MRI	Audited CMS-HCC	Initial Findings
112233_23	R5287	44209*	Submitted		HCC96	HCC Found
112233_23	R5287	44210*	Submitted		HCC96	HCC Found
112233_23	R5287	44211*	Submitted		HCC96	HCC Found
112233_23	R5287	44212*	Submitted		HCC96	HCC Found
112233_23	R5287	44216*	Submitted	Valid	HCC96	HCC Found

*Truncated for short

158. I repeated this process to analyze the CON14-15 PFR Data. My methodology for analyzing this data was the same as described above for the CON11-13 PFR Data with only two exceptions. First, I used the Related Member Identifier Data in connection with the RADV Results Member Identifier Crosswalk to crosswalk the member identifier information from the PFR Data to the First Interrogatory Response. Second, I looked for overlap across both V12 HCCs and V22 HCCs, since diagnosis codes could map to either type of HCC during payment years 2014 and 2015 (and the CON14-15 PFR Data included results for both V12 and V22 HCCs).

iv. Summary of Findings

159. Based on the above approach, I identified 785 members from the government's First Interrogatory Response who had records in the CON11-13 PFR Data. Of these, the members

²²⁹ CMS, *Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 4, 2011.

had 1,891 total diagnosis codes in the First Interrogatory Response across 1,119 unique member-HCC combinations that were reviewed in the CON11-13 PFR Data. While not necessarily a random sample, the 1,891 overlapping records nonetheless appear to have many significant similarities with the codes that map to HCCs in the First Interrogatory Response during this time period (DOS years 2010-2012). First, I performed an analysis of the distribution of HCCs in the overlapping member-HCC combinations in DOS years 2010-2012 and determined that, within this time period, the 56 different unique HCCs that were subjected to the RADV audits map to more than 99% of the records in the First Interrogatory Response. Put another way, virtually all of the unique HCCs from the First Interrogatory Response during this time period were subjected to RADV audits at least once.²³⁰ Second, and relatedly, these 56 HCCs tend to be proportionally similar between (a) the First Interrogatory Response records relating to the overlapping member-HCC combinations and (b) the total First Interrogatory Response records mapping to HCCs during this period. On average across these 56 HCCs, there was only a 0.5% difference between the (a) and (b) proportions.²³¹ Moreover, there are only five (out of 56) HCCs that are in different quartiles in terms of total frequency of (a) and (b) (and, of those, all five are in adjacent quartiles). This means that, when grouping the codes into volume quartiles, the HCCs that comprise the highest volumes in (a) are the same that comprise the highest volumes in (b), and the HCCs that comprise the lowest volumes in (a) are the same that comprise the lowest volumes in (b). Finally, in my experience, a sample of 1,891 codes would generally be considered quite robust for most evaluative purposes. Thus, the RADV audit results form an instructive basis on which to assess the First Interrogatory Response.

160. I also identified 1,403 members from the government's First Interrogatory Response who had records in the CON14-15 PFR Data. These members had 6,324 total diagnosis codes in the First Interrogatory Response across 5,375 unique member-HCC combinations that were reviewed in the CON14-15 PFR Data. While not necessarily a random sample, the 6,324 overlapping records nonetheless appear to have many significant similarities with the codes that map to HCCs in the First Interrogatory Response during this time period (DOS years 2013-2014). I compared the distribution of records by HCC between (a) the First Interrogatory Response

²³⁰ See Exhibit 9.

²³¹ *Id.*

records relating to the overlapping member-HCC combinations and (b) the total First Interrogatory Response records mapping to HCCs during this period. Because both V12 and V22 HCCs were applicable in this period, I further broke down this comparison by HCC type (V12 or V22) and year.²³² For each of these four permutations, I confirmed that the unique HCCs that were subjected to the RADV audits account for more than 99% of the records in the First Interrogatory Response. Also, I confirmed that, in each of these permutations, the average difference at an HCC level between the proportions in groupings (a) and (b) above was 1% or less.

161. Of the 1,891 overlapping diagnosis codes relating to DOS years 2010-2012, 1,688 diagnosis codes (89.3%) mapped to HCCs that were *validated* by CMS's CON11-13 RADV audits. Of the 6,324 overlapping diagnosis codes relating to DOS years 2013-2014, 5,783 diagnosis codes (91.4%) mapped to HCCs that were *validated* by CMS's CON14-15 audits.²³³ In total, of the 8,215 overlapping diagnosis codes relating to DOS years 2010-2015, 7,471 diagnosis codes (90.9%) mapped to HCCs that were *validated* by CMS's CON11-15 audits. Figure 13 below summarizes my analysis.

²³² See Exhibit 9 (Updated as of 12-03-23).

²³³ A diagnosis code was only counted in the numerator in this analysis if all of the HCC(s) that mapped to the diagnosis code and overlapped with the CON14-15 PFR Data were validated by the audit. That is, if a diagnosis code mapped to a V12 HCC and V22 HCC, and both the V12 HCC and V22 HCC were included in the CON14-15 PFR Data for that member in that year, then both had to be validated for the diagnosis code to be counted in the numerator for this analysis. If a diagnosis code mapped to a V12 HCC and V22 HCC, and only one of either the V12 HCC or V22 HCC was included in the CON14-15 PFR Data for that member in that year, then the record would count in the numerator for this analysis if the overlapping HCC was validated. Additionally, I understand that the CON14-15 audits adopted a methodology that selected MAOs for RADV audits using a risk-based approach that focused on HCCs that are more likely to be in error as identified by prior audits. See 88 CFR 6643, published February 1, 2023. The fact that the CON14-15 audits validated the overlapping diagnosis codes at such a high validation rate, despite being designed to focus on areas of higher risk, further supports the reasonableness of United's approach.

Figure 13. Results of RADV Analysis – First Interrogatory Response.²³⁴

DOS Year	First Interrogatory Response Records		% of Total
	Overlap with CON11-15 PFR Data: Total	Overlap with CON11-15 PFR Data: HCC Validated	
2010	341	300	88.0%
2011	360	319	88.6%
2012	1,190	1,069	89.8%
2013	2,758	2,480	89.9%
2014	3,566	3,303	92.6%
Total	8,215	7,471	90.9%

162. In short, for 1,688 of 1,891 diagnosis codes the government has asserted are unsupported for DOS years 2010-2012 – more than 89% of the time – CMS’s own reviewers confirmed that the members’ conditions are supported, and thus could not have led to any overpayment. For 7,471 of 8,215 diagnosis codes the government has asserted are unsupported for DOS years 2010-2014 – approximately 91% of the time – CMS’s own reviewers confirmed that the members’ conditions are supported, and thus could not have led to any overpayment.

163. In addition to analyzing the CON11-13 PFR Data’s overlap with the First Interrogatory Response, I also analyzed the overlap with the In Process CV Codes Data. The In Process CV Codes Data includes approximately 338,000 diagnosis codes from DOS years 2011 and 2012 submitted to RAPS for which the multi-stage CV process had begun but was not completed at the time United discontinued CV. Of these diagnosis codes, 134 mapped to member-HCC combinations that were included in the CON11-13 PFR Data. Out of those 134 diagnosis codes, 86 mapped to member-HCC combinations that were validated by CMS’s RADV auditors – a 64.2% validation rate. Among those 134 diagnosis codes, 114 were codes that were included in the First Interrogatory Response, and those mapped to member-HCC combinations that had a 58.8% validation rate (67 out of 114). These figures are summarized in Figure 14 below. In summary, the majority of the diagnosis codes in the In Process CV Codes Data that overlapped with the CON11-13 PFR Data were validated by CMS’s auditors.

²³⁴ See Exhibit 10 (Updated as of 12-03-23).

Figure 14. Results of RADV Analysis – In Process CV Codes.²³⁵

Diagnosis Codes that...	Number of In Process CV Codes		% of Total
	Total	HCC Validated	
Overlap with CON11-13 PFR Data	134	86	64.2%
Overlap with CON11-13 PFR Data <u>and</u> First Interrogatory Response	114	67	58.8%

E. Opinion 5: Based on the results of CMS’s RADV audits, the First Interrogatory Response codes were no more likely to be unsupported than any other codes submitted in connection with United plans reviewed by CMS’s RADV audits.

164. I understand that the government’s allegation in this case is that when a Chart Review coder did not identify a diagnosis code that had been submitted for risk adjustment, then it means the code was unsupported, or, alternatively, that the code was so much more likely than other codes to be unsupported that it was reckless for United to fail to take further action to validate or delete the code.

165. As discussed in Opinion 4 above, the CON11-13 PFR Data provides information about the results of the member-HCC combinations reviewed by CMS’s RADV auditors for fifteen total United MA contracts across three years. In analyzing member-HCCs in the CON11-13 PFR Data that overlap with the First Interrogatory Response, I found that more than 89% of First Interrogatory Response records were validated by CMS’s auditors. Similarly, I examined the validation rate for all member-HCCs in the CON11-13 PFR data, including the majority that did not overlap with the First Interrogatory Response. Comparing these rates provides an instructive basis for determining whether the First Interrogatory Response codes are more or less likely to be supported than the remaining majority of codes submitted by United about which the government has raised no issue.

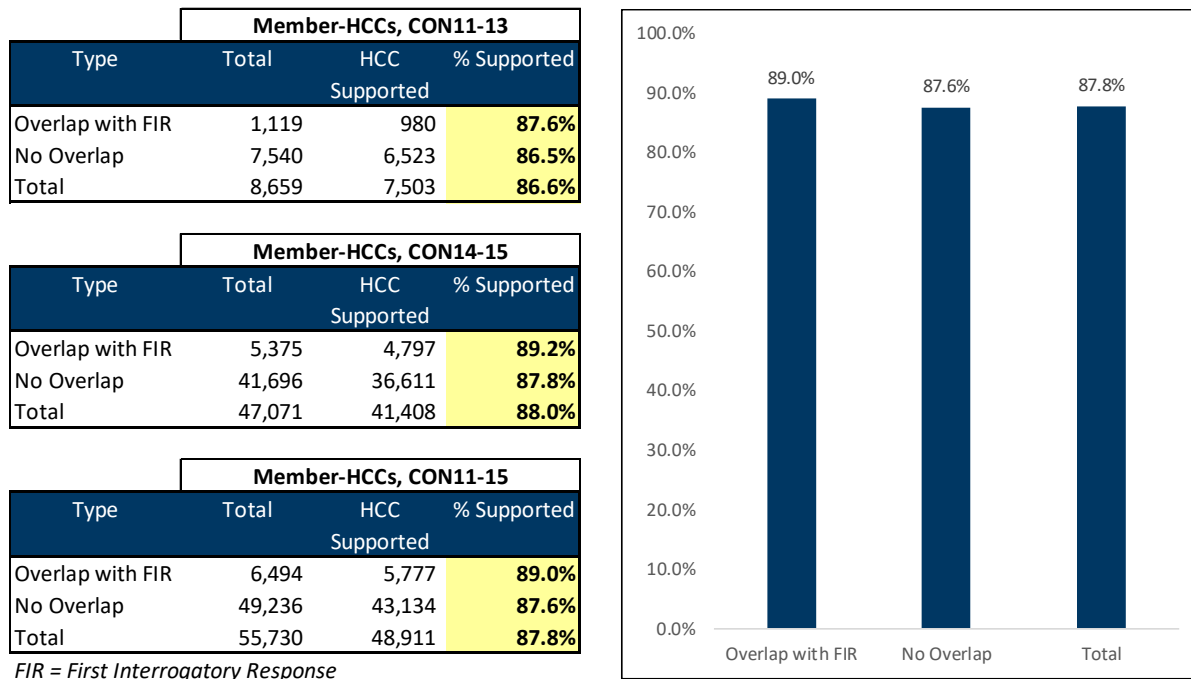
166. Notably, the validation rate is closely equivalent between the member-HCCs from the CON11-13 PFR Data that overlapped with the First Interrogatory Response and those that did

²³⁵ See Exhibit 11.

not. Of the 1,119 member-HCCs that overlapped with the First Interrogatory Response, 87.6% were validated.²³⁶ Of the 7,540 member-HCCs that did *not* overlap with the First Interrogatory Response, 86.5% were validated. In total, out of 8,659 member-HCCs, 86.6% were validated. I also performed a similar analysis for the CON14-15 PFR Data and the CON11-15 PFR data. With respect to the CON14-15 PFR data, 89.2% of the 5,375 member-HCCs that overlapped with the First Interrogatory Response were validated, while 87.8% of the 41,696 member-HCCs that did *not* overlap with the First Interrogatory Response were validated. In total across the CON11-15 PFR data, 89.0% of the 6,494 member-HCCs that overlapped with the First Interrogatory Response were validated, while 87.6% of the 49,236 member-HCCs that did *not* overlap with the First Interrogatory Response were validated. In summary, during this time period, the HCCs on the First Interrogatory Response were found by CMS's own reviewers to be valid at a rate closely equivalent to the average validation rate for all the HCCs submitted by United, or even the HCCs about which the government has raised no issue.

²³⁶ The analysis from Opinion 4 counts the number of First Interrogatory Response records that map to the member-HCCs that overlap with the CON11-13 PFR data. This figure counts the number of unique member-HCCs that overlap with the CON11-13 PFR data. The counts are different because, in many cases, a unique member-HCC maps to more than one First Interrogatory Response record. For the CON14-15 PFR Data, I counted member-V12 HCC and member-V22 HCC combinations separately and added them together.

Figure 15. CON11-13, CON14-15, and CON11-15 PFR Data HCC Validation Rates.²³⁷



167. In other words, based on the available CON11-13 and CON14-15 PFR Data, the fact that a diagnosis code had not been identified by a United coder in Chart Review did not increase the likelihood that the HCC mapping to the code was unsupported.

F. Opinion 6: Contrary to the practice that it typically follows in identifying and quantifying overpayments resulting from diagnosis code errors in the risk adjustment process, the government here has chosen to focus solely on allegedly unsupported codes that were submitted to Medicare rather than considering the net impact of both unsupported codes and codes that should have been, but were not, submitted. Even in cases where an MA plan sponsor has employed a chart review process like the one at issue here, there is a substantial possibility, as demonstrated in the government’s own RADV audits, that there are additional appropriate codes that were missed and not submitted. In fact, the evidence in this matter indicates that such unsubmitted codes can outweigh any submitted codes which may lack proper support. Thus, to fully assess whether and to what extent

²³⁷ See Exhibit 12 (Updated as of 12-03-23).

a possible overpayment exists – even before considering whether any such overpayment was knowingly retained by United - it would be necessary to consider both the codes that may lack support as well as appropriate codes that were not submitted.

168. In this case, the government has chosen to focus solely on the allegedly unsupported codes that were submitted to Medicare, rather than considering the net impact of both unsupported codes and codes that should have been, but were not, submitted. This is inconsistent with the approach the government typically takes in its own chart reviews performed as part of the RADV program for purposes of calculating payment errors. It is also inconsistent with the approach the government takes when calculating the Medicare Part C Improper Payment Measure. In both cases, when calculating either the RADV payment error or the Medicare Improper Payment Measure, the government nets the financial impact of the submission of unsupported diagnosis codes against the financial impact of unsubmitted additional diagnosis codes found to be supported by enrollees' medical records.²³⁸

169. As discussed earlier, to conduct RADV audits, CMS selects a set of MA contracts for each RADV audit cycle. During a RADV audit, CMS selects a sample of the plan members and reviews the HCCs that were assigned based on the diagnosis codes submitted by the MAO to assess whether the diagnosis codes are supported by the applicable member medical records. For each sampled member, the RADV-correct risk score and corrected payment are calculated based on the HCCs that are supported by the RADV medical record review findings for the member. The correct payment in the RADV audit is calculated considering both (a) the HCCs resulting from diagnosis codes that were previously submitted but not supported by medical record documentation reviewed, and (b) any HCCs based on diagnosis codes that were not previously submitted but were found to be supported by the medical record documentation reviewed.²³⁹

²³⁸ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 3.; see also CMS, *Error Rate Findings and Results, Key Terms*, available at: (<https://www.cms.gov/research-statistics-data-systems/improper-payment-measurement-programs/medicare-part-c-ipm/error-rate-findings-and-results>).

²³⁹ See, e.g., Exhibit 1187-1: CON11 RADV Results, CMS, May 26, 2016, further discussed below in my report. In this 2011 RADV presentation, CMS explained that any payment errors identified in the audit were reduced by "HCCs found during medical record review that are not among the audited HCC(s) for the enrollee." See also, CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation*

Member-level payment errors are defined as “the difference between the original payment and the RADV-corrected payment (per member per month).”²⁴⁰ The overall payment error for each member either results in a net overpayment or a net underpayment.²⁴¹

170. Similarly, to calculate the Part C Payment Error Rate, Medicare selects a sample of Medicare Part C eligible members and reviews the relevant medical record documentation to substantiate the related CMS-HCC payments. As part of the review, certified coders code the medical records, and the findings are used to recalculate risk scores for each sampled member. The difference between the payment risk scores and the recalculated risk scores is termed Risk Adjustment Error. CMS calculates the Part C Payment Error Rates in two ways. First, it calculates a “net” error rate which is based on offsetting overpayments and underpayments. Second, it calculates an error rate based on the gross payment errors (also called “Gross Improper Payments”). CMS defines “Gross Improper Payments” as the “absolute value of the sum of overpayments and underpayments.”²⁴²

171. Based on the government’s own methodology when conducting medical record reviews and calculating payment errors, the appropriate way to determine whether any net overpayment exists is to net the individual payments for unsupported diagnosis codes submitted against and the financial impact from unsubmitted but validated codes identified through the medical record review process. However, as noted above, the government has not employed that methodology here. Instead, it has chosen to focus only on allegedly unsupported codes which could potentially generate overpayments.

172. As an illustrative example of how a net underpayment can be found, assume a member had the following diagnosis codes submitted to RAPS in 2013: diagnosis code 332.1 (secondary Parkinsonism), which maps to HCC 73 (Parkinson’s and Huntington’s disease), and diagnosis code 585.4 (Stage 4 chronic kidney disease, or “CKD”), which maps to HCC 131 (renal

Contract-Level Audits, February 24, 2012, p. 3: “Enrollee-level payment errors will be defined as the difference between the original payment and the RADV-corrected payment (per member per month). The payment error for each enrollee will be either positive (representing a net overpayment), or negative (representing a net underpayment).”

²⁴⁰ CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 3.

²⁴¹ *Id.*

²⁴² CMS, *Medicare Part C Improper Payment Measure Program Error Rates and Findings*: (<https://www.cms.gov/research-statistics-data-systems/improper-payment-measurement-programs/medicare-part-c-ipm/error-rate-findings-and-results>).

failure). Also assume that this member's medical record was reviewed via RADV, and that the RADV reviewers found two things. First, they did not find support for the 585.4 diagnosis code, meaning that the HCC 131 was no longer supported. Second, they *did* find support for another diagnosis code which had not been submitted: 263.9 (unspecified protein calorie malnutrition), which maps to HCC 21 (protein calorie malnutrition). In this example, the net effect of the RADV findings would be an *increase* to the member's risk score since the RAF of the unsupported code was less than the RAF of the supported code that had not been submitted.

Figure 16. Illustrative Example: Net Underpayment.²⁴³

ICD-9-CM Code	HCC	Community Risk Adjustment Factor	Diagnosis Code Submission	Supported by Medical Record Documentation through RADV?
332.1 (Secondary Parkinsonism)	73 (Parkinson's and Huntington's Disease)	0.643	Submitted	Supported
585.4 (Stage 4, CKD)	131 (Renal failure)	0.297	Submitted	Not Supported
263.9 (Unspecified Protein Calorie Malnutrition)	21 (Protein calorie malnutrition)	0.745	Not Submitted	Supported

173. Even in cases where an MA plan sponsor has employed a chart review process like the one at issue here, there is a substantial possibility that there are additional appropriate codes that were missed and not submitted. This possibility is apparent from examining the results of the government's own audits of MAOs. For example, in August 2022, the Office of the Inspector General ("OIG") conducted an audit of an MAO, Cigna HealthSpring of Florida, with the objective of determining whether the MAO "submitted diagnosis codes to CMS for use in the risk adjustment

²⁴³ Community Risk Adjustment Factors based on CMS, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2, 2012.

program in accordance with Federal requirements.”²⁴⁴ During this audit, the OIG sampled member HCCs and identified several member HCCs that were not validated by the medical record documentation reviewed. However, the OIG also identified “support for diagnosis codes that Cigna HealthSpring should have submitted to CMS but did not. If Cigna HealthSpring had submitted these diagnosis codes, an additional 18 HCCs would have been included in the enrollees’ risk scores. These risk scores would therefore have increased, and CMS’s payments to Cigna HealthSpring would have been higher.”²⁴⁵

174. In the same vein, CMS has performed RADV audits of United’s MA plans that identified net MA underpayments to United. CMS chose plans to audit based on changes in the coding intensity of those plans – in other words, based on increases in average enrollee risk scores from one year to the next. This approach was presumably based on the government’s hypothesis that plans with higher year-over-year increases in coding might have a higher probability for error.²⁴⁶

175. In a December 2017 presentation, CMS described the results of its CON11, CON12, and CON13 RADV audits.²⁴⁷ In total, 15 United contracts were included in the audits (four from CON11, five from CON12, and six from CON13) and 13 of the 15 were found to have net underpayments.²⁴⁸

²⁴⁴ Frontz, Amy J., Deputy Inspector General for Audit Services, OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes that Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*, Audit 2022, A-03-18-00002, p. 2.

²⁴⁵ *Id.*, pp. 5-6.

²⁴⁶ Ex. 1187-1 at 2; Ex. 1498 at 2; C. Kapustij 30(b)(6) Dep. Tr. at 52:2-54:9; 205:17-206:3.

²⁴⁷ USBP068691383.

²⁴⁸ *Id.*, pp. 19-21. All thirteen contracts had a negative recovery amount – *i.e.*, net underpayments – at the lower bound of the 99% confidence interval.

Figure 17. CON11, CON12, and CON13 Recovery Amount Findings for United Contracts.

RADV Year	HMOID	Parent Org	Recovery Amount*
CON11	H2226	UnitedHealth Group, Inc.	\$ (2,068,360)
	H4522	UnitedHealth Group, Inc.	\$ (4,622,640)
	H4590	UnitedHealth Group, Inc.	\$ (51,017,738)
	H0543	UnitedHealth Group, Inc.	\$ (91,884,129)
CON12	H5420	UnitedHealth Group, Inc.	\$ 15,735,769
	R7444	UnitedHealth Group, Inc.	\$ (3,962,831)
	H5652	UnitedHealth Group, Inc.	\$ (4,740,216)
	H0251	UnitedHealth Group, Inc.	\$ (10,348,919)
	R5287	UnitedHealth Group, Inc.	\$ (69,295,194)
CON13	R9896	UnitedHealth Group, Inc.	\$ 4,065,269
	H3107	UnitedHealth Group, Inc.	\$ (1,581,972)
	H0151	UnitedHealth Group, Inc.	\$ (7,790,780)
	H4514	UnitedHealth Group, Inc.	\$ (9,302,996)
	H2931	UnitedHealth Group, Inc.	\$ (10,078,497)
	R5342	UnitedHealth Group, Inc.	\$ (14,309,264)

*Recovery amount is the extrapolated payment error incorporating the lower bound of the 99% confidence interval. See USBP068691383, p. 3.

176. Using CMS’s methodology, the United plans audited showed, in aggregate, a *net underpayment* of more than \$261 million.²⁴⁹ Nonetheless, CMS does not intend to reimburse plans for such underpayments through the RADV audit process.²⁵⁰

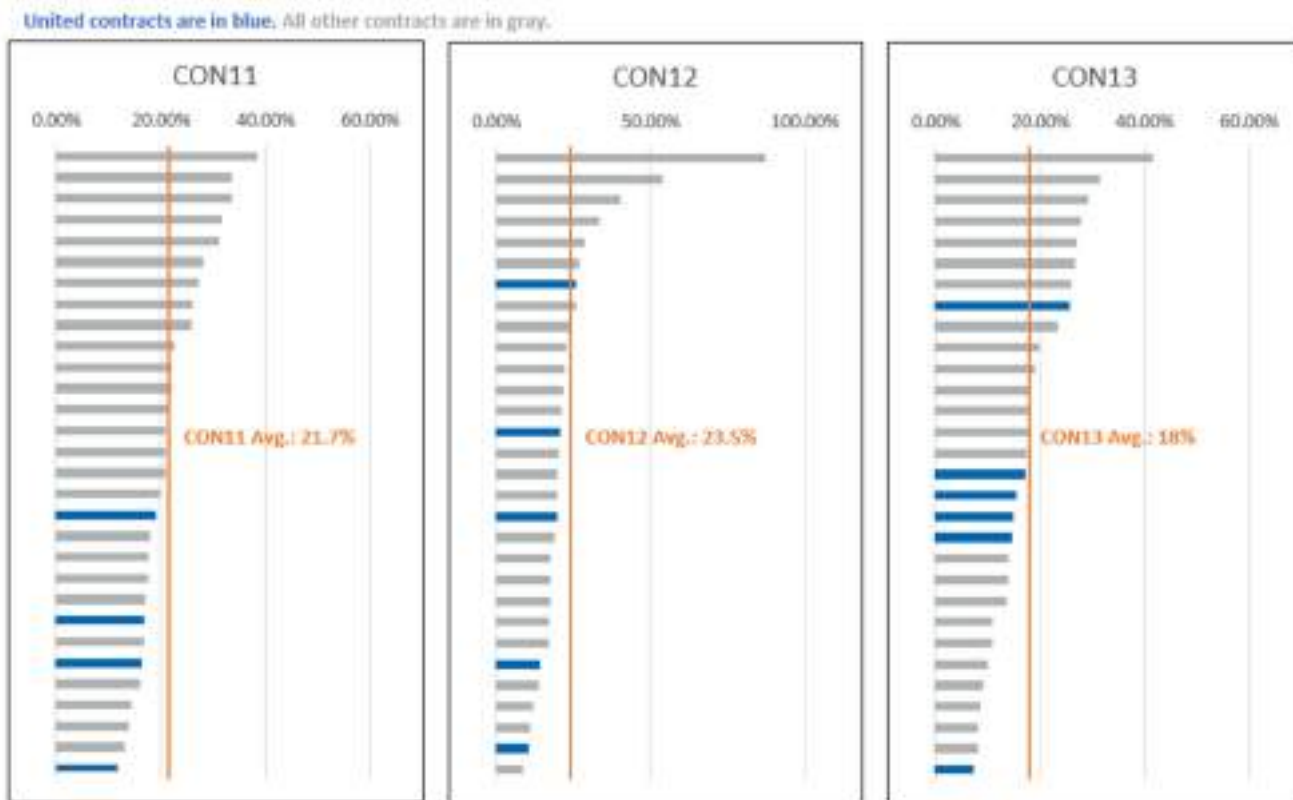
177. Further, the United contracts were found to have lower “discrepancy rates” – the number of discrepant HCCs for sampled members divided by the total audited HCCs – than other MAOs. In a presentation focusing on the CON11 audit, the United sample contracts were found to have the lowest discrepancy rate of any MAO parent organization’s sampled contracts.²⁵¹ Looking across the entire CON11-13 audits, as summarized below, the discrepancy rates for United contracts were below the average for all audited contracts with only two exceptions (one contract in CON12, and another in CON13).

²⁴⁹ Exhibit 1501; C. Kapustij 30(b)(6) Dep. Tr. at 245:6-12.

²⁵⁰ C. Kapustij 30(b)(6) Dep. Tr. at 192:6-25.

²⁵¹ Exhibit 1187 1: CON11 RADV Results, CMS, May 26, 2016, p. 1.

Figure 18. RADV Audit HCC Discrepancy Rate by MA Contract.²⁵²



178. In total, 47 of the 90 sampled contracts across CON11, CON12, and CON13, including 13 out of the 15 United contracts, were reported as having estimated net underpayments under the government’s methodology. This demonstrates that CMS does not identify “overpayments” solely on the basis of unsupported codes, but instead considers the offsetting impact of unsupported submitted codes and unsubmitted supported codes. It further shows that United in particular was *underpaid* on a net basis in at least 13 instances. Notably, these audits are conducted years after the plan year under review, and thus the codes being audited include the results of the plan’s own chart reviews. This demonstrates that even after the chart review process there can still be many unsubmitted but supported codes.

G. Opinion 7: If the results of CMS’s CON11-13 RADV audits hold constant across all of the First Interrogatory Response codes at issue, then over 94% of the

²⁵² Discrepancy rate figures derived from USBP068691383, p. 7. Contracts are listed in descending order of HCC discrepancy rate. United contracts are highlighted in blue. For each year, the average shown is the average of the HCC discrepancy rates across the 30 contracts in that year.

diagnosis codes identified in the government's list could not be overpayments. If the results of CMS's CON11-15 RADV audits hold constant across all of the First Interrogatory Response codes at issue, then approximately 94% of the diagnosis codes identified in the government's list could not be overpayments. This is the result of two factors. First, as noted above, the analysis in Opinion 3 shows that approximately 83.3% of the diagnosis codes in the government's list do not have any financial impact on the government's payments to United plans. Second, with respect to the remaining diagnosis codes, the CMS CON11-13 RADV audits found support for 65.3% of the at-issue diagnosis codes that were (a) addressed in a CON11-13 RADV audit and (b) found to have financial impact based on Opinion 3. Combining these results with those of the CON14-15 RADV audits, the CMS CON11-15 RADV audits in total found support for 62.5% of the at-issue diagnosis codes that were (a) addressed in a CON11-15 RADV audit and (b) found to have financial impact based on Opinion 3. Thus, to the extent that the government's First Interrogatory Response is intended to be used as a basis for assessing either the pervasiveness or the dollar impact of improper diagnosis codes, it is biased and unreliable.

179. When combined, my analyses in Opinion 3 (designed to determine which diagnosis codes on the government's list could have had a financial impact) and Opinion 4 (designed to determine which diagnosis codes on the government's list were validated at the condition level by CMS's auditors) show that more than 94% of the codes on the government's First Interrogatory cannot be considered overpayments.

180. As a starting point, approximately 83.3% of the records in the government's First Interrogatory Response did not have a financial impact and thus could not have resulted in overpayments. That is, for 83.3% of the records, the diagnosis code had no financial impact based on my Simulated Deletion Analysis (as detailed in Opinion 3 above). This significant finding is consistent across the entire time period covered in the government's First Interrogatory Response, ranging from a low of 68.8% of the codes in DOS year 2010 to a high of 90.8% in DOS year 2012.

181. Importantly, the remaining 16.7% of First Interrogatory Response codes not eliminated from consideration by my analysis in Opinion 3 cannot be assumed to have led to

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overpayments. The fact that a Chart Review coder did not identify the code does not mean that the code was incorrect. To the contrary, CMS's reviewers found that, among those audited records not eliminated from consideration by the analysis underlying my Opinion 3, the relevant conditions are supported nearly two-thirds of the time.

182. More specifically, of the 1,891 First Interrogatory Response records that were also subjected to RADV audits per the CON11-13 PFR Data, 441 records (across 321 member-HCC combinations) did not get eliminated from consideration by my Opinion 3 analysis. Of those 441 records, 288 records (65.3%) were ones where the RADV auditors found support for the member HCC.²⁵³ Taking into account the CON14-15 PFR Data, of the 8,215 First Interrogatory Response records that were also subjected to RADV audits per the CON11-15 PFR Data, 1,404 records (across 2,837 member-HCC combinations²⁵⁴) did not get eliminated from consideration by my Opinion 3 analysis. Of those 1,404 records, 877 records (62.5%) were ones where the RADV auditors found support for the member HCC.²⁵⁵ This shows that even those First Interrogatory Response records that were not otherwise removed from consideration by my Opinion 3 analysis cannot be assumed, and could not have been known, to have caused overpayments.

183. Combining my Opinion 3 analysis with the CON11-13 PFR Data suggests that the vast majority of records – more than 94% – in the government's First Interrogatory Response could not have caused overpayments. Combining my Opinion 3 analysis with the aggregated CON11-15 PFR Data suggests that approximately 94% of the records in the government's First Interrogatory Response could not have caused overpayments. That is, assuming the rate of records *not* captured by Opinion 3 but nonetheless supported by the RADV audits (65.3% in connection with CON11-13 and 62.5% in connection with CON11-15, as described above) remained constant across the entire time period covered by the First Interrogatory Response, then only approximately 6% of the records in the First Interrogatory Response could have caused an overpayment.²⁵⁶

²⁵³ See Appendix X12.

²⁵⁴ Here, like with the analysis in Opinion 5, I count member-V12 HCC and member-V22 HCC combinations separately and add them together.

²⁵⁵ See Appendix X12 (Updated as of 12-03-23).

²⁵⁶ 83.3% of First Interrogatory Response plus $(16.7\% * 65.3\% = 10.9\%) = 94.2\%$. 83.3% of First Interrogatory Response plus $(16.7\% * 62.5\% = 10.4\%) = 93.7\%$.

184. Further, given that 13 of the 15 United MA plan years subjected to RADV audits in CON11-13 were reported to have underpayments in the aggregate, even the small residual percentage of potentially impactful incorrect codes could reasonably be assumed to be further reduced by a substantial amount (*i.e.*, they would have been subsumed within a larger aggregate underpayment for the plan year).²⁵⁷ Under this logic, it would be reasonable to expect that the potential overpayment error rate associated with the diagnosis codes in the government's First Interrogatory Response was vanishingly small.

185. Because of these widespread flaws, the government's First Interrogatory Response cannot be relied upon for assessing either the pervasiveness or the dollar impact of allegedly improper diagnosis codes during the time period at issue in this case.

VI. CONCLUSION

186. This report presents a summary of my work and opinions to date. I reserve the right to revise and refine these opinions as additional work is performed and additional information is received. To the extent that any additional evidence becomes available as a result of the Court's reconsideration, I may modify or supplement my opinions as appropriate.

Submitted by: 
M. Timothy Renjilian, CPA

Dated: December 3, 2023

²⁵⁷ For example, if the residual 5.8% (100-94.2%) of records were reduced by 13/15, the estimated percentage of records actually yielding a potential overpayment would be just 0.77% (5.8% X (2/15)).

EXHIBIT D-65

**IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA EX REL.	§	
BENJAMIN POEHLING,	§	
	§	
	§	
Plaintiffs,	§	
	§	
vs.	§	CASE NO.: CV 16-08697 (FMO SSx)
	§	HON. FERNANDO MANZANO OLGUIN
	§	
UNITEDHEALTH GROUP, INC. ET AL.,	§	
	§	
	§	
Defendants.	§	
	§	

UPDATED REBUTTAL REPORT OF M. TIMOTHY RENJILIAN

March 18, 2024

CONFIDENTIAL, ATTORNEYS' EYES ONLY, & OUTSIDE COUNSEL EYES ONLY

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B. Opinion 2: Analysis of the First Interrogatory Response diagnosis codes that overlapped with the RADV audits reveals that, for all the instances that can be identified, the subset of diagnosis codes associated with charts that underwent two levels of blinded review (i.e., an initial Chart Review and then a Second Level Review) were validated by the RADV audits at a rate comparable to that of diagnosis codes associated with charts that underwent only one level of blinded review. Moreover, the member-HCCs associated with diagnosis codes contained in the First Interrogatory Response coming from charts that underwent two levels of blinded review were not significantly less likely to be validated by RADV audits than member-HCCs that did not overlap with the First Interrogatory Response.....	
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CMS's RADV audits have frequently confirmed the appropriateness of many of the conditions mapping to diagnosis codes the government asserts in its First Interrogatory Response were not independently identified by United's chart reviewers and that Dr. Garthwaite identifies as Deletes. Additionally, as evidenced by the underpayment rates from CMS's Part C Improper Payment Measure reports, the government has consistently found substantial numbers of additional supported but unsubmitted HCCs across the industry. 17

E. Opinion 5: Dr. Garthwaite has failed to establish the existence of a Medicare Advantage overpayment to United because he has not considered offsetting amounts for the potential impact of unsubmitted but valid diagnosis codes. Such consideration is a standard part of CMS's methodology for calculating the Part C Payment Error. In fact, in many cases, Dr. Garthwaite calculates financial impact for members' diagnosis codes even though CMS has already determined a net underpayment was made to United for that member's contract. 20

F. Opinion 6: Dr. Garthwaite's financial impact calculations are unreliable because he has not considered the extent to which his alleged financial impacts would be offset by reductions to the remittances that United paid to CMS under the Medical Loss Ratio requirements of the Medicare Advantage program. 22

G. Opinion 7: Dr. Garthwaite's analysis does not establish that United knowingly retained any overpayments. To the contrary, Dr. Garthwaite's analysis shows that it is a highly detailed and complex exercise to (a) identify diagnosis codes associated with charts that underwent Chart Review and were not independently identified in Chart Review; and (b) determine whether such diagnosis codes impacted payment. Moreover, Dr. Garthwaite's analysis makes clear that Chart Review, by its very nature, does not and cannot identify the existence, or even the likelihood, of an overpayment. 25

i. Dr. Garthwaite's analysis demonstrates the difficulty of precisely locating diagnosis codes that were not independently identified in Chart Review 26

ii. Dr. Garthwaite's analysis shows that United's Chart Review process and CV Pipeline Lists, by their very nature, are not sufficient to conclude that a potentially unsupported diagnosis code caused an overpayment 27

H. Opinion 8: If the validation rates of CMS's CON11-15 RADV audits hold constant across all of the Garthwaite Deletes, then the rate of unsupported diagnosis codes with financial impact would be less than 3.5% of the diagnosis codes included in the government's First Interrogatory Response and less than 0.3% of United's total diagnosis codes submitted during this period for the members who underwent Chart Review. In my experience, based on common industry practices in the relevant timeframe, such a low rate of potentially unsupported diagnosis codes with financial impact would not have been expected to necessitate additional investigation or analysis. 30

I. Opinion 9: For the reasons described in my Opinions 1-8 above, Dr. Garthwaite's calculation of the number of members for whom United was allegedly overpaid as a result of the Garthwaite Deletes is also unreliable. 34

VI. CONCLUSION 36

I. QUALIFICATIONS

1. I am a Senior Managing Director with FTI Consulting, Inc. (“FTI”) and am based in Atlanta, Georgia. I am licensed as a Certified Public Accountant in Georgia. The primary focus of my work is (a) to conduct forensic accounting investigations of compliance and legal issues in the health care and life sciences industry, and (b) to provide consulting services related to operational, financial and compliance issues faced by health care and life sciences companies.

2. In an investigation context, I have worked on a wide range of matters involving potential financial and legal exposure related to billings made in connection with the provision of health care services. Among other things, these matters have involved audit and administrative adjustments; legal claims for recoupment of amounts paid; issues related to the preparation and presentation of Medicare cost reports; post-acquisition disputes; and alleged violations of applicable Federal and state laws. My role in such matters has included frequent interaction with corporate management and boards and with regulatory authorities and oversight organizations including, for example, the Department of Health and Human Services, the Department of Justice, and state Medicaid Fraud Control Units.

3. In my consulting role, my work has involved a variety of tasks related to operational issues, financial and accounting matters, auditing and monitoring activities, compliance programs, and evaluating and facilitating mergers and acquisitions.

4. My resume, including a list of all publications I have authored in the previous ten years and all cases in which I have testified as an expert at trial or by deposition in the previous four years, is included as Exhibit 1.

5. FTI is being paid \$695 per hour for my services in this case. In addition, other employees of FTI have worked under my direction in this matter. The billing rates for these individuals ranges from \$350 to \$625 per hour. Compensation for FTI’s services is not dependent on the outcome of this matter.

II. DESCRIPTION OF ENGAGEMENT

A. Scope of Work

6. I have been requested by Counsel for Defendants UnitedHealthcare and related entities (“United”) to review the expert report of Craig Garthwaite dated September 29, 2023 and the related “Errata to Expert Report of Craig Garthwaite” dated October 4, 2023, “Errata to Expert Report of Craig Garthwaite” dated January 5, 2024, and “Errata to Expert Report of Craig Garthwaite” dated March 11, 2024 (together, the “Garthwaite Report”) and the expert report of Jean Acevedo dated September 29, 2023 (the “Acevedo Report”) and to provide my opinions on them.

7. This report sets forth my opinions as of March 18, 2024.

B. Materials Relied Upon

8. A listing of the specific materials on which I have relied in forming the opinions expressed in this report is attached as Exhibit 2.¹

III. BACKGROUND

A. Garthwaite Report

9. Dr. Garthwaite was engaged by counsel for Plaintiffs to provide expert testimony in this matter. Specifically, Dr. Garthwaite was asked to “(1) identify diagnosis codes from service years 2008 through 2016 that Defendants submitted to CMS for risk adjustment payments covering payment years 2009 through 2017, where Defendants reviewed the medical records associated with those diagnosis codes as part of their Chart Review Program and did not find support for the diagnosis codes, and those diagnosis codes affected payment; (2) calculate the financial impact of Defendants’ Medicare Advantage and Medicare Part D risk adjustment payments that would have resulted had Defendants deleted the diagnosis codes [Dr. Garthwaite] identified; and (3) determine the number of beneficiaries in each payment year for whom Defendants would have received

¹ Unless otherwise specified, the definition of any capitalized term is the same as in my original report dated September 29 and updated on December 3 (the “December 3 Report”).

reduced risk adjustment payments from CMS had Defendants deleted the diagnosis codes [Dr. Garthwaite] identified.”²

10. Dr. Garthwaite created a “list of diagnosis codes that [United] submitted to CMS for which [United] did not find support in [the] Chart Review Program.”³ To do this, Dr. Garthwaite identified a list of provider-reported encounters that were allegedly reviewed in United’s Chart Review Program (which he termed the “Reviewed Encounters”). Then, Dr. Garthwaite identified and compared (a) the provider-reported diagnosis codes that were submitted to CMS for risk adjustment allegedly in connection with the Reviewed Encounters (which he termed the “Submitted Diagnosis Codes”) with (b) the diagnosis codes independently identified by Chart Review coders allegedly in connection with the Reviewed Encounters (which he termed the “Supported Diagnosis Codes”).⁴ Dr. Garthwaite identified the Submitted Diagnosis Codes that were not Supported Diagnosis Codes and dubbed them the “Potential Deletes.”⁵ Then, he created a final list of diagnosis codes he deemed the “Deletes” (which I refer to herein as the “Garthwaite Deletes”) by filtering and excluding Potential Deletes according to the presence of other relevant diagnosis codes in United’s data and additional criteria.⁶ The Garthwaite Deletes are listed in Attachment 1 to the Garthwaite Report.⁷

11. Dr. Garthwaite then calculated the alleged Medicare Part C and Part D financial impact attributable to the Garthwaite Deletes. That is, for the United members with diagnosis

² Garthwaite Report, para. 7.

³ *Id.* at para. 85.

⁴ *Id.*

⁵ *Id.* Per an email dated December 1, 2023 from Martha Glover of the United States Department of Justice, “the ‘Potential Deletes list’ mentioned on pages 41-42 [of Dr. Garthwaite’s report] is a useful way to explain how Dr. Garthwaite’s analysis operates in principle, but the code that implements the analysis doesn’t create this actual list at any stage. Thus, there is no list of Potential Deletes to provide.” Dr. Garthwaite did not produce a list of Potential Deletes.

⁶ See *id.* at paras. 116-118. To identify the Deletes, Dr. Garthwaite excluded from the Potential Deletes diagnosis codes that shared an HCC with other submitted diagnosis codes or risk-adjustment eligible but unsubmitted diagnosis codes; that mapped to an HCC recorded in the Claims Verification program; that were flagged as potentially at-issue in the IRADS but not EDPS data or vice versa (with respect to DOS years 2014-2016); that did not impact risk adjustment payments; that were associated with members who were not enrolled in a Medicare Advantage Plan for the whole year; that were associated with members who were not enrolled in United’s plans during the year; and/or that were associated with members with end stage renal disease.

⁷ Dr. Garthwaite provided four separate versions of Attachment 1. The first version was included with Dr. Garthwaite’s original report dated September 29, 2023, and the second, third, and fourth versions were included with Dr. Garthwaite’s Errata dated October 4, 2023, January 5, 2024, and March 11, 2024, respectively. When I refer to Garthwaite Deletes in this report, I refer to the latest revised list from March 11, 2024.

codes on the Garthwaite Deletes list, in each year, Dr. Garthwaite calculated what the members' risk scores would have been had the Garthwaite Deletes not been submitted by United for risk adjustment. He then compared those revised risk scores to the members' actual risk scores, calculated the differences in the per member per month payments for those members for the applicable payment year, and then summed those differences for every month the members were enrolled in a United Medicare Part C or D plan during the year. In total, Dr. Garthwaite calculated \$2,109,423,348 in alleged Part C financial impact and \$25,829,027 in alleged Part D financial impact related to the Garthwaite Deletes for payment years 2009 through 2017.⁸

12. Dr. Garthwaite also separately calculated the alleged financial impact on Medicare Part C and Part D payments resulting from “[United’s] failure to delete the diagnosis codes included on two spreadsheets . . . which contain diagnosis codes that [United] identified as having been included in their Claims Verification program but not having completed all the steps of the program.” Dr. Garthwaite labels these the “Defendants’ CV Pipeline Lists.”⁹ Dr. Garthwaite calculated \$188,402,348 in combined financial impact to Part C and Part D attributable to the diagnosis codes on the Defendants’ CV Pipeline Lists in payment years 2012 and 2013.¹⁰

13. Dr. Garthwaite also noted that, “[f]or service years 2014-2016, [United] also conducted a step in the Chart Review Program called ‘Second Level Review,’ where a *second* blind review was conducted for some Charts.”¹¹ The Garthwaite Report goes on to explain that Dr. Garthwaite calculated \$799,407,848 in alleged financial impact “associated with diagnosis codes submitted by [United] to CMS associated with Charts that were reviewed in [United’s] Second Level Review program.”¹² This amount is a subset of the total alleged \$2,109,423,348 and \$25,829,027 Part C and D financial impacts, respectively, discussed above.

B. Acevedo Report

⁸ Garthwaite Report, p. 53, Exhibit 10.

⁹ *Id.* at para. 8.

¹⁰ *Id.* at para. 144. As further described in my report below, a majority, but not all, of the CV Pipeline List diagnosis codes are also in the Garthwaite Deletes. The Garthwaite Report does not address or quantify the overlap between the alleged financial impact from the Deletes and the alleged financial impact from the CV Pipeline List diagnosis codes.

¹¹ *Id.* at para. 51.

¹² *Id.* at para. 92, fn. 124.

14. Ms. Acevedo was engaged by the Plaintiffs to provide expert testimony in this matter. Specifically, she was asked to provide background on medical record coding, including ICD-9 and ICD-10 diagnosis coding, and its relationship to the HCCs used in the Medicare Advantage risk adjustment program. She was also asked to provide expert testimony on the following topics: “(1) the documentation standards required in risk adjustment coding; (2) the standards and guidelines governing medical record coding; and (3) industry best practices for achieving accurate and complete coding in the Medicare Advantage context.”¹³

15. Of particular relevance here, Ms. Acevedo opined that “if a coder is knowledgeable of the official ICD and CMS coding rules. . . he or she should be able to identify an objectively correct ICD code or set of ICD codes that can be reported based on a particular medical record and thus there should be little variance in code assignment among coders. . . If qualified coders properly follow these rules, they are able to identify appropriate ICD codes and rule out inappropriate codes.”¹⁴ However, Ms. Acevedo later noted that “difficult scenarios” can impact coding accuracy. Such scenarios, she stated, are “caused by and reflect (1) the varying degrees of skill level and experience among coders; (2) errors in how those coders apply the guidelines and rules; and (3) problems extrinsic to the guidelines and required coding process, such as problems with the medical record documentation itself.”¹⁵ Thus, while Ms. Acevedo appears initially to suggest that ICD-9 and ICD-10 diagnosis coding is a precise, objective exercise, she also avers that practical, real-world conditions can and do impact the accuracy with which coders do their work and the consistency of the results reached by different coders.

IV. SUMMARY OF OPINIONS

16. Based on the work I have performed to date, and as further detailed below, I have formed the following opinions:

- i. Opinion 1: Dr. Garthwaite has failed to identify any Medicare Advantage overpayments to United because he has not found that the diagnosis codes at issue were unsupported. Instead, Dr. Garthwaite assumes that any diagnosis code not found by a Chart Review

¹³ Expert Report of Jean Acevedo (“Acevedo Report”), para. 8.

¹⁴ *Id.* at paras. 40-41.

¹⁵ *Id.* at para. 51.

coder is not supported, yet he fails to provide any basis for that assumption. Contrary to Dr. Garthwaite's assumption, when CMS's own RADV auditors reviewed the health conditions associated with allegedly unsupported diagnosis codes, they concluded that a substantial proportion of the diagnosis codes mapped to health conditions that were supported. Specifically, the data available from CMS's RADV audits in payment years 2011-2015 shows that 91% of the diagnosis codes in the government's First Interrogatory Response—which are diagnosis codes the government alleges United should have deleted as overpayments because they were not found in Chart Review—mapped to health conditions that were confirmed to be supported by the government in the RADV audits.

- ii. Opinion 2: Analysis of the First Interrogatory Response diagnosis codes that overlapped with the RADV audits reveals that, for all the instances that can be identified, the subset of diagnosis codes associated with charts that underwent two levels of blinded review (*i.e.*, an initial Chart Review and then a Second Level Review) were validated by the RADV audits at a rate comparable to that of diagnosis codes associated with charts that underwent only one level of blinded review. Moreover, the member-HCCs associated with diagnosis codes contained in the First Interrogatory Response coming from charts that underwent two levels of blinded review were not significantly less likely to be validated by RADV audits than member-HCCs that did not overlap with the First Interrogatory Response.
- iii. Opinion 3: More than 93% of the diagnosis codes in the First Interrogatory Response are *not* included in Dr. Garthwaite's final set of "Deletes," confirming that no alleged overpayment existed as a result of those diagnosis codes.
- iv. Opinion 4: Neither Ms. Acevedo nor Dr. Garthwaite has established that diagnosis codes not independently identified in Chart Review were improper or unsupported. Indeed, it is not unusual for coders to overlook supported diagnosis codes, and Ms. Acevedo's report identifies some of the practical issues that can cause this to occur. Moreover, there is substantial empirical evidence demonstrating that overlooked diagnosis codes are a common occurrence. For example, CMS's RADV audits found many additional

supported HCC codes for United contracts, even after Chart Reviews occurred. Likewise, as noted previously, CMS's RADV audits have frequently confirmed the appropriateness of many of the conditions mapping to diagnosis codes the government asserts in its First Interrogatory Response were not independently identified by United's chart reviewers and that Dr. Garthwaite identifies as Deletes. Additionally, as evidenced by the underpayment rates from CMS's Part C Improper Payment Measure reports, the government has consistently found substantial numbers of additional supported but unsubmitted HCCs across the industry.

- v. Opinion 5: Dr. Garthwaite has failed to establish the existence of a Medicare Advantage overpayment to United because he has not considered offsetting amounts for the potential impact of unsubmitted but valid diagnosis codes. Such consideration is a standard part of CMS's methodology for calculating the Part C Payment Error. In fact, in many cases, Dr. Garthwaite calculates financial impact for members' diagnosis codes even though CMS has already determined a net underpayment was made to United for that member's contract.
- vi. Opinion 6: Dr. Garthwaite's financial impact calculations are unreliable because he has not considered the extent to which his alleged financial impacts would be offset by reductions to the remittances that United paid to CMS under the Medical Loss Ratio requirements of the Medicare Advantage program.
- vii. Opinion 7: Dr. Garthwaite's analysis does not establish that United knowingly retained any overpayments. To the contrary, Dr. Garthwaite's analysis shows that it is a highly detailed and complex exercise to (a) identify diagnosis codes associated with charts that underwent Chart Review and were not independently identified in Chart Review; and (b) determine whether such diagnosis codes impacted payment. Moreover, Dr. Garthwaite's analysis makes clear that Chart Review, by its very nature, does not and cannot identify the existence, or even the likelihood, of an overpayment.
- viii. Opinion 8: If the validation rates of CMS's CON11-15 RADV audits hold constant across all of the Garthwaite Deletes, then the rate of unsupported diagnosis codes with financial impact would be less than 3.5% of the diagnosis codes included in the government's First

Interrogatory Response and less than 0.3% of United's total diagnosis codes submitted during this period for the members who underwent Chart Review. In my experience, based on common industry practices in the relevant timeframe, such a low rate of potentially unsupported diagnosis codes with financial impact would not have been expected to necessitate additional investigation or analysis.

- ix. Opinion 9: For the reasons described in my Opinions 1-8 above, Dr. Garthwaite's calculation of the number of members for whom United was allegedly overpaid as a result of the Garthwaite Deletes is also unreliable.

V. BASIS FOR OPINIONS

A. Opinion 1: Dr. Garthwaite has failed to identify any Medicare Advantage overpayments to United because he has not found that the diagnosis codes at issue were unsupported. Instead, Dr. Garthwaite assumes that any diagnosis code not found by a Chart Review coder is not supported, yet he fails to provide any basis for that assumption. Contrary to Dr. Garthwaite's assumption, when CMS's own RADV auditors reviewed the health conditions associated with allegedly unsupported diagnosis codes, they concluded that a substantial proportion of the diagnosis codes mapped to health conditions that were supported. Specifically, the data available from CMS's RADV audits in payment years 2011-2015 shows that 91% of the diagnosis codes in the government's First Interrogatory Response—which are diagnosis codes the government alleges United should have deleted as overpayments because they were not found in Chart Review—mapped to health conditions that were confirmed to be supported by the government in the RADV audits.

17. A diagnosis code from the Garthwaite Deletes can only result in an overpayment if it was, in fact, not supported by the member's medical record. However, Dr. Garthwaite has done no analysis to evaluate whether the diagnosis codes that United submitted to CMS and that United did not independently identify in Chart Review were actually unsupported. Instead, Dr.

Garthwaite simply assumes that any diagnosis code submitted by a provider that was not independently identified in Chart Review is not supported.

18. As described in his report, Dr. Garthwaite “consider[s] an instance of a given diagnosis code from a provider-reported encounter to be supported if, and only if, the same diagnosis code is included in the chart review record of that encounter in [United’s] Risk Adjustment Databases. Otherwise, [Dr. Garthwaite considers] that particular diagnosis code instance to be unsupported.”¹⁶

19. In fact, the data related to CMS’s RADV audits during payment years 2011–2015 shows that the diagnosis codes alleged to be at issue in this case map to condition codes that were validated by CMS’s own auditors the vast majority of the time. As shown in Opinion 4 of my updated December 3 report, approximately 91% of diagnosis codes that overlap between the First Interrogatory Response and the CON11-15 PFR Data (on a member-HCC basis) mapped to conditions that were *validated* by the RADV auditors. Put another way, just 9% of the diagnosis codes alleged by the government not to have been independently identified in Chart Review that mapped to condition codes that were reviewed by the government’s RADV auditors were found to be unsupported by the government’s RADV auditors. The government’s corporate representative Anne Hornsby testified that “if an HCC is confirmed” in a RADV audit “there would be no overpayment.”¹⁷

¹⁶ Garthwaite Report, Appendix D, para. 44.

¹⁷ See Hornsby 30(b)(6) Dep. (Nov. 21, 2023) Tr. at 56:8-20.

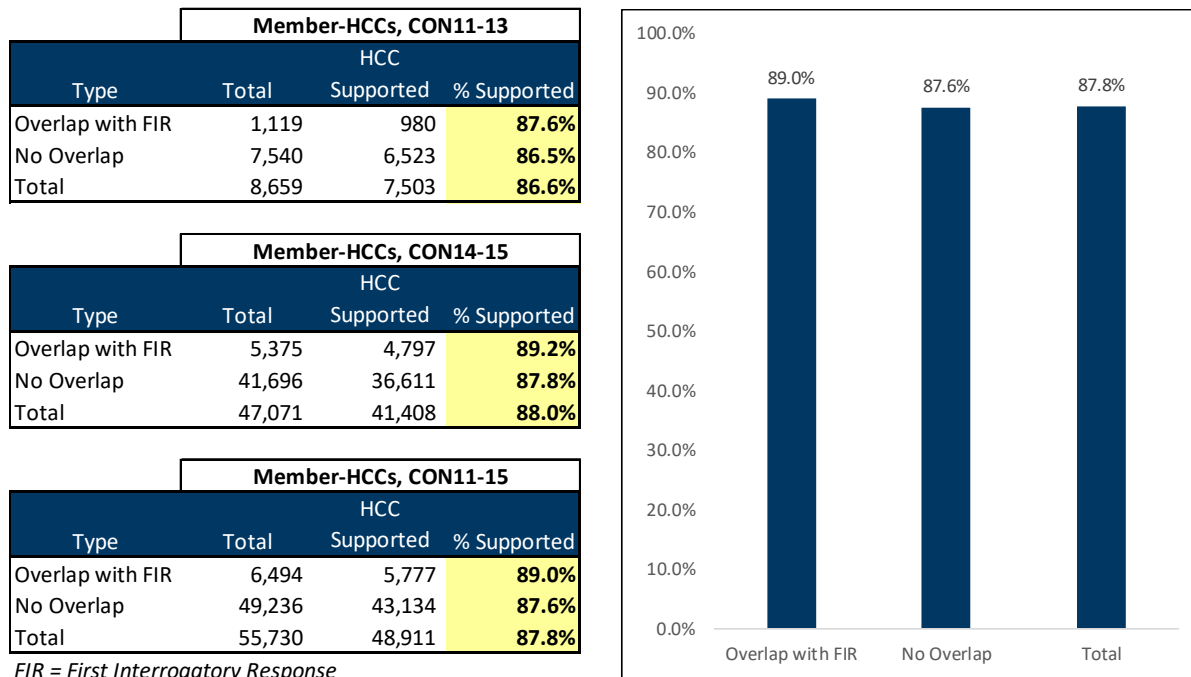
Figure 1. Results of RADV Analysis—First Interrogatory Response.¹⁸

First Interrogatory Response Records			
DOS Year	Overlap with CON11-15 PFR Data: Total	Overlap with CON11-15 PFR Data: HCC Validated	% of Total
2010	341	300	88.0%
2011	360	319	88.6%
2012	1,190	1,069	89.8%
2013	2,758	2,480	89.9%
2014	3,566	3,303	92.6%
Total	8,215	7,471	90.9%

20. Additionally, as shown in Opinion 5 of my December 3 report, the member-HCCs related to diagnosis codes in the First Interrogatory Response were found by CMS’s own reviewers to be valid at a rate closely equivalent to the average validation rate for all the member-HCCs submitted by United, or even the HCCs about which the government has raised no issue. In other words, the condition codes found in the First Interrogatory Response were no less likely to be validated by the RADV audits than any other condition codes included in the RADV audits.

¹⁸ See Updated Expert Report of M. Timothy Renjilian (“Dec. 3 Renjilian Report”) at p. 84, Fig. 13: Results of RADV Analysis—First Interrogatory Response.

Figure 2. CON11-13, CON14-15, and CON11-15 PFR Data HCC Validation Rates.¹⁹



21. The above results of CMS's RADV audits reveal a significant deficiency in Dr. Garthwaite's analysis, because they show that, in the vast majority of cases, the health conditions associated with the diagnosis codes for which United allegedly did not find support in Chart Review were actually *confirmed* to be valid by the government. As such, Dr. Garthwaite's financial impact calculations cannot be relied upon for purposes of calculating overpayments because he unreasonably assumes that all of the diagnosis codes on his list of Deletes are unsupported.

B. Opinion 2: Analysis of the First Interrogatory Response diagnosis codes that overlapped with the RADV audits reveals that, for all the instances that can be identified, the subset of diagnosis codes associated with charts that underwent two levels of blinded review (i.e., an initial Chart Review and then a Second Level Review) were validated by the RADV audits at a rate comparable to that of diagnosis codes associated with charts that underwent only one level of blinded review. Moreover, the member-HCCs associated with diagnosis codes contained

¹⁹ See *id.* at p. 87, Fig. 15: CON11-13, CON14-15, and CON11-15 PFR Data HCC Validation Rates.

in the First Interrogatory Response coming from charts that underwent two levels of blinded review were not significantly less likely to be validated by RADV audits than member-HCCs that did not overlap with the First Interrogatory Response.

22. As described in the Background section above, Dr. Garthwaite observed that United conducted Second Level Reviews for certain charts in service years 2014-2016, and he identified \$799,407,848 in alleged financial impact “associated with diagnosis codes submitted by [United] to CMS associated with Charts that were reviewed in [United’s] Second Level Review program.”²⁰

23. Because Dr. Garthwaite highlighted this Second Level Review process, I analyzed the RADV validation rates for the subset of First Interrogatory Response diagnosis codes associated with member charts that went through Second Level Review and compared them to those associated with charts subjected only to a first level review. I focused on data from service year 2014 because, as further described below, that is the only year for which I could (a) identify charts that underwent Second Level Review, and (b) assess RADV results (per the CON15 PFR Data).

24. To perform this analysis, I relied upon MRM data produced for 2014 service dates (MAPL000724236). I focused on the First Interrogatory Response diagnosis codes that overlapped with the CON15 PFR Data; identified the member charts associated with those diagnosis codes;²¹ and determined if the chart underwent Second Level Review.²² I then compared the RADV validation rates for the conditions associated with the overlapping diagnosis codes to the corresponding validation rates for conditions associated with charts that did not undergo Second Level Review. These findings are shown in **Figure 3** below.

²⁰ Garthwaite Report, para. 92, fn. 124.

²¹ I identified charts associated with particular diagnosis codes on a member-provider basis—i.e., if the chart provider from the MRM data overlapped with the provider listed in the First Interrogatory Response based on the provider ID. As Dr. Garthwaite did, I used the “SAS All Providers” data to bridge the provider identifier information between MRM and the First Interrogatory Response.

²² I assume that a Chart underwent Second Level Review if it had at least one coding result record with “Coding” and at least one with “SLR” populated in the GCM_BUSS_FUNC_NAME field. Consistent with Dr. Garthwaite’s approach, I assume “Coding” indicates the presence of a blinded first level review and “SLR” indicates the presence of a blinded Second Level Review.

Figure 3. RADV Validation–Second Level Review.²³

First Interrogatory Response Records: Charts that Underwent 2LR				First Interrogatory Response Records: Charts that Did Not Undergo 2LR		
DOS Year	Overlap with CON15 PFR Data: Total	Overlap with CON15 PFR Data: HCC Validated	% of Total	Overlap with CON15 PFR Data: Total	Overlap with CON15 PFR Data: Validated	% of Total
<i>Count of diagnosis codes (i.e., First Interrogatory Response records)</i>						
2014	1,833	1,663	90.7%	1,733	1,640	94.6%
<i>Count of unique member-HCCs</i>						
2014	1,655	1,481	89.5%	1,308	1,206	92.2%

25. Based on the above, diagnosis codes from 2014 associated with charts that underwent Second Level Review were validated at the condition level at a similar rate (90.7%) as those associated with charts that were only subjected to first level review (94.6%).

26. I also reviewed the validation rates at a unique member-HCC level and found them to be comparable as well (89.5% for member-HCCs associated with charts that underwent Second Level Review versus 92.2% for those associated with charts that were only subjected to first level of review).²⁴ Moreover, the validation rate for member-HCCs associated with charts that underwent Second Level Review is comparable to the validation rates for member-HCCs from the CON11-15 PFR data that did not overlap with the First Interrogatory Response, as summarized in Opinion 5 of my December 3 Report (and shown again in **Figure 2** above).²⁵

27. Put another way, for the First Interrogatory response diagnosis codes that overlapped with the CON15 PFR data, a diagnosis code that went undetected through two levels of Chart Review was not meaningfully less likely to be validated at the condition level than a diagnosis code that went undetected through just one level of Chart Review. Moreover, a member-HCC that went undetected through two levels of Chart Review was not meaningfully less likely to

²³ See Exhibit 3.

²⁴ The number of observations and validation rates are different when analyzing the First Interrogatory Response at a diagnosis code level versus member-HCC level because, in many cases, a unique member-HCC maps to more than one First Interrogatory Response diagnosis code. Note that, with respect to payment years 2014 and 2015, I counted member-V12 HCC and member-V22 HCC combinations separately and added them together.

²⁵ See Dec. 3 Renjilian Report at p. 87. As shown in Figure 2, the validation rate for member-HCCs from the CON11-15 PFR data that did not overlap with the First Interrogatory Response was 87.6%. This rate was 89.3% for DOS year 2014 / payment year 2015, specifically, as derived in Appendix X1.

be valid than a member-HCC that did not overlap with the diagnosis codes the government has claimed must be deleted as overpayments in the First Interrogatory Response.

28. Additionally, I understand that United performed Second Level Review for certain charts beginning in calendar year 2013 for 2012 dates of service.²⁶ Specifically, my understanding is that approximately 50% of charts with 2012 dates of service underwent Second Level Review in calendar year 2013, and that approximately two-thirds of charts with 2013 dates of service underwent Second Level Review in calendar year 2014.²⁷ While data is not available to allow identification of the specific First Interrogatory Response diagnosis codes from service years 2012 and 2013 associated with charts that underwent Second Level Review, it is notable that, of the First Interrogatory Response diagnosis codes that overlap with the CON11-15 PFR Data, the proportion that map to conditions that were validated in those audits remains consistent over time (as shown in **Figure 1** above). Dr. Garthwaite's focus on Second Level Review notwithstanding, the validation rate did not decrease in service year 2012 despite the fact that a substantial percentage of United's charts began Second Level Review in that year.

C. Opinion 3: More than 93% of the diagnosis codes in the First Interrogatory Response are not included in Dr. Garthwaite's final set of "Deletes," confirming that no alleged overpayment existed as a result of those diagnosis codes.

29. In its First Interrogatory Response, the government produced a list of diagnosis codes that it alleges to be at issue in this case. These diagnosis codes are described as ones for which "(1) the diagnosis code was submitted by UnitedHealth to CMS and was required, by regulation, to be supported by an underlying medical record; (2) that medical record went through UnitedHealth's medical record review program; and (3) UnitedHealth's own reviewers did not find the diagnosis code to be supported by medical records."²⁸ For these diagnosis codes, the government contends that "[United] 'knowingly and improperly failed to delete' or 'knowingly

²⁶ See K. Baker Dep. (Jul. 12, 2022) Tr. at 139:11-17 (testifying that, after the "recode" project in project year 2012 for date of service year 2011, Optum began to send charts through Second Level Review); see also K. Baker 30(b)(6) Dep. (May 30, 2023) Tr. at 355:14-356:22 (testifying about Second Level Review for the 2013 project year for 2012 dates of service).

²⁷ This understanding is based on discussions with Jim Colhour, Vice President of Operations at Optum Quality and Risk Adjustment Operations, and Katie Baker, Vice President of Risk Adjustment Operations and Transformation at Optum.

²⁸ Joint Stipulation Regarding Government's Motion to Compel, dated April 29, 2021, p. 8.

and improperly failed to otherwise return to the Medicare Program the overpayments based on such diagnoses.”²⁹

30. In his analysis, Dr. Garthwaite identified a set of diagnosis codes associated with charts that allegedly underwent Chart Review and were not independently identified by the Chart Review coders *and*, importantly, that had Part C and/or Part D financial impact. The Garthwaite Deletes are listed in 12 data tables. There are nine data tables (labeled with an “IRADS” designation) comprising 1,930,455 line item records relating to diagnosis codes submitted to RAPS from PY 2009–PY 2017. There are also three data tables (labeled with an “EDPS” designation) comprising 701,296 line item records relating to diagnosis codes submitted to EDPS from PY 2015–PY 2017. There is significant overlap between the IRADS and EDPS tables; most of the diagnosis codes in the EDPS tables are found within the IRADS tables. As shown in **Figure 4** below, taking the IRADS and EDPS tables together, there are a total of 1,934,660 unique member + DOS + diagnosis code combinations and 1,975,502 member + DOS + diagnosis code + provider combinations in the Deletes.

Figure 4. Summary of Garthwaite Deletes.³⁰

Count of Garthwaite Deletes Diagnosis Codes (Revised Attachment 1)					
DOS Year	Number of Total Records			Total Unique Diagnosis Codes	
	[A]	[B]	[C]=[A]+[B]	[D]	[E]
	IRADS	EDPS	Total	Unique Member + Dx + DOS	Unique Member + Dx + DOS + Provider
2008	100,781	-	100,781	100,781	100,781
2009	196,938	-	196,938	196,936	196,936
2010	384,120	-	384,120	384,026	384,026
2011	115,093	-	115,093	115,029	115,029
2012	190,493	-	190,493	190,492	190,493
2013	219,903	-	219,903	219,903	219,903
2014	222,637	214,533	437,170	223,271	237,498
2015	223,736	214,237	437,973	225,087	236,936
2016	276,754	272,526	549,280	279,135	293,900
Total	1,930,455	701,296	2,631,751	1,934,660	1,975,502

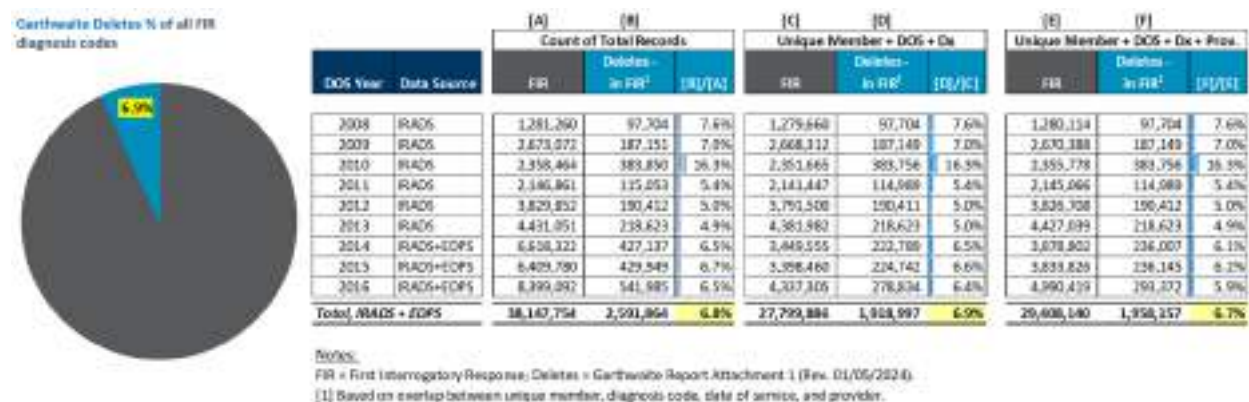
²⁹ Government’s First Interrogatory Response, dated August 17, 2020, p. 9.

³⁰ See Exhibit 4 (Updated as of 03-18-24).

31. The Deletes are the basis for Dr. Garthwaite's calculation of approximately \$2.1 billion of Part C financial impact and approximately \$26 million of Part D financial impact across the relevant time period.

32. Notably, the number of Garthwaite Deletes is significantly smaller than the number of diagnosis codes asserted to be at issue by the government in the government's First Interrogatory Response.³¹ As shown in **Figure 5** below, less than 7% of the First Interrogatory Response diagnosis codes are in Garthwaite's Deletes. This is true whether counting the Garthwaite Deletes and First Interrogatory Response by total records or by unique member + DOS + diagnosis code combinations or by unique member + DOS + diagnosis code + provider combinations.

Figure 5. Garthwaite Deletes Compared to Government's First Interrogatory Response.³²



33. Stated differently, Dr. Garthwaite's analysis shows that less than 7% of the First Interrogatory Response diagnosis codes were diagnosis codes that Dr. Garthwaite deemed to have

³¹ The First Interrogatory Response included 27,937,651 diagnosis codes submitted to RAPS (based on United's IRADS data) and 10,210,103 diagnosis codes submitted to EDPS (based on United's EDPS data). There is significant overlap between the diagnosis codes in the EDPS data and the IRADS data. Approximately 99% of the EDPS diagnosis codes overlap with the IRADS data on a member + DOS + diagnosis code basis. In my December 3 report, I focused on the IRADS/RAPS data because it captured the vast majority of unique diagnosis codes in the First Interrogatory Response and because the small number of additional EDPS diagnosis codes would not have affected my opinions in any material way.

³² See Exhibit 5 (Updated as of 03-18-24). In a prior version of this rebuttal report, I noted that 61,502 diagnosis codes (member-dx-DOS combinations) in the original iteration of the Garthwaite Deletes did not appear in the First Interrogatory Response. I noted that of those diagnosis codes, 46,149 (75%) did *not* appear in the RAPS data. I noted that these 46,149 diagnosis codes appeared to have been included in Dr. Garthwaite's list inadvertently, as the Deletes are designed to include only submitted diagnosis codes. On March 11, 2024, Dr. Garthwaite submitted an errata confirming that his inclusion of these codes was inadvertent. Based on the updated version of the Garthwaite Deletes, more than 99% of the 1,934,660 unique diagnosis codes (member-dx-DOS combinations) in the Garthwaite Deletes are in the First Interrogatory Response (1,918,997 / 1,934,660 = 99.2%).

had a financial impact. Dr. Garthwaite did not include the remaining 93+% of First Interrogatory Response diagnosis codes in his final set of Deletes, confirming that no alleged overpayment existed as a result of those diagnosis codes.

D. Opinion 4: Neither Ms. Acevedo nor Dr. Garthwaite has established that diagnosis codes not independently identified in Chart Review were improper or unsupported. Indeed, it is not unusual for coders to overlook supported diagnosis codes, and Ms. Acevedo's report identifies some of the practical issues that can cause this to occur. Moreover, there is substantial empirical evidence demonstrating that overlooked diagnosis codes are a common occurrence. For example, CMS's RADV audits found many additional supported HCC codes for United contracts, even after Chart Reviews occurred. Likewise, as noted previously, CMS's RADV audits have frequently confirmed the appropriateness of many of the conditions mapping to diagnosis codes the government asserts in its First Interrogatory Response were not independently identified by United's chart reviewers and that Dr. Garthwaite identifies as Deletes. Additionally, as evidenced by the underpayment rates from CMS's Part C Improper Payment Measure reports, the government has consistently found substantial numbers of additional supported but unsubmitted HCCs across the industry.

34. There is no basis to assume that a diagnosis code was unsupported simply because a Chart Review coder failed to independently identify the diagnosis. To the contrary, based on my many years of professional experience supervising coding reviews in a variety of circumstances, there are many practical, real-world factors that can make it difficult to identify diagnosis codes from a medical record comprehensively and with complete accuracy. These can include, among other things, the time available for the review; the completeness, legibility and clarity of the medical record documentation; and the skill and experience of the reviewer. Consequently, it would not be surprising for a Chart Review coder to fail to identify a diagnosis code that was actually supported by the member's record.

35. Similarly, although Ms. Acevedo opines that coding is a theoretically objective exercise, she nevertheless notes that various factors can create "difficult coding scenarios." These

include varying degrees of skill level and experience among coders; errors in how those coders apply guidelines; and extrinsic problems (such as issues with the medical record documentation) that can impact coding results.³³

36. Moreover, empirical evidence *contradicts* the notion that diagnosis codes that were not independently identified in Chart Review were unsupported. As noted earlier, just 9% of the diagnosis codes alleged by the government to be associated with charts that underwent Chart Review and not to have been independently identified by the Chart Review coder were ones that mapped to condition codes that were found to be unsupported by the government's RADV auditors. This result—based on the government's own audits—makes unambiguously clear that submitted diagnosis codes that were not independently identified during Chart Review cannot be assumed to be unsupported. In fact, to the contrary, the government's audits show that the conditions mapping to such diagnosis codes are supported an overwhelming majority of the time, and the conditions mapping to diagnosis codes allegedly not independently identified in Chart Review were no more likely to be unsupported than any other diagnosis codes.

37. The notion that valid diagnosis codes can nonetheless be missed by Chart Review coders is further supported by the fact that CMS's RADV audits of United frequently found underpayments—that is, unsubmitted diagnosis codes that were in fact supported and that would have garnered United additional reimbursement. As discussed in my previous report, for the CON11-13 RADV audits (which, to my understanding, are the only audits for which contract-level recovery amounts have been published), 13 of the 15 United contracts audited were found to have net underpayments.³⁴ This again makes clear that missed or overlooked diagnosis codes are a common occurrence in practice.

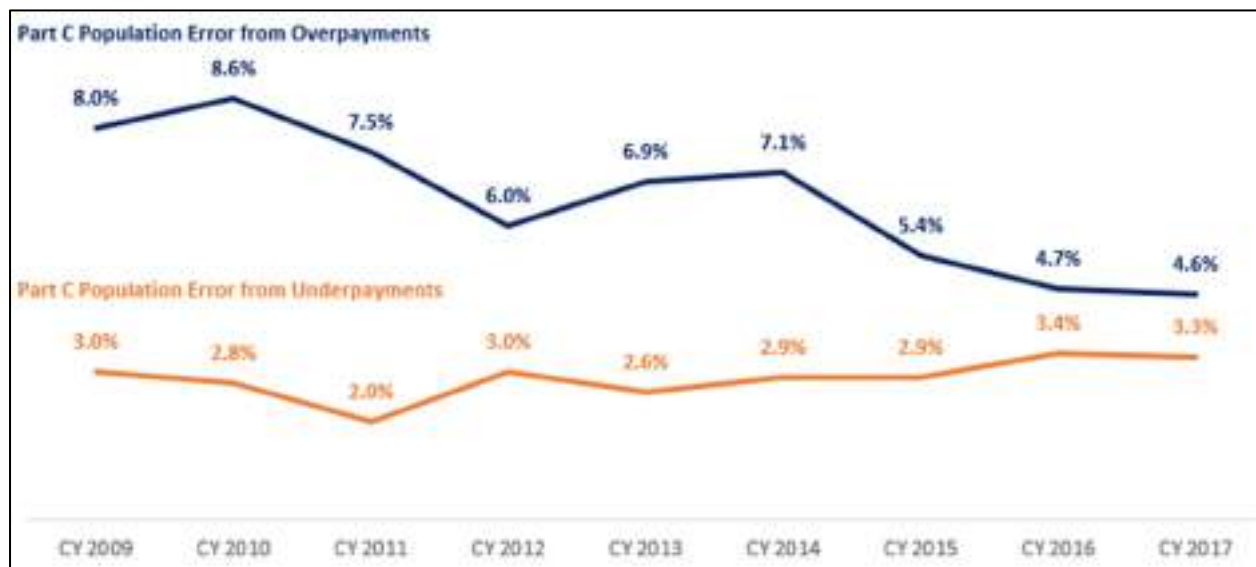
38. In addition, as shown in **Figure 6** below, the CMS Part C Improper Payment Measure Reports show that the Part C population error from underpayments was consistently 2.0%-3.4% across the industry during the time period relevant to this case (whereas the overpayment-related error rates were only somewhat higher, ranging from 4.6% to 8.6%, with the difference between the underpayment rates and overpayment rates gradually decreasing over

³³ Acevedo Report, para. 51.

³⁴ See Dec. 3 Renjilian Report at para. 175.

time). Such underpayments were identified as resulting from “additional” HCCs, which “occur during the medical record review process when the medical record submitted by the MA Organization supports a CMS-HCC that was never submitted for payment, or the medical record supports a more severe diagnosis within the same hierarchy as the CMS-HCC submitted for payment.”³⁵ These underpayment rates again show that coders across the industry commonly overlook diagnosis codes that are actually supported.

Figure 6. Part C Error Rates, CY 2009 – CY 2017.³⁶



39. Taken together, the above observations make clear that coding is, in practice, an imprecise exercise that is subject to a variety of real-world constraints and complications. Such practical challenges can and do often mean that even a qualified coder can overlook an otherwise valid, appropriate diagnosis code. Consequently, the fact that a diagnosis code was not independently identified by United in Chart Review does not mean that the diagnosis code was improper or unsupported.

³⁵ See CMS, Part C Improper Payment Measure (Part C IPM) Fiscal Year 2022 (FY 2022) Payment Error Rate Results, <https://www.cms.gov/files/document/fy-2022-medicare-part-c-error-rate-findings-and-results.pdf-0>.

³⁶ *Id.* Note that this chart shows rates by calendar year, while the comparable chart in the CMS report shows rates by fiscal year. Fiscal year rates are based on payments from the calendar year two years prior (*e.g.*, the FY 2022 rates are based on calendar year 2020 payments).

E. Opinion 5: Dr. Garthwaite has failed to establish the existence of a Medicare Advantage overpayment to United because he has not considered offsetting amounts for the potential impact of unsubmitted but valid diagnosis codes. Such consideration is a standard part of CMS's methodology for calculating the Part C Payment Error. In fact, in many cases, Dr. Garthwaite calculates financial impact for members' diagnosis codes even though CMS has already determined a net underpayment was made to United for that member's contract.

40. Dr. Garthwaite's financial impact calculations are inconsistent with the government's own methodology for evaluating payment errors in the Medicare Advantage program.

41. As explained in more detail in my December 3 Report, when calculating either the RADV payment error or the Medicare Improper Payment Measure, the government nets the financial impact of the submission of unsupported diagnosis codes against the financial impact of unsubmitted additional diagnosis codes found to be supported by enrollees' medical records.³⁷

42. Dr. Garthwaite has focused only on the allegedly unsupported diagnosis codes that could theoretically generate overpayments, ignoring the substantial near-certainty that there are additional appropriate diagnosis codes that were missed and not submitted.

43. Based on the available data from the government's RADV audits, United has often been found to have been *underpaid* at a contract level. As discussed above, 13 of the 15 United contracts reviewed in the CON11-13 RADV audits were found to have net underpayments.³⁸

44. As summarized in **Figure 7** below, Dr. Garthwaite has calculated financial impact for members who were part of contracts for which the government has already found that United was underpaid on that contract through its RADV audits. Specifically, of the 15 United contracts included in the CON11-13 RADV audits, 13 contracts had members with diagnosis codes in

³⁷ See CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, February 24, 2012, p. 3.; see also CMS, *Error Rate Findings and Results, Key Terms*, available at: (<https://www.cms.gov/research-statistics-data-systems/improper-payment-measurement-programs/medicare-part-c-ipm/error-rate-findings-and-results>). See also Dec. 3 Renjilian Report at paras. 169-170.

³⁸ USBP068691383, pp. 19-21. A net underpayment is shown as a negative "recovery amount", which is defined as the "extrapolated payment error amount based on the lower bound of the 99% confidence interval" per USBP068691383, p. 3.

Garthwaite's Deletes in the relevant years. These same 13 contracts were all found to have net underpayments by the RADV audits. This means that, for these contracts, the government's extrapolation of all the accumulated deletions and additions arising from its audits yielded an estimated net underpayment at the lower bound of a 99% confidence interval. In contrast, across the 23,231 members under those 13 contracts, Dr. Garthwaite calculated \$78.6 million in purported Part C overpayments resulting from the Garthwaite Deletes (accounting for approximately 12% of the total alleged Part C overpayments Dr. Garthwaite calculated for all members in these years).³⁹

45. The government's sample-based audits are intended to be statistically valid; they include consideration of both unsupported submitted diagnosis codes and unsubmitted supported diagnosis codes; and they include consideration of the conditions that map to many of the same diagnosis codes questioned by Dr. Garthwaite. To that extent, the extrapolations represent a comprehensive, all-encompassing estimate of the actual net total underpayment or overpayment related to each contract reviewed. Dr. Garthwaite's incomplete, one-sided analysis fails to take this critical fact into account.

³⁹ For context, there were 80, 80, and 78 total unique contracts with members for whom Dr. Garthwaite calculated Part C financial impact stemming from the Garthwaite Deletes in DOS years 2010, 2011, and 2012, respectively, as identified in Attachment 2 to the Garthwaite Report.

Figure 7. Garthwaite Deletes on Contracts Reviewed in CON11-13 RADV Audits.⁴⁰

RADV Year	HMOID	RADV Results	Garthwaite, Part C Impact		
		Recovery Amount	Members with Alleged Financial Impact	Alleged Deletes	Alleged Financial Impact
CON11	H2226	(\$2,068,360)	156	226	\$ 554,514
	H4522	(\$4,622,640)	1,130	1,825	\$ 3,421,371
	H4590	(\$51,017,738)	6,181	9,768	\$ 23,720,086
	H0543	(\$91,884,129)	4,249	6,762	\$ 16,380,547
CON12	H5420	\$15,735,769	n/a	n/a	n/a
	R7444	(\$3,962,831)	310	394	\$ 420,590
	H5652	(\$4,740,216)	15	21	\$ 72,017
	H0251	(\$10,348,919)	201	236	\$ 546,676
	R5287	(\$69,295,194)	1,923	2,487	\$ 5,382,367
CON13	R9896	\$4,065,269	n/a	n/a	n/a
	H3107	(\$1,581,972)	2,973	4,915	\$ 8,863,763
	H0151	(\$7,790,780)	1,627	2,398	\$ 4,735,077
	H4514	(\$9,302,996)	949	1,752	\$ 3,316,349
	H2931	(\$10,078,497)	2,194	3,581	\$ 7,239,676
	R5342	(\$14,309,264)	1,323	1,929	\$ 3,939,954
Total, RADV Underpayment Contracts			23,231	36,294	\$ 78,592,989
All Garthwaite Deletes 2010-2012 (Part C)			201,252	301,698	\$ 647,096,642
% of All Garthwaite Deletes (Part C)			11.5%	12.0%	12.1%

46. Dr. Garthwaite has not considered the fact that the government has already determined that there was a negative recovery amount for all of the above contracts that overlap with his Deletes. More fundamentally, Dr. Garthwaite has failed to account for potential underpayments for *any* of the contracts at issue, which is unreasonable given the overwhelming presence of underpayments on the contracts that were actually audited. Based on these results, it is reasonable to expect that, had more of these contracts been subjected to RADV audits, many, if not most, of them would have been found to have net underpayments.

F. Opinion 6: Dr. Garthwaite's financial impact calculations are unreliable because he has not considered the extent to which his alleged financial impacts would be

⁴⁰ See Exhibit 6 (Updated as of 03-18-24).

offset by reductions to the remittances that United paid to CMS under the Medical Loss Ratio requirements of the Medicare Advantage program.

47. Since contract year 2014, MAOs have been required to submit medical loss ratio (“MLR”) reports to CMS on an annual basis. The MLR, reported at a contract level, represents “the percentage of revenue used for patient care, rather than for such other items as administrative items or profit.”⁴¹ Plans are subject to financial and other penalties for failure to meet the statutory requirement that they have an MLR of at least 85 percent.⁴² These penalties can include remittance of funds to CMS, a prohibition on enrolling new members, and contract termination.⁴³ Of particular relevance here, “[i]f CMS determines for a contract year that an MA organization has an MLR for a contract that is less than 0.85, the MA organization has not met the MLR requirement and must remit to CMS an amount equal to the product of . . . (1) [t]he total revenue of the MA contract for the contract year and (2) [t]he difference between 0.85 and the MLR for the contract year.”⁴⁴

48. CMS publishes annual Public Use Files (the “MLR Public Use Files”) that provide the data submitted by MAOs, Part D sponsors, and cost plans in their MLR reports and identify the MLR remittance amount, if any, due by the plans to CMS.⁴⁵ An MAO’s MLR is defined as the ratio of the MLR numerator to the MLR denominator. The MLR numerator relates to expenditures incurred by the plan and equals the sum of incurred claims for all enrollees, the reduction (if any) in the Part B premium for all MA plan enrollees, and the plan expenditures for activities that improve health care quality.⁴⁶ The MLR denominator equals total revenue under the contract, which is based on CMS’s payments to the MAO for all enrollees under the contract, subject to certain exclusions and deductions.⁴⁷ The MLR may be increased by a statutorily defined

⁴¹ See CMS, Medical Loss Ratio, <https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio>.

⁴² See 42 CFR §422.2410 and §423.2410.

⁴³ See CMS, Medical Loss Ratio, <https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio>.

⁴⁴ See 42 CFR §422.2410.

⁴⁵ See CMS, Medical Loss Ratio, <https://www.cms.gov/medicare/health-drug-plans/medical-loss-ratio>.

⁴⁶ See 42 CFR §422.2420(b)(1).

⁴⁷ See §422.2420(c). Amounts excluded or deducted from the denominator include licensing and regulatory fees, Federal taxes and assessments, State taxes and assessments, community benefit expenditures, unpaid premiums for which the MAO can demonstrate it made a reasonable effort to collect, certain EHR payments and adjustments, and Coverage Gap Discount Program payments.

credibility adjustment, which is based on the number of member-months covered by the plan and adjusted by a deductible factor.⁴⁸

49. Based on the above, keeping all else constant, to the extent that a plan's revenues (the denominator of the MLR calculation) are reduced—such as would be the case if Dr. Garthwaite's "Deletes" had in fact been deleted by United—the plan's MLR would increase. For a plan having an MLR less than 0.85, and thus being required to make a remittance to CMS, this would result in the reduction or elimination of the remittance owed. In other words, the impact of the Garthwaite Deletes would be offset by a reduction in the MLR remittance amount. Dr. Garthwaite has not considered this mitigating effect, thereby overstating his financial impact estimates.

50. As an illustration of this concept, I identified 36 contracts from contract years 2014–2017 for which (a) United remitted funds to CMS because of the contract having an MLR under 0.85, and (b) Dr. Garthwaite identified an alleged Part C or Part D overpayment. For these 36 contracts, I estimated what the revised MLR and remittance to CMS (if any) would have been if Dr. Garthwaite's alleged Part C and Part D financial impact amounts were removed from the MLR denominators, keeping all other factors constant. These results are summarized in **Figure 8** below. Across these 36 contracts, my calculations show that Dr. Garthwaite's alleged Part C and D financial impact, if subtracted from the MLR denominator, would have reduced United's remittances to CMS by \$193,070,093, or approximately 64% of Dr. Garthwaite's total alleged financial impact for these contracts (\$304,007,989). Under this calculation, the remittance to CMS was entirely eliminated for 13 contracts and was reduced for 23 contracts.

⁴⁸ See 42 CFR §422.2440.

Figure 8. Revised MLR Remittances to CMS, 2014–2017.⁴⁹

Year	Number of Contracts	Garthwaite	Total Remittance to CMS	FTI Calculation	
		Total Part C + D Impact		Revised Remittance to CMS	Difference
2014	4	\$ 13,749,619	\$ 18,623,145	\$ 6,977,386	\$ (11,645,760)
2015	4	\$ 16,653,972	\$ 14,523,485	\$ 3,122,061	\$ (11,401,424)
2016	15	\$ 87,239,056	\$ 213,633,918	\$ 139,897,742	\$ (73,736,177)
2017	13	\$ 186,365,341	\$ 175,233,500	\$ 78,946,767	\$ (96,286,734)
Grand Total		36 \$ 304,007,989	\$ 422,014,049	\$ 228,943,956	\$ (193,070,093)

51. Dr. Garthwaite’s failure to consider the extent to which his alleged financial impact figures would have affected these contract-level MLR remittances is another reason his calculations cannot be relied upon to determine the presence of an overpayment to the government.

G. Opinion 7: Dr. Garthwaite’s analysis does not establish that United knowingly retained any overpayments. To the contrary, Dr. Garthwaite’s analysis shows that it is a highly detailed and complex exercise to (a) identify diagnosis codes associated with charts that underwent Chart Review and were not independently identified in Chart Review; and (b) determine whether such diagnosis codes impacted payment. Moreover, Dr. Garthwaite’s analysis makes clear that Chart Review, by its very nature, does not and cannot identify the existence, or even the likelihood, of an overpayment.

52. I understand that the government seeks to prove that United “knowingly and improperly failed to delete . . . invalid diagnoses that had been submitted to the Medicare Program for risk adjustment payments which were made by the Medicare Program to [United] or knowingly and improperly failed to otherwise return to the Medicare Program the overpayments based on the invalid diagnoses.”⁵⁰ Importantly, Dr. Garthwaite has failed to establish that United *knowingly* retained any overpayments. To the contrary, Dr. Garthwaite’s methodology and findings show that the identification of overpayments is a complex and imprecise exercise, and that simply

⁴⁹ See Exhibit 7.

⁵⁰ See Complaint, para. 342.

identifying a diagnosis code as not having been independently identified in Chart Review does not mean that the diagnosis code led to an overpayment.

i. Dr. Garthwaite's analysis demonstrates the difficulty of precisely locating diagnosis codes that were not independently identified in Chart Review

53. Dr. Garthwaite's analysis illustrates the highly detailed and complex process necessary to identify the diagnosis codes that were (a) submitted for risk adjustment, (b) associated with charts that underwent Chart Review, and (c) not independently identified in Chart Review. As Dr. Garthwaite notes, the United/Vendor Chart Review Data and United's Risk Adjustment Claims Data are not structured in a way that allows for direct linking and comparison.⁵¹ Moreover, Dr. Garthwaite notes that "[United]'s databases do not consistently track provider information associated with records from the Chart Review Program" and "[United]'s Chart Review Databases also do not always reflect the actual provider who had the face-to-face encounter with the beneficiary."⁵² Because of these complexities in the data, Dr. Garthwaite had to take multiple steps to transform the data and make certain assumptions to address gaps or ambiguities. This included, for example:

- Standardizing member, provider, and encounter data across multiple disparate systems (*e.g.*, with respect to thousands of Chart Review vendor files relating to service years 2008-2009: converting invalid values to blank values; removing spaces from names; attempting to identify unique members from non-standard numeric or alphanumeric member ID variables, names, and dates of birth);⁵³
- Identifying and applying particular exclusions to the encounter and/or Chart Review data (*e.g.*, excluding Chart Review data from the ChartSync or MRM systems in cases where certain fields indicated that a review may not have been

⁵¹ See, *e.g.*, Garthwaite Report, para. 81 ("provider-reported encounters . . . do not contain encounter identifiers that allow direct linkage to Chart Review Program results" and "connecting a provider-reported encounter to the Chart Review Program Coder's results for that same encounter necessitates taking additional analytic steps."); Bird 30(b)(6) Dep. (Jun. 22, 2023) Tr. at 135:10-136:20; 140:11-142:3; 147:12-148:15 (explaining the difficulties in matching United's Chart Review and claims data).

⁵² *Id.* at para. 82. See also K. Baker 30(b)(6) Dep. (May 30, 2023) Tr. at 65:17-67:14, 112:15-113:9, 126:15-128:7, 229:15-231:20, 250:21-251:7, 251:17-252:7, 254:4-254:10, 311:5-311:19 (describing the complexities and limitations of the provider information collected and maintained in ChartSync).

⁵³ *Id.* at Appendix D, paras. 14-20.

complete;⁵⁴ using particular sets of CPT/HCPCS codes and Type of Bill codes to identify whether EDPS encounters were eligible for risk adjustment);⁵⁵ and

- Designing and implementing multi-step rules-based logic to identify certain scenarios (*e.g.*, identifying that an encounter allegedly underwent Chart Review if (i) there is overlap between the encounter data and Chart Review data at a date of service and provider identifier level, and/or if (ii) there was only one provider who reported a diagnosis on an encounter and the date of service from that encounter was included in the Chart Review data, even if there was no provider identifier overlap).⁵⁶

54. The above examples represent only some of the many intricate steps that Dr. Garthwaite undertook to identify the population of diagnosis codes potentially at issue. His methodology is explained over 18 pages of his report⁵⁷ and is executed by thousands of lines of SAS code. And even that represents only a starting point, with substantial additional analysis necessary to determine whether the diagnosis codes so identified actually impacted payment. Yet more analysis would be required to assess whether such diagnosis codes were truly unsupported (as opposed to having simply been overlooked by the Chart Review coder). In short, the path from a Chart Review result to a known overpayment is a long and complicated one, and Dr. Garthwaite has provided no evidence that United did, or reasonably could have done, the work necessary to know if any overpayments existed.

ii. Dr. Garthwaite's analysis shows that United's Chart Review process and CV Pipeline Lists, by their very nature, are not sufficient to conclude that a potentially unsupported diagnosis code caused an overpayment

55. Even if Dr. Garthwaite had been able to perfectly ascertain every diagnosis code that was subject to Chart Review and not independently identified, and even if he had been able to perfectly narrow that universe down to circumstances in which the Chart Review results were

⁵⁴ *Id.* at Appendix D, paras. 21-22.

⁵⁵ *Id.* at Appendix D, para. 29.

⁵⁶ *Id.* at Appendix D, paras. 30-43.

⁵⁷ *Id.* at Appendix D, paras. 8-48.

complete and accurate and the diagnosis code at issue was truly unsupported, this would still not establish that submitting the diagnosis code led to an overpayment.

56. In considering whether an unsupported diagnosis code led to an overpayment, it is important to note that there is no specific, uniform dollar value that can be ascribed to an isolated diagnosis code. As Dr. Garthwaite shows in his report, the process of determining the financial impact of a given diagnosis code is a complex one that relies on many pieces of information. It requires, at a minimum, identifying whether other providers submitted the same diagnosis code for that member in that year; determining what other diagnosis codes were submitted for that member in the year (including any diagnosis codes that were submitted by non-United plans if the member had coverage from other plans during the year); identifying the HCC and/or RxHCC condition codes that the diagnosis code maps to, and whether those HCC(s)/RxHCC(s) were supported by other, uncontested diagnosis codes; calculating what the member's risk score would have been in that year absent the HCCs/RxHCCs that were wholly/only supported by that given diagnosis code; and translating that risk score into a dollar amount based on the member's contract, the base rate for that contract, and certain year-specific risk factor adjustments.⁵⁸ This multi-step process requires careful consideration of a large set of various factors. In some cases, it requires data from CMS that United would not have had—such as the data about diagnosis codes submitted from other, non-United plans.⁵⁹ In other cases, it relies on information that is only available after the close of the contract year and, thus, months after the completion of the Chart Review giving rise to the question. Importantly, Dr. Garthwaite has not established that these steps—which are key to determining whether an overpayment exists—were part of the Chart Review process.

57. The difficulty of identifying diagnosis codes that were not independently found in Chart Review and that had financial impact is further illustrated by Dr. Garthwaite's revisions to his list of Garthwaite Deletes. He provided one version with his original report (on September 29, 2023), and subsequently issued three revised versions over the course of several months (reflected in his October 4, 2023 Errata, January 5, 2024 Errata, and March 11, 2024 Errata). The version of the Garthwaite Deletes from the October 4, 2023 Errata contained 4% fewer IRADS diagnosis

⁵⁸ *Id.* at Appendix D, paras. 51-90.

⁵⁹ *Id.* at Appendix D, para. 73.

codes and 1% fewer EDPS diagnosis codes than the original version.⁶⁰ The version of the Garthwaite Deletes from the January 5, 2024 Errata contained the same number of IRADS diagnosis codes but 36% fewer EDPS diagnosis codes than the October 4, 2023 Errata version.⁶¹ Moreover, the January 5, 2024 version of the Garthwaite Deletes did not fully reconcile to Dr. Garthwaite's financial impact calculations. Specifically, there were more than 1,200 members across service years 2014–2016 for whom Dr. Garthwaite identified an alleged Part C overpayment but who did not have any diagnosis codes in the January 5, 2024 Errata version of the Garthwaite Deletes.⁶² The March 11, 2024 version of the Garthwaite Deletes removed more than 46,000 IRADS diagnosis codes which had not been submitted to RAPS and had inadvertently been included in his previous lists; added over 200,000 EDPS diagnosis codes which had been inadvertently removed from his January 5, 2024 version; removed approximately 1,000 IRADS diagnosis codes and 4,000 EDPS diagnosis codes which had been erroneously included in his prior lists because of an issue relating to being unable to replicate MARx risk scores; and removed the diagnosis codes for 9 members for whom Dr. Garthwaite calculated no financial impact.⁶³ The various issues and corrections related to the Garthwaite Deletes further underscore the complexity and difficulty of the exercise.

58. Lastly, the Garthwaite Report appears to place special emphasis on diagnosis codes from the “CV Pipeline List.” However, as with the Garthwaite Deletes, Dr. Garthwaite has not established that United knowingly retained any overpayments related to the CV Pipeline List diagnosis codes. First, as Dr. Garthwaite notes, the CV Pipeline List diagnosis codes had not been

⁶⁰ In the October 4, 2023 Errata, Dr. Garthwaite wrote that “there are discrepancies between the total financial impact and beneficiary counts in my report and the total financial impact and beneficiary counts that would be derived from an analysis of [the original version of] Attachment 1. Additionally . . . some diagnosis codes included in [the original version of] Attachment 1 are diagnosis codes whose deletion would not have financial impact, particularly in Part C service year 2014 and Part D service year 2016.” See Errata to Expert Report of Craig Garthwaite, October 4, 2023, para. 4.

⁶¹ Dr. Garthwaite did not explain why the January 5, 2024 version of the Garthwaite Deletes has fewer diagnosis codes than the prior one. In the January 5, 2024 Errata, Dr. Garthwaite described making two kinds of changes to the presentation of HCC codes recorded in the Garthwaite Deletes, but he did not describe removing any diagnosis codes. See Errata to Expert Report of Craig Garthwaite, January 5, 2024.

⁶² See Appendix X2 (Updated as of 03-18-24) for the calculations referenced in this paragraph. I relied upon Attachment 3 to the Garthwaite Report to identify alleged financial impact for specific members. Attachment 3 has not been revised or updated since it was published with Dr. Garthwaite's original report.

⁶³ See Errata to Expert Report of Craig Garthwaite, March 11, 2024, paras. 2-6.

completely evaluated when the CV process was terminated.⁶⁴ Second, as shown in my December 3 report, 64.2% of the In Process CV Codes that overlapped with the CON12-13 PFR data mapped to conditions that were validated by the RADV auditors.⁶⁵ Third, only 85.8% of the total CV Pipeline List diagnosis codes are in the First Interrogatory Response—meaning that, for the remaining 14.2%, the government has not asserted that the codes are of concern.⁶⁶ Moreover, only 54.4% of the total CV Pipeline List diagnosis codes are in the Garthwaite Deletes.⁶⁷ Thus, 45.6% of the total CV Pipeline List diagnosis codes were not identified in Dr. Garthwaite’s own methodology as having had financial impact; consequently, based on Dr. Garthwaite’s analysis, none of those diagnosis codes should be, or be suspected of being, the cause of overpayments. This includes 17.1% of the CV Pipeline List diagnosis codes from 2012, a year for which United attempted to filter the list to include only diagnosis codes with financial impact. For all of these reasons, it would be inappropriate to suggest or conclude that the diagnosis codes in the CV Pipeline Lists were necessarily unsupported or led to overpayments.

H. Opinion 8: If the validation rates of CMS’s CON11-15 RADV audits hold constant across all of the Garthwaite Deletes, then the rate of unsupported diagnosis codes with financial impact would be less than 3.5% of the diagnosis codes included in the government’s First Interrogatory Response and less than 0.3% of United’s total diagnosis codes submitted during this period for the members who underwent Chart Review. In my experience, based on common industry practices in the relevant timeframe, such a low rate of potentially unsupported diagnosis codes with financial impact would not have been expected to necessitate additional investigation or analysis.

⁶⁴ See Garthwaite Report, para. 143.

⁶⁵ See Dec. 3 Renjilian Report at p. 85, Fig. 14: Results of RADV Analysis—In Process CV Codes. I use the term “In Process CV” here because, in this analysis from my earlier report, I considered all four files produced in response to the government’s requests about the In Process CV codes. Dr. Garthwaite’s “CV Pipeline Lists” only incorporate two of those files. When I refer to the “CV Pipeline List” in this paragraph, I refer to the diagnosis codes in the two files that Dr. Garthwaite specifically used.

⁶⁶ See Appendix X8 (Updated as of 03-18-24).

⁶⁷ *Id.* Breaking the CV Pipeline List diagnosis codes down by year, only 21.2% of the 2011 diagnosis codes and 82.9% of the 2012 CV Pipeline List diagnosis codes are in the Garthwaite Deletes. I understand that the CV Pipeline List from DOS year 2011 did not filter out diagnosis codes with no financial impact, which may explain why so many are not in the Deletes. In contrast, I understand that the CV Pipeline List from DOS year 2012 was designed to only include diagnosis codes with financial impact. See Garthwaite Report, para. 143.

59. As discussed above, less than 7% of the diagnosis codes alleged to be at issue by the government in the First Interrogatory Response were among the Garthwaite Deletes. As an additional point of context, the Garthwaite Deletes comprise a minimal percentage of the total diagnosis code submissions for members who had charts that underwent Chart Review during this period. As shown in **Figure 9** below, the Garthwaite Deletes amount to approximately 0.5% of the total diagnosis codes submitted by United for risk adjustment purposes for these members during this time period.⁶⁸

Figure 9. Garthwaite Deletes Compared to All United Diagnosis Code Submissions For Members with Chart that Underwent Chart Review.⁶⁹

Number of Diagnosis Codes (Unique Member - Dx - DOS)			
DOS Year	Garthwaite Deletes	All Submitted to RAPS/EDPS	% of Total
2008	100,781	7,664,458	1.3%
2009	196,936	12,947,948	1.5%
2010	384,026	12,657,695	3.0%
2011	115,029	13,359,726	0.9%
2012	190,492	36,836,367	0.5%
2013	219,903	47,789,547	0.5%
2014	223,271	65,969,774	0.3%
2015	225,087	78,141,438	0.3%
2016	279,135	96,411,956	0.3%
Total	1,934,660	371,778,909	0.5%

60. Moreover, as discussed above, Dr. Garthwaite has not established which, if any, of the Garthwaite Deletes were actually unsupported. In fact, by comparing the Garthwaite Deletes to the results of the CON11-15 RADV audits, I found that more than 55% of overlapping diagnosis codes mapped to condition codes that were *validated* by CMS's auditors.

⁶⁸ To further contextualize the Garthwaite Deletes, I counted all diagnosis codes submitted by United to CMS for risk adjustment purposes during the relevant time period. I only considered diagnosis codes that mapped to an HCC or RxHCC, and I did not include diagnosis codes that had been deleted. The data produced by United in this matter only includes diagnosis code-level information for United members who had at least one chart go through Chart Review. Accordingly, I was only able to count the number of diagnosis codes submitted for these members, which is a subset of the total diagnosis codes submitted for all members during this time period. Thus, the percentages shown below would be even smaller if I had been able to compare the Garthwaite Deletes to the number of diagnosis codes submitted by United for *all* its members, not just the members who had a chart go through Chart Review.

⁶⁹ See Exhibit 8 (Updated as of 03-18-24).

61. More specifically, I reviewed the CON11-15 PFR Data to identify the member-HCC combinations in that data that overlapped with the Garthwaite Deletes. For those overlapping instances, I then determined the percentage of the overlapping HCCs that were validated by CMS's RADV auditors. Through this process, I identified 724 member-HCC combinations that overlapped between the Garthwaite Deletes and the CON11-15 PFR Data.⁷⁰ There were 681 total diagnosis codes in the Garthwaite Deletes that corresponded to these member-HCC combinations. The 681 overlapping diagnosis codes have notable similarities with the full set of Garthwaite Deletes with alleged Part C financial impact during this time period (DOS years 2010-2014).⁷¹ I compared the distribution of records by HCC between (a) the Garthwaite Delete diagnosis codes relating to the overlapping member-HCC combinations and (b) all Garthwaite Deletes with alleged Part C financial impact during this period. Because both V12 and V22 HCCs were applicable in this period for service years 2013 and 2014, I further broke down this comparison in those years by HCC type (V12 or V22) and year.⁷² For each of the permutations I analyzed, I confirmed that the unique HCCs that were subjected to the RADV audits account for more than 87% of the HCCs mapping to the Garthwaite Deletes with Part C financial impact. Also, I confirmed that, in each of these permutations, the average difference at an HCC level between the proportions in groupings (a) and (b) above was 2% or less. Additionally, in my experience, a sample of 681 diagnosis codes would generally be considered robust for most evaluative purposes.

62. Of the 681 overlapping diagnosis codes, 375 diagnosis codes – 55.1% – mapped to condition codes that were validated by CMS's RADV audits, meaning that the members' conditions relating to these diagnosis codes were confirmed to be supported by CMS's own reviewers and, thus, the diagnosis codes could not have led to any overpayment. Thus, even after Dr. Garthwaite had narrowed down the diagnosis codes at issue to only such codes that would have had Part C financial impact, more than half of the diagnosis codes that overlapped with CMS's

⁷⁰ For this exercise, I used the same fundamental methodology with respect to identifying overlapping and validated diagnosis codes as described in Opinion 4 of my December 3 report. The count of overlapping member-HCC combinations is derived in Appendix X7 (Updated as of 03-18-24).

⁷¹ Since the RADV audits only evaluate HCCs, and not RxHCCs, this analysis focuses on Garthwaite Deletes that had alleged Part C financial impact. I assume a Garthwaite Delete had Part C financial impact when any of the HCC fields in the data were populated.

⁷² See Exhibit 9 (Updated as of 03-18-24).

RADV audits were *validated* at the condition level by CMS’s auditors. **Figure 10** below summarizes my analysis.

Figure 10. Results of RADV Analysis – Garthwaite Deletes.⁷³

DOS Year	Garthwaite Deletes		% of Total
	Overlap with CON11-15 PFR Data: Total	Overlap with CON11-15 PFR Data: HCC Validated	
2010	75	45	60.0%
2011	15	9	60.0%
2012	137	70	51.1%
2013	214	113	52.8%
2014	240	138	57.5%
Total	681	375	55.1%

63. If this validation rate held constant across all of the Garthwaite Deletes, then less than half of the Garthwaite Deletes would be unsupported. That would mean that less than 3.5% of the diagnosis codes in the First Interrogatory Response, and less than 0.3% of the total diagnosis codes submitted by United during this period for the members who underwent Chart Review, would be unsupported and have financial impact. Put another way, based on Dr. Garthwaite’s analysis and the results of the CMS RADV audits, for any given First Interrogatory Response diagnosis code, the likelihood that the diagnosis code led to an overpayment is less than 3.5%.

64. Far from establishing knowledge that any particular diagnosis code resulted in an overpayment, this analysis indicates that the likelihood that a diagnosis code not independently identified in Chart Review amounts to an overpayment is very small.

65. Indeed, government communications from various contexts suggests that a potential error rate of 3.5% is not sufficient to warrant additional investigation. For example, even under Corporate Integrity Agreements in this timeframe—which by definition involve organizations that had a past history of substantial compliance issues and that were under enhanced scrutiny by the Department of Health and Human Services Office of Inspector General—error rates up to 5% were viewed as not requiring any expanded review or analysis. Thus, for an entity

⁷³ See Exhibit 10 (Updated as of 03-18-24).

with no past history of Corporate Integrity Agreements, an error rate less than 5%—particularly one involving a highly complex and nuanced analysis—would not have necessarily required deeper analysis. Additional support for this view is found in the Medicare Program Integrity Manual, which suggests that an error rate of 7% would not necessitate further review.⁷⁴ Similar support exists in contemporaneous guidance issued by Medicare Audit Contractors, indicating that error rates of less than 10% could reasonably be viewed as not requiring additional analysis.⁷⁵

66. This view is further supported by the industry error rates found in the government’s Part C Improper Payment Measure. As shown earlier in **Figure 6**, the industry-wide Part C population error from overpayments ranged from 8.6% (in CY 2010) to 4.6% (CY 2017) during the time period relevant to this case for which this Part C error rate data has been published.

67. Further corroboration of this perspective can be found in the results of the Comprehensive Error Rate Testing (“CERT”) program in this timeframe.⁷⁶ In fact, as part of the CERT program, CMS established a goal to reduce the payment error rate to 6.2% by 2012—still higher than the estimated error rate here.⁷⁷

68. Taken together, these varied reference points support the view that an error rate of less than 3.5% (or, in the context of all diagnosis codes submitted by United for the members who underwent Chart Review, less than 0.3%) would not have mandated additional review or analysis.

I. *Opinion 9: For the reasons described in my Opinions 1-8 above, Dr. Garthwaite’s calculation of the number of members for whom United was allegedly overpaid as a result of the Garthwaite Deletes is also unreliable.*

⁷⁴ See Medicare Program Integrity Manual section 3.7.1.2, which states in pertinent part: “Twenty claims from one provider are reviewed. One claim is denied because a physician signature is lacking on the plan of care. The denial reflects 7 percent of the dollar amount of claims reviewed. Judicious assessment of medical review resources indicates no further review is necessary at this time.”

⁷⁵ See, e.g., the Palmetto GBA “Progressive Corrective Action (PCA) Decision Tree” revised on June 4, 2010, which shows that a “charge denial rate” of 0-9% would result in medical review of claims being discontinued. See also the NHIC “Progressive Corrective Action” policy from January 4, 2012, which discusses the CMS requirement that Medicare contractors perform “medical review” to reduce payment error rates and which states that medical review “. . . continues until a supplier reaches an acceptable payment error rate (usually less than 10 percent).”

⁷⁶ See, e.g., the Medicare Fee-for-Service 2010 Improper Payment Report, which noted that the overall Medicare improper payment rate in 2009 was 12.4%.

⁷⁷ *Id.*

69. Dr. Garthwaite has calculated that United's risk adjustment payments would have been lower for 1,154,197 members (counted year-by-year, whether under Part C, Part D, or both) had United removed the Garthwaite Deletes.⁷⁸ Of these, Dr. Garthwaite calculates that 707,152 members would have had lower Part C payments, and 825,936 members would have had lower Part D payments.⁷⁹ In Dr. Garthwaite's March 11, 2024 Errata, he stated that these member counts were overstated to a "de minimis" degree.⁸⁰

70. As set forth above, Dr. Garthwaite has not established that any of the individual diagnosis codes he identifies as Deletes were in fact unsupported or actually resulted in overpayments, and the government's RADV auditors actually validated the majority of condition codes they reviewed that map to diagnosis codes that the government alleged were unsupported. Because Dr. Garthwaite has not established that his purported Deletes led to overpayments, he similarly cannot reliably establish the number of members for whom United was overpaid.

71. One concrete example of the unreliability of Dr. Garthwaite's analysis comes from the members who overlap between the Garthwaite Deletes and the CON11-13 RADV audits. As shown in **Figure 7** and discussed in Opinion 5 above, 23,231 members with alleged Part C financial impact related to the Garthwaite Deletes were covered under the 13 contracts that CMS found to have negative recovery amounts in the CON11-13 RADV audits. Dr. Garthwaite has failed to explain how United could have been overpaid as a result of these members when the government has already determined that there was a negative recovery amount for the members' contract. Had the government conducted RADV audits on additional contract years, the results of the CON11-13 RADV audits strongly suggest that many more would similarly have had net negative recovery amounts.

⁷⁸ See Corrected Exhibit 11 from Errata to Expert Report of Craig Garthwaite, October 4, 2023. Counting year-by-year means that a unique member is counted once for each year in which the member had alleged financial impact. For example, if unique member John Doe had alleged financial impact related to the Garthwaite Deletes in both 2013 and 2014, then the member would count once under each year and twice in total across the years.

⁷⁹ See *id.*

⁸⁰ See Errata to Expert Report of Craig Garthwaite, March 11, 2024, paras. 9-10. Dr. Garthwaite identified two separate issues. First, 10 members were inadvertently included because of an issue with rounding in his risk score calculations. Second, 6,159 members were inadvertently included because of an issue related to the calculation of negative financial impact.

72. The above example, together with the broader failing of Dr. Garthwaite to establish that any of his purported Deletes were actually unsupported, makes clear the unreliability of his estimate of the number of individual members for whom United was allegedly overpaid.

VI. CONCLUSION

73. This report presents a summary of my work and opinions to date. I reserve the right to revise and refine these opinions as additional work is performed and additional information is received. To the extent that any additional evidence becomes available as a result of the Court's reconsideration, I may modify or supplement my opinions as appropriate.



Submitted by: _____
M. Timothy Renjilian, CPA

Dated: March 18, 2024

EXHIBIT D-66



Federal Register

**Thursday,
June 29, 2000**

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 417 and 422

**Medicare Program; Medicare+Choice
Program; Final Rule**

EXHIBIT

00164

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration****42 CFR Parts 417 and 422****[HCFA-1030-FC]****RIN 0938-AI29****Medicare Program; Medicare+Choice Program****AGENCY:** Health Care Financing Administration (HCFA), HHS.**ACTION:** Final rule with comment period.

SUMMARY: This final rule with comment period responds to comments on the June 26, 1998 interim final rule that implemented the Medicare+Choice (M+C) program and makes revisions to those regulations where warranted. We also are making revisions to the regulations that are necessary to reflect the changes to the M+C program resulting from the Balanced Budget Refinement Act of 1999 (BBRA). Revisions to the regulations reflecting changes in the law made by the BBRA are subject to public comment. Issues discussed in this rule include eligibility, election, and enrollment policies; marketing requirements; access requirements; service area and benefit policy; quality improvement standards; payment rates, risk adjustment methodology, and encounter data submission; provider participation rules; beneficiary appeals and grievances; contractual requirements; and preemption of State law by Federal law.

This final rule also addresses comments on the interim final rule published on December 2, 1997, which implemented user fees for section 1876 risk contractors for 1998, and formed the basis for the M+C user fee provisions in the June 26, 1998 interim final rule, and the provider-sponsored organization (PSO) interim final rule published April 14, 1998.

DATES: *Effective date:* This final rule is effective July 31, 2000.

Comment period: Comments on provisions reflecting provisions of the Balanced Budget Refinement Act of 1999 will be considered if received at the appropriate address, as provided below, no later than August 28, 2000. We will not consider comments concerning regulatory provisions that remain unchanged or that are revised in this final rule based on previous public comment.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care

Financing Administration, Department of Health and Human Services, Attention: HCFA-1030-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Since comments must be received by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver by courier, your written comments (one original and three copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201; or C5-14-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to the two above addresses may be delayed and received too late to be considered. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1030-FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, see section IV of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Marty Abeln (410) 786-1032 (for issues related to user fees, service area, point-of-service option, PSOs, and intermediate sanctions).

Wendy Burger (410) 786-1566 and Lynn Orlosky (410) 786-5930 (for issues related to eligibility, elections, and enrollment).

Carol Barnes (410) 786-5496 (for issues related to continuation areas and marketing).

Anne Manley (410) 786-1096 (for issues related to emergency and urgently needed services, provider participation rules, and Federal preemption).

Eileen Zerhusen (410) 786-7803 (for issues related to post-stabilization care).

Tony Hausner (410) 786-1093 (for issues related to access, discrimination, and physician incentive rules).

Amy Chapper (410) 786-0367 (for issues related to information disclosure and confidentiality).

Brian Agnew (410) 786-5964 (for issues related to quality assurance and accreditation).

Al D'Alberto (410) 786-1100 (for issues related to payments, premiums, and ACRs).

James Hart (410) 786-4474 (for issues related to risk adjustment and encounter data).

Chris Eisenberg (410) 786-5509 (for issues related to contracts and contract appeals).

Michele Edmondson (410) 786-6478 (for issues related to beneficiary appeals).

Anita Heygster (410) 786-4486 (for issues related to M+C private fee-for-service plans).

Cindy Mason (410) 786-6680 (for issues related to M+C MSA plans).

SUPPLEMENTARY INFORMATION: For the convenience of the reader, we are providing a complete outline of this final rule, including a topical listing of the major areas raised by the comments, along with numerical regulatory citations.

I. Background

A. Balanced Budget Act of 1997

B. Overview of M+C Regulations

1. Interim Final Rule

2. Correction Notice

3. February 17, 1999 Final Rule

C. M+C Provisions of the Balanced Budget Refinement Act of 1999

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1. Comments on June 26, 1998 Interim Final Rule

2. Issues in February 17, 1999 Final Rule

3. Organization of this Final Rule

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b. Types of M+C Plans (§ 422.4)

c. Application Requirements and Procedures (§§ 422.6 and 422.8)

d. User Fees (§ 422.10)

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1. Eligibility to Elect an M+C Plan (§ 422.50)

2. Continuation of Enrollment (§ 422.54)

3. Election Process (§ 422.60)

4. Enrollment Capacity (§ 422.60(b))

5. Election of Coverage Under an M+C Plan (§ 422.62)

6. Information about the M+C Program (§ 422.64)

7. Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

9. Disenrollment by the M+C Organization (§ 422.74)

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- c. Access to Emergency and Urgently Needed Services
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 - 3. Service Area Requirements (§§ 422.2, 422.100)
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 - 9. Discrimination Against Beneficiaries Prohibited (§ 422.110)
 - 10. Disclosure Requirements (§ 422.111)
 - 11. General Access Requirements (§ 422.112)
 - a. Introduction
 - b. Provider Network (§ 422.112(a)(1))
 - c. Primary Care Providers (PCP) Panels (§ 422.112(a)(2))
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 - 1. Overview
 - 2. Quality Assessment and Performance Improvement Requirements (§ 422.152)
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 - 6. Prohibition on Interference with Health Care Professionals' Communication with Enrollees (§ 422.206)
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 - I. Organization Compliance With State Law and Preemption by Federal Law (Subpart I)
 - 1. State Licensure and Scope of Licensure (§ 422.400)
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 - 9. Certification of Data that Determine Payment/Certification of Accuracy of ACR (§ 422.502(l))
 - 10. Effective Date and Term of Contract (§ 422.504)
 - 11. Nonrenewal of M+C Contracts (§ 422.506)
 - 12. Provider Prior Notification and Disclosure (§§ 422.506(a), 422.508, 422.510(b), and 422.512)
 - 13. Mutual Termination of a Contract (§ 422.508)
 - 14. Termination of Contract by HCFA (§ 422.510)
 - 15. Minimum Enrollment Requirements (§ 422.514)
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 - 8. Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)
 - 9. Deemed Contracting Providers
- III. Provisions of this Final Rule (Changes to the M+C Regulations)
- IV. Collection of Information Requirements—Paperwork Reduction Act
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- VI. Other Required Information
- A. Federalism Summary Impact Statement
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 - C. Response to Comments
- I. Background**
- A. Balanced Budget Act of 1997*
- Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the “Medicare+Choice (M+C) Program.” (The previous Part C of the statute, which included provisions in section 1876 of the Act governing existing Medicare health maintenance

organization (HMO) contracts, was redesignated as Part D.) Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end-stage renal disease, may elect to receive benefits through either the existing Medicare fee-for-service program ("Original Medicare") or a Part C M+C plan, if one is offered where he or she lives.

As its name implies, the primary goal of the M+C program is to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The M+C statute authorizes a variety of private health plan options for beneficiaries, including both the traditional managed care plans (such as those offered by HMOs) that traditionally have been offered under section 1876 of the Act, and new options that were not previously authorized. Specifically, section 1851(a)(2) of the Act describes three types of M+C plans authorized under Part C:

- M+C coordinated care plans, including HMO plans (with or without point of service options), provider-sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.
- M+C medical savings account (MSA) plans (that is, combinations of a high-deductible M+C health insurance plan and a contribution to an M+C MSA).

- M+C private fee-for-service plans.

An entity contracting with us to offer any of the above plans to Medicare beneficiaries is called an "M+C organization."

In addition to expanding the types of health plans that can be offered to Medicare beneficiaries, the M+C program introduces several other fundamental changes to the managed care component of the Medicare program. These changes include:

- Establishment of an expanded array of quality assurance standards and other consumer protection requirements;
- Introduction of an annual coordinated enrollment period, in conjunction with the distribution by us of uniform, comprehensive information about M+C plans that is needed to promote informed choices by beneficiaries;

- Revisions in the way we calculate payment rates to M+C organizations that will narrow the range of payment variation across the country and increase incentives for organizations to offer M+C plans in diverse geographic areas; and

- Establishment of requirements concerning provider participation procedures.

B. Overview of M+C Regulations

1. Interim Final Rule

On June 26, 1998, we published in the **Federal Register** a comprehensive interim final rule (63 FR 34968) to implement the provisions of section 4001 of the BBA that established the M+C program. That interim final rule set forth the new M+C regulations in 42 CFR Part 422—Medicare+Choice Program. The major subjects covered in each subpart of part 422 are as follows:

- Subpart A—Definitions, including definitions of types of plans, application process, and user fees.

- Subpart B—Requirements concerning beneficiary eligibility, election, enrollment and disenrollment procedures, and plan information and marketing materials.

- Subpart C—Requirements concerning benefits, point of service options, access to services (including rules on enrollee assessments and notification upon termination of specialists), and others.

- Subpart D—Quality assurance standards, external review, and deeming of accredited organizations.

- Subpart E—Provider participation rules and the prohibition against interference with health care professionals' advice to enrollees.

- Subpart F—Payment methodology for M+C organizations, risk adjustment, and encounter data requirements.

- Subpart G—Requirements concerning premiums, cost-sharing, and determination of adjusted community rate.

- Subpart H—Requirements concerning PSOs.

- Subpart I—Organization compliance with State law and preemption by Federal law.

- Subpart K—Contract requirements.

- Subpart L—Change of ownership rules.

- Subpart M—Beneficiary grievances, organization determinations, and appeals.

- Subpart N—Contractor appeals of nonrenewals or terminations of contracts.

- Subpart O—Procedures for imposing intermediate sanctions.

2. Correction Notice

On October 1, 1998, we issued a correction notice in the **Federal Register** (63 FR 52610) to correct technical errors that appeared in the interim final rule. All references in this document to regulation text are to the corrected text unless otherwise noted.

3. February 17, 1999 Final Rule

Additionally, on February 17, 1999, we published a final rule in the **Federal Register** (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. It specifically addressed only a limited number of issues raised by commenters on the June 26, 1998 interim final rule. We indicated in the preamble to the February 17, 1999 final rule that we intended to address all other issues raised by commenters on the M+C interim final rule in a comprehensive M+C final rule to be published at a later date. The types of comments we addressed in the February final rule are discussed in more detail in section II.A.2.

C. M+C Provisions of the Balanced Budget Refinement Act of 1999

On November 29, 1999, as we were completing the development of this final rule, the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) was enacted. The BBRA includes a number of provisions that affect the M+C program, and these provisions have necessitated a number of corresponding changes so that the changes in the law made by the BBRA are reflected in the text of the M+C regulations. For the most part, the statutory changes are self-explanatory, and have already taken effect. As noted above, we are accepting public comment on conforming changes to the M+C regulations made as a result of the BBRA provisions. We are revising the regulations to reflect the provisions of the BBRA as follows:

1. Changes in M+C Enrollment Rules (Section 501 of the BBRA)

a. Enrollment in Alternative M+C Plans and Medigap Coverage After Involuntary Terminations

Section 1851(e)(4) of the Act establishes special election periods during which M+C-eligible individuals may disenroll from an M+C plan or elect another M+C plan, including a special election period when an M+C organization or we have terminated a plan or the organization has otherwise discontinued providing the plan in the area in which the individual resides. Section 501(a)(1) of the BBRA revised section 1851(e)(4) to specify that this special election period now becomes available either upon termination or discontinuation or when the organization "has notified the individual of an impending termination or discontinuation of such a plan." We have revised § 422.62(b)(1) to reflect this earlier opportunity for an affected

enrollee to elect an alternative M+C plan or return to original Medicare. We note that section 501(b) of the BBRA set forth conforming amendments to section 1882(s)(3) of the Act (concerning beneficiary rights to guaranteed issue of a Medicare supplemental policy, that is, a Medigap policy) to allow an individual guaranteed issue rights to a Medigap policy within 63 days of an organization's notification of an impending termination or service area reduction.

b. Open Enrollment for Institutionalized Individuals (Section 501(b))

Section 1851(e) of the Act establishes the time frames, or election periods, for making or changing elections. Section 501(b) of the BBRA amended section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. Thus, on or after January 1, 2002 (which represents the first day when limitations are placed on an M+C-eligible individual's enrollment and disenrollment opportunities), M+C-eligible individuals who are institutionalized, as defined by HCFA, may continue to change from original Medicare to an M+C plan, from an M+C plan to original Medicare, or from one M+C plan to another. We have added § 422.62(a)(6) to reflect this provision, with conforming changes at § 422.62(a)(4)(i) and § 422.62(a)(5)(i). We intend to provide guidance on the meaning of the term "institutionalized" in due time to permit orderly implementation of this change before it takes effect in 2002.

c. Continued Enrollment for Certain M+C Enrollees

Section 1851(b)(1) of the Act establishes the residence requirements for eligibility to elect an M+C plan. Section 501(c) of the BBRA amended section 1851(b)(1) of the Act by adding a new subparagraph (C) to allow an individual to choose to continue enrollment in an M+C plan offered by the organization if (1) the M+C organization eliminates the M+C plan in the service area in which the individual resides and, (2) no other M+C plan is offered in the service area at the time of the elimination of the M+C plan in the service area and, (3) the M+C organization chooses to allow the option to continue enrollment in an M+C plan offered by the organization. If the individual chooses to retain his or her enrollment in the M+C plan, the M+C organization may require that he or she agree to obtain the full range of basic benefits (excluding emergency and

urgently needed care) through facilities designated by the organization within the plan's HCFA-approved service area. In the case of home health services, since this is a basic benefit that by its nature involves receipt of services in the home, while the provider of the home health services may be located in the service area, actual services would have to be offered in the beneficiary's home. We have reflected this provision in § 422.74(b)(3), with a conforming change made in § 422.66(e)(2).

2. Change in Effective Date of Elections (Section 502 of the BBRA)

Section 1851(f) of the Act establishes the effective dates for elections and changes to elections made during the various enrollment periods. Prior to enactment of the BBRA, section 1851(f)(2) stated that an election made during an open enrollment period was effective the first day of the following calendar month. Section of the 502 BBRA amended section 1851(f)(2) of the Act to state that an election made during an open enrollment period is effective the first day of the following calendar month, except that if the election or change in election is made after the 10th day of the calendar month, the election is effective the first day of the second calendar month following the date the election or change in election is made. We have revised § 422.68(c) to reflect this provision.

3. Extension of Reasonable Cost Contracts (Section 503 of the BBRA)

Section 503 of the BBRA amended section 1876(h)(5)(B) of the Act to permit the extension or renewal of Medicare cost contracts for an additional 2 years, that is, through December 31, 2004. We are revising § 417.402(b) to effect this change.

4. Phase-In of New Risk Adjustment Methodology (Section 511 of the BBRA)

Consistent with section 1853(a) of the Act, § 422.256 of the M+C regulations provides that M+C capitation payments are adjusted for age, gender, institutional status, and other appropriate factors, including health status, beginning January 1, 2000. In the January 15, 1999, Advance Notice of Methodological Changes for the CY 2000 M+C Payment Rates, we announced the risk adjustment methodology to implement this requirement. One element of the risk adjustment methodology we developed was a transition period during which M+C payments would be based on a blend of payment amounts under the previous system of demographic adjustments and payment amounts

based on principal inpatient hospital diagnoses (the PIP-DCG risk adjustment methodology). Under a blend, payment amounts for each enrollee are separately determined using the demographic and risk methodologies, respectively. Those payment amounts are then blended according to the percentages for the transition year. On January 15, 1999, we announced the following transition schedule:

Year	Demographic method (percent)	Risk method (percent)
CY 2000	90	10
CY 2001	70	30
CY 2002	45	55
CY 2003	20	80
CY 2004		100

(Using encounter data from multiple sites of care.)

Section 511(a) of the BBRA revised the original transition schedule for 2000 and 2001 to provide that the blend percentages will be:

Year	Demographic method (percent)	Risk method (percent)
CY 2000	90	10
CY 2001	90	10
CY 2002	at least 80	no more than 20

This provision does not require any changes in the existing M+C regulations, but we have described it here for the convenience of the reader.

5. Encouraging Offering of M+C Plans in Areas Without Plans (Section 512 of the BBRA)

Section 512 of the BBRA amended section 1853 of the Act by adding a new paragraph (i) to provide for "new entry bonus" payments to encourage M+C organizations to offer plans in payment areas (generally, counties) that currently do not have M+C plans serving the area. Under this provision, which we are incorporating into regulations under § 422.250(g), the amount of the monthly payment otherwise made to an M+C organization that offers the first M+C plan in a previously unserved county will be increased by 5 percent for the first 12 months that the plan is offered and by 3 percent for the second 12 months. These bonus payments will be available only for plans that are first offered during the 2-year period beginning January 1, 2000, and only in counties where no M+C plan has been offered, or where any plan offered was no longer offered as of January 1, 2000.

New section 1853(i)(3) specifies that if more than one M+C organization first

offers a plan in an uncovered area on the same date, the new entry bonus applies to the payments of both organizations. The BBRA does not expressly address situations in which an M+C organization or organizations begin offering more than one M+C plan simultaneously. Since the bonus is offered to the *organization* that first offers an M+C plan in an area, or to all *organizations* that do so on the same date, we interpret this to mean that the bonus would apply to all plans offered by a bonus-eligible organization on the same date. Thus, when an M+C organization offers two M+C plans simultaneously in a previously unserved county, the organization will receive the bonus payment for both plans. Similarly, if two or more M+C organizations first offer two M+C plans on the same date, each M+C organization will receive the bonus payments for each of its plans. Consistent with section 1853(i)(3) of the Act, the bonus payments are not available to M+C organizations offering a plan in a county that is already partially served by another plan, even if the new plan includes a portion of the payment area not previously covered by an existing plan. As we have stated in OPL 2000.117, a plan is considered to be offered when the sponsoring M+C organization has a contract in effect to serve beneficiaries in the previously unserved area and the plan is open for enrollment.

6. Modification of 5-Year Re-Entry Rule for Contract Terminations (Section 513 of the BBRA)

Section 513(a) of the BBRA amended section 1857(c)(4) of the Act to reduce from 5 to 2 years the period during which an M+C organization that has terminated its M+C contract at the organization's request is barred from re-entering into an M+C contract (absent our finding of special circumstances warranting an exception). Section 513(b)(1) further amended section 1857(c)(4) to provide for a new exception to this general exclusion period if, during the 6-month period after an M+C organization notified us of its intention to terminate an M+C contract, a legislative or regulatory change was adopted that resulted in increased Medicare payment amounts for the given payment area. In addition, section 513(b)(2) of the BBRA expressly states that the creation of the new exception does not affect our existing authority to grant an exception to this rule where "circumstances which warrant special consideration," including in the circumstances identified in OPL #103 (OPL 99.103).

OPL 99.103 states that we will grant an exception, for example, when an organization proposes to offer a different M+C plan type than it had previously offered, or an organization is proposing to introduce an M+C plan (1) in a geographic area currently served by two or fewer M+C plans, or (2) in an area other than that from which the organization had previously withdrawn when it ended its earlier contract with the Medicare program. We have incorporated the BBRA's revisions to section 1857(c)(4) of the Act into § 422.501(b)(5).

7. Flexibility to Tailor Benefits under M+C Plans (Section 515 of the BBRA)

Section 515 of the BBRA amended section 1854 of the Act to permit M+C organizations to elect to apply the premium and benefit provisions of section 1854 of the Act uniformly to separate segments of a service area, provided that the segments are composed of one or more M+C payment areas. This change, which is effective for contract years beginning on or after January 1, 2001, is largely consistent with our existing administrative policy, under which an M+C organization may offer multiple M+C plans, each with its own HCFA-approved service area, but must offer uniform benefits and premiums within each plan. For a full discussion of the implications of this change, and the conforming changes to the M+C regulations, we refer the reader to section II.C.3 of this preamble.

8. Delay in Deadline for Submission of Adjusted Community Rates (Section 516 of the BBRA)

Section 516 of the BBRA amended section 1854(a)(1) of the Act to delay the annual deadline for submission of adjusted community rate (ACR) proposals and information about enrollment capacity from May 1 to July 1. The statute provides that this change was effective for information submitted by M+C organizations in 1999 for benefits in calendar year 2000, and we are making changes to §§ 422.60(b)(1), 422.300(b)(2), and 422.306(a)(1) to reflect the new law.

9. Reduction in Adjustment in National Per Capita M+C Growth Percentage for 2002 (Section 517 of the BBRA)

An important element in the methodology used to calculate M+C payment rates involves the determination by the Secretary under section 1853(c)(6) of the Act of a "national per capita M+C growth percentage." Each year, when determining M+C capitation rates, as explained in detail in the June 1998

interim final rule (63 FR 35004), this national growth percentage is applied to the area-specific component of the blended rate and to the minimum amount, also referred to as the "floor". The national per capita growth percentage is HCFA's estimate of the per capita rate of growth in expenditures. Section 1853(c)(6)(B) of the Act provided that in years from 1998 through 2002, the national per capita M+C growth percentage would be reduced, by 0.8 percentage points in 1998 and 0.5 percentage points in 1999 through 2002. Section 517 of the BBRA amended section 1853(c)(6)(B)(v) of the Act to change the adjustment for 2002 from 0.5 percentage point reduction to a reduction of 0.3 percentage points, and we are revising § 422.254(b)(2) to reflect this change.

10. Deeming of M+C Organizations to Meet Requirements (Section 518 of the BBRA)

Section 518 of the BBRA amended section 1852(e)(4) of the Act to set forth several changes related to (1) the process by which an M+C organization can be deemed, based on an accreditation organization's findings, to meet M+C requirements and (2) the standards for which such deeming is permissible. Revised section 1852(e)(4) now includes the following among requirements that must be deemed met if an accreditation body applies and enforces standards at least as stringent as those in this part: those requirements derived from section 1852(b) (concerning antidiscrimination), section 1852(d) (concerning access to services), section 1852(i) (concerning information on advance directives), and section 1852(j) (concerning provider participation rules), in addition to the requirements under section 1852(e)(1) and (2) concerning an M+C organization's quality assurance program and under 1852(h) concerning the confidentiality and accuracy of enrollee records. We are revising § 422.156(b) to add these requirements. In addition, new section 1852(e)(4) specifies that the Secretary must make a determination within 210 days on a private accrediting organization's application to act as an accrediting organization for M+C requirements. This provision in effect mandates the same approval time frame that applies to original Medicare accreditation under section 1865(b) of the Act, and we are incorporating this requirement into § 422.158(e).

11. Quality Assurance Requirements for PPO Plans (Section 520 of the BBRA)

Section 520 of the BBRA amended section 1852(e)(2) of the Act to change the quality assurance requirements for PPO plans, effective for contract years beginning on or after January 1, 2000. In the past, PPO plans had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans. New section 1852(e)(2)(D) establishes that, for purposes of the M+C quality assurance requirements, a PPO plan is an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization. We are incorporating this definition into the M+C regulations at § 422.4. The quality assurance requirements that now will apply for PPO plans are identical to the existing requirements for non-network M+C MSA plans and M+C private fee-for-service plans. Thus, as set forth under revised § 422.152, M+C organizations are no longer required to conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the quality assessment and performance improvement requirements that apply to all plans, such as those relating to health information and program review. See section II.E of this preamble for further detail on the quality assurance requirements for various types of plans.

12. User Fee for M+C Organizations Based on Number of Enrolled Beneficiaries (Section 522 of the BBRA)

Under section 1857(e)(2) of the Act, the Secretary is directed to collect "user fees" from M+C organizations in order to pay for the costs associated with the enrollment and information distribution activities required for the M+C program under section 1851 of the Act and for the health insurance counseling and assistance programs under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103-66). Before enactment of the BBRA, the aggregate amount to be collected from all M+C organizations was the lesser of (1) the estimated costs to be incurred by the

Secretary in carrying out the applicable information dissemination activities or (2) an amount contingent upon the enactment of appropriations. An individual M+C organization's user fee was equal to its pro rata share of the aggregate amount of fees to be collected from all M+C organizations. Section 522 of the BBRA amended section 1857(e)(2) of the Act to provide that the aggregate amount of user fees to be collected from M+C organizations to carry out the required beneficiary education activities will be based on the lesser of the estimated costs of information dissemination or, for 2001 and thereafter, the "M+C portion" of \$100 million, with the M+C portion representing the Secretary's estimate of the ratio of the average number of M+C enrollees for a fiscal year to the average total number of Medicare beneficiaries for the fiscal year. We are revising § 422.10 to reflect the new statutory provisions. Consistent with section 522(b) of the BBRA, these changes are effective for user fees charged on or after January 1, 2001, and the Secretary may not increase the user fees for the 3-month period beginning October 2000, above those in effect during the previous 9 months. While we will comply with this latter limitation, we are not including it in regulations text, just as Congress did not include it in the text of section 1857(e).

13. Clarification Regarding Operation of M+C Plans by Religious Fraternal Benefit Societies (Section 523 of the BBRA)

Section 523 of the BBRA amended section 1859(e)(2) of the Act to clarify that a religious fraternal benefit (RFB) society may offer any type of M+C plan, not just an M+C coordinated care plan. We are revising the definition of an RFB plan in § 422.2 to reflect this change.

14. Rules Regarding Physician Referrals for M+C Program (Section 524 of the BBRA)

Section 524 of the BBRA amended section 1877(b)(3) of the Act to specify that certain Medicare rules establishing prohibitions on physician referrals do not apply for purposes of M+C organizations offering M+C coordinated care plans, although they do apply for purposes of M+C MSA plans and private fee-for-service plans. As discussed in section II.E.10 of this preamble, this policy was incorporated into § 411.355(c)(5) of the Medicare regulations through our June 26, 1998 interim final rule.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on June 26, 1998 Interim Final Rule

We received 87 items of correspondence containing hundreds of specific comments on the June 26, 1998 interim final rule. Commenters included managed care organizations and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospitals and other providers, insurance companies, States, accrediting and peer review organizations, members of the Congress, and others. Consistent with the scope of the June 26, 1998 rule, most of the comments addressed multiple issues, often in great detail. Listed below are the five areas of the regulation that generated the most concern:

- Access issues, including requirements concerning coordination of care, initial assessments of enrollees' health care needs, timely pre-approval of post-stabilization services, and notification responsibilities when an organization terminates its relationship with a specialist.
 - Quality improvement standards.
 - Payment rates and service area policy.
 - Provider participation rules.
 - Beneficiary appeals and grievances.
- Among the other issues that generated substantial numbers of comments were:
- Eligibility, election, and enrollment policies.
 - Marketing restrictions.
 - Risk adjustment methodology and encounter data submission.
 - Contractual requirements.
 - Preemption of State law by Federal law.
 - Deadline for ACR submissions and capacity waivers.

2. Issues in February 17, 1999 Final Rule

In the February 17, 1999 final rule, we attempted to address those issues raised by public commenters where we were convinced that changes were needed and could quickly develop policies necessary to implement the changes. We also included policy clarifications for certain areas in which the material in the interim final rule had been misinterpreted. Also, to the extent possible, we addressed time-sensitive issues, such as those that needed to be resolved before publication of this comprehensive M+C final rule or those that could affect plans or beneficiaries in areas where Medicare risk contractors

initially chose not to participate in the M+C program. Some of the specific issues we addressed related to provider participation procedures, beneficiary enrollment options, and several access-related issues, including initial care assessment requirements, notification requirements when specialists are terminated from an M+C plan, and coordination of care requirements.

3. Organization of Final Rule With Comment Period

In this comprehensive M+C final rule with comment period, we address all comments received on the interim final rule that were not addressed in the February 17, 1999 final rule. (As noted above, we are also incorporating changes necessitated by the BBRA, subject to public comment.) For the most part, we will address issues according to the numerical order of the related regulation sections. However, many of the comments raise interrelated issues that involve multiple sections of the regulations. In these cases, we generally address all comments on these issues together, whenever the first relevant section of the regulations arises. Also, we note that all comments on the definitions set forth in § 422.2 are addressed in the context of the requirements with which the applicable definitions are associated.

4. General Comments and Subpart A Issues

a. Administrative Procedure Act Issues

We received two comments on various aspects of the M+C rulemaking process, as discussed below.

Comment: A commenter contended that the June 26, 1998 interim final rule did not conform to requirements in the Administrative Procedure Act (APA). First, the commenter alleged that HCFA did not engage in “reasoned decision making” because in certain instances cited by the commenter, the preamble contained “no discussion of * * * factual predicates, no discussion of alternatives that were evaluated and rejected, and no cost-benefit analysis.” The commenter specifically cited requirements for a compliance plan and certifications by executives in connection with this contention. Second, the commenter contended that the regulations should have been subjected to prior notice and comment. The commenter argued that the authority in section 1856(b)(1) to issue interim final regulations only applied to existing standards under section 1876, and that failure to publish the rule by June 1 constituted “a failure to satisfy a condition precedent for issuance of an

interim final rule without notice and comment.” Finally, the commenter argued that the rule impermissibly provided for compliance with our instructions, contending that this was an attempt to require compliance with instructions that should themselves be subjected to notice and comment.

Another commenter commended us on our success in issuing comprehensive regulations for a complex new program in a short period of time.

Response: The interim final rule includes an extensive preamble that explains the basis and purpose of the regulations, and meets the cited requirements of the APA. We believe that this preamble more than satisfies the requirements in the law for explaining the reasoning behind the decisions we made in the interim final rule. In some cases when we actively considered alternative approaches and rejected them, we included discussion of this in the interim final rule preamble. For example, in the discussion of grievance procedures (63 FR 35022–35023), we indicated that “we considered” including detailed requirements for M+C organization grievance procedures in the interim final rule, and “we considered requiring certain time frames for addressing grievances.” Our reasons for not doing so in that rule were also set out in detail.

We do not believe that the APA—or certain court decisions cited by the commenter—require us to discuss in the preamble every possible alternative that might have been considered to the approaches taken in the rule, but only to explain our reasons for the choices we made. To the extent we have received specific comments advocating alternative approaches, we explain in this final rule why we have not adopted these suggestions, where this is the case.

With respect to the specific requirement that M+C organizations have a plan in place for ensuring compliance with applicable State and Federal laws, we indicated in the preamble that we believe that such a plan was part of the administrative and managerial capabilities that should be in place to carry out the contract and *comply with* obligations under the contract. Many organizations agree with this conclusion, and had compliance plans in place before this requirement was adopted. We believe that this is an important component of proper management, like an accountable board of directors. We explained in the preamble that we were establishing this requirement as an M+C standard under our authority in section 1856(b)(1) to establish M+C standards by regulation.

As to the requirement for certifications as to the accuracy of data, we clearly explained in the preamble that we believed that since payments to M+C organizations are based on such data, the submission of the data is part of a “claim” for payment in the amount dictated by the data in question. We further explained that a certification of the accuracy of this information will help ensure accurate data submissions, and assist us and the DHHS Office of Inspector General in anti-fraud activities. We believe this is a clear and logical explanation of reasoned decision making in imposing this requirement.

We disagree with the commenter’s contention that we were required to provide prior notice and comment before publishing final regulations. Section 1856(a)(1) gives the Secretary the authority to promulgate regulations establishing the standards that will apply under the M+C program, and that the Secretary is authorized to “promulgate regulations that *take effect* on an interim basis, after notice and *pending opportunity for public comment*.” (Emphasis added.) The commenter suggests that this authority only applies to requirements that are based on existing section 1876 standards. This is incorrect, and is contradicted by other BBA provisions citing this rulemaking authority. The reference to section 1876 merely provides that, “consistent with the requirements of this part” (meaning only to the extent that the BBA does not provide or authorize alternative approaches), “standards established under this subsection shall be *based on* standards established under section 1876 *to carry out analogous provisions* of such section.” section 1856(b)(2). This provision thus only applies to the extent we determine that doing so would be “consistent with” the new Part C provisions, and only with respect to those provisions in Part C that are “analogous” to a section 1876 standard. Even in this case, the new standards need only be “based on” the 1876 standards, not necessarily identical to such standards.

The commenter’s interpretation that section 1856(b)(1) of the Act applies only to the repromulgation of existing 1876 standards is also contradicted by other references in the BBA to this rulemaking authority. For example, section 1876(k)(2), added by section 4002 of the BBA, provides for rules dealing with “grandfathered” Part B only enrollees. Since Part B only enrollees were permitted under section 1876, there were no section 1876 standards addressing the treatment of “grandfathered” enrollees. Yet, section

1876(k)(2) provides that such enrollees may “continue [grandfathered] enrollment in * * * accordance with regulations described in section 1856(b)(1).” Section 1876(k)(2). This makes clear that the rulemaking authority in section 1856(b)(1) is broader than the commenter contends.

The commenter’s contention that we cannot avail ourselves of the interim final rule authority because the rule was not published by June 1, 1998, is illogical. If the Congress authorized interim final regulations because it wanted the rules to be in place by June 1, it would not wish regulations that have already missed this deadline to be delayed further by notice and comment rulemaking. Indeed, the fact that rules were not published by June 1 made the desirability and necessity of issuance in interim final form with an opportunity for public comment all the more urgent.

Finally, with respect to our instructions, we intend only to issue instructions that implement or interpret substantive provisions included in these regulations. To the extent the commenter believes that subsequent instructions are issued that should have been subjected to notice and comment, it can make this argument at that time. The fact that we require compliance with guidance we issue to implement these rules is fully consistent with the APA.

b. Types of M+C Plans (§ 422.4)

i. M+C Coordinated Care Plans (§ 422.4(a)(1))

A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the M+C organization to deliver the benefit package approved by us. The network is approved by us to ensure that all applicable requirements are met, including access and availability, service area, and quality. Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care. Coordinated care plans include plans offered by HMOs, PSOs, and PPOs, as well as other types of network plans (except network MSA plans). We received no comments on our definition of coordinated care plan.

ii. Religious and Fraternal Benefit Society Plan

One specific type of M+C plan authorized by the BBA is a religious and fraternal benefit society plan (RFB plan),

which is defined in section 1859(e) of the Act. An RFB plan is a new plan that may be offered under the M+C program. In § 422.2, an RFB society is defined as an organization that (1) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act and (2) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches. As noted above, an RFB plan was defined in the BBA as a coordinated care plan that is offered by an RFB society. We received two comments regarding RFB plans.

Comment: Two commenters noted that the definition of religious and fraternal benefit (RFB) society found in § 422.2 of the regulations would be clearer if the word “benefit” were added to the beginning of this definition.

Response: We agree that the word “benefit” was inadvertently omitted and have added the word “benefit” after the words “religious and fraternal” in that section.

Comment: One commenter asked whether RFB society plans are limited to being a coordinated care plan, or whether an RFB society could also offer a private fee-for-service plan or an MSA plan. A related question asked by the commenter is whether RFB plans can include a point of service (POS) option.

Response: As noted above, under the BBA, a RFB society could only offer a coordinated care plan as a RFB plan. Section 523 of the BBRA, however, amended section 1859(e)(2) of the Act to provide that an RFB society may offer any type of M+C plan. An RFB plan that operates as an M+C coordinated care plan may include a POS option, as could any other M+C coordinated care plan.

iii. M+C MSA Plans (§ 422.4(a)(2))

The comments received regarding M+C MSA plans are discussed in section III of this preamble. *iv. Multiple Plans (§ 422.4(b))*

In the interim final rule, we specified that under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO offering a coordinated care plan, has received from us a waiver of the State licensing requirement).

Comment: Noting that an M+C organization can offer multiple plans under a single contract with us, a commenter asked how multiple plans would work, and whether each would be required to have a separate health

services delivery system. The commenter stated that in order to reduce the administrative cost of multiple plans, we should maximize assessment of compliance with Medicare requirements at the M+C organization level and minimize compliance assessment at the individual plan level.

Response: An M+C organization may offer multiple M+C plans under a single contract with us. Each M+C plan must have its own HCFA-approved service area, and a separate ACR submission that also must be approved by us. For coordinated care and network MSA plans, we will verify that each plan has a health care provider network under contract that meets M+C standards for access and availability to health care services for beneficiaries who enroll in the given plan. Although we will attempt to achieve all appropriate monitoring efficiencies when contractual elements are identical across plans, we have a responsibility to ensure compliance at the plan level when requirements are plan-specific, such as those noted above.

c. Application Requirements and Procedures (§§ 422.6 and 422.8)

These sections set forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan. One of the new requirements we set forth in the interim final rule was that organizations wishing to contract with us must submit documentation of their appropriate State licensure, or submit documentation of State certification that the entity is, in fact, able to offer health insurance or health benefits coverage meeting State fiscal solvency standards and is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health care services. We further specified that entities meeting the definition of a PSO can be exempted from this requirement if they meet conditions for a waiver, which can be granted by us in accordance with subpart H of part 422. Section 422.8 of the interim final rule describes the application requirements for entities seeking to contract with us to offer M+C plans, as well as our application evaluation procedures.

Comment: One commenter suggested that our use of terms referring to entities that qualify for M+C contracts (M+C organization) and applicants for such contracts are inconsistent and confusing. For instance, at §§ 422.8(a)(3), 422.8(e), and 422.8(g), we use the term “entity” to refer to an organization applying to become an M+C organization, while at §§ 422.8(d)

and (f) we use the term “M+C organization.”

Response: Clearly, we should not refer to an organization that has not obtained approval from us to become a contractor under the M+C program as an “M+C organization.” Accordingly, we have revised § 422.8 to uniformly refer to organizations that apply to become M+C organizations as “contract applicants.” This is consistent with our use of this term elsewhere in this final rule.

We likewise agree with the comment that organizations that have received approval to operate as an M+C organization should uniformly be called an “M+C organization.” Accordingly, we have revised applicable subsections of § 422.8 to uniformly use the term “M+C organization” to refer to an existing contractor under the Medicare+Choice program.

d. User Fees (§ 422.10)

This section implements section 1857(e)(2) of the Act, as revised by section 522 of the BBRA. Section 1857(e)(2) requires that M+C organizations share in costs associated with beneficiary enrollment in M+C plans, including the costs of providing information and counseling on plan choices. It sets forth the maximum amount of the aggregate “user fees” that can be collected from M+C organizations as well as the procedures that we follow to assess and collect these amounts from M+C organizations.

In the June 26, 1998 interim final rule, we referred to interim final regulations published on December 2, 1997, which implemented section 1857(e)(2) for risk contractors under section 1876. (Under section 1876(k)(4)(D), the obligation under section 1857(e)(2) applied to section 1876 contractors in 1998.) These December 1997 interim final regulations set forth a methodology for determining an individual organization’s “pro rata share” of the beneficiary costs to be assessed (62 FR 63669). We also explained in the June 26, 1998 interim final rule that we were simply adopting at § 422.10, for purposes of the M+C program, the user fee provisions previously set forth in § 417.472(h) of the December 1997 interim final rule. As we indicated in the June 26, 1998 interim final rule, we are addressing the comments received on the substance of the December 1997 interim final rule in this comprehensive M+C final rule. (Since there are no remaining section 1876 risk contractors, § 417.472(h) itself no longer has any applicability.)

As described above, section 522 of the BBRA subsequently amended the user fee provisions set forth in section 1857(e)(2) of the Act, effective for user

fees charged on or after January 1, 2001. Revised section 1857(e)(2) now establishes that beginning in the year 2001 the maximum amount of aggregate user fees that we may collect during a fiscal year from M+C organizations will be determined by the percentage of Medicare enrollees in M+C plans. Specifically, we will calculate: the annual average number of Medicare beneficiaries enrolled in M+C plans during a fiscal year divided by the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year. This ratio will be multiplied by \$100,000,000 to determine the maximum aggregate user fees we may collect from all M+C organizations in a given fiscal year. (Under section 1857(e)(2), we collect the lesser of (1) the actual costs of carrying out the required information dissemination activities or (2) the maximum aggregate amount permitted under the Act.)

We received five letters of comment regarding the interim final rule of December 2, 1997, which established the assessment method under which all M+C organizations are assessed the same fixed percentage of their total monthly Medicare payments, in order to collect the M+C user fee. Two commenters supported the user fee assessment methodology selected by us and considered that it was equitable both to organizations and beneficiaries; three commenters opposed the methodology. We also received six letters commenting on the same methodology in response to the interim final M+C regulation of June 26, 1998. Again, three commenters argued that the user fee was unfair to M+C organizations since it resulted in these organizations funding an information campaign for all Medicare beneficiaries, not just those enrolled in M+C organizations. These latter concerns are now moot in light of the BBRA amendments limiting M+C user fees to the percentage of information dissemination costs representing the percentage of total Medicare beneficiaries that are M+C enrollees. Comments that remain relevant are discussed below.

Comment: A commenter expressed concern about the costs of the education campaign implemented by us and how the funds collected from M+C organizations would be spent. The commenter asked that we make available detailed information on the budget, resource allocation, and past and projected expenditures for the beneficiary information campaign, in order to justify the user fee funding levels. The commenter also expressed

concern that we should not collect more in user fees than entitled by law. Specifically, the commenter noted that at § 422.10(d), we are only entitled to collect the lesser of the estimated costs necessary to implement educational activities in that fiscal year or the appropriated amount. The commenter also stated that the reduction in M+C payments due to the assessment of the user fee will deter new organizations from entering the M+C program.

Response: Although not required under the statute or the BBA, we provide an annual report to the Congress that includes an assessment of the implementation of the M+C program. This report also provides budgetary information on the expenditures of the fees we have collected to fund the M+C information campaign. As stated in revised § 422.10(d)(2), beginning in fiscal year 2001, we will collect in a fiscal year the lesser of either the amount needed to implement the required information dissemination and other activities, or the amount equal to the M+C portion of \$100 million. The fees collected from any one organization would represent a very small percentage of the total annual Medicare payments to that organization, and we do not believe that they would deter an organization from entering the M+C program.

Comment: A commenter argued that the assessment method adopted by us, under which a percentage of the monthly payment to an M+C organization is assessed, is unfair because it results in organizations in high capitation payment areas paying more (in total dollars) than organizations in lower payment areas. The commenter expressed the view that it is unfair to charge an organization in New York more than an organization in Nebraska.

Response: In selecting an assessment methodology, we sought an approach that is as financially equitable as possible regardless of an M+C organization’s size or geographical location. We also wanted a methodology that would not present a barrier to participation for smaller and new M+C organizations. We adopted the percentage of payment approach because it bases each organization’s assessment on the total Medicare dollars flowing to that particular organization. Thus, the fee each organization pays is directly proportional to the total dollars the organization receives from the Medicare program. M+C organizations that receive larger payments (based on monthly enrollment and payment levels) will pay more in total dollars

than M+C organizations with less Medicare money coming in.

Comment: A commenter stated that the assessment of a user fee should be directly related to the costs of providing services. Since no evidence has been presented that the costs of a national mail campaign are higher in one county than another, the user fee should be even across all counties.

Response: While the fees collected from M+C organizations will be used primarily to fund a national information campaign designed to reach all Medicare beneficiaries, some funds will go to local efforts, where, as noted above, costs do vary. In any event, this assessment is not an organization-specific “user fee” such as those imposed under the user fee statute. The assessments are not based on specific costs associated with an individual M+C organization, but on a share of aggregate costs. Specifically, the statute provides for each M+C organization to pay its pro rata share “as determined by the Secretary” of the “aggregate amount” spent on the specified costs. Thus, data on actual costs associated with an individual organization are not relevant. Rather, we consider the fee as an assessment to be levied in a manner that, to the extent possible, equitably balances the financial impact on all organizations.

Comment: A commenter stated that we should not use the user fee assessment as a way to equalize Medicare managed care payments in different areas of the country. Noting that the Congress has provided for a minimum update in high payment areas, the commenter contended that we will be violating the spirit of the law by taking more from organizations offering M+C plans in these areas.

Response: No consideration was given to using the user fee assessment methodology as a tool to adjust the level of Medicare payment to M+C organizations in different parts of the country. In fact, since the percentage impact on all M+C Medicare payments is equal (a fixed percentage of total payment), this is the one approach that maintains the relative payment levels of all organizations.

Comment: Another commenter asserted that the user fee assessment method we selected—with fees based on percentage of an organization’s M+C payment—has the effect of penalizing those M+C plan enrollees who reside in counties with higher payment rates. The commenter wrote that enrollees in high payment rate areas will pay much more for their existing benefits.

Response: In terms of total dollars, it is true that M+C organizations in high

payment areas will pay more on a per member basis than organizations in lower payment areas. However, as previously noted, the assessment percentage is the same for all organizations. A method that does not take into account the total dollars flowing to each plan would be regressive and unfair, because it would have a disproportionately high financial impact on organizations (and their members) located in mid to lower payment areas and those with low enrollment.

Comment: One commenter recommended that all M+C organizations pay a minimum user fee amount and then, on top of that minimum amount, organizations should also pay a flat monthly amount for each member. The commenter stated that this approach would ensure that the user fee is reasonably related to the benefit that the organization will receive from the M+C program.

Response: We considered the approach suggested by the commenter but rejected it because, unless the flat fee were set at a very low level, it would present an entry barrier for organizations with relatively low enrollment levels. We also rejected a flat per member monthly assessment because it does not adjust for the geographic variation in our monthly capitation payments to M+C organizations.

B. Eligibility, Election, and Enrollment

1. Eligibility to Elect an M+C Plan (§ 422.50)

Section 1851(a) of the Act sets forth the criteria for an individual to be eligible to elect an M+C plan. Consistent with the statute, § 422.50 specifies that an individual is eligible to elect an M+C plan if he or she:

- Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or Competitive Medical Plan (CMP) with a risk contract under part 417 on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);
- Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or other health plan offered by an M+C organization may continue to be enrolled in the M+C plan, or if enrolled in another health plan, may enroll in an M+C plan offered by the organization, if the individual is otherwise eligible to enroll in the M+C plan;

- Resides in the service area of the plan, except that an individual who resides in a continuation area of an M+C plan while enrolled in a health plan offered by the M+C organization may continue to be enrolled with the M+C organization as an M+C plan enrollee under the terms that apply to enrollees in the continuation area;

- Completes and signs an election form and gives information required for enrollment; and

- Agrees to abide by the rules of the M+C organization after they are disclosed to him or her in connection with the election process.

We specified in the interim final rule that an M+C-eligible individual may not be enrolled in more than one M+C plan at any given time. Comments on the M+C eligibility rules are discussed below.

Comment: Several commenters objected to the omission from the regulations of any provision permitting individuals to remain enrolled with an organization upon becoming Medicare eligible if they were enrolled with the organization as a commercial enrollee, but live outside the Medicare service area. In particular, commenters recommended that beneficiaries residing outside of an M+C plan’s service area be allowed to remain enrolled with the M+C organization offering the M+C plan as an M+C plan enrollee upon becoming eligible for Medicare, even if they live outside the M+C service area. Commenters noted that the previous regulations in Part 417 that applied to section 1876 risk contracts allowed an individual enrolled with an organization as a commercial enrollee to remain enrolled with the organization as a Medicare enrollee upon becoming eligible for Medicare even if the individual did not live in the Medicare service area. Several commenters asserted that the continuation area option provided for in the BBA (discussed in further detail below) was not an adequate replacement for the previous option; they believe that prohibiting out-of-area members from voluntarily remaining enrolled in M+C plans unduly restricts the options available to beneficiaries and causes unnecessary disruptions in care. One commenter noted that section 1851(b)(1)(A) of the Act gives us the discretion to make an exception to the requirement that the individual reside in the M+C plan’s geographic area.

Response: The last commenter is correct that section 1851(b)(1)(A) states that, “Except as the Secretary may otherwise provide (emphasis added), an individual is eligible to elect an M+C plan offered by the M+C organization

only if the plan serves the geographic area in which the individual resides.” In accordance with the statute, existing § 422.250(a) generally limits eligibility to elect an M+C plan to individuals living in the plan’s service area. The only discretion exercised by the Secretary in the M+C regulations was to permit individuals the option of continuing enrollment in the plan if they move out of the service area and into a plan’s “continuation area” (which can be established pursuant to section 1851(b)(1)(B) of the statute and § 422.254 of the M+C regulations, as discussed in detail below.)

Based on the comments we received on the interim final rule, however, as well as the reluctance of M+C organizations to establish formal continuation areas, we have become convinced that the regulations should be amended to provide for additional choices for beneficiaries. Thus, we are amending § 422.50 (with conforming changes to §§ 422.66(d)(1) and 422.74(b)(2) and (b)(4)) to permit M+C organizations to offer a “seamless conversion” option to individuals who, upon becoming entitled to Medicare, live outside of an M+C plan’s service area but are already enrolled in a commercial health plan offered by the same organization. If an M+C organization chooses to offer this option, it must offer the option to all individuals who were enrolled in a commercial health plan offered by the organization at the time they become Medicare-eligible. We do not believe it is appropriate to limit the availability of this option only to beneficiaries who had previously been enrolled in employer group health care plans, but instead are providing that both individual and employer group members of commercial health plans may elect to remain enrolled with their organization under an M+C plan under an expanded “seamless conversion” option. Similarly, we note that this expanded eligibility requirement is not limited to situations in which an enrollee becomes eligible for Medicare by virtue of age (referred to in the past as “age in” enrollees), but will apply to all newly eligible Medicare beneficiaries, including the ESRD and disabled population. (As noted above, we previously determined, in the interim final rule, that people with ESRD who are enrolled with an organization before becoming Medicare eligible may remain enrolled with the organization as an M+C plan enrollee.) We note that organizations that wish to offer this option must meet the M+C access standards under § 422.112, and

must furnish the same benefits to these enrollees as to enrollees who reside in the plan service area. Such enrollees should be made aware by the M+C organization of the extent to which they will need to travel into the plan service area to obtain service.

Comment: One commenter pointed out that State-authorized managed long term care plans may identify a chronically ill target population to be served, while the M+C regulations at § 422.50 do not allow an M+C plan to discriminate within an approved service area among those who are eligible to enroll in M+C plans. The regulations also do not provide for plans to enroll special populations. The commenter asked whether these provisions are waivable to permit plans authorized as managed long-term care plans under State law to participate in the M+C program.

Response: There is no authority in the statute to “waive” the requirement that M+C organizations accept all M+C-eligible individuals in the service area who wish to enroll. However, we have approved demonstration projects under independent demonstration authority that involve managed care entities that restrict Medicare enrollment to long-term care populations. Long-term care plans may be able to participate in Medicare under such a demonstration.

Comment: One commenter asked for clarification regarding whether individuals who are enrolled only in Medicare Part B or who have ESRD, and were grandfathered into M+C plans as of January 1, 1999, can move from plan to plan in the same M+C organization or to another organization. The commenter supported allowing the individual to move between plans and organizations. Another commenter suggested that we allow an individual enrolled only in Medicare Part B who retained his or her enrollment in an M+C plan as of January 1, 1999, to enroll in another M+C organization for a period of time after disenrolling from an M+C plan. In addition, the commenter suggested that individuals enrolled only in Medicare Part B should be able to enroll in an M+C plan at any time until 2002.

Response: We agree that grandfathered Part B-only individuals and individuals with ESRD should be allowed to move between plans within an M+C organization, and have specified that this is permissible in OPL 99.084, issued on February 26, 1999. With respect to beneficiaries with ESRD, this policy is based on section 1851(a)(3)(B) of the Act, which we interpret as permitting an existing enrollee who develops ESRD while enrolled with an organization to remain

enrolled with that organization. This is an exception to the general rule that an individual medically determined to have ESRD is not eligible to enroll in an M+C plan. However, we do not have statutory authority to permit a beneficiary with ESRD to enroll in a plan offered by a different M+C organization. Similarly, under section 1851(a)(3) of the Act, Part B-only enrollees generally are ineligible to enroll in an M+C plan. Section 1876(k)(2) of the Act, however, permitted a Part B-only beneficiary enrolled with an organization under a section 1876 risk contract on December 31, 1998, to continue enrollment in that organization if the organization has entered into an M+C contract effective January 1, 1999. Again, we have no statutory authority to expand upon this exception by permitting that individual to enroll with a different M+C organization from the one in which he or she was enrolled on December 31, 1998, under a section 1876 risk contract.

Comment: One commenter stated that individuals enrolled only in Medicare Part B who disenroll from M+C should be permitted to immediately enroll in Medicare Part A, and the surcharge for late enrollment should be eliminated.

Response: Provisions affording such beneficiaries these protections have been in place for some time. The Omnibus Reconciliation Act of 1990 established the Transfer Enrollment Period (TEP) during which individuals who have Part B only and whose coverage in a Medicare managed care plan is terminated for any reason may immediately enroll in Premium Part A. This provision is found at section 1818(c)(7) of the Social Security Act, and § 406.21(f) of our regulations, which also provide for relief from the premium surcharge for late enrollment. Under the TEP provisions, individuals may enroll in Premium Part A during any month in which they are still enrolled in the managed care plan or during the 8-month period following the last month of coverage under the plan. Under certain circumstances enrollment may occur up to 3 months in advance. If the individual enrolls in Premium Part A while still enrolled in the managed care plan or during the first full month when not so enrolled, Part A coverage is effective with the month of enrollment or, at the individual’s option, the first day of any of the following 3 months. If enrollment occurs during the 7 remaining months of the TEP, Part A coverage is effective the month after the month of enrollment.

Comment: One commenter suggested that the regulation be revised to permit individuals with ESRD who have been

enrolled in a commercial plan or a Medicare Cost HMO offered by the M+C organization to enroll in an M+C plan of that organization.

Response: Existing § 422.50(a)(2) provides this protection, stating that an individual who develops ESRD while enrolled in an M+C plan, or in a health plan offered by the M+C organization offering an M+C plan in the area in which the individual resides, may continue to be enrolled in an M+C organization as an M+C plan enrollee. Also, consistent with section 1851(a)(3)(B) of the Act, we have specified in OPL99.084 that individuals with ESRD may move among plans within an M+C organization. (We note that under this final rule, the individual may remain enrolled even if he or she does not live in the service area if new § 422.50(a)(3)(ii) applies.) For purposes of § 422.50(a)(2), “a health plan offered by the M+C organization” includes any commercial health plan and any cost contract held by that organization. In the case of an individual who develops ESRD while enrolled in a commercial plan offered by a cost contractor, the section 1876 rules similarly allow such an individual to remain enrolled with that organization under its cost contract after becoming eligible for Medicare.

Comment: One commenter believes that we are interpreting the phrase “entitled to benefits under Part A and enrolled in Part B” incorrectly.

Response: Our interpretation of this phrase is explained in detail in the interim final rule (63 FR 34979), and we would refer the commenter to that detailed explanation. To briefly reiterate our reasoning, we believe that the Congress intended that a newly eligible individual be given the opportunity to be enrolled in an M+C plan only after he or she is actually entitled to receive benefits under Part A and Part B. This view is supported by language in section 1851(e)(1) of the Act, which refers to “the time an individual first becomes entitled to benefits under Part A and enrolled under Part B,” and provides for the Secretary to specify an initial coverage election period under which such an individual may elect coverage under an M+C plan “effective as of the first date on which the individual may receive such [Part A and Part B] coverage” (emphasis added). While an individual technically may have “enrolled” in Part B once an application has been completed, such an individual’s right actually to “receive” coverage of services under Part B may not occur for a period of months. (See 63 FR 34979.) Since M+C organizations are paid in part from Part B trust funds, we do not believe it

would be appropriate for an individual to be enrolled in an M+C plan before he or she is entitled to “receive” Part B trust fund payments. We therefore have interpreted “enrolled in Part B” to mean entitled to receive Part B coverage. Consistent with section 1856(b)(2) of the Act (which provides for use of section 1876 standards to carry out analogous M+C provisions), this interpretation follows our longstanding interpretation of identical language in section 1876(d) of the Act.

2. Continuation of Enrollment (§ 422.54)

Section 1851(b)(1)(B) of the Act permits M+C organizations to offer enrollees the option of continued enrollment in an M+C plan when enrollees leave the plan’s service area to reside elsewhere (that is, in the “continuation” area) on a permanent basis. M+C organizations that choose to offer a continuation of enrollment option must explain the option in marketing materials, and make it available to all enrollees in the service area of the plan. Enrollees may choose to exercise the option of continued enrollment when they move out of the plan’s service area, or they may choose to disenroll.

An M+C organization must obtain our approval of the continuation area and related marketing materials, and meet the access requirements under section 1851(b)(1)(B) of the Act, before it may offer a continuation of enrollment option to Medicare beneficiaries.

The payment rate for the M+C organization is based on the rate and adjustment factors that correspond to the beneficiary’s permanent residence. Under section 1851(b)(1)(B) of the Act, the M+C organization must, at a minimum, provide or arrange for the provision of Medicare-covered benefits under section 1852(a)(1)(A) of the Act in the continuation area. This does not include any additional benefits the organization is required to provide to noncontinuation area members under section 1852(a)(1)(B) of the Act.

Section 1851(b)(1)(B) of the Act requires that “reasonable access” be provided in the continuation area, and that enrollees be subject to “reasonable cost sharing.” In the interim final rule, we required that M+C organizations satisfy the access requirements in § 422.112, and provide services either through written agreements with providers or by making payments that satisfy the requirements in § 422.100(b)(2).

We are defining “reasonable cost sharing” in the continuation area as limited to the cost-sharing amounts required in the M+C plan’s service area

(in which the enrollee no longer resides).

The interim final rule also provides that appeals and grievances of enrollees in the continuation area must be handled in the same timely fashion as for other enrollees. The ultimate responsibility for the handling of appeals and grievances is with the organization that is receiving payment from us.

We received 11 comments requesting further guidance regarding the continuation of enrollment option. Generally, commenters endorsed the continuation of enrollment concept and urged us to define continuation areas broadly in order to enhance coverage options for enrollees.

Comment: One commenter asked whether the beneficiary may choose the continuation area option verbally or in writing.

Response: Our current policy, as outlined in OPL 99.100 (which was published August 9, 1999), requires that the beneficiary choose the continuation area in writing, so that there is documentation of this choice. We further believe that in the absence of an affirmative choice to remain enrolled in an M+C plan under the different terms that apply to continuation enrollees, a move out of an M+C service area should be treated as a decision to disenroll from the M+C plan. We accordingly have amended § 422.54(c)(2) to provide that a beneficiary’s choice to continue enrollment in a continuation area must be made in a manner specified by us, and that in the absence of such a choice, the beneficiary will be considered to have chosen to disenroll from the M+C plan if he or she moves out of its service area.

Comment: Commenters recommended that the benefits in the continuation area should reflect the level of reimbursement the M+C organization receives, and thus should include any additional benefits.

Response: As the commenters point out, the existing continuation of enrollment regulations at § 422.54(d) require, at a minimum, that M+C plans provide Medicare-covered services in the continuation area. We recognize that this permits M+C plans to offer less generous benefits in the continuation area while still receiving the full Medicare payment. Section 1851(b)(1)(B) of the Act provides that individuals exercising the continuation of enrollment option have access to the “full range of basic benefits” described in section 1852(a)(1)(A) of the Act. However, section 1852(a)(1)(A) of the Act refers only to those benefits available under Parts A and B, and not

to additional benefits, which are described in section 1852(a)(1)(B) of the Act. Thus, although we agree that it would be preferable that M+C organizations be required to provide additional benefits to continuation area enrollees, the statute does not support this requirement. Therefore, we are considering a legislative proposal that would correct this inequity.

Comment: Several commenters inquired about the process for applying to us for a continuation area.

Response: We are adding a continuation area chapter to the M+C application for new M+C organization applicants. A separate application form will be available for current M+C contractors who wish to apply for a continuation area. Further guidance regarding the application process will be available in a forthcoming OPL.

Comment: One commenter asked whether a member must use only Medicare-certified facilities in the continuation area.

Response: The pertinent requirements in § 422.204(a)(3) apply equally to services furnished in a continuation area. Under § 422.204(a)(3), benefits must be provided through, or payments must be made to, providers that meet applicable title XVIII requirements. Further, a hospital, nursing home, home health agency, or other “provider of services” as defined in section 1861(u) of the Act, must have a provider agreement with us in place. (See section II.E of this preamble for further details on this requirement.) We believe these requirements help to assure the quality of care that is provided to beneficiaries.

Comment: Another commenter suggested that we allow M+C organizations a 1-year transition period to establish continuation areas and implement any continuation area requirements.

Response: We believe the regulations provide organizations with sufficient opportunity to implement continuation area requirements. M+C organizations are not required to establish a continuation area for their enrollees. Thus, an M+C organization may choose not to offer a continuation area until it is ready to implement the requirements outlined in § 422.54.

Comment: One commenter questioned whether State licensing regulations may supersede the potential advantages or enrollment flexibility of the continuation area.

Response: We believe the commenter is questioning how State licensing requirements will affect an M+C organization’s ability to establish or offer the continuation of enrollment option. Section 422.400(a) states that an

M+C organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity eligible to offer health insurance or health benefits coverage. Therefore, an M+C organization may establish a continuation area only in a State in which it is licensed under State law or otherwise authorized to operate. The individual States have the authority to determine whether they are going to require licensure or, for example, permit the M+C organization to use the licensure of an affiliate if it wishes to establish an out-of-State continuation area. Although we are not aware of State laws that unduly restrict the establishment of continuation areas, we would refer the reader to section II.I of this preamble for a detailed discussion of situations in which State laws are preempted by M+C laws and regulations.

Comment: Some commenters contended that we interpreted section 1851(b)(1)(B) of the Act too restrictively. For example, commenters objected to the requirement in § 422.54 that an M+C plan’s service area must be geographically distinct from its continuation area. Commenters also questioned whether enrollees who move to continuation areas in counties adjacent to the M+C plan’s service area may continue to receive services in the M+C plan’s service area.

Response: A continuation area, as defined at § 422.54(a), is an additional area outside the service area in which the M+C organization furnishes or arranges for furnishing services to its enrollees. The regulation does not prohibit continuation areas adjacent to the M+C plan’s service area, as the commenter appears to believe. Further, we agree that enrollees residing in a continuation area adjacent to the M+C plan’s service area may receive services in the M+C plan’s service area, as long as the access and service requirements of § 422.112 are met.

Comment: One commenter suggested that we allow enrollees to obtain services in the continuation area, even if they are not living in the continuation area permanently.

Response: The continuation area is intended for those enrollees who reside permanently outside of the service area (and permanently inside the continuation area) and want to remain enrolled in the plan. We do not have the authority to direct M+C plans to offer enrollees, temporarily residing in the continuation area, benefits in excess of the urgent/emergent care required by the statute and those benefits

voluntarily offered by an M+C plan in its traveler/visitor policy.

Comment: One commenter requested clarification regarding whether the continuation of enrollment option is intended to replace current travel programs. The commenter also inquired whether an enrollee would remain enrolled for the first 12 months with coverage only for emergency and urgently needed care, and then convert to a continuation of enrollment option.

Response: The continuation of enrollment option is not designed to replace current travel programs. In general, the purpose of traveler/visitor programs is to allow enrollees the opportunity to continue obtaining health care services while traveling outside the service area of the M+C plan in which they are enrolled. In contrast, the continuation of enrollment option is intended to permit enrollees to remain enrolled with an M+C plan if they move permanently outside of the plan’s service area. If the enrollee moves permanently into an area other than a continuation area, the member must be disenrolled as soon as the M+C organization is aware of the move and the enrollee has been notified. If an enrollee moves permanently into a geographic area designated as a continuation area, and chooses to remain a member of the M+C plan as a continuation of enrollment member, the enrollee must receive, at a minimum, Medicare-covered services. If an enrollee moves temporarily into the continuation area, or any area outside the service area, the M+C plan must provide coverage for emergency and urgently needed care. With respect to the question of whether an enrollee would remain enrolled for the “first 12 months” after a move, before converting to a continuation enrollment option, an individual can be a continuation enrollee as soon as he or she moves permanently to the continuation area. There is no waiting period.

3. Election Process (§ 422.60)

The general rule for acceptance of enrollees is that, except for the limitations on enrollment in an M+C MSA plan (§ 422.62(d)(1)), and for cases in which a plan has reached its enrollment capacity, each M+C organization must accept without restriction eligible individuals who elect an M+C plan during initial coverage election periods, annual election periods, and special election periods specified in §§ 422.62(a)(1), (a)(2), and (b).

Additionally, M+C organizations must accept elections during the open enrollment periods specified in

§§ 422.62(a)(3), (a)(4), (a)(5), and new (a)(6) if their M+C plans are open to new enrollees.

We stated in the interim final rule that the election form must comply with our instructions regarding content and format and have been approved by us as described in § 422.80. The form must be completed and signed by the M+C eligible individual (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between the DHHS and its designees and the M+C organization. Persons who assist beneficiaries in completing forms must sign the form and indicate their relationship to the beneficiary.

We further stated that the M+C organization must file and retain election forms for the period specified in our instructions. An election in an M+C plan is considered to have been made on the date the election form is received by the M+C organization. Also, the M+C organization must have an effective system for receiving, controlling, and processing election forms that requires that each election form is dated as of the day it is received and election forms are processed in chronological order, by date of receipt. Additionally, the M+C organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by us. We also provided that a notice of acceptance, in a format specified by us, informs the beneficiary of the date on which enrollment will be effective under § 422.68; and if the M+C plan is enrolled to capacity, explains the procedures that will be followed when vacancies occur. Also, a notice of denial explains the reasons for denial in a format specified by us. Within 30 days from receipt of the election form (or from the date a vacancy occurs for an individual who was accepted for future enrollment), the M+C organization transmits the information necessary for us to add the beneficiary to our records as an enrollee of the M+C organization.

Comment: Several commenters had concerns with allowing M+C organization representatives to assist individuals in completing any part of the election forms. One commenter believes that the common practice should be the beneficiary completing and signing his or her own form. Another commenter believes M+C organizations should be allowed to assist beneficiaries in completing the election forms only in limited circumstances, such as if the enrollee is disabled and needs assistance, and that organizations abusing this process

should be subjected to meaningful penalties. One commenter suggested that when assistance is provided to a beneficiary in completing the election form, a reason for the assistance also be documented on the form, especially if an M+C organization agent completes the form. In contrast, two commenters supported a provision that permits individuals to assist a Medicare beneficiary in completing an election form.

Response: As discussed in the preamble of the interim final rule (63 FR 34984), section 1851(h)(4)(B) of the Act indicates that the “fair marketing standards” may include a prohibition against an M+C organization (or agent of such an organization) completing any portion of any election form used to carry out elections on behalf of any individual. However, we have decided at this time not to prohibit an M+C organization (or agent of such an organization) from assisting beneficiaries in completing the election form. We recognize that we must provide accommodations for persons with disabilities and for situations in which such a prohibition could represent a potential physical burden to beneficiaries. We believe requiring the signature of the individual who assisted the beneficiary in completing the form and an indication of his or her relationship to the beneficiary is a fair compromise.

We agree that the M+C organization should be allowed to assist beneficiaries in completing the election form only under limited circumstances. For this reason, representatives should be assisting the beneficiary in completing the election forms only when assistance is needed, such as for a person who is disabled, illiterate, or otherwise impaired by age or health. In fact, in some circumstances assistance may be required to comply with civil rights requirements, for example, to ensure that individuals with disabilities or limited English proficiency have an equal opportunity to participate. Any M+C organization that unduly influences beneficiaries through this assistance should be identified by our monitoring procedures and subject to sanctions as specified in § 422.750.

We believe requiring the signature and identifying their relationship to the individual who is enrolling in the M+C plan is a sufficient beneficiary protection. It provides adequate information to monitor a beneficiary’s understanding that the form is for enrollment. The reason why an individual needs assistance should not be included on the enrollment form because it could undermine a Medicare

beneficiary’s right to privacy by disclosing health related information without his or her consent.

Comment: One commenter asked how enrollment and disenrollment requirements under Medicare compare to Medicaid rules, which the commenter erroneously believes allow the enrollee to enroll and disenroll at any time.

Response: Dually eligible individuals, that is, those individuals who are entitled to Medicare as well as Medicaid, have the same freedom of choice under Medicare as those who are entitled to Medicare only. M+C election provisions under section 1851(e) of the Act and § 422.62 of our regulations apply to all M+C-eligible individuals, and prior to 2002, permit Medicare enrollees to disenroll at any time. Under Medicaid rules, in contrast, managed care organizations (MCOs) are permitted to preclude Medicaid enrollees from disenrolling without cause for up to a year. MCOs are required only to permit disenrollment without cause in the first 90 days of enrollment, and annually thereafter. See section 1932(a)(4) of the Act.

Comment: One commenter requested clarification on when M+C organizations are required to be open for enrollment. In particular, the commenter expressed confusion over the meaning of the term “open enrollment period.”

Response: We recognize the potential for confusion associated with the use of the term “open enrollment period.” In accordance with section 1851(e)(6)(A) of the statute, § 422.60(a)(1) specifies that M+C organizations must be “open for enrollment” (that is, must accept enrollments) during annual, initial coverage, or special election periods unless they have reached enrollment capacity. However, under section 1851(e)(6)(B) of the Act, an M+C organization may accept elections at *such other* times as the organization provides. These latter time periods, during which an M+C organization has the discretion to decide whether to be “open” for enrollment are frequently referred to as “open enrollment” periods. We note that, if an M+C organization chooses to be open to new enrollees during all or a portion of these discretionary “open enrollment” periods, it must be open for all M+C-eligible individuals.

Comment: One commenter found § 422.60(a)(2), which states that M+C organizations must accept elections during open enrollment periods if their plans are open to new enrollees, to be confusing and detrimental to newly eligible individuals. The commenter believes that new Medicare eligibles

should not be limited to these time frames.

Response: The new enrollees being referred to in § 422.60(a)(2) are individuals newly electing the M+C plan and not individuals newly eligible for Medicare. Individuals newly eligible to Medicare are given a different “open enrollment” period under which they may elect or change M+C plans. In particular, §§ 422.62(a)(4)(ii) and 422.62(a)(5)(ii) allow newly eligible individuals to make an election beginning the month the individual is entitled to Medicare Parts A and B and ending on the last day of the sixth month of entitlement (in 2002) or the third month of entitlement (in 2003 and thereafter) or on December 31, whichever is earlier. Therefore, we do not believe a regulatory change is necessary.

Comment: One commenter asked if we would be modifying our enrollment transmission schedule to account for the 30-day period in which the M+C organization must transmit the enrollment information as stated in § 422.60(e)(6).

Response: Based on this comment, we are amending § 422.60(e)(6) to state that “upon receipt of the election form (or from the date a vacancy occurs for an individual who has been accepted for enrollment), the M+C organization transmits the information, within time frames specified by us, necessary for us to add the beneficiary to our records as an enrollee of the M+C organization.” We are also revising § 422.60(f)(3) to state that “upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA.” These changes will allow us the flexibility to vary the time frames in the future, should technological or policy changes warrant it.

Comment: One commenter asked that we clarify and provide guidance as to when an election is considered to have been made.

Response: Section 1851(f)(2) of the Act, as revised by section 502 of the BBRA, states that the effective date of coverage during continuous open enrollment periods is the first day of the first calendar month following the date on which the “election is made,” except that if the election or change of election is made after the 10th day of a calendar month, the election or change of election takes effect on the first day of the second calendar month following the date on which the election or change is made. As noted in the preamble of the interim rule, it was necessary to define when an election is made in order to establish the effective date of coverage

and to establish the date of our liability for payment. Therefore, the regulations at § 422.60(d) state that an election is considered to have been made on the date it is received by the M+C organization.

4. Enrollment Capacity (§ 422.60(b))

Sections 422.60(b) and 422.306(a) of the original M+C regulations required M+C organizations to submit information on the enrollment capacity of plans they offer by May 1 of each year. As noted in section I.C.8 of this preamble, section 516 of the BBRA amended section 1854(a)(1) of the Act to move the annual deadline for submission of ACR proposals and enrollment capacity data (if any) from May 1 to July 1, effective in 1999. If a plan reaches its HCFA-approved capacity limit, the M+C organization offering the plan generally is not obligated to accept new enrollees.

Comment: One commenter requested that we change the date that M+C organizations must notify us of the need for a capacity limit from May 1 to a date later in the year in order to allow the M+C organizations more time to analyze the previous year’s capacity and better determine the need for a capacity waiver.

Response: While we had no discretion under the BBA to make the change in question, as just noted, Congress has done so. We have revised §§ 422.60(b)(1) and 422.306(a)(1) to reflect this BBRA change.

Comment: A commenter asked that we clarify our language on capacity limits within a service area. The commenter also asked what would happen if there are too many patients and too few providers.

Response: Section 422.60(b) allows an M+C organization to limit enrollment in the M+C plans it offers during any enrollment period, subject to our approval. If an M+C organization elects to establish a capacity limit for an M+C plan, the request normally must be submitted to us at the time the Adjusted Community Rate Proposal (ACRP) is submitted (except as provided in new § 422.60(b)(3)), as discussed below. This submission should take into account the number of providers, and how many patients they can serve. The situation described by the commenter, in which “there are too many patients and too few providers” generally should not occur if capacity is limited to the number submitted by the M+C organization on July 1.

As the commenter suggested, however, we recognize that under certain circumstances, there may be a legitimate need for an M+C organization

to request a capacity limit or a revision of a capacity limit for an M+C plan during the contract year. The circumstances under which a capacity limit will be approved after the ACRP date would likely occur when a portion of a provider network that furnishes services under an M+C plan becomes unavailable during the course of a contract year. We have provided for HCFA to consider enrollment capacity requests outside of the ACR process under new § 422.60(b)(3), which permits consideration of such requests only if the health and safety of beneficiaries is at risk, such as if the provider network is no longer available to serve enrollees in all or a portion of the service area. The requirements for a midyear capacity limit request are also described in OPL99.095.

5. Election of Coverage Under an M+C Plan (§ 422.62)

All M+C plans must be open to M+C-eligible enrollees residing in the service area served by the plan during initial coverage election periods, annual election periods, and special election periods, unless such enrollment in the plan is limited based upon a limit on enrollment capacity.

The initial coverage election period is the period during which a newly M+C-eligible individual may make an initial election. This period begins 3 months prior to the month the individual is first entitled to both Part A and Part B and ends the last day of the month preceding the month of entitlement. An election made during this period is effective when entitlement to Part A and Part B coverage begins.

The month of November is the annual election period for the following calendar year. During the annual election period, an individual eligible to enroll in an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan. This election is effective on January 1.

Special election periods are periods during which enrollment must be made open to certain beneficiaries, for various reasons specified in the statute, or by us. We specify the effective date of elections made during special election periods.

M+C plans may be open to new enrollees at other times of the year (that is, during open enrollment periods) at the discretion of the M+C organization offering the plan.

From 1998 through 2001, the number of elections or changes that an M+C-eligible individual may make is not limited (except for M+C MSA plans).

Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an M+C plan may change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan any number of times. In 2002, an individual who is eligible to elect an M+C plan in 2002 generally may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan only once during the first 6 months of that year. For 2003 and subsequent years, an individual who is eligible to elect an M+C plan generally may elect or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan only once during the first 3 months of the year. (Note that consistent with section 501(b) of the BBRA, the restrictions that begin in 2002 do not apply to institutionalized individuals.) Even after the above limitations on changes in elections are in place, if certain circumstances exist, an individual may discontinue the election of an M+C plan offered by an M+C organization and change his or her election to original Medicare or to a different M+C plan. These circumstances include:

- When the individual is no longer eligible to be enrolled in a certain plan due to a change of residence,
- When HCFA terminates the organization's contract for the plan, or the organization terminates the plan or discontinues offering the plan in the service or continuation area in which the individual resides,
- When the M+C organization has violated a material provision of its contract or materially misrepresented the plan's provisions in marketing the plan to the individual, or
- When the individual meets such other exceptional conditions as we may provide.

Comment: Several commenters expressed concern because the new M+C election periods do not coincide with the time frames under which M+C eligible individuals elect health benefit options through their employer group health plans. The commenters believe these individuals should not be subject to the M+C election periods. One commenter pointed out that employer groups will experience considerable disruption in their yearly enrollment process, and, as a result, may have to stop offering their retirees wrap-around coverage to M+C plans, or they will have to modify their entire enrollment process.

Response: Section 422.62(b) states that we may grant special election periods for individuals who meet exceptional conditions. We have determined that the dilemma addressed by the commenters presents an "exceptional condition" that justifies the establishment of a special election period for M+C-eligible individuals who are members of an employer group plan that has open enrollment at a time other than the month of November. This is because such an individual could only change one part of his or her coverage at a time, which effectively would lock the beneficiary into his or her existing plan. As set forth in OPL 99.100, such M+C-eligible individuals may choose to elect an M+C plan offered by their employer during their employer group's open season, which constitutes a special election period for these individuals, as well as during the other election periods established under section 1851(e) of the Act.

Comment: Several commenters were opposed to the establishment of "lock-in" requirements beginning in 2002. They believe it will eliminate competition created in an environment where managed care plans compete continuously for enrollments. Several commenters also wanted to know who will be responsible for keeping track of the number of elections made by an individual once lock-in takes effect in 2002. They noted that beneficiaries and M+C organizations may not be aware of the number of elections an individual has made during a particular election period. One commenter recommended that we develop a mechanism that will allow exceptions to the limit of one change under §§ 422.62(a)(4) and (5).

Response: Sections 1851(e)(2)(B) and (C) of the Act limit an individual's election to one change during the open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. This "lock-in" requirement represents a gradual transition from the current system, under which a beneficiary may make any number of elections during the continuous open enrollment periods outlined in section 1851(e)(2)(A) of the Act to a restrictive system of annual "lock-in." We do not have the authority to modify this requirement, or to provide for any exceptions to this limit. We are aware of the need for us to maintain a history of the number of times an individual has made an election during a specific election period. Such information will be necessary in order to determine whether an individual is eligible to elect an M+C plan at a given time.

Comment: One commenter believes that limiting the open enrollment and disenrollment opportunities defined in §§ 422.62(a)(4) and (5) to one election per period should not apply to plan changes within the same M+C organization.

Response: Section 1851(a)(1) of the Act requires that an M+C-eligible individual "elect" to receive benefits through the original Medicare fee-for-service program or through enrollment in an M+C "plan." That is, enrollment in an M+C "plan" constitutes an election under Part C. Section 1851(e) of the Act further limits the "election" of an M+C "plan" or of original Medicare to one change during open enrollment periods in the first 6 months of 2002 and the first 3 months of subsequent years. Therefore the law does not permit us to allow M+C-eligible individuals to move from plan to plan without considering it an election, even if the change in plans occurs among plans offered by the same M+C organization.

Comment: One commenter requested further clarification of enrollment and disenrollment periods, while another asked whether a beneficiary who defaults to original Medicare has the option to elect an M+C plan.

Response: An individual who defaults to original Medicare may elect another M+C plan during any election period during which the plan is accepting new enrollments. As discussed in detail above, section 1851(e) of the Act and § 422.62 of the M+C regulations describe the election periods in which individuals can enroll in and disenroll from an M+C plan. M+C-eligible individuals may make or change an election during an initial coverage election period, an annual election period, a special election period, or an "open enrollment" period. The initial coverage election period is the 3-month period prior to the month an individual becomes entitled to Medicare Part A and Part B. The annual election period is November of every year. Special election periods are also allowed when M+C-eligible individuals experience certain circumstances that warrant the need to make a change in election. These include our termination of the M+C plan contract or M+C organization termination or discontinuance of the M+C plan in the service or continuation area in which the individual resides, a change in place of residence to a place outside of the M+C plan's service or continuation area, demonstration by the individual that the M+C organization substantially violated a material provision of its contract or materially misrepresented the M+C plan's provisions in marketing materials, or

other exceptional conditions as provided by us. In addition, § 422.62(c) also provides for a special election period for individuals age 65. Beginning in 2002 individuals age 65 who elect an M+C plan during the initial enrollment period may disenroll from the M+C plan and elect coverage under original Medicare within 12 months of their enrollment in an M+C plan.

Through 2001, open enrollment periods are continuous, that is, every month through 2001. Beginning in 2002, the open enrollment periods are the first 6 months of the year, or the first 6 months of Medicare Part A and Part B entitlement (or December 31, 2002, whichever is earlier). In 2003 and in subsequent years, the open enrollment periods are the first 3 months of the year, or the first 3 months of Medicare Part A and Part B entitlement (or December 31, 2003, whichever is earlier). Again, open enrollment periods remain continuous for institutionalized individuals during and after 2002.

The election rules for M+C MSA plans (see § 422.62(d)) include some exceptions to the election periods described above. M+C-eligible individuals may only enroll in an MSA plan during an initial coverage election period or an annual election period. They may not make an election of an MSA plan during open enrollment periods or special election periods. M+C-eligible individuals may only disenroll from an MSA plan during annual election periods and special election periods, excluding special election periods for individuals age 65. In addition, if an individual elects an M+C MSA plan for the first time during the annual November election period, he/she may revoke that election by December 15 of that same year.

Comment: One commenter supported the special election period for individuals age 65 as outlined at § 422.62(c), and requested that the provision also apply to newly eligible individuals with disabilities.

Response: Section 422.62(c) implements the last sentence in section 1851(e)(4) of the Act, which applies only to individuals who enroll in an M+C plan upon turning 65. Congress chose to provide this opportunity to individuals who become eligible based on age, but did not provide for such a benefit in the case of individuals who become eligible based on disability or ESRD status. We thus cannot apply section 1851(e)(4) of the Act to individuals who are not 65, since they do not meet an explicit condition set forth in the statute.

Comment: One commenter noted that § 422.62(b)(3) allows an individual a

special election period if the M+C organization violates a material provision of its contract with the individual. However, it does not allow the M+C organization an opportunity to comment on the enrollee's assertion that the contract was violated. The commenter stated that we should be sensitive to the severity of this issue and should establish a timely and fair review process. Two other commenters stated that we should develop reasonable, consistent guidelines for establishing special election periods for exceptional conditions, as provided at § 422.62(b)(4).

Response: Section 1851(e)(4) of the Act gives us the authority to develop guidelines to establish special election periods for exceptional conditions and to establish the procedures for granting a special election period for contract violations that specify when individuals are entitled to disenroll from an M+C plan after disenrollment rights become limited in 2002. This authority provides us with the discretion and the time to develop beneficiary protection requirements that will be sensitive to the issues identified by the commenters. As we gradually transition from the current system of totally free movement to a restrictive system of annual "lock-in," we have every intention of developing reasonable and consistent guidelines as the need for these guidelines in the year 2002 approaches.

Comment: One commenter requested that we clarify at § 422.62(a)(2)(ii) that eligible beneficiaries may elect to enroll in managed care demonstrations, section 1876 cost plans, and health care prepayment plans during the annual election period.

Response: The annual election period is an election period for M+C organizations operating under section 1851 of the Act. Health care prepayment plans, section 1876 cost plans, and some managed care demonstrations do not fall under section 1851 of the Act. Therefore, we do not have the authority to require these plans and demonstrations to be open for enrollment during an annual election period. Although such plans and demonstrations have the option of being open for enrollment to eligible individuals during that same time frame, this regulation only addresses requirements under section 1851 of the Act.

6. Information About the M+C Program (§ 422.64)

a. Overview

Section 422.64 contains requirements related to information about M+C plans.

Paragraph (a) applies to M+C organizations, and requires that organizations annually provide to us, using a prescribed format and terminology, the information we need to carry out our annual information campaign for all Medicare beneficiaries. However, the remaining paragraphs of existing § 422.64 essentially reflect statutory provisions governing our information distribution activities.

Comment: Several commenters expressed confusion about whether we or M+C organizations were responsible for various information distribution requirements specified under § 422.64.

Response: We recognize the commenter's concerns and believe that the best means to avoid introducing confusion in this regard is to eliminate from the regulations the portions of § 422.64 that serve solely to delineate our responsibilities. Deleting these provisions from the Code of Federal Regulations in no way affects our information distribution responsibilities that had been reflected in these provisions, since these are set forth in the statute in sections 1851(d)(1) through (d)(4) of the Act. Also, we note that § 422.111 continues to list the information that M+C organizations are responsible for disseminating to their plan enrollees.

Comment: Two commenters were concerned that the many changes introduced by the M+C program to the plan enrollment and disenrollment process (for example, changes to the effective date, annual open enrollment, lock-in requirements) would lead to beneficiary confusion and disruption of the program, and stressed the need for improved communication with beneficiaries.

Response: We agree that the many changes necessary for the implementation of the M+C program will require that we carry out substantial educational efforts for beneficiaries and the health industry. We are strongly committed to keeping beneficiaries informed and educated about their choices, and have undertaken many efforts to accomplish this task. For example, we have created a toll-free line for M+C information (1-800-MEDICARE), developed the Medicare & You handbook, and have carried out special educational and publicity campaigns to inform M+C-eligible individuals about the availability of plans offered in different areas and about the election process. In 1999, we began conducting a nationally coordinated educational and publicity campaign about M+C plans and the election process that occurs every November. We also provide information

via our Internet website (www.Medicare.gov), which is a Medicare beneficiary-centered consumer website designed to provide a broad array of information on program benefits and health promotion. These are just a few of the many efforts we have begun to disseminate information to beneficiaries and prospective beneficiaries on their coverage options under the M+C program, and we believe that they should alleviate the potential confusion associated with the M+C program.

b. Access

Comment: A commenter recommended that § 422.64 specifically require notification and disclosure of Medicare's screening Pap smear benefit and of the ability of beneficiaries to directly access specialists to obtain this preventive service.

Response: The 2000 Medicare & You handbook includes a description of the new preventive benefits. With respect to direct access to a specialist who would perform a pap smear, § 422.112(a)(3) guarantees female M+C enrollees "direct access to a women's health specialist within the network for women's routine and preventive health care services," which would include Pap smears (see section II.C of this preamble for further details on this issue.)

c. Performance Measures

Comment: Several commenters expressed concerns about the validity, reliability, and comparability of information to be provided by us to Medicare beneficiaries, particularly through Medicare Compare, our Internet-based database of comparative information on M+C plans. The commenters want us to ensure that the information presented to beneficiaries is objective, accurate, and complete. They also emphasize the importance of recognizing the audience for particular types of information.

Response: Medicare Compare is our electronic database of health plan comparison information. The database is designed to educate beneficiaries and others about their health care options so they can make informed health care choices. The information for this database is compiled by us with cooperation from M+C organizations. The Medicare Compare database is also updated regularly to reflect changes in cost and benefits. We are continuing to implement enhancements to ensure that the data submitted by M+C organizations are valid and reliable. Medicare also collects quality-of-care information known as Health Plan Employer Data and Information Set

(HEDIS) from M+C organizations and we carefully check it for accuracy. This information should help beneficiaries compare the quality of health care that an M+C organization delivers by explaining how well the organization keeps enrollees healthy or treats them when they are sick. Medicare's Consumer Assessment of Health Plans Study (CAHPS), developed in collaboration with the Agency for Healthcare Research and Quality, is an initiative to collect and report information on beneficiaries' experience in receiving care through M+C organizations. We have also worked closely with the industry and researchers in order to provide the most accurate information for the Medicare & You 2000 handbook.

d. Continuation and Improvements

Comment: Commenters were concerned about the amount of information provided to Medicare beneficiaries by us. They recommend that the information specified in § 422.64 be included in the general information brochures and contain the customer service telephone numbers for each M+C organization. They also suggested that we need to differentiate between information provided to beneficiaries in written form, and that available to interested persons via the Internet. Written comparative information, which is to be available to all beneficiaries at specified intervals, should be easy to understand and focused in content.

Response: We provide access to information from a variety of sources. Beneficiaries, M+C organizations, providers, family members, and others can receive up-to-date information about the Medicare health plans available in their area, Medicare health benefits, fraud and abuse, nursing homes, appeals and grievances, patient rights, etc., at the following locations:

- Internet at www.Medicare.gov. Local libraries or senior centers may be able to help the person find the information on their computers.
- Medicare Choices Help line at 1-800-MEDICAR(E) and TTY for the speech and hearing impaired at 1-877-486-2048.
- State Health Insurance Assistance Program (SHIP) in the beneficiary's area.
- Local outreach events.

Comment: Several commenters encouraged us to evaluate all aspects of the information campaign in order to determine the most effective approach for reaching beneficiaries.

Response: We aim for timely distribution of all of our materials. We are legislatively mandated to mail

specified information on the M+C program and individual M+C plans to beneficiaries at least 15 days prior to the annual election period. We are evaluating the impact of this timing on beneficiary decision making. Our ongoing evaluation of National Medicare Education Program (NMEP) includes assessment of telephone referrals, including toll-free line and State Health Insurance Assistance Programs (SHIPs), which are entities jointly funded by us and by the States to provide information and counseling to Medicare beneficiaries. The toll-free line has been operational nationally since March 15, 1999.

e. Beneficiary Input

Comment: Several commenters noted that in developing any educational materials or activities, it is important to ensure that the information is meaningful to beneficiaries. These commenters believe that we need to convey information to beneficiaries in an organized, straightforward manner to assure as complete an understanding as possible. For example, the commenters suggest that materials should be reviewed to determine whether they will provide needed information or simply raise more questions among beneficiaries, or whether beneficiaries will understand that they do not need to make any changes. The commenters specifically recommended that we conduct focus groups to gauge beneficiary responses to the Medicare & You handbook, and would like us to revisit our future plans and communications.

Response: We have performed extensive evaluation of the Medicare & You handbook, including focus-testing the Medicare & You 1999, and customer-testing of the Medicare & You 2000. We also used the results of the NMEP evaluation, survey of beneficiaries, expert review, plain language review, and comments submitted to us by mail and the Internet. The results received from all of these sources were used in the development of the Medicare & You 2000 handbook. We will continue evaluating our efforts to improve beneficiary communication.

Comment: Two commenters offered suggestions on the public input approach outlined in the preamble of our June 26, 1998 interim final rule. (In that preamble, we discussed in detail the process of obtaining public input about data collection and dissemination of selected data. We addressed only those data elements that would be disseminated as part of Medicare Compare or as part of any beneficiary

information campaign efforts.) One commenter suggested ensuring that physicians are involved in determining data specifications for M+C organizations, and the other looked forward to seeing our strategy for public input.

Response: As discussed in the interim final rule, we recognize the importance of obtaining public input on data needed by beneficiaries to make health plan choices. We also agree that we need to ensure physician input, particularly in areas such as quality of care. Our strategy for obtaining public input into the process, which is well under way and wide ranging, includes the following:

- Obtaining public input through currently established communication activities (for example, committees, consultation avenues, public meetings, training seminars). Limited resources and time demands do not permit the establishment of separate or overlapping processes with those already established and working (such as industry council meetings). It may not always be possible to hold public meetings to invite interested individuals to comment and provide input on the process of determining data specifications.

- Obtaining public input through normal data collection clearance channels when we are the lead for the data collection activity. The OMB clearance process is a very effective and efficient way to obtain broad public comment on the content and format specifications for data collection (for example, the Plan Benefit Package). However, it may not always be possible to publish a notice or a summary of public processes regarding data elements to be collected.

- Obtaining public input through collaborative efforts with private industry, health care providers, researchers, and other interested parties. This approach allows the Federal government to be a partner with other experts (private and public) in the field of managed care and thereby not duplicate already successful and useful collaborative efforts (such as HEDIS).

Thus, our strategy strongly supports the use of efficient and effective methods of public input into the determination of information and specifications for beneficiary information campaign material. We also recognize the need to collaborate with organizations and individuals involved in the development of quality and performance measurements that support beneficiaries' increased understanding of managed care.

7. Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

An individual who wishes to elect an M+C plan offered by an M+C organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by us.

Additionally, an individual who wishes to disenroll from an M+C plan may change his or her election during the election periods specified in § 422.62 by either electing a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by us. Individuals may also disenroll by submitting a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by us or by filing the appropriate disenrollment form through other mechanisms as determined by us.

Under existing § 422.66(d)(1), an M+C plan offered by an M+C organization must accept any individual (residing in the service area or continuation area of the M+C plan) who is enrolled in a health plan offered by the M+C organization (regardless of whether the individual has end-stage renal disease—see §§ 422.50(a)(2) and (a)(3)) during the month immediately preceding the month in which he or she is entitled to both Part A and Part B. This is generally known as a “conversion” of enrollment for the enrollee (from commercial status to M+C enrollee status).

Subject to our approval, under § 422.66(d)(2), an M+C organization may set aside a reasonable number of vacancies in order to accommodate conversions. Any set aside vacancies that are not filled within a reasonable time must be made available to other M+C-eligible individuals.

If the individual enrolled in a health plan offered by an M+C organization chooses to remain enrolled with the organization as an M+C enrollee, the individual must complete and sign an election form as described in § 422.60(c)(1). In that case, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B. The M+C organization may disenroll an individual who is converting from its commercial plan to M+C status only under the conditions specified in § 422.74. The M+C organization must transmit the information necessary for us to add the

individual to our records as specified in § 422.60(e)(6).

An individual who has made an election under this section is considered to have continued to have made that election until the individual changes the election under this section or the elected M+C plan is discontinued or no longer serves the service area in which the individual resides, and the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided in § 422.54, whichever occurs first.

Comment: Several commenters stated that they support procedures that would permit seamless continuation of coverage, under which an individual would be deemed to have elected an M+C plan at the time of the individual's initial coverage election period if they are enrolled in a commercial health plan that is offered by the same M+C organization. Several specific recommendations were made. One commenter recommended that we require M+C organizations to prospectively provide the necessary information that would allow us to default individuals into the M+C plan. One commenter recommended that M+C organizations notify individuals in their commercial plans who are about to become Medicare eligible that they are being enrolled in the M+C plan, and to transmit the necessary information to us. Another commenter suggested that we alert individuals through the mailing of the initial enrollment package. Two commenters were concerned about deeming an individual to have elected an M+C plan if the M+C organization offers more than one M+C plan from which he/she could receive benefits. One commenter suggested that if we decide to deem an individual to have elected an M+C plan, the organization should be required to provide the individual with a description of Medigap guaranteed issues and age rating policies. One commenter supported procedures that would permit seamless continuation of coverage, but expressed concerns about deeming an individual enrolled in an M+C plan if Medicare is a secondary payer.

Response: Although we have addressed an individual's right to choose to remain enrolled with an organization as an M+C enrollee upon becoming Medicare eligible (as discussed above), a default process through which an individual would be deemed by us to have elected a specific M+C plan would require that we identify M+C-eligible individuals, as well as their relevant health plan information before the individual's initial coverage election period. At

present we do not have access to information on the health plans in which specific individuals are enrolled, because such plans are private health plans, and do not have established linkages with our systems, nor is there a mechanism in our Medicare managed care data system to capture such information. While some M+C organizations may want to share this information with us, others may not. It should also be noted that enrollment in an M+C plan is contingent upon the individual's entitlement to Medicare Part A and Part B. Individuals that have not previously filed for Social Security and/or Medicare benefits will not have an entitlement record, nor will they receive an initial enrollment package from Medicare. Frequently, individuals in commercial plans who are about to "age in" to Medicare are still employed, and have not yet filed for Social Security or Medicare benefits. Individuals who have filed for benefits will receive general information on Medicare and comparative information on M+C plans available in their service area. They will have the opportunity to enroll in the M+C plan 3 months prior to their entitlement to Medicare Part A and Part B.

The expansion of the managed care provisions under the BBA has presented an extraordinary challenge to us and to the Medicare managed care data system that supports our information system business requirements. We anticipate that in the future, we will develop strategies to incorporate information collection activities in our managed care systems that will allow this kind of mechanism to be put in place. As we develop strategies that will incorporate additional information collection activities under our authority under section 1851(c)(2) of the Act, we will consider procedures necessary to identify in which plan a beneficiary wants to enroll if the M+C organization offers more than one M+C plan and also whether Medicare Secondary Payer rules apply. Until that time, and in accordance with § 422.66(d), an M+C plan offered by an M+C organization must accept enrollments from any eligible individual residing in the service area or continuation area of the M+C plan, who is enrolled in a commercial health plan offered by that same M+C organization during the month immediately preceding the month in which he/she is entitled to Medicare Part A and Part B.

Comment: Two commenters were opposed to the requirement in § 422.66(b)(3)(i) that disenrollment transactions be submitted within 15 days of receipt. Commenters pointed out

that we do not process disenrollments every 15 days and suggested the requirement be modified to coincide with the 30-day requirement for enrollment transactions outlined at § 422.60(d)(6).

Response: Our intent when establishing this requirement was to ensure that a beneficiary's choice to disenroll would be handled as expeditiously as possible. We are in the process of implementing a system that will be capable of processing these transactions more than once a month. However, we recognize that until the systems are modified, the requirement may not allow a sufficient amount of time to process a disenrollment action. Therefore, we have modified the regulations at § 422.66(b)(3)(i) to state that the time frame to submit disenrollment transactions will be "specified by HCFA," and have made a conforming change at § 422.66(f)(2). This will give us the flexibility to make changes as system enhancements are developed in the future. For the time being, we are specifying that disenrollment transactions be submitted within the same time frame as enrollment transactions.

Comment: Several commenters asked that we provide additional clarification in § 422.66(b)(5)(i) with respect to when an enrollment is not legally valid. Two of the commenters stated that we should clarify whether a lack of understanding would be included in the definition of a "legally valid enrollment," and whether it would result in a retroactive disenrollment. One commenter stated that we should clarify that an enrollment is not legally valid if it is determined at a later date that the individual did not meet eligibility requirements at the time of enrollment.

Response: There are a number of circumstances that would result in an enrollment not being considered "legally valid," and we agree that the lack of understanding of plan rules (such as the "lock-in") and ineligibility would be among these circumstances. However, a determination that an individual did not understand the terms of enrollment must be made on an individual basis. The criteria used in establishing evidence that an individual did not understand the terms of enrollment could include the following: continuing Medigap insurance coverage after receipt of the confirmation of enrollment letter from the M+C organization; an enrollment form signed by the member in situations where a legal representative should be signing for the member; enrolling in a supplemental insurance program immediately after enrolling in the M+C

plan; or receiving nonemergency or nonurgent services out-of-plan immediately after the effective date of coverage under the plan. OPL 99.100 sets forth specific guidelines to assist M+C organizations when making determinations about lack of understanding and incorrect eligibility determinations.

Comment: One commenter asked for clarification of our process for approving retroactive disenrollments (either voluntary or involuntary) and the subsequent effective dates.

Response: Section 422.66(b)(5) describes retroactive disenrollments, which are disenrollments with a retroactive effective date in cases in which we determine that there was never a legally valid enrollment, or in which a valid request for disenrollment was properly made but not processed or acted upon. In cases of involuntary disenrollments, such as disenrollment for disruptive behavior or failure to pay premiums, the disenrollment actions are prospective and would not be retroactive. In cases in which we find that an enrollment was not legally valid, the disenrollment results in cancellation of the enrollment as of the effective date of the enrollment. Therefore, the effective dates for these retroactive disenrollments are based upon the effective dates for elections, as provided under § 422.68. If the election subsequently found to be invalid was made during the annual election period in November, the effective date would be the first day of the following calendar year. If the election was made during an open enrollment period, the election would be effective the first day of the first calendar month following the month in which the election is made (or for elections made after the 10th day of a month, the first day of the 2nd calendar month following the date of the election). Effective dates for elections made during a special election period vary, dependent on the situation, and guidelines concerning these effective dates are provided in instructions to the M+C organizations. Elections made during special election periods for individuals age 65 would be effective the first day of the first calendar month following the month in which the election is made.

Comment: Section 422.66(d) states that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by "an" M+C organization. One commenter stated that this section needs to clearly state that the M+C organization must accept any individual who is enrolled in a health plan offered by "the" M+C organization

offering the other plan in which the individual is enrolled.

Response: We agree that the use of the term “an” could imply that the requirement applies to any organization, such that all M+C organizations must accept all eligible individuals enrolled in any commercial health plan offered by any M+C organization. In fact, our intent is for the requirement to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling. Therefore, we are revising § 422.66(d)(1) to specify that a plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by “the M+C organization.”

Comment: One commenter believes there is a conflict between paragraphs (3) and (5) in § 422.66(d). The commenter reads § 422.66(d)(3) to provide that the individual will convert to the M+C plan unless he disenrolls, while § 422.66(d)(5) provides that the individual must fill out an election form in order to convert.

Response: We do not agree that there is a conflict between the two sections of the regulation, but recognize that some clarification is desirable to prevent confusion. We are revising § 422.66(d)(3) of the regulation to refer to the individual affirmatively choosing to remain enrolled with the organization as an M+C enrollee, and to state that conversion is effective the month of entitlement to both Medicare Part A and Part B “in accordance with the requirements in section § 422.66(d)(5).” We also have deleted a reference in § 422.66(e)(2) to an individual being “deemed” to have made an election, since this reference is inconsistent with the requirement in § 422.66(d)(5) that an election form be completed and signed. These revisions will clarify that while we have established the effective date of coverage under § 422.66(d)(3), the coverage may begin only if the individual completes and signs an election form, as required at § 422.66(d)(5).

Comment: One commenter believes that § 422.66(e)(2) (which states that an individual is considered to have continued an election in an M+C plan until the M+C plan is discontinued or no longer services the area in which the individual resides, and the organization does not offer or the individual does not elect the option of continuing enrollment) may be interpreted to absolve the M+C organization of any obligations when the person leaves the service area and has not selected a new

health plan or original Medicare. The commenter suggested that the regulations should make clear that an individual who leaves his or her M+C plan service area is entitled to a special election period, as is the case when the M+C plan ceases to serve the service area.

Response: If an M+C plan enrollee leaves the plan’s service area, but has not informed the M+C organization offering the plan of a permanent move, the M+C organization does have continued obligations to cover emergency and urgent services that must be covered out of area. Once the M+C organization is made aware of such a permanent move, the organization is obligated under § 422.74(b)(2)(i) to disenroll the individual unless he or she has moved to a continuation area and requests to continue enrollment as a continuation area enrollee. With respect to the commenter’s concern about a special election period being provided under these circumstances, § 422.62(b)(2) clearly provides an M+C plan enrollee who moves out of his or her M+C plan service area with the same right to a special election period that the enrollee gets under § 422.62(b)(1), cited by the commenter, in the case of an M+C plan termination.

Comment: One commenter was concerned about ensuring that all enrollees under a section 1876 risk contract—without regard to residence—be deemed to be enrollees of an M+C plan offered by the section 1876 contractor on January 1, 1999.

Response: We agree, and note that the interim final rule preamble states that we have interpreted the statute to allow an individual to transition from the section 1876 plan to an M+C plan “without regard to location of residence” (63 FR 34977). Our intent was to ensure that no individual enrolled in a section 1876 plan on December 31, 1998, would be adversely affected by the BBA changes, but instead would be able to maintain an established relationship with a Medicare contracting organization. Therefore, we clarified in the interim final rule that all individuals enrolled in a section 1876 plan on December 31, 1998 could convert to the corresponding M+C plan on January 1, 1999. We further clarified this “grandfathering policy” in OPL 99.084, dated February 26, 1999, which states that an individual who was enrolled in a section 1876 risk plan effective December 1, 1998 or earlier and remained with the risk plan on December 31, 1998, automatically continued to be enrolled in the M+C organization on January 1, 1999.

Comment: One commenter suggested that we include in the regulations text our operational policy recognizing State laws that govern who may sign election forms for beneficiaries. The commenter also believes we should clearly incorporate recognition of the State law, including health care consent laws.

Response: In general, and as previously discussed in the preamble of the June 26, 1998 interim final rule, we believe that the M+C-eligible individuals should personally complete and sign any election form or disenrollment request (referenced at § 422.66(b)) whenever possible. We also recognize that there may be times that an individual is unable to sign for himself or herself. Laws governing who may sign a health insurance application vary from State to State. Therefore, while the regulations provide for the beneficiary to sign an election form, we defer to State laws (for example, laws governing the exercise of a power of attorney) on who may sign on behalf of a beneficiary where a beneficiary signature is required. We do not believe it is necessary to make provision for this in the regulations text, because where State law permits another individual to sign for a beneficiary with respect to health care decisions, this authority would extend to cases in which the beneficiary’s signature is required under Medicare regulations.

Comment: Section 422.66(d)(1) states that an M+C plan offered by an M+C organization must accept any eligible individual who is enrolled in a health plan offered by an M+C organization during the month immediately preceding the month in which the individual is entitled to Medicare Part A and Part B. One commenter asked us to clarify whether the use of the term “health plan” refers only to fully insured products, or whether the term would include self-funded members.

Response: The term “health plan” in § 422.66(d)(1) refers to any commercial health plan that the M+C organization offers. This may include fully insured products, self-funded products, and indemnity products.

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as of the first day of the month of entitlement to both Part A and Part B. Also, for an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year. For an election or change of election made during the open

enrollment periods described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made (except that if the election or change of election is made after the 10th day of a calendar month, the election takes effect on the first day of the second calendar month after the date of the election.)

For an election or change of election made during a special election period as described in § 422.62(b), we determine the effective date of coverage, to the extent practicable, in a manner consistent with protecting the continuity of health benefits coverage. For an election of coverage under original Medicare made during a special election period for an individual age 65 as described in § 422.62(c), coverage is effective as of the first day of the first calendar month following the month in which the election is made.

Comment: Several commenters objected to the effective date in the interim final rule for elections made during open enrollment periods, which was the first day of the month after the month the election is received. The commenters believe this effective date did not allow enough time to process the enrollment. They believed that this deadline would result in increased retroactive transactions and would be burdensome on M+C organizations. Commenters also expressed significant concerns over liability and access to services if Medicare entitlement is not verified expeditiously. Commenters also noted the need for us to make system changes to accommodate the new effective date requirements, and to clarify how we intend to implement the requirements with respect to M+C organization submission of data. The commenters recommended the effective dates be as they were under section 1876 of the Act which, under § 417.450(a)(2), may not be earlier than the first month after, nor later than the third month after, the month in which we receive the information necessary to include the beneficiary as a Medicare enrollee of the HMO or CMP in our records.

Response: Section 1851(f) of the Act supersedes all prior section 1876 requirements and specifically delineates the effective dates for elections made in the M+C program. Consistent with the changes to section 1851(f) of the Act made by section 502 of the BBRA, we are revising § 422.68(c) to provide that coverage is effective either on the first day of the calendar month after the date of an election or change of election or, for elections or changes of election made after the 10th day of a calendar

month, on the first day of the second calendar month after the date of the election or change of election. In addition, based on our authority to establish requirements that can reduce the potential for retroactive transactions, we have developed guidelines for M+C organizations that include requirements for M+C organization verification of Medicare entitlement before submission of enrollment data (see OPL 99.100). The verification policy should minimize the potential for retroactive enrollment situations. Additionally, the new effective dates outlined in section 1851(f) of the Act have resulted in the need to clarify a number of operational issues. While the expansion of managed care provisions under the BBA has presented an extraordinary challenge to us, we have successfully implemented the necessary systems requirements to support this change in effective dates. Additionally, we have issued other guidelines to M+C organizations (OPL 98.074, our November 17, 1999 Systems Informational Letter, and OPL 2000.113) that outline how to identify the correct effective date and process the enrollments through our systems.

Comment: Several commenters were concerned that the new effective date requirements will not allow the M+C organization to receive our confirmation of the enrollment before the effective date, which could in turn increase beneficiary confusion.

Response: Section 1851(f) of the Act clearly outlines the effective dates of enrollment in M+C plans. If an eligible individual has elected an M+C plan, the M+C organization must cover the individual beginning on the effective date of coverage, even if the organization has not yet received final confirmation from us. An M+C organization can take several actions to reduce the chance of beneficiary confusion, including verifying Medicare entitlement before submission of enrollment data to us. This should increase the likelihood that we will confirm the individual's enrollment.

Comment: One commenter stated that original Medicare should pay M+C organizations for services furnished to individuals for whom retroactive disenrollments were processed.

Response: If a retroactive disenrollment is processed for a beneficiary, the M+C organization in which the beneficiary was enrolled can always bill for Medicare covered services rendered to the beneficiary.

Comment: One commenter stated that the effective date of coverage for individuals who enroll during an open enrollment period (the first day of the first calendar month following the

month the election is made) is too rigid, and that delayed effective dates should be permitted.

Response: Again, section 501(b) of the BBRA provided for some relief in this regard by changing the effective dates for elections or changes in election made after the 10th day of a month. We also note that we have the authority under section 1851(f)(4) of the Act to establish effective dates for individuals who meet the condition for special election periods. We have provided for prospective effective dates for individuals electing benefits through their employer group health plans, and published this guidance on April 20, 1999 in OPL 99.087. We provided additional guidance on the effective dates of coverage for other special election periods authorized under § 422.62(b) in OPLs 99.098 and 99.100.

Comment: Two commenters questioned how M+C organizations will be expected to handle multiple transactions, given the new effective date requirements.

Response: As stated at § 422.50(b), an individual may not be enrolled in more than one M+C plan at any given time. Nevertheless, there are times when an individual will try to elect more than one plan for the same effective date, and it is not always clear with which plan the individual truly intends to be enrolled. On August 9, 1999, we issued OPL 99.100, which includes guidelines on what actions an M+C organization must take in the event of a multiple transaction in order to determine with which M+C plan the beneficiary should be enrolled.

Comment: One commenter stated that we should establish performance standards that take into account difficulties that we and M+C organizations will have in meeting effective date requirements.

Response: We recognize that section 1851 of the Act has resulted in significant changes to the Medicare program and that M+C organizations need time to prepare for the changes. We have provided additional guidance on implementation of M+C entitlement, eligibility, and elections to M+C organizations through various OPLs (98.072, 98.073, 99.083, 99.084, 99.087, 99.098, 99.100, 99.104, 99.105, 99.109, and 2000.113) and a November 17, 1998 Systems Informational Letter. These letters outline how to identify the correct effective date, how to process enrollments with the new effective dates, how to transition from section 1876 to M+C enrollment and disenrollment rules, and when grandfathered members must be disenrolled from M+C plans. As a result,

we believe we have given adequate time to modify operations and systems to implement the new M+C program. In addition, we continue to develop guidelines for M+C organizations on M+C entitlement, eligibility, and elections to M+C organizations. Any monitoring of performance will take into account the time M+C organizations have needed to implement the new program.

9. Disenrollment by the M+C Organization (§ 422.74)

The general rule for disenrollment by the M+C organization is that an M+C organization may not disenroll an individual from any M+C plan it offers; or request or encourage (orally or in writing, or by any action or inaction) an individual to disenroll. However, § 422.74(b) describes the conditions under which the M+C organization may either be permitted or required to disenroll an individual. Under § 422.74(b)(1), the M+C organization may choose to disenroll an individual based on that individual's (1) failure to pay premiums, (2) disruptive behavior, (3) provision of fraudulent information on his or her election form, or (4) having permitted his or her enrollment card to be abused. Section 422.74(b)(2) requires the M+C organization to disenroll the individual if the individual no longer resides in the M+C plan's service area, the individual loses entitlement to Medicare Part A or Part B benefits, or the individual dies. The M+C organization must follow the procedures specified at § 422.74(c) and (d) when disenrolling an individual. The procedures to be followed and the consequences of the disenrollment vary depending upon the cause of the disenrollment.

Comment: One commenter believes that the 90-day grace period that must be afforded to an enrollee before a disenrollment for nonpayment of premium could be financially burdensome in 1999 since ACRs that did not necessarily reflect these costs were filed before the M+C regulations were published.

Response: We recognize that 1999 was a transition year with many new requirements. With respect to 2000, however, M+C organizations were fully aware of all regulatory requirements before filing their ACRs.

Comment: Several commenters believed that the 90-day grace period for nonpayment of premiums is too long. Two commenters recommended a 30-day grace period rather than the 90-day grace period. They noted that if an organization has to wait 90 days before disenrolling an individual, this

potentially results in 4 months without the organization receiving payment, since organizations do not send notice to beneficiaries until the beginning of the month after payment is due. One commenter recommended that grace period extend until the last day of the third month following the date payment is due.

Response: Section 1851(g)(3)(B)(i) of the Act requires us to provide for a "grace period" before enrollment can be terminated for nonpayment of premiums. In determining the grace period, we adopted the grace period that Congress provided for in section 1836(b)(2) of the Act with respect to a termination for nonpayment of premiums for Supplementary Medical Insurance Benefits for the Aged and Disabled (that is, Part B). This results in consistent standards between the M+C program and the original Medicare program.

Comment: Several commenters believe that M+C organizations should be permitted to allow an enrollee to remain enrolled and eliminate only optional benefits if a member fails to pay premiums charged for such optional benefits. Some commenters believe that the option to disenroll for nonpayment of premiums implied that an organization could only disenroll the beneficiary from the plan, and could not simply eliminate the optional benefits. One commenter questioned whether under our rules, it might be necessary to disenroll the individual and re-enroll them as a "standard option" enrollee to accomplish this.

Response: We agree that providing the M+C organizations the option to retain an enrollee while eliminating an optional benefit for which premiums are not paid is a desirable and appropriate means of promoting continuity of care for beneficiaries. We are adding a provision to § 422.74(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.

Such an action would not affect the beneficiary's status as a member of the M+C plan, and would not constitute a new election. Therefore, the M+C organization does not have to formally disenroll and re-enroll the individual when downgrading the member's enrollment to the standard benefit package because the beneficiary fails to pay the plan premiums.

Comment: One commenter recommended that the M+C organization should be required to send notice to enrollees that premium payment is overdue within 10 days,

rather than 20 days. Another commenter supported the 20-day time frame.

Response: Section 1856(b)(2) of the Act provides for the use of standards established under section 1876 to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Section 417.460(c)(1)(iii) requires section 1876 contractors to send notices of disenrollment for nonpayment of premiums to the enrollee before it notifies us. In addition, § 417.460(c)(1)(i) requires that the contractor demonstrate to us that it made reasonable efforts to collect the unpaid amount. Section 422.74(d)(1) of the M+C regulations carries over both of these requirements and clarifies that "reasonable efforts" include sending a notice of nonpayment to the beneficiary within 20 days after the date the payment was due. The notice advises the beneficiary that he or she has 90 days from the date of the notice to provide payment. We continue to support this policy and believe that 20 days is a reasonable maximum time frame within which to make an effort to collect unpaid premiums. We note that an M+C organization may notify the individual as soon as the premium payments are past due (that is, send a notice before 20 days have passed), in which case the 90-day grace period would begin on the day the M+C organization sends the notice.

Comment: One commenter requested clarification of the effective date of disenrollments for nonpayment of premiums following the 90-day grace period. The commenter asked that we clarify for how long the organization is obligated to provide benefits and we will continue to pay capitation.

Response: The effective date of disenrollment for nonpayment of premiums is the first day of the month after the 90-day grace period ends.

The M+C organization must continue to provide benefits and we will continue to pay capitation until the disenrollment is effective. We clarified this policy in OPL 99.100, issued on August 9, 1999. We note that § 422.74(d)(1) erroneously refers to the possibility of disenrollment for an individual who fails to pay any "basic or supplementary premiums." Section 1851(g)(3)(B)(i) of the Act refers to "basic and supplementary premiums" and we are revising the regulations accordingly.

Comment: Two commenters requested clarification regarding the standards for disenrollment for disruptive behavior under the Health Insurance Portability and Accountability Act (HIPAA) and

BBA, unsure if the two statutes were in conflict in this area.

Response: For any issues for which there is a perceived conflict in the disenrollment standards established under the BBA (or the BBRA) and those established under HIPAA, the BBA standards (that is, the standards in § 422.74 pursuant to section 1851(e) of the Act) would control for M+C purposes.

Comment: One commenter recommended that disenrollments for fraud and abuse should include other fraudulent activities related to the delivery of health services, such as visiting multiple doctors for the purpose of obtaining specific drugs and/or using another enrollee's membership card when benefits have been exhausted.

Response: As noted above, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. The regulations in section 1876 of the Act addressing disenrollments for fraud and abuse at § 417.460(d) have been largely adopted in § 422.74(d)(3), which permits disenrollment of a beneficiary for providing fraudulent information that affects eligibility to enroll or for permitting others to use his or her enrollment card to obtain services. Manual instructions implementing § 417.460(d) further clarified that any abuse relating to a membership card was included as a ground for disenrollment. Thus, using another member's card would constitute grounds for disenrollment, just as would loaning someone else a card. With respect to the commenter's other example about multiple visits to physicians to obtain drugs, an M+C organization's utilization review system should be able to identify these abuses.

Comment: One commenter requested that we add clarification regarding when a disenrollment is effective in cases of fraudulent behavior.

Response: Disenrollment of an individual who has committed fraud or who permits the abuse of his/her enrollment card is effective the first day of the calendar month after the month in which the M+C organization gives the member the written notice of his/her termination.

Comment: One commenter is concerned that our process for making disenrollment decisions related to disruptive behavior would result in numerous retroactive disenrollment situations. The commenter suggested that we clarify or revise the regulation to assure that any effective dates for

disenrollment be prospective in situations where an individual is being disenrolled for disruptive behavior.

Response: Section 422.74(d)(2)(v) establishes procedures for our review of an M+C organization's proposed disenrollment of an individual for disruptive behavior. Under these procedures, we review documentation submitted by the M+C organization within 20 working days, and notify the organization within 5 working days of whether it may disenroll the individual. Section 422.74(d)(2)(vi) then states that if we permit the disenrollment for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the M+C organization gives the individual written notice of the disenrollment. Since these procedures do not allow an M+C organization to disenroll an individual for disruptive behavior until after we have approved the disenrollment, we believe the process provides only for prospective disenrollments.

Comment: Several commenters believe that 12 months is too long to wait before disenrolling an individual for being permanently out of the service area. Many commenters are concerned that the beneficiary will be able to receive only urgent and emergency care during this time, and that 12 months is too long without routine and coordinated care. They made several recommendations. One commenter recommended that 6 months would be reasonable to cover those individuals who live in different parts of the country during the year, while still maintaining contact with the primary care physician for preventive care. Two commenters recommended maintaining past policy of disenrollment of members that move outside of service area for more than 90 days, unless the plan has an affiliate. Another commenter also supported a return to a 3-month time frame. One commenter requested clarification regarding the requirements for disenrolling members from M+C organizations if they move permanently before the 12 months have expired. The commenter believes that if the request to disenroll was written or other acceptable evidence was presented, the M+C organization may disenroll the individual from the plan.

Response: We must first clarify that if an M+C organization determines that an individual has *permanently* left the service area of the M+C plan, it must disenroll the individual from that plan regardless of whether 12 months have passed, unless the individual chooses a continuation of enrollment option. This is outlined at §§ 422.74(b)(2)(i) and

422.74(d)(4). However, we believe that this point may not be entirely clear in the existing regulations and thus we are revising § 422.74(d) to specify that an individual who has "permanently" moved out of a plan's service area must be disenrolled. Note that this disenrollment requirement also applies to individuals who are enrolled in a plan under the expanded seamless conversion option for former commercial plan enrollees that is now set forth at §§ 422.50(a)(3)(ii) and (a)(4). That is, should the individual change his or her residence, he or she would be treated the same as any other enrollee who moves to a residence outside of the service area.

The 12-month rule set forth under existing § 422.74(d)(4) establishes the time limit for how long an individual who has left the service area on a temporary basis may remain a member of the M+C plan. That is, an M+C organization must disenroll an individual who has not permanently changed his or her address but has been out of the service area for over 12 months.

After considering the comments on this provision, we agree that 12 months is too long for a beneficiary to have access only to emergency and urgently needed care (based on our operational policy that when a member is out of the service area, the M+C organization is required to cover only emergency and urgently needed care). Therefore, we are further revising § 422.74(d)(4) to state that the M+C organization must disenroll an individual, unless he or she chooses the continuation option, if the individual leaves the plan's service area on a nonpermanent basis for over 6 months. This change is within the parameters of the previous requirement under section 1876 of the Act which, as provided in § 417.460(f)(2), allowed an uninterrupted absence from the geographic area for more than 90 days but less than 1 year. However, we believe it is appropriate to extend the time frame from 90 days to 6 months to accommodate the many beneficiaries who leave the service area for seasonal periods each year, which often last more than 90 days, but rarely more than 6 months.

We note that on August 9, 1999, we issued OPL 99.100, specifying that: (1) If an M+C organization receives notice of a permanent change of address from the member (or member's legal representative) at any time, then it must disenroll that individual from the plan if that change of address is outside the M+C plan's service area unless the member chooses the continuation of enrollment option; and (2) if a member

leaves the service area of the plan, then the M+C organization must disenroll the member if the absence extends beyond 12 months (now, 6 months).

Comment: One commenter asked whether an M+C plan can provide out-of-area coverage in excess of that required by Medicare for only part of the 12-month period when a member is out of the M+C plan's service area.

Response: We allow M+C organizations the flexibility to develop programs to continue benefits for those members who temporarily leave the service area. We have developed operational policies regarding visitor programs. Again, note that revised § 422.74(d)(4) requires an M+C organization to disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area, for over 6 months.

Comment: One commenter asked for clarification of the effective date when an individual is disenrolled for being out of the area for over 12 months.

Response: Consistent with the change in § 422.74(d)(4), the effective date of disenrollment if a member is out of the area and has not informed the M+C organization that the move is permanent will be the first day of the calendar month after the 6 months has passed, and after appropriate written notice has been provided to the member. If the M+C organization is made aware of a permanent move out of the service area, disenrollment is effective the first day of the calendar month after the date the member begins residing outside of the M+C plan's service area, and after written notice has been provided to the member.

Comment: One commenter recommended that § 422.74(d)(7), which provides for disenrollment when a plan terminates services in the area in which the enrollee resides, explicitly states that disenrollment is automatic in this case.

Response: The effective date of a disenrollment based on an M+C plan termination or reduction in service area is the date that the M+C plan termination is effective, and disenrollment is automatic. Beneficiaries would have already received advance notice of such a termination as part of the nonrenewal requirements in § 422.506(a)(2). Accordingly, we have revised § 422.74(d)(7)(ii) to reference the time frames in § 422.506(a)(2).

Comment: One commenter recommended that notices for involuntary disenrollments should be mailed to individuals authorized to

make elections on behalf of an enrollee as well as the enrollee.

Response: In general, and as indicated by our requirement that the beneficiary complete and sign the M+C enrollment form, we believe that an M+C-eligible individual should personally complete and sign any election form or disenrollment request whenever possible. If for some reason a beneficiary is unable to sign the election form and needs a surrogate, we defer to State law on who may sign for other persons. Legal representatives of such individuals who authorize the election of an individual must also sign the election form and specify their relationship with the enrollee. In instances of involuntary disenrollment, notifications of disenrollment occur before any action is taken, to ensure that the individual has adequate time to review his or her health care options. Since the legal representative has identified him/herself to the M+C organization, the M+C organization should ensure that both the legal representative and the enrollee subsequently receive, in a timely manner, any important information provided by the M+C organization related to the health care decisions of the beneficiary.

Comment: One commenter is concerned that the time frames for our review of an M+C organization's proposed disenrollment for disruptive behavior (20 working days for a determination and the subsequent 5 days to notify the M+C organization) are too long. The commenter believes that 5 days is reasonable for us to make our determination.

Response: Again, section 1856(b)(2) of the Act provides for the use of section 1876 standards to implement analogous provisions of the M+C statute when those standards are consistent with standards established in the BBA for the M+C program. Regulations at § 417.460(e)(5), which set forth the requirements for our review of an HMO's or CMP's proposed disenrollment for cause, addressed this issue. Under § 417.460(e)(5)(ii), we make this decision within 20 working days after receipt of the documentation material and notify the HMO or CMP within 5 working days after making our decision. We see no reason not to retain this standard under the M+C program, and have done so in § 422.74(d)(2)(v)(B). We believe that this period of time ensures that we can conduct a thorough review of all documentation submitted by the M+C organization and the beneficiary.

Comment: With respect to an M+C organization termination of an enrollee

for disruptive behavior, one commenter asked for clarification of the process. For example, the commenter wanted to know who makes the determination, what appeal rights the beneficiary has, the time frame for a determination, and whether the beneficiary stays in the plan during the review of a determination. The commenter also asked if there is a possibility of coverage days lost while we are making the decision, and whether premiums would be refunded if the beneficiary is disenrolled.

Response: The M+C organization must make a serious effort to resolve the problems presented by the beneficiary, which includes the use of the M+C organization's grievance procedures. The M+C organization must notify the beneficiary of its intent to request such a disenrollment, as well as the beneficiary's rights under the M+C organization's grievance procedures. As described above, the final decision regarding the determination of disruptive behavior is made by us, as provided by § 422.74(d)(2)(v), which outlines our review authority of the M+C organization's proposed disenrollment. After reviewing the documentation submitted by the M+C organization and any information submitted by the beneficiary, we decide whether the M+C organization has met the disenrollment requirements. Until the disenrollment is effective, the beneficiary will continue to receive services from the M+C organization. Any premiums or other charges paid for coverage after the effective date would be refunded to the beneficiary; however, the beneficiary would be liable for the original Medicare cost-sharing and permitted balance billing in the case of any Medicare covered services provided by the M+C organization after the effective date of the disenrollment.

Comment: One commenter requested clarification regarding when to send out notices for disenrollments for cause.

Response: The basic requirement for notices is provided at § 422.74(c), which states that for any optional or required disenrollment (other than death or loss of entitlement), the organization must give the individual written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll. The notice must be mailed to the individual before submission of the disenrollment notice to us. Please note that we have amended §§ 422.74(c)(1) and (c)(2) to clarify that these notice provisions do not apply for disenrollments resulting from plan terminations or reduction of service or continuation areas, since there are no grievance rights provided in these

situations. The notice requirements for plan termination are outlined in §§ 422.74(d)(7) and 422.506(a)(2).

Comment: One commenter noted that § 422.74 only provides the opportunity for an individual to express a grievance to the M+C organization for an enrollment or disenrollment decision. The commenter believes that we should allow these decisions to be appealed because such decisions should not be left to the M+C organization.

Response: We agree with the commenter that decisions to disenroll for fraud or disruptive behavior should not be left solely to the M+C organization, which is why the regulations, at §§ 422.74(d)(2)(iv) and (3)(iii) provide for our role in these cases. However, in other cases, we believe that beneficiaries will be well-protected from a potentially wrongful disenrollment by the internal grievance procedures of the M+C organization. An M+C organization's decision to disenroll an individual does not meet the regulatory definition of an organization determination and thus, by definition, is not an issue that is eligible for the M+C reconsideration process.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

Section 1851(h) of the Act outlines the requirements related to marketing by M+C organizations. These provisions are implemented in § 422.80 of the interim final rule. Section 422.80(a) implements the requirements in section 1851(h)(1) that all marketing material and application forms be submitted to us for approval 45 days before distribution, and that such materials may be used only if we do not disapprove such use by the end of the 45-day period. Section 422.80(b) defines the "marketing materials" that must be submitted for approval. We note that we have made a minor revision to this regulation to reflect the fact that HCFA does not review newsletters as marketing material. The reference to newsletters was included in the interim final rule because it appeared in the part 417 regulations governing marketing by section 1876 contractors. In fact, HCFA did not treat newsletters as marketing materials in the case of section 1876 contractors, and there was no intent in the interim final rule to change HCFA's practice on this point. The interim final rule thus should not have included the reference to newsletters, and we are correcting our error in doing so.

Section 1851(h)(2) of the Act requires that the M+C standards include guidelines for review of marketing materials and requires that the guidelines provide that the Secretary

will not approve materials that are inaccurate or misleading. Section 422.80(c) establishes the guidelines for our review of marketing materials.

Consistent with the provision in section 1856(b)(2) of the Act for use of existing section 1876 standards, the guidelines in § 422.80(c) include existing marketing guidelines for HMOs and CMPs (from § 417.428), which have been in effect since the inception of the Medicare risk contract program.

Section 1851(h)(3) of the Act provides that if we have not disapproved the dissemination of marketing materials or forms with respect to an M+C plan in an area, we are deemed not to have disapproved the distribution in all other areas covered by the M+C plan and M+C organization except with regard to any portion of the material or form that is specific to the particular area. This "deemed approval" or "one-stop shopping" provision is implemented in § 422.80(d).

Section 1851(h)(4) of the Act provides that M+C organizations shall conform to "fair marketing standards" and requires that the fair marketing standards prohibit organizations from providing cash or other monetary inducements for enrollment. Section 422.80(e) outlines the fair marketing standards provided for under section 1851(h)(4) of the Act, and includes existing section 1876 standards as provided for in section 1856(b)(2) of the Act.

Finally, § 422.80(f) specifies that we may permit M+C organizations to develop and distribute marketing materials specifically designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization. Although these materials must be submitted for approval under § 422.80(a), we do not review portions of these materials that relate only to employer group benefits, rather than to M+C plan benefits.

The public comments that addressed marketing issues governed by § 422.80 are discussed below.

Comment: Two commenters suggested that we consider lengthening the review and approval processing time for marketing material from 45 days to either 60 or 90 days. The commenters believe that we need additional time to perform adequate review of marketing material submitted by M+C organizations. Another commenter suggested that the processing time be reduced to 14 days and the deemed approval time period be 30 days. The commenter asserted that M+C contractors must complete obligations within 14–30 days; therefore, we should be held to the same standard. The

commenter also stated that 45 days for approval of marketing material is too long for effective marketing or to correct misinformation in the press.

Response: As noted above, section 1851(h)(1) of the Act establishes a 45-day limit for our review and approval of marketing materials. That is, absent our disapproval of such materials, the statute permits an M+C organization to distribute marketing materials 45 days after submitting the materials for review. Since any materials that are not affirmatively "disapproved" are effectively "approved" for distribution, we recognize the importance of completing our review of all marketing materials within 45 days. Accordingly, we are evaluating our marketing review procedures to identify ways we can promote greater efficiency in the marketing review process. We do not believe that reducing the marketing review and deemed approval periods would allow our staff adequate time to ensure that marketing material is accurate and not misleading to potential enrollees and beneficiaries.

Comment: Many commenters expressed concern regarding inconsistent review and treatment of marketing material by our different regional offices. A few commenters recommended that we consider centralized review of marketing material to promote greater consistency across the regions and central office. Several commenters also suggested that we require standard language and at a minimum, 12-point print, in all M+C marketing materials.

Response: We understand the concerns of M+C organizations regarding uniform application of marketing review and guidelines. To address these concerns, we have convened a team of representatives from our 10 regional offices and our central office that is responsible for addressing marketing issues which arise in policy and operationally. We recognize that centralized review may promote more consistent application of marketing review policy, and we are currently evaluating the feasibility of such review. Although we want to provide M+C organizations with the flexibility to develop marketing material that will distinguish their products and services from other organizations, we also believe that standardizing M+C marketing materials will facilitate beneficiary use and choice. Thus, we have taken steps to standardize beneficiary materials. Pursuant to our authority under § 422.80(c)(1) to require the use of "a format * * * and * * * standard terminology * * * specified by HCFA," we required M+C

organizations to use a standardized Summary of Benefits format in describing their 2000 benefits, beginning in the fall of 1999. This Summary of Benefits provides beneficiaries with information on M+C plans that is standardized in terms of format, language, and content. We also plan to identify other beneficiary notification materials for which standardization will be required. The current marketing guide already directs M+C organizations to use 12-point print. M+C organizations can obtain the marketing guide from our website (www.hcfa.gov).

Comment: One commenter suggested that we clarify that documents developed by pharmacies to conduct pharmacy compliance programs are not marketing and promotional materials. Another commenter recommended that we clarify that marketing materials intended to promote the M+C organization (distinct from its Medicare contracting function) should not be subject to the marketing review process.

Response: To the extent that “pharmacy compliance” documents are directly related to health care or quality, we do not review them as marketing materials. On the other hand, if the “pharmacy compliance” materials are used to market the program in pre-enrollment marketing materials and advertisements, we treat them as marketing materials subject to our review and verification.

We do not review materials that are directed solely at an HMO’s commercial population. However, we believe that any materials targeted at the Medicare population, and designed to inform beneficiaries about benefits, or encourage beneficiaries to enroll or remain enrolled, should be subject to our review on their behalf. Thus, we are retaining the provision under § 422.80(b)(1) that calls for review of materials that “promote the M+C organization.”

Comment: A few commenters, particularly those providing services in rural areas, urged that we require M+C organizations to include a list of subcontracted providers in their pre-enrollment marketing material. Others suggested that we require organizations to include a list of participating providers in their marketing materials.

Response: We understand that provider directories are generally available at sales presentations or when a beneficiary visits the M+C organization. Thus, we do not think it is necessary or appropriate to mandate that an M+C organization identify subcontractors or furnish provider directories in general marketing

materials or sales kits. We note that § 422.80(c)(1) directs M+C organizations to provide Medicare beneficiaries interested in enrolling in an M+C plan with a written description of plan rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges. M+C organizations also must meet the detailed disclosure requirements outlined in § 422.111, which include informing enrollees of the “number, mix, and distribution (addresses)” of available providers. We believe that these requirements adequately address beneficiary information needs.

Comment: Several commenters requested that we define “significant non-English speaking population.” One commenter recommended that 5 percent of the Medicare-eligible population be the standard, while another recommended a standard of 25 percent.

Response: Section 422.80(c)(5) of the interim final regulation requires, for markets with a significant non-English speaking population, that M+C organizations provide marketing materials in the language of these individuals. The term “significant” can refer to either the number or percentage of the affected population. We note that the Office for Civil Rights within the Department of Health and Human Services is responsible for implementing standards and providing guidance concerning the obligations of Federal fund recipients (such as M+C organizations) to provide language assistance to individuals who have limited English proficiency. As more information becomes available to HCFA, we will provide further guidance on M+C organizations’ responsibility in this regard.

Comment: Some commenters asked that we clarify the role of physicians in the marketing of M+C products to their patients. The commenters also requested further guidance regarding whether physicians are allowed to counsel patients about their health insurance choices. Commenters both supported and opposed allowing physicians to advise potential enrollees and beneficiaries about M+C plan options.

Response: We agree that the role of physicians should be clarified. Accordingly, we are amending the standards for marketing to add a new § 422.80(e)(1)(vi) that permits provider groups and individual providers to distribute health plan brochures (exclusive of applications) at a health fair or in their own offices. Physicians may discuss, in response to an individual patient’s inquiry, the various

benefits in different health plans. While this discussion is entirely appropriate within the doctor-patient relationship, M+C organizations may not use providers/provider groups to distribute printed information comparing the benefits of different health plans, unless the materials have the concurrence of all organizations involved and have received prior approval from us. Physicians and other providers may not accept plan applications. We also are adding a new § 422.80(e)(1)(vii) that prohibits M+C organization representatives from accepting applications in provider offices or other places where health care is delivered.

Comment: One commenter recommended that we revise § 422.80(c)(4) to reflect a statutory reference in section 1851(h)(2) of the Act to marketing material that is “materially inaccurate or misleading or * * * makes a material misrepresentation.” The commenter believed that the omission of the term “material” creates a more stringent standard of review than that intended by Congress.

Response: We concur with this recommendation. As noted, section 1851(h)(2) states that “the Secretary shall disapprove * * * such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.” Therefore, we are modifying § 422.80(c)(4) to read as follows: “In reviewing marketing material or election forms under paragraph (a) of this section, HCFA determines that the marketing materials: * * *. (4) are not materially inaccurate or misleading or otherwise make material misrepresentations.” This language is more consistent with the standard outlined in the statute, and we believe it can help avoid delays in the review and approval of marketing materials for immaterial or irrelevant errors.

Comment: Commenters also requested further guidance regarding the permissibility of offering “value-added services” to beneficiaries.

Response: In general, “value-added items and services” (VAIS) are items or services offered to beneficiaries by an M+C organization that do not meet the definition of a benefit as stated in § 422.2; that is, benefits are health care services for which the M+C organization incurs a cost under the M+C plan that are submitted and approved through the ACR process. Examples of VAIS may include but are not limited to discounts in restaurants, stores, entertainment, or travel; they could also include discounts on health club memberships and on insurance policy premiums.

Because VAIS do not constitute a benefit under the M+C program, neither the actual costs of the VAIS nor associated administrative costs may appear in the ACR, nor are they subject to the Medicare appeals process. Nonetheless, VAIS may be of value to some enrollees, and we do not wish to deprive M+C enrollees of access to items and services commonly available to commercial enrollees. Therefore, M+C organizations may offer VAIS to Medicare enrollees, but materials describing VAIS must clearly distinguish between VAIS and M+C benefits, including clarifying that VAIS are not subject to the M+C appeal procedures. VAIS may not appear in the Beneficiary Information Form or the Plan Benefit Package. Further, VAIS may not be described in Medicare Compare, the Medicare and You handbook, or the Standardized Summary of Benefits. We will provide further guidance regarding VAIS in a forthcoming OPL.

Comment: One commenter inquired if the prohibition of monetary rebates to induce enrollment applies to the distribution of coupons.

Response: Cash or monetary rebates, including coupons that have more than a nominal cash value (if converted to cash) are prohibited under § 422.80(e)(1)(i). This prohibition does not apply to items of nominal value (\$10 or less). The coupons, or the combined value of the coupons, must not exceed the nominal value standard. Coupons that offer discounts on premiums or copayments are not permitted, because they would violate the “uniform premium” provisions of the statute, as outlined in § 422.304. If coupons are for VAIS in excess of nominal value, they cannot be distributed or advertised pre-enrollment. However, these coupons may be used after enrollment.

Comment: Commenters objected to the fact that the regulations are silent regarding the consequences if an M+C organization violates the marketing standards. Two commenters recommended that we begin retrospective review of marketing materials, and pull the advertising campaign for those found to be egregiously inaccurate. Similarly, another commenter suggested that we nonrenew or terminate contracts with organizations that are substantially out of compliance with the marketing regulations.

Response: We recognize that marketing material distributed by M+C organizations must be accurate and not misleading to potential enrollees, and that M+C organizations should be subject to sanction for a substantial

failure to comply with marketing rules. We accordingly are adding a new § 422.510(a)(12) to specify that a substantial failure to comply with marketing guidelines is a ground for termination, and thus also a ground for nonrenewal or intermediate sanction (consistent with §§ 422.506(b)(1)(iii) and 422.572(b)).

Comment: Several commenters requested that we provide additional guidance regarding the documentation necessary to demonstrate that marketing resources are allocated for marketing to both the disabled and beneficiaries age 65 and over.

Response: Section 422.80(e)(2)(i) requires M+C organizations to demonstrate to our satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over. We plan to issue further guidance on this issue but, until then, we expect organizations to adopt their own procedures to implement these provisions. As a starting point, organizations may consider developing a formal marketing strategy that considers the needs of persons with disabilities and consulting with disability advocacy groups and outreach programs. We expect M+C organizations to avoid developing plans that could discourage the enrollment of persons with disabilities through the imposition of unusually large cost-sharing requirements for items and services frequently used by the disabled. M+C organizations are also expected to make their marketing materials accessible to persons with disabilities (including, for example, through use of alternative formats), and to establish mechanisms for making their marketing sessions accessible to the disabled Medicare population. Also, as discussed further in section II.C of this preamble, M+C organizations must comply with other applicable Federal statutes, including the Americans with Disabilities Act.

Comment: One commenter recommended that we revise or delete the heading “Employer Group Retiree Marketing” in § 422.80(f) to reflect marketing to Medicare-eligible employees of the employer.

Response: We believe that “Employer Group Retiree Marketing” is an appropriate heading. This provision addresses only marketing materials geared toward retirees of an employer group that reflect non-Medicare benefits offered to group members by that employer. These retirees generally would include individuals who have retired based on a disability rather than age. Thus, a reference to “retirees” is not necessarily limited to the over-65

Medicare market. Moreover, this provision in no way limits an M+C’s obligation to market to both disabled and over-65 beneficiaries, both in a retiree group and otherwise.

Comment: Some commenters requested further clarification regarding the review of marketing material developed by employers for purposes of employer group marketing. One commenter inquired whether we will definitely permit M+C organizations to develop marketing materials for employer groups. Presently, § 422.80(f) states that we “may” permit M+C organizations to develop marketing materials for employer groups.

Response: Although we will not review all the specific benefits offered by the employer group, we will review those items that fall within the disclosure requirements of § 422.111. Further, we agree that the wording of § 422.80(f) may be unclear; thus we are revising the regulation to: (1) Specify that M+C organizations are permitted to develop marketing materials for employer groups; and (2) clarify that we will not review those portions of such marketing materials that relate solely to employer group benefits.

Comment: One commenter questioned whether it is appropriate to allow the term “senior” or the number “65” to appear in the name of an M+C plan. The commenter stated that including these terms could discourage some beneficiaries from enrolling in a particular M+C plan.

Response: We recognize that certain plan names may discourage enrollment by disabled beneficiaries. Accordingly, pursuant to our authority under section 1851(h)(4) of the Act to establish marketing standards, we have added a new § 422.80(e)(1)(viii) that will prohibit M+C plan names that suggest that a plan is available only to Medicare beneficiaries age 65 or over, rather than to all beneficiaries. This prohibition generally bars plan names involving terms such as “seniors,” “65+,” etc. In fairness to M+C organizations with an existing investment in a plan name, we are “grandfathering” existing M+C plan names, that is, plan names established before this final rule takes effect.

Comment: One commenter believes that tax dollars should not be spent on insurance counseling and assistance programs, such as State Health Insurance Assistance (SHIP) or Information Counseling and Assistance (ICA) programs. In the commenter’s view, there are less expensive and better alternatives, such as licensed insurance agents. The commenter asserted that the licensure of these individuals assures public accountability, and that the

insurance professional is the best alternative for providing consumer information and expertise about the new M+C options. On the other hand, several commenters recommended that we not permit independent marketing agents to sell M+C products to potential enrollees.

Response: We believe that SHIPs and ICA programs are valuable, objective, and necessary resources for Medicare beneficiaries. These programs provide one-on-one counseling to beneficiaries on many complicated insurance issues and provide essential links to other important services and programs available to beneficiaries. SHIPs provide a service through a network of 10,000 trained volunteers. In addition, these programs effectively network with other key partners such as insurance carriers, departments of social services, and legal service agencies. SHIPs are able to provide assistance related to a broad spectrum of Medicare issues, and are required to conduct their programs with impartiality and confidentiality. While we strongly support these programs, which have been extremely valuable in educating beneficiaries on the new M+C provisions, we will continue to explore additional information mechanisms to ensure that beneficiaries receive information in the most efficient and effective manner.

We recognize that independent insurance agents may be able to provide a necessary service to Medicare beneficiaries who are considering enrolling in the M+C program. In the past, our position has been to strongly discourage, but not prohibit, Medicare managed care organizations from employing independent insurance agents to sell their products. Recently, we have engaged in extensive consultations on this issue with the DHHS Office of the Inspector General, and we intend to issue guidance to M+C organizations in the near future regarding the parameters for the participation of independent agents in marketing M+C plans.

C. Benefits and Beneficiary Protections

1. Introduction

Subpart C of these regulations details the scope of benefits a Medicare beneficiary is entitled to receive when electing coverage through an M+C plan, as well as establishing a number of beneficiary protections in areas related to access rules, enrollee notification requirements, confidentiality and others. The statutory authority for most of the provisions of subpart C is found in section 1852 of the Act, which outlines benefit requirements and

provides authority for beneficiary protections under Medicare Part C. Many of the statutory provisions are the same as, or similar to, benefit provisions of section 1876 of the Act. Therefore, much of the regulatory language of part 417 is retained for purposes of establishing M+C standards, as provided for in section 1856(b)(2) of the Act (which provides for basing M+C standards on section 1876 standards implementing analogous provisions, where consistent with Part C).

All M+C organizations are required to cover the full range of Medicare benefits that are available under original Medicare to beneficiaries in the area who are not enrolled in an M+C plan, subject to certain rules regarding an accessible network of providers. M+C organizations are further required to cover Medicare preventive benefits with the same frequency that they are covered under original Medicare (for example, annual screening mammography examinations). Beneficiaries may be required to contribute to the cost of covered services in the form of cost sharing provided for under the M+C plan. Beneficiaries may have to cover all costs until a deductible is met (including the high deductible provided for under an MSA plan—see section III of this preamble), a percentage of costs in the form of coinsurance, or a fixed amount for services, in the form of a copayment. As discussed in section II.G below, there are limits that apply to the cost sharing that can be imposed on beneficiaries under M+C plans. For benefits that are covered under original Medicare, the benefits must be obtained through providers meeting the conditions of participation of the Medicare program.

This section of the preamble mainly discusses the requirements for network plans. Sections III and IV of the preamble provide more extensive information about benefit requirements applicable to non-network M+C MSA plans and to private fee-for-service plans, respectively. Organizations with network plans, which include coordinated care plans and network M+C MSA plans, are permitted to restrict enrollees to a specified network of providers in the case of non-emergency/urgent services if they have a network in place to provide these services directly or through arrangements (that is, written agreements with providers) that meet the availability and accessibility requirements of section 1852(d)(1) of the Act and § 422.112, discussed below.

2. Emergency, Urgently Needed, and Post-Stabilization Care Services (§§ 422.2, 422.100, 422.112, and new § 422.113)

In some situations, an M+C organization is required to assume liability for services provided to Medicare enrollees through noncontracting providers. In particular, under § 422.100(b), the organization is required to assume financial responsibility for the following items and services obtained from a provider that does not contract with the M+C organization:

- Emergency services;
- Urgently needed services;
- Renal dialysis services provided while the enrollee was temporarily outside the M+C plan's service area;
- Post-stabilization care services; and
- For both network and non-network plans, services denied by the M+C organization and found upon appeal (under subpart M of this part) to be services the enrollee was entitled to have furnished or paid for by the M+C organization.

The requirements that the M+C organization assume financial liability for renal dialysis services and post-stabilization care are new requirements introduced by the BBA that were not included in the requirements of section 1876 of the Act. The definitions of emergency services and urgently needed services in the M+C regulations are based on section 1852(d) of the Act, and thus differ from those used under the previous Medicare managed care program (see § 417.401). In accordance with section 1852(d)(3) of the statute, an "emergency medical condition" exists if a "prudent layperson" could reasonably expect the absence of immediate medical attention to result in serious jeopardy or harm to the individual. In addition, the new definition of "emergency services" includes emergency services provided both within and outside of the plan, while the definition of "urgently needed services" continues to encompass only services provided outside of the plan's service area (or continuation area, if applicable), except in extraordinary circumstances (as discussed below). Under section 1852(d)(1)(C)(i) of the Act, M+C organizations are required to pay for nonemergency services provided other than through the organization where the services are immediately required because of unforeseen illness, injury or condition, and it is not reasonable given the circumstances to obtain the services through the organization.

In the June 26, 1998 interim final rule, definitions of emergency services and

urgently needed services were provided at § 422.2; financial responsibility of the M+C organization for emergency, urgently needed, and post-stabilization care services provided outside of the organization was addressed at § 422.100; and special coverage rules for emergency services and urgently needed services were provided at § 422.112. In this final rule, general requirements for financial responsibility for services provided outside the M+C organization remain at § 422.100, while definitions and policies relating to all types of emergency episodes of care, including ambulance services, emergency services, urgently needed services, and post-stabilization care services, have been consolidated at § 422.113. Comments on these aspects of the subpart C regulations are discussed below.

a. Definitions (§ 422.2 and new § 422.113)

Comment: Two commenters requested that we specify in the definition of “urgently needed services” that these are not “emergency services.”

Response: Section 1852(d)(1)(C)(i) of the Act specifies that urgently needed services are not emergency services. Thus, as the commenters suggested, we are revising the definition of urgently needed services to include the requested clarification.

Comment: One commenter expressed support for, while another commenter opposed, the inclusion of in-area unusual events in the definition of urgently needed services. The commenter opposing the inclusion of in-area urgently needed services suggested that if this provision is retained, M+C organizations should not be required to disclose it in member materials or that we give examples of circumstances in which this exception would apply. One commenter asked if this meant that beneficiaries could unilaterally obtain care out-of-plan if their M+C organization did not provide the care they requested. The commenter supporting our position provided the example of equipment failure as a case in which in-area services might not be available.

Response: As discussed in the preamble to the June 26, 1998 interim final rule (63 FR 34973), the inclusion of in-area unusual events in the definition of urgently needed services is based on the statutory language at section 1852(d)(1)(C)(i) of the Act, which does not specify that these services are covered only when the beneficiary is out-of-area. Rather, the statute provides for coverage of urgently needed services when “it was not reasonable given the circumstances to

obtain the services through the organization.” As stated in the regulations, in-area coverage of urgently needed services applies only under unusual and extraordinary circumstances, for services provided when the enrollee is in the service or continuation area, but the organization’s provider network is temporarily unavailable or inaccessible, and such services are medically necessary and immediately required. We believe that examples of when this could arise would include unusual events such as an earthquake or strike, if such events impede enrollee access to care through M+C plan providers. This regulatory definition of urgently needed services should be used in any materials that include a description of urgently needed services.

With regard to the request that the in-area exception in the definition of urgently needed services be interpreted to mean that beneficiaries could seek care out-of-plan if the particular services are not provided by an M+C organization, we believe that the commenter is asking about situations where an M+C organization has made a judgment that services are not necessary or not covered, rather than one in which the network is unavailable. There are other mechanisms in place to handle such situations. We may require a plan to take corrective action, where necessary, if a plan fails to provide services. In addition, services that the beneficiary believes he or she was entitled to receive from the M+C organization, but that the organization denied or otherwise did not provide, may be appealed under the regulations in subpart M of part 422. Whether situations involving equipment failures would be considered urgently needed services depends upon the clinical condition of the patient, and the M+C organization’s ability to make services available notwithstanding the equipment failure.

We note that, inherent to the various requirements under § 422.112 relating to an M+C organization’s responsibility to provide adequate access to covered services, is the obligation of an M+C organization to provide access to necessary care through out-of-network specialists when its network is inadequate or unavailable. That is, if in an individual case a plan’s provider network is not adequate to meet an enrollee’s health care needs (for example, the plan includes no specialist qualified to treat an enrollee’s rare condition), the organization shall authorize the individual to go out of network to obtain the necessary care. We are revising § 422.112(a)(3) to make

this requirement explicit. As discussed in detail in section II.M.9 of this preamble, failure to authorize such care constitutes an adverse organization determination, with concomitant appeal rights.

Comment: One commenter requested further elaboration on what is meant by “prudent layperson” within the definition of emergency services.

Response: Section 1852(d)(3) of the Act provides the definition of emergency services that includes the prudent layperson standard. Specifically, section 1852(d)(3)(B) of the Act states that an emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, (ii) serious impairment to bodily functions, or (iii) serious dysfunction of any bodily organ or part. This entire definition should be considered when making a determination of whether a beneficiary acted appropriately in seeking emergency care. This definition is what the independent review entity under contract with us will consider when making determinations on beneficiary appeals of emergency services that an M+C organization has denied. With respect to the term “prudent layperson,” we believe that the term “prudent” has a commonly understood meaning, and would refer the reader to the general dictionary definition of this term. A layperson refers to an individual with an average knowledge of health and medicine, as the definition of “emergency medical condition” states. We do not believe that further elaboration of the term prudent layperson is necessary.

b. Enforcement of Emergency Requirements (§§ 422.80, 422.100, 422.113)

Comment: Commenters requested clarification of what steps we were taking to ensure that M+C organizations provide access to emergency services intended by law.

Response: One mechanism we use to ensure appropriate provision of covered services by M+C organizations is a review process of all organization materials provided to beneficiaries, including both pre-enrollment marketing materials provided to prospective enrollees and post-

enrollment member materials for enrollees. For example, § 422.80(b)(5)(v) lists examples of membership communication materials we review, including membership rules, subscriber agreements (evidence of coverage), and member handbooks. In considering our response to this comment, we have determined that “wallet-sized” instruction cards that might be used in the case of an emergency should also be expressly included as materials to be reviewed, because these cards may contain instructions to enrollees on how to access care, including instructions on what to do in an emergency. We, therefore, are adding wallet card instructions to the list of examples of marketing materials to be reviewed under § 422.80(b)(5)(v) to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services. We note that, as part of our monitoring of the “prudent layperson” standard, we have asked our independent review entity to report, on a quarterly basis, each instance in which it overturns a denial of a claim for emergency services.

Also in response to this comment, we have decided to specify at § 422.100(b)(1)(i) that M+C organizations are required to cover ambulance services provided other than through the organization that are dispatched through 911 or its local equivalent. Section 422.113 specifies that the M+C organization bears financial responsibility for ambulance services where other means of transportation would endanger the beneficiary's health. This policy is consistent with original Medicare's coverage of ambulance services where other means of transportation would endanger the health of the beneficiary as provided by section 1861(s)(7) of the Act, as well as with the emergency coverage provisions of section 1852(c)(1)(E) of part C of the Act. In particular, we believe that the law's reference to use of the 911 telephone system indicates statutory intent for coverage of ambulance services whether provided through the organization or other than through the organization. Ambulance services provided through the organization would also be considered part of basic benefits under §§ 422.100(a) and 422.101. We note that nonemergency ambulance services generally would be covered only when provided through the organization, to the same extent the services are covered under the general Medicare principles set forth in section 1861(s)(7) of the Act

(that is, when use of other forms of transportation would endanger the health of the beneficiary.) Regulations on original Medicare coverage of ambulance services may be found at § 410.40.

c. Access to Emergency and Urgently Needed Services (§§ 422.112(c) and 422.113)

Comment: Commenters generally supported emergency services policies, such as the prudent layperson definition, the prohibition of prior authorizations, the requirement for out-of-plan coverage, and the requirement that the treating physician determine when the patient is stable. Commenters requested clarification of the prohibition on prior authorization.

Response: In considering our policy prohibiting prior authorization for emergency services as required under section 1852(d)(1)(E) of the Act, we have determined that the regulations should expressly reflect the fact that two parties are protected from prior authorization requirements, that is, the beneficiary and the emergency provider treating the beneficiary. We are clarifying at § 422.113(b)(2)(ii)(A) that prior authorization may not be required from the beneficiary in any materials furnished to enrollees (including wallet card instructions) and that, consistent with section 1852(c)(1)(E) of the Act, disclosure of an enrollee's right to coverage of services must include disclosure of the enrollee's right to use the 911 telephone system. Also, § 422.113(b)(2)(ii)(B) specifies that materials furnished to providers (including contracts with providers) may not include instructions to seek prior authorization before an enrollee has been stabilized.

We believe that these clarifications will promote compliance with the prohibition in section 1852(d)(1)(E) of the Act on prior authorization requirements for emergency services.

Comment: A commenter requested that we specify that retroactive denials should not be allowed based solely on a final diagnosis, and that the presenting condition from the perspective of the prudent layperson should determine coverage.

Response: As noted in our preamble discussion of the provisions of § 422.112 in the June 26, 1998 interim final rule, long-standing Medicare managed care manual policy (§ 2104) prohibited retrospective denial for services that appeared to be emergencies, but turned out not to be emergency in nature. This policy is consistent with the “prudent layperson” element of the definition of an emergency medical condition, in that

the perspective of the enrollee is a significant factor in determining whether an enrollee acted appropriately in seeking emergency care. As explained in the preamble to the interim final rule, we believe that the current regulations already require such coverage. However, in light of the commenter's concern, we are including in new § 422.113(b)(2)(iii) the explicit requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson standard in the definition of emergency medical condition, regardless of final diagnosis.

Comment: We received a number of comments regarding the limit in § 422.112(c) on copayments for emergency services obtained outside the M+C plan's provider network (the lower of \$50 or whatever the plan would charge for in-plan emergency care). Some commenters argued that significant copayments were necessary to deter unnecessary visits to the emergency room, and noted that commercial fee-for-service insurance plans have copayments for emergency care that may be higher than the \$50 limit. Other commenters thought the \$50 limit was a reasonable standard. Some commenters suggested that the copayment for an emergency room visit should be higher than that for a physician office visit. One commenter requested that a requirement for advance disclosure of the emergency room copayment amount be substituted for a dollar limit. One commenter requested clarification that the \$50 limit be for the “sum total” for all care received for the emergency episode. Another commenter argued for a rule prohibiting copayments altogether, or at least for a reduced limit for low-income beneficiaries.

Response: We appreciate the commenters' responses to our request for public comment on the policy of limiting the amount that can be imposed as a copayment for emergency services. As we stated in the preamble to the June 26, 1998 interim final rule, our data showed that only 7 percent of Medicare managed care plans were charging more than \$50 for emergency services. We believe that all of the above comments have some merit, but that, on balance, retaining the current policy (the lower of \$50 or whatever the plan would charge for in-plan emergency care) is the best course of action. Although we agree that copayments can effectively deter unnecessary use of services, we believe that a \$50 copayment accomplishes this objective, since 93 percent of M+C organizations do not exceed this amount. We also believe, however, that a copayment higher than this amount

could potentially deter an enrollee from receiving necessary emergency services. M+C organizations retain flexibility to set copayment amounts up to \$50, including possible consideration for low-income beneficiaries, and organizations may provide for a substantial differential between copayments for physician office visits and emergency room visits. We believe that the difference between a \$50 copayment for an emergency room visit and the typical \$5 to \$10 copayment for a physician's office visit is sufficient incentive to receive nonemergency services at a physician's office. With respect to the commenter who advocated disclosure of emergency room copayments, such copayments are already disclosed in the MedicareCompare database on the Internet at HCFA's website, www.hcfa.gov, and M+C organizations are required to disclose these amounts in membership materials provided to beneficiaries. Finally, we believe that the current language already conveys that \$50 is the sum total limit for copayment for services defined as emergency services, and that further clarification beyond this response is not necessary.

Comment: One commenter suggested that beneficiaries be issued a single Medicare identification card that could be presented to their treating physicians and staffs, rather than one card issued by the M+C organization and one issued by Medicare. The commenter stated that beneficiaries frequently do not present the correct card denoting M+C plan coverage to their treating physicians. The commenters believe that the use of a single card would allow physicians and staffs to easily identify exact Medicare coverage and the appropriate administrative and billing procedures to be applied.

Response: The purpose of the Medicare card issued to the beneficiary is to serve as proof of entitlement to the Medicare program. We believe that the Medicare card and the M+C plan membership card serve two different purposes—to identify the individual as entitled to Medicare and to subsequently identify how the individual receives the services. Combining these elements into a single identification card would require the issuance of a new card each time the beneficiary chose a new plan or returned to original Medicare. Thus, although we welcome suggestions to improve the efficiency of our operations, we do not believe that a single card should be issued to the beneficiary.

d. Post-Stabilization Care Services (§§ 422.100 and 422.113)

Section 1852 (d)(2) of the Act gives the Secretary express authority to establish requirements needed to promote the “efficient and timely coordination of appropriate maintenance and post-stabilization care” (hereafter together referred to as “post-stabilization care”). Section 1852(d)(1)(C)(iii) of the Act establishes an M+C organization's responsibility to provide reimbursement for these services. Implementing regulations at §§ 422.100(b)(1)(iii) and 422.113(c) specify that an M+C organization is financially responsible for post-stabilization care services obtained within or outside of the M+C organization. This requirement applies both to services pre-approved by the organization and services that were not pre-approved, under certain circumstances, including situations where an M+C organization fails to respond within 1 hour to a request for pre-approval from a provider of post-stabilization care services (as discussed in detail below). We received a number of comments regarding this section.

In this final rule, the special rules for post-stabilization care services are included under new § 422.113. The requirement for financial responsibility for post-stabilization care services provided outside the organization remains at § 422.100.

Comment: One commenter stated that after stabilization of the emergent medical condition, no immediate health risks should exist. This commenter asked why there is a need to change the time frame for obtaining approval of post-stabilization care, which the commenter apparently believed was 48 hours. Several commenters responded favorably to the 1-hour window for responding to a request for authorization of post-stabilization services, with one commenter suggesting that 30 minutes would be a better time frame.

Response: If no immediate health risks exist following an emergency episode, the patient would most likely be discharged. Post-stabilization care services are administered to ensure that the patient remains stabilized following an emergency episode. We agree with the majority of commenters who supported the 1-hour time frame. We believe that an untimely response to a request for post-stabilization care services would delay the delivery of these services, thereby compromising their effectiveness. We are not aware of the 48-hour time frame referenced by

one commenter, as no such time frame exists under Medicare law.

Comment: Several commenters recommended that we require that the request for approval not be made until after the enrollee is stabilized, so that the organization will have the necessary information at its disposal. Commenters requested clarification as to what constitutes a response by the M+C organization to a call from the hospital. For instance, one commenter asked if an organization would be in compliance with the 1-hour rule if it calls back within the hour and states it needs more time to make a decision on post-stabilization care services. One of these commenters also stated that we should require that the emergency department treating the member contact the M+C organization within an hour of the point at which the member is stabilized. Another asked how the emergency provider would be held accountable for notification to the M+C organization once the patient is stable.

Response: Section 1852(d)(1)(E) of the Act states that the M+C organization must provide coverage for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the organization. Implicit in this requirement is the fact that the organization may not require the provider to call for approval of services prior to the point of stabilization. If the hospital chooses to notify the organization while the patient is still being stabilized, the organization will still need an update on the status of the patient at the point of stabilization, in order to make an informed decision. If the provider calls when the enrollee is stabilized, an organization which calls back within the hour should not need more time to make a decision. Therefore, we consider a response by the M+C organization to be when the M+C organization submits a decision to the provider about its request for post-stabilization care. While we believe it is reasonable to expect the emergency provider to contact the M+C organization within an hour of the point at which the member is stabilized, we do not believe that this final rule, which establishes and clarifies the requirements that M+C organizations must meet, is an appropriate vehicle to impose such a requirement on hospitals. (We are considering including such a requirement in future hospital provider agreements with Medicare, however.) It is clearly in the hospital's best interest to contact the organization as soon as a patient is stabilized in order to ensure plan coverage of post-stabilization services furnished by the hospital. In

addition, in order to be able to bill the beneficiary in circumstances where the plan is not liable for payment, the treating provider is expected to provide the stabilized patient with a notice of non-coverage, such as an Advance Beneficiary Notice.

Comment: A number of commenters asked for clarification of the definition of post-stabilization care services. The majority of these commenters requested that post-stabilization care services be linked to the emergency episode. Two commenters inquired if the term post-stabilization care replaces the pre-BBA term “follow-up” care, which includes only routine care following an out-of-area emergency medical episode.

Response: We agree that the concept of post-stabilization care services could be clarified further, and we have expanded on the definition, including the addition of language addressing services furnished while waiting for a response to a request for authorization from an M+C organization. We also agree with the commenter that post-stabilization services should be limited to services related to the emergency medical condition.

By post-stabilization care services, we generally mean covered services, related to an emergency episode, provided after the enrollee is considered to be stable (see new § 422.113(c)). Under the post-stabilization provisions set forth in the interim final rule, “post-stabilization” services were limited to services authorized by the M+C organization or services furnished when the organization cannot be reached, or fails to respond to a request for authorization within an hour. This definition did not address services that may be required during that hour to keep the patient stabilized. We believe that it is necessary to ensure that the patient continues to receive necessary treatment during the 1-hour time frame when the provider waits for the organization to respond. These services consist of those necessary to maintain the stable condition achieved through previously administered emergency services. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under § 422.113(b).

Section 422.113(c) also establishes that if the M+C organization does not respond within the 1-hour time frame, the M+C organization cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. When an M+C organization representative who is a non-physician and the treating

physician cannot reach agreement on a course of treatment, the M+C organization must allow the treating physician to speak with a plan physician. By allowing the treating physician to proceed with care of the patient in these cases, we are ensuring that M+C enrollees receive the same standard of timely care as beneficiaries under original Medicare.

Accordingly, the revised definition of post-stabilization care services at § 422.113(c)(1) reads as follows:

“(c) Post-stabilization care services means covered services, related to an emergency medical condition, that are provided after the enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (2)(iii) below, to improve or resolve the enrollee's condition.”

Section 422.113(c)(2) then describes the M+C organization's financial responsibility for post-stabilization care services. Specifically, “the M+C organization is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside of the M+C organization that are— (i) Pre-approved by a plan provider or other M+C organization representative; (ii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the stabilized condition, within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization services; or (iii) Not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the treating physician may continue with the care of the patient until a M+C organization physician is reached or one of the criteria in § 422.113 (c)(3) is met.”

To further clarify the above requirements, consider the following example: A patient is brought to the emergency department with the preliminary diagnosis of a seizure. The patient is screened and receives services to stabilize his condition. Thus far, the services that the patient has received are emergency services under § 422.113(b). Once the emergency room physician

considers the patient stabilized, the M+C organization is notified of the need to consult a neurologist in order to proceed with relevant diagnostic tests to determine the cause of the seizure, and to treat the cause of the seizure definitively. While the emergency provider waits 1 hour for a response from the organization, post-stabilization services necessary to maintain the stable condition achieved through previously administered emergency services are administered.

If the M+C organization responds within 1 hour, it can approve the request for additional post-stabilization services under § 422.113(c)(2)(i) or make other arrangements for additional services. If the organization did not respond within the 1-hour time frame, if the organization could not be contacted, or if the organization representative and the treating physician could not reach an agreement and a plan physician was not available for consultation during the hour, the treating physician can proceed with post-stabilization services administered not only to maintain the stabilized condition, but to improve or resolve the patient's condition. Again, if the organization representative and the treating physician cannot reach an agreement, the M+C organization must give the treating physician the opportunity to speak with a plan physician concerning the care of the patient. If a plan physician responds to a request for consultation outside the one hour time frame, the plan physician and the treating physician are expected to execute a plan for safe transfer of responsibility of the patient.

Comment: One commenter sought clarification as to when the M+C organization's liability to pay ends. This commenter does not believe that the M+C organization physician should have to “arrive,” as stated in the preamble of the June 26, 1998 interim final rule, in order to terminate the organization's responsibility to pay. This commenter also recommended that we explicitly state that even if the M+C organization does not respond within the hour, once it does respond, it should have the absolute right to control the care that is given to the member.

Response: We agree that the issue of when the M+C organization's financial responsibility ends needs further clarification. We also agree that the physician should not have to arrive in person at the hospital in order to assume responsibility for his or her patient. Therefore, we are incorporating the following language into § 422.113(c)(3): “The M+C organization's financial responsibility

for post-stabilization care services it has not pre-approved ends when—(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care; (ii) A plan physician assumes responsibility for the enrollee through transfer; (iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or, (iv) The enrollee is discharged."

We do not agree that the M+C organization should have the absolute right to control the care that is given to the member when it does eventually respond and the one hour time period has elapsed. For example, a late response could result in a scenario where post-stabilization care services may have already started, and in such a situation, we believe that interruption of a procedure in progress in order to transfer the enrollee to another facility could be harmful to the member. The M+C organization is financially responsible for post-stabilization services until the M+C organization and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Several commenters asked that HCFA clarify that only an M+C plan physician with privileges at the treating hospital may assume responsibility for the M+C plan enrollee's care.

Response: Generally, only an M+C plan physician may assume long-term responsibility for care furnished to an enrollee of that M+C plan. However, if there are no M+C plan physicians with privileges at the treating hospital, we would expect the treating physician and the M+C organization to make arrangements for appropriate care to be provided. Thus, we do not agree that an M+C plan physician with privileges at the treating hospital must necessarily assume responsibility for a plan enrollee's care.

Comment: Several commenters asked that we address how disputes between M+C organizations and providers would be resolved. One commenter asked that we develop guidelines for notification of organizations. Another commenter wanted to know how we will determine if a call was made, or responded to within 1 hour, if the provider's and M+C organization's records do not agree. Still another commenter suggested a provision holding the patient harmless for disputes between M+C organizations and the emergency

provider regarding post-stabilization benefits and coverage.

Response: We believe that providers and M+C organizations will develop methods of documentation to ensure that calls are made and received in a timely manner, so that the 1-hour response requirement can be met and the possibility of disputes can be minimized. We do not believe the development of guidelines by HCFA to be necessary or appropriate. Complaints and disputes are addressed in the HCFA monitoring process, and resolution would depend on the circumstances encountered. Ultimately, if agreement cannot be reached, a dispute over whether the conditions for M+C coverage for post-stabilization care services under § 422.100 and § 422.113 have been met could be resolved in an enrollee's appeal of the M+C organization's denial of payment for post-stabilization services, or an appeal by a provider if the provider agrees not to charge the enrollee. (We note that the rules governing payment for services furnished by noncontracting providers would apply in post-stabilization cases, as set forth in § 422.214 and discussed in detail in section II.E of this preamble. We have made this explicit at § 422.113(c)(2).) Based on this comment, we agree that M+C enrollees should be protected from excessive charges for post-stabilization care services. Therefore, new § 422.113(c)(2)(iv) provides that cost-sharing for post-stabilization care services must not exceed cost-sharing amounts for services obtained through the organization.

Comment: One commenter stated that if an enrollee is admitted to a hospital for services that are later determined not to be emergency services, the M+C organization has no obligation to pay for services that a provider asserts are for post-stabilization care. In addition, a commenter asked whether, if there is a denial of post-stabilization care services, the treating physician can be given the right to speak with an M+C plan physician regarding the patient. Another commenter recommended we add protections against denials of post-stabilization care services.

Response: Section 1852(d)(3) of the statute states that the M+C organization is responsible for services required to treat an emergency medical condition under the prudent layperson standard. Organizations are not responsible for care sought by the enrollee when this standard is not met. Post-stabilization services are similarly covered only following treatment for an emergency (as noted above, we have revised the definition, at § 422.113(c)(1), to make

this explicit.) If the patient did meet the prudent layperson standard, but the condition did not turn out to be an actual threat to the health of the patient, the M+C organization would not be responsible for any services beyond those services provided as part of the medical screening to determine whether an emergency medical condition existed. In such a nonemergency situation, the treating physician is expected to provide the patient with an Advanced Beneficiary Notice (ABN) to inform the patient that further services will not be covered.

With respect to the comment concerning denials, if the organization representative and the treating physician cannot reach an agreement concerning the enrollee's care, the M+C organization must give the emergency physician an opportunity to consult with an M+C organization physician.

With respect to the request for further patient protections, as noted above, the enrollee (or, the provider, if the provider agrees not to charge the enrollee) has the right to appeal any decision by an M+C organization to deny payment for post-stabilization services.

Comment: One commenter asked that post-stabilization care services be limited to services that can be furnished at the facility at which the emergency treatment was provided. Another commenter recommended that we require M+C organization staff, including plan providers, to defer to an emergency provider's preference to keep an enrollee in an emergency facility after stabilization to prevent any needless disruption in the patient's care.

Response: We disagree that treatment decisions should be limited by what services a facility can provide. If a treating physician or facility is prepared to provide additional needed treatment to a patient, and the M+C organization cannot be reached, or has not responded within an hour, we do not believe that the patient should have to wait for this treatment until the organization responds, simply because it would not be provided in the same physical location as the emergency services. Section 422.113(b)(3) specifies that the physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge and that decision is binding on the M+C organization. We would expect the M+C organization to allow the treating physician to speak with a plan physician if he or she is concerned about the care (for example, a transfer) planned for the patient.

Comment: One commenter asked which provider, the emergency provider

or the M+C plan provider, has the authority to establish a plan of care.

Response: In providing emergency services, the emergency provider has the authority to establish the plan of care. Once the enrollee has been stabilized, post-stabilization care services are provided in accordance with § 422.113(c). Thus, once the M+C provider assumes responsibility, then he or she has the authority to revise the plan of care or establish a new plan of care as long as the new plan of care is consistent with a safe transfer of responsibility.

Comment: One commenter recommended that the language in § 422.100(b)(iv)(A) be changed from “Pre-approved by the organization” to “Pre-approved by a plan provider or other M+C organization representative.”

Response: In response to this comment, we have changed the language in question to read, “Pre-approved by a plan provider or other organization representative.” (See § 422.113(c)(2)(i).)

3. Service Area Requirements (§§ 422.2, 422.100, 422.304(b)(2))

In the June 26, 1998 interim final rule, we defined the term “service area” as a geographic area approved by us within which an M+C eligible individual may enroll in a particular M+C plan offered by an M+C organization. We specified that for coordinated care plans and network medical savings account (MSA) plans only, the service area also is the area within which a network of providers exists that meets the access standards in § 422.112. Existing regulations also require that an M+C plan’s uniform benefit package must be available throughout a plan’s service area (see the discussion below of modifications to this policy made by the BBRA). In deciding whether to approve a service area proposed by an M+C organization for an M+C plan, we consider the M+C organization’s commercial service area for the type of plan in question (if applicable), community practices generally, whether the boundaries of the service area are discriminatory in effect, and, in the case of coordinated care and network MSA plans, the adequacy of the provider network in the proposed service area. As discussed in the interim final rule preamble, because of unique rules pertaining to the amount deposited in MSA plan accounts, we may approve single county M+C non-network MSA plans even if the M+C organization has a different commercial service area (63 FR 34971).

We note that since the publication of the interim final rule, we have issued

further guidance implementing the definition of service area set forth in § 422.2, including an affirmation of our longstanding policy of not approving less than full county service areas unless circumstances justify an exception to this rule. This policy, which we refer to as the “county integrity policy,” is explained in detail in OPL 99.090 released April 23, 1999. The county integrity rule, which implements the reference in the service area definition to consideration of whether boundaries are discriminatory in effect, prevents the establishment of boundaries that could “game” the county-wide M+C payment system by excluding high cost areas of a county. (Note that M+C organizations are paid based on Medicare expenditures at the county level.) Under limited circumstances, as described in OPL 99.090, we will allow an M+C organization to establish a service area that includes a partial county. However, it is never acceptable for an M+C organization to devise an M+C plan service area that excludes portions of a county because it anticipates enrollees with higher health care needs.

Under § 422.100(f), an M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations for each M+C plan set forth in subpart C of the M+C regulations. For example, § 422.100(g) provides that we review and approve each M+C plan to ensure that the service area boundaries do not promote discrimination (for example, that they do not include partial counties unless justified), discourage enrollment, steer specific subsets of Medicare beneficiaries to particular M+C plans, or inhibit access to services.

We received about 20 letters commenting on various aspects of M+C service area policy and an M+C organization’s ability to offer multiple M+C plans.

Comment: Several commenters objected to the requirement that each M+C plan offered by an M+C organization must be offered to beneficiaries with a uniform benefit package and cost-sharing structure that cannot vary throughout each M+C plan’s service area. Some of these commenters expressed concern that this requirement will make it difficult for M+C organizations to serve multi-county areas due to the differences in Medicare payment rates across counties, and that this could result in beneficiaries in low-payment or rural counties having decreased access to M+C plans.

Response: As noted by the commenters, existing M+C regulations

provide that each M+C plan offered by an M+C organization must be offered to all beneficiaries in an M+C plan’s service area with a uniform benefit package and uniform cost-sharing arrangements. This requirement implemented the requirement of section 1854(c) of the Act for uniform premiums for all individuals enrolled in an M+C plan. Thus, under § 422.2, an M+C plan was defined as health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan. The BBA requirement that an M+C plan consist of a uniform benefit package that cannot vary in terms of benefits or price throughout the plan’s HCFA-approved service area contrasted with our previous “flexible benefits” policy, which permitted HMOs and CMPs under section 1876 to vary premium and benefit offerings by county within a service area. As discussed in the preamble to the interim final rule, however, an M+C organization was able to achieve the same result as the flexible benefits policy by offering multiple M+C plans, either in the same or in different service areas. This administrative policy allowed an M+C organization great flexibility to offer M+C plans that take into account varying county payment rates and preferences of the Medicare population. (Each M+C plan offered by an M+C organization must have a HCFA-approved service area and meet access standards for health care services as described in our regulations at § 422.112.)

As noted in section I.C of this preamble, section 515 of the BBRA amended section 1854 of the Act by adding a new paragraph (h) to permit, effective for contract years beginning on or after January 1, 2001, the application of the uniformity rule to individual “segments” of an M+C plan service area, provided that each segment is composed of one or more M+C payment areas (that is, one or more counties), and a separate complete ACR is submitted for each such segment. The practical implications of this option are similar to our existing administrative policy, under which M+C organizations have the flexibility, by offering multiple plans in a given area or areas, to tailor the benefits offered under their M+C plans to the areas where the plans are offered. In practice, we anticipate that organizations will likely continue to offer multiple M+C plans, since they have already established such separate

plans, and they would have to submit the ACR information required under section 1854(a)(2) of the Act for each segment under the BBRA option, just as they do for each M+C plan now.

However, the statute gives M+C organizations the alternative of choosing instead to establish a single M+C plan consisting of segmented service areas, with a separate ACR submission for each segment of the service area. In this final rule, we are adding a new § 422.304(b)(2) which reflects section 515 of the BBRA. We also are making needed conforming changes to the definitions of “service area” and “M+C plan” in § 422.2, and to § 422.100(d) concerning the structure of M+C plans.

Comment: A commenter asked that we clarify our requirements for approving the service area of M+C plans. The commenter stated that the discussion of service area in the preamble and the definition at § 422.2 did not provide specific guidance on what constitutes an acceptable service area for an M+C plan offered by an M+C organization.

Response: Although we believe that the service area definition in § 422.2 is fairly detailed and specific, we agree that some additional guidance and reorganization of the definition could be of value. Specifically, while our county integrity policy discussed above implements language in the current definition with regard to discriminatory boundaries, the current regulation text does not expressly reflect our longstanding county integrity policy. In response to this comment, and under our authority in section 1856(b)(1) of the Act to establish M+C standards, we are revising the service area definition to specify that in deciding whether to approve an M+C plan’s proposed service area, we consider the following criteria:

(1) Whether the area meets the “county integrity rule” that a service area generally consists of a full county or counties. However, we may approve a service area that includes a portion of a county if we determine that the “partial county” area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed service area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan’s service area, HCFA must determine that all services covered

under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, we may approve single county non-network M+C MSA plans even if the M+C organization’s commercial plans have multiple county service areas.

We believe that these revisions to the service area definition, although they do not constitute policy changes, should help to clarify for M+C organizations our method for determining whether a service area is acceptable.

Comment: A commenter supported the M+C standard that the delineation of an M+C plan’s service area should not discriminate against beneficiaries through “gerrymandering” or “red-lining” to deliberately avoid particular areas (for example, to prevent the enrollment of poorer Medicare beneficiaries, or those known to be in poor health). The commenter asked that we also include cultural accommodations (for example, language access) as part of the requirements for service area designation.

Response: We are very concerned that the service areas for M+C plans be drawn in a manner that avoids discriminating against certain groups of beneficiaries who may be perceived as having higher than average health care needs. The general requirement that M+C plan service areas be made up of whole counties, as discussed in OPL 99.090, is intended in part to preclude any incentive to create M+C service areas that serve only the lowest cost population of a particular county. We believe that the revised service area definition, which continues to provide for our consideration of discriminatory effects, already provides sufficient authority to disapprove a service area if there is evidence that an M+C organization attempted to establish boundaries based upon cultural discrimination, or discrimination against non-English speaking beneficiaries.

Comment: A commenter pointed out that the definition of service area states that the service area also is “the area within which a network of providers exists that meets the access standards in § 422.112.” The commenter believes that this wording implies that all services must be provided in the service area itself, and that this requirement conflicts with § 422.101(a), which states that services obtained outside the geographic area are acceptable if it is common practice to refer patients to sources outside the geographic area. The commenter asked that we allow some services to be furnished outside of an M+C plan’s service area if patients traditionally go outside the service area

to receive such services. Another commenter stated that the M+C organizations should be permitted the flexibility of structuring plan benefits and provider networks in accordance with local patterns of care regardless of political boundaries. The commenter believes this would afford a broader choice of health care options to beneficiaries.

Response: The intent of the cited language from the service area definition is to require that services are available to a plan’s enrollees through an M+C plan provider network that is accessible from the service area. We have not interpreted this language to prohibit the inclusion in a plan’s network of providers physically located outside the area. In fact, as noted above, we allow M+C coordinated care and network MSA plans to establish a provider network with contracting providers located outside of the M+C plan service area, provided that we determine that the M+C organization’s contracted provider network meets Medicare access and availability standards at § 422.112. We believe that the revised service area definition described above should eliminate any implication that all network providers must be located within the service area.

Under both the former risk contracting program and the M+C program, we generally have required that M+C organizations make health care services available through a network of contracting providers located within the boundaries of the M+C plan service area. Under certain circumstances, however, we have always allowed exceptions to this policy, such as in rural areas when providers were not available in a plan’s service area, when traveling outside the service area to obtain health care is not uncommon, and also when the services are still reasonably accessible and available. We have also allowed plans to provide certain specialist services outside of a plan’s service area if the specialist services were not available in the plan’s service area and if the specialist was reasonably accessible.

Another reason that we do not require an M+C plan’s provider network to be located entirely within the plan’s service area is to allow for multiple M+C plans in the same or close geographic areas that share the same provider network, as discussed in the next comment and response. However, we will continue to employ the same criteria in evaluating whether beneficiaries enrolling in an M+C plan are provided with the required access and availability to health care services. Generally, we will evaluate the provider

network supporting an M+C plan by considering the prevailing community patterns of care in obtaining health care services (for example, where people obtain care, the types of providers available in the community, reasonable travel times to obtain care) and the access standards at § 422.112.

Comment: A commenter notes that an M+C organization can offer multiple M+C plans under a single M+C contract with us. The commenter asks how multiple plans would work, and whether each would be required to have a separate health services delivery system.

Response: In order to respond to the commenter's question, we will briefly review the principal requirements that each M+C plan offered by an M+C organization must independently meet. We note that these M+C plan requirements also are discussed in greater detail in other parts of this preamble. Each M+C plan must be approved by us through the adjusted community rate (ACR) process, and each M+C plan must be offered to all beneficiaries in the given M+C plan's service area. An M+C organization can offer multiple M+C plans. Each M+C plan offered by an M+C organization must have a HCFA-approved service area that is generally made up of whole counties consistent with our county integrity policy discussed above, and reflected in OPL 99.090. The M+C plans offered by an M+C organization can have the same or different service areas. For example, an M+C organization may choose to offer more than one M+C plan in the same service area in order to provide beneficiaries with a choice of plan benefit packages and cost-sharing structures, including differing basic premium amounts. Also, each M+C coordinated care plan must provide enrolled beneficiaries access to health care service through a network of contracting providers. M+C plans may share the same provider network and portions of the provider network may be located outside of the plan's service area. However, the provider network supporting an M+C plan must meet M+C access standards with respect to all enrollees in that plan's service area (see § 422.112) as determined by HCFA. We note that under § 422.501(e), when an M+C organization includes several M+C plans under a single contract, the contract must provide for an amendment upon our request to remove an individual M+C plan from the contract, so that we have the flexibility to nonrenew or terminate only a single M+C plan if a problem is confined to one such plan.

4. Benefits (§§ 422.2, 422.100, 422.101, 422.106)

The regulations contained in subpart C describe the requirements for M+C organizations' benefit offerings. The statutory basis for these provisions generally can be found in section 1852 of the Act. The basic categories of benefits parallel those that applied under the section 1876 risk contracting program with the exception of the use of the term "basic benefits," which we now define as both original Medicare benefits and additional benefits. Despite the limited changes, we believe it is important to carefully define the different benefit categories, because, historically, organizations participating in the risk-contracting program often used different terminology in describing their benefit packages to beneficiaries and in structuring benefits under Medicare risk contracts.

Thus, in order to promote consistency, M+C organizations must use the benefit terminology specified in the M+C regulations and in instructions and operational policy letters. We intend to provide further instructions over the next several years to assist organizations in standardizing the structure and terminology used in describing their benefit offerings. In addition to issuing instructions, we will be reviewing benefit design closely to provide feedback to M+C organizations on ways they can improve their benefit descriptions and ensure that the benefits comply with our requirements. The use of consistent terminology in describing benefit categories will result in better information for Medicare beneficiaries to compare their Medicare options as well as help us to review both benefits paid for with Medicare capitation payments and benefits for which Medicare beneficiaries are charged a premium.

Comment: Several commenters asked for additional clarification regarding the new definitions of the benefit categories under the M+C program.

Response: We have been aware of confusion about the benefit terminology used in the Medicare risk contracting program, and have attempted to clarify the terminology in the M+C regulations. As noted above, a significant change under the M+C program involves the definition of the term "basic benefits." Under the M+C program, basic benefits means both benefits covered under original Medicare and additional benefits, not otherwise covered under original Medicare, that are paid for with Medicare payments. Additional benefits are grouped with original Medicare benefits because they are part of the

package of basic benefits for which beneficiaries are not charged a premium, beyond any premium the M+C organization is permitted to charge for original Medicare benefits. As discussed more fully below in section II. D, the costs of additional benefits are funded by the difference between an organization's ACR for the original Medicare benefit package, and the M+C payment plus any approved enrollee cost sharing.

Mandatory supplemental benefits are M+C plan benefits not otherwise covered under original Medicare for which anyone who enrolls in an M+C plan is charged a premium. Thus, additional benefits (included in the basic benefit package) and mandatory supplemental benefits are similar in that they are not covered by original Medicare, and *all* M+C enrollees receive them as part of their M+C plan. The difference is in the way these benefits are funded: additional benefits are funded with Medicare payments through the M+C payment rate, and mandatory supplemental benefits are fully paid for by M+C enrollees through a separate premium or cost sharing.

Like additional benefits and mandatory supplemental benefits, optional supplemental benefits are not covered by original Medicare. However, plan enrollees may choose whether to elect and pay for optional supplemental benefits. M+C organizations may offer M+C plans that have individual items or groups of items and services as optional supplemental benefits.

We are making several minor technical changes to improve the accuracy and consistency of the benefit-related definitions set forth in § 422.2. For example, we are clarifying under the definitions of "mandatory supplemental benefits" and "optional supplemental benefits" that these categories of benefits consist of "health care services" that may be paid through premiums "and/or" cost sharing. Also, we are clarifying in the definition of "benefits" that the costs an M+C organization incurs in providing benefits may not be solely an administrative processing cost and that benefits must be "submitted and approved through the ACR process."

Comment: Commenters suggested that we consider developing standardized definitions or descriptions for the individual items and services that make up a benefit package.

Response: The intent of the regulations is to clarify the meaning of the terms used in the statute, which reflect the funding source for various groups of benefits. We recognize the value of standardizing the definitions of

individual items and services that might be included as additional or supplemental benefits, such as a drug benefit. Both the annual Summary of Benefits and the Plan Benefit Package are important parts of our standardization efforts. As noted above, we intend to provide further instructions over the next several years to assist organizations in standardizing the terminology used in describing their benefit offerings. Work on defining individual items and services so that beneficiaries may compare benefit offerings is taking place predominantly within the context of our information campaign. We are not including standardized definitions in this final rule.

Comment: Several commenters asked for further clarification of the meaning of the requirement in § 422.101(a) that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in a plan's geographic area, including services obtained outside of the area if it is common practice to refer patients to sources outside the area. Two commenters noted that the term "common practice" might be misleading, and recommended that we revise the regulations to state that services may need to be provided outside the area, provided that the services are reasonably accessible to enrollees and such use is consistent with community practice patterns. One commenter recommended that we confirm in the final rule the basic premise that M+C organizations must provide all their enrollees with all services covered under original Medicare, including any needed out-of-area care. Another commenter questioned whether the requirement that an M+C organization provide all Medicare-covered services that are available to beneficiaries residing in the service area implies that the M+C organization's health care delivery patterns must mirror care delivery patterns in original Medicare.

Response: Consistent with section 1852(a)(1)(A) of the Act, § 422.101(a) establishes the principle that an M+C organization must provide its plan enrollees with all the Medicare-covered services available to other Medicare beneficiaries in the area served by the plan. We recognize that the existing regulatory language in this section creates some potential for confusion and are making several changes along the lines suggested by commenters in order to clarify the regulations. Revised § 422.101(a) continues to specify that an M+C organization must provide coverage of all Medicare-covered

services available to beneficiaries residing in a plan's service area. We are adding a provision to state explicitly that services may be provided outside of the service area of the plan if the services "are accessible and available to enrollees in the same area."

When we assess the capability of any proposed plan to serve an M+C service area, we consider the numbers, types, and locations of all providers needed to provide all Medicare-covered services or, in regulation terms, the access and availability of Medicare-covered services. We continue to believe that it is in the best interest of the Medicare program and Medicare beneficiaries to evaluate proposed M+C plan networks on a case-by-case basis taking into account the patterns of care and access to care in particular geographic areas. It is not unusual for services such as a dialysis center or transplant center not to be available in a county. If, for example, a Medicare beneficiary would normally have to travel to a different county for renal dialysis or a transplant, we believe it would not be unreasonable for an M+C plan enrollee to be required similarly to travel outside of a service area for access to such services. Such exceptions to in-area care access should, however, be limited in order to have a viable M+C plan.

The fundamental requirement under § 422.101(a) that an M+C organization provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. For example, M+C organizations may furnish a given service using a defined network of providers, some of whom may not see patients in original Medicare. M+C organizations may also encourage patients to see more cost-effective provider types than would be the typical pattern in original Medicare (as long as those providers are working within the scope of care they are licensed to provide, and the M+C organization complies with the provider antidiscrimination rules now set forth under new § 422.205).

M+C organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the M+C program. If original Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Medicare benefits component of an M+C plan. M+C plans may cover the same service when the conditions are not met, but these benefits would then be defined as additional or supplemental.

In summary, each M+C plan must include all Medicare-covered services available in the service area served by the M+C plan, with the exception of hospice services. Our longstanding policy of allowing organizations flexibility in the provision of services (for example, in terms of who provides the service, what equipment is used, where the service is provided, and what procedure is used) has not been affected by the BBA. Organizations are required to provide services within the guidelines of Medicare national coverage policy and other Medicare rules and requirements that apply to the traditional Medicare fee-for-service system. When a health care service can be Medicare-covered and delivered in more than one way, or by more than one type of practitioner, we continue to recognize a managed care organization's right to choose how services will be provided. These decisions have been left to managed care organizations to allow them to maximize their value purchasing power, and use resulting savings to provide services not covered by the Medicare program.

Comment: Several commenters raised questions about the requirements in § 422.101(b) that M+C organizations comply with our national coverage decisions and with the coverage decisions of local carriers and intermediaries with jurisdiction for claims in an M+C plan's geographic area. Among the issues raised were the following.

- The national requirements which must be followed, and the meaning of "HCFA's national coverage decisions".
- General confusion about the relationship between national coverage decisions and local medical review policy.
- Need for additional guidance in situations when plan service areas extend over a geographic area involving multiple carriers or intermediaries, and thus potentially conflicting medical review policies.
- Difficulties in obtaining coverage decisions by local carriers and intermediaries, and the unwillingness of some carriers to permit M+C organizations to be represented on carrier advisory boards.

Response: As discussed in detail above, M+C organizations must provide their plan enrollees access to all Medicare covered services. However, there is a distinction between the general rule that a health care service is covered under Medicare and the decision that an individual patient fits the clinical criteria necessary for receipt of the service. National coverage determinations and local medical

review policies establish what could be a covered benefit under Medicare and the clinical criteria under which the benefit must be provided. The M+C organization must determine whether or not an individual patient fits this clinical criteria. This process at the plan level constitutes an organization determination. In making organization determinations, M+C organizations are required to follow all national coverage determinations and relevant local medical review policies.

It is important to note, that all M+C organization determinations must be made based on the individual circumstances of a given case, using the best and most relevant information available. All organization determinations are subject to enrollee appeals to the M+C organization and subsequently to an independent review entity. The fact that an M+C organization determination was applying a local medical review policy does not in itself ensure that an appeal to the independent review entity might not result in a determination that the service in question was medically necessary for the individual enrollee and therefore should be covered.

In this final rule, we are revising § 422.101(b)(1) to clarify that the requirement that M+C organizations comply with national coverage decisions includes following the general coverage guidelines included in original Medicare's manuals and instructions to contractors, unless superseded by the M+C regulations or operational policy letters. The Coverage Issues Manual is the primary resource for national coverage decisions. Additional guidance on coverage of hospital and skilled nursing services, home health services, physician services, and other Medicare services can be found in the instructions in the Carriers, Intermediaries, and other HCFA manuals. In the absence of a national standard, M+C organizations should follow local medical review policies in making medical necessity decisions.

We recognize the potential for conflicting local medical review policies when an M+C plan's service area extends across the jurisdictions of more than one carrier, for example. Our general rule under OPL 46 continues to be that the M+C organization should apply the medical review policy of the Medicare carrier in the area where the services are furnished, since that is the policy that would apply to those services under original Medicare. However, as one commenter pointed out, an M+C organization is not precluded from covering services that a local carrier may have determined are

not covered, if the organization's own utilization and quality management standards support the medical necessity of the service. Similarly, an organization may occasionally need to make a coverage determination in a situation when there is neither national coverage policy or relevant local review guidelines. In all such cases, an M+C organization's fundamental responsibility is to use the best information available to make an informed decision on the medical necessity of a given service, and then to provide the medically necessary service, even if doing so may conflict with local medical review policies.

One way for an M+C organization to attempt to pursue consistency in medical review policies is to participate on the review boards of local carriers or intermediaries. We are aware of the difficulties M+C organizations are encountering in some areas of the country in participating on these boards, and are actively working to address this issue. We remain committed to establishing more standardized procedures for developing medical review policies, and for increasing M+C representation in formulating these policies.

Comment: Several commenters requested clarification of our policy regarding employer groups and the coordination of benefits with employer group health plans (EGHPs). They asked for clarification as to whether members of an EGHP had to be offered the same benefits as other Medicare enrollees, and whether it would be acceptable to offer an actuarial equivalent package. Another commenter asked that § 422.106 be amended to address coordination of Medicaid benefits, as well as EGHP benefits.

Response: EGHPs that are offered by an M+C organization must provide Medicare-eligible EGHP members the same benefits provided to all other Medicare enrollees under the M+C plan in which the beneficiary is enrolled. The benefits in the M+C plan may not be reduced or otherwise changed, and actuarially equivalent benefits may not be substituted in place of the M+C plan benefits. As noted below in the next response, EGHP benefits beyond those benefits offered under the M+C plan are considered outside the purview of our regulatory authority under the M+C program. However, we retain the authority and responsibility to assure that all Medicare beneficiaries enrolled in organizations that have a contract with Medicare (even if they are dually entitled to coverage under another plan) receive the same benefits and

protections as other Medicare beneficiaries enrolled in the plan.

We recognize that the existing regulations describing these situations are somewhat unclear. Therefore, we are revising the language at § 422.106 by reorganizing its requirements for clarity. Revised § 422.106(a)(1) clarifies that if an M+C organization contracts with an EGHP that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits supplementing the M+C plan benefits. Section 422.106(a)(1) states that all M+C program requirements apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract. We also are revising § 422.106 to delineate clearly that our review authority extends only to the M+C plan benefits provided to members of the EGHP, and the associated marketing materials, rather than to any other complementary benefits provided only under the EGHP. The rules contained in this regulation and the corresponding instructions and operational policy letters take precedence for benefits included in the M+C plan.

We are also adopting the commenter's suggestion that § 422.106 incorporate our requirements concerning the coordination of M+C and Medicaid benefits. These rules are conceptually identical to those governing EGHPs. Thus, for individuals dually eligible under Medicare and Medicaid who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the Medicaid benefits supplementing the M+C plan benefits.

Comment: One commenter questioned whether group health benefits offered by employers were considered to be supplemental benefits under the M+C program.

Response: Employer group health plan benefits paid by an employer on behalf of an employee or retiree, as well as Medicaid benefits furnished under a Medicaid State plan, are neither basic nor supplemental benefits. They are therefore outside the scope of M+C plan benefits regulated by the Medicare program. Other laws and regulations may apply to these benefits (such as ERISA requirements for EGHPs). We recognize in § 422.106 that M+C organizations may contract with employers to furnish benefits that complement those that an employee or

retiree receives under an M+C plan. Such benefits may include M+C plan premiums, cost sharing, and additional services. M+C organizations may design an M+C plan with the expectation that an employer group will offer a particular set of complementary benefits. In such a case, however, the M+C plan must be offered to all Medicare beneficiaries in the service area, regardless of whether they are eligible for the employer group benefits, and meet all other M+C plan requirements.

Comment: Several commenters expressed confusion regarding the benefit-related implications of the “conscience protection” provision contained in section 1852(j)(3) of the Act, which is a new provision giving enrollees rights to unrestricted physician counseling and advice. Under the conscience protection provision in section 1852(j)(3)(B) of the Act, implemented in § 422.206(b), the prohibition on interference with provider advice to enrollees in section 1852(j)(3)(A) of the Act (reflected in § 422.206(a)) may not be construed to require an M+C organization to provide or pay for counseling or referrals if the organization objects on moral or religious grounds and notifies enrollees of its policies in this regard. Some commenters asked whether the conscience clause in section 1852(j)(3)(B) of the Act and § 422.206(b) would permit an M+C organization to refuse to include a Medicare-covered service in its M+C plan, as otherwise required under § 422.101.

Response: The conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A) of the Act, not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) of the Act to cover all Medicare-covered services available in the area served by the M+C plan. To the extent the operation of the right to advice and counseling under section 1852(j)(3)(A) of the Act would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) of the Act allows the organization to decline to provide such service on conscience grounds if appropriate notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A) of the Act, it could not be affected by a provision that by its own terms affects only the way that “[s]ubparagraph (A) [of section 1852(j)(3)] shall * * * be construed.” It in no way affects obligations that arise

elsewhere in the statute. Therefore, an M+C organization could not rely upon section 1852(j)(3)(B) of the Act or § 422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover.

We note, however, that in the case of abortion-related services, Congress has provided M+C organizations with conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 211 of the fiscal year 2000 Department of Health and Human Services Appropriations Act, Pub. L. 106–113, we are prohibited from denying a M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. We are required, however, to make appropriate adjustments to such an entity’s M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

Comment: Commenters requested that copayments for outpatient psychiatric services be limited to the same percentages of copayments allowed for other services.

Response: With the sole exception of out-of-area emergency services, we have not prescribed limitations on copayments for individual Medicare services in the M+C regulations. In this case, the commenter’s suggestion would impose a requirement on M+C organizations that is inconsistent with the cost-sharing structure of original Medicare. We do not believe this would be appropriate.

5. Special Rules for Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine (§ 422.100(h))

Section 422.100(h) establishes special rules for screening mammography, influenza vaccine, and pneumococcal vaccine. Enrollees of M+C organizations may directly access, through self-referral, screening mammography and influenza vaccine. In addition, M+C organizations may not impose cost sharing for influenza vaccine and pneumococcal vaccine.

Comment: Several commenters expressed concern that enrollees may directly access out-of-network providers through self-referral. They believe that self-referrals should be limited to in-network providers. Furthermore, they feared that an enrollee may self-refer to noncertified facilities or noncredentialed providers.

Response: The right to directly access screening mammography services and flu vaccines does not include accessing these services out of network. Section 422.112(a) specifies that an M+C organization “may specify the networks

of providers from whom enrollees may obtain services” if the organization meets a number of specified conditions. M+C organizations thus have the discretion under § 422.100(h)(1) to require that self-referrals be made to a provider within the M+C plan’s network, as long as sufficient access is provided in that network. We note that if an M+C organization offers a point-of-service (POS) option under its M+C plan, an enrollee selecting this option could self-refer to an out-of-network provider, consistent with the payment rules established by the M+C organization.

Comment: One commenter stated that we should prohibit cost sharing for mammography as well as vaccines, noting that both health care services are preventive in nature and would be cost-effective measures for the Medicare program in the long term. The commenter pointed out that women constitute a substantial portion of the Medicare population, and asserted that allowing cost sharing for screening mammographies could be perceived as both gender-specific and discriminatory in nature.

Response: Various provisions of Title XVIII of the Social Security Act specify the coverage of mammography, influenza vaccine, and pneumococcal vaccine. The Act provides that there should be no deductible for any of these services. Further, while the Act indicates that there be no copayment for influenza and pneumococcal vaccine, it provides for a 20 percent coinsurance for mammography. (See, for example, section 1834(c) of Title XVIII and 42 CFR 410.152(h).) These are policies established by statute for the original Medicare program, and we see no basis for requiring M+C organizations to provide more favorable treatment to M+C enrollees than that provided to original Medicare beneficiaries.

Comment: A commenter requested that we clarify in the regulations that the prohibition on cost-sharing for influenza and pneumococcal vaccine applies to the imposition of cost-sharing on M+C plan enrollees.

Response: As requested by the commenter, we have added language to the regulation text to clarify that M+C organizations are prohibited from imposing cost sharing “on their M+C plan enrollees” for influenza and pneumococcal vaccines.

6. Special Rules for Point-of-Service (POS) Option (§ 422.105)

A POS benefit is an option that an M+C organization may offer under an M+C coordinated care plan, or network M+C MSA plan, to provide enrollees in

such plans with additional choice in obtaining specified health care services. A coordinated care plan may include a POS option as an additional benefit, a mandatory supplemental benefit, or an optional supplemental benefit. A network MSA plan may include a POS option only as a supplemental benefit.

Under a POS option, the M+C organization generally permits enrollees to obtain specified items and services outside of the M+C plan's normal prior authorization rules, but provides that enrollees will incur higher financial liability for such services. The enrollee may be required to pay a premium for the benefit unless the benefit is offered as an additional benefit. M+C organizations can establish what services are available under a POS benefit and the amount of member cost sharing subject to ACR limits. M+C organizations may also place other limits on the benefit; for example, a plan could offer a POS benefit as a travel benefit allowing members to access specified services when the member is traveling outside of the plan's service area.

Comment: Several commenters objected to the restriction in the interim final regulation at § 422.105(a) stating that a POS benefit can be used only to obtain services from providers that do not have a contract with the M+C organization. The commenters maintained that an important aspect of a POS benefit is that it allows beneficiaries who have reservations about joining a managed care plan the opportunity to enroll without following strict prior authorization requirements to access services, and that this consideration applies without regard to whether the provider is part of the M+C plan network. Some commenters also noted that the restriction against in-network use of a POS benefit was particularly unfair to M+C plans with large provider networks, since the likelihood of an in-network referral was much greater. Several commenters stated that if we are concerned about in-plan use of a POS benefit, the solution is monitoring rather than prohibiting beneficiary choice.

Response: In the interim final M+C regulations, we specified that an M+C POS benefit could be used by plan members only to obtain health care services from providers outside of the plan's contracted provider network (non-network providers). The intent of this restriction was to ensure that plan enrollees were not inappropriately induced to use a POS benefit to obtain services at higher cost from plan contracting providers that they could otherwise receive at lower cost by

following the plan authorization rules for obtaining health care services. However, we have reconsidered this position in response to the above comments, and in recognition of the fact that a number of organizations withdrew their POS benefit due to this restriction. We recognize that for some beneficiaries the ability to obtain health care services directly from providers without obtaining advance authorization is an important choice. Accordingly, in order to ensure that beneficiaries have the widest possible array of choices, we have decided to allow plans the option of offering a POS benefit that can be used by plan members to receive services from plan contracting providers.

We remain concerned about the potential for inappropriate cost-shifting to beneficiaries. To help guard against this possibility, we have revised § 422.105 to require that M+C organizations offering a POS benefit must track, and report to us upon request, POS utilization at the M+C plan level by both contracting providers and noncontracting providers. In monitoring use of the POS benefit, we will pay particular attention to potential overutilization of the POS benefit by plan enrollees in obtaining services from the plan contracting provider network. We will attempt to verify that it is a matter of choice when a plan member uses a POS benefit to obtain services, rather than due to the member being inappropriately denied prompt access to the service by the plan. We note that an M+C organization still has the option of offering a POS benefit through an M+C plan that can be used by plan members only to obtain health care services from providers who do not contract with the plan.

Comment: A commenter asked if the POS regulations apply to POS benefits that are offered only for employer group members. The commenter noted that under § 422.106, employer group benefits that are designed to complement the Medicare benefits are exempted from our review.

Response: An employer may through negotiation with an M+C organization provide a POS benefit for members of an employer group who elect to join an M+C plan. As described in the regulations at § 422.106, such enhancements to the Medicare-approved benefit package are not subject to our review or approval.

Comment: A commenter expressed concern about the requirement at § 422.105(d)(2)(iv) that a POS benefit must have a maximum annual out-of-pocket cap on enrollee liability. The commenter questioned whether capping

enrollee out-of-pocket expenses would leave the plan at risk for all out-of-network care received by the enrollee once the cap was exceeded.

Response: As the commenter stated, M+C plans offering a POS benefit must place an annual maximum cap on an enrollee's financial liability in using a POS benefit. The reason for requiring a cap on beneficiary financial liability is to ensure that beneficiaries understand in advance what their maximum financial risk is in using a POS benefit. However, once the annual maximum for a POS benefit is reached (including the beneficiary cap), the plan does not have to continue paying for health care service under a POS benefit. For example, consider a plan that offers a POS benefit with a \$5,000 annual maximum, and requires 20 percent coinsurance from the beneficiary using the POS benefit. In this example, the member's annual maximum financial liability under POS is \$1,000 (20 percent of \$5,000). Once the \$5,000 overall POS annual maximum is reached, the beneficiary has paid the out-of-pocket maximum of \$1,000 and the plan has contributed \$4,000 of the \$5,000 annual maximum for the POS benefit. At this point, the plan has no further obligation to cover services for the beneficiary under the POS benefit. Thus, any use of the POS benefit beyond this maximum would be at the enrollee's financial liability. We note that § 422.105(d)(2)(iii) specifies that an M+C organization must explain in the Evidence of Coverage the enrollee's financial responsibility for services that are not covered under the POS benefit or services beyond the maximum POS limit.

In general, we expect that organizations offering a POS benefit will be able to provide enrollees with timely information on the POS financial limits, coverage rules, and enrollee cost-sharing for a given service, including the capacity to provide enrollees with advance coverage information over the phone. For example, if the POS benefit has an annual dollar cap, enrollees should be able to phone the organization offering the POS benefit and be informed of how close they are to reaching the financial cap on the benefit. In addition, the plan should be able to advise an enrollee whether a particular service will be paid for under a POS benefit, how much the member will pay out-of-pocket, and how much the plan will contribute under the POS benefit.

7. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

As stated in the June 26, 1998 interim final rule, Medicare does not pay for services to the extent that there is a third party that is to be the primary payer under the provisions in section 1862(b) of the Act and 42 CFR Part 411. The M+C organization must, for each M+C plan, identify payers that are primary to Medicare under section 1862(b) of the Act and part 411; determine the amounts payable by those payers; and coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

The M+C organization may charge, or authorize a provider to charge, other individuals or entities for covered Medicare services for which Medicare is not the primary payer. If an enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may charge, or authorize a provider to charge the insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and part 411 of this chapter, or the M+C enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

Where Medicare is a secondary payer to employer coverage in the case of certain working Medicare beneficiaries, an M+C organization may charge a group health plan (GHP) or large group health plan (LGHP) for services it furnishes to a Medicare enrollee who is also covered under the GHP/LGHP, and may charge the Medicare enrollee to the extent that he or she has been paid by the GHP/LGHP.

Comment: Two commenters requested that the M+C regulations provide that Medicare secondary payer regulations apply generally to M+C organizations. One of these commenters also favored a cross reference to the Medicare overpayment regulations.

Response: M+C organizations are to apply only the Medicare secondary payer (MSP) rules as found in section 1852(a)(4) of the Act and in § 422.108. Other MSP provisions do not apply to M+C organizations, and they do not have recourse to them. However, M+C organizations are expected, as provided under § 422.108(a), to look to section 1862(b) of the Act and 42 CFR Part 411 to determine whether Medicare or some other party is the primary payer.

Since section 1852(a)(4) of the Act and § 422.108 are the only MSP

provisions that apply in the M+C context, M+C organizations would pursue their Federally authorized claims under State law. Federal preemption of State laws in the MSP context would occur only to the extent a State law would prohibit an M+C organization from complying with what the Federal rules authorize (that is, from billing and recovering from specified third parties, and from beneficiaries to the extent they have received third party payments that are primary to Medicare under MSP rules). These recoveries are not made on behalf of the United States and, therefore, the Federal overpayment rules cited by the commenter do not apply.

Comment: One commenter requested that enrollees be given written notice of their right to appeal an M+C organization decision to withhold payment under MSP rules, or file a request for a waiver of recovery of the overpayment.

Response: Section 422.568 requires an M+C organization to give an enrollee written notice of any denial, in whole or in part, which includes a description of the enrollee's appeal rights. It is not necessary to create a separate requirement in the MSP context. With respect to a request for waiver of recovery of the overpayment, since any recoveries are not obtained on behalf of the United States, State laws rather than Federal overpayment rules would apply.

Comment: One commenter believes that if an M+C plan enrollee with coverage primary to Medicare obtained services from providers not participating in the M+C plan, the M+C organization should pay for the services. By paying nonplan providers first, and then seeking recovery from the primary payer, the beneficiary would not be held responsible for the bill.

Response: There is no statutory authority to require M+C organizations to make payments to nonplan providers, except in the circumstances set forth in § 422.100(b)(1) (for example, emergency or urgently needed services, out-of-area dialysis) and § 422.114(b) (for example, access to services under an M+C private fee-for-service plan).

Comment: Three commenters recommended that since some States have laws that do not allow HMOs and health insurers to seek payment from primary payers, the regulations should be clarified to indicate that MSP rules preempt any State laws that would prevent an M+C organization from complying with the Federal law and regulations.

Response: We are adding a new paragraph "f" to § 422.108 to clarify that a State cannot take away an M+C

organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer. However, nothing in section 1852(a)(4) of the Act would prohibit a State from limiting the amount of the recovery; therefore, State law could modify an M+C organization's rights in this regard, but could not deny them entirely.

Comment: One commenter believes that the use of the term "charge" in this section is not appropriate. The commenter pointed out that "charge" has a specific meaning in the Medicare context (as in "reasonable charge"), and the use of "charge" in this section is not consistent with the commenter's understanding of the common meaning of this term. The commenter recommended revising the regulations to use the term "bill" or "collect from." The same commenter also suggested that there was ambiguity in the use of the word "determine" in § 422.108(b)(2), because "determine" and "determinations" also have different specific meanings under Medicare. "Calculate" or "identify" was suggested as a replacement.

Response: The intended meaning of "charge" as used in this section is "the imposing of a pecuniary obligation on another entity." Although this usage is technically correct and consistent with statutory language, in the interest of clarity, we are adopting the commenter's request, and changing "charge" to "collect from" in the regulation headings, and to "bill" in the body of the regulation text. We also have changed "determining" to "identify" in subsection (b)(2).

8. National Coverage Determinations (§ 422.109)

Section 422.109 addresses how M+C organizations are paid when a new Medicare benefit is required under a national coverage determination, but payment for this benefit is not yet included in the organization's capitation rate. Frequently, we develop coverage policy on new procedures or technology during the year. M+C organizations must provide these benefits as soon as they are covered by Medicare, even if this occurs during the middle of a contract year. If the cost of such new benefits exceeds a specified threshold, we pay the M+C organization on a fee-for-service basis under original Medicare payment rules to cover the services in question.

Comment: Commenters requested that we include a definition of "national coverage determination" in the M+C regulations, and objected to the fact that beneficiaries would be liable for paying

the Part A deductible, when the beneficiary in most cases has already been charged premium or cost-sharing amounts based on the actuarial value of this deductible.

Response: The definition of “national coverage determination” was not included in the M+C regulations because it is already set forth in § 400.202 of title 42 of the CFR; however, for the convenience of users of the M+C regulations, we have now repeated this definition in § 422.2. With respect to the issue of the Part A deductible, section 1852(a)(5)(A) of the Act provides that services covered by a national coverage determination involving significant costs not included in M+C capitation payments are not covered as a service that must be provided under the M+C contract in exchange for capitation payments. Section 1852(a)(5)(B) of the Act provides that the normal rule that capitation payments are made in lieu of regular Medicare payments (section 1851(i)(1) of the Act) does not apply in the case of additional services covered under a national coverage determination. Thus, the services would be covered under original Medicare’s coverage rules. Congress did not provide for a similar exception, however, to the rule in section 1851(i)(2) of the Act providing that “only the M+C organization shall be entitled to receive payments from the Secretary under this title for services furnished to [an M+C enrollee of that organization].” Read together, these provisions mean that the M+C organization will receive Medicare payment under original Medicare’s payment rules for services covered by a national coverage determination that triggers the procedures in § 422.109.

Under these payment rules, a beneficiary is liable for deductible and cost-sharing amounts, which is why § 422.109(b)(5) provides that enrollees would pay these amounts. Although the enrollee has in most cases paid a premium and other cost sharing based on the actuarial value of Part A and Part B deductibles and cost sharing, this amount is for services covered under the contract. These services are covered outside the contract under original Medicare payment rules. However, since the general Part A deductible arguably would already have been satisfied for the beneficiary through M+C plan premiums and cost sharing, we are revising § 422.109(b)(5) in response to this comment to provide that M+C enrollees are responsible only for coinsurance amounts. Medicare payments will thus be made without regard to satisfaction of the Part A deductible.

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

Consistent with section 1852(b)(1) of the Act, § 422.110 establishes that an M+C organization may not discriminate among Medicare beneficiaries based on any factor that is related to health status, including, but not limited to the following factors: medical condition (including mental as well as physical illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), or disability. The only exception to this rule is that an M+C organization may not enroll an individual who has been medically determined to have end-stage renal disease (unless the individual is already enrolled with the organization under a different plan). M+C organizations are required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act.

Comment: One commenter suggested that we require M+C organizations to provide handicapped-accessible facilities for marketing presentations, full access to plan information and plan providers, as well as access to the M+C organization itself.

Response: This comment speaks to the practice of health screening and the allocation of marketing resources with respect to disabled populations. Section 422.110(c) requires M+C organizations to meet the requirements of the Americans with Disabilities Act (ADA). Consistent with ADA, an M+C organization must ensure that its providers and marketing presentations accommodate persons with disabilities, both in terms of physical accessibility and communication of information. Thus, the organization and providers must afford the same freedom of choice with respect to providers to all enrollees. Further, access to information must be provided in appropriate alternative formats upon request, such as Braille, enlarged font (at least 14 point), audio cassette, closed or open captioning, or formats that accommodate low-literacy beneficiaries. In providing information access to hearing-impaired individuals, M+C organizations must not rely on relay services but must make available TTY/TDD service as well. Again, these requirements are consistent both with the Americans with Disabilities Act and with the M+C provisions in § 422.80(e)(2) regarding marketing to the disabled population.

10. Disclosure Requirements (§ 422.111)

Section 1852(c) of the Act lists several areas where an M+C organization must disclose specific information to each M+C plan enrollee. These disclosure requirements are set forth in § 422.111 of the regulation. M+C organizations are required to provide to each M+C plan enrollee, at the time of enrollment and at least annually thereafter, in a clear, accurate, and standardized form (that is, through the Evidence of Coverage), the following information regarding the enrollee’s M+C plan: Service area, benefits offered under the plan and under original Medicare, access to providers, out-of-area coverage, emergency coverage, supplemental benefits, prior authorization rules, grievance and appeals rights and procedures, quality assurance programs, and disenrollment rights and responsibilities.

M+C organizations are also required to provide additional information upon request of a beneficiary, including: General coverage and comparative plan information, information on the number and disposition of grievances and appeals, information on the financial condition of the M+C organization, the procedures the organization uses to control utilization of services and expenditures, and a summary of physician compensation arrangements. Section 422.111 also includes procedures for an M+C organization to follow when it intends to change its rules for an M+C plan, and describes the enrollee notification requirements when there are changes in a plan’s provider network.

Finally, as discussed in section II.B of this preamble, § 422.64 no longer lists the information that we must provide to beneficiaries. However, because § 422.111 referred to this material in several places, we are revising § 422.111 to incorporate the necessary specifications into a new paragraph (f).

Comment: Several commenters acknowledged the importance of providing beneficiaries with information on their range of health care choices, so that they can make informed decisions about their Medicare coverage. However, they were concerned that duplication of efforts will result from our responsibilities to provide beneficiaries with the information formerly specified in § 422.64(c) (now set forth in § 422.111(f)) combined with the requirements in § 422.111 concerning information that an M+C organization must disclose to its enrollees. The commenters viewed these requirements

as an unnecessary overlap of information.

Response: We have no intention of burdening M+C organizations with unnecessary disclosure requirements that duplicate our efforts. However, just as section 1851(d) of the Act mandates our responsibilities for distributing information to all beneficiaries (including the requirement at section 1851(d)(7) of the Act that M+C organizations provide us with the information needed to carry out these responsibilities), section 1852(c) of the Act establishes several specific requirements for M+C organizations to disclose plan information to their enrollees, and to individuals eligible to enroll in their plans. The M+C regulations do not expand upon the disclosure requirements set forth in the M+C statute. In general, the plan-specific information that we collect from M+C organizations for Medicare Compare (our database of comparative plan information) can also be used by M+C organizations to meet their statutory information disclosure responsibilities. Thus, although the statute does mandate that M+C organizations report similar information both to us and to their plan enrollees, we do not believe that the M+C disclosure requirements should result in significant additional burdens for M+C organizations.

Comment: Commenters discussed the importance of conveying required information to beneficiaries in a culturally competent manner. They suggested that criteria be developed by us for use by M+C organizations.

Response: We agree that plan information needs to be provided to beneficiaries in a culturally competent manner, so that beneficiaries are provided with the opportunity to make fully informed health care choices. We note that § 422.80(c)(5) addresses this concern by specifying that, for markets with a significant non-English speaking population, marketing materials and election forms must be provided in the language of those individuals. In order for M+C organizations to provide beneficiaries with plan information in a culturally competent manner, we provide guidance for both developing and reviewing marketing materials through our managed care manual, marketing guidelines, and operational policy letters. M+C organizations are required to submit their marketing materials and election forms to us for review prior to distribution to Medicare beneficiaries. The Regional Offices (RO), with direction from Central Office, are involved in reviewing and approving plans' marketing materials. In carrying

out these efforts, the ROs balance the M+C organizations' needs for flexibility in developing beneficiary information with our responsibility to assure that materials are compliant with the regulation and are consistent nationwide. The ROs require that information be changed if it is inaccurate, misleading, or unclear.

Our plans for standardizing beneficiary enrollment and appeals notices, including the Evidence of Coverage (EOC), involve consulting with interested parties, including beneficiary advocacy groups. We are now in the process of consumer testing the enrollment and appeals notices to ensure that the message of each notice is clearly understood by beneficiaries. (For a further discussion of cultural competency issues as they pertain to the delivery of services, see section II.C.11 below.)

Comment: Commenters suggested that information should be disclosed in a standard format or model notice, including information that must be provided upon request of the beneficiary.

Response: We agree that standardized formats for M+C beneficiary notification materials are needed. Health care information that is provided in a well-designed standardized format, using consistent, descriptive terminology, assists beneficiaries in making important decisions about their health care.

We have initiated a two-phase Marketing Material Standardization Project that includes input from the managed care industry and beneficiary advocacy groups. In Phase I, we have implemented, beginning October 15, 1999, a standardized Summary of Benefits (SB), the key pre-enrollment marketing document provided to beneficiaries, so that they can compare the same benefits and costs across several M+C plans and original Medicare. Phase II will involve standardizing beneficiary enrollment and appeals notices. We are conducting consumer testing of these notices in preparation for the final phase of the standardization initiative.

Phase II of our standardization project includes the EOC, also known as the Subscriber Agreement and Member Contract. The EOC contains an explanation of plan benefits (covered services), member rights, and member/M+C plan contractual responsibilities and obligations. The EOC is provided to beneficiaries when they join the M+C plan and annually thereafter. As part of the standardization process for the EOC, we released a model EOC on December 1, 1999, for use in contract year 2000,

that M+C organizations are required to distribute to all enrolled members by May 15, 2000. In developing the model EOC, we consulted with managed care industry representatives and beneficiary advocacy groups, and we intend to use this model as a baseline for developing the standardized EOC. The process for standardizing a document as important and comprehensive as the EOC requires adequate time for input from the industry and beneficiary advocacy groups, for public review and comment, and for implementation of the standardized document. We plan to begin standardization of the EOC in the Spring of 2000 and to complete the process in time for the November 2001 annual election period for contract year 2002.

We also have provided guidance to M+C organizations on the manner and form for disclosing the information required under § 422.111(c) upon a beneficiary's request. For example, OPL 099.081, issued on February 10, 1999, addresses appeal and grievance data disclosure requirements, and further clarifying instructions were issued in OPL 2000.114. These disclosure requirements are consistent with the reporting units for the Health Plan Employer Data and Information Set (HEDIS), the Medicare Consumer Assessment of Health Plans Study (CAHPS), and the Medicare Health Outcomes Survey (HOS). We have also issued guidance on how M+C organizations can best provide information relating to compensation for physicians, specifically incentive arrangements. The guidance includes suggested language for marketing materials as well as suggested responses for requests from beneficiaries. Again, our ROs will review these materials as part of their usual responsibilities for pre-approving beneficiary materials.

Comment: Commenters expressed concern that information concerning the number and disposition of appeals and grievances from M+C plans with low enrollment may not be statistically valid, and suggested that reporting such data could be misleading to beneficiaries. They recommended that, if an M+C organization offers a number of different M+C plans in a single service area, the organization should report appeals and grievance data on an aggregate basis, rather than on a plan-specific basis.

Response: We assessed alternative ways to report this information and decided that the most meaningful way to report this information would be to make it consistent with the reporting unit for HEDIS, CAHPS, and the Medicare HOS. The reporting unit for

these instruments is the “contract market,” which implies either reporting by contract or by a market area within a contract. M+C organizations must report for each contract unless we divide the contract service area into “market areas.” We will assess all contract service areas to determine whether M+C organizations must report by market area, and will notify plans as soon as possible whether they must report by market area. Further details on subdividing the contract service area into market areas can be found in OPL 099–081. The OPL also describes the data collection periods and reporting periods that have been established in order for M+C organizations to report data consistently. We and our contractors are working with M+C organizations and consumer groups to determine additional information needed to develop a national managed care appeal and grievance data collection and reporting system, with data disclosure requirements to be built into this system.

Comment: Several commenters expressed concerns over the requirement for public reporting of quality improvement results. They feared that this reporting could result in: (1) M+C organizations altering their decision making to produce competitively attractive numbers” at the expense of good patient care, or (2) the dissemination of data that could easily be misinterpreted by Medicare beneficiaries, rather than of value in facilitating informed beneficiary choice.

Response: The reporting of plan-specific quality and performance indicators is based directly on the requirements of section 1851(d)(4)(D) of the Act. Moreover, we believe that it is essential for plan comparison purposes that M+C organizations report on standardized quality measures. The standardized measures that we are requiring, as discussed in detail in section II.D of this preamble, are largely those of HEDIS. These measures are predictive of health care outcomes, well-defined, and well-established in the private sector. Thus, we do not believe that the commenters’ concerns that the reporting of these measures will negatively affect M+C organizations’ decision making and lead to widespread public misinterpretation are justified.

Comment: We received several comments regarding notification of beneficiaries of changes in an M+C plan’s provider network. Three commenters suggested that the requirement that written notification to the enrollee occur within 15 working days of the receipt or issuance of a notice of provider termination would be

confusing for enrollees and an administrative burden for M+C organizations. Another commenter suggested that the 15 working days be converted to calendar days to be consistent with the appeals requirements under Subpart M.

Response: We recognize that the requirement that written notice be provided “within 15 working days of receipt or issuance of a notice of termination” has the potential in some situations to cause confusion for beneficiaries and impose an unnecessary administrative burden on M+C organizations. For example, because contract negotiations with providers often extend beyond a 15-day period after initial notice of termination, an M+C organization may be unable to furnish definitive network information to its enrollees within the 15-day time frame. Therefore, we are revising § 422.111(e) to decouple the enrollee notice time frame from the “issuance or receipt” of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date. (As the commenter suggested, we agree that measuring this time frame by using calendar days, rather than working days, would improve the internal consistency of the M+C regulations, as well as eliminating any possible confusion over what constitutes a “working day.”)

Comment: Two commenters suggested defining “regular basis” for purposes of § 422.111(e). Under this requirement, a M+C organization must notify “all enrollees who are patients seen on a regular basis by the provider whose contract is terminating.” One commenter suggested that “regular basis” be defined as seeing a provider within the last 180 days or 6 months.

Response: Section 422.111(e) is clear that all enrollees who are patients of a primary care professional (PCP) must be notified by the M+C organization when a PCP’s contract is terminated. We are not making any change in this regard. For other providers, the regulations establish the “regular basis” standard. Generally, we would interpret this standard to require the notification of all enrollees who have a referral to a specialist for an ongoing course of treatment, or of all regular patients of an OB/GYN, for example. In combination with the explicit requirement for notification of all patients of a PCP, we believe that the “regular basis” standard is sufficient for accomplishing the objective of notifying all enrollees who are likely to be affected by a provider termination. We note that this

requirement does not preclude the providers themselves from notifying M+C enrollees of the termination of their participation in an M+C plan’s provider network.

11. General Access Requirements (§ 422.112)

a. Introduction

Section 422.112 establishes a series of requirements aimed at ensuring that enrollees in M+C plans have adequate access to services. As discussed in our June 26, 1998 interim final rule (63 FR 34989), these requirements stem from section 1852(d) of the Act and existing regulations and policies under part 417, as well as addressing recommendations from the Consumer Bill of Rights and Responsibilities, and reflecting standards from the Quality Improvement System for Managed Care (QISMC).

On February 17, 1999, we published a final rule (64 FR 7968) that set forth limited changes to the M+C regulations published in the June 26, 1998 interim final rule. In the February 17, 1999 final rule, we made changes to several of the access provisions of this section. These changes involved the coordination of care requirements, provisions related to complex or serious medical conditions, notification requirements when specialists are terminated from an M+C plan, and initial care assessment requirements.

More specifically, for serious and complex conditions, the treatment plan may be updated by a health care professional other than the primary care provider. Furthermore, this section now requires that the M+C organization ensure adequate coordination of providers for persons with serious or complex medical conditions. Under the general coordination of care requirements, the responsibility for ensuring coordination of care is not limited to an individual provider. Instead, the organization must: (1) Establish policies to ensure coordination; and (2) offer each enrollee a primary source of care. Further, as to the initial assessment, each organization will be expected only to demonstrate a “best effort” attempt to complete the assessment of health care needs within 90 days of enrollment. Finally, we no longer require, when a specialist is involuntarily terminated from an M+C plan, that the M+C organization offer to provide enrollees with the names of other plans in the area that contract with the specialist. However, as discussed above, the general requirements regarding notification of affected patients upon provider

termination remain in effect. Comments on aspects of the access requirements that were not addressed in our February 17, 1999 final rule are discussed below.

b. Provider Network (§ 422.112(a)(1))

Section 422.112(a)(1) requires M+C organizations that wish to limit an enrollee's choice of providers to maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. We received several comments regarding access standards and one comment regarding contracting with community pharmacies.

Comment: Several commenters asked us to elaborate on access standards by including time and distance travel standards, such as specifying a 30-mile standard except where travel is difficult.

Response: Both the Medicare managed care manual and the QISMC guidelines issued on September 28, 1998 specify that a 30-mile standard must be satisfied in order to meet access requirements, except where a different standard is justified by geographic factors. We believe the inclusion of this requirement in these documents provides sufficient guidance on this subject. Furthermore, because the community pattern of care in some rural areas is to travel further than 30 miles for care, we do not believe it would be appropriate to establish an absolute 30-mile standard in the regulations.

Comment: One commenter requested that we require M+C organizations to contract with community pharmacies that are easily accessible.

Response: Community pharmacies have a number of advantages, and thus, M+C organizations should consider this as an option in providing pharmacy services. However, other options, such as pharmacy benefit management companies or mail order pharmacies, may have other advantages that are appropriate for M+C organizations to consider, such as lower cost. In choosing among these options, the M+C organizations must ensure that the providers of pharmacy services meet the various access and quality standards required by these regulations, implementing manuals and guidelines. Given these criteria, we do not believe it appropriate to require that community pharmacies be mandated as the source of pharmacy services.

c. Primary Care Provider Panel (§ 422.112(a)(2))

Section 422.112(a)(2) requires an M+C organization that wishes to limit an enrollee's choice of providers to

establish a panel of PCPs from which an enrollee may choose. We received two comments regarding the PCP panel.

Comment: One commenter specified that all PCPs should be licensed physicians or Doctors of Osteopathy.

Response: QISMC Standard 3.2.1.2 provides additional guidance with respect to our policies regarding PCPs. The guideline states:

An organization may permit licensed practitioners other than physicians to serve as primary care providers, consistent with requirements of applicable State laws. (Qualifications of such practitioners, and the degree of supervision required, are generally established under State law). If an organization designates nonphysician practitioners as primary care providers, it must still ensure that each enrollee has a right to direct access to a physician for primary medical care. This right may be ensured in either of two ways: (a) the enrollee may choose between a physician and nonphysician primary care provider, and may change this choice at any time; or (b) when the enrollee is not allowed such a choice, an enrollee with a nonphysician primary care provider may have timely access to a physician upon request.

The guideline further states: "An organization may allow an enrollee to select a physician group, clinic, federally qualified health center, or other facility with multiple practitioners as his or her primary source of care. To the extent feasible, the enrollee must be allowed to choose an individual primary care provider within the group or facility."

Thus, the QISMC guidelines do not limit enrollees to the use of physicians or Doctors of Osteopathy as PCPs. However, as indicated, an M+C organization must provide enrollees with access to physicians or Doctors of Osteopathy upon request. Furthermore, § 422.112(a)(1) requires that the M+C organization have an adequate network of providers and § 422.112(b)(2) requires the organization to offer each enrollee a source of primary care. In addition, consistent with the BBA provisions regarding antidiscrimination, and the Consumer Bill of Rights and Responsibilities, we intend to provide enrollees with freedom of choice in the selection of providers subject to the above constraints. Therefore, we are not adopting the commenter's suggestion. We note that an M+C organization's use of nonphysicians to deliver Medicare benefits must be consistent with Medicare coverage requirements, such as "incident to" supervision requirements. To the extent nonphysicians are providing non-Medicare covered services as an additional or supplemental benefit, these requirements do not apply.

d. Specialty Care (§ 422.112(a)(3))

This section requires an M+C organization to provide or arrange for necessary specialty care, and gives women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services, notwithstanding that the M+C organization maintains a PCP or some other means for continuity of care.

Comment: One commenter expressed concern that an M+C organization may prohibit enrollee access to a specialist without a referral from a PCP, even when not all enrollees will choose to select, or be provided, a PCP. This would effectively deny access to specialist care to such individuals.

Response: Again, all M+C organizations must provide an adequate network of providers (§ 422.112(a)(1)), offer to provide each enrollee with an ongoing source of primary care (§ 422.112(b)(2)), and provide a primary source of care to each enrollee who requests one. In addition, § 422.112(a)(3) requires an M+C organization to provide or arrange for necessary specialty care. (As discussed above in section II.C.1, we are revising § 422.112(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.) If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, specialty care is medically necessary, and the enrollee has not selected a PCP, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to provide the necessary care. Accordingly, we have revised § 422.112(a)(2) to specify that the M+C organization must make specialty care available even if a plan enrollee has not selected a PCP.

Comments: Several commenters asked for clarification of the terms "routine" and "preventive" as they apply to women's health services. They asserted that routine services should include more than just preventive services, while the examples offered in the preamble to the June 26, 1998 interim final rule only were limited to preventive services. One commenter noted that there are many services that OB/GYNs are most appropriately qualified to provide that should not require a referral from another physician, such as hormonal replacement therapy, and treatment of osteoporosis, genital relaxation disorders, incontinence, abnormal uterine bleeding, urinary tract infections

(UTI), and sexual dysfunction. Another commenter suggested that we clarify that even though women have direct access to women's health specialists, it was not intended that the PCP be bypassed.

Response: We consider routine and preventive women's health care services to mean: an exam that is provided on a regular, periodic basis, in the absence of presenting symptoms, diagnosis or complaints, for disease prevention and health maintenance. The examples from the commenter, therefore, are not routine and preventive.

In the setting of such an exam, abnormalities may be found, such as incidental vaginitis or UTI, or abnormal Pap smear. We would consider routine services to follow up on such gynecologic abnormalities to be included under this definition.

We agree that the provision is unclear about the role of PCPs, and have deleted from § 422.112(a)(3) the reference to "while the plan maintains a PCP or some other means for continuity of care."

Although the regulations require that M+C organizations allow women direct access (that is, without referrals or preauthorization) to a women's health care specialist within the network for women's routine and preventive services, if there is a PCP, he or she needs to be kept informed of the health care provided by such specialists. It is up to the M+C organization to develop appropriate strategies for assuring such an outcome.

We note that an M+C organization may place restrictions on enrollees as to the eligible universe of providers to whom they may "self-refer" for women's health services. Thus, QISMC guideline 2.2.3.2 provides for M+C organizations to create formal subnetworks. In these cases, an organization can require an enrollee at the time of initial selection of a PCP, to choose an entire subnetwork that may also include specialists, hospitals, or other providers. The enrollee may be required to obtain covered services, including routine and preventive women's health services through providers affiliated with the system. Under the QISMC guideline, an enrollee could change his or her choice of subnetwork at any time. (See the guidelines for further details, including an M+C organization's responsibilities to ensure that enrollees are aware of the implications of their choice of a PCP in terms of the available subnetworks associated with a given PCP.)

Comment: One commenter suggested that we allow OB/GYN specialists to serve as PCPs.

Response: Although such a practice is permissible under the M+C regulations, we believe that this is a decision that should be made by the M+C organizations, based upon the needs of their enrollees and available resources. This position is consistent with that adopted regarding use of specialists with respect to "serious and complex" medical conditions, as stated in the February 17, 1999 final rule.

e. Serious Medical Conditions (§ 422.112(a)(4))

Under § 422.112(a)(4), M+C organizations must have procedures that enable the organization to identify individuals with serious or complex medical conditions, assess and monitor those conditions, and establish and implement treatment plans.

Comment: Several commenters asked for clarification of what is meant by "serious or complex medical conditions."

Response: On August 31, 1999, the Institute of Medicine (IOM) submitted a final report to us, entitled "Definition of Serious and Complex Medical Conditions." This report is available through the Internet at "www.nas.edu".

A key recommendation made in the report is: "The committee recommends that the Health Care Financing Administration should provide guidance [emphasis added] to health plans to assist their efforts to identify patients with serious and complex medical conditions. Specifically, the committee recommends the following language be used to facilitate efforts of plans to identify their enrollees with 'serious and complex conditions': A serious and complex condition is one that is persistent and substantially disabling or life-threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member."

In view of the committee's recommendation that it is premature to establish an administrative definition of these terms, we have decided not to make any changes at this time to the regulations regarding serious medical conditions. We will provide further policy guidance on the meaning of this definition through a future OPL. For now, M+C organizations have the option of adopting the IOM definition or developing an alternative definition.

The committee also recommended that rather than focus on access to specialists, the treatment plans that M+C organizations develop should address access to specialty care. Furthermore, the committee recommended that M+C organizations

develop a care management strategy that integrates the participation of all those involved in the care of the patient, including primary care physicians; medical and surgical specialists; nurses and nurse specialists; behavioral and mental health specialists; physical, occupational, and speech therapists; social workers; allied health professionals; and community-based service providers. The forthcoming OPL will address these strategies, as well as provide guidance on implementation and monitoring procedures.

f. Written Standards (§ 422.112(a)(7))

Section 422.112(a)(7) (as recodified in the February 17, 1999 final rule) requires the establishment of written standards for specified areas of policy and procedures (coverage rules, practice guidelines, payment policies, and utilization management). This section is based on existing regulations and policies under part 417. We received two comments regarding this requirement.

Comment: In a comment cosigned by one hundred and fifty advocacy organizations, it was suggested that we amend the regulations regarding use of practice guidelines to specifically encourage or require contracting managed care plans to use Federally-developed practice guidelines, where appropriate.

Response: In general, we concur with the commenters that the use of Federally-developed practice guidelines, such as those produced by the Department of Health and Human Services, in the provision of services is a desirable objective. However, we believe that the commenter's suggestion that use of these guidelines be mandated by regulation would be inconsistent with section 1801 of the Act, which provides that the Medicare statute "shall [not] be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided. * * *" While we thus do not believe that mandating use of Federal guidelines is appropriate, we do encourage M+C organization health provider committees to explicitly consider such recommendations, particularly as they relate to care of enrollees with high-risk, complex care needs (such as those with HIV disease, cancer, etc.).

Comment: One commenter requested that we specify that the "responsible health professionals" be included in the development of practice guidelines and medical review criteria.

Response: We encourage M+C organizations to include the responsible health professionals in the development of such written standards. In some cases, however, a physician may be qualified to develop standards that apply to other health professionals, and it could impose an undue burden on M+C organizations to require that all responsible health care professionals always be consulted about standards. We therefore do not believe it would be appropriate to impose an absolute requirement that all health professionals always be included in developing written practice guidelines. We believe, however, that as a general matter, it is important that health care professionals such as physician assistants, advanced practice nurses, clinical psychologists and others integrally involved and knowledgeable regarding treatment planning and delivery, contribute to the process of standard development. We would thus expect that M+C organizations generally will consult with such professionals in developing guidelines in their areas, even though we are not imposing an absolute requirement for such consultation in all cases. For a further discussion of this issue, see the portion of the February 17, 1999 final rule dealing with provider participation rules.

g. Cultural Considerations
(§ 422.112(a)(9))

Section 422.112(a)(9) (as recodified in the February 17, 1999 final rule) requires that services be provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, diverse cultural and ethnic backgrounds, and physical or mental disabilities. We received many comments regarding this section.

Comment: Many commenters asked for clarification regarding the term “culturally competent” and our expectations with respect to the implementation and monitoring of this requirement. While some commenters asserted that the cultural competence requirement would be too burdensome and should be deleted, most supported the requirement, but requested additional detail and guidance regarding its interpretation.

Response: In reviewing the comments received, there were several recurrent themes: (1) Widespread support of the general requirement that all health care services be provided in a culturally competent fashion; and (2) a need for us to clarify our expectations with respect to acceptable activities undertaken to achieve that goal.

We do not believe that changes to the regulation text regarding the definition of cultural competence are needed, other than to delete the reference in the regulations to mental and physical disabilities (as discussed below). However, in this preamble, we will attempt to provide further guidance on this issue. We also intend to incorporate the principles discussed here into the QISMC guidelines as we revise the QISMC cultural competence standards.

We believe that the delivery of culturally competent health care and services requires health care providers and administrative staff to possess a set of attitudes, skills, behaviors, and policies that enables the organization to function effectively in cross-cultural situations. Appropriate care delivery should reflect an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices and communication patterns of beneficiaries and their families to improve services, strengthen programs, increase community participation and eliminate disparities in health status among diverse population groups.

Activities to promote achievement of this objective fall under a variety of categories, including but not limited to what we refer to as “Organizational Readiness,” “Community Assessment,” “Program Development,” and “Performance Improvement,” for example. Under Organizational Readiness, M+C organizations would conduct educational programs to increase the knowledge of their staff about the unique health care beliefs, attitudes, practices, and communication patterns of the populations served by their plan. Title VI of the Civil Rights Act (see 28 CFR § 42.405(d)(1)) specifically requires that M+C organizations provide assistance to persons with limited English proficiency, where a significant number or percentage of the eligible population is likely to be affected. These requirements may require the organization to take some of the following steps: assess the language needs of beneficiaries in their service area, provide sufficient access to proficient interpreters, and disseminate written policies on the use of interpreters. In addition, the M+C organization provider network should be capable of meeting the cultural, linguistic, and informational needs of the beneficiaries residing in the service area. Ideally, the racial and ethnic diversity of the service area would be reflected in the provider network and staff of the M+C organization. The literature has demonstrated that

enrollees are more likely to seek and accept health care services when delivered by one of their own racial or ethnic group. The M+C organization must ensure that all employees have received education regarding the importance of providing clinically competent and culturally appropriate services.

Community Assessment entails conduct of a market assessment to identify the specific health care needs of the beneficiary population as they relate to enrollee groups’ health problems (for example, some diseases are ethnically and genetically linked). Using existing and secondary data resources, organizations would collect data to the extent necessary to identify any special culturally-based health care needs among their beneficiaries. Program Development would entail implementation of formal programs and culturally sensitive patient education projects that reduce and eventually eliminate cultural, linguistic, and informational barriers known to deter or discourage health-seeking behavior.

Finally, Performance Improvement would entail addressing an identified need or opportunity for improvement, either through a quality improvement project or other formal program that seeks to resolve undesirable differences in utilization of services and outcomes of care across all relevant racial, ethnic and cultural groups served by the managed care organization.

The goal is to promote quality health care services, ensure effective dissemination of information, and enhance consumer rights and protections by fostering a demonstrated commitment to and establishing a coordinated and integrated system for, cultural competence. This approach is consistent with other Federal initiatives and recommendations from the President’s Race Initiative and from the President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

As achieving this objective is a M+C program requirement, M+C organizations will be monitored for compliance in this regard. We have developed additional implementation tools to assist M+C organizations in meeting the cultural competency requirement, such as operational specifications for five initial test measures and further steps which could be taken to improve, test, and expand on enrollee, disparity and standard-based inventories. The specifications for the five initial measures were developed based upon the recommendations of an expert panel and would require no new data collection on the part of the M+C

organization. We will soon be offering these measures to M+C organizations for use in their QAPI projects.

Finally, ensuring culturally competent care is congruent with our commitment to being a prudent purchaser of health care services. A growing body of knowledge demonstrates that when care is provided in a clinically competent and culturally appropriate fashion, it is more readily understood and accepted by the patient. As a result, patient compliance with treatment is enhanced, outcomes are improved, and health care costs and expenses are reduced as a result of diminished morbidity and mortality.

Comment: One commenter pointed out that physical and mental disabilities are unrelated to cultural competence issues. The commenter stated that including a reference in § 422.112(a)(9) to individuals with physical and mental disabilities was insensitive and inappropriate, noting that such disabilities are not a “culture”.

Response: We believe that the principle objective underlying the requirement to provide services in a culturally competent manner is to address unique racial and ethnically-related health care concerns. Thus, we agree with this commenter, and are deleting the relevant language. We note that the special concerns and rights of individuals with physical or mental disabilities are addressed elsewhere in the M+C regulations (for example, under §§ 422.110(c) and 422.502(h)(1)(iii)).

Comment: One commenter believes that Federal law prohibits providing material below high school reading level.

Response: We were unable to locate any statutory citation in support of the commenter's view, and none was provided by the commenter. We believe that the commenter is mistaken that materials at a reading level below high school cannot be provided. Market research has shown that the majority of Medicare enrollees are able to most effectively comprehend the complex issues addressed in our literature when the information is targeted for those at a 4th–6th grade reading level. The Medicare Handbook accordingly is geared for individuals at precisely that level. Therefore, we believe that our current approach is both appropriate and well-justified.

12. Confidentiality and Accuracy of Enrollee Records (§ 422.118)

Consistent with section 1852(h) of the Act, § 422.118 requires M+C organizations to establish procedures that safeguard the confidentiality and accuracy of enrollee records that

identify a particular enrollee, including medical documents, administrative documents, and enrollment information. The regulations specify that information from these records may be released only to authorized individuals. Each M+C organization must establish procedures for complying with the confidentiality standards, including policies governing access to information within the organization as well as when and how information may be disclosed outside the organization without enrollee authorization. Additionally, the M+C organization must maintain accurate records and ensure timely access for enrollees who wish to examine their own records.

The M+C organization must abide by all applicable State and Federal laws regarding confidentiality and disclosure of health information and any other information about enrollees. In the existing regulations, “mental health records” are mentioned separately as subject to this requirement. However, because mental health records clearly constitute a subset of the other health records specified at § 422.118 (that is, “medical records, health information, and any other enrollee information”), we are revising the regulations via this final rule to eliminate the redundant separate reference. This has no effect on the substance of the requirement.

Comment: Several commenters have suggested that the industry needs one Federal standard for confidentiality, especially in light of the fact that State confidentiality laws would not be preempted unless they conflict with Federal requirements. One commenter stated that there thus could be 50 different sets of patient confidentiality standards.

Response: The M+C regulations are not the appropriate vehicle for establishing the balance between State and Federal confidentiality laws. This issue is under discussion in Congress, which is a more appropriate venue for making this determination. Further, because Federal standards for confidentiality and privacy of individually identifiable health information have recently been proposed by the Secretary (as discussed in some detail below), and because M+C organizations will be required to comply with those regulations once they are finalized, we have chosen not to make substantive changes in the existing M+C confidentiality regulations at this time. In the interests of clarification, however, we have made some technical changes in the existing requirements, including reorganizing them to (1) promote consistency with the confidentiality requirements under other Federal health

care programs (such as Medicaid) and (2) emphasize the importance of applicable Federal and State laws, while still ensuring that the privacy of M+C enrollees' health information is safeguarded in the absence of other applicable laws.

Pursuant to Section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191), the Secretary of Health and Human Services was directed to promulgate regulations on the confidentiality and privacy of individually identifiable health information if confidentiality legislation governing electronic health information was not enacted by August 20, 1999. Such legislation was not enacted, and the Secretary published a notice of proposed rulemaking, Standards for Privacy of Individually Identifiable Health Information, in the **Federal Register** at 45 FR 160, *et seq.*, on November 3, 1999. (This proposed rule is available at the Administrative Simplification web site, <http://aspe.hhs.gov/admsimp/>). As proposed, these regulations would apply to health information that has been maintained or transmitted electronically, or held by health plans, health care providers who engage in certain electronic transactions, and health care clearinghouses. M+C organizations would be considered health plans for the purposes of the proposed privacy regulation. The proposed rule would establish detailed standards for the use and disclosure of electronic health information.

Comment: Several commenters suggested that we develop procedures regarding the maintenance of confidentiality of patient records, and have said that these procedures should be provided to the beneficiary.

Response: As noted above, in light of the pending privacy regulations, we are not imposing any additional requirements here. The Secretary's proposal would require health plans (including M+C organizations) and other covered entities to develop procedures for maintaining the privacy of health information and to inform patients and enrollees of their confidentiality practices.

Comment: Several commenters asked for clarification of preamble language at 63 FR 34991, which they read to preclude M+C organizations from sharing patient information with outside contractor claims administrators without individual patient consent.

Response: The M+C regulations are not intended to prohibit the sharing of patient identifiable information within an M+C organization or between the

organization and its contractors for the purposes of payment, treatment or coverage decisions. Thus, an M+C organization may circulate such information within the organization, and externally, to the extent that such information is needed to coordinate or bill for the care of an M+C enrollee. However, M+C organizations generally are prohibited from selling or circulating patient identifiable data to outside organizations or entities that are not involved in payment, treatment, or coverage decisions, without specific authorization from the enrollee or an enrollee's authorized representative.

Comment: Several commenters asked us to specify that patient data may be shared for bona fide medical research, and to limit the extent to which patient identifiable information could be released for research purposes. One commenter asked for clarification as to whether information can be shared in the event of a court order or subpoena.

Response: As discussed above, we are not expanding on the existing M+C confidentiality requirements to address specific issues here, such as to whom and under what conditions release of patient identifiable information is authorized. To the extent that M+C organizations have proper safeguards in place and to the extent that State law authorizes the release of such information, this section of this regulation does not bar the use and disclosure of records for medical research. Section 422.118(a) expressly states that medical records may be released in accordance with "court orders or subpoenas." The Department's proposed privacy regulation would set forth specific standards for disclosing information in both of these situations, and when that regulation is finalized, M+C organizations will be permitted to disclose information only in accord with those standards. In the interim, M+C organizations could voluntarily use those proposed privacy standards as a guide in formulating their policies and making disclosure decisions.

13. Information on Advance Directives (§ 422.128)

Advance directives are documents recognized under State law, signed by a patient or his/her authorized representative that explain the patient's wishes concerning a given course of medical care should a situation arise when he or she is unable to make these wishes known. The M+C organization is legally responsible for providing enrollees with information on their rights under State law to establish advance directives, and ensuring that advance directives are documented in a

prominent part of the beneficiary's medical record. The M+C organization is permitted to contract with other entities to furnish information concerning advance directives requirements. The M+C regulations retain for M+C organizations the requirements that applied to HMOs and CMPs under part 417, which state an HMO must maintain written policies and procedures concerning advance directives as defined in § 489.100 with respect to all adult individuals receiving medical services by or through HMOs.

Comment: Commenters asserted that M+C organizations should not be responsible for obtaining or documenting the existence of an advance directive, and that organizations should ensure that "responsible health care entities educate patients and document the existence of advanced directives." The commenters stated that an M+C organization cannot reasonably be held responsible for documenting whether an individual has elected an advance directive because the chart is in the control of the primary care physician.

Response: Our position that an M+C organization should be responsible for obtaining and documenting the existence of advance directives is consistent with the requirements of both State law and the Patient Determination Act of 1991, which we expanded upon in our final rule on June 27, 1995 (42 CFR § 489.100). Both the Act and the regulations include managed care organizations among the entities responsible for obtaining and documenting advance directives information. The BBA made these same standards applicable to M+C organizations.

Comment: A commenter asked for clarification as to what we will accept as evidence of best efforts and reasonable plan oversight. Another commenter suggested we should require M+C organizations to submit and receive approval on all advance directive documents. This commenter feared (and alleged that there is proof) that an M+C organization might lead beneficiaries down a path of less care in times of greatest need, and that advance directives could be used by an organization to coerce a beneficiary to forego care.

Response: The M+C advance directive requirements, which fee-for-service providers have been following for some years, are guidelines which refer to State law. Therefore, M+C organizations must comply with the advance directive requirements of the States which they serve, and we cannot give detailed guidelines as to what constitutes best

efforts in each State. We believe the Medicare regulations give provider entities and States a great deal of flexibility, and we are prepared to work with them on specific entities.

Regarding the commenter's concerns about possible encouragement of inappropriate underutilization as the result of advance directives, we believe that the monitoring process will prevent and/or identify abuses of advance directives. For example, the M+C contractor interim monitoring guide states that an organization's policies must promote enrollee understanding of their conditions and facilitate the development of mutually agreed upon treatment goals. We have stated in QISMC and OPL 98-72, that with respect to advance directives, the M+C organization must meet several criteria, including that it may not make treatment conditional or otherwise discriminate on the basis of whether an individual has executed an advance directive. Underutilization patterns should be revealed by other aspects of the monitoring process, and, with regard to advance directives specifically, we are exploring the possibility of developing further monitoring criteria.

D. Quality Assurance

1. Overview

The quality assurance requirements for M+C organizations were addressed in subpart D of the June 26, 1998 interim final rule. These requirements implement and are based on the provisions of section 1852(e) of the Act. Further, they incorporate the requirements of section 1851(d)(4)(D) of the Act, which provides that the information made available to Medicare beneficiaries for plan comparison purposes must include plan quality and performance indicators, to the extent available. Section 1852(e)(1) of the Act sets forth the general rule that each M+C organization must establish an ongoing quality assurance program, consistent with implementing regulations, for the health care services it provides to enrollees in the organization's M+C plan or plans. The remaining portions of section 1852(e) of the Act contain the required elements of the quality assurance program, requirements for external review, and provisions concerning the use of accreditation organizations to determine compliance with the quality assurance requirements.

2. Quality Assessment and Performance Improvement Requirements (§ 422.152)

Section 422.152 incorporates each of the explicit statutory requirements of

sections 1852(e)(1) and (2) and section 1851(d)(4)(D) of the Act. Section 422.152 also includes additional detail to clarify what an M+C organization must do to meet the statutory requirements. Sections 422.152(b) through (d) of the interim final rule set forth requirements that M+C organizations must meet with respect to M+C coordinated care plans and network MSA plans.

Section 422.152(c) requires that the organization: (1) measure and report its performance to HCFA using measures required by HCFA; and (2) for M+C coordinated care plans, achieve any minimum performance levels that may be established locally, regionally, or nationally by HCFA.

Section 422.152(d) establishes the requirements for performance improvement projects, beginning with the requirement that performance improvement projects focus on specified areas of clinical and nonclinical services. It also explains that we will set M+C organizational and plan-specific requirements for the number and distribution of these projects among the required areas. In addition, it authorizes us to direct an M+C organization to undertake specific performance improvement projects and participate in national and state-wide performance improvement projects. Section 422.152(d) reflects many of the provisions of section 1852(e)(2) of the Act.

In enacting the quality assurance provisions of the BBA, Congress recognized that not all of the quality assessment and performance improvement activities that are appropriate for a plan with a defined provider network would be appropriate for an M+C non-network MSA plan or an M+C PFFS plan. The requirements specific to these types of plans are addressed in § 422.152(e). (Note that, as discussed below and in section I.C of the preamble, section 520 of the BBRA amended section 1852(e) of the Act to apply the non-network plan requirements to PPO plans as well.)

In order to support the measurement of performance levels and the conduct of performance improvement projects, if applicable, M+C organizations offering all types of M+C plans must maintain a health information system that collects, analyzes, integrates, and reports data. This requirement is covered at § 422.152(f)(1). Section 422.152(f)(2) requires that for each M+C plan an M+C organization offers, it has a process for formal evaluation, at a minimum annually, of the impact and effectiveness of the quality assessment and performance improvement program

strategy with respect to services under that plan.

Comment: A number of commenters asserted that the quality assessment and performance improvement (QAPI) requirements will be difficult for M+C organizations offering M+C plans with loosely organized provider networks to meet, and will discourage such organizations from participating in the M+C program. In particular, commenters were concerned that the QAPI requirements will deter organizations from offering MSA plans, PFFS plans, and PPO-type coordinated care plans. One commenter explained that organizations offering non-HMO plans cannot require physicians to track outcomes for these plans because the organizations do not have contracts with the physicians, making data collection and reporting infeasible. Four commenters specifically addressed the challenges facing PPOs in producing performance data and influencing provider practice patterns as required to demonstrate performance improvement. Two commenters complained that it is not appropriate to require reporting of all clinical performance indicators from the "Healthplan and Employer Data and Information Set" (HEDIS) in the case of a broad access PPO-type coordinated care plan. These and other commenters suggested that we instead establish quality standards that account for variation in organization capabilities.

Response: The BBA recognized that the structure of health plans has a direct impact on the degree to which the organizations that offer them can reasonably be expected to directly affect the health care services provided to their enrollees. As a result, the M+C statute and interim final regulations, as well as guidance implementing these provisions, have been tailored to the varying structural differences and associated capabilities of M+C organizations. As discussed in section I.C of this preamble, section 520 of the BBRA amended section 1852(e) of the Act to revise the quality assurance requirements for PPO plans. Consistent with the commenters' concerns, the quality assurance requirements for PPO plans are now the same requirements that apply to non-network M+C MSA plans and M+C PFFS plans. Thus, while PPO plans are still considered coordinated care plans, they are treated differently than other coordinated care plans for the purposes of the M+C quality assurance requirements of § 422.152, in recognition of the fact that their provider networks are subject to a lesser degree of control and accountability. The result is that M+C organizations are no longer required to

conduct performance improvement projects relative to their PPO plans, or to have their PPO plans meet minimum performance levels. M+C organizations offering PPO plans must still report on standard measures, however, and continue to comply with the QAPI requirements that apply to all plans, such as those relating to health information and program review. We are revising § 422.152 to implement these changes.

Section 520(a)(3) of the BBRA defined a PPO plan as an M+C plan that (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization. This definition is being added to the regulation at § 422.4.

Comment: A few commenters addressed the costs associated with collecting and reporting QAPI data. They argued that the data required will add significant administrative costs to M+C organization operations, with two commenters contending that most of the patient encounter data required for quality improvement projects go beyond the claims data currently collected and processed by organizations and Medicare fiscal intermediaries. Another commenter suggested that because the data collection and reporting costs will be so significant, we should make decisions as to what information to require only after much deliberation. One commenter expressed concern that M+C organizations will pass along the costs of data collection and reporting to hospitals.

Response: While not all M+C organizations are accredited, the majority are either seeking or have already been granted accreditation by national bodies such as the National Committee for Quality Assurance (NCQA). For those organizations in particular, the collection and reporting of standard measures does not constitute a new activity as it is a condition of the accreditation process. In addition, many managed care organizations have been voluntarily conducting a variety of quality improvement projects over the years, although they may not have routinely reported on standard measures. Again, for these organizations, the process of identifying quality of care concerns, selecting a patient population for study, implementing an intervention and

collecting data on the outcomes of that intervention are not at all new. The quality improvement process under the M+C program is essentially comparable to current industry practice, with the slight addition of the requirement to report on specific types of indicators relevant to the condition in question. For these reasons, we do not believe that the data collection and reporting requirements established under the M+C regulations will impose unreasonable costs, and we believe that a great deal of deliberation has already gone into the establishment of these requirements (for example, the collection and reporting of HEDIS measures) at this time.

With respect to the issue of whether hospitals will be asked to bear costs associated with data collection, we do not expect these costs to be unreasonable, and we note that they are voluntarily assumed when the hospital decides to participate in the M+C organization's network.

Comment: A few commenters contended that the costs of implementing their QAPI programs would be excessive.

Response: We have given M+C organizations significant latitude in terms of designing their performance improvement projects, so that they can choose efforts that are relevant to their enrollees and that involve cost effective interventions. To further reduce administrative and financial burden, M+C organizations may collaborate with entities such as the Peer Review Organizations (PROs) on their performance improvement projects.

Comment: Two commenters addressed the collection and reporting of HEDIS measures. These commenters were concerned that the HEDIS measures do not, in their view, adequately address the health issues of older adults in Medicare, and they do not track the experiences of people with chronic and disabling conditions.

Response: M+C organizations are required to report HEDIS measures for the purposes of §§ 422.152(c)(1) and (e)(1). Currently, the HEDIS measures offer the most comprehensive view of managed care performance available. We have been working with the Geriatric Measurement Advisory Panel to develop additional measures for people with chronic and disabling conditions. It is important to recognize that HEDIS is an evolving instrument, and as valid measures of other aspects of care are developed, they will be incorporated. For example, HEDIS 1999 added measures for cholesterol management after acute cardiovascular events, and HEDIS 2000 has added a

measure to assess whether blood pressure was controlled among people with diagnosed hypertension. Additionally, Medicare will be requiring six measures for people with diabetes. Additions such as these, plus others that will be added as valid measures are developed, should address the commenters' concerns.

Comment: Two commenters suggested that we add other areas for standard measures in § 422.152(e)(1) for M+C PFFS and non-network MSA plans. These commenters believe that the information collected for these types of plans should be as consistent as possible with that collected for other types of M+C plans to allow for comparison among them. The commenters recommended that if certain types of data are unavailable for non-network M+C MSAs and M+C PFFS plans, a statement should be made available to beneficiaries explaining the lack of information.

Response: We agree with commenters that for purposes of plan comparison, reporting on standard measures should be as consistent across plan types as possible. Therefore, we are revising § 422.152(e) to specify that the standard measures on which reporting will be required for M+C PFFS plans, non-network MSA plans and now PPO plans will relate to the same areas to which the measures required for M+C coordinated care plans (other than the PPO plans) and network M+C MSA plans relate. As stated in the preamble to the interim final rule, no M+C organization will be required to report information to which it does not reasonably have access under a plan. Where data on particular measures are not reasonably available with respect to a given plan, organizations will be allowed to report "not available."

Comment: A number of commenters addressed the form and content of the required standard measures. One commenter asked that we develop core measures not just at the M+C plan level, but also at the provider and facility level. Another commenter asked that we develop core measures for high-risk, low-incidence conditions. Another commenter asked that we develop measures for all persons with disabilities under age 65 that are comparable to the senior health status data that are being collected for a sample of Medicare beneficiaries over 65 in Medicare managed care plans as part of HEDIS 3.0.

Response: Each of these suggestions has merit; however, we are taking an incremental approach to implementation with respect to the QAPI activities under the M+C program

that includes working with private purchasers to expand the set of measures. We believe it is important to give M+C organizations time to adjust to the current standard measures before imposing further requirements. Our experience with the standard measures in place now will also be helpful in deciding whether additional measures are appropriate, and if so, which measures would be most effective.

Comment: Certain commenters asked that the standard measures we require be predictive of outcomes, and be established utilizing evidence-based medical research. One commenter asked that we establish a "data dictionary" that will give M+C organizations detailed and clear definitions of the required measures. Another commenter cautioned that the development of another set of core measures for M+C organizations will result in unnecessary duplication and lead to confusion if the measures are defined differently by accreditation organizations and by HCFA.

Response: As mentioned earlier, M+C organizations are required to report HEDIS data. The HEDIS measures are predictive of outcomes, are well defined, and are well established in the private sector. Our requirements may change in future years as the HEDIS instrument evolves and as other measurement instruments are developed.

Comment: One commenter asked what role, if any, JCAHO's ORYX performance indicators will have in meeting our data reporting requirements, and whether there would be duplication. One commenter asked that we consider the OASIS data set and OBQI system for home care (and eventually PACE) to be reasonable alternatives to HEDIS for managed long-term care plans.

Response: Again, our goals with respect to data management are to minimize burden and maximize effectiveness. We are working collaboratively with accredited organizations like the JCAHO, with these goals in mind. The ORYX indicators are still in the developmental stage and, furthermore, since they focus specifically on hospitals, they cannot be used to measure much of the performance of managed care organizations. All home health agencies serving Medicare beneficiaries, whether in managed care or traditional Medicare, are required to provide information through OASIS. In general, we are not requiring managed long-term care plans to provide HEDIS information, with the exception of several demonstration sites. However, reporting requirements

for long-term care entities may change in the future.

Comment: A few commenters addressed our intention to consider historical plan and original Medicare performance data and trends when establishing minimum performance levels. One asked for clarification as to the standards we will use. Two objected to basing minimum performance levels on historical performance data and trends, explaining that many Medicare program requirements, including those related to access to services, emergency services and due process, are not ideal targets, but rather legal requirements under Federal law. The commenters were concerned that looking to historical performance might result in establishing a minimum performance level that is less than what the law requires.

Response: We agree with commenters that it would not be appropriate to establish minimum performance levels for aspects of care or service for which required levels of performance have already been dictated by regulation or statute. However, there are many measures of care, such as mammography or immunization rates, for which no mandated minimum exists. In these areas, it is useful to know what historical performance has been, because while we are interested in establishing minimum performance levels that motivate improvement, we want those levels to be achievable. At this time, the process for establishing minimum performance levels has not been finalized, but we expect that we will set the minimum at a percentile of previous performance, and revise the minimum year by year as overall performance rises.

Comment: A number of commenters objected to our intention to establish minimum performance levels. One commenter said that it would be inconsistent with our statement in the preamble to the interim final rule that we would not adopt a "one size fits all" approach to performance measurement. Another commenter, although not opposed to minimum performance levels, asked that we take into consideration variation in the model of delivery, such as network-model or group-model, when establishing the levels.

Response: We believe that it is feasible and in the best interest of Medicare beneficiaries to require that the quality of care provided by M+C organizations offering network plans meet minimum standards. This is an additional protection above making performance information available to beneficiaries for the purpose of plan

selection. We believe that there would be a de facto requirement that organizations achieve minimum performance levels, even if there were no explicit requirement in the regulation. That is, even if the regulation required only that organizations report their performance on standard measures, we would still judge their performance by comparing it with some benchmark for the purpose of determining whether to take remedial action or continue contracting with the organization, which would have the same effect as applying a minimum performance level. We see no reason not to recognize this implicit requirement in the regulation.

As we stated in the preamble to the interim final rule, we are sensitive to the different structures of plans. We will consider the impact plan structure has upon the ability of an M+C organization to affect provider behavior. We will consider these issues when making our decisions regarding the standard measures for which it is appropriate to establish minimum levels of performance.

Comment: Two commenters addressed the possibility that some of the minimum performance levels HCFA establishes will be regional instead of national. One commenter objected to establishing non-national performance levels. The other supported the idea of establishing minimum performance levels with consideration for regional area variation.

Response: Because it is our intention to establish minimum performance levels that are meaningful as well as achievable, we must consider regional variation where it exists. It is our ultimate goal to have national minimum performance levels, but it may be necessary to move towards this goal incrementally by first establishing regional performance levels.

Comment: One commenter asked how we can require that M+C organizations meet minimum performance levels 1 year after the levels are established, if we recognize a 3-year cycle as the standard for performance improvement.

Response: The purpose of performance improvement projects is not to bring plan performance up to minimum performance levels, but rather to move it closer to national benchmarks. In most cases, we believe that plan performance would already surpass the "minimum performance levels" that we are now in the process of developing. An immediate intervention and not a lengthy performance improvement project would probably be called for if a plan

offered by an M+C organization failed to meet a minimum performance level.

Comment: One commenter asked that we establish some minimum performance levels related to the care of persons with disabilities.

Response: As noted above, we are still in the early stages of identifying the measures for which minimum performance levels will be established. When we do, we will consider the commenter's suggestion.

Comment: A number of commenters objected to the possibility that we will nonrenew an organization's contract on the basis of its failure to meet minimum performance levels. Two of these commenters complained that any organization might fall short of a specific numerical standard because of random events beyond its control. As an alternative to nonrenewal, one commenter asked that we impose intermediate sanctions. Another asked that we not impose sanctions at all if an organization is making a good faith effort to meet the requirements. Some commenters suggested that we work with organizations to improve their performance in lieu of nonrenewal. In particular, one commenter recommended that we require organizations to participate in PRO-sponsored improvement projects when minimum performance levels are not met.

Response: As a value-based purchaser, HCFA has a responsibility to implement requirements that promote accountability on the part of M+C organizations. Although we have the authority to nonrenew an organization's contract for failure to meet quality assurance requirements, we have stated that in most instances we will first offer technical assistance and/or require corrective action plans. Intermediate sanctions are also within HCFA's prerogative.

Comment: One commenter asked that we reward an organization that shows demonstrable improvement in the health status of beneficiaries by giving it a bonus payment such as a percentage of its capitation rate. The commenter contended that a bonus payment is necessary to ensure that organizations are equitably reimbursed, since under a risk-adjusted ACR, organizations will receive lower payments for healthy enrollees.

Response: It is appropriate that an M+C organization receive lower payments for healthy enrollees because the cost of caring for them is proportionately lower. Because an organization that successfully completes a performance improvement project will have reduced the incidence of negative

outcomes and the expenses associated with them, any reduction in Medicare payment as the result of risk adjustment should not adversely affect the organization's profitability. Indeed, the successful completion of performance improvement projects should bolster an organization's business. The information that an organization has successfully completed performance improvement projects will be shared with potential enrollees, and should help its market position.

Comment: One commenter asked that we establish public recognition awards at the state and national level for innovative and successful organization performance improvement projects.

Response: Although there has been much discussion around the issue of establishing performance incentives, we currently have no plans to develop an awards program for M+C organizations. However, they may wish to consider promoting their excellent performance themselves through the media and their marketing materials.

Comment: One commenter requested that we specify the nature and form of the documentation and data that organizations must make available to demonstrate compliance.

Response: With respect to monitoring compliance, we have completed the design of a revised M+C interim monitoring tool that follows the structure of both the M+C regulations and the Quality Improvement System for Managed Care (QISMC) Interim Standards and Guidelines (which provide interpretive guidance for both subpart D standards as well as standards relating to the delivery of health care and enrollee services). The monitoring tool specifies the documentation and data that we will look for in our compliance monitoring.

Comment: Many commenters emphasized the importance of collaboration between the managed care industry and HCFA as implementation of the regulation proceeds. One commenter recommended that we establish a formal advisory counsel composed of representatives of industry associations. Other commenters urged that we consult with physicians and accreditation organizations in selecting standard measures and setting minimum performance levels.

Response: Since we began developing QISMC 4 years ago, we have been engaged in an ongoing dialogue with representatives of the managed care industry, advocacy groups, various health care providers, and state regulatory bodies to ensure broad involvement in the document development process. We recognize the

value of this type of collaborative exchange and intend to continue this activity.

Comment: A number of commenters asked that we coordinate our quality improvement efforts with those of the private sector, particularly NCQA. One commenter was concerned that we are establishing an independent system of quality improvement requirements rather than building upon the collaborative public-private efforts that we have participated in, such as HEDIS.

Response: The QAPI requirements established in the regulation build upon a number of the public-private efforts mentioned by commenters. For instance, as noted above, the standard measures on which M+C organizations now are required to report to comply with § 422.152 (c)(1) and (e)(1) are the HEDIS measures; we have been collaborating with private sector group purchasers since 1994 to develop these measures, and we recognized the value of incorporating them into our QAPI strategy.

Comment: One commenter questioned HCFA's authority to require that performance improvement projects achieve "significant" improvement, pointing out that the statute requires only that M+C organizations "take action" to improve quality. Another commenter questioned our authority to impose as much structure on performance improvement projects as we have, asserting that by requiring that projects focus on specified areas of clinical and nonclinical services, and directing M+C organizations to undertake specific projects among the required areas, we have exceeded our statutory mandate.

Response: We believe that our responsibility as a value-based purchaser and duty as a trustee of Medicare funds includes requiring that M+C organizations provide high quality services, and the statute recognizes this responsibility. For instance, section 1852(e)(2)(A)(vi) of the Act requires that M+C organizations "provide the Secretary with such access to information collected as may be appropriate to monitor and ensure the quality of care provided under this part" (emphasis added). Requiring that M+C organizations conduct projects that achieve improvement that is significant and sustained over time is one way for us to meet our obligation under the statute. We also believe that the language quoted by the commenter, requiring that M+C organizations "take action" to improve quality can be reasonably interpreted to require that improvement actually occur. A requirement to "take action" to improve

quality clearly suggests that the M+C organization have an objective in mind in doing so. We believe that a significant improvement is a reasonable and logical objective for "action" to improve quality. While the structure imposed in the interim final rule is flexible, and grants M+C organizations broad discretion in many areas in designing their QAPI programs, we believe that some structure is necessary in order to ensure that the projects will be meaningful for Medicare enrollees. We believe that the M+C quality assurance requirements represent a reasonable interpretation of requirements in section 1852(e), and a reasonable exercise of our broad authority under section 1856(b)(1) to establish M+C standards by regulation.

Comment: Two commenters addressed the issue of the number of performance improvement projects M+C organizations are required to perform. One commenter explained that it is difficult to conduct valid and reliable performance improvement projects with a small number of participants, and asked that the number of required performance improvement projects be proportionate to the size of the plan. The second commenter asked that we limit the number of required performance improvement projects to one new project per year, and limit the number of projects required to be underway at any one time to four.

Response: QISMC requires that M+C organizations initiate two performance improvement projects a year. Given that projects are allowed 3 years in which to achieve significant improvement, once QISMC is fully implemented an organization will not need to have more than six projects underway at any one time: two in the initiation stage, two in the intervention stage, and two in the completion stage. We believe this is a reasonable burden for both large and small plans. Smaller plans are not at a disadvantage because organizations are not required to show statistically significant improvement on every topic affecting a small population. Statistical significance is only required in instances when an organization chooses to sample its population. For small populations, an organization has a strong incentive to measure the results of its project on the entire affected population, because, when the organization's project targets the entire affected population, only a 10 percent reduction in the "performance gap" is required, not statistical significance. For example, if an organization chose to study a condition that affected only 100 enrollees, and its current performance was 50 percent, to achieve a 10 percent

reduction in the performance gap it would have to demonstrate that it improved the care to five enrollees. If the organization measured the results of its project on a sample of the population, it would have to show improvement for many more enrollees to achieve statistical significance.

We are aware that a number of technical issues relating to improvement project design remain to be resolved. For instance, we must decide what to do when a project population is so small that measurement of the results of the project is not meaningful or what to do if the baseline performance is so high that the sample size required for statistical significance is very large. We intend to resolve these issues in an updated version of QISM.

Comment: One commenter pointed out that a significant period of time will be required following the intervention before improvements are observed at the population level, and the commenter was concerned that there appears to be no allowance for this time period.

Response: QISM allows for such a time period. As mentioned earlier, QISM does not require a performance improvement project to achieve significant improvement until the end of its third year. Experience has shown that there are many opportunities for an intervention to yield results within three years. QISM makes an even more generous allowance for more complicated projects.

Comment: Many commenters addressed the requirement that performance improvement projects achieve significant improvement. The majority of these commenters opposed the 10 percent standard for reduction in the performance gap. As discussed above, this standard (which is specified in QISM) requires that the organization reduce by at least 10 percent the percentage of cases in which the quality indicator that measures its performance in the project's focus area is failed. Several of these commenters complained that the standard is not realistic. One commenter explained that in many data situations, administrative claims may not be complete or be reliable to allow for a meaningful evaluation. Other commenters offered other examples of impediments to achieving significant improvement, including regional variation of utilization and imperfect provider and enrollee compliance. One commenter asked us to recognize that enrollee lifestyle choices, diet, and compliance with medical treatment will impact upon an organization's ability to achieve significant improvement in health status. Another commenter asked that

we recognize that it is the provider who actually has control of the care process. For these reasons, these commenters asked that we not hold organizations responsible for achieving significant improvement, but for initiating activities that, if followed by enrollees and providers, are likely to improve the health status of enrollees.

Two other commenters suggested that we take a different approach. They recommended that in lieu of requiring a 10 percent reduction in the performance gap, we follow NCQA's approach and require that managed care organizations provide meaningful evidence that they are making improvements in clinical care and service. One of these commenters suggested that to define "meaningful," we consider whether the improvement resulted in a better outcome for the enrolled population, whether it is attributable to the organization's actions, and whether it affects high-volume, high-risk, and/or high-cost conditions or services. The commenter added that this would be more effective in encouraging complex or innovative projects that have a high risk of failure but that offer significant potential, a comment that was echoed by other commenters who were concerned that a rigid numerical significant improvement standard would encourage organizations to pursue performance goals that are easily attainable.

A third alternative to the 10 percent standard was submitted by a commenter concerned that certain characteristics of the Medicare population will complicate the achievement of significant improvement. This commenter pointed out that the elderly population is at a higher risk of illness and disease, and that a greater percentage of Medicare beneficiaries have multiple disabilities and comorbidities, which results in greater instability in their health status. This commenter recommended that we require only that organizations establish measurable goals for their interventions, and that we evaluate organizations on their ability to demonstrate the strength of their interventions and performance gains over time. Further support of this approach was offered by an additional commenter who was concerned that the 10 percent standard would encourage risk selection and discourage the enrollment of sicker beneficiaries with more complex health issues.

Response: We chose to make a 10 percent reduction in the performance gap the standard because we believe it is necessary to have an objective standard to assess whether an organization has achieved significant

improvement in health care quality, and because we have observed much higher percentage increases in performance than 10 percent. Therefore, 10 percent is a reasonable benchmark to use based on our observation of past organizational performance in improving health care quality. Nationally recognized standards that do not incorporate objective standards for determining if quality improvement has occurred have been criticized as being subjective and lacking in reliability and validity. We have learned from the lessons of such standards, and based on the strong evidence from the Medicare and Medicaid programs, have elected to implement a standard that is consistent with our knowledge of quality improvement in both the Medicare and Medicaid programs.

The 10 percent improvement standard is the best way we have at present to ensure that projects are meaningful, and that they translate into positive changes in enrollees' lives. In the long run, in order to mitigate the incentive to choose trivial projects, we will attempt to devise a way to measure and report the relative contribution of each performance improvement project, taking into account such factors as the number of enrollees affected by the improvement and the impact the improvement actually has upon enrollee health and satisfaction. Such a system is years away, but we have taken a first step towards it by starting to develop a common vocabulary for performance improvement projects.

As for the comment that requiring a 10 percent reduction in the performance gap will encourage risk selection, we believe that there exist numerous opportunities for M+C organizations to improve performance on measures relating to the care of sicker enrollees with complex health care needs. In fact, we believe the improvement potential associated with the care of sicker enrollees exceeds that associated with the care of healthier enrollees. In addition, the introduction of risk-adjusted payments to M+C organizations should further discourage risk selection.

Comment: One commenter was concerned that allowing an organization to set its own performance goals would be a disincentive to undertaking any project that might "lower its status" with us or with enrollees.

Response: We believe the commenter is referencing the QISM standard that addresses projects in which data are collected on the entire population to be studied (that is, in which a census is involved). QISM specifies that, in the case of a project developed by the

organization itself, significant improvement is demonstrated by achieving a benchmark level of performance that is defined in advance by the organization. However, the standard goes on to say that the organization's benchmark must reduce the opportunity for improvement by at least 10 percent, which is the same standard for HCFA specified projects. So, the commenter's concern is unfounded because the objective nature of the benchmark ensures an acceptable level of effort on the part of the organization.

Comment: One commenter noted that when multiple interventions are employed, they all would have the potential to bring about improvements in outcomes. The commenter asked how we will determine which intervention was responsible for the observed change.

Response: It is only necessary that an M+C organization show that its improvement was the result of its own actions and not chance. It is not necessary to determine to which of its interventions the improvement should be attributed, although we expect that the M+C organization will want to do so for its own management purposes.

Comment: A number of commenters addressed the issue of required participation in national or statewide performance improvement projects. Half of the commenters supported the idea of such projects. One commenter asked that we consider the identification and diagnosis of persons with Alzheimer's as a possible national performance improvement project, and another asked that we require organizations to participate in national improvement projects pertaining to persons with disabilities.

One of the commenters opposed to national or statewide performance improvement projects complained that mandated projects will detract from the flexibility organizations need to best care for their enrollees. This commenter pointed out that many organizations have already conducted projects addressing flu and pneumonia; consequently, it would be a poor use of resources for them to be required to conduct another such project. Another opponent argued that national or statewide performance improvement projects may prove to be inconsistent with local market considerations.

Response: In response to these concerns, we included in OPL 98-72 a statement that an M+C organization is not required to participate in the HCFA-sponsored national diabetes project but may, at its discretion, conduct another diabetes-focused project that utilizes the

Diabetes Quality Improvement Program (DQIP) indicators, and meets the project requirements as outlined in QISMC Domain 1. For their second performance improvement project, M+C organizations were free to select a topic and focus area of their choice.

With respect to the concern that organizations may have already conducted projects addressing influenza and pneumonia, which have been selected as the national project topics for 2000, there are many aspects to the care and prevention of these diseases that organizations may not have fully addressed in previous projects that would lend themselves very well to further projects.

At this point, we have not selected national project topics beyond year 2000, but we will consider the care of enrollees with Alzheimer's and with disabilities when making future selections.

Comment: One commenter asked us how we will decide who must participate in national or statewide performance improvement projects.

Response: It is a contracting requirement for all M+C organizations offering coordinated care plans that they conduct a project addressing a topic that we have determined represents a national health care priority. At this time, although we have the authority to specify State-specific topics, we have not done so.

Comment: One commenter advocated that we explicitly include requirements in the regulation for organization participation in PRO-sponsored activities.

Response: There is no requirement that organizations participate in PRO-sponsored activities: there is only the requirement, as stated in QISMC, that one of the two performance improvement projects that an organization initiates per year relate to a topic and involve quality indicators chosen by us. The PRO is required to provide technical assistance on the national project (and on all other projects) if an organization requests it, but organizations are not required to work with the PROs on their projects. However, we expect that many organizations will choose to work with the PROs, because the PROs can provide clinical and biostatistical expertise; assistance in the design and conduct of projects; advice on sampling, data collection and analysis; and, review and analysis of project findings and interventions.

Comment: A few commenters opposed allowing organizations to select the topics of their performance improvement projects from within the

specified clinical and nonclinical areas. One commenter was concerned that organizations will choose the disease with which they are most familiar, thereby neglecting low-incidence diseases. Two other commenters were concerned that organizations will avoid undertaking projects in areas that highlight poor performance or that relate to discrete, but vulnerable, cohorts of patients, such as those with disabilities or rare conditions. These commenters recommended that as alternatives to allowing organizations to select their own performance improvement project topics, we standardize the topics across all organizations; we standardize the topics across all organizations within a given service area, selecting the topics on the basis of the morbidity and mortality measures for seniors in the service area; or, we select the topics for each individual organization on the basis of needs identified through an annual onsite audit.

Response: We believe it is essential that M+C organizations be allowed to target at least some of their performance improvement activities to those areas they determine would be of most benefit to their enrollees. Balanced against this opportunity is the obligation to address areas that we consider to be of universal importance to the Medicare population. Between organization-specific projects and national projects, we expect that all significant improvement opportunities can be addressed. If upon review we find that an organization's performance in a particular aspect of care or service is poor and the organization has repeatedly failed to initiate action to improve it, we have the authority to direct that the organization do so.

Comment: Two commenters asked that we expand the required clinical focus areas. One asked that we include high-risk, low-incidence conditions and populations, and the other asked that we include laboratory and other diagnostic services.

Response: High-risk, low-incidence conditions are subsumed within the high-risk focus area. Although issues selected for study generally should affect a significant portion of the organization's Medicare enrollees (or a specified subpopulation of enrollees), organizations should target infrequent conditions or services if data indicate they warrant study. As for laboratory and other diagnostic services, they could fall under a number of the current focus areas. Therefore, we do not find it necessary to add to the current list of focus areas.

Comment: One commenter asked how “high-volume services” and “high-risk services” are defined.

Response: We did not provide a definition of “high-volume” or “high-risk” services for several reasons. First, it was our intention to allow organizations discretion in developing their own definitions and criteria, consistent with the needs of their organizations. For the most part, both terms have commonly understood meanings, and therefore, we did not think they required explanations.

Since M+C organizations will be monitored on whether they conduct QAPI projects addressing these focus areas, and to respond to the request for further information, we suggest that organizations consult the QISMC Interim Standards and Guidelines (specifically, Standards 1.3.4.5 and 1.3.4.6) for further guidance as to our expectations. In selecting a quality improvement project focusing on high-risk or high-volume services, we note that the focus does not necessarily have to be on a clinical condition per se, but on a service and how it may be improved. In HEDIS 99, Volume 2, Technical Specifications, there are several clinical conditions for which suggested indicators are provided in assessing “High-Occurrence/High-Cost” DRGs. Congestive heart failure, angina pectoris, chronic obstructive pulmonary disease and other conditions which place the enrollee at risk of increased morbidity or mortality would certainly constitute appropriate conditions under the “high-risk” category. An organization may assess experiences of care received from specialized centers inside or outside of its network, such as burn centers, transplant centers, or cardiac surgery centers. With respect to “high-volume” services, an M+C organization may target quality improvement in a frequently performed surgical procedure, or across different surgical or invasive procedures.

Comment: One commenter asked how “clinical area” is defined. The commenter asked whether it is a clinical condition, such as diabetes, or, an opportunity within a clinical condition, such as the number of glycohemoglobin blood tests performed for diabetic enrollees.

Response: The answer is that it can be either. Standard 1.3.4 of the QISMC Interim Standards and Guidelines provides additional detail regarding the specific focus areas. It should be noted that in choosing the areas, we avoided a disease-specific focus, opting instead to define them in a broad sense and therefore allow M+C organizations maximum discretion in determining

where their specific project might best fit. For example, performance of dilated eye exams in the diagnosis and treatment of diabetic retinopathy might best be placed under the clinical focus area of Secondary Prevention of a chronic condition (Standard 1.3.4.2), as it serves to identify and potentially control a diabetes-related condition.

Comment: One commenter recommended that the clinical area of “continuity and coordination of care” include an evaluation of whether the appropriate mix of services is being furnished, and of whether there is adequate access to specialty care.

Response: These are aspects of continuity and coordination of care that organizations may choose to select as project topics. However, we will not require these as topics because such specificity might serve to unduly restrict an organization in its efforts to identify those aspects of care and service most in need of a formal performance improvement project. General requirements and concepts relating to continuity of care and access to services are found at § 422.112.

Comment: Two commenters addressed the need to coordinate performance improvement projects. The first commenter asked that in areas where there are multiple M+C organizations, we require that organizations coordinate their selection of project topics so as to minimize the data gathering and reporting burden that will be imposed on hospitals. The second commenter asked that we allow M+C organizations serving in more than one region to partner in collaborative projects, perhaps under the aegis of a national organization such as the Blue Cross Blue Shield Association. This commenter also asked that we permit collaborative projects through the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality) or professional organizations/societies.

Response: We agree with these commenters. We have consistently stated that we encourage M+C organizations to collaborate across plans, with other organizations, and within their States and regions to promote reduction of administrative burden and to enhance the general applicability of study findings. Certainly, the PROs may serve in a convener/collaborator role with respect to promoting such activity. To further this effort, we co-sponsored a National Diabetes Conference in conjunction with the American Association of Health Plans and the American Diabetes Association to provide additional guidance and materials which may be

used uniformly by M+C organizations in the conduct of their diabetes performance improvement projects. We expect other ad hoc collaborations to occur in the future.

Comment: One commenter asked that we encourage M+C organizations to work with their contracted providers, as well as other health care professionals and associations, in developing their performance improvement projects.

Response: As indicated in the previous response, we recognize the importance of collaboration. To that end, QISMC requires that an organization allow its providers (and enrollees) an adequate opportunity to provide input regarding the selection and prioritization of performance improvement projects.

Comment: Two commenters addressed the requirements relating to health information. One commenter claimed that without uniform collection methods, it is unreasonable to require organizations to ensure that the information they receive from providers of services is reliable and complete. This commenter believes that some organizations, especially those offering non-network M+C MSA plans and M+C PFFS plans, will be unable to meet this requirement. The other commenter asked that we clarify what level of organization oversight will be necessary for an organization to meet the requirement that it ensure the reliability and completeness of the information it receives from providers of services.

Response: To promote continuous quality improvement, it is essential that collection and management of meaningful statistical information be seen as means to that end. Statistically valid data that assist in explaining patterns of care and in justifying variations in care are as valuable as data that identify problems in the provision of care. Without good data, we cannot make scientifically defensible or financially meaningful health care decisions. Therefore, collection of appropriate and accurate data is both good science and good business. To the extent that a particular M+C organization currently is unable to meet these requirements, we believe that the answer is not to change the requirements, but for the organization to make the changes necessary to be able to meet these requirements.

As for oversight of the health information system, the organization is ultimately responsible for determining at what level within its structure there will be oversight which ensures the reliability and completeness of information received from providers.

Comment: One commenter suggested that we require that organizations, in processing requests for initial or continued authorization of services, follow written policies and procedures that reflect scientifically sound and evidence-based medical guidelines, rather than reflect current standards of medical practice. The commenter contended that not all current standards reflect the best medical practices.

Response: Historically, current standards of medical practice have been the benchmark for care provided by managed care organizations. The purpose of using these standards has been to ensure that the quality of care delivered through managed care organizations was comparable to, or better than, that provided by fee-for-service entities. During the last decade, advances in quality measurement and the development of practice guidelines and improved mechanisms for assessing utilization management have been adopted as standard practice in many organizations.

We agree with the commenter that in processing requests for authorization of services, the organization should follow policies and procedures that are based on scientifically sound and evidence-based guidelines. Nevertheless, we recognize that in instances where such guidelines do not exist, individuals making authorization determinations may need to refer to current standards of medical practice. In those cases, an M+C organization must have in place written policies and procedures to ensure that all coverage decisions are designed to provide care in the safest, most beneficial and cost-effective fashion.

Comment: One commenter asked that we require organizations offering M+C PFFS and non-network MSA plans to use written protocols for utilization review, and to provide their utilization review findings to enrollees and providers at least annually.

Response: Section 1852(e)(2) of the Act does not require that M+C PFFS and non-network MSA plans (and under the BBRA, PPO plans) establish written protocols for utilization review. To the contrary, section 1852(e)(2)(B)(ii) imposes requirements "insofar as" an organization provides for such protocols, clearly contemplating that some M+C organizations may choose to do so, and some may not. Thus, we do not believe that such a requirement would be consistent with statutory intent.

Comment: Four commenters were concerned about the lack of an explicit requirement that organizations take immediate remedial action when

individual quality problems are found. Two commenters explained that performance measurement and performance improvement projects result in the collection of data that can be used to establish baselines and track performance over time, but neither serves as a mechanism for ensuring that real problems experienced by current enrollees are systematically identified and corrected. These commenters recommended that we require that organizations "take appropriate remedial action whenever inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided."

Response: Clearly, an essential component of any effective "ongoing quality assurance program" as required under section 1852(e) of the Act is the correction of identified problems. QISMC already requires that an organization correct significant systemic problems that come to its attention through internal surveillance, complaints or other mechanisms. As the commenters suggested, we are adding a modified version of this requirement under new § 422.152(f)(3) to require correction of all identified problems, because it is our intention that an organization take appropriate remedial action whenever a problem comes to its attention. Although § 422.152 generally focuses on systemic improvement, we believe it is appropriate to make our intention explicit. In monitoring this requirement, HCFA reviewers will operate by a "rule of reasonableness," taking into consideration factors including but not limited to the severity and prevalence of the complaints and the level of effort demonstrated by the organization in seeking to resolve the matter.

Comment: Many commenters addressed the relationship between QISMC and the M+C regulations. Two commenters asserted that it was premature to model the regulation on the QISMC requirements, arguing that the QISMC requirements should be tested and evaluated before being applied to M+C organizations. These commenters asked that we scale back the quality assurance requirements until after they have been tested and evaluated, and if appropriate, restore them to the regulation using the normal notice and comment process. Two other commenters also recommended deleting the QAPI requirements of QISMC from the final rule, explaining that there are areas within QISMC that should be refined before they are implemented, such as the number and kinds of

performance improvement projects that will be required.

Response: As we mentioned earlier, we have developed a cross-walk between the QISMC requirements and the NCQA accreditation requirements, which are currently considered the industry standard. For the most part, QISMC requirements are either identical to or consistent with NCQA requirements. Therefore, we are confident that our expectations have not outpaced the state of the art. Also, the HEDIS measures on which M+C organizations must report have already been fully tested and adopted by the managed care industry.

Finally, in response to concerns raised by managed care organizations regarding the potential burden imposed by the QISMC performance improvement project requirements, we significantly scaled back the number of required projects per year from nine required projects to only two per year. To assist M+C organizations further in this effort, we are currently developing model performance improvement projects and other implementation tools.

Comment: Two commenters addressed the time frame for QAPI program implementation. The first commenter recommended that the regulation reflect the transition policy found in the QISMC document, which allows organizations a period of time in which to build and refine their quality assessment infrastructure before their quality improvement projects will be expected to achieve significant improvement. The second commenter echoed the need for a long implementation time frame.

Response: Implementation policy is more appropriately handled through the issuance of operational policy letters and program manuals than through regulation. In addition, we have stated publicly that we will "phase-in" both implementation and enforcement of these requirements, in recognition of the fact that many organizations are still navigating the performance improvement learning curve.

Comment: A few commenters objected to the statement in the preamble to the interim final rule that we would not make public the results of an organization's performance improvement projects. One commenter complained that such a policy would be contradictory to our commitment to informed consumer choice. Another commenter challenged our rationale for withholding results, which was that releasing them might compromise enrollee confidentiality as they might involve enrollee-specific information. This commenter suggested that we

redact enrollee-specific information, or direct organizations to report information in ways that protect enrollee identities. Another commenter also supported the notion of releasing pertinent, non-confidential information about organization quality gleaned from performance improvement projects.

One commenter praised the policy we put forth in the preamble, explaining that providing the results of performance improvement projects to Medicare beneficiaries could undermine the legal confidentiality of peer review activities and could make such information reported outside the organization discoverable in legal proceedings. Another commenter also expressed support for our disclosure policy, noting that performance improvement requirements are new and that a non-punitive atmosphere is most conducive to improvement. However, this commenter recommended that we reexamine our disclosure policy in the future, and make it our goal to provide public access to performance information that will not violate patient confidentiality.

Response: To promote collaboration, we believe that it is important where possible to share development of best practices and interventions that work. In addition, to provide the necessary information to assist enrollee decision-making as they choose among various health plans, it is essential that we inform the public generally as to whether an M+C organization has met its responsibility to achieve demonstrable improvement. M+C organizations are free to release the specific results of their performance improvement projects, and we encourage this, but we do not believe such release should be mandatory. We are concerned that M+C organizations might be reluctant to undertake projects addressing their areas of poorest performance, if that means that their poor performance will be highlighted. The natural progression of performance improvement projects will be to generate additional measures for inclusion in the HEDIS data set. At that point all organizations will be required to submit this information for public disclosure.

We note that we do make a substantial amount of information available to the public for research purposes, such as the HEDIS public use file on our website; moreover, there is nothing to preclude researchers from attempting to obtain information directly from the M+C organizations themselves as long as enrollee confidentiality is protected.

Comment: Certain commenters asked that we require M+C organizations to

report their performance on standard measures and the results of their performance improvement projects to entities other than HCFA. One commenter asked that we require that organizations report their performance on standard measures to their designated external review entity. The commenter explained that this information would help optimize the effectiveness and timeliness of interventions by the PROs, which as the external review entities will be assisting organizations in meeting their QAPI requirements. Another commenter recommended that organizations be required to make information available to their State, in that the organization is licensed under State law. A third commenter asked that organizations be required to share the results of their performance improvement projects with the Agency for Health Care Policy and Research (now known as the Agency for Healthcare Research and Quality).

Response: We agree that it is essential that the PRO, in its role as independent quality review and improvement organization, have access to performance data, but it is preferable that the data not go directly from the M+C organization to the review organization (or State) for two reasons. First, the M+C organization's reporting burden would be doubled. Also, raw performance data are not useful to the review organization, State, or HCFA, which is why we have contracted with NCQA to analyze the data for us. M+C organizations will report the HEDIS measures to NCQA, and after its analysis, NCQA will report the measures to us. At this point, we will share summary data with the review organizations and States.

The same is true for the results of performance improvement projects. We again believe it preferable that performance improvement project data not go directly to the PRO. The data will be reported either to HCFA or to the specialized quality review organizations with which we have contracted to evaluate the success of performance improvement projects (the M+C/QROs). HCFA or the M+C/QROs will then present and interpret the results for the PROs.

3. External Review (§ 422.154)

Section 422.154 implements section 1852(e)(3) of the Act. Section 1852(e)(3) requires, subject to certain exceptions, that each M+C organization, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization approved by us to perform functions of the type described in part 466 of chapter

42, which establishes review responsibilities for utilization and quality control Peer Review Organizations (PROs). This general requirement appears in § 422.154(a) of the interim final rule. The terms of the agreement are described in § 422.154(b), and the exceptions to the general requirement are stated in § 422.154(c).

Comment: One commenter expressed concern that organizations contracting with both Medicare and Medicaid would be burdened by dual external reviews.

Response: Sections 1932(c)(2)(B) and (C) of the Act specifically address this scenario. The first provision authorizes a State to exempt a Medicaid-contracting managed care organization (MCO) that is accredited by a private independent entity, or that has a Medicare review conducted under section 1852(e)(3) of the Act, from Medicaid review activities conducted under section 1932(c)(2)(A) of the Act that would be duplicative of the accreditation process or the Medicare review activities. The second provision provides a State with the option to exempt entirely from the external review requirements under section 1932(c)(2)(A) a Medicaid MCO that is also an M+C organization, as long as that organization has had a Medicaid contract under section 1903(m) for at least 2 years during which the new BBA external quality review procedures are in effect. On December 1, 1999, we published a separate notice of proposed rulemaking setting forth our proposed interpretation of these provisions of section 1932(c)(2) of the Act (64 FR 31101).

Comment: A number of commenters asked that the regulation identify distinct review organization functions. One commenter recommended the following functions: population-based surveillance monitoring of access, quality and outcomes of care in M+C plans; auditing and validating the results of performance improvement projects; sponsoring national and statewide performance improvement projects; investigating quality complaints; conducting reconsiderations of hospital notices of non-coverage and conducting expedited appeals; and collaborating with consumer assistance organizations to better understand and use national and statewide performance improvement information when counseling beneficiaries on plan selection. Another commenter asked that we define external review requirements in the regulation that align with the PRO contractual requirements delineated in the Sixth Scope of Work.

Response: As we explained in the preamble to the interim final rule, we have approved the PROs to serve as independent quality review and improvement organizations (review organizations) for the purpose of this section of the regulation. We believe that the functional specifics of review organization responsibility are more appropriately detailed in the PRO scope of work than in the regulation. As M+C organizations implement their QAPI programs, needs may become apparent that will suggest that the review approach of the PRO be refined. The scope of work process permits a more rapid response to changing circumstances than does the regulatory process, which we believe should be used only for purposes of making changes in substantive standards for review.

Comment: One commenter asked that we require review organizations to involve broad community interests, particularly representatives of the Medicare beneficiary and consumer communities, in policy making and review activities.

Response: Such a requirement already exists. As stated in the PRO manual, each PRO is obligated to have at least one consumer representative on its governing board, and that representative must be a Medicare beneficiary. In addition, the Sixth Scope of Work requires each PRO to conduct beneficiary outreach and to maintain a Medicare hotline to facilitate communication with beneficiaries within its State.

Comment: One commenter addressed the external review waiver, supporting our decision to delay rulemaking on the waiver until we have experience with the implementation of the QAPI program.

Response: We appreciate the commenter's support of our decision.

Comment: A few commenters addressed our intention to exempt M+C organizations from external review activities that duplicate our monitoring activities. Two commenters argued that such a policy has no statutory basis and advocated its elimination. These commenters believe that this policy is inconsistent with the fact that HCFA, as Medicare purchaser and regulator, is ultimately responsible for monitoring and overseeing all quality assurance functions including the work of both review organizations and accreditation organizations. The commenters stated that our work, by definition, necessarily duplicates the work of review organizations, and therefore they were concerned that we would use the duplication as a pretense to design a

PRO scope of work that is meaningless and insignificant. One commenter, although not opposed to exemption in principle, asked that any exemption of external review activities be subject to the notice and comment process.

Response: Section 1852(e)(3)(B) of the Act mandates that the Secretary ensure that the external review activities under section 1852(e)(3)(A) of the Act "are not duplicative of review activities conducted as part of the accreditation process." The commenter is correct that HCFA has overall responsibility for monitoring and overseeing quality assurance functions. We believe that this extends to our review of areas addressed in the accreditation process. In this sense, we believe that our quality monitoring activities constitute a part of an overall "accreditation process" in that they are relevant to the continuing accreditation of M+C organizations. We also believe that Congress intended in section 1852(e)(3)(B) of the Act to require that we ensure that external review activities are not duplicative generally. Because there is little value and much additional burden in having the review organization repeat monitoring activity already conducted by HCFA, we are interpreting section 1852(e)(3)(B) of the Act broadly to extend to review activities that would be duplicative of our own monitoring activities. We believe that this interpretation of the intent of section 1852(e)(3)(B) of the Act, combined with our broad authority under section 1856(b)(1) of the Act to establish M+C standards by regulation, supports our decision to ensure that external review activities are not duplicative of our own review.

With respect to the comment that our application of the "anti-duplication" policy in section 1852(e)(3)(B) of the Act be subjected to notice and comment, we believe that the process of determining whether review activities are duplicative in a given case represents "operational" implementation of the substantive standard set forth in the regulations. We believe it would be neither workable nor appropriate to subject such operational judgments to notice and comment rulemaking.

Comment: Two commenters complained that the regulation does not indicate how we will determine what constitute duplicative review activities. One commenter recommended that we place the burden on the M+C organization to demonstrate how the accrediting process duplicates a specific external review activity. The commenter advocated that such demonstration include full disclosure of the standards and protocols used by the accrediting

organization to reach accreditation decisions, a comparison of the actual survey data and reports, and information about the composition of the review teams. The commenter recommended that the M+C organization's enrollees be informed when the organization seeks exemption from external review activities, and that they be given an opportunity to comment upon the application for exemption. Finally, the commenter asked that the exemption not be granted for more than one year at a time, and not be granted if the accreditation results in nonpublic reports.

Response: We intend to make the decision as to which external review activities an M+C organization accredited by an approved accreditation organization is exempt from as part of the process of approving the accreditation organization. The accreditation organization will supply us with all the information necessary to determine where its activities overlap with those of the review organization. The exemption will be reviewed as the accreditation process or scope of work changes. We are revising § 422.154(b)(2) to make it clear that an exemption based on duplicative review under the accreditation process will be made only with respect to approved accreditation activities because these are the only activities we will be in a position to evaluate when determining whether there is duplication.

With respect to the commenter's advocating that we require "disclosure" by accreditation bodies of their protocols, and disclosure to beneficiaries of decisions on duplication (with an opportunity to comment), we do not believe these steps are warranted. The quality standards that apply to M+C organizations apply without regard to whether duplication has been found. A beneficiary has access to detailed information on these standards, which are all public. We believe that it should not make a difference to the beneficiary whether our judgment that these standards are being satisfied is based on the findings of an accreditation body, HCFA, or an external review entity, as long as HCFA is responsible for ensuring that they are met.

We do not see the point in limiting exemptions to a year, if there is no reason to believe that the factors we will consider in making a decision on duplication will be changing.

On the issue of "nonpublic reports," we expect that the public will have access to the same quality information for all M+C organizations, without regard to whether specific review activities were found to be duplicative.

Comment: One commenter asked that we designate the PROs as review organizations in the regulation text, and not simply in the preamble.

Response: We currently have the authority to contract with non-PRO entities to perform functions of the type described in part 466, and although we have not chosen to exercise this authority at this time, we believe that it is important to maintain it. There may come a time when we decide that it is desirable to allow other entities to serve as review organizations; thus, we are not designating the PRO as the review organization in the regulation text.

Comment: One commenter expressed concern that the regulation does not explicitly obligate M+C organizations to cooperate with review organizations' investigation of quality of care complaints. This commenter suggested that § 422.154(b)(1)(ii) be revised to require that the M+C organization provide to the review organization all pertinent data it needs to carry out its reviews and make its determinations, including assessments of beneficiary quality of care complaints.

Response: Because assessments of beneficiary quality of care complaints are among the determinations that the review organization makes, we believe the existing requirement as written is sufficient to compel M+C organizations to cooperate with any complaint investigations conducted by the review organization.

Comment: One commenter asked that M+C organizations not be responsible for the cost of the external review.

Response: HCFA pays the cost of the external review, not the M+C organization. The M+C organization might initially bear the cost of duplicating medical records requested by the review organization, but the organization will be reimbursed for that cost.

Comment: Two commenters stressed the importance of public access to external review results. One of the commenters specifically asked that we require review organizations to release an annual report to the public summarizing their activities and the results of M+C organization performance improvement projects.

Response: In the PRO manual, there are detailed requirements relating to an annual report, which the PRO is required to send to the State and local offices of aging, and to senior citizen groups. In addition, the PRO is obligated to make the report available to beneficiaries upon request. Because specialized quality review organizations (the M+C/QROs), rather than PROs, will be evaluating the results of M+C

organization performance improvement projects, the PRO annual report will not include this information. However, we will ensure that there is a vehicle to inform the public of whether M+C organizations have met the requirement for achieving significant improvement.

Comment: One commenter asked that the regulation require that the external review address each component of the health delivery system, including laboratory services.

Response: Our own monitoring will assess the adequacy of an organization's health delivery system, of which we acknowledge laboratory services are a part.

Comment: One commenter asked that we define the adequate space and data requirements in paragraph (b)(1).

Response: We are not defining "adequate space" because the PRO's need for room in which to work could vary with each review. As for data requirements, they are generally stated in § 476.102(c). This paragraph requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services provided to Medicare patients as required by the PROs.

4. Deemed Compliance Based on Accreditation (§ 422.156)

Section 1852(e)(4) of the Act gives the Secretary the authority to deem that an M+C organization meets certain requirements if the M+C organization is accredited and periodically reaccredited by a private organization under a process that we have determined ensures that the M+C organization, as a condition of accreditation, meets standards that are no less stringent than the applicable HCFA requirements.

Section 422.156(a) of the M+C regulations specifies the conditions under which an M+C organization may be deemed to meet the HCFA requirements permitted to be deemed under section 1852(e)(4) of the Act.

The current version of § 422.156(b) specifies the requirements that could be deemed under the original BBA deeming provisions. In accordance with those BBA provisions, these included only the quality assessment and performance improvement requirements of § 422.152, and the requirements of § 422.118 related to confidentiality and accuracy of enrollee records. As discussed in section I.C. of this preamble, the BBRA amended section 1852(e)(4) of the Act to provide for deeming of additional requirements. An M+C organization accredited by an approved accreditation organization could be deemed to meet any or all of the requirements specified in section

1852(e)(4) of the Act, depending on the specific requirements for which its accreditation organization's request for approval was granted.

Section 422.156(c) establishes when deemed status is effective. Deemed status is effective on the later of the following dates: The date on which the accreditation organization is approved by us, or the date that the M+C organization is accredited by the accreditation organization.

Section 422.156(d) establishes the obligations of deemed M+C organizations. An M+C organization deemed to meet Medicare requirements must submit to surveys to validate its accreditation organization's accreditation process, and authorize its accreditation organization to release to us a copy of its most current accreditation survey, together with any information related to the survey that we may require (including corrective action plans and summaries of unmet HCFA requirements.)

Section 422.156(e) addresses removal of deemed status. We will remove part or all of an M+C organization's deemed status if: (1) We determine, on the basis of our own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted; (2) we withdraw our approval of the accreditation organization that accredited the M+C organization; or (3) the M+C fails to meet the requirements of paragraph (d) of this section.

Finally, § 422.156(f) explains that we retain the authority to initiate enforcement action against any M+C organization that we determine, on the basis of our own survey or the results of the accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

In addition to expanding the types of requirements that are deemable, section 518 of the BBRA also specified procedural changes to the accreditation process which are also discussed in section I.C. above and in several responses below. As noted above, these changes have been reflected in a revised version of § 422.156.

The comments and responses regarding § 422.156 are discussed below.

Comment: Several commenters expressed general support for the deeming provisions as stated in the regulation.

Response: The M+C deeming provisions are modeled on those that have been used successfully in original Medicare, and commenters have validated our belief that these

provisions will work equally well in Medicare managed care.

Comment: One commenter was concerned that if we allow deeming, we will not be able to ensure access for disabled enrollees. This commenter recommended that we ensure that accreditation organizations include in their review an assessment of an organization's ability to treat members with disabilities and complex care needs.

Response: We appreciate this comment, and agree that it is important that the needs of disabled enrollees not be overlooked. In evaluating whether standards imposed by an accreditation organization are at least as stringent as HCFA's, specifically QISM Standard 3.1, we will take into account whether these standards account for the needs of disabled enrollees.

Comment: Two commenters recommended that we expedite the implementation of the deeming program.

Response: We recognize the value of deeming to M+C organizations and intend to proceed with deeming at the earliest opportunity. As a first step in this process, we will require that accreditation organizations develop crosswalks between their standards and the QISM standards relating to the M+C requirements for which the organizations are seeking deeming approval. Only after we have revised the interim QISM standards to reflect the changes made in this final rule and the final rule published February 17, 1999, will we have an accurate set of standards for use by the accreditation organizations in completing their crosswalks. We expect to release a revised set of QISM standards shortly after publication of this final rule. Thirty days after publication we will begin accepting applications from accreditation organizations. A **Federal Register** notice formally announcing this timetable is being published concurrently with this final rule.

Comment: Three commenters addressed the requirement that, as a condition of deemed compliance, an M+C organization be "fully accredited." The commenters believe this condition would be problematic, given that many accreditation organizations have multiple accreditation categories. One of the commenters, an accreditation organization, stated that this policy is " * * * a significant and substantive change from the current process under Medicare. At this time there exists a variety of accreditation levels * * *," not only within accreditation organizations but among them. A second accreditation organization

complained that restricting deeming to only M+C organizations that have been "fully accredited" contradicts the stated policy of deeming on a standard-by-standard basis. It explained that requiring an M+C organization to meet all of an accreditation organization's standards decreases the potential savings and efficiencies associated with deeming.

Response: Because accreditation categories differ among accreditation organizations, we expect that "fully accredited" will have to be defined on an organization by organization basis. Fully accredited will generally mean that all elements within all the accreditation standards for which the accreditation organization has been approved by HCFA have been surveyed and fully met or otherwise determined as acceptable without significant findings, recommendations, required actions or corrective actions. The commenter who complained that the requirement that an M+C organization be fully accredited is inconsistent with our intent to approve accreditation organizations on a standard-by-standard basis has misunderstood the requirement. The M+C organization must be fully accredited for only those standards for which the accreditation organization has been approved, not all of the accreditation organization's standards. We understand how the commenter misinterpreted the existing regulations, and we are revising § 422.156(a)(1) to clarify this requirement.

Comment: One commenter pointed out that if an M+C organization chooses not to be accredited, we will perform a complete audit of its functions. Because there is no cost to the M+C organization for our audit, the commenter believes it would be to an M+C organization's advantage not to be accredited, because it would avoid the cost of accreditation as well as duplicate reviews (for example, an accredited M+C organization's grievance and appeal program would be reviewed both by the accreditation organization and by HCFA because the grievance and appeal requirements are not deemed). The commenter asked whether this interpretation is correct.

Response: The commenter's interpretation is correct, although there are benefits associated with accreditation, such as improved marketability, that we believe make accreditation attractive.

Comment: Many commenters addressed the scope of deeming. The majority of commenters supported the limited deeming reflected in the interim final regulation. One of these

commenters cited as support for limited deeming a recent report regarding the problems associated with deeming based on private accreditation of hospitals. One commenter advocated the continued development and implementation of the "enhanced review" process begun several years ago. One commenter opposed limited deeming. This commenter, an accreditation organization, asserted that the regulation does a disservice to its clients as they are still subject to a our survey. Further, this accreditation organization complained that the regulation fosters "the very duplication of effort and stifling of innovation that the BBA sought to avoid by requiring deemed status."

Response: In recognition of the efficiencies associated with deeming, section 518 of the BBRA amended section 1852(e)(4) of the Act to provide for the deeming of additional requirements. Specifically, the additional deemable requirements are those related to the following sections of the Act: section 1852(b) (which relates to antidiscrimination); section 1852(d) (which relates to access to services), section 1852(i) (which relates to information on advance directives), and section 1852(j) (which relates to provider participation rules). We are revising § 422.156(b) to add these requirements.

We note that HCFA's oversight of managed care accreditors will be different from that of hospital accreditors, *i.e.*, the JCAHO. Deeming based on JCAHO accreditation is explicitly required by statute, whereas potential M+C accreditors must demonstrate their ability to apply and enforce standards at least as stringent as our own as a condition of approval. In the event that a managed care accreditor fails to perform as promised, we retain the authority to withdraw its approval. Therefore, there are safeguards in place to prevent the situation that has arisen in hospital deeming from repeating itself in managed care.

Comment: Four commenters addressed the topic of approving accreditation organizations on a standard by standard basis as outlined in the regulation. Three commenters were in favor. One commenter asked if approving on a standard by standard basis means that we will " * * * approve an accreditation organization for some standards but not for others." One commenter contended that our decision to approve accreditation organizations on a standard by standard basis is "inconsistent with the need to reduce the duplication of effort." This commenter, an accreditation

organization, recommended that accreditation organization standards be assessed to determine if overall they equal or exceed HCFA's requirements. This commenter continued to state that " * * * approving individual standards will lead to a stifling of innovations and improvements over time."

Response: Section 518 of the BBRA has caused us to revise our approach to approving accreditation organizations. Originally, section 1852(e)(4) of the Act stipulated that "the Secretary shall provide that a Medicare+Choice organization is deemed to meet requirements" of certain subsections of the Act if the organization were accredited by an approved organization. The BBRA changed the provision to read that "the Secretary shall provide that a Medicare+Choice organization is deemed to meet *all the* requirements" (emphasis added) of certain cites within the Act. The result of the change is this: it is still possible for us to approve an accreditation organization for a subset of the deemable requirements alone; for instance, we may approve an accreditation organization for the quality assurance subset (which includes the quality assessment and performance improvement program requirements of § 422.152) without approving it for any others. However, the accreditation organization must now have a comparable standard to every one of the M+C requirements within the quality assurance subset. Prior to enactment of the BBRA, an accreditation organization with only some quality assurance standards equivalent to the M+C requirements would have been permitted to participate in deeming; HCFA would have monitored for compliance with the M+C requirements for which no equivalent accreditation organization standards existed. Now, because the BBRA requires, in essence, that HCFA deem an accredited M+C organization by subset, rather than by requirement, we can approve an accreditation organization only if it has a standard that meets or exceeds each of the M+C requirements of the subset. While this policy could limit the extent to which an accreditation organization may be involved in deeming, it could be viewed as simplifying the oversight process, since there is no longer the potential for HCFA and an accreditation organization to divide responsibility for monitoring an M+C organization's compliance with the requirements of the same subset. We have revised the introductory clause in § 422.157(a) (discussed below) to reflect this BBRA change.

Comment: One commenter requested that public notice be given if an M+C

organization's deemed status is removed or an accreditation organization's approval is withdrawn.

Response: We agree that when we withdraw an accreditation organization's approval, HCFA should give public notice because the information may influence the choice of accreditation organization made by M+C organizations seeking accreditation. We expect to give this notice by posting it on our website.

When we withdraw an accreditation organization's approval, we also remove the deemed status of all M+C organizations accredited by the organization. Upon removal of an M+C organization's deemed status, HCFA immediately assumes responsibility for ensuring that the organization meets our standards. Because beneficiaries are not at risk, and because notifying them of the loss of their M+C organization's deemed status could cause them to be concerned that they are at risk, we do not believe it is necessary or appropriate to so notify beneficiaries.

Comment: A few commenters addressed our authority under § 422.156(e)(1) to remove deemed status on the basis of a review of accreditation survey results. One of the commenters, an accreditation organization, strongly disagreed with the provision, complaining that it " * * * would allow us to take the results of an accreditation survey and essentially ignore the decision of the accreditation organization without any independent data gathering." The commenter contended that the provision presumes that HCFA staff understand the accreditation requirements, and are better able to judge the performance of the M+C organization against those requirements than the accreditation organization's own surveyors. This commenter encouraged HCFA to conduct its own survey if we believe an M+C organization is not in compliance. If we reach a different conclusion than the accreditation organization after its own survey, then the commenter believes that we would be justified in removing deemed status. Another accreditation organization expressed similar concern with § 422.156(e)(1), stating that the regulation language could be used by us to "second guess the compliance determination using only the results of the accreditation survey." This commenter recommended limiting the removal authority to reflect this concern.

Response: We do not intend to overrule an accreditation organization's survey decision without doing our own investigation. If our own investigation reveals, however, that a condition is not

met, we reserve the right to remove deemed status even when the accreditation organization has not removed accreditation with respect to that condition. In order to clarify the distinction between—(1) a removal of deemed status by HCFA, based on HCFA's own survey, and (2) a removal based on a determination of noncompliance by an accreditation organization as a result of its accreditation survey, we have revised § 422.156(a) to separate these two situations. This should make it clear that we will not "second guess" the accreditation organization's conclusions based on its review without doing our own independent investigation.

5. Accreditation Organizations (§ 422.157)

In § 422.157(a), we discuss three conditions for our approval of an accreditation organization. We may approve an accreditation organization if the organization applies and enforces standards for M+C organizations that are at least as stringent as Medicare requirements (as discussed above); the organization complies with the application and reapplication procedures set forth in § 422.158, "Procedures for approval of accreditation as a basis for deeming compliance;" and, the organization is not controlled by the managed care organizations it accredits, as defined at § 413.17.

Section 422.157(b) of the interim final rule describes notice and comment procedures. Because the approval of an accreditation organization could have broad impact upon large numbers of organizations, providers, and consumers, we are providing notice and comment opportunities similar to those provided in the fee-for-service arena.

Section 422.157(c) establishes ongoing accreditation organization responsibilities. These responsibilities largely parallel those currently imposed upon accreditors under original Medicare. One exception is the requirement at § 422.157(c)(4) that an accreditation organization notify us in writing within 3 days of identifying, with respect to an accredited M+C organization, a deficiency that poses immediate jeopardy to the M+C organization's enrollees or to the general public.

Section 422.157(d) establishes specific criteria and procedures for continuing oversight and for withdrawing approval of an accreditation organization. Oversight consists of equivalency review, validation review, and onsite observation.

Section 422.157(d) states that an accreditation organization dissatisfied with a determination to withdraw our approval may request a reconsideration of that determination in accordance with subpart D of part 488 of this chapter. The comments and responses regarding § 422.157 are discussed below.

Comment: One commenter recommended that HCFA, when making a determination based on its own survey or the results of an accreditation survey that an M+C organization does not meet Medicare requirements, “define the requirements, data collection tools, and scoring (including relative weights) guidelines” used to make the determination. The commenter explained that disclosure of such information is consistent with assuring beneficiaries and providers that HCFA determinations and surveys are objective and based on criteria that are public, relevant and valid.

Response: We agree with the need to make our process for making determinations available to the public. That is why materials such as our monitoring protocol are available to the public on HCFA’s website, www.hcfa.gov/medicare/mgdcar1.htm.

Comment: We received six comments requesting public disclosure of accreditation survey results. One commenter requested that we require in the regulation that enrollees be able to obtain from us their organization’s accreditation survey results. An accreditation organization itself agreed with the need for public disclosure and stated that “If the accreditation is to be used for a public purpose, participation in Medicare, then we are accountable for the decision and the information upon which it was based.”

Response: We agree that public disclosure of accreditation survey results is appropriate. If an accreditation organization does not have a policy for publicly disclosing accreditation survey results, it will be required to develop one as a condition of our approval.

Comment: An accreditation organization recommended that we provide accreditation organizations with quality-related information, for example, performance measurement data, quality improvement projects, etc.

Response: We concur with the importance of “two way communication,” which is why we routinely publish or otherwise make available to interested parties the types of information referred to by the commenter, such as HEDIS results.

Comment: One accreditation organization contended that the monthly reporting requirements exceed

our needs, and it recommended that the regulation reflect our right to receive the information but not specify a reporting frequency until after information use and need is determined.

Response: We believe the reporting requirements of § 422.157(c)(1) accurately reflect our need for information. The information that accreditation organizations are required to report and the time frames in which they are required to report it are based on requirements that have proven their usefulness and necessity in deeming under original Medicare. We have no reason to believe that the organizations that accredit M+C organizations should be held to a different standard.

Comment: Two commenters addressed the conflict-of-interest provision at § 422.157(a)(3). One commenter stated that the provision is “so broadly drawn as to preclude managed care organizations from serving on the boards of accreditation organizations, or otherwise participating in the accreditation development process.” This commenter requested that we clarify that such activities are permissible. The second commenter also objected to the conflict-of-interest provision as written, recommending that we focus instead on whether the accreditation organization has policies in place that separate individuals affiliated with an M+C organization from an accreditation decision impacting that organization. This commenter asked for a definition of “controlled” that allows M+C organizations to participate in appropriate accreditation organization governance and policy making activities, but prohibits M+C organizations from having inappropriate influence on accreditation decisions affecting themselves.

Response: We believe it is important that no single or group of managed care organizations be allowed to exert undue influence over a private accreditation organization in any decision making process that would allow that single or group of organizations to benefit at the expense of others. However, we recognize the valuable role that representatives of managed care organizations may play in private accreditation organizations, and we agree that the regulation as written appears to prohibit a number of acceptable activities. Therefore, we are revising § 422.157(a)(3) to require that an accreditation organization ensures that: (1) Any individual associated with it who is also associated with an entity it accredits does not influence the accreditation decision concerning that entity; (2) the majority of the

membership of its governing body is not comprised of managed care organizations or their representatives; and (3) its governing body has a broad and balanced representation of interests and acts without bias.

Comment: One commenter asked whether we must act on an accreditation organization’s application for approval within 210 days, as is the case with respect to fee-for-service accreditation.

Response: The 210-day time frame that applies to accreditation under original Medicare is set forth in section 1865(b)(3) of the Act, and was not originally included by the Congress in section 1852(e)(4) of the Act. However, section 518 of the BBRA amended section 1852(e)(4) of the Act to add this requirement, and we are incorporating it into § 422.158(e).

In addition, because we are now required to make our decision on an accreditation organization’s application within 210 days, we are revising § 422.157(b)(1) to restructure the provisions concerning timing and content of the **Federal Register** notice that solicits public comments on accreditation organization applications to allow for a comment period that is concurrent with HCFA’s review. This process, also used by original Medicare, will give the public a meaningful opportunity to comment on the applications.

In the interim final rule, we modeled § 422.157(b)(1) on the original Medicare deeming regulation at § 488.8(b)(1). However, § 488.8(b)(1) was written before section 1865(b)(3)(A) of the Act was amended to require 210-day turnaround on accreditation organization applications, and we are now in the process of revising § 488.8 to conform with the Act. If we do not revise § 422.157(b)(1) to follow original Medicare’s model, we are concerned that our review of the accreditation organization’s standards will be so time consuming, there will be little time left within the 210 days for the public comment period. Therefore, revised § 422.157(b)(1) specifies that the **Federal Register** notice will announce our receipt of the accreditation organization’s application for approval, describe the criteria we will use in evaluating the application, and provide at least a 30-day public comment period. Again, the timing and content of this notice are consistent with the way in which we solicit comments on accreditation organization applications in original Medicare deeming, pursuant to section 1865(b)(3)(A) of the Act.

Comment: One commenter argued that it is not appropriate for us to take action against an accreditation

organization “irrespective of the rate of disparity” between certification by the accreditation organization and certification by us or our agent. The commenter agreed that accreditation organizations are “accountable to us and the public for the decisions they make and failure to properly assess the performance of the organizations they accredit should be grounds for action.” However, the commenter complained that open-ended authority to withdraw an accreditation organization’s approval regardless of the rate of disparity is inappropriate.

Response: It is an approved accreditation organization’s responsibility to ensure that accredited M+C organizations meet or exceed our standards. As per the regulation, if widespread or systematic problems are identified that indicate that an accreditation organization can no longer make that assurance, we reserve the right to take appropriate action, regardless of the disparity rate. However, we can assure the commenter that in Federal oversight of accreditation organizations, a variety of factors and measures are considered and utilized, only one of which is the disparity rate.

In response to the commenter’s concern, we are requiring that accreditation organizations provide us annually with summary data relating to their accreditation activities and observed trends. These data will assist us in making a comprehensive assessment of accreditation organization performance, and will help ensure that our oversight decisions are well-informed and appropriate. This change appears at § 422.157(c)(6).

Comment: One commenter requested that we clarify the term “enforces” as it is used in §§ 422.157(a)(1) and 422.158(a)(3)(iii)(C).

Response: An approved accreditation organization must apply and enforce standards that are at least as stringent as HCFA’s requirements. By that, we mean that we expect the accreditation organization to assess compliance with the approved standards, and where it finds that an M+C organization is not in compliance, to ensure that corrective action is taken.

6. Procedures for Approval of Accreditation as a Basis for Deeming Compliance (§ 422.158)

The requirements of § 422.158, which pertain to required application materials, the mechanics of the approval process, and the reconsideration of an adverse determination, are essentially restatements of the original Medicare requirements under § 488.4.

Comment: One commenter disagreed with the provision that prohibits an accreditation organization that has requested reconsideration of a denial from filing a new application while the reconsideration is pending. The commenter believes that this provision will discourage accreditation organizations from challenging a denial and result in a denial of due process.

Response: An accreditation organization may request a reconsideration if it receives a denial of its application. This may be done by submitting a request for reconsideration, the requisite supplemental information, and any necessary supporting documentation. In lieu of the reconsideration, an accreditation organization may select the option of submitting a new application that has been revised to address the deficient areas that led to the initial denial. Therefore, the prohibition against simultaneously submitting a request for reconsideration and a new application does not deprive an M+C organization of the right to submit a new application.

E. Relationships With Providers

Part 422, subpart E of the M+C regulations focuses on requirements for relationships between M+C organizations and health care professionals with whom they contract to provide services to beneficiaries enrolled in an M+C plan. Many of these requirements stem from the rules regarding provider participation that are set forth in section 1852(j) of the Act. In our February 17, 1999 final rule, we addressed comments and made changes concerning several aspects of the provider participation requirements contained in subpart E, including the scope and applicability of the provider participation procedures. This final rule addresses comments on all other requirements in subpart E.

1. Provider Participation Procedures (§§ 422.202(a) and 422.204(c))

For the most part, we responded to comments on issues related to §§ 422.202(a) and 422.204(c) of the regulations in our February 17, 1999 final rule (64 FR 7975). In reviewing the comments on the interim final rule, however, we believe that additional clarification may be necessary on the applicability of the provider appeals procedures now set forth under § 422.204(c).

Comment: Several commenters objected to language in the preamble to the June 26, 1998 interim final rule that implied that health care professionals should have access to a formal appeals process when they viewed changes in

an M+C organization’s provider participation policies as having an adverse effect. The commenters pointed out that these policies should be subject to the consultation rules set forth under § 422.204(b), but did not believe that changes in these policies warranted a formal appeals process.

Response: As discussed in the February 1999 rule, the appeals procedures set forth under existing § 422.204(c) apply only in cases of adverse participation decisions, that is, when an M+C organization suspends or terminates a physician’s contract with the organization. We believe this policy is consistent with the intent of section 1852(j)(1) of the Act, which provides for a process for appealing “adverse decisions” relating to the “participation of physicians” under a plan. We did not intend to imply that a physician has a right to a formal hearing to appeal a participation policy adopted by the M+C organization, although we would expect physicians to have input on those policies through the consultation process required under § 422.202(b). Clearly, however, an M+C organization ultimately is legally entitled to adopt the policies necessary to govern its operations, as approved by its board of directors, provided they are consistent with applicable Federal requirements. Please note that as part of a minor restructuring of the M+C provider participation provisions, and to help clarify that the appeals procedures apply only for adverse participation decisions, we are redesignating the provider appeals procedures from § 422.204(c) to new § 422.202(d).

Comment: Two commenters objected to the requirement in existing § 422.204(c)(3) that an M+C organization must notify the appropriate licensure or disciplinary bodies when it suspends or terminates a contract because of deficiencies in the quality of care. These commenters suggested that we leave State reporting requirements to the States. Another commenter recommended that the appeals hearing panels (under § 422.202(c)(2)) be required to include physicians that did not contract with the M+C organization as a means of ensuring the “independence” of the panel’s review.

Response: Existing statutes and regulations consistently establish the need for cooperation between Federal and State authorities in their administration of the Medicare program. A primary example is the requirement under section 1855(a)(1) of the Act that an M+C organization generally must be licensed under State law in order to qualify for participation in the M+C program. Thus, we believe it is wholly

appropriate to require in Federal regulations that the suspension or termination of a physician's contract with an M+C organization be reported to State licensing and disciplinary bodies.

With regard to the membership of appeals panels, an M+C organization is free to enlist non-contracting physicians on these panels if it chooses to do so. However, section 1852(j)(1)(C) of the Act refers to an appeals process "within the organization," and we do not believe it would be reasonable to require the participation of non-contracting physicians.

Comment: A commenter pointed out that at least one State has laws exempting an organization from the State's requirements for provider notification and review procedures in cases of imminent harm to a patient, determination of fraud, or final disciplinary action by a State licensing board. The commenter asked whether the notification and appeals provisions of subpart E would preclude exemption in these situations.

Response: As discussed in further detail below, section 1856(b)(3)(B) of the Act specifies that State "requirements relating to inclusion or treatment of providers" are superseded by the analogous Federal standards. Thus, State reporting exceptions to the M+C notification and appeals procedures are precluded under the existing M+C regulations. However, we do not believe that the general notice requirement under existing § 422.204(c)(1) and (3), which do not include specific time frames for notification, should present a conflict with the State law mentioned by the commenter. We note that 60-day time frame for termination notifications under § 422.204(c)(4) applies only for terminations "without cause," rather than in situations addressed by the law in question.

2. Consultation Requirements (§ 422.202(b))

In accordance with section 1852(j)(2) of the Act, § 422.202(b) specifies that an M+C organization must consult with physicians participating in its M+C plans regarding the organization's medical policies, quality assurance programs, and medical management procedures. Under the regulations set forth in our June 26, 1998 interim final rule, these provisions were applied to other health care professionals as well as physicians. However, in response to comments on the interim rule, we revised this section in our February 1999 final rule to limit the applicability of these requirements to physicians. We also received a number of comments on

other aspects of the consultation provisions, which are discussed below.

Comment: Commenters generally supported the objectives of the consultation requirements contained in § 422.202(b). However, several commenters representing physician groups suggested that the regulations should be expanded to establish a specific methodology for obtaining consultative input. For example, one commenter advocated requiring the establishment of a medical committee structure broken down into separate subcommittees focusing on various aspects of medical management policy (for example, professional relations, credentialing, quality improvement, etc.).

Other commenters representing M+C organizations asked for confirmation that the use of physician committees to obtain consultation was an acceptable means of satisfying the consultation requirements. Two M+C organizations suggested that we define "consultation" as "soliciting and considering advice from participating professionals through committees established by the M+C organization." Another commenter noted that local medical review procedures (LMRP) should be part of the consultation process, and could in some instances substitute for the consultative process. One commenter indicated that the consultative requirements could be read to require consultation with hundreds of individual physicians and expressed concern that the consultative requirements would interfere with an individual physician's judgement in treating patients.

Response: We agree that the most appropriate method for an M+C organization to consult with its contracting physicians is likely to be through the establishment of a committee structure. Rather than limit organizational flexibility by establishing a single model for consultation, however, we are revising § 422.202(b) to state that an M+C organization must "establish a formal mechanism" for consulting with the physicians who provide services under plans offered by the organization. As we monitor the types of consultative arrangements implemented by M+C organizations, we will consider whether more specific regulatory guidance is necessary.

Similarly, although we agree with the definition of consultation offered by the commenters, we believe that the term is sufficiently self-explanatory and that inserting a formal definition of the term into the regulations is unnecessary. We also agree that M+C organizations should take local medical review policies into consideration in

establishing and updating their medical review policies. However, we believe that the regulations need not include that degree of specificity concerning the evidence-based guidelines an M+C organization must consider in adopting practice guidelines. We will consider adding such policies to the list of guidelines now described in the QISMC standards on this subject (QISMC Guideline 3.4.1.1).

Finally, we do not agree that the consultation requirement infringes on the ability of an individual physician's judgement in the practice of medicine. As their name implies, practice "guidelines" are intended for general application rather than as procedures to be followed in every case independent of physician judgment.

3. Treatment of Subcontracted Networks (§ 422.202(c))

Under § 422.202(c), an M+C organization that uses subcontracted physician groups or other networks of health care professionals must provide M+C participation procedures that apply equally to these subcontracting groups.

Comment: Many commenters raised questions concerning the meaning and implications of the requirement under § 422.202(c), which states that when an M+C organization operates an M+C plan through subcontracted physician groups or other subcontracted networks, it must ensure that "the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups." (Note that this provision was amended in our February 1999 final rule to limit its applicability to physicians.) Although some commenters supported this requirement as written, others were concerned that the requirement was too broad in scope. Several commenters suggested that we clarify that an M+C organization can comply with this provision by requiring subcontracting networks to have their own procedures for consultation and for participation appeals. They believe that it would be imposing "unreasonable downstream responsibilities" to require that the subcontractor's consultation and appeals procedures establish participation rights equivalent to those required under § 422.202. Other commenters recommended that we require the subcontracts to include the same specific appeals procedures as required at the M+C organization level. Finally, several commenters asked whether appeal rights extend to all physicians in a terminated group practice or to individual physicians. They recommended that the

subcontracting group practice exercise appeal rights on behalf of its employees.

Response: M+C organizations are contractually obligated to meet all requirements contained in the M+C regulations. They may meet these requirements either by directly providing the requisite health or administrative services or by entering into contracts for the provision of these services. Although we recognize the need for further clarification of how the provider participation rules and other provisions of the M+C requirements apply to subcontracting entities, the presence of a subcontract does not alter the underlying substance of those requirements. Note that § 422.502(i) of the M+C regulations contains a great deal of general information regarding the delegation of responsibility under subcontracts as well as some specific requirements (for example, with respect to provider credentialing). Please see section II.K of this preamble for a further discussion of many related issues. In addition, readers may wish to consult OPL #77, released on December 8, 1998, which offers extensive guidance in this regard (available through the HCFA website at www.hcfa.gov).

As spelled out under § 422.502(i), under any type of subcontracting arrangement, the M+C organization retains ultimate responsibility for ensuring that its subcontractors achieve full compliance with all terms and conditions of the organization's contract with us. This includes ensuring that activities performed by its subcontractors are consistent and comply with the M+C organization's contractual obligations. For activities that are delegated to contractors (such as provider appeals), the contract must specify that the subcontractor must comply with all Medicare laws, regulations, and instructions. Thus, a physician who is employed by a group practice that contracts with an M+C organization would have the same fundamental consultation and appeal rights as a physician who contracts directly with the M+C organization. Whether that physician exercises those rights at the subcontractor level, or directly through the M+C organization, would be left to the discretion of the M+C organization and its subcontractors. For example, an M+C organization could enter into a contract with a physician group under which all individual appeals of adverse participation decisions were adjudicated at the subcontractor level. However, the subcontractor's appeals process would need to meet the requirements established under redesignated § 422.202(d), as discussed

above: all procedural rights established there would apply equally for the subcontracting physicians. For situations in which a subcontract with an entire group practice was terminated by an M+C organization, we would expect that the appeal rights would fall to the subcontracting group practice to exercise on its physicians' behalf.

Similarly, with respect to the consultation requirements, we can envision various ways in which the requirements could be met under subcontracting arrangements, such as through direct representation for the subcontractor's providers on M+C organization committees, or through committees convened by the subcontractor, with its consultative input channeled to the M+C organization. In either case, though, the underlying requirement must be met that practice and utilization management guidelines be developed in consultation with contracting physicians.

In general, our policy to date has been to afford extensive flexibility to M+C organizations in meeting subcontracting requirements. In 1999, for example, we required risk contractors that became M+C organizations to submit a plan demonstrating how they would work toward executing new or revised provider or administrative service contracts, with full compliance required by January 1, 2000. Again, for further information on the ways in which an organization can demonstrate compliance with provider contracting requirements, please see OPL 77.

4. Provider Antidiscrimination (§§ 422.100(j), 422.204(b), new 422.205)

Sections 422.100(j) and 422.204(b) both relate to the provision set forth in section 1852(b)(2) of the Act that precludes M+C organizations from discriminating against providers based on their licensure or certification. Section 422.204(b), for the most part, simply incorporates the statutory prohibitions on discrimination based on provider licensure or certification, but also provides that these prohibitions do not preclude the "use of different reimbursement amounts for different specialties." Section 422.100(j) states that if more than one type of practitioner is qualified to furnish a particular service, the M+C organization may select the type of practitioner to be used.

Comment: Numerous commenters addressed the provider antidiscrimination provisions set forth at §§ 422.100(j) and 422.204(b). Commenters generally believed that additional guidance beyond that offered

in the June 1998 interim final rule was necessary to clarify our interpretation of the antidiscrimination provisions of the statute (section 1852(b)(2) of the Act). Commenters differed in their views on how these provisions should be interpreted and implemented, however.

In general, commenters representing M+C organizations supported the inclusion of the choice-of-practitioners provision (§ 422.100(j)); they believe that this provision establishes that M+C organizations are not required to adopt an "any willing provider" policy, but rather have the flexibility to choose the practitioners that participate in an organization's provider network. In contrast, commenters representing physicians and other health care professionals believe that the choice-of-practitioners provision is unnecessary and confusing; they see the provision as undermining the antidiscrimination provisions of the statute and the M+C regulations. These commenters particularly objected to the wording in § 422.100(j) that allows an M+C organization to select the "type of practitioner" to be used. These commenters offered various recommendations, including: (1) delete the provision in its entirety; (2) add a requirement that an M+C organization employ a "representative range of providers" (comparable with the available range of providers under original Medicare); (3) amend the provision so that it would focus on the availability of all Medicare-covered "benefits" (many of which can be furnished only by qualified practitioners), rather than "services".

Commenters displayed similar perspectives with regard to the antidiscrimination prohibitions set forth under § 422.204(b). As noted above, the only portion of this section that is not taken directly from the statute is the provision under existing § 422.204(b)(2)(ii) that indicates that an M+C organization is not precluded from use of different reimbursement amounts for different specialties. Commenters representing M+C organizations generally supported the addition of this language, although one commenter believed that it unnecessarily restricted an M+C organization's ability to negotiate with physicians or other practitioners. This commenter stated that the regulations do not give an organization sufficient leeway to take into consideration the reputation, volume, or experience of a practitioner, or alternative payment methods, in establishing compensation.

Other commenters representing various types of physicians and other health care professionals objected to this

provision because they believe that it confers too much authority on M+C organizations. They argued that permitting an M+C organization to pay different amounts for different specialties was inconsistent with legislative intent. They also contended that this language was inconsistent with the Supreme Court's decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), which they characterized as requiring that Medicare "reimburse similar services in an equal manner regardless of who performs the service." These commenters believed that we should require that payment rates be tied to the services provided, as under the fee schedules used in original Medicare. One commenter suggested that we revise § 422.204(b)(2)(ii) to clarify that payment differences are permissible only if they "result from competition or other legitimate factors," rather than differences based solely on licensure or certification.

Response: The statutory antidiscrimination provision is intended to ensure that health care providers are not arbitrarily excluded from participation under a managed care plan's provider network solely on the basis of their license or certification. We recognize that the existing regulations, which refer to this prohibition on discrimination in both §§ 422.100(j) and 422.204(b), have created the potential for confusion.

To assist in clarifying the relevant requirements, we believe it is appropriate to consolidate the regulations concerning antidiscrimination and choice of providers into a new, separate § 422.205, Provider antidiscrimination. This section will begin with the general rule prohibiting discrimination based solely on licensure or certification, consistent with the law. We then will specify that in choosing its practitioners, an M+C organization must ensure that all Medicare-covered services must be available to a plan's enrollees. We are also incorporating under § 422.205(a) a revised version of the existing provision regarding choice of practitioners that eliminates any reference to "type of practitioners." Thus, the general rule will continue to permit M+C organizations the flexibility to choose their practitioners, consistent with the statute's antidiscrimination constraints, which are set forth under § 422.205(b). At the same time, this provision will emphasize the mandatory availability of all Medicare-covered services (such as physical therapy or manual manipulation of the spine to correct a subluxation).

Finally, we are adding at, § 422.205, a requirement that when an M+C organization declines to include a given provider or group of providers in its network, it must notify the provider(s) of the reason for its decision. Although this provision does not impart any appeal rights, we believe it is both a reasonable business practice and a means of ensuring that such decisions are subject to our monitoring efforts.

Our goal in implementing these changes is to strike a balance between our responsibility to ensure that M+C organizations are employing all the types of health care professionals needed to ensure that required Medicare-covered services are available to their enrollees, and our aversion to limiting organizations' flexibility in providing these services. Over the next few years, we intend to closely monitor organization compliance with the antidiscrimination provisions, including examining encounter data as it becomes available and tracking organizational participation decisions, to determine the degree to which all Medicare-covered services are made available under different plans.

We believe that the statute is not intended to preclude an M+C organization from negotiating appropriate, market-based, payment rates with its providers. It is quite possible, for example, that the "market rate" that must be paid to get a particular type of specialist to participate in an M+C organization's network may be higher or lower than that dictated by the market with respect to another type of practitioner. Section 1852(b)(2) of the Act expressly provides that its antidiscrimination rule "shall not be construed to prohibit a plan from * * * measure[s] designed to * * * control costs. * * *" Paying no more than the market rate for a given provider is clearly a component of cost control. We believe that establishing requirements concerning the comparative rates M+C organizations pay for contracting provider services would be inconsistent with the overall design of the M+C program, under which we pay a fixed amount to ensure that Medicare beneficiaries receive the services to which they are entitled, but M+C organizations have wide discretion in managing enrollee care and establishing provider networks. Inherent to this design is the premise that payment rates should be established through negotiated contracts rather than micro-managed by the Federal government. Thus, new § 422.205(b) specifies that an organization may use different reimbursement amounts for

different specialties, or different practitioners within the same specialty.

Further, we do not agree with the commenter that the payment rules established under original Medicare's fee schedules necessarily represent the appropriate model for payment under the M+C program, or that it would be appropriate or feasible to establish a requirement that an M+C organization's provider network reflect the identical mix of providers participating in Medicare generally. Beneficiaries have the option of returning to original Medicare if they place a premium on being able to receive services from any provider they wish, or are not satisfied with being limited to a defined network established by an M+C organization.

In addition to addressing measures designed to control costs, section 1852(b)(2) of the Act also makes clear that the antidiscrimination rule therein shall not be construed to prevent an M+C organization from taking measures to "maintain quality" of services. For example, we would not want to preclude higher payments to providers for demonstrating quality improvement, or preclude an M+C organization from imposing quality-related requirements, such as using only board-certified physicians.

Finally, section 1852(b)(2) of the Act makes clear that its antidiscrimination provision "shall not be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees." If an M+C organization can provide all physicians' services through a doctor of medicine, it may not "need" to contract with another practitioner who can provide only a discrete subset of physicians' services (such as a podiatrist or a chiropractor who under section 1861(r) of the Act are considered physicians under Medicare only for specified purposes). As long as all Medicare-covered services are available in the plan, there may be no "need" to assume the additional administrative costs of contracting with another practitioner when an existing contractor is able to perform the services the additional practitioner would be providing. This would not constitute discrimination based "solely" on the basis of license or certification, but rather, not contracting with practitioners not "needed" to provide the full Medicare range of benefits.

With respect to the choice-of-practitioners provision, this right has always been inherent in the managed care model of health care delivery. While a practitioner is not to be discriminated against *solely* due to his or her license, we believe that M+C

organizations must have the flexibility to deliver services through the most cost-effective practitioner who is qualified to perform the service in question. Again, this is a “cost control” measure authorized under the last sentence in section 1852(b)(2) of the Act.

We do not understand the commenter’s reference to the Supreme Court’s *Michigan Academy* decision, since this decision did not involve a ruling on the merits of any reimbursement issue. Rather, the issue in *Michigan Academy* was whether certain types of claims were subject to judicial review. Even if the decision did hold what the commenter suggested, rules that apply to payments under original fee-for-service Medicare do not apply to payments by M+C organizations to contracting providers.

Comment: Commenters asked how we intended to enforce the antidiscrimination requirements, noting that strong enforcement was particularly necessary in view of the specific preemption of State laws dealing with the inclusion of providers. Several commenters asked how a provider would pursue an antidiscrimination claim, and they urged us to establish an administrative review process for investigating allegations of discrimination based on licensure or certification. To facilitate the reviews, these commenters suggested that the regulations require that notices of adverse participation decisions include a statement of the reasons for the determination.

Response: Although we do not intend to establish a separate administrative review process for investigating allegations of discrimination against providers, we intend to place a strong emphasis on verifying that M+C organizations are in compliance with the antidiscrimination provisions. This will occur both through our scheduled monitoring activities and under our authority to conduct complaint investigations when we believe there is credible evidence of violations.

In addition, as noted above, § 422.205 will now incorporate the requirement that an M+C organization must state in writing its reasons for declining to include any given provider or group of providers in its provider network. This should enhance our ability to identify violations of the antidiscrimination requirements, for example, by detecting situations in which organizations exhibit a pattern of repeated refusal to contract with certain types of practitioners. If a prospective provider has evidence of discrimination on the basis of licensure, the appropriate

avenue to raise this concern is the HCFA regional office in the relevant area.

Comment: One commenter expressed concern that without further clarification, the choice-of-practitioners provision at existing § 422.100 could be construed as giving an M+C organization complete and final authority over an enrollee’s choice of health care provider. The commenter recommended that we clarify that an enrollee may appeal a plan’s decision not to allow access to a specialist, or a specific provider, that the enrollee believes is necessary to furnish adequate services.

Response: The regulations concerning choice of practitioners are not intended to limit in any way the appeal and grievance rights of enrollees under subpart M of the M+C regulations. If an enrollee is denied access to a specialist, the enrollee clearly has the right to a timely organization determination and, if necessary, a reconsideration of this determination. Situations involving whether a specific provider is necessary are more likely to be subject to either the organization’s grievance procedures or possibly to external review by a PRO if quality issues are involved.

5. Provider Credentialing (§ 422.204(a))

Ensuring that providers have the proper credentials for the services they are providing is a key component of an overall “ongoing quality assurance program for health care services,” as required under section 1852(e)(1) of the Act. Section 422.204(a) accordingly sets forth basic requirements that an M+C organization must follow with respect to the credentialing and recredentialing of the providers and suppliers with whom it enters into participation agreements. The M+C organization must ensure that providers and suppliers meet applicable State and Federal requirements. Basic benefits must be provided through, or payments must be made to, providers that meet applicable requirements of title XVIII and part A of title XI of the Act. Also, in the case of providers meeting the definition of “provider of services” in section 1861(u) of the Act, § 422.204(a)(3)(i) specifies that basic benefits may only be provided through such providers if they have a provider agreement with us permitting them to provide services under original Medicare. An M+C organization may not employ or contract with providers excluded from participation in Medicare.

Comment: Although commenters generally supported the flexibility built into the M+C credentialing provisions, several commenters suggested that the

credentialing standards used by the NCQA be incorporated into the M+C regulations because these commenters believe that they are clear and adequate to protect M+C beneficiaries. Several commenters contended that many of the M+C credentialing standards were somewhat vague; one commenter identified as particularly unclear the requirement under § 422.204(a)(2)(iii) to establish a process to “receive advice” from contracting health care professionals with respect to credentialing criteria. Another commenter asked if, in general, an M+C organization that complies with NCQA credentialing standards would also be in compliance with the M+C requirements. The commenter asked for confirmation that, like under the NCQA standards, the following categories of practitioners are not subject to the credentialing requirements: (1) hospital-based practitioners that provide care for an M+C organization’s enrollees only as a result of members being directed to the hospital, and (2) practitioners who provide care only under the direct supervision of a contracting physician. Another commenter asked for additional clarity as to what types of practitioners must be credentialed and suggested following NCQA standards. One commenter argued that the credentialing provisions should include substantive criteria governing which physicians will be credentialed in the network, which excluded, and on what grounds.

Response: In view of these comments, we have reexamined the existing credentialing provisions and are making several changes. First, as discussed above, we have removed both the antidiscrimination and the provider appeals provisions from § 422.204. Section 422.204 will now be entitled “Provider selection and credentialing” and will include a new § 422.204(a) to establish the general rule that an organization must have written policies and procedures for the selection and evaluation of providers. These policies and procedures must conform with the existing credentialing requirements, which will be redesignated as § 422.204(b), as well as the antidiscrimination procedures now contained under new § 422.205. These changes do not impose new substantive requirements on M+C organizations, but we believe they constitute both a necessary reorganization of the existing requirements, and a means of clarifying in the regulations the inherent purpose of the credentialing rules—the need for a systematic approach to provider selection. We note that both the NCQA standards and our QISMC standards

already incorporate the underlying concept that an organization's credentialing requirements are an integral component of its provider selection policies.

This change in no way obviates our awareness that an organization's selection criteria, and thus its credentialing policies and procedures, should be tailored to take into account the individual characteristics of each M+C organization. The process of provider selection also should be integrated with the process of establishing and maintaining an adequate provider network to assure enrollee access to plan services. Thus, we do not intend to add to the regulations greater specificity concerning the procedures an M+C organization must follow for credentialing and recredentialing purposes, or establish detailed criteria as to what constitute adequate credentials. Instead, the regulations will continue to require that M+C organizations follow a "documented process" for these activities that meets the relatively flexible existing standards.

With respect to the question about whether meeting NCQA standards would constitute compliance with M+C requirements, we are currently evaluating this question in the context of the "deeming" provisions discussed in section II.D above. If we find that NCQA, or any other private accreditation organization, applies and enforces standards that are at least as stringent as those set forth in § 422.204, then satisfying NCQA standards would constitute compliance with M+C requirements. Until we make such a determination, however, meeting NCQA credentialing standards does not necessarily achieve compliance with the M+C requirements. We note that we agree with NCQA that credentialing is not required for health care professionals who are permitted to furnish services only under the direct supervision of a physician or other provider, or for hospital-based health care professionals (such as an emergency room physician, anesthesiologist, or certified registered nurse anesthetist (CRNA)) who provide services to enrollees only incident to hospital services. (This exception does not apply if the practitioner contracts independently with the M+C organization or is promoted by the organization as being part of its provider network.)

Finally, we agree that the requirement that an M+C organization's process include "receiving advice" from contracting health care professionals could be misconstrued. We are changing

this requirement to indicate that the organization must have a process for consulting with its contracting health care professionals on its credentialing and recredentialing criteria.

Comment: Several commenters suggested technical changes to the regulations in subpart E. For example, one commenter recommended that the credentialing provisions consistently refer to suppliers as well as providers, noting that the subpart E basis and scope section (§ 422.200) explicitly mentions both providers and suppliers, while § 422.204(a)(3)(i) only refers to the furnishing of basic benefits through "providers." The commenter also recommended that pharmacies be considered as providers. Another commenter suggested that we add "or certification" to the licensure verification requirement under § 422.204(a)(2)(i), and asked whether Joint Commission on Accreditation of Health Care Organizations/Community Health Accreditation Program or Medicaid certification of an HHA was sufficient to meet the provider credentialing requirements, as has been the case in the past for Medicare managed care.

Response: The definition of providers that applies for purposes of the M+C program is found at § 422.2 and includes both entities that would be considered providers and suppliers for other Medicare purposes. However, to avoid any possible confusion, we are adopting the commenter's recommendation that suppliers be explicitly mentioned under existing § 422.204(a)(3)(i) (now redesignated as § 422.204(b)(3)(i), as discussed above). Pharmacies, thus, are considered "providers" for purposes of the M+C program. We are also amending the regulations to indicate that initial credentialing should include verification of licensure or certification.

Existing § 422.204(a)(3)(i) requires that in the case of providers of services that meet the original Medicare definition of "providers" under section 1861(u) of the Act (such as HHAs or SNFs), that provider must have a provider agreement with us in order to be permitted to furnish basic benefits under an M+C plan. Under this requirement, neither accreditation nor approval under the Medicaid program is necessarily sufficient to enable an HHA to furnish services under an M+C plan, unless the HHA is Medicare-certified. The objective of this policy is to ensure that M+C enrollees are guaranteed services of a quality level at least equal to that available to other Medicare beneficiaries. We continue to believe that the existence of a provider

agreement with us is the best way to ensure that HHAs providing services to M+C enrollees meet uniform standards in all States and are subject to Federal enforcement authority. Thus, we believe it would be inappropriate to create an exception for HHAs to the general rule that "providers of services" as defined under section 1861(u) of the Act must have a provider agreement that permits them to furnish services under original Medicare.

Comment: One commenter stated that the credentialing requirements appeared to require individual credentialing for physicians in group practices. The commenter believed that this requirement is too inflexible and could delay a physician's inclusion in a network. Instead, the commenter recommended that an M+C organization have the option of credentialing a group practice as network participants, and then transferring the obligation to credential new members of the practice to the practice itself.

Response: When an M+C organization contracts with a group practice, it has an obligation to ensure that all members of that practice meet its credentialing standards. Consistent with the discussion of subcontracting rules above (and with the subcontracting requirements of § 422.502(i)(4)), subsequent credentialing may be carried out either by the M+C organization itself or be delegated to the subcontracting organization (that is, the group practice). If delegated, however, the M+C organization must review and approve the credentialing process, and audit the process on an ongoing basis.

Comment: One commenter objected to several aspects of the credentialing requirements, and urged that they be modified to take into account the varying characteristics of M+C networks such as PPOs. The commenter recommended that the requirement for site visits be eliminated for PPOs, and that the requirement for recredentialing every 2 years be modified in favor of permitting M+C organizations to determine when recredentialing was appropriate depending upon the size and stability of the provider network.

Response: Under the existing regulations, site visits are required "as appropriate" for initial credentialing; thus, sufficient flexibility already exists in this regard. We believe that recredentialing every 2 years is a reasonable time frame and note that it coincides with NCQA standards. We believe it would be inappropriate for each M+C organization to substitute its judgment for a national standard as to when it should recredential its practitioners. If the provider network is

small and stable, the administrative burden associated with the recredentialing process should be relatively small.

Comment: One commenter noted that the prohibition on entering into contracts with providers that are excluded from participation in the Medicare program (under existing § 422.204(a)(3)(ii)) is impossible to implement unless the HCFA website includes a Social Security number (SSN).

Response: As noted in the interim final rule, M+C organizations are expected to consult the Office of Inspector General's (OIG) website (www.dhhs.gov/progorg/oig) to access the list of providers that are excluded from participation in the Medicare program. For privacy reasons, this listing does not include SSNs. However, we also maintain an internal excluded provider list (HCFA Publication 69) that includes unique identifying information for the providers in question. This publication generally is available to all of our contractors, including M+C organizations. We suggest that any M+C organization that needs this information contact either its regional or central office plan manager, or HCFA's Office of Issuances to obtain the latest version of Publication 69.

6. Prohibition on Interference With Health Care Professionals' Communication With Enrollees (§ 422.206)

Consistent with section 1852(j)(3)(A) of the Act, § 422.206(a) prohibits an M+C organization from interfering with the advice of a health care professional to an enrollee who is his or her patient. Thus the health professional may act within his or her scope of practice in advising the enrollee about his or her health status, all relevant medical or treatment options available regardless of whether care or treatment is provided under the plan. Section 422.206(b) incorporates the requirements of section 1852(j)(3)(B) of the Act. The regulations state that the prohibition against interference with the content of advice a health care provider has given to enrollees regarding medical treatment should not be construed as requiring counseling by a professional, if the M+C organization objects, based on moral or religious grounds, and fulfills certain notification requirements to prospective and current enrollees. The regulations incorporate the notification process and time frames included in the law and clarify that the plan must also notify us at the time of application and within 10 days of submitting its ACR proposal. We

received 12 comments addressing the provisions set forth under § 422.206.

Comment: The majority of the commenters simply expressed their support for this provision, which has been referred to as the "anti-gag rule." One commenter asserted that an M+C organization should not be forced to provide care that is not medically effective, approved by the Food and Drug Administration (FDA), or covered under the enrollee's plan. A commenter also suggested that M+C organizations be prohibited from requiring health care professionals to sign "gag rule" clauses that interfere with full disclosure of all treatment options, regardless of whether these options are covered under a plan. Another commenter noted that § 422.206(d) states that an M+C organization is subject to intermediate sanctions for violations of these provisions, and recommended that the regulations also specify that we will not renew the contract of an M+C organization that substantially violates the provisions in § 422.206.

Response: As indicated in the June 1998 interim final rule, a health care professional's freedom to inform an enrollee about available treatment options in no way implies that all of the possible treatment options (for example, experimental or noncovered alternatives) are covered under the enrollee's M+C plan. In other words, the prohibition on interference with provider-enrollee communications does not affect the M+C benefit and coverage requirements. Clearly, these rules prohibit an M+C organization from requiring health care professionals to sign a "gag rule" clause, such as that mentioned by the commenter. Finally, we note that under § 422.506(b)(1)(iv) of the M+C contracting regulations, an M+C organization that commits any acts that can support the imposition of intermediate sanctions is also subject to nonrenewal of its contract.

Comment: One commenter representing health insurance agents recommended that the regulations include a prohibition on physicians "advising seniors on M+C plans." The commenter asserted that only individuals with health insurance licenses should be permitted to proffer such advice.

Response: Although we recognize that there are situations where it would be inappropriate for physicians or other health care professionals to "steer" beneficiaries to particular health care plans, we do not believe that prohibiting patients from seeking advice from physicians regarding insurance coverage choices is either necessary or practical. For example, a physician should be able

to disclose to a patient the M+C plans in which he or she is a network provider. (For additional discussion of this issue, please see the portion of section II.B of this preamble that discusses M+C marketing requirements at § 422.80.)

Comment: Two commenters recommended that we either delete or clarify the requirement in § 422.206(a)(2) that health care professionals provide information regarding treatment options in a "culturally competent manner."

Response: We recognize that the term "culturally competent" can be subject to various interpretations, as discussed in detail above in section II.C of this preamble concerning M+C access requirements. For the purposes of this provision, our intent is that M+C organizations establish and maintain effective communication with enrollees, including informing them of treatment options in a language they can understand.

Comment: Two commenters raised concerns related to the conscience protection exceptions set forth in § 422.206(b). One commenter strongly supported the provisions, but recommended that the final rule clarify that: (1) nothing in the conscience protection provisions be construed as limiting the range of services to which Medicare beneficiaries are entitled; (2) an enrollee may terminate enrollment and choose another M+C plan if he or she receives notification under this section that an M+C organization will not cover or pay for a particular counseling or referral service; and (3) like other disclosure requirements, notifications required under § 422.206(b)(2) must be provided in a clear, accurate, and standardized form, consistent with the special needs of individual enrollees.

Another commenter asserted that there was a potential conflict between the conscience protection provisions and the information disclosure rules in § 422.111 and recommended that we establish an exception to the advance disclosure rules for "duly adopted religious policies." The commenter noted that the conference agreement to the BBA indicates the Congress' intent that the Secretary not "impose burdensome regulatory, legal, or stylistic requirements with respect to this notice requirement." (House Report, 105-217, pg. 607.)

Response: As the commenter points out, the conscience protection provisions in no way diminish or otherwise affect the range of benefits or services to which Medicare beneficiaries are entitled. As discussed in section II.C

above, the conscience protection in section 1852(j)(3)(B) of the Act affects only obligations under section 1852(j)(3)(A), not obligations that arise elsewhere in the statute, such as the obligation under section 1852(a)(1) to provide all Medicare-covered services available in the area served by the M+C plan. To the extent that the operation of the right to advice and counseling under section 1852(j)(3)(A) would obligate an M+C organization to cover counseling or referral services that it would not otherwise be obligated to cover, section 1852(j)(3)(B) allows the organization to decline to provide such service on conscience grounds if notice is provided to beneficiaries. However, if the service is one that the organization is obligated to provide independent of section 1852(j)(3)(A), it could not be affected by a provision that by its own terms affects only the way that “[s]ubparagraph (A) [of section 1852(j)(3)] shall * * * be construed.” It in no way affects obligations that arise elsewhere in the statute. Therefore, an M+C organization could not rely upon section 1852(j)(3)(B) or § 422.206(b) in an attempt to avoid coverage of services that it is obligated under section 1852(a)(1) to cover. We note, however, that in the case of abortion-related services, the Congress has provided M+C organizations with certain conscience protections independent of that in section 1852(j)(3)(B) of the Act. Specifically, under section 216 of the fiscal year 1999 appropriations legislation (Pub. L. 105–277), we are prohibited from denying an M+C contract to an entity on the grounds that it refuses on conscience grounds to cover abortions. Beneficiaries, nevertheless, retain the right to such services, and Medicare must cover them. We are required, however, to make appropriate adjustments to such an entity’s M+C capitation payments to cover our costs in providing Medicare-covered abortion services outside the M+C contract.

We agree that the disclosure provisions under § 422.206(b) should be read consistently with other disclosure provisions in the regulations, and thus M+C organizations must take into account the special needs of individuals who are blind, disabled, or cannot read or understand English. The notification requirements set forth in § 422.206(b)(2) are not intended to result in an M+C organization being put in the position of being required to furnish counseling or referral services that violate a duly adopted religious policy. Experience indicates that neither changes in Medicare coverage policies nor in “duly adopted” religious policies take place so

quickly as to preclude an M+C organization from providing advance notice to us, and then to enrollees, concerning service restrictions based on such policy changes. Thus, we believe that only very rarely, if ever, would a conflict exist between the advance disclosure requirement of § 422.111(d) and the provision that permits an organization to implement a conscience exception, provided that it notifies its enrollees of such changes within 90 days after adopting the change. Consequently, we do not view the advance disclosure procedure as a burdensome requirement.

7. Physician Incentive Plans (§§ 422.208 and 422.210)

Sections 422.208 and 422.210 outline the limitations and disclosure rules for physician incentive plans. Specifically, § 422.208 applies to an M+C organization and any of its subcontracting arrangements that use a physician incentive plan in their payment arrangements with individual physicians or physician groups. With the exception of the deletion of a requirement that information on expenditures of capitation payments be reported to us, the provisions in these sections are essentially the same as those that previously applied to Medicare risk plans under § 417.479. We received several comments regarding physician incentive rules.

Comment: A commenter contended that the 25 percent threshold for substantial financial risk is too high, noting that we have acknowledged that this represents an outlier approach, and that risk arrangements in the range of 10 to 15 percent are far more prevalent than those in excess of 25 percent. This commenter argued that the 25 percent threshold may render the rule irrelevant as applied to the majority of M+C organizations. In addition, the commenter is concerned that because the exemption level is set so high, the effect of the exemption may be to discriminate against plans that are in the process of growth, thus giving the larger plans a competitive advantage.

Response: As we indicated in the preamble to the physician incentive plan regulation published on March 27, 1996 (61 FR 13430), we believe that the 25 percent risk threshold is appropriate because of the outlier methodology that we used. The median withholds are in the 10 to 20 percent range. This was the best methodology in formulating the risk threshold. Actuarial analyses also supported the 25 percent risk threshold. Furthermore, many physicians typically give discounts in the 25 percent range.

The majority of arrangements that exceed the threshold are capitation arrangements, where 100 percent of the income is put at risk. For these arrangements, the precise amount at which we set the threshold will not make a difference, they will exceed any reasonable risk threshold.

Comment: One commenter pointed out a conflict in the regulatory language. At § 422.208(c)(2), the regulation specifies that the M+C organization provides stop-loss protection; while at § 422.208(f), it specifies that the M+C organization must assure that all physicians and physician groups have stop-loss protection.

Response: The commenter is correct and we are revising the incorrect language in § 422.208(c)(2) to eliminate this discrepancy. We note that paragraph (f) incorporates the language from § 417.479 (the physician incentive regulation that applied to section 1876 contracts) that we indicated in the preamble to the physician incentive regulation that we intended to adopt.

Comment: One commenter contended that the physician incentive plan requirements are excessively detailed, prescriptive, and confusing. The commenter argued that the detailed stop-loss insurance requirements impose additional costs on the delivery of health care, costs that are increasingly borne by the physician practices, not M+C organizations. The commenter urged us to monitor the stop-loss insurance market carefully, and provide prior review of panel size, and deductible limits set forth in the rule to ensure that they are not necessarily restrictive.

Response: In the preamble to the December 31, 1996 final rule (61 FR 69034) containing the section 1876 physician incentive requirements upon which §§ 422.208 and 422.210 were based, we presented a regulatory impact analysis. In that analysis, we concluded that only a small number of organizations and physician groups would need to increase their stop-loss protections, and that this increase would be small relative to the total amount of income. Furthermore, stop-loss insurance is required by statute where substantial financial risk is imposed, and it provides increased protection to physicians that helps reduce possible incentives to deny necessary care. These requirements have been in place for 3 years, and do not appear to have caused any significant problems for M+C organizations or their predecessors.

Comment: A commenter requested that these rules should apply to Federally Qualified Health Centers

(FQHCs) and all associated health care providers. The commenter pointed out that these rules appear limited to individual physicians, physician groups, and intermediate entities acting as subcontractors.

Response: If the FQHC is an intermediate entity, subcontractor, or a physician group as specified in these regulations, then the provisions apply.

Comment: One commenter wanted to know if we review disclosures for both the Medicare and Medicaid programs.

Response: The regulations require that M+C organizations that participate in the M+C program must disclose incentive plan arrangements to us, while managed care organizations that participate in the Medicaid program disclose incentive plan arrangements to the State Medicaid Agencies. We review the monitoring activities of State Medicaid Agencies.

Comment: One commenter indicated support for the methodology for disclosing incentive plans, but requested that we make clear that we do not require the precise formula and payment amounts be disclosed.

Response: Section 422.210(b) requires that an M+C organization must provide the following information to any Medicare beneficiary who requests it: (1) Whether the M+C organization uses a physician incentive plan that affects the use of referral services; (2) the type of incentive arrangement; (3) whether stop-loss protection is provided; and (4) if the M+C organization was required to conduct a survey, a summary of the survey results.

As we indicated in guidance provided in December 1996 to section 1876 contractors, M+C organizations do not have to disclose to beneficiaries the precise formula and payment amounts involved, nor do they have to provide incentive plan information for individual physicians or physician groups. Only summary information needs to be reported. However, the M+C organizations are required to report more detailed information to us or the State Medicaid Agencies.

8. Special Rules for Services Furnished by Noncontract Providers (§ 422.214)

Consistent with sections 1852(k)(1) and 1866(a)(1)(O) of the Act, § 422.214 requires that any health care provider that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan must accept, as payment in full, the amounts that they could collect if the beneficiary were enrolled in original Medicare (less the amounts specified in §§ 412.105(g) and 413.86(d) of the

regulations on hospital graduate medical education payments, when applicable). Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an M+C plan also apply to the payment described in § 422.214(a)(1) of our regulations. We received three comments regarding this section.

Comment: Several commenters suggested that we revise § 422.214 to provide that payment to a noncontracting provider must equal the amount that provider would be allowed to collect under original Medicare. These commenters believe that M+C organizations should only be permitted to pay the billed amount when this is the same amount that Medicare would pay under original Medicare.

Response: Section 422.214 implements section 1866(a)(1)(O) of the Act, with respect to services furnished by a “provider of services” as defined in section 1861(u), and section 1852(k)(1), with respect to other services. Neither of these provisions requires an M+C organization to pay a provider more than the amount of the provider’s bill, or even impose obligations on M+C organizations at all. Rather, these provisions serve as a limit on the amount the provider can collect from the M+C organization. Specifically, each of these provisions states that a provider “shall accept as payment in full” the amount (less the amounts specified in §§ 412.105(g) and 413.86(d) of the regulations) that it would receive under original Medicare, including cost sharing and permitted balance billing (“the Medicare payment amount”). While this means that under these provisions the provider cannot collect more than the Medicare payment amount if its billed amount is higher, this obligation to “accept” the Medicare amount as payment in full does not obligate the M+C organization to pay this amount if the provider’s bill is lower. Thus, in the case of emergency services and certain other services referred to in section 1852(d)(1)(C) of the Act furnished to an enrollee in a coordinated care plan, the provider or providers must accept the Medicare payment amount for the services if their billed amount is higher, but would have no right under sections 1852(k)(1) or 1866(a)(1)(O) to be paid more than the amount of their bill if the billed amount is lower than the Medicare payment amount.

We note, however, that a provision in the BBA does give providers furnishing services to coordinated care plan enrollees the right to be paid the Medicare payment amount under

certain circumstances. Section 1852(a)(2) provides that where an M+C organization chooses to furnish services through providers that do not have contracts with the organization in order to meet its obligation under section 1852(a)(1) to make Medicare services available, it must provide for payment “equal to at least” the Medicare payment amount. (Emphasis added.) This new provision, unlike section 1866(a)(1)(O) or section 1852(k)(1), establishes a “floor” for payment when it applies. This “floor,” combined with the “ceilings” under sections 1866(a)(1)(O) and 1852(k)(1), essentially requires that the Medicare payment amount be paid where section 1852(a)(2) applies. Because section 1852(a)(2) refers to an M+C organization’s furnishing services in fulfillment of its obligations under section 1852(a)(1), we are interpreting section 1852(a)(2), in the coordinated care plan context, as providing M+C organizations with the opportunity to arrange to provide nonemergency services through noncontracting providers. Under this interpretation, the “minimum payment” requirement in section 1852(a)(2) would only apply where the M+C organization has arranged for the services in question to be provided by a noncontracting provider. In the coordinated care plan context, therefore, payment for emergency services and those services referred to in section 1852(d)(1)(C) would continue to be subject only to the rules in sections 1852(k)(1) and 1866(a)(1)(O). In the private fee-for-service plan context, however, section 1852(k)(2)(B)(i) of the Act provides that all services furnished by noncontracting providers are subject to the “minimum payment rate” in section 1852(a)(2).

To summarize our position, in the case of services arranged by an M+C organization to be furnished by a noncontracting provider to a coordinated care plan enrollee, or any services furnished by a noncontracting provider to a private fee-for-service plan enrollee, section 1852(a)(2) applies, and the M+C organization must pay the Medicare payment amount. In the case of emergency services (referred to in section 1852(d)(1)(E)), urgently needed services (referred to in section 1852(d)(1)(C)(i)), renal dialysis services provided out of the M+C plan’s service area (referred to in section 1852(d)(1)(C)(ii)), and maintenance care or poststabilization services (referred to in section 1852(d)(1)(C)(iii)) furnished to a coordinated care enrollee by a noncontracting provider, the provider is required to accept the Medicare

payment amount as payment in full, but the M+C organization is not required to pay more than the billed amount.

Comment: One commenter suggested that we should clearly lay out the process and requirements for compliance with the provisions of § 422.214. In order to implement the payment limits in § 422.214 and not overpay noncontracting providers, M+C organizations will have to develop a process that would apply applicable Medicare payment limits to charges for services furnished to enrollees by noncontracting providers. M+C organizations will need detailed information from us describing each of Medicare's payment limits, how each limit is applied, and which limits apply to which provider.

Response: The comment addresses the need for a process to implement the payment limits contained in § 422.214. We understand that any process used to apply Medicare payment limits will require a significant amount of data and will be relatively complex. However, we do not feel that the requirements for such a process should be set forth in regulation. Each M+C organization should be allowed to develop a process that will satisfy that organization's needs.

As discussed in further detail in section II.Q of this preamble, we anticipate that the organizations offering M+C private fee-for-service (PFFS) plans may have a particular need for such a process, both to pay non-contracting providers who must be paid at least the amount they could collect under original Medicare, and to pay contracting and deemed contracting providers, assuming that the M+C organization offering the PFFS plan has chosen to meet access requirements by paying contracting providers "no less than" the amount paid under original Medicare. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish "proxies" for use in paying services for which no Medicare prospective payment system or fee schedule exists, provided that the proxy methodology has been approved by us as not being less than the expected Medicare payment amount.

We emphasize that the proxy methodologies will be designed to provide an accurate estimate of the Medicare payment amount, including possible beneficiary cost-sharing under original Medicare. In some cases (for example, for Medicare-certified hospitals, SNFs, or HHAs, or for Medicare-participating physicians), this is the amount that a noncontracting provider is required to accept as payment in full from the M+C

organization. In other cases, the amount that a noncontracting provider may collect is not limited to the Medicare payment amount but could include allowable balance billing amounts under original Medicare. In such a case, the provider has a right to collect more from the M+C organization than the Medicare payment amount reflected in the proxy (and in the case of a noncontracting provider furnishing services to a PFFS plan enrollee, the M+C organization may have an obligation to pay more than the proxy amount).

Comment: One commenter asked whether the statement in the preamble that "the M+C organization must hold beneficiaries harmless against any such balanced billing" means that an M+C organization must pay billed charges to noncontracting providers regardless of the Medicare fee schedule.

Response: No. Section 422.214 clearly states that a noncontracting provider must accept as payment in full what the provider could collect under original Medicare (less any payments under §§ 412.105(g) and 413.86(d)). Please note that some providers may be entitled to receive an amount that is in excess of the Medicare fee schedules, but that does not exceed the limiting charge.

9. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

An M+C organization may not pay, directly or indirectly, on any basis, for services (other than emergency or urgently needed services as defined in § 422.2) furnished to a Medicare enrollee by a physician (as defined in section 1861(r)(1) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare carrier an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts with the beneficiary under section 1802(b) of the Act. An M+C organization must pay for emergency or urgently needed services furnished by a physician or practitioner who has not signed a private contract with the beneficiary.

Comment: One commenter contended that it is difficult to exclude private contracting physicians and practitioners from payment because there is no central list of private contractors. This commenter believes that we should list these physicians and practitioners on our website, and include unique identifiers, like the physician or practitioner's SSN.

Response: We recognize that it is difficult for M+C organizations to acquire timely and accurate information on "opt out" physicians with whom

they do not have a contract, and we are working on a way of making this information available to them as soon as possible. M+C organizations offering coordinated care plans could seek this information from the provider or supplier before they authorize the use of a noncontracting physician or practitioner. Moreover, we do not anticipate that the absence of such knowledge would be a problem in cases of emergency or urgent care since in those cases, the services of the opt-out physician or practitioner are covered (unless the enrollee/beneficiary has previously signed a private contract).

As part of our effort to streamline the flow of information on opt-out physicians and practitioners, we are also considering what information can be placed on a list or made available through a website. Some information such as the SSN cannot be disclosed under the Privacy Act.

Currently, M+C plans should contact the Medicare carrier with jurisdiction over the payment of claims under original Medicare in their service area to work out a mutually agreeable means of receiving this information on a timely basis. Disputes should be referred to the HCFA regional office for resolution.

With respect to contracting physicians, M+C organizations may, through their contracts, require contract providers to notify them immediately when they enter into private contracts under section 1802(b). This will provide the information more timely than any process that might be arranged with Medicare carriers or through a listing prepared by us, and will permit the M+C organization to cease payment immediately to the contracting physician or practitioner who has opted out of Medicare.

Comment: One commenter urged that we monitor the disease type and severity of diseases of beneficiaries who privately contract with physicians to determine what future program changes are appropriate.

Response: We are required by section 4507 of the BBA to provide a report to the Congress by October 1, 2001 on the effect of private contracting and to provide recommendations for legislation in this regard. We are conducting a broad study of claims data that will be used to prepare that report.

Comment: A commenter suggested that the private fee-for-service plan discussion of deemed and non-contracting providers be revised to indicate that these payment restrictions do not apply if the provider has opted out under § 422.220.

Response: We have included a clarification by cross reference.

Comment: A commenter believes that beneficiaries need to be advised in both HCFA and M+C plan information that no payment can be made by the M+C organization for services provided under private contract with a physician who has entered into a contract under section 1802(b).

Response: We agree that it is important that M+C plan enrollees know that no payment can be made under the M+C plan for services of physicians and practitioners who have entered into contracts under section 1802(b). Section 1802(b) and private contracting regulations at § 405.400 both require that a private contracting physician or practitioner have the beneficiary (enrollee in the case of M+C plans) sign a private contract that notifies him or her that no Medicare payment will be made for the services of the opt-out physician or practitioner, and that he or she accepts full responsibility for payment of the opt-out physician or practitioner's services (except in cases of emergency medical condition or urgent care in which the physician or practitioner cannot ask the beneficiary to sign a private contract and Medicare will pay for the care). Hence, the plan enrollee should be specifically aware of the effect of receiving services from an opt-out physician or practitioner before he or she receives these services. We will, however, also consider adding a discussion of private contracting to the model evidence of plan coverage.

10. M+C Plans and the Physician Referral Prohibition

The physician referral prohibition in section 1877 of the Act concerns M+C organizations, although the implementing regulations are located in subpart J of part 411 rather than in part 422. Under section 1877, if a physician or a member of a physician's immediate family has a financial relationship with a health care entity (through an ownership interest or a compensation relationship), the physician may not refer Medicare patients to that entity for any of 11 designated health services, unless an exception applies. Under section 1877(b)(3) of the Act and § 411.355(c) of the regulations, services furnished by section 1876 contractors to their enrollees were exempted from the physician referral prohibition. In the June 1998 interim final rule, we revised § 411.355(c) to similarly exclude from the physician referral prohibition services furnished under an M+C coordinated care plan to an enrollee. We did not exclude services furnished by private fee-for-service plans or MSA plans from the physician referral

prohibition. Subsequently, section 524 of the BBRA amended section 1877(b)(3) of the Act by adding a new subparagraph (E) to exempt an M+C organization offering an M+C coordinated care plan from the physician referral prohibition. The comments and responses regarding this subject are discussed below.

Comment: One commenter argued that services furnished under an MSA plan or private fee-for-service plan should also be excluded from the physician referral provisions. The commenter believed that while there are differences between these types of plans and coordinated care plans, patients who elect coverage under an MSA plan or a fee-for-service plan do so knowing that their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan. In the commenter's view, concerns about beneficiaries should be addressed in the context of disclosures by the M+C organization offering the MSA plan or private fee-for-service plan, prior to enrollment, rather than by the section 1877 provisions. At most, this commenter would require only that M+C organizations offering plans of these types disclose financial interests in entities that furnish designated health services in return for an exception from the prohibition in section 1877.

Response: As we understand the argument, the commenter has suggested that we should exclude M+C private fee-for-service plans and M+C MSA plans from the prohibition on referrals under section 1877 because the concerns addressed by section 1877, that, in general, a physician should not profit from his or her referrals for certain services, has already been accommodated. The commenter believes that beneficiaries already understand that in these plans their out-of-pocket liabilities are not controlled to the same degree as in a coordinated care plan, and that any problems that still might exist can be addressed by more disclosure.

We do not understand why a beneficiary's knowledge of the differences between coordinated care plans and private fee-for-service/MSA plans addresses the concerns behind our decision not to exempt services furnished under the latter plans from the prohibition in section 1877. Under section 1877, we can create a new exception only if the Secretary determines, and specifies in regulations, that a financial relationship between a physician and an entity to which the physician refers does not pose a risk of program or patient abuse. Pursuant to this authority, we exempted services

furnished under coordinated care plans because the Congress had already exempted the identical type of arrangement when it exempted services furnished under section 1876 contracts, (and likely inadvertently failed to make a conforming change to this exception when M+C contracts replaced section 1876 contracts), and because we did not see a potential for program or patient abuse in the case of coordinated care plans. This latter conclusion was based on the facts that, as in the case of a section 1876 risk contractor: (1) A physician working with an M+C organization offering a coordinated care plan has no incentive to order unnecessary care, since physicians are not paid for ordering additional services; (2) the organization has control over its network of providers, and provides incentives for its network providers to avoid unnecessary care; and (3) incentives to deny necessary care are addressed by physician incentive plan requirements limiting the risk that can be imposed on physicians. These are the same physician incentive plan requirements that are incorporated in a section 1877 provision permitting certain risk arrangements that would otherwise be subject to the referral prohibition. (See section 1877(e)(3)(B) of the Act.)

In contrast, under M+C MSA plans or private fee-for-service plans, individual providers, including physicians, are paid on a fee-for-service basis for services provided, and thus have the same kind of incentives to provide unnecessary services that gave rise to the enactment of section 1877. Although this would not result in more Medicare funds being expended during the year in question, it could harm beneficiaries in two ways. First, it could result in higher cost-sharing paid by beneficiaries in the current year. Second, it could result in the M+C organization offering less in benefits the following year than it would otherwise be able to offer if its expenses were not as high. For these reasons, we do not believe that the exception from the physician referral prohibition that we have created for services furnished under coordinated care plans should apply to services under M+C private fee-for-service plans or MSA plans. We note that the Congress implicitly endorsed our position through the amendments to section 1877 included in section 524 of the BBRA. This section explicitly exempted M+C coordinated care plans from the physician referral prohibitions, but did not include any changes related to other types of plans.

F. Payments to M+C Organizations

1. General Provisions

Part 422 Subpart F sets forth rules that govern payment to M+C organizations, including the methodology used to calculate M+C capitation rates. These rules are based primarily on section 1853 of the Act. (For a complete discussion of these requirements, see the June 26, 1998 interim final rule at 62 FR 35004.)

One of the more significant payment changes in section 1853 of the Act is a gradual transition from rates based on local Medicare costs to “blended” rates based on a 50/50 mix of local and national costs. Under the Adjusted Average Per Capita Cost (AAPCC) payment methodology that applied to section 1876 risk contracts, payment was based on Medicare fee-for-service expenditures in the county in which the enrollee resided. These fee-for-service expenditures were adjusted for demographic factors (that is, age; sex; institutional, welfare, and employment status).

The AAPCC was criticized for its wide range of payment rates among geographic regions: in some cases payment rates varied by over 20 percent between adjacent counties. It was also criticized for its poor risk adjustment capabilities and inappropriate provision of graduate medical education funds to some Medicare risk plans. Moreover, the AAPCC was criticized for setting erratic annual payment updates, which often made it difficult for contracting health plans to engage in long-term business planning. The BBA introduced a new payment methodology that addressed these and other concerns.

“Greatest of” Payment Rate: Since January 1, 1998 (when the M+C payment methodology under section 1853 was made applicable to section 1876 risk contractors pursuant to section 1876(k)(3) of the Act), the Medicare capitation rate for a given county has been the greatest of: (1) The above-referenced blended capitation rate; (2) a “minimum amount” rate established by statute; or (3) a minimum percentage increase. These county rates are then adjusted by demographic factors (and after 2000, by risk adjustment factors) to determine the actual payment amount.

- The blended capitation rate is a blend of the area-specific (local) rate and the national rate, with the latter adjusted for input prices. The blended capitation rate is then adjusted by a budget neutrality factor designed to ensure that payment is not higher than it would be under purely local rates.

- The minimum amount rate was \$367 per month per enrollee in 1998 for all areas in the 50 States and the District of Columbia. Outside the 50 States and the District of Columbia, the rate was limited to 150 percent of the 1997 AAPCC for the area in question, if this amount was lower than \$367. The minimum amount rate is adjusted each year using the update factors described in § 422.254(b).

- The minimum percentage increase is 2 percent. The minimum percentage increase rate for 1998 was 102 percent of the 1997 AAPCC. Thereafter, it is 102 percent of the prior year’s capitation rate.

With the exception of payments under M+C MSA plans, we pay M+C organizations monthly payments for each enrollee in an M+C plan they offer $\frac{1}{12}$ th of the annual M+C capitation rate for the payment area described in § 422.250(c). Except for ESRD enrollees, these payments are adjusted for such demographic risk factors as an individual’s age, disability status, sex, institutional status, and other factors determined to be appropriate to ensure actuarial equivalence. Since January 1, 2000, these rates also have been adjusted for health status as provided in § 422.256(c). For 2000, only 10 percent of the capitation payment will be risk adjusted, with the other 90 percent determined based on the 1999 methodology.

Comment: Several commenters contended that section 1853(c) of the Act set forth artificial and arbitrary limits on capitation rate increases. Because the budget neutrality adjustment applies only to the “blended rate,” and the final rate is based on the greatest of the three rates specified, it was not possible to achieve budget neutrality in 1998 or 1999. Once the blended rate was lowered below at least one of the other two rates in each county, no further savings could be achieved through a budget neutrality adjustment. As a result of the adjustments made in an attempt to achieve budget neutrality, however, capitation rates in 1998 and 1999 were all based either on the minimum percentage increase of 2 percent from the prior year, or the new minimum payment rate. The commenters argued that the effect of this would be that M+C organizations would withdraw from Medicare, either entirely or in low payment areas. These commenters suggested that we propose legislative changes to section 1853 of the Act in order to change the formula used to calculate the county payment rates.

Response: The commenter’s suggestions concerning changes in

legislation are outside the scope of this rulemaking. In this rulemaking, we are charged with implementing the BBA as enacted (and in this final rule, as revised by the BBRA).

However, passage of the BBRA may alleviate some concerns of the commenters. The BBRA requires several modifications to the payment calculations set forth in the BBA, including: lowering the reduction of the national per capita growth percentage defined in § 422.254(b), offering bonus payments to eligible M+C organizations as described in § 422.250(g), and revising our original schedule for transitioning to risk-adjusted payments to providing for an even more gradual introduction of risk adjustment. (See Section I.C for a full discussion of the BBRA provisions.)

Comment: One commenter wanted to know if adjusted excess amounts (determined through the Adjusted Community Rate process identified in § 422.312) affect the computation of the county payment rates if these amounts are placed in a stabilization fund, described in § 422.252.

Response: Amounts deposited in a stabilization fund reduce the payment to the M+C organization for the year in which the funds are deposited (the organization gives up that amount to use it for benefits in a future year), but do not affect the county payment rates.

Comment: Some commenters argued that funding for the ESRD network (§ 422.250(a)(2)(B)) should not be taken from capitation payments to M+C organizations.

Response: Section 422.250(a)(2)(B) implements section 1853(a)(1)(B) of the Act, which specifically requires this reduction in payment rates for enrollees with ESRD. We have, however, changed the wording of our regulations to ensure that the amount taken from the capitation payments remains consistent with the amount required under section 1881(b)(7) of the Act. This does not change our current policy in any way; it merely allows that, if the amount mandated by changes in section 1881 of the Act changes for any reason, our regulations at § 422.250(a)(2)(B) will remain consistent with such a change.

Comment: One commenter requested clarification on the application of the budget neutrality adjustment contained in § 422.250(e)(3).

Response: Section 422.250(e)(1) allows a State’s chief executive to request a geographic adjustment of the State’s payment areas for the following calendar year. The chief executive may elect to change the area in which a uniform rate is paid from a county to one of the three alternative payment

areas identified in § 422.250(e)(1). Specifically, the governor may choose to have—(1) a single Statewide M+C payment area, (2) a single non-metropolitan payment area, with a separate payment area including metropolitan areas defined in one of two ways, or (3) consolidation of non-contiguous counties. Section 422.250(e)(3) requires us to make a budget neutrality adjustment to all payment areas within that state regardless of which payment area designation is selected by the chief executive. The budget neutrality adjustment is designed to limit the aggregate Medicare payment for Medicare enrollees residing in that state to what would have been paid absent any geographic adjustment.

Comment: One commenter proposed a statutory change that would permit a budget neutrality adjustment to be made to the final capitation rate, not just the “blended rate,” as currently provided. Such a change could result in lower payment rates.

Response: The full impact of the BBA and the subsequent revisions included in the BBRA are not yet known; thus, it may be too soon to give Congress recommendations that would have a major effect on our payment to managed care organizations. Therefore, we are not pursuing such a statutory change at this time.

Comment: One commenter suggested that we provide for increased payments to an M+C organization for Part B services provided by contract with federally qualified health centers, and require the increased payment be passed on these centers.

Response: The statute does not authorize us to pay certain M+C organizations differently than others, other than the special rules that apply to determining payments made to an M+C organization offering an M+C MSA plan. Payment for services furnished by a contracting federally qualified health center is limited to the amount negotiated by the two entities.

Comment: One commenter suggested that payment rates should be structured on a regional basis instead of a county by county basis.

Response: Section 1853(d) of the Act defines what is considered an M+C payment area. For Medicare enrollees without ESRD, the payment area is a county. For Medicare enrollees with ESRD, the payment area is a State. The only exception to these rules would be a State that has exercised its right under section 1853(d)(3) of the Act to request an alternative payment area in accordance with § 422.252(e).

Comment: A commenter believes that it is important that M+C organizations have the opportunity to validate our calculations and methodology in calculating payment rates. The commenter accordingly suggested that we cooperate with interested parties by releasing sufficient data to allow those parties to validate our calculations.

Response: We agree. We have complied, and will continue to comply, with all reasonable requests for all relevant and releasable data. M+C organizations must keep in mind that we use a significant amount of confidential data that cannot be released to the public.

2. Risk adjustment and encounter data (§§ 422.256 through 422.258)

Section 1853(a)(3) of the Act required implementation of risk adjustment for payment periods beginning on or after January 1, 2000. In the June 26, 1998 rule, we provided for such risk adjustment in § 422.256(d). We also provided that, in the period prior to the implementation of risk adjustment, we would continue to apply the demographic adjustments used under the old AAPCC methodology.

On September 8, 1998, we published a **Federal Register** notice describing our preliminary risk adjustment methodology and requesting public comments (53 FR 173, pp. 47506 *et seq.*). On January 15, 1999, we published an advance notice, as provided under § 422.258(b) of the regulations, describing the risk adjustment methodology that we implemented for 2000. This advance notice included a detailed description of the new risk adjustment methodology that is in effect in 2000, and information on how risk adjustment will be implemented, including an explanation of the transition method that would be employed. It also responded to comments received in response to the September 8, 1998 **Federal Register** notice. Briefly, the approach we used to meet the year 2000 mandate for risk adjusted payments was:

- (1) Based on inpatient data;
- (2) Applied individual enrollee risk scores in determining fully capitated payments;
- (3) Utilized a prospective PIP–DCG risk adjuster to estimate relative beneficiary risk scores;
- (4) Applied separate demographic-only factors to new Medicare enrollees for whom no diagnostic history is available;
- (5) Applied a rescaling factor to address inconsistencies between demographic factors in the rate book and the new risk adjusters;

(6) Used 6-month-old diagnostic data to assign PIP–DCG categories (the “time shift” model, as opposed to using the most recent data and making retroactive adjustments of payment rates part way through the year);

(7) Allowed for a reconciliation after the payment year to account for late submissions of encounter data;

(8) Phased-in the effects of risk adjustment, beginning with a blend of 90 percent of the demographically-adjusted payment rate, and 10 percent of the risk-adjusted payment rate in the first year (CY 2000); and

(9) Implemented processes to collect encounter data on additional services, and move to a full risk adjustment model as soon as is feasible.

On March 1, 1999, we published the annual Announcement of Calendar Year (CY) 2000 Medicare+Choice Payment Rates, as provided under § 422.266(a) of the regulations. In this announcement, we informed Medicare+Choice organizations of the county rates and factors that were employed for payment in calendar year 2000, including the rescaling factors for use with the risk adjusted portion of payment, and tables of risk and demographic adjustment factors. We also responded to questions and comments on the January 15 notice. (These notices are available on the HCFA Web site, at <http://www.hcfa.gov/stats/hmorates/aapccpg.htm>.)

Section 1853(a)(3)(B) of the Act provided for the collection from M+C organizations, of encounter data needed to implement the risk adjustment methodology. The BBA required the collection of inpatient hospital data for discharges beginning on or after July 1, 1997, and allowed the collection of other data for periods beginning on or after July 1, 1998. We were prohibited from requiring the actual submission of data before January 1, 1998. This data submission requirement appeared in section 1853(a)(3) of the Act, which was titled “Establishment of Risk Adjustment Factors.” (See § 422.256(d).)

Requirements concerning collection of encounter data apply to M+C organizations with respect to all M+C plans, including private fee-for-service plans. Instructions for the collection of hospital encounter data were sent to M+C organizations in December 1997 (OPL 97.064) and May 1998 (OPL 98.71). Hospital discharges for the period July 1, 1997 through June 30, 1998 have been collected and used for estimating the impact of risk adjustment at the contract level and in the aggregate. We announced in the January 15, 1999 notice of methodological changes that comprehensive risk adjustment would be implemented for

payments beginning on January 1, 2004. We will soon be providing M+C organizations with guidance concerning requirements for submission of outpatient, physician, and other non-inpatient encounter data.

There are two different ways encounter data are used for risk-adjustment purposes. To calculate payment rates, encounter data are necessary to tie payment to expected patient resource use using diagnosis codes. (The initial risk-adjusted payment will be based on inpatient hospital encounter data. However, we are developing a more comprehensive risk-adjustment methodology that uses diagnosis data from physician services and hospital outpatient department encounters.) Encounter data are also necessary to "recalibrate" any risk-adjusted payment model. Recalibration adjusts payment models for changes in resource requirements that derive from such factors as technological change and improved coding.

While these are the primary purposes collecting the encounter data, we discussed other possible uses of these data in the June 1998 interim final rule. These other uses include identification of quality improvement targets and monitoring the care received by M+C enrollees through targeted special studies (such as an examination of post-acute care utilization patterns). Encounter data will also be useful for program integrity functions, both by providing additional utilization norms for original Medicare billing and by providing additional information regarding M+C organizations' behavior.

As noted above, the notices of January 15, 1999, and March 1, 1999, contained detailed discussions of the risk adjustment methodology and responses to comments. Similar notices, reflecting BBRA changes, and our methodology and rates for 2001, were published in January and March of 2000. Here we respond formally to comments submitted on the June 26, 1998 rule.

Comment: A number of commenters recommended that we not adopt a risk adjustment system based solely on

hospital encounter data. As a matter of public policy, the commenters objected that basing the initial risk adjustment methodology solely on inpatient data would create inappropriate incentives to hospitalize patients, skew payments toward plans with higher hospitalizations, and penalize plans that have appropriately reduced inpatient services by focusing on outpatient care. Other commenters requested a phase-in of the methodology to minimize the disruption on M+C organizations, and allow time to assess the impact of the new methodology.

Response: We do not believe it would be desirable to delay implementation of risk adjustment until data other than inpatient data are available. We have analyzed the PIP-DCG system sufficiently to be confident that it represents an improvement over the current system of demographic-only adjustment, that it provides an appropriate interim step toward a comprehensive risk adjustment model, and that it provides appropriate levels of payment for different classes of beneficiaries. We believe that the blend transition methodology should relieve concerns about disruption of payments, especially since the initial blend percentage for the risk-adjusted portion is 10 percent.

Even if we believed that delaying risk adjustment were desirable, we do not have the authority to do so. The Balanced Budget Act specifically required "implementation of a risk adjustment methodology * * * no later than January 1, 2000." In order to meet that deadline, we were constrained to employ a model based on hospital encounter data alone in the interim until the data to implement a comprehensive risk adjustment methodology can be provided by all plans and processed by us. The Medicare+Choice legislation (section 1853(a)(3)(B) of the Act) provided for the collection of non-inpatient data for periods beginning on or after July 1, 1998, a full year later than the date for which inpatient data would be collected. This provision envisioned

that a hospital-only system would be implemented initially, both because it seemed more feasible for M+C organizations to produce inpatient data only in the short term, and because the effect of a hospital-only system on payments would be smaller than a system based on comprehensive encounter data. (The Medicare+Choice regulations further provided that we would collect physician, outpatient hospital, SNF, or HHA data no earlier than October 1, 1999. See § 422.257(b)(2)(i).) However, the statute grants us broad authority to develop a risk adjustment methodology, and does not prohibit us from including a transition or "phase-in" period as a component of the methodology we develop.

We therefore included a transition period as a component of our risk adjustment methodology, initially using a blend of payment amounts under the current demographic system and the PIP-DCG risk adjustment methodology. Under a blend, payment amounts for each enrollee would be separately determined using the demographic and risk methodologies (that is, taking the separate demographic and risk rate books and applying the demographic and risk adjustments, respectively). Those payment amounts would then be blended according to the percentages for the transition year.

In order to provide adequate safeguards against abrupt changes in payment, our transition mechanism initially provided for a low blend percentage of the risk-adjusted payment rate. Specifically, first year blend percentages will be 90 percent of the demographically adjusted rates, and 10 percent of the risk-adjusted payment rate. We are also contemplating a five-year transition, which would culminate in full implementation of comprehensive risk adjustment, using all encounter data, in the fifth year. Our initial transition schedule, announced in the January 5, 1999, Advance Notice of Methodological Changes for the CY 2000 Medicare+Choice Payment Rates was:

	Demographic method	Risk method
CY 2000	90 percent	10 percent.
CY 2001	70 percent	30 percent.
CY 2002	45 percent	55 percent.
CY 2003	20 percent	80 percent.
CY 2004	100 percent comprehensive risk adjustment (using encounter data from multiple sites of care).	

Subsequently, passage of Section 511(a) of the BBRA has revised the original transition schedule, providing for an even more gradual introduction of risk adjustment. Specifically, the legislation provides that the blend percentages will be:

	Demographic method	Risk method
CY 2000	90 percent	10 percent.
CY 2001	90 percent	10 percent.
CY 2002	at least 80 percent	no more than 20 percent.

In order to implement comprehensive risk adjustment in CY 2004, we will soon be providing M+C organizations with guidance concerning requirements for submission of outpatient, physician, and other non-inpatient encounter data.

Comment: Some commenters emphasized that implementation of risk adjustment could inject uncertainty and reduce the predictability of payments to M+C plans.

Response: Our most recent estimate, based on the 285 organizations that were active in September, 1998, and that did not terminate their contracts with Medicare in 1999, (including 10 organizations that merged into other active M+C organizations as of January 1, 1999), was that aggregate payments would decrease 0.6 percent, taking into account the blend percentages in effect for 2000, (90 percent demographic adjusted amount, 10 percent risk adjusted amount). While the impact on specific organizations will vary, our analysis suggests that, except for highly unusual circumstances (for example, a high proportion of working aged enrollees), the maximum decrease in payment to any organization from risk adjustment alone will be less than 2 percent. The analysis did not suggest that smaller organizations, or any other specific category, would experience a disproportionate impact. We will, however, continue to monitor the impacts on organizations throughout the transition period. We believe that our transition mechanism should alleviate concerns about large and abrupt changes in payment.

Comment: One commenter expressed concern about the effect on people with Alzheimer's disease of a risk adjustment methodology based solely on hospital encounter data. Because Alzheimer's and dementia are often not included in the recorded diagnoses of hospitalized beneficiaries, hospital data alone cannot support accurate conclusions about the cost of hospital care for these beneficiaries. Several other commenters expressed similar concerns about the implications of the initial risk adjustment methodology for beneficiaries with other chronic conditions.

Response: Our validation tests on the PIP-DCG model actually show that this model offers a substantial improvement over the system of demographic-only

adjustments that has been previously in use. One measure of a model's accuracy is its ability to predict mean expenditures for groups correctly. Health Economics Research (HER), which served as a contractor to HCFA in developing the PIP-DCG model, measured the predictive ratios, (that is, the ratio of mean predicted expenditures to mean actual expenditures), for groups of Medicare beneficiaries that are of policy or technical interest. Among the groups used in this validation analysis were chronic condition groups, defined by ambulatory as well as inpatient diagnoses. HER found that, while the PIP-DCG model underpredicted for many chronic disease groups, this model performed better than the demographic model. For example, the predictive performance for persons with dementia (which includes individuals diagnosed with Alzheimer's) increased from 0.91 under the demographic system to 1.07 under the PIP-DCG model. Further detail on the validation analyses can be found in our "Report to Congress: Proposed Method of Incorporating Health Status Risk Adjusters into Medicare+Choice Payments," and in the HER report "Principal Inpatient Diagnostic Cost Models for Medicare Risk Adjustment," which is appended to it. The reports can be found on our Web site (<http://www.hcfa.gov/ord/rpt2cong.pdf>).

Comment: One commenter objected that the risk adjustment system does not account for secondary diagnoses. A patient with two acute diagnoses could be more ill and more costly than a patient with the same primary diagnosis, but a less severe secondary diagnosis. Another commenter supported the development of an initial risk adjustment methodology based on inpatient data alone, since inpatient costs represent the largest expense item of health plans. But this commenter recommended that such a methodology should account for both primary and secondary diagnoses, since secondary diagnoses are necessary to account for the higher costs of beneficiaries with multiple health problems and chronic conditions that are more expensive to treat.

Response: The analysis conducted in the early stages of developing an inpatient-based risk adjustment model

included consideration of incorporating secondary diagnoses. The analysis concluded that secondary diagnoses did not contribute significantly to predictive accuracy in the context of an inpatient model. As noted above, the inpatient hospital model represents a significant improvement in predictive accuracy over the demographic adjustments that have been in use. However, it is only an interim step toward a comprehensive risk adjustment system. We anticipate that the comprehensive risk adjustment model under development will base risk scores on multiple diagnoses from disparate sites of care.

Comment: One commenter recommended that we develop the capability to use diagnosis data from all sites of care as quickly as possible in the risk adjustment system. Other commenters expressed concern about the costs and burdens of collecting the physician, outpatient hospital, skilled nursing facility, and home health agency encounter data that will be necessary for the implementation of comprehensive encounter data in 2004. Several commenters objected that the time frame contemplated for the submission of these data is too short to allow M+C organizations to procure and install the required systems. One commenter urged that, in preparing for submission of encounter data from physician offices, mechanisms should be established for the transition from paper claims to electronic bills for those practices that "have not entered the electronic age."

Response: The PIP-DCG model represents a substantial improvement over the current system. Because it identifies a subset of seriously ill beneficiaries for increased payment and because the effect of a hospital-only system on payments is smaller than a system based on comprehensive encounter data, the PIP-DCG model is an appropriate interim step toward comprehensive risk adjustment. A comprehensive model is nevertheless preferable, and we plan to move toward implementing such a model as expeditiously as possible. However, implementation of the comprehensive risk adjustment model is not operationally feasible for 3 to 4 years, because of data constraints on both plans and on us. The transition plan announced in the January 15, 1999

notice therefore provides for implementation of comprehensive risk adjustment in 2004, without ever reaching full payment under the PIP-DCG system. In the interim, the PIP-DCG model offers a substantial improvement over the current system.

In providing for payment under a comprehensive risk adjustment system in 2004, we have taken into account the costs and burdens necessary for organizations to develop the capacity for collecting and submitting physician, outpatient hospital, skilled nursing facility, and home health agency encounter data. This is the most ambitious schedule that we believe we can adopt consistent with allowing sufficient time for organizations and the agency to prepare.

Comment: A number of commenters objected that the collection of encounter data is burdensome and expensive. Some commenters asserted that this requirement may deter new managed care contractors, especially smaller organizations, from participating in the M+C program. Several commenters observed that not all the data required for submission of encounter data are necessary for computing risk adjustment. Another commenter urged us to monitor the trade-off between risk adjustment accuracy and risk adjustment data-collection requirements, and seek opportunities to streamline the burdens of encounter data collection. One commenter recommended that we explore alternatives to collection of all encounter data, such as survey-based approaches.

Response: We have made every effort to minimize the burden of collecting encounter data, and to assist M+C organizations with problems that have arisen in collecting and processing these data. In the initial stages of collecting encounter data, we are permitting organizations to use an abbreviated version of the standard UB-92 form employed in hospital billing. Data elements in the abbreviated UB-92 form have been restricted to those items necessary to calculating risk scores and pricing the discharge, as well as some document identification items that are normally generated automatically in electronic processing. (As we discuss below, pricing of discharges is necessary to allow recalibration of the model.) Use of the abbreviated UB-92 form will be allowed for discharges at least through June 30, 2001.

The legislation mandating risk adjustment also provides for the collection of inpatient and other encounter data. The legislation therefore contemplates a risk adjustment system

based on encounter data rather than surveys. We believe that the greater accuracy of a system based on full submission of encounter data justifies the additional burdens that this requirement entails.

A range of problems in the submission of encounter data have arisen. These problems have included: not following the required UB-92 format, difficulties in accurately tracking counts of discharges, failure to arrange hospital submission of encounter data, difficulties in understanding Fiscal Intermediary reports, and HCFA/FI and FSS processing problems. Plans themselves may have problematic data processing systems in-house. We have worked with Medicare+Choice organizations, managed care associations, and other parties to address many specific issues that have arisen concerning data transmission and processing, and we will continue to do so. We have taken a number of specific steps to facilitate and improve the encounter data submission process. These activities have included the following:

- **Encounter Data Reconciliation Analyses**—We have shared with M+C organizations analyses of their individual M+C plan level data. The data have been successfully posted at our offices. We have further conducted analyses upon request at the provider level and by the different methods of submission to help explain discrepancies. We are in the process of sharing these analyses with the plans. The detailed provider level analyses are requiring additional time to conduct, and the results of these analyses will be shared with plans over the coming weeks.

- **Onsite Consultations**—Our contractor conducted a series of onsite consultation visits to 20 M+C organizations in order to learn more about the process of data submission. The majority of the 20 organizations selected for the visits were those that experienced problems with encounter data submission. The information gained during these visits will be used to assist plans to identify and resolve problems.

- **HCFA Data System Fixes**—Processing problems have been identified that relate to beneficiaries who change from one M+C plan to another. The estimated number of affected encounters from all plans is less than 3,000. These problems will be fixed over the next 2 months, and they are not expected to impact the March 1 rate estimates, which, in any case, will not be used to make direct enrollee payments.

- **Communication with the FIs**—We have shared data problems raised by M+C organizations with the FIs. Furthermore, discussions between us, FI's, and plans have been encouraged in order to address problems.

Comment: Several commenters objected that we should not place the burden of collecting encounter data and assuring their accuracy solely on M+C organizations, but rather on the providers submitting the data to the organizations. Some of these commenters suggested imposition of a requirement on providers that they cooperate with M+C organizations in collecting encounter data.

Response: We did not include requirements on providers in the interim final rule because we traditionally have tried to minimize the adoption of measures that would insert our requirements into the contractual relationships between managed care organizations and providers. We therefore suggested to M+C organizations that they modify their contracts with hospitals to ensure that managed care discharges are identified, and the appropriate records are provided to the organization by the hospital. We also have taken every opportunity to inform hospitals and hospital associations of the encounter data requirements and the importance of collecting complete and accurate encounter data to assure correct payment. Collection of encounter data for the "start up" year of July 1997 through June 1998, which was the basis for estimating the impacts of risk adjustment, was quite successful, and we have every reason to believe that collection of data for the next year, which will be used to determine actual risk adjustments in 2000, will go at least as well.

However, M+C organizations have informed us that some providers are either failing to submit encounter data at all, or submitting data that do not conform to quality standards for submission to our systems (for example, that the coding often fails to meet standards required to pass the coding edits). To the extent usable data are not submitted, M+C organizations are denied the benefit of any risk adjustment that might be justified based on the costs in question. We are therefore proposing to make several changes to the rules that are designed to give M+C organizations greater leverage in obtaining adequate cooperation from providers to submit complete and accurate data.

First, we will make explicit in § 422.257 that M+C organizations are required to obtain from providers,

suppliers, physicians, or other practitioners information sufficient to submit the required encounter data. (Currently the regulation states that M+C organizations must submit encounter data, but leaves the requirement of obtaining the necessary information from providers and others to inference.)

Second, we will specifically state in the rules that M+C organizations may include a requirement for submission of complete and accurate encounter data, conforming to the format used under original Medicare, in their contracts with providers, suppliers, physicians, and other practitioners. Contracts with providers and others may impose financial penalties, including withholding payment, for failure to submit complete and accurate data conforming to all requirements for submission. We have revised § 422.257 of the regulations to reflect these two changes.

Third, as discussed below in section K, we have modified the definition of “clean claim” in § 422.500 to specify that a claim must include information necessary for purposes of encounter data requirements, and must conform to the requirements for a clean claim under original Medicare. This will exempt claims that do not, for example, meet accurate coding requirements from the application of the “prompt payment” standard that applies to claims submitted by non-contracting providers. This standard requires that “clean claims” submitted by non-contracting providers be paid within 30 days, or interest will be owed. M+C organizations will therefore be able to withhold payment in cases in which non-contracting providers submit claims with inadequate coding or other deficiencies that make the claims impossible to use for encounter data purposes.

Fourth, we are providing a reconciliation process which will give M+C organizations additional time to submit encounter data before final payment determinations are made. M+C organizations have approximately 3 months after the end of a data collection year to submit the encounter data that will be used to develop beneficiary risk scores to their fiscal intermediary. For example, M+C organizations must submit encounter data for the period July 1, 1998 through June 30, 1999 to their fiscal intermediary by September 17, 1999. If organizations submit encounters after this date, they will not be incorporated into payments for CY 2000. However, in response to concerns expressed by M+C organizations over this short time frame, we expect to

institute a reconciliation process that will take into account late data submissions. M+C organizations should attempt to have all data in by the annual deadline of September 10. However, if organizations receive UB-92s from hospitals after this date, they may submit the encounter to their fiscal intermediary and the data will be processed. M+C organizations should note that the deadline for submission of all data from a payment year will be June 30 of the payment year for the period ending the previous June 30 (for example, the final deadline for the period of July 1, 1998 to June 30, 1999, which is used for payment in 2000, will be June 30, 2000). After that date, the fiscal intermediary will no longer accept these data. After the payment year is completed, we will recalculate risk factors for individuals who have late encounters submitted. Then, we will determine any payment adjustments that are required. This reconciliation will be undertaken after the close of a payment year and will be a one-time only reconciliation for each payment year. We are adding § 422.256(g) to provide for this reconciliation process.

Comment: Some commenters expressed doubts about the completeness and accuracy of the encounter data submitted during the “start up year,” which was used to develop estimates of the impact of risk adjustment. Some expressed concern that systems problems have impeded the posting of complete and accurate data. Several commenters expressed doubts that sufficiently complete and accurate encounter data could be available in time to begin risk-adjusted payment on January 1, 2000.

Response: Hospital encounter data were collected from managed care organizations for discharges between July 1, 1997 and June 30, 1998. Approximately 1.5 million encounters were submitted to us for over 5.7 million beneficiaries. The volume of data received is sufficient to generate an estimate of the impact of risk adjustment, and to conduct other analysis in order to prepare for implementation of risk adjustment. Based on this experience, we are confident that sufficient data will be generated to calculate beneficiary risk scores and other information necessary for implementation of the PIP-DCG model.

Comment: One commenter requested clarification of the statement in the preamble that encounter data may be used for purposes other than calculating risk adjustments.

Response: We commonly use data collected in the course of calculating

payments for other purposes. These purposes include monitoring program integrity, studying utilization patterns and quality of care, and a variety of research purposes. Our use of data is always governed by consideration of privacy concerns and confidentiality of business operations.

Comment: Several commenters asked for further information concerning how we intend to recalibrate risk-adjusted payments to account for upcoding. Another commenter questioned whether use of the full UB-92 is necessary for this recalibration, and suggested that we consider other approaches.

Response: As we discussed above, recalibration is necessary to adjust the payment models for changes in resource requirements that derive from such factors as technological change and improved coding. Upcoding may occur if plans improve coding of beneficiary diagnoses and, as a result, the average use of resources for enrollees in a particular category may be less than when the relative payment rates were determined. When this happens, the average actual expenditures per enrollee for these diagnoses may be less than the average expenditures used to assign the original payment weights. The result is overpayment for some diagnoses in the risk adjustment model. On the other hand, technological changes, which often result in more intensive use of resources for certain diagnoses, can lead to underpayment for certain diagnoses unless the model is recalibrated. Recalibration is a standard feature of well-established payment systems, such as the hospital prospective payment system. We have not yet developed a specific timetable for recalibrating the PIP-DCG model. We will not recalibrate the model until we have sufficient data from Medicare+Choice organizations to incorporate managed care practice patterns into the recalibration.

Comment: Several commenters expressed concern about the attestations required of M+C organizations, with respect to the accuracy and completeness of encounter data. One of these commenters expressed the view that the requirement for an attestation that submitted encounter data are “accurate, complete, and truthful” is designed more as a legal trap for those that might innocently submit incomplete or inaccurate data, than as good public policy. Another commenter recommended that the attestation allow for honest mistakes and unavoidable margins of error.

Response: Attestation of encounter data has been a contentious issue. Attestation of encounter data is essential for guaranteeing the accuracy and

completeness of data submitted for payment purposes, and to allow us to pursue penalties under the False Claim Act, where it can be proven that a plan knowingly submitted false data. However, in response to concerns from M+C organizations, we have restricted the attestation requirement to confirmation of the completeness of the data and the accuracy of coding. Since this is information that M+C organizations are, or should be, in the position to know, the attestation requirement is thus in no way a legal trap.

Comment: One commenter recommended that we develop mechanisms, with the assistance of consumer representatives, to make encounter data available to Medicare beneficiaries and their representatives.

Response: The commenter did not identify the “beneficiary representatives” to whom encounter data would be made available, nor the purposes for which the data would be used. We would consider specific requests for data in the light of privacy and other considerations which normally govern the use of data gathered for official purposes in the program.

Comment: Several commenters expressed concern about the short time frame for submission of Adjusted Community Rate proposals after the release of county rates, rescaling factors, and risk adjustment impact estimates on March 1. The commenter urged disclosure of key information such as the rescaling factors earlier in order to give plans the opportunity to base their rate and benefit submissions on more complete financial information.

Response: Section 516 of the BBRA extended the ACR deadline to July 1, and applied that extension retroactively to 1999. Therefore, we have changed our regulations at § 422.306(a)(1) to reflect this statutory change, which has addressed the commenter’s concerns.

3. Special Rules for Hospice Care (§ 422.266)

Comment: One commenter requested clarification on reporting institutionalized members who have elected hospice care, and how the M+C organizations will determine whether a new member is in hospice care.

Response: Medicare enrollees who have elected hospice care should not be reported as institutionalized. Medicare beneficiaries that have elected hospice, and subsequently elect an M+C plan will be identified by our system.

Comment: One commenter requested clarification of the M+C organization’s responsibility in arranging for the

provision of hospice care for those enrollees who have elected hospice care.

Response: Section 422.266 requires the M+C organization to inform each Medicare enrollee eligible to elect hospice care about the availability of hospice care in the area or outside the area, if it is common practice to refer patients accordingly. An M+C organization is not required to arrange for hospice services when the hospice election has been made.

Comment: One commenter requested further clarification on our payment for a Medicare enrollee when the enrollee elects hospice.

Response: Our monthly capitation is reduced to the adjusted excess amount developed in the ACR. The amount of the reduction is the ACR value (less the actuarial value of Medicare’s deductibles and co-insurance) for Medicare-covered items and services. For Medicare-covered items and services, the M+C organization or provider furnishing the service would bill us using Medicare’s normal billing rules under original Medicare. Also, hospice services are billed under original Medicare rules.

G. Premiums and Cost-Sharing

1. General Provisions

Part 422, subpart G is based on the provisions found in section 1854 of the Act. These provisions were discussed in detail in the June 26, 1998 interim final rule (63 FR 35007). This subpart addresses how limits on M+C plan enrollee premiums and other cost-sharing are established through the Adjusted Community Rate (ACR) approval process. The ACR process is applicable to all M+C plans except M+C MSA plans. M+C organizations offering an M+C MSA plan are not required to submit an ACR for that plan, but they are required to submit other information for our review using the ACR process.

Section 422.300(b) provides that for contract periods beginning before January 1, 2002, M+C organizations may modify an M+C plan by adding benefits at no additional cost to the M+C plan enrollee; lowering the premiums approved through the ACR process; or lowering other cost-sharing amounts. Also prior to January 1, 2002, under § 422.504(d), contracts may be for a longer period than 12 months, and may begin on a date other than January 1. In the case of such contracts, under § 422.300(b)(2), ACRs must be submitted on the date specified by us. The transition rules for this period are found in § 422.300(b).

Comment: One commenter suggested a revision of the ACR form used to establish the pricing structure for an M+C plan. The commenter suggested that the new form produce more accurate information. The commenter urged that we monitor data submitted in the ACR form to determine whether established policies should be revisited.

Response: We agree. We are developing various systems to capture ACR data for policy analysis. We intend to use the data to determine the effect of established policies so that we can examine policies that need revision.

Comment: One commenter suggested that we consider alternatives to the ACR for private fee-for-service and MSA plans.

Response: Under the June 1998 interim final rule, we do not review or approve premium amounts submitted for private fee-for-service plans or MSA plans. In addition, in the case of an MSA plan, an M+C organization does not complete those parts of the ACR form that request cost information. Thus, in essence, there is an “alternative” arrangement in place for these types of plans.

Comment: One commenter suggested that we, in consultation with industry representatives, develop acceptable standards for cost accounting to be used by M+C organizations to complete its ACR form.

Response: We agree that M+C organizations should be using uniform cost accounting standards to complete the ACR form. Therefore, we specified in § 422.310(a)(5) that generally accepted accounting principles (GAAP) should be used instead of other accounting principles (for example, statutory). We have not ruled out the establishment of a standardized accounting system at this time. However, we feel that the existing accounting systems based on GAAP developed by M+C organizations should produce sufficiently accurate information for ACR purposes. We will monitor the accuracy of the ACR data produced by the M+C organizations’ accounting systems through audit and other monitoring procedures.

Comment: One commenter suggested that we should either allow M+C organizations to modify their M+C plan after the M+C plan has been approved, or make the transition period rules described in § 422.300(b) permanent. The commenter felt this would benefit the Medicare beneficiary.

Response: After 2002, Medicare beneficiaries will be “locked in” to their M+C plan choice for the last 9 months of the year (6 months in the case of 2002 only). The beneficiary will be locked in

for the entire year if he or she wants to remain in the M+C program, and no other M+C plan in the area is open during January, February, and March. The choice of an M+C plan during the annual November open enrollment period thus will be extremely significant, since, in most cases, it will determine enrollment for the entire following calendar year. We believe that under this program design, it is important that beneficiaries have complete information in November about what the benefits will be in each M+C plan in their area for the full following calendar year. If M+C organizations were permitted to change plan benefits mid-year, this could result in a beneficiary deciding that an M+C plan that is changing benefits would have been a better choice had he or she known in November that this change would be made, but it would be too late for the beneficiary to enroll in that plan after April 1.

We accordingly believe that beginning in 2002, (when beneficiaries will be locked in for the last 6 months of the year), benefits for a given calendar year should be established in advance of the November open season. This will allow beneficiaries to make informed decisions about which M+C plan they will choose for the following calendar year. In order for this to happen, the benefits that will apply throughout the following calendar year must be included in the ACR submission filed with us, so that these benefits can be approved by us in time to provide reliable information to beneficiaries.

Our decision to require uniform benefits throughout the calendar year after a transition period is further supported by the nature of the ACR process under M+C. As under the section 1876 risk program, the ACR process under the M+C program serves three important purposes. First, we are required to examine an M+C organization's ACR proposal for each M+C plan to determine if Medicare beneficiaries are entitled to receive additional benefits as a result of Medicare payments that are higher than the organization's charge (adjusted for differences in utilization characteristics of the Medicare population) to a non-Medicare enrollee for a Medicare-covered benefit. Second, we are required to review ACR proposals to determine whether the pricing structure (premiums and cost-sharing charged to beneficiaries) is within the limits established by law as required under section 1854(b)(1) of the Act, and is applied uniformly to all Medicare enrollees as required under section 1854(c) of the Act. Third, we review

benefit package information to determine if the benefit package is in compliance with the requirements contained in subpart C. Once this process is complete, M+C organizations are allowed to market the M+C plan as approved.

Under the M+C program, we focus on an entire calendar year in performing the above tasks. Our approval of the pricing structure of an M+C plan is based on the appropriate actuarial value of furnishing the items and services for the entire calendar year. Limits on the amount of premiums (section 1854(b) of the Act), and on the liability of the Medicare beneficiary (section 1854(e) of the Act), are based on a 12 month period. In addition, the capitation payments that will be made to the M+C organization under section 1853(a) of the Act for the M+C plan is an integral part of establishing the value of additional benefits that must be offered under section 1854(f) of the Act. Capitation payments are based on the annual M+C capitation rate for the county (that is, the amount for the full calendar year), adjusted for various demographic and other risk factors. Section 1853(c)(1) of the Act clearly states that capitation rates are based on a contract year consisting of a calendar year. We believe that this entire scheme assumes that benefits will be the same over the 12 month period at issue. This is another reason why we believe our decision to eliminate mid-year changes after a transition period is appropriate.

2. Rules Governing Premiums and Cost-Sharing (§ 422.304)

This section implements provisions of the BBA relating to premiums paid by or on behalf of beneficiaries. The beneficiary in an M+C plan, other than an M+C MSA plan offered by an M+C organization, pays the monthly basic premium plus the monthly supplemental premium, if any. In the case of an M+C MSA plan, the beneficiary must pay the monthly supplemental premium, if any. The M+C monthly basic beneficiary premium, the M+C monthly supplemental premium, and the monthly MSA premium may not vary among individuals in the M+C plan, unless the M+C organization offering the plan has elected to apply this rule to individual segments of a plan service area, as provided in section 515 of the BBRA (See section I.C of this preamble). Also, the M+C organization cannot vary the level of cost-sharing (copayments, coinsurance, or deductibles) charged for the basic benefits or supplemental benefits, if any, among the individuals enrolled in the M+C plan, again unless

the M+C organization has elected to apply this rule to segments of the plan service area, as provided in section 515 of the BBRA.

As discussed in section I.C above, under section 515, the premium and cost-sharing uniformity requirements may be applied only within segments of an M+C plan's service area, with premiums or cost-sharing varying between such segments, provided: (1) a separate, and complete ACR is filed for each such segment; and (2) each segment is composed of one or more M+C payment areas. We have revised § 422.304(b) to add a new paragraph (b)(2) that provides for this option.

Comment: A commenter noted that some M+C organizations offer enrollees economic incentives to use mail-order pharmacies by imposing a copayment on all prescriptions dispensed in the community pharmacies, but do not charge a copayment if the same prescription is mailed to the enrollee. The commenter wanted to know whether this practice is prohibited under the uniform cost-sharing rule in § 422.304(b).

Response: The practice the commenter has described is not prohibited, since all enrollees under the plan would pay the same cost-sharing for drugs not ordered by mail, and the same cost-sharing for drugs ordered by mail. However, an M+C organization would not be permitted to impose a structure of cost-sharing that would have the effect of denying access, as described in section 1852(d) of the Act, to an item or service advertised by the organization as being available to the enrollee.

3. Submission Requirements for Proposed Premiums and Related Information (§ 422.306)

This section reflects the original BBA version of section 1854(a)(1) of the Act, which prior to the BBRA provided that each M+C organization, and any organization intending to contract as an M+C organization in the subsequent year, submit specified data for every plan it intends to offer no later than May 1 of each year.

Comment: Many commenters recommended that the May 1 deadline for the submission of the ACR proposal be changed.

Response: As discussed in section I.C above, section 516 of the BBRA extended the ACR deadline permanently to July 1, and applied that extension retroactively to 1999. Therefore, we have changed our regulations at § 422.306(a)(1) to reflect this statutory change.

4. Limits on Premiums and Cost-Sharing Amounts (§ 422.308)

Section 422.308(a) imposes a limit on the amount that an M+C organization can charge as a basic beneficiary premium for a coordinated care plan, or impose as cost-sharing under such a plan. Specifically, the basic premium (multiplied by 12), the actuarial value of any cost-sharing, or a combination of these two forms of beneficiary liability, may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable on average to beneficiaries entitled to Medicare Part A and enrolled in Part B if they were not enrollees of an M+C organization. For those M+C enrollees who are enrolled in Medicare Part B only, the monthly basic premium (multiplied by 12), plus the actuarial value of cost-sharing, may not exceed the annual actuarial value of the deductibles and coinsurance that would be applicable to beneficiaries enrolled in Medicare Part B if they were not enrollees of an M+C organization. With respect to supplemental benefits under coordinated care plans, the monthly supplemental beneficiary premium (multiplied by 12) charged, plus the actuarial value of its cost-sharing, cannot exceed the ACR for such services.

In the case of a private fee-for-service plan, there is no limit on premium charges. However, under § 422.308(b), the actuarial value of any cost-sharing imposed under the plan may not exceed the actuarial value that would apply to beneficiaries entitled to Medicare Part A and enrolled in Part B if they were not enrolled in an M+C plan as determined in the ACR. In the case of supplemental benefits, the actuarial value of cost-sharing may not exceed the ACR amounts for the benefits. Additionally, if inadequate data is available to determine actuarial value, we can make the determination with respect to all M+C eligible individuals in the same geographic area or State or in the United States on the basis of other appropriate data.

Comment: One commenter suggested that the limits on premiums in § 422.308 should not apply in the case of dual eligibles, to the extent that the Medicaid program is paying the premiums.

Response: We do not agree. Section 422.308 limits the amount that can be charged to Medicare enrollees, or anyone on their behalf, for the M+C plan. However, we recognize that the Medicaid program may pay additional amounts for Medicaid-covered benefits not included in the M+C plan. Therefore, we have clarified our

jurisdiction over Medicaid benefits for dual eligibles in § 422.106. (See the discussion in section II.C of this preamble.)

Comment: One commenter requested clarification of the limit on charges to a Part B-only member for Part A services.

Response: If an M+C organization chooses to include in the B-only M+C plan an equivalent Part A benefit, it may do so as an additional, mandatory supplemental, or as an optional supplemental benefit. There is a limit on what is allowed to be charged for this benefit: the lesser of the ACR for the benefit, our payment amount, (or, in the case of a working individual (or spouse) for whom Medicare is secondary, the amount Medicare would pay if Medicare was not secondary), increased by the actuarial value of Medicare's Part A deductible and coinsurance, or the amount we charge for coverage of Part A services to those individuals that are not otherwise eligible for those services.

Comment: One commenter requested clarification of § 422.308, Limits on premiums and cost-sharing amounts, that the commenter believes to be a new provision. Another commenter asked about a limit on amounts actually collected in cost-sharing.

Response: The limit on premium and cost-sharing charges in section 1854(e) is not new, and in the case of coordinated care plans, is the same as the limit that applied in the case of section 1876 risk contracts. As discussed above, in the case of a coordinated care plan, section 1854 of the Act specifically limits the amount, regardless of source, a Medicare beneficiary may be charged for the M+C plan elected. This would include premiums and cost-sharing collected by the M+C organization or any provider (either contracting or non-contracting with the M+C organization) furnishing services covered by the plan. This limit is applied to the actuarial value of the cost-sharing provided for under the M+C plan. Specifically, in the case of a coordinated care plan, the premium and the actuarial value of cost-sharing cannot exceed the actuarial value of original Medicare cost-sharing. Thus, as noted above, in approving the ACR, we will not approve of beneficiary cost-sharing for Medicare covered services if the actuarial value of the cost-sharing exceeds the actuarial value of the deductible and coinsurance imposed under original Medicare.

Once we have approved cost-sharing amounts specified in an ACR, however, an M+C organization is permitted to collect those amounts, even if the actual amount collected turns out to exceed the amount projected in the original

estimate of the cost-sharing's actuarial value. While some of our guidance has indicated that a "cap" would be imposed on the aggregate cost-sharing amount actually collected, we have determined, in examining the language in section 1854(e)(1) of the Act in response to this comment, that the limit on cost-sharing was intended to limit the amount of cost-sharing that can be provided for under an M+C plan, not on the amount that is actually collected. The statute provides that the "actuarial value" of M+C plan cost-sharing (and any premium charged) cannot exceed the "actuarial value" of cost-sharing under original Medicare. Since we do not keep track of cost-sharing actually collected under original Medicare, but instead rely only on the "actuarial value" projected up front, we believe that the same approach should apply to the M+C plan side of the equation.

We note that, as discussed above, in the case of private fee-for-service plans, the limit on beneficiary liability applies only to cost-sharing. The actuarial value of cost-sharing for Medicare services may not exceed the actuarial value of the deductible and coinsurance imposed under original Medicare.

Comment: One commenter suggested that we set a limit on the amount that may be charged to low-income beneficiaries and beneficiaries with disabilities.

Response: Section 1854(c) of the Act requires that premium charges be uniform for all enrollees in an M+C plan (or in a segment of a plan service area as provided for in section 515 of the BBRA). As a result, a separate limit for low income beneficiaries would not be permissible. The statute also specifies the overall limits on beneficiary liability, and we do not have the discretion to change them. We note, however, that M+C organizations may not design or market M+C plans in a manner that discriminates against low-income or disabled beneficiaries.

Comment: One commenter suggested that we should prohibit the imposition of a deductible for Federally qualified health center (FQHC) services.

Response: The actuarial value of the cost-sharing imposed by an M+C organization for Medicare-covered items and services cannot exceed the actuarial value of Medicare's deductible and coinsurance under original Medicare. We establish this amount using data on all Medicare beneficiaries that did not elect a managed care organization, regardless of where the beneficiary received the item or service. Therefore, data on items and services that do not have a deductible or coinsurance were taken into account, and M+C enrollees

already have received the benefit of the fact that there is no deductible for FQHC services.

5. Incorrect Collections of Premiums and Cost-Sharing Amounts (§ 422.309)

Section 422.309 requires an M+C organization to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf. We further stated that amounts incorrectly collected include: (1) Exceeding the limits imposed by § 422.308 (that is, exceeding the amounts approved in the ACR as falling within these limits); (2) in the case of an M+C private fee-for-service plan, exceeding the M+C monthly basic premium or monthly supplemental premium; (3) in the case of an M+C MSA plan, exceeding the M+C monthly supplemental premium, or the deductible for basic benefits; and (4) amounts collected from an enrollee who was believed ineligible for Medicare benefits but was later found to be entitled. In addition, "other amounts due" include amounts due for services that were considered an emergency, urgently needed, or other services obtained outside the M+C plan; or initially denied, but upon appeal, found to be services that the enrollee was entitled to have furnished by the M+C organization.

Comment: A commenter believes that an M+C organization should be permitted to collect additional amounts if, as a result of utilization patterns, it collects less than the amount actuarially projected in its ACR. The commenter notes that if an M+C organization collects more than the amounts permitted in the M+C plan approved in the ACR process, it has to refund amounts to enrollees, and believed that this same principle should permit the organization to collect additional amounts if it collects less than the amount projected.

Response: We do not agree. There is no indication in section 1854 of the Act that the Congress intended to allow an M+C organization to collect additional amounts from Medicare enrollees when the amount it collects ends up being less than the amount projected in its ACR. An M+C organization, when it submits its ACR, should be providing its best estimate of its charges and collections within the confines of the statute. If we accept this estimate, the M+C organization should be held to the amounts estimated. As noted above, we agree that HCFA also should be held to an estimate we have approved in the ACR process, and will not attempt to

limit the aggregate amount an M+C organization can actually collect as long as it collects only approved cost-sharing amounts from any given enrollee. We believe there is a distinction between the process of projecting enrollee liability for the purpose of establishing a premium and cost-sharing structure and the question of whether charges are made in excess of this established structure. Once the premium and cost-sharing structure is established, a charge in excess of the amounts provided for under this structure is impermissible, and grounds for sanction. A refund is appropriate. If the organization inadvertently charged less than the cost-sharing amounts approved in the ACR, it could collect the balance of the approved charge from the beneficiary. To the extent the commenter was referring to our earlier guidance discussing a limit on the aggregate amount that an organization can collect in premiums, as noted above, we have decided not to impose such a limit. This premise of the commenter's point accordingly is no longer valid.

6. ACR Approval Process (§ 422.310)

The June 1998 interim final rule requires that, except M+C MSA plans, each M+C organization must compute a separate ACR for each coordinated care or private fee-for-service plan offered to Medicare beneficiaries. If an M+C organization opts to apply uniformity requirements to segments of an M+C plan service area, a separate ACR must also be submitted for each such segment. We also stated in the June 1998 interim final rule that, in computing the ACR for years beginning in 2000, the M+C organization calculates an initial rate according to the specifications in § 422.310(b), that represents the "commercial premium" that the M+C organization would charge its general non-Medicare enrollees for Medicare-covered benefits and any supplemental benefits covered by the M+C plan. The M+C organization would also calculate a separate ACR value for each optional supplemental benefit it offers under the plan. Then, the organization either adjusts the initial rate by the factors specified in § 422.310(c), or requests that we adjust the rate.

Section 422.310(b) dictates that the initial rate for each M+C plan is calculated on a 12-month basis for non-Medicare enrollees, using either a community rating system or a system approved by us, under which the M+C organization develops an aggregate premium for each M+C plan for all non-Medicare enrollees of that M+C plan that is weighted by the size of the

various enrolled groups and individuals that compose the M+C's enrollment in that plan. Regardless of the method the M+C organization uses to calculate its initial rate, the rate must equal the premium that the M+C organization would charge its non-Medicare enrollees on a yearly basis for services included in the M+C plan.

The June 1998 interim final rule also established special rules in § 422.310(d) for M+C organizations that do not have non-Medicare enrollees or sufficient Medicare enrollment experience to sufficiently calculate ACR values. We have amended § 422.310(d) because the interim final rule used incorrect citations in describing how such an M+C organization may estimate ACR values.

Comment: One commenter suggested that we test the new ACR methodology before implementation.

Response: We do not agree. The new ACR process requests data from organizations that should be readily available in an organization that has an adequate accounting system used to track the costs and revenues of the products it sells. In addition, we intend to develop a mechanism designed to identify unexpected problems. The form implementing the new ACR methodology allows M+C organizations to identify specific problems. We intend to gather information from our review, approval, and audit processes to develop manual instructions, clarify the ACR instructions, and modify the ACR form, if necessary.

Comment: One commenter suggested that the component of the ACR formula attributable to revenues in excess of expenses ("the additional revenue component," or "profit" in the case of a for-profit company) should be the same percentage of the Medicare ACR amount as it is in the case of the initial rate (the "commercial premium").

Response: We do not agree. Each product an organization offers may have a different additional revenue or profit margin. This would include each of the non-Medicare products included in the base cost figures and the initial rate. To use the same percentage of additional revenue margin included in the initial rate for the ACR for Medicare enrollees would apply an "average" additional revenue margin for non-Medicare enrollees to all Medicare enrollees. In addition, using a percentage method, as suggested, would increase the amount of the additional revenue margin for Medicare enrollees if Medicare health care costs were higher. (If costs are higher, the profit margin percentage can be lower while producing the same amount in profit.) We believe actual

additional revenues received in a prior period are the best measure of the amount of additional revenue an organization would expect in a future period, absent some changed circumstances or variables.

While we do not agree with the commenter's specific proposal, in light of this comment, we have reconsidered the relative cost ratio formula contained in the regulations at § 422.310(c)(3). Since additional revenues are produced when revenues exceed expenses, we believe the best way to project additional revenues for a benefit or group of benefits is to first project total revenues of that benefit or group of benefits and, then, subtract projected total expenses of that benefit or group of benefits. Therefore, we have modified the formula in § 422.310(c)(3) to project total revenues using a relative cost ratio of revenues charged in a base period for Medicare enrollees compared to revenues charges to non-Medicare enrollees of the same period and, then, subtracting projected expenses. We have used the calendar year prior to the calendar year the ACR is submitted as the "base year" for this purpose. If an M+C organization believes the computation produced under this formula does not adequately reflect the future period for an M+C plan, the organization may, with adequate justifying documentation, make an expected variation adjustment to the amount calculated.

Comment: One commenter interpreted § 422.310(c)(4) to provide that adjustments to additional revenues, after application of the relative ratios, are allowed to reduce the ACR value, but not increase the ACR value.

Response: The language of § 422.310(c)(4) was incorrect as published in our June 1998 interim final rule. On October 1, 1998, we published a technical revision to this section (63 FR 52614) to clarify that adjustments may increase or decrease the amount of additional revenue included in the ACR value of the service or services. These adjustments would be allowed as long as the organization submitted sufficient documentation to justify the need to increase or decrease the ACR values so calculated.

Comment: One commenter suggested that we allow M+C organizations to use representative data to develop ACR values for an M+C plan.

Response: The new ACR process requires M+C organizations to report the costs it incurs for an M+C plan using GAAP. Organizations in business routinely review the costs of each product it sells for various reasons, (for example, budget analysis, profitability).

The new ACR method does not create a new process to determine those costs. We have designed the ACR process to require the least amount of information needed to price an M+C plan without creating a new accounting process. We are relying on GAAP since these principles are widely known and are in use by most M+C organizations. We feel M+C organizations should not encounter significant problems in capturing the costs of the Medicare and non-Medicare populations of a prior period using accounting systems already in use to track each of the products it sells. Using representative data would not be as accurate as using costs actually incurred.

Comment: One commenter suggested that some group and staff model M+C organizations may not be able to provide cost data in the form and detail required in the ACR form.

Response: We do not agree. The regulations and the ACR form used to implement those regulations allow for a significant amount of flexibility. The instructions are very clear that there are a limited number of line items that must be reported. Most of the remaining entries will be dependent on the accounting system of the organization. Staff and group models may need to use an apportionment strategy to segregate costs between Medicare and non-Medicare enrollees. These apportionment strategies should be based on the same statistics currently being submitted for the ACR form under section 1876 of the Act.

Some organizations have argued that their accounting systems cannot segregate the revenues and cost of providing services to Medicare enrollees between different service areas and among various products sold. These organizations should discuss these matters with their HCFA-assigned plan manager. Since the M+C ACR process is still relatively new, we expect to grant some flexibility to M+C organizations. M+C organizations unable to comply with ACR requirements would be required to submit a plan of action designed to bring the organization in compliance with the regulations.

7. Requirement for Additional Benefits (§ 422.312)

Section 422.312(b) requires that the M+C organization provide additional benefits if there is an adjusted excess amount for the plan it offers. The actuarial value of these additional benefits, less the actuarial value of any cost-sharing associated with the benefit, must at least equal the adjusted excess amounts. We received no comments on this provision, but are making a

technical change to § 422.312(b) to use the term "cost-sharing" rather than copayment or coinsurance because the term cost-sharing has been previously defined in § 422.2 to include copayments and coinsurance.

H. Provider-Sponsored Organizations (Subpart H)

Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). A PSO is described in section 1855(d) of the Act as a public or private entity—

- That is established or organized, and operated, by a health care provider or group of affiliated health care providers;
- That provides a substantial portion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of these items and services, and have at least a majority financial interest in the entity.

The PSO regulations at §§ 422.350 through 422.390 include definitions, solvency standards (developed through negotiated rule making), and waiver requirements that have been established through three previous **Federal Register** publications. On April 14, 1999, we published an interim final rule with comment, titled "Definition of Provider-Sponsored Organization and Related Requirements" (63 FR 18124), setting forth the PSO definition, clarifying certain terms, and establishing related requirements. On May 7, 1998, we published an interim final rule with comment, titled "Waiver Requirements and Solvency Standards for Provider Sponsored Organizations" (63 FR 25360), establishing solvency requirements that apply to PSOs that obtain a waiver of the M+C State licensure requirements, and setting forth procedures and standards that apply to requests for the waivers. The solvency portion of the PSO regulation was based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act. On December 22, 1999, we published a final rule titled "Solvency Standards for Provider-Sponsored Organizations" (64 FR 71673), that addressed the comments we received on the PSO solvency standards and waiver requirements. In this final rule, we are responding to comments on the April 14, 1998 PSO definitions interim final rule.

Comment: A commenter believes that the interim final rule did not sufficiently ensure that a PSO is actually

controlled by providers. Another commenter thinks that effective control is defined too loosely in the regulation.

Response: We believe that the existing regulatory requirements are sufficient to ensure that PSOs are organizations that are owned and controlled by health care providers. Among the basic requirements for PSOs at § 422.352(a)(3) is the requirement that to be considered a PSO for purposes of the Medicare+Choice program, an organization must be controlled by a health care provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO. Under the definitions at § 422.350(b), we define control as meaning “that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.” This definition is essentially the same as the long-standing definition of control that is used for purposes of providers in the Medicare fee-for-service program (see § 413.17). We believe that the general definition for control we have adopted, which will result in case-by-case determinations by us, will ensure that PSOs are controlled by providers.

Comment: A commenter requested that we exempt PSOs formed by community health centers from the requirement in § 422.352(b)(1) that a non-rural PSO must deliver 70 percent of the health care services and items through the provider or affiliated providers responsible for running the PSO.

Response: We do not believe that a special exemption from § 422.352(b)(1) for community health centers is warranted. As we will note below, we do allow a lower percentage of health care services delivery for rural PSOs as compared to non-rural PSOs. However, because the percentage of health services delivery is in part designed to ensure that the PSO will remain solvent, we believe it would not be prudent to reduce the percentage for different types of organizations such as community health centers. To put our response in perspective, we will briefly discuss the PSO requirement that the PSO providers deliver a substantial proportion of health care services, and the reasons we have selected 70 percent for non-rural PSOs and 60 percent for rural PSOs.

The M+C regulations at § 422.352(b) specify that a PSO must deliver a substantial proportion of the health care items and services through the provider or affiliated group of providers responsible for operating the PSO. We have concluded that setting the

substantial proportion requirement at 70 percent for a non-rural PSOs and 60 percent for rural PSOs balances two key interests. These interests are, specifically: (1) That we not set the proportion of services so high as to prevent participation by all but the most sophisticated provider organizations; and (2) that the substantial proportion threshold be sufficient to ensure that a PSO have a well-developed capacity to deliver services, thus meeting the financial stability objective explicit in the statute, and increasing the prospects for successful development and solvent operation of a PSO. There is no indication in the PSO provisions in Part C that the Congress intended that a different standard be applied to community health centers, or any other entity. We see no basis for doing so.

Comment: A commenter recommends that we measure substantial proportion based on encounters rather than expenditures.

Response: As discussed in the previous response, § 422.352(b) requires that a PSO deliver a substantial proportion of the health care items and services through the providers or affiliated providers responsible for operating the PSO. In calculating the substantial proportion percentage, we considered what would be the best method for comparing the proportion of items and services furnished by a PSO-affiliated provider with the overall amount of items and services furnished through the PSO. The two possible approaches we identified involved either the use of Medicare encounter data or Medicare expenditure data. Based on discussions with the health care industry, we learned that using expenditure data generally would not be burdensome for PSOs, because it is already commonly collected for management purposes. Furthermore, expenditure data may also produce a measurement more in line with the intent of the substantial proportion requirement. For example, the expenditures associated with an acute hospital visit would reflect a higher draw upon the PSO's resources than a physician office visit. Likewise, with expenditure data, the dollar amounts associated with each physician office visit, home care visit, etc., will reflect resource use and the ability of PSO providers to manage medical utilization. Therefore, based upon its immediate availability and arguably greater relevance and significance, we have concluded that use of expenditure data is the better approach for determining compliance with the substantial proportion requirement.

Comment: A commenter recommended changing the language in § 422.376 from “the waiver is effective for 36 months, or through the end of the calendar year in which the 36 months period ends” to “the waiver is effective for 36 months.”

Response: We do not believe it is appropriate, as suggested by the commenter, to change § 422.376(b) so that it reads, “the waiver is effective for 36 months.” The reason we have chosen to allow a waiver to remain in effect until the end of the calendar year in which the 36 month period ends is that this ensures that the PSO's Medicare contract also remains in effect through the calendar year. To do otherwise could require a mid-year contract termination with significant disruption for beneficiaries enrolled in the PSO.

I. Organization Compliance with State Law and Preemption of Federal Law

1. State Licensure and Scope of Licensure (§ 422.400)

Section 1855 of the Act requires that a potential M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in every State in which it wishes to offer an M+C plan. (An exception to the licensure requirement is made for PSOs, as provided for in part 422, subpart H.) Section 1855(b) of the Act specifies that, with limited exceptions, an M+C organization must assume full financial risk for the cost of the health services it provides under its contract. Thus, the licensure requirement is a two-pronged requirement, and any potential M+C organization must meet both prongs, such that it is licensed, and is assuming the appropriate risk level for its license.

To establish the licensure status of potential M+C organizations, and in particular to determine compliance with the requirement that the organization's M+C contract falls within the scope of its licensure, we require that new M+C applicants supply documentation from the appropriate State regulatory authorities that the organization meets both the licensure and scope of licensure requirements. In the case of noncommercially licensed entities, § 422.400(b) requires that they obtain a certification from the State that they meet appropriate solvency standards.

Comment: With regard to the scope of licensure requirements, one commenter has asked for clarification as to whether managed care organizations with enrollment limited to Medicaid beneficiaries are eligible for M+C contracts. Another is concerned about States licensing organizations to offer

more than one M+C plan, noting that States may not have the resources to monitor multiple plans from multiple organizations. Other commenters have asked for clarification as to what happens if a State does not license insurers to offer high-deductible MSA plans, or does not license preferred provider organizations (PPOs). These commenters wish to know how MSA and PPO plans would be available in States which do not authorize these types of options. A commenter also asked whether States may require, for licensure purposes, that M+C organizations offer only products with “gatekeepers.” The commenter believes that these requirements should be preempted in order to permit managed care organizations to offer more choices to Medicare beneficiaries.

Response: Section 1855(a)(1) of the Act requires that an M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in any State in which it offers an M+C plan. As discussed in detail in the interim final rule (63 FR 35011), an entity does not have to have a commercial license to offer the type of M+C plan it seeks to offer under the M+C program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, in the case of an organization that is authorized by the State to assume risk under a Medicaid contract, but is not commercially licensed, the State in which the organization wishes to offer an M+C plan would have to certify that the organization has authority to assume the risk involved in offering the M+C plan in question (e.g., by meeting State solvency requirements). In some States, Medicaid-contracting managed care organizations are operated under the authority of the State Medicaid agency, and the State may take the position that this authority is limited to assuming risk for Medicaid beneficiaries. Since the statute requires that M+C organizations (with the exception of PSOs) be licensed by the State, the State has the discretion to make this decision.

With regard to State monitoring of M+C organizations that they license, we do not have the authority to second guess a State’s judgment concerning the sufficiency of its resources to monitor M+C plans for which it has given authorization. The States have the sole authority for licensure of M+C organizations, and can set their own standards for monitoring conditions of licensure.

The question of availability of MSA plans in States that do not approve high-deductible plans again goes back to the question of licensure. An organization wishing to offer an MSA plan must be licensed as a risk-bearing entity eligible to offer health insurance or health benefits in the State in question. If the organization wishes to offer a high-deductible policy as part of an MSA plan, the organization must be authorized by the State to assume risk, and under § 422.400(c)(1), must demonstrate that it is authorized to offer a high-deductible policy to Medicare beneficiaries under an M+C contract. This does not mean that it must be authorized by the State to offer such a policy commercially in the State.

With regard to the availability of PPOs in States that do not have a category of licensure into which PPOs would fit, the organization again would have to demonstrate that it was licensed as a risk-bearing entity or otherwise authorized to assume risk, and that it was authorized by the State to offer a PPO product to Medicare enrollees. (We note that under new section 1852(e)(2)(D), for purposes of the applicability of certain quality assurance requirements, a PPO is defined as an entity that is not licensed as an HMO.) If a State does not have a category for a PPO product, an organization may not offer a PPO product in that State unless it is able to demonstrate that the State has authorized it to do so in the context of an M+C contract. This same analysis applies to the question of whether a State may only allow products with “gatekeepers.” If the State only has licensure categories for “gatekeeper” products, then only those products may be offered in the State, absent State authorization of an alternative product in the M+C context.

The only exception to the above requirements that the State authorize the M+C organization to offer the type of plan at issue is the exception provided by Congress for PSOs that are unable to obtain a State license.

2. Federal Preemption of State Law (§ 422.402)

a. General Preemption (§ 422.402(a))

Section 1856(b)(3)(A) of the Act reflects the general principle that under the supremacy clause of the constitution, State laws are “preempted” when they conflict with applicable Federal laws. Specifically, section 1856(b)(3)(A) of the Act provides that “any State law or regulation” with respect to M+C plans is superseded “to the extent such law or

regulation is inconsistent” with M+C standards. This general preemption authority does not extend to non-M+C enrollees or non-M+C lines of business or activities. We apply this provision in the same manner that Executive Order 12612 on Federalism was applied to managed care organizations with contracts under section 1876 of the Act prior to the BBA. Under that Executive Order (recently superseded by Executive Order 13132; see section VI.1 below), the requirements of section 1876 of the Act did not preempt a State law or standard unless the law or standard was in direct conflict with Federal law. Put another way, if a State law required a managed care organization to do something that it would be permitted to do under section 1876 of the Act, there was no preemption. As discussed below, new Executive Order 13132 (64 FR 43255) contains this same standard for general preemption. The general preemption rule in section 1856(b)(3)(A) of the Act is implemented in § 422.402(a).

Comment: A commenter asked whether State laws that are more restrictive than Federal laws are preempted under our general preemption authority at § 422.402(a).

Response: In its description of the House bill’s provision for preemption of State laws “inconsistent with” the new BBA standards, the BBA Conference Report (H. Rept. 105–217, page 637) makes clear that this provision (which was retained in the conference agreement) “should not be construed as superseding a state law or regulation * * * that provides consumer protections in addition to, or more stringent than, those provided under [the BBA].” We thus believe it is clear that Congress expected the States, in some cases, to have more rigorous or more comprehensive standards for quality and consumer protection that would enhance, rather than be subsumed under, the M+C standards for quality and consumer protection. Except when one of the “specific preemptions” discussed below applies, State laws or standards that are more strict than the M+C standards would not be preempted unless they are in conflict with (for example, would preclude compliance with) M+C requirements.

Comment: One commenter representing many plans argues that our interpretation of general preemption is too narrow, and that it should be broadened to encompass State laws that the commenter believes serve as obstacles to the purposes and objectives of the M+C program. This commenter suggests that there are situations in which compliance with both a Federal

law and a State law is theoretically possible, but the administrative burdens associated with dual compliance would be tremendous, making compliance counterproductive in terms of meeting the goals of the M+C program. In these situations, the commenter believes that the State requirements should be preempted, thus relieving the burden of dual compliance.

Response: As just noted above, the legislative history of section 1856(b)(3)(A) of the Act makes clear that Congress contemplated that M+C organizations would be subject to State requirements that were “more stringent” than M+C standards. We believe that Congress intended in section 1856(b)(3)(A) of the Act to incorporate the basic principles of Federalism, as applied to section 1876 contractors at the time the BBA was passed. We do not believe that the fact that a burden may be involved in complying with State laws makes those laws “inconsistent” with Federal requirements. We therefore believe that under section 1856(b)(3)(A) of the Act, only State standards that prevent compliance with Federal standards are preempted under this general preemption provision. As noted earlier, this position is also consistent with new Executive Order 13132.

Comment: Many commenters sought clarification of the basic principles of general preemption, and asked whether specific issues are covered under the general preemption authority of section 1856 of the Act. Some of these commenters suggested that consumer protection standards should be left to the States. For example, a commenter representing many States believes that the following types of standards are not subject to general preemption: Market conduct evaluation; complaint handling (except to the extent specifically preempted by the BBA as discussed below); enforcement of unfair claim settlement practice standards (except to the extent specifically preempted by BBA); enforcement actions generally; filing and review of policy forms and rate filings; filing and review of advertising and marketing materials; provider access standards; credentialing standards; filing and review of provider contracts; utilization review programs and standards; quality assurance programs; supplemental benefits and cost-sharing arrangements; network adequacy; enforcement of loss ratio standards; standards and enforcement of commission limitations; and provider licensing and regulation. In addition, other commenters have asked for clarification as to whether or to what extent Medicare Secondary Payer mental health parity requirements are

preempted. Another commenter suggested that we interpret general preemption as covering all State laws except for financial solvency standards.

Response: We agree that the areas mentioned by the commenter would not be preempted under the general preemption rule in section 1852(b)(3)(A) of the Act, as long as the State law did not conflict with an M+C requirement. In most of the areas mentioned, if an M+C organization could comply with State law without compliance resulting in a violation of an M+C requirement, there would be no preemption. While the commenter has recognized that some of the above-referenced areas of State regulation are subject to the specific preemption provision discussed below (see the second and third items in the above list), there are other areas among those identified by the commenter that are subject to specific preemption as well. For example, State regulation of supplemental benefits would be preempted under the specific preemption of State laws relating to benefits. In addition, some “provider regulation” could be preempted under the specific preemption of laws relating to the inclusion or treatment of providers. Thus, while we agree with the commenter that laws in the specified areas would not be preempted under section 1856(b)(3)(A) of the Act absent a conflict with M+C standards, the commenter should consult the discussion below concerning specific preemption of State laws in the areas referenced in section 1856(b)(3)(B) of the Act. With respect to the comment that all areas should be subject to general preemption except solvency, we disagree with this comment. As noted above, we believe that general preemption would only apply in the case of a specific conflict with M+C requirements.

Comment: A commenter asked for clarification as to whether and how State M+C laws apply to employee groups.

Response: As noted in the preamble to the June 26, 1998 M+C interim final rule (63 FR 35013), there is neither general nor specific Federal preemption of State requirements that apply to arrangements between employers and M+C organizations for the provision of negotiated group benefits not covered under an M+C plan. These are purely private benefits that fall outside the scope of the M+C program and the ACR process. Thus, if there are applicable State laws not preempted by the Employee Retirement Income Security Act of 1974, these State laws could apply to employer group benefits, and would not be preempted by M+C

standards. M+C standards apply only to M+C plan benefits, including: (1) Medicare-covered benefits; (2) additional benefits paid for with Medicare payments; and (3) both optional and mandatory supplemental benefits for which a premium is charged.

Comment: A commenter asked whether State confidentiality laws are preempted.

Response: General preemption applies to confidentiality requirements. Thus, just as with other consumer protection standards, State requirements that are more stringent than the new M+C standards would not be preempted, unless compliance with the State confidentiality requirements made compliance with the Federal requirements impossible.

b. Specific Preemption (§ 422.402(b))

There are three areas in which section 1856(b)(3) of the Act provides for specific (rather than general) Federal preemption of State law: benefit requirements; requirements relating to treatment and inclusion of providers; and coverage determinations (including related appeals and grievance processes.) In the BBA Conference Report (H. Rept. 105–217, page 638), the conferees noted that benefit requirements, provider participation requirements, and coverage determinations (and related appeals mechanisms) are governed exclusively by Medicare standards under original Medicare, and expressed their view that this should be the case under the M+C program as well. That is, under original Medicare, States cannot specify what must be included as a Medicare benefit; States do not specify the conditions of participation for Medicare providers (though they license providers and practitioners and determine their scope of practice); States may not specify how a coverage determination is made with respect to whether or not the Medicare program covers a benefit; and States do not determine the type of appeal mechanism that is used to appeal a coverage decision made by a Medicare carrier or intermediary with respect to a Medicare benefit. In the specific preemption provisions in section 1856(b)(3)(B) of the Act, Congress provided that States similarly cannot regulate M+C plans in these areas. As in the case of general preemption, these specific preemption provisions do not extend to non-M+C enrollees, activities, or lines of business of the managed care organization.

In the interim final rule (63 FR 35012), we stated our intention to adopt a narrow interpretation of the

applicability of the three areas of specific preemption, thus giving States maximum flexibility within the parameters of the statutory language. (As discussed below, this view is consistent with new Executive Order 13132 on Federalism.) We identified the following examples of areas in which State standards would be preempted:

- Benefit mandates (note that we did not interpret a limit on cost-sharing to be a “benefit”).
- Appeals and grievances with respect to M+C coverage determinations.
- Requirements relating to the inclusion of providers (such as “any willing provider” laws or requirements to included specific types of providers within a plan’s provider network). We note that State laws providing enrollees with a right to directly access providers are considered to provide a “benefit” to enrollees, and to affect the “inclusion” and the “treatment of” providers, and thus also are specifically preempted.

Comment: In the interim final rule, we solicited comments on whether the specific preemption of benefits should be extended to cost-sharing requirements, and if there were particular types of cost-sharing that should, or should not, be included under the benefits preemption. We received many comments on this issue. Most industry commenters recommended that we include all State cost-sharing standards within the benefit preemption. They believe that cost-sharing is an integral part of a benefit; that the cost to a beneficiary for a particular service weighs on how much of a benefit he or she is actually receiving; and that the cost-sharing formula is what gives a benefit its market value. Commenters also argued that preempting State cost-sharing requirements would reduce variation in benefit packages, thus making comparison easier for beneficiaries, and easing the administrative burden on organizations that offer plans across State lines. They asserted that not preempting State cost-sharing standards would severely impede M+C organization’s efforts to offer national plans. Another commenter wrote that it was unclear whether a State could continue to apply some of its benefit-related provisions, such as limits on copayments, State coordination of benefits and subrogation rules, and required benefit differentials for PPOs.

In contrast, commenters representing the States and beneficiary advocacy groups recommended that we continue to construe the benefit preemption as narrowly as possible, and thus not change our policy to consider cost-

sharing a part of a benefit for preemption purposes. They supported our existing policy of generally not preempting State cost-sharing requirements. One commenter believed that even benefit requirements should not be preempted, however, arguing that if States cannot mandate certain benefits, then beneficiaries in M+C plans might have different, lesser benefits than beneficiaries with original Medicare and a Medigap policy.

Response: In the interim final rule, we stated that the specific preemption of benefit requirements does not extend to State cost-sharing standards (63 FR 35013). As discussed in detail in that rule, our position was that a State law establishing limits on cost-sharing generally, or limits on cost-sharing that can be imposed for a particular benefit, would not fall under the benefit preemption as we have defined the term “benefit.” We recognize that this is a narrow interpretation of the term “benefit,” and that we could have interpreted “benefit requirements” to extend to limits on cost-sharing. However, we wanted to minimize the extent to which beneficiary protections enacted by a State were preempted by Federal law. This decision is consistent with our support for beneficiary rights, as well as new Executive Order 13132 on Federalism, which calls for granting States the maximum flexibility permitted under Federal law. If the benefit to which State cost-sharing limits apply is not a Medicare-covered benefit, the State standard would apply only if the M+C organization chooses to offer the benefit, since any State mandate that the benefit be offered would be specifically preempted. Thus, to the extent that limits on cost-sharing are linked to a benefit mandate, the State cost-sharing limits could be seen to be “indirectly” preempted, in that the obligation to provide the benefit to which they apply is preempted. To the extent that an M+C organization offers the benefit to which State cost-sharing limits apply (whether as part of the package of Medicare-covered services, or as an additional or supplemental benefit), State cost-sharing standards would remain in effect unless they would be preempted under the general preemption authority discussed above.

Comment: Several commenters representing the State of Massachusetts wrote to request that we reconsider our position that the BBA prohibits State-mandated benefit laws, particularly when such a benefit is neither required by, nor funded by, the Federal government. These commenters believe that where Federal money is not involved, there is no preemption of

State law, and that the M+C regulations should be modified accordingly. These commenters were particularly concerned about the effect of Federal preemption on Massachusetts’ mandated prescription drug benefit, and pointed out that M+C enrollees in the State will not have access to a comprehensive prescription drug benefit in the absence of the State mandate. The commenters noted both that there is no Federal prescription drug benefit, and that the cost of the Massachusetts benefit is borne in no way by the Federal government.

Response: Throughout the development of the interim final rule and during the summer of 1998, we discussed in depth with Massachusetts officials the effect that Federal preemption would have on the prescription drug benefit in Massachusetts. Although we recognized the State’s concerns, we did not believe that the statute permitted any discretion on the issue, absent a legislative amendment. We believe that the reference to “benefit requirements” must refer to non-Medicare benefits like those at issue in Massachusetts, since, as noted above, States have never been permitted to mandate what is covered by Medicare. In September of 1998, the Massachusetts Association of Health Plans sued the Commonwealth of Massachusetts, in an attempt to resolve the apparent conflict between the State and Federal regulatory approaches. A Federal court ruled that the specific preemption in section 1856(b)(3)(B) of the Act did apply to the Massachusetts drug benefit. The State appealed, and on October 8, 1999, the ruling was affirmed by the United States Court of Appeals for the First Circuit. *Massachusetts Assn. of HMOs v. Ruthardt*, 194 F.3d 176 (1st Cir., Oct. 8, 1999). The Court found that the M+C regulations “dominate these particular fields, leaving no room therein for State standard-setting” for benefit requirements (194 F.3d, at 183). We agree with the Court’s conclusions.

Comment: Several commenters have asked us to revise § 422.402 to exempt State “return home” laws from preemption under sections 1856(b)(3)(B)(i) or (ii) of the Act. These laws generally allow a hospitalized beneficiary, who lived in a retirement home that includes a Medicare-approved nursing facility, to return to this “home” facility for post-hospitalization skilled nursing services, even if that facility is not part of his/her managed care plan’s network. Commenters argued that these types of provisions are not benefits requirements and are not related to treatment and

inclusion of providers, but rather are consumer protection requirements.

Response: As discussed above, section 1856(b)(3)(B)(ii) of the Act clearly establishes Federal preemption for requirements relating to the inclusion or treatment of providers. We believe that a law granting an enrollee the right to coverage from a particular provider would certainly have to be considered a requirement “relating to the inclusion or treatment of providers,” since it requires that the provider in question be “included” in the network of providers through which covered services may be obtained.

As a matter of policy, we believe that return home laws have value for beneficiaries, families, and communities, and we encourage M+C organizations to offer a return home option where it would not adversely affect quality or continuity of care, and does not pose an unreasonable administrative burden. However, absent legislative change, we do not believe that the statutory preemption provisions permit any alternative interpretation that would allow enforcement of these State laws for M+C enrollees. We are exploring developing a legislative proposal to establish a limited exception to the M+C preemption provisions to accommodate State return home laws.

Comment: Several commenters offered differing opinions of our interpretation that section 1856(b)(3)(B) of the Act preempts direct access laws. Again, some commenters believe that these requirements are contract or consumer protection laws, and should not be subject to specific preemption; other commenters believe that direct access laws are clearly and specifically preempted. One commenter asked for clarification on the specific preemption of State standards related to the “treatment and inclusion of providers and suppliers.” Specifically, this commenter asked for clarification on the following situations: (1) Whether the preemption applies to State standards on how providers are paid; (2) whether State standards that are more stringent than the M+C provider antidiscrimination provisions in existing § 422.204(b) are preempted; (3) whether State requirements that certain categories of health professionals must be treated the same as other providers by an HMO or insurer are preempted.

Another commenter asserted that “any willing provider laws,” specific benefit requirements, and requirements for the inclusion of specific types of providers should not be preempted. This commenter believes that if State standards are more stringent than Federal standards and not inconsistent

with them, they should not be preempted, regardless of whether these standards relate to the areas specifically preempted by Congress.

Response: In the interim final rule, we indicated that direct access laws and any willing provider laws were illustrative of the types of laws that we believe Congress intended to preempt through the BBA’s specific preemption provisions. Although we recognize that these types of State standards may be viewed as consumer protections, we believe that such standards clearly also involve both plan benefits and the treatment and inclusion of providers, and therefore are specifically preempted. With regard to the specific questions raised by the commenter, these standards all appear to involve the inclusion or treatment of providers. In order to make a final determination, however, we would have to review the specific State law in question.

Comment: A commenter asked for clarification regarding whether certain aspects of State law, such as State definitions of medical necessity, and requirements that subscribers be notified of the right to file complaints with State regulators, would be preempted under § 422.402(b)(3), which preempts State requirements for coverage determinations, including appeals and related grievances.

Response: For the purposes of coverage determinations, a State definition of “medical necessity” is preempted under § 422.402(b)(3) because any such definition is integral to the determination of coverage. A State’s general complaint process, as distinct from a process for appealing coverage decisions, would be subject only to general preemption under § 422.402(a), not specific preemption under § 422.402(b)(3). The State should indicate, however, that its process is separate, and that if the complaint involves a coverage determination, the sole mechanism for resolution is the Federal appeals process outlined in subpart M of part 422. For more information on this issue, please see guidelines issued by the National Association of Insurance Commissioners (NAIC).

Comment: A commenter who was generally supportive of Federal preemption argued that the regulations fail to clarify the ramifications of such preemption at the State level. The commenter requested that we “formalize the process” with the relevant State entities, so that managed care organizations are not held liable by a State for noncompliance with a State mandate when the organization is acting in accordance with Federal regulations.

Response: The NAIC and our staff have developed guidelines for use by the States in developing and implementing their managed care regulations and operational policies. We believe that these guidelines should address the commenter’s concerns about formalized guidance for States.

Comment: Many commenters support a broader interpretation of Federal preemption such that State law related to grievance procedures would be preempted. Other commenters believe that Congress intended to specifically preempt State grievance procedures.

Response: The statute says only that grievances related to coverage determinations are subject to specific preemption; therefore, we do not believe that Congress intended to preempt all State grievance procedures. We believe that Congress recognizes that many States use the term “grievance” to describe a complaint or define a process that constitutes an “appeal” under Medicare. Thus, we believe that the intent of the statute was to specifically preempt State requirements for grievances related only to coverage determinations, and to apply general preemption to State requirements for all other types of grievances. Thus, the State requirement would stand so long as it is not inconsistent with a Federal requirement, as discussed in detail above.

Since enrollees may have complaints that involve matters unrelated to coverage determinations, there needs to be a mechanism in place to address other types of complaints involving the manner in which enrollees receive care. Therefore, M+C organizations are required to have a grievance process in place to handle complaints unrelated to coverage determinations.

The preamble to the interim final rule alerted the public that we would establish a grievance procedure through proposed rulemaking, and sought comments on ways to make it meaningful. Until publication of that proposed rule, M+C organizations should look to State requirements for resolving complaints unrelated to coverage determinations.

Comment: A commenter asked for clarification as to whether a State law requiring the external review of all coverage determinations where the independent reviewer’s decision would be binding on the M+C organization would be preempted under the specific preemption rules.

Response: Specific preemption would apply in that situation. The M+C appeals process is the only method that can result in a binding decision on the M+C organization. A State may choose

to require external review of coverage determinations for monitoring or licensure purposes, but the requirement would be preempted to the extent that it requires a decision by any entity other than one prescribed under the M+C appeals process.

Comment: A commenter asked that we revisit our position that State tort or contract remedies may be available to beneficiaries whose coverage determination dispute goes through the Medicare appeals process. This commenter believes that coverage determination cases are contract disputes, and therefore should be the sole province of the Medicare appeals process.

Response: In some cases, a case that is cast as a State contract claim may amount to a claim that services are covered under an organization's M+C contract. We agree with the commenter that in that case, the claim would be pre-empted. However, there are other tort or State contract law, or consumer protection-based claims that would be entirely independent of the issue of whether services are required under M+C provisions. For example, a State consumer protection law may provide that certain claims made by an HMO in advertising give rise to particular obligations under State law, that exist independent of the question of what the HMO's M+C contract requires. In other cases, a tort action may exist independent of the question of whether services are covered under an M+C contract. We believe that under principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption narrowly, a beneficiary should still have State remedies available in cases in which the legal issue before the court is something other than the question of whether services are covered under the terms of an M+C contract.

3. Prohibition on State Premium Taxes (§ 422.404)

Section 1854(g) of the Act provides that "no State may impose a premium tax or similar tax with respect to payments to M+C organizations under section 1853." This prohibition does not apply to enrollee premium payments made to M+C plans, which are authorized under section 1854 of the Act. Section 402.404(a) sets forth the statutory provision, and specifies that the term "State" includes any political subdivision or other governmental authority within a State.

Section 422.404(b) clarifies the scope of what constitutes a prohibited premium tax, establishing that the prohibition generally does not apply to

a generally applicable tax on the net income or profits of any business. As noted in the preamble to the interim final rule, if the tax applies to premium revenue specifically, there is no exception to the prohibition of such a tax, based on the purpose of the tax.

Comment: One commenter agreed with our interpretation that the term "State" should include all political subdivisions, and recommended that we retain the regulatory language prohibiting State-levied taxes on payments made by Medicare to M+C organizations.

Response: We agree with the commenter. Since counties and other political subdivisions of a State derive their powers from the State, we believe this broad interpretation of the term "State" is the intended and necessary interpretation of the statutory provision. Thus, any prohibitions of State actions contained in Federal statute should be interpreted as prohibitions on actions at any level of State government or any State or local governmental body within the State.

Comment: One commenter noted that section 1854(g) of the Act prohibits only a "premium tax or other similar tax," and argued that this does not support our inclusion of "fees and other similar assessments" in the regulatory language at § 422.404(a). The commenter argued that assessments to fund State high risk pools should be permitted.

Response: We believe that any mandatory fee or assessment imposed on premium revenues clearly would fall within the reference to a premium tax or "other similar tax." As noted in the preamble to the interim final rule, we considered whether to exempt an assessment that is used for purposes of an insolvency insurance pool, but determined that if the assessment was mandatory, it amounted to a tax. We noted, however, that an M+C organization that wished to rely on the proceeds from such a pool as part of its plan for insolvency protection could voluntarily contribute to such a pool.

Comment: A commenter objected to statements in the preamble to the interim final rule (63 FR 35014) suggesting that an M+C organization may participate in a "guaranty fund" by paying premium taxes voluntarily. The commenter pointed out that the NAIC Life and Health Insurance Guaranty Association Model Act excludes managed care organizations from its definition of a "membered insurer." The commenter recommended that we clarify that State life and health insurance guaranty associations are excepted from the preamble discussion of "guaranty funds," or at least note that

under many States' life and health guaranty association laws, M+C organizations would not be considered member insurers.

Response: To the extent the commenter is referring to a guaranty fund operated by a private association, the prohibition on premium taxes would not apply. Our reference in the preamble to voluntary contribution to a guaranty fund involved a State mandated insurance pool established and operated by the government. In this case, the mandate to contribute premium revenue would be preempted, but an M+C organization could voluntarily participate.

4. Medigap

Section 1882 of the Act governs the sale of Medicare supplemental ("Medigap") policies, private health insurance policies that are designed to cover certain out-of-pocket costs incurred by Medicare beneficiaries. With minor exceptions, a Medigap policy cannot be sold in any State unless it conforms to one of ten standardized benefit packages, labeled plans "A" through "J".

Before enactment of the BBA, Federal law provided for only one opportunity for a Medicare beneficiary to purchase a Medicare supplemental ("Medigap") policy on a "guaranteed issue" basis. (Generally, this term means that the Medigap insurer cannot deny the application, delay the issuance or effective date of the policy, or charge an additional amount based on the individual's health status.) This opportunity occurs only during the 6-month period beginning with the date the beneficiary is both age 65 or older and enrolled in Medicare Part B.

Section 4031 of the BBA amended section 1882(s) of the Social Security Act to specify additional situations in which beneficiaries are able, as of July 1, 1998, to buy specific types of Medigap policies on a guaranteed issue basis, if they apply within 63 days of losing certain other types of health coverage, and if they submit evidence of the date that the prior coverage terminated. The law also requires that the entity that provided the prior coverage advise the beneficiary of these rights. While the M+C regulations do not implement the Medigap provisions of the BBA or the BBRA, it is important to understand the implications for M+C organizations, since some situations addressed by the Medigap provisions involve beneficiaries who leave M+C plans and return to original Medicare.

The situations that give rise to the obligation to notify the beneficiary include, for example, termination of

coverage by an M+C plan, reduction in an M+C plan's service area, termination of the M+C plan's contract by us, or loss of coverage under an M+C plan due to a change in the beneficiary's place of residence. As mentioned previously, section 501(a) of the BBRA amended section 1882(s)(3) of the Act to allow an individual to choose between two options: (1) Voluntarily disenrolling before coverage under the M+C plan is terminated involuntarily, and applying for a Medigap policy no later than 63 days after being *notified* by the M+C organization of the impending termination or service area reduction; or (2) waiting and applying no later than 63 days following the date of the involuntary termination or service area reduction. In these instances, the beneficiary is guaranteed the right to buy Medigap plans A, B, C, or F, subject to availability of those policies from insurers selling in the State.

With regard to availability, we note that not all 10 standardized Medigap plans may be available in all States, and all plans available in a State might not be offered by every insurer. Wisconsin, Minnesota, and Massachusetts have alternative forms of standardized policies under a waiver granted them by the Omnibus Budget Reconciliation Act of 1990 (OBRA). Federal law does not generally require sale of Medigap policies to beneficiaries under age 65 (eligible for Medicare by reason of disability or ESRD). However, State law may require insurers to sell to these populations under certain circumstances. Also, some insurers voluntarily sell policies to the disabled, usually on an underwritten basis. Where an insurer has filed in a State to sell to the under 65 population, these policies are subject to the BBA guaranteed issue protections.

The beneficiary may also have the right to guaranteed issue of a broader selection of Medigap policies if he or she either: (1) Directly enrolls in an M+C plan upon first becoming entitled to Medicare at age 65; or (2) enrolls for the first time in an M+C plan after previously having been covered under a Medigap policy, and, in both instances, later disenrolls from the M+C plan within 12 months of the effective date of the M+C enrollment. Beneficiaries who were previously enrolled in original Medicare and who purchased a Medigap policy, who disenroll from the M+C plan before the 12-month "trial" period has expired, are guaranteed the right to return to their old Medigap policy, if it is still available from their former insurer; (otherwise they have the choice of plans A, B, C, or F from any insurer). Alternatively, if an M+C plan

was their first choice as newly entitled Medicare beneficiaries at age 65, and they disenroll during the first 12 months after enrolling, they have their choice of all 10 Medigap plans, including plans H, I, and J, which provide some outpatient prescription drug coverage. This broader array of choices for beneficiaries who elected an M+C plan when they first became entitled to Medicare at 65, in effect, compensates them for having forgone their 6-month Medigap open enrollment opportunity, which began when they reached age 65.

In all these cases of voluntary or involuntary terminations from an M+C plan, beneficiaries must apply for the Medigap policy of their choice, from among the options available to them, within 63 days. If they fail to act within this time period, they lose both their guaranteed issue right to purchase the policy of their choice at the standard premium rate, and their protection from pre-existing exclusion periods. Outside of this guaranty issue period, they may be able to find some Medigap insurers who are willing to sell to them, but they may not be able to purchase the policy they want. Additionally, the insurer can apply a pre-existing condition exclusion period of up to 6 months and/or charge them an additional amount based on their health status.

Because the Medigap provisions establish specific deadlines for beneficiaries who wish to take advantage of these new rights, prompt action by the M+C organizations to notify beneficiaries of their rights, or by us to provide accurate evidence of recently terminated coverage, is essential. We are committed to providing beneficiaries whose M+C coverage is terminated with timely and accurate evidence of the recently terminated coverage. To this end, we will provide M+C plans with, among other things, a model final termination letter that must be sent 90 days prior to termination of a contract. This letter will contain detailed information about beneficiaries' rights to Medigap under BBA and the BBRA.

We urge M+C organizations to keep in mind that they are obligated to notify beneficiaries whose coverage terminates of their rights under the Medigap provisions. Those provisions are complex, and beneficiaries will be entitled to guaranteed issue of Medigap policies at standard premium rates and with no preexisting condition exclusion periods only under certain circumstances. As noted above, their choice of Medigap policies will depend on the precise reason for, and timing of, the termination of their coverage under the M+C plan. It also matters whether

they disenroll voluntarily or wait to be involuntarily disenrolled. However, if their initial 12-month trial period will expire before the M+C plan's contract will terminate, they have the option of disenrolling before the 12-month period has expired if they wish to obtain the broader selection of Medigap policies that may be available to them.

Further guidance is available to beneficiaries from their State Health Insurance Assistance Program (SHIP) or State insurance department.

Comment: A commenter has asked whether Medigap coverage is still applicable when a beneficiary chooses to privately contract for health services.

Response: Medigap policies cover two basic types of costs. The first includes costs such as deductibles and coinsurance that apply with respect to services covered by Medicare. The second includes costs of non-covered items and services such as outpatient prescription drugs. Medigap insurers are only required to make payment for the first type of services if a bill is submitted to and processed by Medicare. When a beneficiary privately contracts with a physician or practitioner under section 1802(b) of the Act to receive services that would otherwise be covered under Medicare, the services are excluded from Medicare payment under section 1862(a)(19) of the Act, and the beneficiary agrees not to submit a bill. As the beneficiary acknowledges in the private contract, as required by section 1802(b)(2)(B)(iv) of the Act, the Medigap policy will not pay for costs related to these services.

The policy may, however, be required to make payment with respect to the types of costs that are not otherwise covered by Medicare.

Comment: Commenters asked for clarification of the effective date of the BBA guaranteed issue requirements for Medigap A, B, C, and F plans, and for clarification of the rights of disabled beneficiaries with regard to guaranteed issue.

Response: As discussed above (and in greater detail in the **Federal Register** on December 4, 1998 and February 17, 1999, 63 FR 67078 and 64 FR 7968, respectively), the BBA's guaranteed issue provision took effect for all insurers on July 1, 1998. In addition, as noted previously, any Medigap policy that is available to beneficiaries under age 65 under any other circumstances must be offered to beneficiaries under age 65 who meet the criteria for BBA guaranteed issue protections.

Comment: One commenter was concerned about the wide variation in premiums of the 10 Medigap plans, and

was worried about beneficiaries being overcharged.

Response: It is true that there is wide variation in the premiums charged for the 10 standardized Medigap policies, both within States and from State to State. Regulation of Medigap insurance rates is ultimately within the discretion of the States, although federal Medigap law imposes some general requirements. In particular, Medigap policies must meet certain loss-ratio standards that are intended to ensure that policies provide refunds or credits if aggregate premiums exceed aggregate benefits by too high a margin. In addition, during the initial open enrollment period, and when the BBA guaranteed issue situations are in effect for a beneficiary, the insurer cannot increase the premium based on the beneficiary's health status.

Comment: Commenters voiced concern over the possibility of a beneficiary being penalized when a health plan terminates without timely enough notice for the beneficiary to find the appropriate Medigap insurance. Commenters also believe that we should provide plans with information as to which States have Medigap policies without pre-existing condition limitations as of January 1, 1999, and in general that plans need more information on Medigap.

Response: We have developed a clear termination policy and systems to provide for timely beneficiary notification, so that beneficiaries will be aware of their rights and protections if a plan terminates. In addition to developing internal processes, we are working with the States and M+C organizations to develop model language that will clearly and timely inform beneficiaries of their rights and protections.

In addition, we are working with the NAIC and the States to develop the Medigap Compare database, which will identify available Medigap policies and allow beneficiaries to compare costs and benefits. Beneficiaries and M+C plans will be able to access this database to gain the appropriate information a beneficiary needs when seeking Medigap insurance.

J. Subpart J, Part 422

Subpart J of part 422 has been reserved for future use.

K. Contracts with M+C Organizations (Subpart K)

Subpart K sets forth provisions relating to the contracts that are entered into by M+C organizations, including a description of terms that must be included in the contract, the duration of contracts, provisions regarding the

nonrenewal or termination of a contract, and minimum enrollment, reporting, and prompt payment requirements.

1. Definitions (§ 422.500)

Comment: As discussed above in section II.F.2, we received comments suggesting that we impose requirements on providers to cooperate with M+C organizations in their collection of encounter data to be used in implementing risk adjustment.

Response: As discussed in section II.F.2, in response to this comment, we have taken several steps to facilitate the cooperation of providers in supplying valid data that can be used by M+C organizations to comply with encounter data requirements. In the case of contracting providers, we have specified under § 422.257 that M+C organizations may include in their provider contracts provisions requiring submission of valid data. Therefore, an M+C organization could provide in its contract that it will not make payment if claims do not meet the standards specified. In the case of noncontracting providers, however, § 422.520 requires M+C organizations to pay 95 percent of "clean claims" within 30 days, or pay interest on the amount. Also, based on the existing definition of "clean claims," an M+C organization could not withhold payment based on a failure to submit a claim in the form required for use in complying with encounter data requirements. As noted in section II.F.2, we are revising the definition of "clean claim" in § 422.500 to require that clean claims include the substantiating documentation needed to meet the requirements for encounter data submission, and meet the original Medicare "clean claim" requirements. This change will, in effect, also require noncontracting providers submitting claims to an M+C organization to provide the organization with the information it needs to be able to use the claim in encounter data submissions, by exempting claims that do not meet these requirements from application of the 30-day "prompt payment" standards articulated at § 422.520. M+C organizations will therefore be able to withhold payment longer than the 30-day prompt payment standard in cases where noncontracting providers submit claims that do not contain substantiating documentation necessary for encounter data submissions or have other deficiencies (for example, inadequate coding). We believe that this clarification of the clean claim definition at § 422.500 is consistent with section 1957(f)(1) of the Act, which incorporates the Medicare fee-for-service prompt payment provisions in sections 1816(c)(2)(B) and

1842(c)(2)(B) of the Act, and simply fleshes out the concept in the existing definition that a claim is not clean if it lacks "any required substantiating documentation." Providers should note that submission of claims with complete and accurate encounter data is ultimately in their best interest, since M+C organizations must submit complete and accurate encounter data in order to get the full payment to which they are entitled under the risk adjustment system. While HCFA does not regulate payments to providers by M+C organizations, we believe that M+C organizations should share appropriately with providers any gains under the risk adjustment system.

2. National Contracting

The BBA does not specifically define or directly address the issue of national contracting. It facilitated such contracting, however, when it provided in section 1857(a) of the Act that an M+C contract "may cover more than 1 Medicare+Choice plan," and, in section 1851(h)(3) of the Act, provided that marketing material need only be approved once to the extent it is consistent from area to area. While we are interested in national contracting, we similarly have not expressly provided for it in the regulations. One national contracting approach we would be willing to consider would permit an M+C applicant to request that we enter into a national contract with the applicant if the applicant holds license as a risk-bearing entity in each State where it intends to operate. The applicant would have the option of adopting a single M+C plan across the country, with one service area and a national ACR proposal, or offering different M+C plans in different areas under the same national contract.

While we have not at this time entered into a national contract with any M+C organization, HCFA has entered into national "agreements" with national chain organizations that hold M+C contracts. These arrangements apply to those chain organizations that enter into separate contracts in multiple States. These agreements allow a chain organization to establish a uniform policy across all of its States as to marketing, quality assurance, utilization review, claims processing, etc. HCFA pre-approves these national policy procedures. We continue to contract separately with individual, albeit related, M+C organizations affiliated through common ownership or control. We likewise continue to monitor operational activities for each organization in each State, but, having approved national policy, the need for

review at the State and local level is reduced.

Nine commenters addressed national contracting for M+C organizations. While most of the public comments favored extending the option of national contracting to M+C organizations and applicant organizations, commenters generally linked their support for the concept to a request that we provide additional information on the specifics of any national contracting policy.

Comment: While several commenters that supported national contracting raised individual concerns, (in most instances related to the need for HCFA to provide additional information), one commenter raised concerns that national contracting would undermine our ability to adequately monitor the performance of M+C organizations. Another commenter raised concerns that national contracting would provide M+C organizations the ability to bypass existing limits pertaining to the provision of cross-state and national radiology services.

Response: We continue to believe that national contracting has potential advantages for Medicare beneficiaries, M+C organizations, and HCFA. Indeed, we have already observed the benefits of allowing M+C organizations that operate in many markets throughout the country to establish uniform operational functions in the areas of marketing, quality assurance and claims processing. However, some issues pertaining to national contracting, (for example, monitoring and oversight, enforcement actions, etc.), require additional study. While HCFA continues to explore these issues, we are not able to provide detailed guidance. At such time as additional guidance is developed, we anticipate notifying the public through an operational policy letter.

3. Compliance Plan (§ 422.501(b)(3)(vi))

As a condition for entering into an M+C contract with HCFA, applicant organizations must demonstrate that they have certain administrative and management arrangements in place. There are six specific administration and management requirements at § 422.501(b)(3). One of these requirements is that M+C organizations have in place a compliance plan for meeting all applicable Federal and State standards. The regulations list the required elements of the compliance plan, which generally follow the standards applied under the U.S. Sentencing Commission's Federal Sentencing Guidelines in determining whether the existence of a compliance plan should mitigate penalties. We

received nine public comments on the M+C compliance plan requirement.

Comment: Although some commenters agreed with the spirit of the compliance plan requirement, most objected to its mandatory nature, especially in light of OIG guidance on compliance plans for M+C organizations.

Response: We believe that the unique financial incentives and health care delivery systems of M+C organizations justify the compliance plan requirement. Medicare beneficiaries who enroll in plans are essentially "locked in" to that plan's benefit structure and provider network and may not obtain services under original Medicare. M+C organizations are responsible for a significantly broader range of program activities than original Medicare providers, including marketing, enrollment, appeals and grievances, utilization management, and claims payment. Each of these activities presents the potential for noncompliance that could directly and adversely affect a beneficiary's rights under the Medicare program. For example, an M+C organization's failure to report enrollment data properly to HCFA may result in incorrect payments to that organization.

While HCFA and the OIG conduct ongoing M+C program monitoring and enforcement activities, the number and variety of M+C operational requirements presents a significant regulatory challenge to both of these agencies. As a result, we believe that the additional level of scrutiny imposed by a compliance plan is a reasonable requirement.

While the OIG stated in its November 1999 guidance that the document was intended only to provide assistance for M+C organizations, the OIG did note that it "believes an effective compliance program provides a mechanism that brings the public and private sectors together to reach mutual goals of reducing fraud and abuse, improving operational quality, and ensuring the provision of high-quality cost-effective care." The OIG also stated that a compliance plan is a tool for an M+C organization "to ensure that it is not submitting false or inaccurate information to the Government or providing substandard care to Medicare beneficiaries * * *." We agree with the OIG's judgement with respect to the utility of the compliance plan tool and have adopted this requirement to protect the integrity of the M+C program.

Comment: Several commenters asked when M+C organizations are responsible for meeting the compliance

plan requirements stated at § 422.501(b)(3)(vi), and noted that no detailed guidance on compliance has been issued by HCFA in connection with the interim final rule.

Response: The requirements in § 422.501(b)(3)(vi), as revised in this final rule, are in effect and must be met by M+C applicants and M+C organizations. Pending any further guidance, M+C organizations are free to reasonably interpret the provisions in § 422.501(b)(3)(vi), and should be prepared to demonstrate, upon request, how the organization meets each compliance plan element, as specified at § 422.501(b)(3)(vi), *et seq.*

Comment: Many commenters addressed the requirement at § 422.501(b)(3)(vi)(H) that M+C organizations develop "an adhered-to process for reporting to HCFA and/or the OIG credible information of violations of law by the M+C organization, plan, subcontractor, or enrollee for determination as to whether criminal, civil, or administrative action may be appropriate." Commenters generally stated that this requirement was too vague, and should be more clearly defined to enable organizations to demonstrate compliance to HCFA. Several commenters requested that we specify what "credible information" means within the context of requiring M+C organizations to submit information to HCFA and/or the OIG. Commenters also requested that we specify: (1) Exactly what information must be self-reported; (2) to which agency; and (3) pursuant to violations of which laws. Commenters also noted that while paragraphs (A) through (G) correspond to provisions found in the Federal Sentencing Guidelines, paragraph (H) appears to be an M+C requirement only. These commenters believe that it is unfair to subject M+C organizations to a self-reporting requirement that does not apply to other sectors of the health care industry.

Response: Commenters correctly point out that the first seven elements of the mandated compliance plan guidance at § 422.501(b)(3)(vi) *et seq.* reflect the areas identified in the U.S. Federal Sentencing Guidelines. We previously added the eighth element in an attempt to ensure an enhanced level of program safeguard through self-reporting. We recognize, however, that it is arguably unfair to impose a self-reporting requirement on M+C organizations but not on other types of health care providers and suppliers participating in the Medicare program, and we have eliminated any requirement of self-reporting.

Nevertheless, we believe that the existence of voluntary self-reporting procedures of potential misconduct is an appropriate part of an M+C organization's compliance program. While this rule does not make any type of self-reporting mandatory, M+C organizations may wish to consider the following suggestions, as a matter of voluntary good business practice. These suggestions are not mandatory. Where the M+C organization discovers evidence of misconduct related to payment or delivery of health care items or services under the M+C contract, the M+C organization may conduct a timely, reasonable inquiry into the misconduct. After the reasonable inquiry, if the organization has determined that the misconduct resulted in an overpayment, the M+C organization is encouraged voluntarily to report the overpayment to HCFA. If the M+C organization has determined that the misconduct may violate the statutes of direct concern to the HHS Office of Inspector General, it is encouraged voluntarily to report the existence of the misconduct to that office. Finally, the M+C organization is encouraged voluntarily to initiate and implement appropriate corrective actions to ensure the problem does not recur.

While we are withdrawing all requirements for self-reporting in this rule, we believe that the required reporting of overpayments is an effective tool for promoting Medicare program integrity generally. Accordingly, HCFA intends to develop policies through separate notice and comment rulemaking in cooperation with the HHS Office of Inspector General that would require all Medicare providers, suppliers and contractors to report overpayments to HCFA.

Comment: Some commenters considered the M+C compliance plan requirements at § 422.501(b)(3)(vi) to be overly prescriptive, and asserted that they would result in M+C organizations being forced to "reinvent the wheel," even though they may have existing compliance structures in place that meet the intent of the regulations. Many of these same commenters questioned our authority to prescribe these requirements in the M+C final rules.

Response: It is not our intent through these rules to require M+C organizations with effective compliance plans in place to make major changes. We believe that the requirements in § 422.501(a)(3)(vi) based on the Federal Sentencing Guidelines are sufficiently broad and general in nature that an effective compliance plan currently in place should satisfy M+C requirements.

However, we do want some assurances that M+C organizations will have procedures in place to ensure compliance with Federal laws and requirements. We believe that our compliance plan requirements include the basic framework required for organizations to prevent and detect activities that will render the organization out of compliance. Moreover, the elements of the Federal Sentencing Guidelines from which these requirements are drawn are present in other guidances issued by the OIG over the last several years and should be familiar to most M+C compliance officials.

M+C organizations and contract applicants have broad discretion under § 422.501(b)(3)(vi) to design their compliance plan structure to meet the unique aspects of each organization. We recognize that there is no one best way for an organization to take steps to ensure that it is operating in compliance with all applicable regulations and requirements. Thus, we intend to work with M+C organizations and contract applicants to apply a flexible standard in reviewing M+C compliance plans, while still ensuring that these compliance plans serve their intended purpose: to detect and prevent compliance problems, in addition to identifying aspects of the organization that may be vulnerable to such problems.

We believe that one way for us to determine if an organization's corporate compliance plan is effective is to evaluate and audit the performance of the organization according to the M+C requirements articulated in the M+C contract and regulations. Since we have an established monitoring process for M+C organizations, we believe that the infrastructure is already established that may assist HCFA in its efforts to assess the effectiveness of organizations' compliance plans based in part on the results of our monitoring efforts.

4. Access to Facilities and Records (§ 422.502(e))

Under § 422.502(e) of the regulations, an M+C organization must agree to allow access to HHS or the Comptroller General to evaluate the quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract; the facilities of the M+C organization; and the enrollment and disenrollment records for the current contract period, and 6 prior contract years. We received two comments regarding access to M+C organization records.

Comment: A commenter asked what an M+C organization's obligations are in

relation to information concerning nonplan providers, with whom an M+C organization has no contract. The commenter questioned how M+C organizations could be expected to provide access to governmental entities for nonplan provider records in order to meet the requirements of § 422.502(e).

Response: We recognize that HHS, the Comptroller General or their designees can require only M+C organizations and their subcontractors to make available their facilities and records. If an M+C organization does not have a contract or other suitable written arrangement with a provider, it cannot compel the provider to provide the same access that an M+C organization or its subcontractors must provide under the terms of their M+C contract with HCFA. In order for HHS or the Comptroller General to gain access to the facilities and records of noncontracting providers, these agencies would be required to resort to other available legal remedies, such as subpoenas.

We would add, however, that as a general principle, if Federal funds are going to a provider of Medicare or Medicaid services, appropriate Federal officials have a right to review that provider's facility or books as a condition of receipt of those Federal funds.

Comment: A commenter suggested that the 6-year time period for which data must be retained under the regulations should be tied to the end of the year in question, and not the date of the completion of the audit, as provided in § 422.502(e)(4).

Response: The 6-year period specified for retention of records was established in reliance on the 6-year "statute of limitations" that generally governs the initiation of a civil action by the Government, either under the False Claims Act (FCA) or the Civil Monetary Penalties Law (CMPL). A statute of limitations specifies the time period during which the Government may initiate an action. Generally, a statute of limitations begins to run on the date that an audit was completed. For this reason, we are requesting that books and records be kept for at least 6 years from either the end of a contract or the completion of an audit, whichever is later.

For purposes of clarity, we also point out that the 6-year record retention requirement requires M+C organizations to keep a specific year's records for 6 years, after which the organization is free to dispose of any records they deem appropriate. This is to clarify one misconception that M+C organizations must maintain 6 years of records for an additional 6-year period. We instead

envision the obligation for M+C organizations to retain records to expire on a rolling basis, with M+C organizations having the right to discard each year the records from more than 6 years earlier. For example, in 2000, M+C organizations could discard records from 1993 or earlier. In 2001, M+C organizations could discard records from 1994, etc. Under this system of record retention, if the Government has not audited or determined any wrongdoing within a 6-year period following the year when records were developed, the Government would be otherwise precluded under law from taking any action against an M+C organization.

5. Disclosure of Information (§ 422.502(f)(2)(v))

Pursuant to authority at section 1851(d) of the Act, § 422.502(f)(2) describes the information that M+C organizations must submit to HCFA. We specify that this information is necessary for us to fulfill our responsibilities in evaluating and administering the program. Our dissemination of some of this information to current and prospective Medicare beneficiaries enables them to exercise informed choice in obtaining Medicare services. We received one comment on this section of the interim final rule.

Comment: One individual commented on the requirement in § 422.502(f)(2)(v) that M+C organizations submit to us information about beneficiary appeals and their disposition. The commenter recommended that we amend this section of the regulations to include the additional requirement that M+C organizations disclose to HCFA information regarding beneficiary grievances and their disposition.

Response: Consistent with section 1852(c)(2)(c) of the Act, § 422.111(c)(3) of the regulations distinguishes between information that an M+C organization must provide to a Medicare enrollee annually, and information that the M+C organization must disclose to any M+C eligible individual upon request. The requirement states that M+C organizations must disclose to M+C eligible individuals, upon request, the aggregate number of disputes, and their disposition, including both grievances and appeals. Thus, Medicare beneficiaries have access to information on M+C organization grievances.

Also, pursuant to both sections 1851(d)(3) and 1852(c)(2)(C) of the Act, § 422.502(f) requires that M+C organizations disclose to us the appeal data that they are required to disclose upon request to beneficiaries. We

believe that this is necessary so that we can begin to capture important baseline data on the appeals process. Our contractor (the Center for Health Disputes Resolution) is responsible for making reconsideration decisions when an enrollee files an appeal, and these decisions are appealed to HHS administrative law judges and the Departmental Appeals Board. In addition, HCFA enforces decisions made by these entities, which necessarily involve the critical question of whether services will be covered by the M+C organization.

While the regulations provide for beneficiary access to information on an M+C organization's grievance process, we do not at this time believe that it is necessary for HCFA to collect this information for administrative purposes. We would advise M+C organizations, however, that while we are not requiring that M+C organizations disclose grievance data to us at this time, we intend to propose additional requirements pertaining to M+C grievances, including quality of care grievances, in a notice of proposed rulemaking to be published later this year. Thus, we anticipate that M+C organizations may be required to report grievance data in the future.

6. Beneficiary Financial Protection (§ 422.502(g))

In the interim final rule, we addressed enrollee financial protection provisions at § 422.502(g). These provisions are designed to protect enrollees from incurring liability for payment of any fee for which M+C organizations are legally obligated. Section 422.502(g) incorporates enrollee financial protections that were in place before the BBA in § 417.122(a)(1), which applies to all section 1876 contractors under § 417.407(f). Section 422.502(g)(1) is intended to protect enrollees from being held financially responsible for fees for which the M+C organization is legally liable; § 422.502(g)(2) addresses M+C organizations' obligation to provide for continued coverage of health care benefits, and § 422.502(g)(3) sets forth the mechanisms M+C organizations can employ to provide the required enrollee protections. We received three comments regarding § 422.502(g).

Comment: A commenter suggested that we provide appropriate "hold harmless" language for inclusion in M+C organizations' contracts because different States have different requirements regarding hold harmless language. (By "hold harmless" language, the commenter is referring to language included in an M+C organization's contract with a provider that protects

enrollees from being charged for services, (other than pursuant to M+C plan provisions that allow for cost-sharing), furnished by the provider, even if the provider has not received payment from the M+C organization for the services.)

Response: Implicit in the commenter's request is recognition that many States have adopted hold harmless contract language requirements for managed care organizations operating within a given State. We generally recommend that M+C organizations adopt the National Association of Insurance Commissioners' (NAIC) model hold harmless language. However, given the wide variety of individual State requirements loosely categorized under member or enrollee protections, we do not believe that it is prudent to *require* M+C organizations to adopt the NAIC model language, because that requirement may well place some M+C organizations at odds with State provisions. The NAIC-approved language is available through most State insurance commissioners' offices, or by contacting the NAIC directly.

Comment: One commenter recommended that we strengthen the beneficiary protection provisions in subpart K by explicitly prohibiting providers from bringing "collection actions" against M+C enrollees, as a means of preventing providers from billing beneficiaries enrolled in M+C plans for fees that are the legal obligation of the M+C organization. The commenter also suggested that we define the word "fees" for purposes of this section of the regulations.

Response: Section 422.502(g)(1) is designed to ensure that beneficiaries are not held liable for fees for which the M+C organization is legally responsible. As discussed above, under § 422.502(g)(1)(i), contracts with M+C plan providers must contain language that prohibits these providers from holding beneficiary enrollees liable for payment of fees that are the obligation of the M+C organization. (This language is commonly referred to as "hold harmless" language.) Under § 422.502(g)(1)(ii), M+C organizations are responsible for indemnifying enrollees for payment of any fees that are the legal obligation of the M+C organization to pay when services are furnished by providers that do not have a contract or other acceptable written arrangement with the M+C organization. We believe that these two provisions generally are adequate to ensure that M+C enrollees are not held responsible for fees for which an M+C organization is liable.

In instances where providers do bill M+C enrollees for amounts beyond those approved in an M+C plan, we believe that it is the responsibility of the M+C organization to take appropriate steps, such as recovering these amounts from the providers, to see that beneficiary enrollees are made financially whole. If they fail to do so, we would take appropriate action against the M+C organization. We believe it would be inappropriate for us to engage in activities directed at individual providers.

We note, however, that even in situations, (such as insolvency or other financial difficulties), where an M+C organization fails to satisfy its responsibility to pay a provider for services furnished to an M+C enrollee, the principle that the beneficiary is protected still applies. Although we believe this principle is inherent in the existing regulations, to clarify this point, we are revising § 422.502(g)(1) to indicate that the applicable beneficiary financial protections apply in situations such as insolvency or other financial difficulties.

We believe that the term “fee” is commonly understood, and does not need a special definition. In this context, the term refers to the fees charged by a provider (for example, a physician’s fee for services provided). M+C organizations are responsible for payment of such fees, except for applicable enrollee cost-sharing amounts specified under the M+C plan, which are the obligation of the Medicare enrollee.

Comment: A commenter contended that there is an inconsistency in the language in §§ 422.502(g)(2), (g)(3), and (i)(3)(i)(B). Section 422.502(g)(3) gives M+C organizations several options for meeting requirements in § 422.502(g) (other than the “hold harmless” requirement in § 422.502(g)(1)(i)), including the options of providing for continuation of benefits through contractual arrangements, insurance, financial reserves, or other arrangements acceptable to HCFA. Section 422.502(i)(3)(i)(B), however, effectively requires that continuation of benefits be provided for in contract language.

Response: We agree with the commenter that the language in these sections is inconsistent. Accordingly, we are revising §§ 422.502(i)(3)(i) to eliminate the requirement that the continuation of benefits protection be addressed through contractual arrangements. In conjunction with this technical change, we also are revising § 422.502(g)(3) to clarify that the alternative arrangements spelled out there are linked only to the

indemnification provision in § 422.502(g)(1)(ii) and to the continuation of benefits provision in § 422.502(g)(2).

7. Requirements of Other Laws and Regulations (§ 422.502(h))

Section 422.502(h) requires that contracts reflect the M+C organization’s obligations under other laws, specifically, the Civil Rights Act of 1964, the Age Discrimination Act of 1975, the Americans with Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.

Comment: Several commenters wanted us to define “other laws applicable to recipients of Federal funds” and “other applicable laws and rules” as used in § 422.502(h).

Response: These references are intentionally broad and all-encompassing. We have already identified various specific laws. These references are intended to encompass laws that may be enacted in the future, or current laws that we might inadvertently omit if we were to attempt to be more specific in this regulation. It is important to note, however, that these references only apply to laws that are, by definition and by their own terms, “applicable” to an M+C organization. Thus, these provisions of the regulations do not result in an organization being required to comply with any laws that do not already apply to them. Rather, they simply call for a commitment to comply with these laws.

8. Contracting/Subcontracting Issues (§ 422.502(i))

The requirements found at § 422.502(i)(3) pertaining to M+C contracting requirements with providers, suppliers, and administrative service entities were developed pursuant to our authority under section 1856(b)(1) of the Act to “establish” M+C “standards.” We developed these rules in recognition of the fact that managed care organizations commonly enter business relationships with entities that they place under contract to perform certain functions that would otherwise be the responsibility of the M+C organization. Section 422.502(i)(3) establishes these requirements in three broad categories: enrollee protection provisions, accountability provisions, and a provision that assures that services performed by other entities are carried out in a manner that complies with the M+C organization’s contractual obligations to us. We received three comments concerning the subcontracting issues addressed in § 422.502(i)(3).

Comment: Two commenters believe that HCFA should provide additional guidance on its contracting/subcontracting requirements; they suggested that HCFA apply a flexible standard in holding M+C organizations accountable for meeting these requirements in a timely manner. A third commenter wanted to know if our subcontracting guidance would compel entities with whom M+C organizations contract to comply with HCFA’s Y2K systems compliance requirements.

Response: We are cognizant of the importance of providing detailed contracting guidance to M+C organizations, and to individuals and entities that might choose to contract with them. We have issued significant guidance in the past and intend to continue doing so as needed in the future. For example, in OPL 98.077 we addressed two major issues. First, we clarified the contracting requirements that affect M+C organizations, applicant organizations, contractors, and subcontractors. Second, we addressed implementation guidance for organizations that wished to begin operation as an M+C-contracting organization. We believe that this OPL sufficiently addresses concerns raised by the managed care industry concerning the need for a higher degree of specificity regarding contracting and subcontracting requirements. We likewise believe that OPL 98.077 established flexible implementation standards in recognition of the labor-intensive nature inherent in activities aimed at amending or otherwise establishing contracts and subcontracts that follow the standards specified in the M+C regulations and elsewhere in OPL 98.077. Commenters and other interested parties may access OPL 98.077 on the Internet at <http://www.hcfa.gov>.

Regarding the question on Y2K requirements, this issue is moot, since all contracting M+C organizations appear to have succeeded in avoiding related problems. We would note, however, that to the extent an M+C organization provided services through subcontractors, it was responsible for ensuring the Y2K compliance of those subcontractors to the extent necessary to ensure overall Y2K compliance.

Comment: Some commenters expressed confusion regarding use of the terms “related entities, contractors, and subcontractors” in § 422.502(i)(1), and the applicability of these terms. Some have pointed out that although the term “related entity” is defined at § 422.500, the terms “contractor” and “subcontractor” are not defined.

Response: In response to the confusion suggested by this comment, we now recognize that the terms “contractor” and “subcontractor” are somewhat amorphous, and could mean different things to different parties. For instance, a contract between an M+C organization and members of an IPA might be considered a “contract” by one party and a “subcontract” by another party. Likewise, organizations or individuals might sometimes call a contract between the IPA and its member physicians a “subcontract,” while in other instances call it a “provider participation agreement.” We have consulted with the managed care industry about terms that may be universally recognized, and have also considered developing new terminology with clear definitions.

As a result, and in response to the comment, we have added two terms—“first tier” and “downstream”—to the list of definitions at § 422.500. We believe these definitions will clarify the types of entities to which the M+C contracting requirements described at § 422.502(i) apply. We began using the terms “first tier” and “downstream” in OPL 98.077, and believe that both terms satisfactorily enhance the description of entities or individuals that are the intended audience for satisfying the requirements found at § 422.502(i).

9. Certification of Data That Determine Payment/Certification of the Accuracy of ACR Information (§ 422.502(l))

Under § 422.502(l), M+C organizations must certify to the accuracy, completeness, and truthfulness of the data used to calculate payments to the organizations. These data include enrollment information, encounter data, and the information included in an M+C organization’s ACR proposal. In the preamble to the interim final rule, we noted that in submitting these data, M+C organizations are making a “claim” for payment from HCFA, since this information directly affects the calculation of payment rates and amounts. We stated that the certifications would help ensure accurate data submissions and assist us in maintaining the integrity of the Medicare program.

Comment: Several commenters suggested that the certification requirement should include a “good faith” standard. Given the significance of the penalties that HCFA, OIG, and the Department of Justice (DoJ) may potentially impose in the case of a “false claim,” and the complexity of the data required, these commenters believe that it would be unfair and unrealistic to hold M+C organizations to a “100

percent accuracy” certification standard.

Response: We first addressed this issue during the drafting of the 1999 M+C coordinated care plan contract. In developing the certification forms M+C organizations would use to meet the payment data certification requirement, we consulted with OIG and DoJ in drafting language that requires the M+C organization to certify the accuracy, completeness, and truthfulness of this data based on “best knowledge, information, and belief.” This language was included in the 1999 contract forms in recognition of the fact that M+C organizations cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that HCFA, the OIG, and DoJ believe is reasonable to enforce.

In presentations to industry, HHS representatives have emphasized that simple mistakes will not result in sanctions. Generally, the Federal government can bring an action only when one of three states of mind exists: (1) Actual knowledge of falsity of a claim or information; (2) reckless disregard; or (3) deliberate ignorance of information supporting the truth or falsity of a claim or other information (42 CFR 1003.101). However, no specific intent to defraud is required. The “best knowledge, information, and belief” standard of the M+C contract certification forms is consistent with these standards.

It is appropriate that the M+C regulations be consistent with the standard of knowledge reflected in Federal fraud statutes. Therefore, we are modifying § 422.502(l) as needed to reflect the “best knowledge, information, and belief” certification standard.

Comment: Several commenters suggested that the signatory authority for payment certifications should not be limited to the chief executive officer (CEO) and chief financial officer (CFO) of an M+C organization. The commenters noted that as a practical matter, it is difficult to obtain a CEO or CFO signature on a monthly basis, given the workload and travel obligations of these officers. Therefore, the regulations should permit a CEO or CFO to designate another individual in the M+C organization to sign the certifications.

Response: We agree that the CEO/CFO signature requirement can create operational difficulties for M+C organizations in their efforts to comply with the payment certification requirements of § 422.502(l). However, we believe that it is important that certifications be made by a high level individual who has authority to obligate

the M+C organization, or someone who has been delegated the authority of such an individual. Therefore, we are modifying § 422.502(l) to require the “CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such an officer,” to certify the M+C organization’s enrollment data, encounter data, and ACR proposal information.

Comment: A commenter contended that M+C organizations should not be required to certify the accuracy of the encounter data they receive from third parties. Rather, this commenter believes that organizations should be required to certify only that they have not altered the data, and that they have transmitted it to HCFA as they received it from the provider. The commenter asserted that M+C organizations do not control the operations of those providing encounter data, and that the volume of data is such that no M+C organization has the resources to verify the accuracy of these submissions.

Response: Under the M+C program, encounter data will be used as a factor in calculating payments to M+C organizations. Therefore, encounter data submissions, like enrollment data and ACR information, represent a “claim” for payment. As such, M+C organizations have an obligation to take steps to ensure the accuracy, completeness, and truthfulness of the encounter data.

We acknowledge that encounter data come into M+C organizations in great volume and from a number of sources, presenting significant verification challenges for the organizations. However, we believe that M+C organizations have an obligation to undertake “due diligence” to ensure the accuracy, completeness, and truthfulness of encounter data submitted to HCFA. Therefore, they will be held to a “best knowledge, information, and belief” standard. Therefore, M+C organizations will be held responsible for making good faith efforts to certify the accuracy, completeness, and truthfulness of encounter data submitted.

10. Effective Date and Term of Contract (§ 422.504)

Section 1857(c)(3) of the Act provides that the effective date of an M+C contract is to be specified in the M+C contract, and section 1857(c)(1) requires that contracts be for a term of at least one year. The Secretary was provided the discretion under section 1857(c)(1) to provide for contracts to be “automatically” renewable in the absence of notice.

Section 1857(c)(2) of the Act authorizes us to terminate an M+C contract if we determine that an M+C organization substantially fails to carry out its M+C contract, carries out the contract in a manner that is inconsistent with the effective and efficient administration of the M+C program, or fails to continue to meet the M+C requirements.

Section 422.504 of the June 1998 interim final rule implements section 1857(c)(1) and (3) of the Act. Section 422.504(b) provides that contracts generally are for a 12-month period beginning January 1 and ending December 31. Section 422.504(d) provides for a limited exception to this rule, permitting HCFA the discretion, prior to January 1, 2002, to approve a contract for longer than 12 months beginning on a date other than January 1. This decision permits us to accept M+C applications on a continuous "flow" basis until the beginning of the lock-in periods contemplated under the BBA starting in 2002. We received one comment pertaining to the effective date and term of the M+C contract.

Comment: A commenter expressed concerns regarding the effect of open enrollment requirements on our requirements governing the effective date and term of M+C contracts. In particular, the commenter had concerns about the elimination of the right to disenroll (and enroll) in an M+C plan at any time. The commenter believes that this shift in enrollment policy contributed to our decision no longer to approve contract applications on a continuous "flow" basis after 2002, since most Medicare beneficiaries, (excluding newly eligible beneficiaries and those beneficiaries eligible to make an election based upon a special enrollment period), would not otherwise be able to enroll in the new M+C organization until the beginning of the next annual open enrollment period. The commenter suggested that M+C organizations retain the ability to enroll Medicare beneficiaries on an ongoing basis without regard to the annual lock-in periods contemplated by the BBA at section 1851(e).

Response: This comment raises two related issues. The first pertains to enrollment and disenrollment policies, and the second pertains to HCFA's rationale for considering a policy that would establish a cutoff date for making contracts effective on a date other than January 1. We believe the statute clearly indicates that continuous open enrollment and disenrollment may continue only through the end of 2001. Currently, M+C organizations are only required to be open for enrollment in

November of each year, to newly Medicare-eligible individuals, and during specified "special election periods." (See § 422.60(a).) Thus, it is not necessarily the case even now that there is "continuous" open enrollment, though the right to disenroll exists all year. During the first 6 months of the transition year of 2000, a beneficiary will be able to disenroll without cause, and enroll in any M+C plan open for enrollment, with a limit of one change in enrollment status during this period. This same situation will apply to the first 3 months of every year after 2002, with a limit of one change in elections during this 3-month period. Other than this, beneficiaries will only be permitted to enroll or disenroll during the annual November open enrollment period, a special election period, or upon first becoming eligible for Medicare (with the exception of institutionalized individuals, consistent with section 501 of the BBRA). These enrollment limitations will, in effect, limit the number of Medicare beneficiaries that an M+C organization can enroll mid-year. Yet, after considering the comments, we do not believe that the enrollment policies pursuant to the BBA necessarily preclude us from entering into contracts on dates other than January 1 beginning 2002. While we recognize the inherent enrollment limitations for M+C organizations that will result from a mid-year enrollment eligibility pool that will be comprised largely of individuals that become newly eligible for Medicare, we nevertheless believe that enrollment and the term of an M+C contract are distinct issues that can be considered independent of each other. Regarding the term of an M+C contract, we further believe that the statute permits us to continue to approve mid-year contracts post-2002. Since section 1857(c)(1) requires that contracts be for a term of at least one year, HCFA may continue to enter contracts that may begin on dates other than January 1 for terms longer than 12 months. We have modified § 422.504 to reflect this policy.

11. Nonrenewal of M+C Contracts (§ 422.506)

Section 422.506 specifies the process that M+C organizations and HCFA must use should HCFA decide not to renew the organization's contract, or should the organization give HCFA notice that it does not want its contract to be renewed. We received four comments addressing our M+C contract renewal policy.

Comment: Some commenters believe that requiring M+C organizations to notify HCFA of their intent to nonrenew

their M+C contract(s) by May 1 does not provide enough time for organizations to conduct the requisite analysis necessary to decide whether the organization should remain in the M+C program.

Response: We agree with the commenter that the May 1 deadline does not provide organizations enough time to decide whether to remain in the M+C program. We recognize that the May 1 deadline affords organizations only 60 days from the date such organizations received the upcoming year's M+C payment rates to make business decisions affecting their participation in the M+C program. Congress recently recognized this problem when it amended section 1854(a)(1) of the Act to change the deadline for submitting an ACR from May 1 to July 1. (See section 516 of the BBRA and section I.C of this preamble.) In light of the commenter's concern, and the change in the ACR deadline enacted by Congress, we are revising § 422.506(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year. An M+C organization that does not signify its intent not to renew its M+C contract by July 1, and that has not otherwise been notified by HCFA of our intent not to renew the M+C organization's contract by May 1, will be obligated to contract for the upcoming contract year.

Comment: One commenter questioned our authority under § 422.506(b)(ii) to decide not to renew M+C contracts based on our assessment that an M+C organization's level of enrollment or growth in enrollment threatens the viability of the organization under the M+C program. This commenter likewise questioned the authority under which we could decide not to renew a contract based upon our assessment that lack of enrollment could be viewed as an implied measure of dissatisfaction with a particular M+C organization.

Response: We believe that HCFA should be a prudent purchaser of health care services on behalf of Medicare beneficiaries. This entails a fiduciary responsibility to Medicare beneficiaries and tax payers to maintain contracts with organizations that display a sustained and ongoing commitment toward meeting the highest quality standards, and that offer a product attractive enough to attract Medicare beneficiaries to enroll. In promulgating § 422.506(b)(1)(ii), we determined that it might not be worth the costs associated with contracting with an M+C organization if that organization fails to attract or keep at least some level of Medicare enrollment.

However, in response to the commenter's concern, we have determined that the standard outlined at § 422.506(b)(1)(ii) for declining to renew an M+C contract may be too vague to enforce; therefore, we are deleting § 422.506(b)(1)(ii).

12. Provider Prior Notification and Disclosure (§§ 422.506(a), 422.508, 422.510(b), and 422.512)

We address M+C contract determinations in several sections throughout subparts K and N of the M+C regulations. As noted above, § 422.506 contains provisions governing our decisions and M+C organization decisions concerning whether to renew an M+C contract. Section 422.508 specifies that HCFA and an M+C organization may together elect, upon mutual consent, to modify an M+C contract. Sections 422.510 and 422.512 describe M+C contract termination procedures when initiated by either HCFA or an M+C organization. When M+C contract determinations occur, either the organization initiating the determination, or the organization impacted by the determination, must meet certain notification requirements described in §§ 422.506, 422.508, 422.510, and 422.512. The notice requirements compel either HCFA or the M+C organization to notify: (1) The party affected by the contract determination (for example, if HCFA elects to terminate a contract, HCFA must notify the M+C organization of our determination); (2) the Medicare beneficiaries from the affected M+C organization's M+C plans; and (3) the general public.

Comment: Several commenters suggested that we consider developing a requirement that would compel HCFA and/or an M+C organization to notify providers affected by M+C contract determinations about the contract determination, regardless of which party initiates the contract determination action. The commenters contended that the notice is necessary to grant providers sufficient time to react to contract determinations that may adversely affect them. (A related section of regulations that the commenters did not reference, but would logically be affected by the recommendations of the commenters, is § 422.641 of subpart N.)

Response: We believe there are several reasons why separate provider disclosure and notification is unnecessary. First, we do not believe that notifying an M+C organization's network providers of an M+C contract determination is feasible for HCFA, since we do not routinely maintain this information at a level of specificity that

would be necessary to provide such notice. Further, we do not believe that it is necessary to require M+C organizations to provide such notice, since we believe that they would necessarily have to notify affected providers that their contracts were being nonrenewed.

In any event, since M+C organizations and/or HCFA are already required to disclose specified information to the general public, a subset of which are the M+C organization's providers, pursuant to an M+C contract determination, we believe that any additional notification requirements may be duplicative and unnecessary.

13. Mutual Termination of a Contract (§ 422.508)

Section 422.508 provides that M+C organizations and HCFA may mutually agree to modify or terminate an M+C contract. When a contract is terminated by mutual consent, M+C organizations must provide notice to affected Medicare enrollees and the general public. If the contract terminated by mutual consent is replaced on the following day by a new M+C contract, the notice requirements do not apply.

Comment: One commenter expressed concerns that our policy, as outlined at § 422.508, does not provide enough beneficiary protection, and may potentially compromise beneficiary continuity of care. Further, the commenter recommended that mutual contract termination should automatically trigger a special enrollment period for affected Medicare beneficiaries, as outlined at § 422.62(b).

Response: We believe that § 422.508 provides Medicare beneficiaries affected by mutual consent contract termination with the protections necessary for affected beneficiaries to choose new Medicare health service delivery options. In particular, the requirement that M+C organizations provide Medicare beneficiaries and the general public with a notice of termination to conform to the 60-day notice requirement in §§ 422.512(b)(2) and (3) should enable affected Medicare beneficiaries to arrange for alternative health care coverage, such as returning to original Medicare, or choosing a different M+C plan before the effective date of termination.

We agree with the commenter that a termination (and not modification) of an M+C contract by mutual consent should trigger a special election period as described at § 422.62(b), and we believe that the existing language at § 422.62(b)(1) supports this position. In stating "HCFA has terminated * * * or the organization has terminated * * *

the [M+C] plan in the service area or continuation area in which the [Medicare eligible] individual resides * * *," we believe that termination of a contract by mutual consent of the two aforementioned parties is consistent with the intent of the provision at § 422.62(b)(1). Thus, we believe that any change to the regulation language at § 422.508 or § 422.62(b)(1) is unnecessary.

14. Termination of Contract by HCFA (§ 422.510)

Section 422.510 implements the provisions in section 1857(c)(2) of the Act pertaining to our authority to terminate an M+C organization's contract if we determine that the organization: (1) Fails to substantially carry out the contract; (2) is carrying out the contract in a manner inconsistent with the efficient and effective administration of Medicare Part C; and/or (3) no longer substantially meets the applicable conditions of Part C. In § 422.510(a), we set forth the above standards, as well as several specific circumstances that we believe constitute a substantial failure to carry out the contract, justifying termination. The procedures under which we would take action to terminate an M+C contract are described in section 1857(h) of the Act. In general, we may terminate an M+C contract after: (1) We provide the M+C organization with an opportunity to correct identified deficiencies; and (2) we provide the organization with notice and opportunity for a hearing, including the right to an appeal of an initial decision.

We received three comments on § 422.510. One commenter requested further explanation regarding the termination process, for which we refer the commenter to subpart N of the regulations. The other comments are addressed below.

Comment: Two commenters requested that we define what we mean by the term "substantially fails to comply," as used throughout § 422.510(a).

Response: In the June 1998 interim final rule, and at § 422.510(a)(4) through (11), we identify circumstances that we believe constitute examples of what the statute identifies as substantially failing to carry out an M+C contract. They are: the M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program; the M+C organization substantially fails to comply with requirements in subpart M relating to grievances and appeals; the M+C organization fails to provide us with valid encounter data as required under § 422.257; the M+C organization fails to

implement an acceptable quality assessment and performance improvement program as required under subpart D; the M+C organization substantially fails to comply with the prompt payment requirements in § 422.520; the M+C organization substantially fails to comply with the service access requirements in §§ 422.112 or 422.114; or the M+C organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

We have longstanding compliance standards for Medicare managed care contractors. In addition to those set forth in the statute and regulations, compliance standards are set forth in our Medicare Managed Care Performance and Monitoring protocol. We use this document when conducting performance/monitoring evaluations of contracting Medicare managed care organizations, including M+C organizations. Pursuant to these reviews, each contracting organization must demonstrate that it again complies with all applicable statutory, regulatory and contract requirements that apply to M+C organizations. These reviews result in findings as to whether a failure to comply with requirements constitutes a "substantial failure" for purposes of § 422.510(a). In determining whether a failure is "substantial," we consider both the frequency and the seriousness of the noncompliance. In the case of a serious violation that could put the health of an enrollee at risk, even a single violation might be considered substantial. In the case of a less serious violation, the noncompliance would have to be more pervasive or systematic in order to be considered substantial.

Comment: Some comments reflected confusion regarding § 422.510(c), and its reference to subpart N of part 422. Section 422.510(c) indicates that if we make a determination to terminate an M+C contract, we must first allow the affected M+C organization the opportunity to submit a corrective action plan in accordance with "time frames specified at subpart N" of part 422. The commenter noted that subpart N does not contain any time frames that apply specifically to activities related to corrective actions.

Response: We agree that subpart N does not contain time frames that appear applicable to an opportunity to take corrective action, and that this reference is an error. We accordingly are deleting this reference from § 422.510(c).

15. Minimum Enrollment Requirements (§ 422.514)

Section 1857(b) of the Act specifies that we may not enter into a contract with an M+C organization unless the organization has at least 5,000 enrollees (or 1,500 if it is a PSO), or at least 1,500 enrollees (or 500 if it is a PSO) if the organization primarily serves individuals residing outside of urbanized areas. Section 1857(b)(3) creates a transition standard for meeting this requirement by allowing us to waive the minimum enrollment requirement during the M+C organization's first 3 years.

Comment: A commenter asked if we would consider a permanent minimum enrollment waiver for "smaller scale service models."

Response: A review of both the statute at section 1857(b) of the Act and the Conference Committee report indicates that the Congress intended for the minimum enrollment waiver to apply only during the first 3 contract years for any organizations. The minimum enrollment thresholds themselves are necessary to enable organizations to adequately spread risk across enrolled populations.

16. Reporting requirements (§ 422.516)

The M+C regulations contain various provisions that specify information disclosure requirements. The requirements address both information to be provided by M+C organizations to HCFA (see §§ 422.64, 422.502, and 422.512), by M+C organizations to beneficiaries (see §§ 422.80 and 422.111), and by HCFA to beneficiaries (under existing § 422.64). Section 422.516 specifies requirements that M+C organizations must meet regarding disclosure of statistics and information to HCFA, M+C enrollees, and the general public.

Comment: A commenter requested that we expand the reporting requirements specified at section § 422.516 to require M+C organizations to report the statistics and other information specified in § 422.516 *et seq.* directly to the organization's network health care providers.

Response: The commenter seeks to carve-out a separate category of individuals, providers, to receive statistics and other information that M+C organizations are already obligated to disclose to HCFA, to M+C plan enrollees, and to the general public. We believe that it is unnecessary for M+C organizations to report statistics and other information separately to providers. Since M+C organizations (or HCFA) are already required to disclose

specified information to the general public, (a subset of which is the M+C providers), any additional requirement to disclose information separately to an organization's providers is duplicative and unnecessary. Moreover, we are concerned about the administrative burden that such a requirement could impose upon M+C organizations, which may contract with thousands of providers. Further, we suspect that many organizations already voluntarily furnish providers with much of the information required under § 422.516, such as information on health plan benefits, premiums, quality and performance measurements, and utilization control mechanisms.

17. Prompt Payment by M+C Organization (§ 422.520(a))

Section 422.520 indicates that contracts between M+C organizations and HCFA must specify that the M+C organization agrees to provide prompt payment of claims that have been submitted by providers for services and supplies furnished to Medicare enrollees when these services and supplies are not furnished by an organization-contracted provider. Specifically, 95 percent of "clean claims" must be paid within 30 days of receipt. While this provision closely follows requirements already in place for section 1876 contractors, (including provisions pertaining to interest to be paid if timely payment is not made), section 1857(f) of the Act extends similar prompt payment requirements to claims submitted by Medicare beneficiaries enrolled in M+C private fee-for-service plans. Section 422.520(a) incorporates this requirement of new section 1857(f), as well as the general 30-day requirement that applied to noncontracting providers under section 1876. In the preamble to the June 1998 interim final rule, we indicated that pursuant to our authority under section 1856(b)(1) to establish standards under Part C, M+C organizations would be required to act upon (either approve or deny, not necessarily pay) all claims not subject to the 30-day standard within 60 calendar days from the date of request.

Comment: Commenters noted that the "approve or deny" language in § 422.520(a)(3) was inconsistent with rules regarding M+C organization determinations and reconsiderations as described in subpart M. Also, it has been brought to our attention that the requirement that "non-clean" claims (and up to 5 percent of clean claims) be "approved or denied," but not necessarily paid, within 60 calendar days from the date of the request for payment, is inconsistent with the

standard that applied to contractors under section 1876 of the Act. Under the Medicare risk program, HCFA traditionally required that HMOs or CMPs with Medicare risk contracts pay or deny non-clean claims within 60 calendar days from the date of the request for payment. The “approve or deny” language may permit gaps of time between when an organization approved a claim for payment and when the organization actually paid a claim.

Response: After further review of this issue, we agree that M+C organizations should be required to either pay or deny non-clean claims (and clean claims not subject to the 30-day standard) within 60 calendar days from the date of the payment request. This standard removes the possible ambiguity associated with “approving”, but not necessarily paying, a claim for payment, and any related ambiguities pertaining to M+C organization determination and reconsideration policies articulated in subpart M of this final rule. Thus, we are revising § 422.520(a)(3) to indicate that claims for services that are not furnished under a written agreement between M+C organization and its network providers, and that are not paid within 30 days, must be either paid or denied within 60 calendar days from the date of the request.

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract (Subpart L)

The provisions set forth in subpart L of part 422 by the June 1998 interim final rule merely constituted a redesignation of the provisions in part 417 on change of ownership or leasing of facilities. However, since the June 1998 interim final rule was published, it has come to our attention that M+C organizations have serious concerns about language in the italicized title to § 422.550(a)(2) which has been construed to present an impediment to an asset sale by one corporation to another. Section 422.550(a) sets forth what constitutes a “change of ownership” for purposes of provisions in § 422.552 which permit an M+C contract to be transferred to a new owner under certain circumstances (for example, the new owner must meet the requirements to qualify as an M+C organization). Because this italicized title refers to an “unincorporated sole proprietor,” it suggests that a “[t]ransfer of title and property to another party” does not constitute a change of ownership if the assets are transferred by a corporation, rather than a sole proprietor. This has presented problems in cases in which transactions that would benefit Medicare beneficiaries by

keeping a M+C plan option available do not appear to fall within the definition of change of ownership. If an M+C contract accordingly could not be transferred as part of an asset sale, this could prevent the sale from going forward, or limit the sale to commercial or Medicaid lines of business, in either case, potentially depriving Medicare beneficiaries of an M+C plan option they would otherwise have.

The italicized language in question was adopted from rules in section 1876 of the Act, which in turn were adopted from longstanding original fee-for-service Medicare change of ownership regulations containing identical language (see § 489.18(a)). These original Medicare change of ownership regulations apply to a change of ownership in the case of a Medicare provider, and address the assumption of a Medicare provider agreement, rather than an M+C contract. However, the language in § 489.18(a)(2) is identical to that in § 422.550(a)(2). In the original Medicare context, this language has consistently been interpreted to encompass an asset sale from one corporation to another. This interpretation was applied by the U.S. Court of Appeals for the Fifth Circuit in *U.S. v. Vernon Home Health Care Inc.*, 21 F.3d 693 (5th Cir.), cert. denied, 115 S. Ct. 575 (1994). While we have determined that the current M+C change of ownership regulation containing identical language should similarly be interpreted to encompass an asset sale by a corporation, we believe that it would be helpful to eliminate the reference in the title of § 422.550(a)(2) to a “sole proprietorship” in order to avoid confusion. We therefore are changing this title in this final rule to read “Asset sale.”

M. Grievances, Organization Determinations, and Appeals (Subpart M)

1. Background and General Provisions (§§ 422.560 through 422.562)

Subpart M of part 422 implements sections 1852(f) and (g) of the Act, which set forth the procedures M+C organizations must follow with regard to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f) of the Act, an M+C organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its M+C plans. Section 1852(g) of the Act addresses the procedural requirements concerning

coverage (“organization”) determinations and reconsiderations and other appeals. Only disputes concerning “organization determinations” are subject to the reconsideration and other appeal requirements under section 1852(g). In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term “appeal” to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review.

For the grievance, organization determination, and appeal requirements, an M+C organization must establish procedures that satisfy these requirements with respect to each M+C plan that it offers. These requirements generally are the same for each type of M+C plan—including M+C non-network MSA plans and M+C PFFS plans. (Please refer to the preamble material on M+C appeals and grievances in the June 26, 1998 interim final rule (63 FR 35021) for a detailed discussion of the specific requirements under Subpart M.)

Additional regulatory improvements to the M+C appeal and grievance processes are currently under development. We included in the M+C interim final rule those improvements that were practical within the short time frame allotted for completing that interim final rule. As we indicated in the preamble to the M+C interim final rule (63 FR 35030), we intend in the near future to publish a proposed rule implementing a variety of other improvements to the M+C dispute resolution process, including both appeals and grievances.

Sections 422.560 and 422.561 contain the basis and scope and the relevant definitions for subpart M. Section 422.562, General Provisions, provides an overview of the rights and responsibilities of M+C organizations and M+C enrollees with respect to grievances, organization determinations, and appeals. The responsibilities of M+C organizations, under § 422.562(a), essentially parallel those applicable to

HMOs under § 417.604(a), with the added provision that, if an M+C organization delegates any of its responsibilities under subpart M to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the applicable grievance and appeal requirements are still met.

Section 422.562(b) explains the basic rights of M+C enrollees under subpart M, and provides regulatory references to the sections that fully explain the relevant rights. This section does not establish any rights beyond those previously provided for HMO enrollees under part 417, but consolidates general information about enrollees' rights into a central location in the regulations.

Like the part 417 regulations, § 422.562(b) contains provisions addressing the applicability of other regulations that implement Social Security appeals procedures under title II of the Act.

2. Grievance Procedures (§ 422.564)

Section 1852(f) of the Act requires that each M+C organization provide "meaningful procedures for hearing and resolving grievances." We have defined this term in § 422.561 as any complaint or dispute other than one that involves an "organization determination" (as described under § 422.566(b)). (This definition retains the meaning of grievance used in part 417.) An enrollee might file a grievance if, for example, the enrollee received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, as specified under §§ 422.570(d)(2)(ii) and 422.584(d)(2)(ii), grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to grant an enrollee's request to expedite an organization determination or a reconsideration.

Under § 422.564(a), an M+C organization must resolve grievances in a timely manner using procedures that comply with any guidelines which we establish. Section 422.564(c) clarifies that the PRO complaint process under section 1154(a)(14) of the Act addresses quality issues, but is separate and distinct from the M+C organization's grievance procedures. Thus, there are three different complaint processes (grievance, appeals and PRO processes) available to an enrollee in an M+C organization.

3. Organization Determinations (§§ 422.566 through 422.576)

Section 1852(g) of the Act requires an M+C organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations. In accordance with section 1852(g)(1) of the Act, § 422.566 specifies that an M+C organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. Also, an M+C organization's refusal to provide services that the enrollee believes should be furnished or arranged for by the M+C organization is an action that constitutes an organization determination. Disputes involving additional benefits, as well as mandatory and optional supplemental benefits, also constitute organization determinations and are subject to the appeals process.

Section 422.566(b) lists actions that are organization determinations, and with two exceptions, follows the previous HMO regulation at § 417.606(a). The exceptions involve the inclusion as organization determinations of decisions involving—(1) optional supplemental benefits, and (2) payment for post-stabilization services.

Section 422.568 includes the standard time frame and notice requirements for organization determinations. Under § 422.568(a), an M+C organization must make a determination with respect to an enrollee's request for service as expeditiously as the enrollee's health status requires, and in no case later than 14 calendar days after the organization receives the request. An M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee; (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must include a written justification for the extension in the case file.

Section 422.568(b) specifies that time frames for requests for organization determinations on payment issues are identical to the "prompt payment" requirements set forth under § 422.520. Thus, for issues relating to payment, the requirements are as follows: (1) For "clean claims," an M+C organization

must make a determination regarding the claim within our current "clean claim" rules, that is, 95 percent of clean claims must be paid within 30 calendar days after receipt of the request for payment; (2) for all other claims, an M+C organization must make a determination regarding the claim within 60 calendar days after receipt of the request for payment. (Under existing § 422.500, "clean claims" are claims that have no defect, impropriety, lack of any required substantiating documentation, or particular circumstances requiring special treatment that prevents timely payment. See section II.K of this preamble for a further discussion of rules regarding clean claims and prompt payment.)

Consistent with section 1852(g)(1)(B) of the Act, § 422.568(c) and (d) require that an M+C organization issue written notification for all denials of a request for services, including the specific reasons for the denial in understandable language, information regarding the enrollee's right to either an expedited or standard reconsideration, and a description of both the expedited and standard review processes, as well as the rest of the appeals process.

Sections 422.570 and 422.572 set forth the requirements for M+C organizations with respect to expedited determinations. Sections 422.570(a) (for expedited organization determinations) and 422.584(a) (for expedited reconsiderations) allow either an enrollee or a physician to request an expedited organization determination or reconsideration, regardless of whether the physician is affiliated with the M+C organization. Under § 422.570(a), any physician can request an expedited organization determination. Section 422.584(a) provides that a physician who requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative.

Section 422.570(b)(2) specifies that a physician may provide written or oral support for a request for expedition, and under § 422.570(c)(2)(ii), requests for expedited organization determinations that are made or supported by a physician must be granted by the M+C organization if the physician indicates that the enrollee's health could be jeopardized.

Under § 422.568(d)(1), an M+C organization must automatically transfer a denied request for an expedited organization determination to the standard 14-day time frame described in § 422.568(a), and § 422.570(d)(2)(ii) requires an M+C organization to inform the enrollee of the right to file a grievance if he or she disagrees with the

M+C organization's decision not to expedite. We also require under § 422.570(c)(1) that an organization establish an efficient and convenient means for individuals to submit oral or written requests for expedited organization determinations and document any oral requests. We clarify under § 422.570(b)(1) that procedures may involve submitting a request to another entity responsible for making the determination, as "directed by the M+C organization."

Section 422.572(a) requires an M+C organization to notify the enrollee (and the physician involved, as appropriate) of an expedited determination as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. Under § 422.572(b), an M+C organization may extend the 72-hour deadline for expedited review by up to 14 calendar days if the enrollee requests the extension or if the organization finds that additional information is needed and the delay is in the interest of the enrollee. Also under this section, an M+C organization must notify an enrollee of a determination as expeditiously as the enrollee's health care needs require but no later than upon expiration of the extension.

Provisions in both §§ 422.570(f) and 422.584(f) prohibit an M+C organization from taking or threatening to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited organization determination or reconsideration.

Section 422.574 identifies the parties to an organization determination, which include the enrollee, certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and any other entity (other than the M+C organization) determined to have an appealable interest in the proceeding.

4. Reconsiderations by an M+C Organization or an Independent Review Entity (§§ 422.578 through 422.616)

If a decision regarding a request for payment or service is unfavorable (in whole or in part) to the enrollee, the enrollee or any other party to an organization determination as listed in § 422.574 who is dissatisfied with the organization determination may request that the M+C organization reconsider the decision. Reconsiderations represent the first step in the appeals process. The reconsideration process encompasses both standard and expedited reconsiderations, as described under §§ 422.582 and 422.584. The time frame and notice requirements for

reconsiderations are set forth under § 422.590.

Section 422.590(a)(1) requires that, with respect to standard reconsiderations concerning requests for service, an M+C organization must issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the request for reconsideration. As with organization determinations, § 422.590(a) also provides that the M+C organization may extend the time frame by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information, and how the delay is in the interest of the enrollee. Under § 422.590(b)(1), for standard reconsiderations involving requests for payment, the M+C organization must issue any fully favorable determination no later than 60 calendar days from the date it receives the request for the reconsideration.

In the case of expedited reconsiderations (which involve only requests for services), § 422.590(d)(1) requires that an M+C organization issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 72 hours after it receives the request for expedited reconsideration, again with the possibility of a 14-day extension as described in § 422.590(d)(2). If, however, the M+C organization's reconsideration results in an affirmation, in whole or in part, of its original adverse organization determination, this decision is automatically subject to further review by an independent entity contracted by us. (Again, the time frame within which an M+C organization must reconsider a standard or expedited case has been tied to the enrollee's health needs for service requests, subject to either a 30-day or 72-hour maximum (with a possible 14-day extension), while the time frame remains at 60 days for reconsideration requests involving payment.)

Section 1852(g)(4) of the Act requires us to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm, in whole or in part, an M+C organization's denial of coverage. Thus, unless an M+C organization completely reverses its coverage denial, it must prepare a written explanation, and refer the case to the independent review entity for a new and impartial determination concerning the payment or service at issue.

Section 422.590(a)(2) provides that for standard requests for services, an M+C organization that makes a reconsidered determination affirming, in whole or in part, its adverse organization determination, must send the case file to the independent review entity as expeditiously as the enrollee's health requires, but no later than 30 calendar days from the date the M+C organization receives the request for a standard reconsideration (or the date of an expiration of an extension). For standard requests for payment, § 422.590(b)(2) allows the M+C organization 60 calendar days from the date it receives the request to send the case to the independent review entity. In instances involving expedited requests for reconsideration, § 422.590(d)(5) requires that the M+C organization forward its decision to the independent entity as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation of the adverse expedited organization determination.

Section 422.590(g)(2) requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by a physician with expertise in the field of medicine that is appropriate for the services at issue.

For the most part, the procedures outlined above were carried over into the M+C requirements from the existing part 417 standards. We also implemented several changes in the reconsideration requirements that are analogous to those described for organization determinations, such as the requirement under § 422.584(d)(1) that an M+C organization automatically transfer a denied request for an expedited reconsideration to the standard 30-day time frame described in § 422.590(a). In addition, § 422.590(e) requires that if an M+C organization refers a case to the independent entity, it must concurrently notify the enrollee of that action.

Consistent with section 1852(g)(4) of the Act, §§ 422.592 and 422.594 address reconsiderations by an independent entity. If the independent review entity's reconsidered determination is not fully favorable to the enrollee, subsequent review possibilities include ALJ and Departmental Appeals Board (DAB) hearings, as well as judicial review. Provisions addressing these forms of review are set forth in §§ 422.600 through 422.616.

5. Effectuation of a Reconsidered Determination (§ 422.618)

Section 422.618 established effectuation requirements for payments

and services. For reconsiderations of requests for payment, when an M+C organization reverses its adverse organization determination, it must pay for the service no later than 60 calendar days after the date that the M+C organization receives the request for reconsideration. For reconsiderations of requests for service, when an M+C organization reverses its adverse organization determination, it must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the M+C organization receives the request for reconsideration, or no later than upon expiration of a 14 calendar day extension. When the M+C organization is reversed by the independent review entity or higher review level, the M+C organization must pay for, authorize, or provide the service as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date the M+C organization receives notice reversing its organization determination.

6. Notification of Noncoverage in Inpatient Hospital Settings (§§ 422.620 and 422.622)

Sections 422.620 and 422.622 pertain to M+C organizations' responsibilities in connection with inpatient hospital care. The existing provisions clarify that inpatient services continue to be covered only until written notice of noncoverage in situations in which the hospital admission was authorized in the first instance by the M+C organization, or in which the admission constituted urgent or emergent care. This notice now is issued to enrollees by the M+C organization, either directly or through the hospital, with the concurrence of the attending physician responsible for the enrollee's hospital care. Section 422.622 provides enrollees with the right to seek PRO review by noon on the day after the receipt of the notice if the enrollee believes that he or she is being discharged too soon. The enrollee bears no additional financial liability for care furnished during the period of PRO review, regardless of the proposed date of discharge. If the enrollee misses the noon deadline for requesting PRO review, the enrollee may file an expedited appeal with the M+C organization. Unlike the PRO review process, there is no financial protection afforded to the beneficiary while the M+C organization conducts its review.

Subpart M Comments and Responses

7. Definitions and General Provisions

Comment: One commenter suggested that the definition of appeal should read as follows: "Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care or health care services an enrollee is entitled to receive, including delay in providing or approving the health care or health care services."

* * *

Response: We generally agree with the commenter and are revising the definition in § 422.561 to incorporate most of the commenter's suggested language. We are omitting "health care" as we believe the language duplicates and is inferred in the meaning of "health care services." We are adding the term "arranging for" to the definition. Therefore, we are adopting the following revision to the appeals definition: "Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review."

8. Grievances (§§ 422.564, 422.570, and 422.584)

Comment: Two commenters contended that we should not establish prescriptive grievance procedures, while several supported establishing standards. One commenter stressed that any grievance requirements we imposed should be consistent with those applied by accrediting organizations, so that M+C organizations would not have to change current procedures to a great extent. The commenter expressed concern about State privacy requirements, as M+C organizations currently are prevented under State law in some cases from providing specific information on how grievances have been resolved. Rather, in these cases, organizations are only allowed under State law to inform enrollees that the complaint has entered the tracking system. One commenter stated that grievance procedures should be flexible, given our interpretation of preemption provisions. One commenter strongly

encouraged establishing mandatory time frames for the resolution of grievances as soon as possible, and suggested that the time frames and notices mirror those applicable to organization determinations (including expedited time frames). Two commenters suggested a 30-calendar day time frame to render a grievance decision, with an opportunity for a 14-calendar day extension for peer review. Both commenters stated that for non-quality of care grievances, both oral and written, M+C organizations should be encouraged to provide personalized service. One commenter believes that if a denial of expedited consideration is considered a grievance, then the grievance procedure must have a mechanism to resolve the dispute within 24 hours, so that an inappropriately denied request for expedited consideration can proceed quickly. Additionally, a commenter asserted that M+C organizations should be required to provide clear, accurate and standardized information concerning grievance and appeal procedures. One commenter asked who will determine which route is more appropriate for the beneficiary in pursuing a remedy to a complaint, since we acknowledge that the same claim or circumstances that give rise to an appeal may have elements of a grievance. This may cause the beneficiary to be unclear as to which route is most appropriate.

Response: Currently, M+C organizations are required under section 1852(f) of the Act and § 422.564 to provide "meaningful procedures" for hearing and resolving grievances. In the interim final rule (63 FR 35030), we requested comments on whether to establish requirements for grievance procedures, and indicated that we would consider prescribing specific requirements for grievances through a forthcoming notice of proposed rulemaking. As anticipated, commenters indicated varying approaches to organization-level grievance procedures. As noted in the interim final rule, we believe that all parties would benefit from subjecting proposed grievance procedures to public notice and comment, and we will do so as part of the notice of proposed rulemaking we are in the process of developing. Thus, we are not including additional grievance requirements in this final rule.

Comment: One commenter disagreed with treating a denial of an expedited determination as a grievance rather than permitting an appeal of such a denial. The commenter argued that such a denial should be considered an adverse organization determination on the

health care services an enrollee is entitled to receive, and should be appealable. This commenter contended that denying a request for an expedited determination is not analogous to the example of a grievance provided in the preamble to the interim final rule.

Response: The preamble to the interim final rule cites the regulatory definition of a grievance at § 422.561—that is, a grievance is “any complaint or dispute other than one involving an organization determination.” The revised definition of organization determination at § 422.566(b) (discussed in detail below) includes determinations regarding payment or services that the enrollee believes should be furnished or arranged for by the M+C organization, and discontinuations of a service if the enrollee believes that the service continues to be medically necessary. In this context, we believe that the term “services” clearly refers to health care services, as opposed to member or customer services, that the M+C organization provides under its contract. Expedited review is a process provided by the M+C organization versus a health care service which is subject to appeal, such as mandatory and optional supplemental benefits. We believe there is a clear distinction between a substantive decision whether benefits should be covered and a procedural decision as to the timing of making such a substantive decision. Indeed, we do not believe that the latter type of determination falls within the statutory language establishing the reconsideration and appeals process, which refers to situations in which the enrollee believes he or she is entitled to services, and to the amount of enrollee liability for services. Therefore, we will continue to require that an organization’s denial of expedition generally will be subject to the organization’s grievance procedures. We intend to monitor the frequency with which M+C organizations deny requests for expedited determinations.

Comment: One commenter believes that a beneficiary should be able to appeal a disenrollment by an M+C organization, rather than simply being able to utilize the grievance process, as provided in § 422.74(d)(2)(ii). In addition, the commenter asserted that decisions on disenrollment should not be left to the M+C organization. Another commenter suggested that we permit a beneficiary to appeal a decision as to whether he or she is entitled to a special enrollment period, and that an M+C organization’s decision regarding enrollment or disenrollment, based on the circumstances in § 422.62, should be

considered an organization determination subject to appeal.

Response: While we do not believe all disenrollment decisions require an appeals process, we recognize the need in some instances, in particular, when a M+C organization disenrolls an individual for disruptive behavior. Accordingly, in § 422.74(d)(2), M+C organizations must forward all proposed disenrollments for disruptive behavior to HCFA for administrative review. M+C organizations may not disenroll an individual unless HCFA approves of the decision. With respect to the other, limited circumstances under which a M+C organization has the option to disenroll an individual (that is, failure to pay premiums, or fraud), the enrollee has a right to file a grievance if he or she disagrees with an M+C organization’s decision. We believe that this approach to these issues has been proven to be sufficient over the years. As indicated above, we will monitor M+C organizations’ implementation of their grievance procedures to ensure that they are meaningful. Our monitoring will include investigating a complaint from a beneficiary who believes that the M+C organization did not properly handle a complaint about one of the issues discussed by the commenters above.

9. Organization Determinations (§ 422.566)

Comment: We received numerous comments on various aspects of the definition of an organization determination, including requests for clarification of whether specific types of situations constitute organization determinations. For example, several commenters suggested that reductions in service should be included in the list of actions that constitute organization determinations. The commenters asserted that when services are reduced, beneficiaries receive no notice and are completely unaware of their ability to contest this reduction through the appeals process. Some commenters noted that the vacated 1997 *Grijalva* order expressly required written notice for a reduction of services. One commenter believes that notice of a reduction in services is of particular importance in the delivery of home care and therapy services. Some commenters believe that § 422.566(b)(4), which provides for notice of a termination only if the enrollee disagrees with the determination that the service is no longer medically necessary, is inconsistent with other Medicare regulations, which the commenter believes require written notice for discontinuation of inpatient services both in a hospital or a skilled nursing

facility, regardless of whether the beneficiary agrees with the decision. One commenter suggested that the regulations require M+C organizations to send notices one day in advance of termination, reduction, suspension or delay in services. One commenter suggested that § 422.566(b) should include a fifth category indicating that the failure of the M+C organization to approve or provide health care or health care services in a timely manner, or to provide the enrollee with timely notice of an organization determination, constitutes an organization determination. Additionally, some commenters suggested that if, in the future, we require that notices of appeal rights must be given in instances in which the current definition of organization determination is not met, we should incorporate the requirement into the regulations.

Response: As these commenters suggested, we believe there is a need to revise § 422.566(b) to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights. Therefore, we are revising § 422.566(b) as follows:

- Paragraph (b)(1), which concerns payment for out-of-plan services, is revised by adding payment for out-of-area renal dialysis to the existing list of such services (which already included emergency, urgently needed, and post-stabilization services);
- Paragraph (b)(3) includes additional language to clarify that an organization’s refusal to pay for or provide services “in whole or in part, including the type or level of services” can constitute an organization determination if the enrollee believes they should be furnished or arranged for;
- Paragraph (b)(4) is restructured to indicate that a discontinuation of services when an enrollee believes that the services continue to be medically necessary constitutes an organization determination (thus eliminating any implication that an organization must make a formal determination as to medical necessity to give rise to appeal rights); and
- New paragraph (b)(5) is added to specify that another situation that constitutes an organization determination is an MC organization’s failure to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or failure to provide the enrollee with timely notice of a determination, if such a delay would adversely affect the health of the enrollee.

Thus, we agree that a reduction in services can be considered an

organizational determination that is subject to appeal. To the extent that a reduction results in an enrollee no longer receiving services to which the enrollee believes he or she is entitled, this would be subject to appeal under the language in the first sentence in section 1852(g)(5) of the Act, which addresses appeals based on failure to receive a health service. Also, since a reduction in services could constitute a “[d]iscontinuation” of services to the extent they were no longer being provided, these cases could fall within the language in § 422.566(b)(4). Finally, to the extent that the organization was refusing to continue to provide all or part of the services the enrollee believes should be furnished, and the enrollee has not received the services, this would also fall within the language in § 422.566(b)(3).

Examples of other situations that are intended to fall within the clarified definition of an organization determination include:

- A physician requests approval of 10 home health visits, but the organization approves only five visits (even though Medicare allows more than five visits);
- An organization approves a referral to a specialist, but the specialist it designates does not have experience in treating the enrollee’s rare condition;
- A physician requests inpatient surgery for a patient because of the patient’s history of complications with anesthesiology, but the organization will approve only outpatient surgery; or
- Although an organization agrees to pay for an in-network service, it imposes greater cost-sharing than the enrollee believes is permissible.

We believe that each of these examples fit within the statutory language at section 1852(g)(1)(A) and (B) of the Act that establishes that an M+C organization must have an appeals procedure for determinations as to whether an enrollee “is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service.” Thus, the purpose of the revisions to § 422.566(b) is not to expand on our interpretation of what types of situations constitute organization determinations but rather to provide additional insight into how we continue to interpret the intent of the applicable statutory provisions.

As we explained above, we are developing a proposed regulation that would provide additional specific guidance as to when a reduction in services gives rise to the obligation to provide a written notice. This has been an extremely difficult issue to resolve, and despite extensive consultations

with beneficiary advocates, industry representatives, and State officials, we still have not been able to reach conclusions as to standards beyond those already in the statute and regulations and quoted above. Again, we will address the issue in connection with a separate rulemaking that is being developed in close consultation with all affected groups. Finally, as commenters suggested, if in the future we believe that it is necessary to require notices of appeal or other rights for situations other than organization determinations, we would do so through notice and comment rulemaking.

Comment: Some commenters requested confirmation that a discontinuation on grounds other than medical necessity is not an organization determination.

Response: As noted above, we have made a minor change to § 422.566(b)(4) to clarify that any discontinuation situation in where the enrollee believes that the services continue to be medically necessary constitutes an organization determination, rather than only those situations where a formal medical necessity determination is involved. Moreover, § 422.566(b)(3) continues to cover any refusal to provide services (including a refusal to *continue* to provide services) that the enrollee believes should be provided. While many cases may involve a medical necessity judgment, others may involve a question of how a limit on benefits (including additional or supplemental benefits) applies to given facts. In some cases, the case for noncoverage on grounds other than medical necessity may be so clear-cut that an appeal would not be requested. For example, in a case in which a service is expressly limited to a fixed number of days, and there is no dispute as to how many days the service has been provided, it is unlikely that the enrollee would “believe” that the M+C organization is obligated to cover days beyond the limit. In other cases, however, there may be ambiguities as to how a limit on benefits is to be interpreted, or applied to a given set of facts, or there may be a dispute as to facts relevant to whether the benefit is covered. In these cases, the beneficiary should have the right to a reconsideration of a denial, so that these issues could be addressed on appeal.

10. Written Notice (§§ 422.566, 422.568, 422.572, and 422.620)

Comment: Several commenters believe that the regulations at §§ 422.566 and 422.568 do not make clear that a written notice is required for discontinuations of services.

Response: Except in the case of inpatient hospital care, written notice currently is not required for all discontinuations in services. We believe that our policies on what constitutes a denial in the case of a discontinuation of service (other than in the case of inpatient hospital care) are set forth in the regulations concerning organization determinations. According to revised § 422.566(b)(4), discontinuation of a service is considered to constitute an organization determination “if the enrollee believes that continuation of the services is medically necessary.” Therefore, if an M+C organization discontinues coverage, and an enrollee indicates that he or she believes that the services continue to be necessary, this action would constitute an organization determination for which a written notice must be provided. We recognize that there may be circumstances that make it difficult to tell whether a written notice is required in a particular case. We therefore are developing a notice of proposed rulemaking that would address this issue, and clarify rules for M+C organizations and beneficiaries.

Comment: Several commenters suggested that written notice should take place in all instances where services are reduced or discontinued, not only in instances where the enrollee has indicated disagreement. One reason provided for this suggestion is that it would ensure that enrollees always would receive notice of their appeal rights, even if they have not formally objected to the reduction or discontinuation. Another reason given was that this would make the rule consistent with the rule that applies to hospital inpatient discharges. Other commenters suggested that M+C organizations should provide written notice when services actually terminate, or when services discontinue prior to the time for which the M+C organization initially authorized services. Two commenters suggested that we require notice when there are financial implications to the enrollee.

Other commenters supported the current requirement that the M+C organization provide notice when the enrollee disagrees that the services are no longer medically necessary. One commenter stated that where there is no disagreement, it is wholly inappropriate to provide notice and appeal rights. Instead, it is more appropriate to provide notice at the beginning of a course of treatment. One commenter recommended that we provide advance notice for reductions and terminations in writing, describing the basis for the decision and appeal rights. Some

commenters stated that providing detailed notice in all situations would be confusing, burdensome, and intrusive upon the physician/patient relationship. Two commenters recommended we include in this subpart notice requirements for discharge from a SNF.

Response: We recognize that the issue of when it is appropriate for M+C organizations to issue written notice for organization determinations that involve reductions and discontinuations of services is a controversial one. As stated in the preamble to the June 26, 1998 interim final rule (63 FR 35030), we are developing proposed regulations that would further clarify these requirements. At this time, however, we believe that the current regulations serve to balance the need for adequate notice with the potential for inappropriate burdens or beneficiary confusion that might ensue if notice were provided in all cases.

To eliminate confusion, we want to point out that written notice is always required for inpatient hospital discharges regardless of whether the enrollee agrees with the discharge decision. The issuance of a notice to an enrollee prior to an inpatient hospital discharge required under § 422.620 is a separate requirement that should not be confused with the provisions at §§ 422.566(b)(4) and 422.568(c). We will address the SNF issue in the forthcoming proposed rule.

Finally, as the commenters suggested, we recognize the potential compliance difficulties and burden associated with existing § 422.568(c), which requires that if an M+C organization denies services or payment, in whole or in part, it must give the enrollee a detailed written notice that meets the content requirements of § 422.568(d) (such as stating the specific reason for the denial and describing the available appeals procedures). We understand that in practice, plan practitioners generally are responsible on behalf of M+C organizations for issuing these detailed notices to their patients, given that most care decisions about future care are made at the practitioner level; and we agree that this practice may be unnecessarily burdensome and intrusive on the practitioner/patient relationship. Moreover, we can understand that requiring M+C organizations to ensure that appropriately detailed notices are given to enrollees in practitioners' offices may be difficult to monitor and enforce in all circumstances.

Therefore, we have revised the provisions at §§ 422.568(c) through (e) to establish a process under which—(1) practitioners routinely notify enrollees

at each patient encounter of their right to receive a *detailed* notice about their services from the M+C organization itself, and (2) when an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, the M+C organization must give the enrollee a detailed written notice of the determination, consistent with existing content requirements.

The practitioner's notification must inform enrollees of their right to receive a detailed notice from the M+C organization and provide enrollees with all information necessary in order to contact the M+C organization. Consistent with other notification requirements set forth in subpart M (for example, under existing § 422.568(d)(4) or under § 422.572(e)(2)(ii)), we also specify that the content of the practitioner's notification must comply with any other requirements established by HCFA. We are now developing standardized language for use by affected practitioners, and will provide an opportunity for public comment through OMB's Paperwork Reduction Act process. Once that process is completed, we intend to provide further guidance on the content and form of the required practitioner notice. We believe that this requirement will serve to improve M+C organizations' ability to assure implementation of the requirement for detailed written notices while at the same time reducing the administrative burden on practitioners by freeing them from the obligation to routinely provide such detailed notices to their patients.

11. Time Frames (§§ 422.568, 422.572, 422.590, 422.592, 422.618)

Comment: Several commenters asserted that the standard determination time frames are too long, with some commenters specifically suggesting the time frame of 5 working days that was adopted by a district court judge in a since-vacated March 3, 1997 order in *Grijalva v. Shalala* (a class action lawsuit filed by Medicare HMO enrollees in 1993, challenging, among other things, the appeals procedures that applied under section 1876 of the Act and part 417). One commenter suggested that upon receipt of complete information, a decision should be rendered within 2 business days. Other commenters stated that the M+C time frames are too short. One commenter suggested that we require M+C organizations to make a good faith effort to meet time frames as opposed to a requirement that M+C organizations

must meet absolute time frames. A number of other commenters supported the time frames established through the M+C interim final regulation.

Response: Before deciding to incorporate into the interim final rule reductions in the time frames within which M+C organizations are expected to render standard organization determinations and reconsiderations for service requests, we consulted with representatives of the managed care industry and beneficiary advocacy community, and conducted extensive research on the subject of organization-level resolution time frames. All groups with which we consulted agreed that the 60-day time frames provided for under the HMO regulations in part 417 were too long. Reports from independent organizations, such as the Physician Payment Review Commission, the General Accounting Office, and medical journals also advocated the reduction of standard time frames. Additionally, we realized the 60-day time frames in part 417 were based on the original fee-for-service Medicare appeals process, which is mostly retrospective. We were aware that new time frames needed to account for the fact that pre-service requests for organization determinations exceed the number of retrospective requests, and that reduced time frames are of critical importance when an individual is awaiting prior authorization for a service. Further, public comments received prior to publication of the M+C interim final rule indicated strong support for a reduction in time frames.

In view of the range of opinions contained in the comments on the M+C interim final rule, we believe that we succeeded in establishing an appropriate middle ground for the maximum time frames. It has also been reported to us that the majority of organizations make decisions within our reduced time frames. Only one commenter contended that the 14-day time frame could not be met as a general rule. We believe that the opportunity for up to a 14-day extension to the time frames for service-related requests allows the M+C organization adequate time in which to render a determination. We also believe that the new 14 and 30 calendar day time frames are appropriate from both consumer protection and industry feasibility standpoints. The medical exigency standard, which requires that decisions be rendered as expeditiously as an enrollee's health requires, provides for a quicker response where appropriate. Likewise, the opportunity for up to a 14-day extension for both organization determinations and reconsiderations

permits M+C organizations additional time to make a coverage decision when appropriate; for example, an M+C organization may extend the time frame at an enrollee's request, or if additional medical documentation is necessary and the M+C organization justifies the reason for the extension.

Comment: Another commenter who advocated reductions to reconsideration time frames suggested that we also reduce the time frame within which M+C organizations are permitted to forward case files to the independent review entity under the standard appeals process.

Response: M+C organizations must forward standard reconsideration cases to the independent review entity within the time frames permitted for resolution of standard requests. That is, when an M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must make the determination and send the case file for external review as quickly as the enrollee's health condition requires but no later than within 30 calendar days for service requests, or within 60 calendar days for payment requests. Time frames begin on the date the organization received the request for a standard reconsideration. Since time frames for submitting case files to the independent entity are incorporated into the resolution time frames, and we are not reducing time frames for standard reconsiderations, it would not be appropriate to reduce the time frames for submitting information to the independent review entity.

Comment: One commenter stated that we should provide a definition of "good cause" for extensions of time frames. Another commenter suggested that we should clarify that a 14-day extension may be granted in any instance where an organization determination demonstrates a need for additional information.

Response: The regulations for both expedited and standard requests for organization determinations (§§ 422.568(a) and 422.572(b)) permit an M+C organization to obtain an extension "if the organization justifies a need for additional information and how the delay is in the interest of the enrollee". We believe that this standard is largely self-explanatory. As indicated in the preamble to the M+C interim final rule, the M+C organization must include written justification of the extension in the enrollee's case file. Although forthcoming operational instructions will provide further clarification of the M+C organization's ability to grant itself an extension, we would like to clarify

that a 14-day extension for service-related requests may be granted where an organization finds and notes in the enrollee's case file that it needs additional information to make a determination.

Moreover, to further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both §§ 422.568(a) and 422.572(b) that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision. Relatively few enrollees utilize the appeals process, and most organizations are able to make determinations on requests for services within 30 days. Therefore, we do not foresee that requiring M+C organizations to notify enrollees upon initiating an extension will create an undue burden on M+C organizations.

Comment: Some commenters supported the requirement that M+C organizations must make decisions "as expeditiously as the enrollee's health requires" (the "medical exigency" standard). In contrast, other commenters stated that the medical exigency standard was vague and uncertain, and likely to cause every reconsideration to become expedited.

Response: We believe that the "medical exigency" standard is needed to ensure that M+C organizations will not routinely avail themselves of the maximum time frames for all decisions. Although the expedited review process incorporates the medical exigency standard, this standard is separate and distinct from the process M+C organizations use to handle cases in which a physician or the M+C organization determines that an enrollee's life, health or ability to regain maximum function could be jeopardized in applying the standard time frames.

In our consultations with the public before publishing the M+C interim final rule, industry representatives advised us that each request is different; where some organization determinations are likely to require a 14-day time frame, and possibly 14 additional days, other decisions require less resolution time. Likewise, resolution of some reconsiderations will take up to 30 calendar days, and may require more time to gather additional information. The medical exigency standard requires M+C organizations to prioritize those cases where waiting for a decision is more likely to affect an enrollee

adversely. We interpret this standard as requiring that the M+C organization or the independent entity apply, at a minimum, established, accepted standards of medical practice in assessing an individual's medical condition. Evidence of the individual's condition can be demonstrated by indications from the treating provider or from the individual's medical record (including such information as the individual's diagnosis, symptoms, or test results). We established the medical exigency standard by regulation to ensure that M+C organizations would develop a system for determining the urgency of both standard and expedited requests for services, and give each request priority according to that system. That is, we intend that M+C organizations treat every case in a manner that is appropriate to its medical particulars or urgency, rather than systematically use the maximum time permitted for service-related decisions.

Also, as indicated in the preamble to the interim final rule (63 FR 35028), we continue to believe that the emphasis on the health needs of the individual enrollee is consistent with the statutory requirement that determinations be made on a timely basis. Thus, the fact that an organization makes a determination on a service-related issue within 14 days does not necessarily constitute compliance with the law or regulations if there is evidence that an earlier determination was necessary to prevent harm to the enrollee's health.

We intend to issue additional guidance on the medical exigency standards in a future operational policy letter.

Comment: Several commenters suggested shortening the maximum time frame for M+C organizations to pay for, or provide, services once the independent review entity has ruled in the beneficiary's favor. One commenter suggested the effectuation time frame should be reduced to 15 days. Another commenter expressed concern that the effectuation requirements in § 422.618 do not provide for shorter implementation periods for expedited appeals. One commenter observed that if an M+C organization completely reverses its organization determination on reconsideration of a request for service, the organization must authorize, or provide the service; however, given the fact that the enrollee must seek the service, it may prove difficult to ensure that the service has actually been provided. Thus, this commenter suggested that a letter authorizing the service should be sufficient.

Response: We agree with the commenters concerning the need for a reduction of effectuation time frames for both standard cases overturned upon review by the independent review entity, and expedited cases overturned by the M+C organization or the independent review entity. However, we believe that since M+C organizations are permitted to authorize, provide or pay for the service in order to effectuate the decision, there is no need to establish a separate requirement for an authorizing letter. Based on these comments, we are revising § 422.618 to reduce the time frame within which M+C organizations must pay for, authorize or provide services to enrollees following a decision rendered by the independent review entity. For service-related requests, the revised language states that “the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee’s health condition requires, but no later than 14 calendar days from that date.” For requests regarding payment, we are reducing the time frame to effectuate the independent review entity’s determination from “no later than 60 calendar days” to “no later than 30 calendar days.” We continue to maintain a distinction for payment-related appeals because most billing practices are on a 30-day cycle.

We also agree with the comments that expedited effectuation requirements should be incorporated into the regulations. To promote consistency in implementation, and to ensure enrollees receive the services they need as quickly as possible, we are establishing a new § 422.619 to require M+C organizations to effectuate overturned, expedited determinations as quickly as necessary, but no later than within 72 hours. Under the new provision, if the M+C organization reverses its original adverse organization determination, in whole or in part, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee’s health condition requires, but no later than 72 hours from the date it receives the request for the determination.

Where the independent entity reverses, in whole or in part, the M+C organization’s initial expedited determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee’s health condition requires, but no later than 72 hours from the date it receives notice reversing the determination. In instances where the

independent review entity expedites certain cases on its own accord (for example, where an enrollee or physician did not originally request an expedited appeal at the M+C organization level, but the independent review entity determines an expedited appeal is warranted), the expedited effectuation requirements of § 422.619 still apply.

If the ALJ or higher level reviewer reverses the independent review entity’s expedited reconsidered determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee’s health requires, but no later than 60 calendar days from the date of the decision.

Comment: Several commenters urged that we incorporate the review time frames for the independent review entity into the regulations text. Section 422.592(b) provides that an independent outside entity must conduct reconsideration reviews “as expeditiously as the enrollee’s health condition requires but must not exceed the deadlines specified in the contract.” One commenter noted that the contract with the independent outside entity may change each time it is negotiated, and that the general public is not informed of such negotiations, or the time frames produced by these negotiations. Thus, this commenter believes that regulations should specifically impose appropriate time limits on the independent review entity, and the time limits should be consistent with those specified in the vacated 1997 *Grijalva* order. One commenter expressed concern that the public has no remedy when the independent review entity fails to comply with time frames in the contract. This commenter added that the public plays no role in contract negotiation through which the independent review entity’s time limits will be determined; and therefore, there is no assurance that an appropriate time limit will be imposed. One commenter recommended that we contract with PROs for the expedited review process instead of our current contractor, the Center for Health Dispute Resolution (CHDR). (PROs are organizations under contract with us to perform utilization and quality review of Medicare services generally, and review of the quality of services furnished by M+C organizations to their enrollees.) There was also concern about the notices provided by the independent review entity. Some commenters suggested that § 422.594 specify that the notice should be written in “understandable language,” as provided in § 422.568. Additionally, these commenters believe that the notice should also inform the enrollee about the PRO complaint

process under section 1154(a)(14) of the Act.

Response: The time frames for the independent entity’s review currently are the same as those time frames within which M+C organizations are required to decide standard and expedited cases, as detailed in the chart provided in the interim final rule (63 FR 35024). The time frames appear in our contract with the independent entity (as opposed to the regulation), however, to provide flexibility in the case of an unanticipated increase in the volume of appeal cases—since the independent contractor reviews cases from organizations nationwide. We have provided public notice of the time frames in the interim final rule and again in this rule. We agree with the commenters that beneficiaries should be informed of any changes that we might make to the current time frames, and will inform beneficiaries if these time frames are changed.

Additionally, we agree with one of the recommended changes to the independent entity’s reconsideration notice, and are amending § 422.568 to require that the notice be written in “understandable language.” We also will consider issuing instructions to require the independent entity to advise an enrollee of his or her right to review by the PRO for quality of care concerns; (the same requirement on M+C organizations is set forth via model notice instructions).

12. Expedited Organization/ Reconsidered Determinations (§§ 422.570, 422.572, 422.584, and 422.590)

Comment: Several commenters expressed concern with § 422.572(d), which provides that the 72-hour time period under § 422.572(a) does not begin until medical information is received from noncontract providers where such information is required. One commenter stated that such an open-ended requirement poses an unreasonable risk of delay for the enrollee; especially in cases where time is of the essence, this provision could allow a decision to be postponed indefinitely. Another commenter suggested that M+C organizations should be required, at a minimum, to contact the noncontract provider within 24 hours of the initial request for an expedited reconsideration in order to request the necessary information from the noncontract provider and provide a fax number where the information can be submitted. Additionally, the commenter suggested that the enrollee, the representative, and the physician should be contacted to: Explain the

delay, inform them of the information needed, and provide them with a fax number. One commenter stated that the regulations should place the burden on the M+C organization to make prompt, good faith efforts to communicate with the noncontract provider to obtain the needed information. Additionally, information from noncontract providers should be provided within the 14-day extension period and under the same conditions that an extension would be granted in other circumstances. However, one commenter stated allowing an M+C organization to grant itself a 14-day extension beyond the 72-hour time frame gives the M+C organization too much additional discretion. This commenter stressed that an M+C organization will always state that it needs more than 72 hours, particularly if treatment will be expensive.

Response: We largely agree with the commenters, and are revising the regulation text to ensure that M+C organizations must make determinations within the same expedited time periods for cases involving noncontract providers. Accordingly, we are revising §§ 422.572(d) and 422.590(d)(4) to eliminate the provisions indicating that the 72-hour period begins when the organization receives information from the noncontracting provider. Instead, the regulations will require the organization to meet the same time frames set forth in §§ 422.572(a), (b), and (f) for expedited organization determinations and §§ 422.590(d) and (f) for expedited reconsiderations regardless of whether the M+C organization must request information from noncontracting providers. We agree that in situations where either a physician or the M+C organization has already determined that an expedited decision is crucial, open-ended time frames may put the enrollee at risk. We likewise are incorporating into § 422.572(d) the recommended provision for expedited reviews that requires the M+C organization to request any necessary information from the noncontract provider within 24 hours of the initial request for expedition. We continue to require noncontract providers to make “reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required time frames.” We believe an opportunity for an M+C organization to take up to a 14-day extension under the 72-hour expedited review process provides the M+C organization with a reasonable opportunity to obtain

information from non-contract providers. We will monitor M+C organizations to ensure M+C organizations do not routinely, or unnecessarily, avail themselves of the 14-day extensions. Where appropriate, M+C organizations must notify the physician involved; M+C organizations are always required to notify enrollees of the decision, whether the decision is adverse or favorable to the enrollee, in accordance with the regulation. However, we do not agree that the M+C organization must always contact or notify the enrollee’s physician.

Comment: Several commenters stated that the criteria for deciding whether a determination must be expedited may be too rigorous. Some commenters suggested that we revise §§ 422.570(c)(2) and 422.584(c)(2) to reflect language from the district court’s vacated order in the *Grijalva* case, under which reconsiderations were to be expedited “when services are urgently needed.” The district court provided the examples of when acute care services are being denied or terminated, certain types of nursing facility care, certain types of home health and therapy services, and denials of certain types of non-cosmetic surgery. This commenter suggested that the regulation state that expedited consideration may be granted, in certain circumstances, upon lay evidence and without a request by the physician. One commenter contended that the regulations should clearly articulate what constitutes “seriously jeopardizing the enrollee’s life, health, or ability to regain maximum function.” The commenter argued that a more specific definition should be provided that takes into account both a substantial risk of an adverse outcome, and a small (but significant) risk of a serious and adverse outcome such as permanent disability or death. Some commenters expressed concern that if an enrollee does not obtain physician support to expedite a determination, the M+C organization has broad discretion in deciding whether to expedite.

Response: We do not believe that the adoption of the “urgently needed” standard from the vacated *Grijalva* order would be appropriate. First, we believe it is too broad and vague. Second, the term “urgent” is already used in connection with “urgently needed services” (for which enrollees do not need to obtain prior authorization). Using the same term here could cause unnecessary confusion. We also believe that the “serious jeopardy” standard is sufficiently clear. It is unclear how we could expand on what is meant by “serious jeopardy” to an enrollee’s “life” (that is, could put his or her life

in serious jeopardy), “health” (that is, could put his or her health in serious jeopardy), or “ability to regain maximum function” (that is, could put his or her ability to regain maximum function in serious jeopardy). We believe that the commenter’s suggestion that the requirement to expedite a case in which there is a “significant” risk of a “serious and adverse outcome such as permanent disability” is already addressed in language referring to “seriously jeopardizing the enrollee’s * * * ability to regain maximum function.” With respect to the commenter’s suggestion that the regulations provide for cases to be expedited based on “lay evidence” (that is, in the absence of the involvement of a physician), this is already required under section 1852(g)(3)(B)(ii) of the Act “if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function.” The interim final rule and this final rule similarly provide for expedition without the need for a physician’s involvement. (See §§ 422.570(a) through (b), and 422.584(a) through (b).) Although this decision is made by the M+C organization in the absence of a physician’s involvement, the decision is subject to the grievance process, and we will monitor M+C organizations closely to ensure that they are expediting cases where appropriate.

Comment: Several commenters strongly urged the removal of the requirement that physicians requesting an expedited appeal must be acting as an enrollee’s authorized representative. Commenters contended that the regulation as written is inconsistent with their view of statutory intent, intrudes in the doctor-patient relationship, and could present a problem for incapacitated enrollees.

Response: We agree that a physician who requests an expedited reconsideration on behalf of an enrollee should not have to be formally appointed as the enrollee’s authorized representative. We initially included this provision based on our belief that the physician served a different role in the context of an organization determination versus an appeal. In the case of an organization determination, we regarded the physician as a provider who is requesting a service for his or her patient. On the other hand, in the context of a reconsideration, we viewed the physician as serving as the enrollee’s representative in the first

level of the appeals process. Thus, we believed the physician would need to be appointed by the enrollee in the same manner as any one else who served as a representative. However, in response to the above comments, we have reconsidered our position, and recognize the operational problems with requiring that physicians be authorized representatives when requesting expedited reconsiderations on an enrollee's behalf. For example, under the M+C program, each appeal request requires completion of a separate authorized representative form, which may cause an undue burden on physicians. For this reason and those set forth in the comment above, we have decided to revise § 422.584(a) by eliminating this requirement. Therefore, physicians may request expedited reconsiderations on a patient's behalf without being appointed as the enrollee's authorized representative.

We want to make clear, however, the distinction between a physician acting on behalf of the enrollee, and a physician who meets the conditions for being a party in his or her own right. When a physician seeks either a standard or expedited organization determination for services on behalf of the enrollee, the physician does not need to be an authorized representative. But, if the physician seeks a standard reconsidered determination for purposes of obtaining payment, then the physician must sign a waiver of liability, consistent with § 422.574(b).

Comment: One commenter suggested that the ability to request an expedited organization determination should be expanded. The commenter suggested the following options for expansion: (1) All health care professionals, (2) health care professionals that have been designated by a physician to carry out such tasks, or (3) all health professionals providing care in medically underserved areas. Another commenter suggested that we should permit an "authorized representative" to request an expedited determination.

Response: The statute explicitly lists enrollees and physicians as those permitted to request expedited organization determinations and expedited reconsiderations, (see sections 1852(g)(3)(a)(1) and (2) of the Act). We note that authorized representatives may request expedited determinations or reconsiderations, since the definition of "enrollee" in § 422.561 includes the enrollee's authorized representative. Therefore, the regulations already permit health care professionals who enrollees authorize as their representatives to request expedited organization

determinations and expedited appeals. As described in the previous comment, physicians now may make requests without being authorized representatives. We do not believe it would be appropriate, however, to grant health care professionals other than the enrollee's physician the right to make requests on the enrollee's behalf absent an authorization. There are so many potential health care professionals involved in a patient's care, this could create confusion, and potentially cause duplicate or conflicting requests.

Comment: One commenter suggested that we incorporate a separate notice requirement provision whereby, before deciding whether to expedite a determination, the M+C organization must notify the enrollee of the M+C organization's obligation to expedite any request for a determination that was accompanied by a physician's statement that "applying the standard time frame for making a determination could seriously jeopardize the life of the enrollee or the enrollee's ability to regain maximum function." Several commenters requested that we define "prompt oral notice" of a denied request for expedition, as provided in § 422.570(d)(2). This section provides that, if the M+C organization denies a request for an expedited determination, it must give the enrollee prompt oral notice of the denial and follow up within 2 working days with a written letter explaining their right to file a grievance. One commenter asked whether this meant the enrollee is supposed to receive the written notice within 2 working days of the decision, or that the organization is to mail it within 2 working days. Additionally, the commenters suggested that this section also specify that the enrollee be given the right to make an oral, immediate request for a reconsideration when given oral notice of denial, followed by written verification of the reconsideration request.

Response: M+C organizations are required under § 422.111(a)(8) to provide notice of grievance and appeal rights upon enrollment and at least annually thereafter. Thus, all enrollees should receive notice of the right to automatic expedition of determinations and reconsiderations when a physician supports the request. However, in a case in which an enrollee submits a request for an expedited organization determination or an expedited appeal, but does not indicate that the request was supported by a physician, we recognize that the enrollee may not have read the required notice carefully, and thus be unaware that a physician's support would make the expedition of

the request automatic. We therefore are revising §§ 422.570(d)(2) and 422.584(d)(2) to require that when an M+C organization denies a request for an expedited determination or reconsideration, its notification letter must inform the enrollee of the right to resubmit the request with a physician's support.

As noted above, upon denial of an enrollee's request for expedited review, existing regulations require an M+C organization to provide the enrollee with "prompt oral notice" of the denial, and follow up with a written letter within 2 working days. We believe that this is a reasonable requirement which indicates that an M+C organization must contact and advise the enrollee of the denial without delay. As suggested by the commenter, we are clarifying the regulations to indicate that subsequent to providing oral notice of the denial, M+C organizations must "deliver" to the enrollee, within 3 calendar days, a written letter that includes the information listed in the regulation at §§ 422.570(d)(2) and 422.584(d)(2). We interpret this provision as requiring an M+C organization to first orally notify an enrollee of a denial, and subsequently deliver written notice to the enrollee within 3 days after the decision. Note that we have revised the regulations at §§ 422.570(d)(2), 422.572(c), 422.584(d)(2), and 422.590(d)(3) to establish a requirement of 3 calendar days, rather than 2 working days. We believe this is a reasonable amount of time within which to require M+C organizations to deliver written notice enrollees (following the oral notice) of a denied expedited request, and that the change to calendar days will eliminate confusion over what constitutes a working day. This change is consistent with the general replacement of standards related to "working days" with "calendar day" standards throughout the M+C regulations.

We also wish to clarify that if an enrollee's request for an expedited organization determination is denied, the M+C organization will automatically transfer and process the enrollee's request under the standard process. If the M+C organization denies the request in whole or in part, the enrollee (or a physician on the enrollee's behalf) then has a right to orally request expedited reconsideration. The M+C organization continues to be responsible for documenting all oral requests in writing and maintaining the documentation in the case file.

13. Authorized Representative (§§ 422.561 and 422.574)

Comment: A commenter suggested that § 422.574, which addresses parties to the organization determination, should include surrogates under State law as a possible party to an organization determination. This commenter added that by excluding such surrogates, enrollees who are incapacitated and cannot appoint representatives may lack persons authorized to handle appeals on their behalf. Similarly, two other commenters stated that the “authorized representative” definition should be expanded to allow individuals who can act on behalf of an individual under State law to be authorized representatives. This commenter believes that the current definition is limited to an individual appointed under the Social Security Act, and requires completion of the Appointment of Representative form. The commenter believes that this requirement makes it difficult for those who have written Durable Power of Attorney to act in place of the beneficiary. Several commenters suggested that the definition of “enrollee” should not include an authorized representative. One commenter argued that an authorized representative is not the enrollee, since an enrollee is someone who is entitled to health services. Further, the commenter recommended that an authorized representative receive copies of all communications sent to the enrollee concerning the appeal.

Response: We agree with the commenters concerning the need to include those individuals appointed under State law (such as surrogates) in M+C requirements, as well as those with Durable Power of Attorney. For this reason, we are amending the definition of authorized representative at § 422.561 to include an individual authorized by an enrollee, “or under State law,” to act on his or her behalf in obtaining an organization determination, or in dealing with any of the levels of the appeals process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in subpart M. We believe that the revised definition of an authorized representative includes those individuals with Durable Power of Attorney. Therefore, an individual authorized to act as a surrogate of an enrollee and those who have written Durable Power of Attorney are permitted to act on behalf of an enrollee in the organization determination, reconsideration and appeal processes. By adding individuals authorized under

State law to the definition of authorized representative, such individuals are included as one of the parties to an organization determination listed at § 422.574, since the definition of an enrollee (who is a party) includes the enrollee’s authorized representative. Thus, a surrogate authorized by the State is not only a party to the organization determination, but is permitted to act on behalf of the enrollee under all provisions of subpart M.

We disagree with the commenters who requested that the definition of “enrollee” exclude an authorized representative. Although we recognize that an authorized representative is not an enrollee in the literal sense of being entitled to health services, we believe that to ensure authorized representatives are always permitted to act on behalf of an enrollee, the regulations should include an authorized representative in the definition of “enrollee” under subpart M. We note that § 422.561, which sets forth the definitions used in the appeals regulations contained in subpart M, specifies that the definitions are only “as used in this subpart, unless the context indicates otherwise.” An authorized representative thus would not be considered an enrollee for general M+C program purposes, such as under enrollment or financial liability provisions, but would be able to exercise the rights available to an enrollee for appeal and grievance purposes, such as the right to act on behalf of an enrollee in requesting an appeal or to receive applicable notifications.

Comment: One commenter commended our appeal and grievance rights as providing substantial protection, yet expressed concern over access for enrollees with special health care needs (the disabled and/or chronically ill). One commenter stated that M+C organizations will face a challenge in serving the increasing population of beneficiaries with questionable, fluctuating or diminished capacity, and further stated that M+C organizations need to identify enrollees who have surrogates in order to keep them informed. This commenter stated that the regulation should require information and notices be sent to surrogates of incapacitated beneficiaries, and surrogates should be listed as requesters of expedited decisions.

Response: As noted above, to the extent that such a surrogate is authorized under State law to act on the beneficiary’s behalf, he or she would be considered an authorized representative who is included in the definition of

enrollee and permitted to make requests on the beneficiary’s behalf. With respect to other additional procedural protections for enrollees with special health care needs, we believe that such additional protections for enrollees with special health care needs should be included in a notice of proposed rulemaking to provide the public with ample opportunity for input on final standards. We plan in this rulemaking to address the issue of special protections for beneficiaries with limited capacity, and consider possible additional notice requirements for surrogates in such cases.

14. Other Appeal Rights (§§ 422.596, 422.600, 422.602, 422.608, 422.612, and 422.616)

Comment: One commenter suggested that we revise § 422.596 to clarify that an M+C organization cannot appeal to an Administrative Law Judge (ALJ). However, two commenters argued that M+C organizations should have the right to appeal to an ALJ.

Response: Section 422.600 addresses the “Right to a hearing.” Section 422.600(a) provides that “any party to the reconsideration (*except the M+C organization*) who is dissatisfied with the reconsidered determination has the right to a hearing before an ALJ.” (Emphasis added.) Section 422.600(a) then expressly states that “[t]he M+C organization does not have the right to request a hearing before an ALJ.” While we believe that the regulations thus are already clear on this point, we have no objection to the commenter’s suggestion that § 422.596 be revised to also reflect this restriction.

The policy limiting ALJ appeal rights to Medicare enrollees has been in place since the inception of the Medicare risk contracting program under section 1876 of the Act. As noted above, under section 1856(b)(2) of the Act, M+C standards are to be based on standards established under section 1876 of the Act to the extent consistent with M+C rules. More importantly, the M+C statute expressly grants a right to a hearing only to an enrollee, with the M+C organization given the right to: (1) Be made a party to such a hearing; and (2) appeal from an ALJ. Section 1852(g) of the Act sets forth a three step process for appeals of coverage determinations. Section 1852(g)(1) of the Act establishes the process for making initial organization determinations and providing notice of appeal rights. Section 1852(g)(2) of the Act provides for the reconsideration process, which is conducted initially by the M+C organization. (Section 1852(g)(3) of the Act provides for M+C organizations to

expedite certain organization determinations under section 1852(g)(1) of the Act and reconsiderations under section 1852(g)(2) of the Act; and section 1852(g)(4) of the Act provides for review by an independent review entity as part of the reconsideration process established under section 1852(g)(2) of the Act). It is section 1852(g)(5) of the Act which provides for the ALJ level of review if the amount in controversy is at least \$100, and for ultimate judicial review. Under section 1852(g)(5) of the Act, “[a]n enrollee with a Medicare+Choice organization * * * is entitled (if the amount in controversy is \$100 or more) to a hearing before the Secretary * * * and in any such hearing the Secretary shall make the [M+C] organization a party.”

Comment: A commenter suggested that some denied services that do not reach the \$100 threshold represent legitimate disputes that could adversely affect patients. This commenter believes that patients should be able to request ALJ hearings for denials of services needed to maintain or regain health or physical functions, without regard to the cost involved. Another commenter similarly asserted that an enrollee’s ability to obtain an ALJ hearing and seek judicial review should not be based on the amount in controversy, because this could arbitrarily prevent some enrollees with legitimate disputes from appealing. This commenter suggested modifying the provision to allow a decision to be appealed if the amount in controversy meets the identified threshold, or if the patient’s life or health may be jeopardized as a consequence of the decision.

Response: Although we are sensitive to the concerns of the commenters, amount in controversy (AC) requirements in the case of appeals under the M+C program are set forth in the statute at section 1852(g)(5) of the Act. A statutory change would be required to alter the current threshold levels; therefore, we are not modifying the M+C regulations.

Comment: A commenter expressed concerns about the process for obtaining judicial review. The commenter also requested clarification as to what constitutes the “final decision of HCFA.” The commenter believes that some enrollees may not have the resources to pursue their rights in court. This commenter recommended that the reimbursement of attorney fees or associated court costs be left to the discretion of the judge performing the judicial review.

Response: A decision by our agent, the independent review entity, becomes “final” and binding on all parties unless

a party other than the M+C organization files a request for an ALJ hearing, or unless the decision is reopened and revised by the independent entity. This is the earliest “final” decision that involves us (through our agent), since organization determinations are made by M+C organizations. If this decision is not appealed or re-opened, it is in essence, a “final decision of HCFA.” A failure to appeal this decision, however, would mean that the right to further administrative and judicial review has been forfeited. An ALJ decision is similarly final and binding if it is not appealed by a party; (unlike a reconsidered determination, an M+C organization has the right to appeal an ALJ decision). If a timely appeal is filed, the ALJ decision is subject to further review by the Departmental Appeals Board (DAB). At this point, if the DAB declines to review the case, under § 422.612(a), the ALJ’s decision becomes a “final” decision for purposes of the right to judicial review. If the DAB agrees to hear the case on appeal, the DAB’s decision is the “final decision of HCFA” for purposes of judicial review.

We believe that the commenter’s confusion about what constitutes a “final decision of HCFA” may be due to some confusing regulatory text in § 422.612(b). Section 422.612(b) provides that a decision of the DAB may be appealed to Federal court if “(1) It is the final decision of HCFA; and (2) The amount in controversy is \$1,000 or more.” This implies that there is a distinction between a DAB decision and a “final HCFA decision.” In fact, a DAB decision constitutes a “final decision” on our behalf, since it is not subject to any further administrative review. We therefore are revising § 422.612(b) to provide that a DAB decision may be appealed to district court if the amount in controversy is \$1,000 or more.

Comment: One commenter suggested that we include other rights found in State managed care laws, such as requiring M+C organizations to provide beneficiaries, on request, with clinical guidelines upon which a denial is based.

Response: M+C organizations must provide enrollees with written notice of the reasons for a denial, as set forth at §§ 422.568(c) and (d). This includes providing all the information necessary for the beneficiary to understand why the service was denied, including any Medicare coverage criteria or policies applied in making the decision, as well as specific clinical rationales if applicable. To the extent that particular guidelines or screens are used in the determination process, but are not determinative of coverage (for example,

services falling outside certain screens will be given closer review, but still covered if coverage standards are met), we do not believe it is critical for beneficiaries to have access to these documents. We note that Medicare does not make similar documents used by carriers and intermediaries under the fee-for-service program available to the public.

15. Inpatient Hospital Notice of Discharge (§§ 422.580, 422.586, 422.620 and 422.622)

Comment: Two commenters urged that we simplify the language used in the notice of noncoverage (hereafter referred to as the Notice of Discharge & Medicare Appeal Rights (NODMAR)). One commenter suggested working with us to craft a notice outlining beneficiary rights of appeal while avoiding unnecessary paper work, especially since most of the NODMAR information is already contained in the “Important Message From Medicare” issued upon admission to a hospital. One commenter stated that the notice should be on a clear and readable form, in at least 12-point font, and in understandable language. One commenter stated that beneficiaries are confused by the content and intent of the notice, and that the notice should include a contact person at the M+C organization. Two commenters stated that this should be a form developed by HCFA.

Response: Shortly after the promulgation of the notice requirement, which is reiterated in § 422.620, we began receiving comments that the notices of noncoverage being issued to beneficiaries were confusing, contained a great deal of sophisticated “legalese,” were too long (the notices were ranging from five to nine pages), and that the many variations of the document posed administrative burdens. Therefore, we committed to drafting a more comprehensive and beneficiary-friendly notice.

We began consulting with industry groups, beneficiary advocacy groups, and peer review organizations in support of drafting a notice that would serve the intended purpose. On February 11, 1999, we issued OPL 99.082. This OPL conveyed: (1) Our new notice, the NODMAR; (2) our intent to consumer test and standardize the model language; and (3) our continued effort to find the best balance of beneficiary protections with administrative burden. The model language conveyed in the OPL contains language that is in 12 and 14-point fonts, is written in understandable language, and is only three pages in length.

The Important Message from Medicare (IMM) and the NODMAR are two documents that contain similar information. The IMM is currently given to the Medicare beneficiary at or about the time of admission, while the NODMAR is given in advance of the patient's discharge. We recognized the burden associated with issuing two notices with similar information. Therefore, we have developed a single document and process that allows patients to be informed about their inpatient hospital rights at a time and in a form that will be most beneficial to them and in a manner that reduces administrative burden. This single document is a revision to the existing Important Message from Medicare.

Accordingly, we have revised the IMM to provide for the inclusion of information on patients' inpatient hospital discharge rights. All Medicare beneficiaries will receive a revised notice, the "Important Message About Medicare Rights: Admission, Discharge, & Appeals," as required under section 1866(a)(1)(M) of the Act.

This revised standardized form will be issued to all Medicare beneficiaries who are inpatients of a hospital at or about the time of their admission. Once a Medicare beneficiary's time of discharge is determined, an amended notice that includes the reasons for the discharge would again be provided to the beneficiary prior to his or her actual discharge. The revised Important Message About Medicare Rights: Admission, Discharge, & Appeals has been consumer-tested, and has received favorable feedback. (Pursuant to the Paperwork Reduction Act of 1995 (PRA), a notice outlining this document was published in the **Federal Register** on April 12, 2000, with public comments accepted through June 12, 2000. See 65 FR 19783.) The content of the revised notice (and amended follow-up notice) will meet the requirements of the PRA and section 1866(a)(1)(M) of the Act (the Important Message from Medicare), and the notice requirements set forth at § 422.620 that are now contained in the NODMAR.

Comment: One commenter stated that the notice should include standardized language that indicates that review by PROs is usually preferable to a plan review, and should clearly explain that the enrollee is obligated to make a request in this fashion under these tight time restraints in order to be protected from financial liability.

Response: As explained in the preamble to the June 26, 1998 interim final rule, there are advantages to filing for immediate PRO review. The most significant advantage in utilizing the

immediate PRO review process is protection from financial liability for a continued hospital stay until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. In addition, the immediate PRO review process offered the enrollee direct communication with the PRO and a decision that is generally rendered more quickly than an M+C organization's determination.

Therefore, when the model language, NODMAR, was drafted, we included language that would allow the enrollee to understand the significance of meeting the immediate PRO review deadline. Likewise, the revised Important Message stipulates that if the enrollee meets the deadline for filing for immediate PRO review, the enrollee's M+C organization continues to be responsible for paying the costs of the enrollee's hospital stay until noon of the day after the PRO notifies the enrollee of its official decision.

In addition to stating that the enrollee has financial protection if he/she meets the immediate PRO review deadline, we have included a section that explains what happens to the enrollee if he/she misses the deadline and has to appeal to the M+C organization.

Comment: One commenter strongly supported the M+C regulations that improve notice requirements for hospital discharges. The commenter stated that the requirement that hospitals provide notice at the time of discharge instead of at admission gives M+C enrollees an additional protection against premature discharges. One commenter stressed the importance of always issuing a notice with respect to termination of any form of inpatient care, even when the enrollee has not expressed disagreement, because these are such significant changes in circumstances. The commenter suggested that these notices must be given in advance of the termination, and inpatient care must continue, without financial liability to the enrollee, until the appeal is resolved.

Response: We agree with the commenter that a notice of appeal rights should be issued at discharge without regard to whether the beneficiary expresses disagreement with the termination of care. Section 422.620(a) already provides that an M+C enrollee has the right to continued coverage of inpatient hospital services unless a proper discharge notice is provided. We are concerned that the commenter appears not have understood the existing regulations to require a notice in all cases. This misinterpretation of our current requirements is consistent with what we have heard from

beneficiaries discharged from hospitals during the year prior to consumer testing conducted on the NODMAR, who reported that they were unaware that they had the right to appeal the decision that it was time to leave the hospital, and left based on the belief that they had no choice in the matter. Given that the existing regulations text may not be sufficiently clear, we are responding to this comment by revising § 422.620(a) to expressly require that written notice be issued to enrollees in the case of all discharges and by revising the introductory clause in § 422.620(c) to provide that "In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, each enrollee must receive a written notice that includes the following * * *."

With respect to the commenter's suggestion that the enrollee not be financially liable until an appeal is resolved, as noted above, if the enrollee disagrees with a discharge decision, the enrollee may file for immediate PRO review by noon the day after a discharge notice is received. If such a timely request for review is filed, the enrollee is protected from financial liability until at least noon on the day after notice of the PRO's decision, if the PRO upholds the decision to discharge the enrollee. If the PRO decides that hospital services are still necessary, coverage would continue until a new discharge notice is issued.

Comment: Several commenters did understand the current regulations to require issuing the NODMAR to every enrollee prior to being discharged from an inpatient hospital setting, and indicated that they found this requirement difficult to administer. One commenter believes that M+C organizations need the cooperation of hospitals to fulfill this requirement, and contended that such cooperation was not always possible to obtain. Therefore, this commenter suggested that we reconsider our decision to require that a NODMAR be provided to every M+C organization member prior to discharge, or that we at least articulate this requirement as a "good faith effort" versus an absolute requirement. Two commenters said that in cases in which the responsibility for providing the notice has not been delegated by the M+C organization to the hospital, or where hospitals refuse to assist in this process, M+C organization staff would have to be available to visit each hospital on an ongoing basis 7 days each week, thereby creating a significant increase in the level of staffing. One commenter reported that in some cases,

hospitals are demanding compensation from M+C organizations for providing the notice to enrollees. Another commenter contended that it is inappropriate and unhelpful for hospitals to issue the notice, since there is no reimbursement from M+C organizations or Medicare, and it is impossible for hospital staff to explain decisions they did not make.

Response: We understand the burdens associated with an M+C organization directly providing notices in a hospital setting, and agree with the commenters who stated that hospitals are in the best position to give the discharge notice required under § 422.620. In light of the above comments, we have completed development of a single document that combines the NODMAR with the "Important Message." (The Important Message is the document we have determined that hospitals are already required, under section 1866(a)(1)(M) of the Act, to issue to all Medicare beneficiaries, including M+C enrollees.) While this regulation is not the appropriate vehicle to impose requirements on hospitals, some of which do not contract with M+C organizations, we intend, through a more appropriate vehicle, to require that all hospitals provide discharge notices for all Medicare patients. Thus, we are revising § 422.620 to eliminate the existing requirement that M+C organizations issue the notice of noncoverage to M+C enrollees.

Lastly, we note that it is the responsibility of the entity that made the discharge decision to ensure that an enrollee's questions about the discharge decision be directed to someone within that entity who can provide assistance. Thus, where a discharge decision is made by an M+C organization, that organization should be available to answer questions, even though the notice is issued on the organization's behalf by a hospital.

Comment: Several commenters suggested that the requirement to issue a NODMAR to all enrollees prior to discharge should be repealed or significantly modified. Four commenters suggested that the NODMAR should be given only if the enrollee or the physician disagrees with the hospital's decision to discharge. One commenter contended that issuing a notice in cases where the enrollee agrees with the discharge decision is unnecessary, will confuse the enrollee, and may result in the delay of appropriate discharge or the increase in hospital costs.

Response: The intent of the notice requirement set forth at § 422.620, as with all notice requirements, is to

provide enrollees with information that will help them make an informed decision about their health care at a time when it would be most needed and effectively received. The notice requirement is an important and necessary beneficiary protection.

Again, the revised Important Message has undergone extensive consumer testing. This has helped us to improve the content of the notice to make it less confusing to the beneficiary. Since the revised notice will be used to satisfy the requirement for notice of discharge/termination of coverage, beneficiaries will have the benefit of the consumer testing in this context as well.

Comment: One commenter supported an extension of the notice requirement to original Medicare beneficiaries, that is, all Medicare beneficiaries would receive a notice prior to being discharged from the hospital regardless of whether the beneficiary agrees with the decision. The commenter stated that until this requirement is extended, it will be very difficult to achieve full compliance, and urged that we defer any evaluation of plan compliance with this requirement until such an extension is secured.

Response: We have received many inquiries as to whether the M+C policy of issuing NODMARs in all cases will also apply to original Medicare beneficiaries. Currently, the practice has not been for hospitals to issue notices (that is, the Hospital-Issued Notices of Noncoverage (HINN)) to all original Medicare beneficiaries in advance of their hospital discharge, but to do so only in cases in which the beneficiary disagrees. We believe that it is in the best interests of all Medicare beneficiaries and the entities responsible for distribution of such notices to implement a uniform policy for M+C program and original Medicare purposes, and we intend to provide for this through an appropriate vehicle. This final rule, however, sets forth only those requirements that apply in the case of M+C enrollees.

Comment: One commenter contended that our inpatient hospital notice requirement generates ill will among M+C organizations, contracting providers, and beneficiaries. Two commenters opposed the notice requirement because they believe it would raise costs to hospitals.

Response: The intent of the notice requirement is not to supplant the doctor/patient relationship nor to harm the working relationships among M+C organizations, contracting providers, and/or beneficiaries. We believe that standardized instructions, and the eventual implementation of a uniform

policy for original Medicare beneficiaries, will help to alleviate a great deal of contention between the various entities. In the long run, this should make the referenced relationships function more smoothly.

Comment: One commenter suggested that the regulation should make clear that if a notice is not issued, the M+C organization (not the hospital) is liable for services.

Response: We agree that if proper notice is not provided, the M+C organization is liable for coverage, unless the hospital has been delegated the authority to make coverage decisions on behalf of the M+C organization. This liability is provided for under § 422.622(c), which expressly addresses liability for services, and § 422.620(a), which makes clear that the enrollee is entitled to coverage until noon the day after notice is given.

Comment: One commenter suggested that the only information that should be reviewed in an appeal of a decision not to admit a patient to a hospital, or to discharge a patient, is that which was available at the time that the decision was made.

Response: We disagree with the commenter. We believe that the entity reviewing an inpatient hospital discharge decision, or decision not to admit an enrollee to the hospital, should base its review on all the facts and evidence available—regardless of whether such information was available at the time of the decision not to admit or to discharge. In particular, in the case of review by the M+C organization, § 422.586 provides the parties to the reconsideration with an opportunity to present related evidence and allegations of fact or law in person as well as in writing; (the regulation notes that such an opportunity may be limited in the case of expedited reconsideration). Further, § 422.580 defines a reconsideration as a review of an adverse organization determination, the evidence and findings upon which it was based, and any other evidence the parties submit or the M+C organization or we obtain. Thus, there is ample precedent for not limiting information to be reviewed in the case of an appeal, and we plan to continue that policy.

Comment: One commenter suggested that, in order to avoid stalemates, the M+C regulations (like the original Medicare regulations) should provide a process to resolve cases in which the physician and the M+C organization disagree about the discharge decision.

Response: We agree with the commenter that the existing regulations do not provide for a clear resolution process in situations where an M+C

organization determines that inpatient care is no longer necessary, but the physician who is responsible for the patient's hospital care does not agree. We are currently examining different methods to resolve these situations, such as a method comparable to the existing Medicare fee-for-service system. Under that system, if a hospital believes that an inpatient is ready for discharge, but cannot obtain the concurrence of the attending physician, the hospital may request PRO review of the case. We intend to discuss this issue in our forthcoming notice of proposed rulemaking.

16. Other Comments

Comment: As alluded to above, several commenters suggested that we modify the subpart M regulations to reflect the provisions of the 1997 district court order in *Grijalva* that was vacated by the Ninth Circuit on appeal in 1999. For example, several commenters suggested we provide for the continuation of coverage during the pendency of an expedited appeal as provided under that district court order. Two commenters suggested that we clarify the enrollee's right to submit evidence in person. Additionally, several commenters suggested that the regulation should state that the enrollee has the right to informal, in-person communication with the reconsideration decision maker and that telephone hearings could be conducted if appropriate. One commenter opposed the implementation of the provisions in the vacated *Grijalva* order as too burdensome on M+C organizations.

Response: In general, we intend to implement regulatory changes that stem from the *Grijalva* order through upcoming notice and comment rulemaking. Thus, several of the commenters' suggestions are not addressed here. We note, however, that in some respects, we believe that the improvements to the appeals process that have been made under the M+C program already incorporate several of the provisions in the vacated *Grijalva* order, and in many instances are stronger. For example, the *Grijalva* order would have required that organization determinations be rendered within 5 working days, with the possibility of a 60-day extension. Under this regulation, we require that when an enrollee requests a service, the M+C organization must respond as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days. The M+C organization may not extend the time frame beyond an additional 14 calendar days. More significantly, unlike under the *Grijalva* order, the M+C program

provides an expedited 72-hour time frame for organization determinations in some cases that is shorter than the *Grijalva* time frame, and a similar expedited 72-hour time frame for the resolution of certain reconsiderations, while the *Grijalva* order provides neither. In another example illustrative of how our current M+C regulations meet or exceed the *Grijalva* order, at § 422.586, the M+C organization is required to provide parties to the reconsideration with a "reasonable opportunity to present evidence and allegations of fact or law * * * in person."

Comment: One commenter urged that we eliminate the phrase in § 422.574(b) which reads "and formally agrees to waive any right to payment from the enrollee for that service," because this language demeans the role of physicians as patient advocates for medically necessary services.

Response: We do not believe changes are needed in § 422.574(b), which requires a physician or other provider who has furnished a service to an enrollee to formally agree to waive any right to payment from the enrollee for that service. The waiver is only required in the case of retrospective payment denials, where an enrollee has *already* received medically necessary services, but the noncontract physician or provider is seeking payment for furnishing those services; therefore, this phrase does not affect the role of physicians as patient advocates for medically necessary services. In the context of receipt of payment, the role of the physician or provider is no longer as a patient advocate for medically necessary services. Therefore, the M+C regulation does not adversely affect or demean a physician's role as an advocate in prospective instances where an enrollee has not yet received health care services.

Comment: A commenter asked whether we would offer clarification of respective Medicare/Medicaid authorities, particularly with respect to New York State's existing 1115 Medicaid demonstration project. Additionally the commenter wondered if we will establish an administrative linkage between the States and the Medicare review authority for the provision of reports on reviews of adverse determinations in M+C organizations also operating as a State-defined managed long term care plan. (The commenter noted that managed long term care plans will predominantly serve the dually eligible.)

Response: We agree that access of dual eligibles to both the Medicare and Medicaid external hearing process

should be clarified. The external hearing process accessed depends upon the type of services being provided. For example, in original Medicare, enrollees who are dually eligible access Medicare services through the Medicare system. Therefore, appeals of Medicare services may be appealed through the Medicare external hearing process, if the beneficiary chooses to do so. Medicaid-only wraparound services (such as pharmacy services) must be accessed through Medicaid. Therefore, appeals of Medicaid-only services must be appealed through the Medicaid external hearing process. Likewise in capitated managed care, when a dually eligible enrollee is enrolled in a Medicaid MCO, the capitated rates are set based on an assumption that Medicare services are accessed through the Medicare system. Therefore, the Medicaid fair hearing system is accessed only for the Medicaid capitated services. The Medicare external hearing is accessed for the Medicare services outside of the Medicaid capitation contract. If a dually eligible individual is enrolled in an M+C organization, then the Medicare external hearing is accessed for the Medicare services within the capitation contract. The enrollee accesses the Medicaid State Fair Hearing only for services outside of the Medicare contract. The key to this example is that the enrollee and the M+C organization need to know whether the service provided is a Medicare- or Medicaid-covered service.

Comment: A commenter suggested that § 422.568(e), which addresses the effect of failure to provide timely notice of an organization determination, should be revised to specify that: (1) Failure to give timely and proper notice shall result in an automatic authorization/approval; and/or (2) failure to give timely and proper notice shall result in automatic sanctions by us. Furthermore, the commenter stressed that if an M+C organization fails to give proper notice, the M+C organization should be required to submit the file directly to an independent organization as described in § 422.590(c). Another commenter suggested that M+C organizations that fail to comply with grievance and appeal requirements should be subject to other intermediate sanctions.

Response: If we determine that an M+C organization substantially fails to comply with the notice requirements relating to grievances and appeals in subpart M, we have the option to terminate the contract under the requirements of § 422.510(b), impose intermediate sanctions as described in §§ 422.756(c)(1) and (c)(3), and/or

impose civil money penalties as described in § 422.758. We note that, depending on the seriousness of a violation (for example, in terms of the degree of risk to an enrollee's health), failure to comply with notice or appeal requirements in only one or two cases could constitute a substantial failure. Intermediate sanctions include the suspension of enrollment and marketing. We believe that these sanction requirements are most appropriately set forth in the sections of the M+C regulations dedicated to contract provisions (subpart K) and intermediate sanctions (subpart O).

We do not agree that we should add the requirement that an M+C organization's failure to give timely and proper notice shall result in an automatic authorization/approval, or that failure to give timely and proper notice shall result in *automatic* sanctions. In fact, we believe the first recommendation could seriously jeopardize the enrollee's health if, for example, an enrollee requested service that could be harmful to his or her health. We note that in the case of hospital and nursing home services already being provided, we have in part implemented the commenter's suggestion, in that the M+C organization is obligated to continue to cover the services until notice of noncoverage is provided. Also, as mentioned earlier, our sanction authority includes cases where we determine an M+C organization substantially fails to comply with the requirements relating to grievances and appeals in subpart M, including the organization's failure to provide the enrollee with timely and proper notice. Finally, where an M+C organization fails to give proper notice within the time frames required for resolution, § 422.590 requires the M+C organization to submit the file to the independent entity for review. We expect M+C organizations to provide enrollees with written notice for all denials (including the case of a discontinuation of a service where the enrollee disagrees (that?) the services are no longer medically necessary) according to the time frames and notice requirements set forth under subpart M and in operational instructions. However, we do not agree that it is practical, nor does the law mandate, that we require M+C organizations to automatically forward cases for independent review when content of the notice is at issue, and there has not been an adverse organization determination (that is, a coverage denial).

Comment: A commenter suggested that M+C organizations should be

required to establish an independent appeals procedure for denials of care.

Response: The M+C statute requires that we contract with an independent review entity to independently review plan denials of care. We believe that this arrangement, along with the other M+C appeal requirements, provide Medicare enrollees with the rights they need, and the rights to which they are entitled.

Comment: Two commenters did not believe that the physician reviewing the reconsideration needed to be of the same specialty or sub-specialty as the treating physician. Requiring the same specialty as the treating physician unduly complicates the reconsideration process in this commenter's view. One commenter pointed out that the BBA Conference Report states that "It is not the conferees intent to require that a physician involved in the reconsideration process in all cases be of the same specialty or sub-specialty as the treating physician." One commenter suggested that *expertise* should be defined in terms of board certification in the specialty, years of experience practicing in the specialty, and active practice. One commenter also suggested that physicians have qualifications other than expertise in the field of medicine that is appropriate for the services at issue. The commenter believes that the reviewing physician should also be formally qualified in the specialty treatment (licensed and actively practicing in the same jurisdiction) as the practitioner providing (or who would provide) the services, and have the appropriate level of training and experience to judge the necessity of the service. To ensure greater professional accountability, a commenter recommended that the reviewing physician's identity be accessible to the physician who recommended, rendered, or would have rendered the treatment under review. One commenter suggested that we also include other rights found in State managed care laws, such as requiring initial (organization) determination denials to be made or approved by a physician.

Response: We agree that a physician involved in the reconsideration process need not in all cases be of the exact same specialty or sub-specialty as the treating physician; therefore, we are revising § 422.590(g)(2) to make this clear. For example, we believe that there may be situations where only one specialist practices in a rural area, and therefore, it would not be possible for the M+C organization to obtain a second reviewer with expertise in the same specialty. In addition, we recognize that there may be some situations where there are few practitioners in highly

specialized fields of medicine. Under these circumstances, it would not be possible to get a physician of the same specialty or sub-specialty involved in the review of the adverse organization determination.

With respect to the commenter who specified training that the commenter believes reviewing physicians should have, we believe that our standard of "appropriate" expertise addresses this comment. Nor do we believe that it would be appropriate for the reviewing physician's identity to be provided to the treating physician being reviewed. The treating physician has the right to challenge the M+C organization's decision on the merits through several levels of an appeals process. We believe that sufficient accountability exists for reviewing physicians through the appeals process, since a physician whose decisions are reversed on appeal would be accountable to his or her M+C organization. Providing the name of the physician making the initial decision for the M+C organization could result in needless personal harassment of that physician by the physicians he or she reviews.

Finally, we do not agree with the comment that organization determinations should be made or approved by a physician. We do not believe that it is necessary to require physician involvement in all organization determinations that are adverse. Nevertheless, we expect that where adverse determinations are based on a lack of medical necessity, M+C organizations will ensure that appropriate health care professionals will be involved in the decision-making. For example, a nurse practitioner could render an adverse organization determination without the need to involve a physician. Furthermore, if an enrollee believes that the lack of physician involvement was a central factor in an adverse organization determination, then the enrollee need only request a reconsideration since the reconsideration requirements (§ 422.590(g)(2)) specify that a denial of coverage based on a lack of medical necessity must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. (We note that we have made a minor technical change to § 422.590(d) to clarify that the term "medical necessity" includes any substantively equivalent term used by an M+C organization to describe the concept of medical necessity.)

Comment: Several commenters provided suggestions on elements for grievance and appeal data.

Response: We appreciate the variety of comments we received concerning categories of meaningful data elements. The comments have provided valuable insight as we continue to work with the public to develop collection and reporting requirements related to organization-level appeals and grievances. Please note that OPLs 99.081 and 2000.114 provide guidance on the manner and form in which M+C organizations will be expected to comply with the requirement under § 422.111 for disclosing grievance and appeal data upon request to M+C-eligible individuals. Collection began April 1, 1999, and the first reporting went into effect on January 1, 2000.

N. Medicare Contract Appeals (Subpart N)

Subpart N of Part 422 addresses M+C contract determinations. There are three types of contract determinations addressed under Subpart N: (1) A determination that a contract applicant is not qualified to enter into a contract with us under Part C of title XVIII of the Act; (2) a determination to terminate a contract with an M+C organization; and (3) a determination not to authorize a renewal of a contract with an M+C organization. Regarding item (1), above, this type of contract determination likewise applies to service area expansion applications.

As indicated in the June 1998 interim final rule, pursuant to section 1856(b)(2) of the Act, most of what comprises subpart N was drawn from regulations in part 417 governing similar contract determinations involving contracts under section 1876 of the Act. We received nine public comments concerning subpart N of the interim final rule.

Comment: We received one comment on § 422.641. The commenter objected to the fact that subpart N, and § 422.641 in particular, does not provide for an appeal mechanism when we and an M+C organization disagree over a term of the organization's M+C contract. The commenter believes that because the Federal Acquisition Regulations (FAR) and contract disputes procedure in Subpart 33.2 of that regulation do not apply to M+C contracts, the M+C final rule should address how these disputes or disagreements will be resolved.

Response: The M+C statute does not contemplate a contract disputes procedure akin to the contract disputes procedure contained in Subpart 33.2 of the FAR. Unlike acquisition contracts subject to the FAR, the terms of M+C contracts are dictated by statute and regulations. M+C organizations have an opportunity for input on the regulations

that govern what is included in M+C contracts through the notice and comment process. Ultimately, however, as a matter of Federal administrative law, we are charged with implementing the M+C statute in regulations, and with interpreting and applying its regulations. We attempt, through Operational Policy Letters and other means, to provide guidance to M+C organizations on our interpretations of regulatory provisions, and ultimately, M+C contract terms. In some cases, M+C organizations, or associations representing M+C organizations, have objected to our interpretations of the regulations or to M+C contract terms. In some of these cases, we have taken these objections into account, and we have made modifications. To the extent that an M+C organization remains uncomfortable with the terms of the M+C contract, or of our interpretation of these terms, it ultimately is free not to renew its contract for the following calendar year. We believe that this informal process has worked well, and that there is no need to create a formalized adjudicatory process for addressing disagreements between an M+C organization and us about an M+C contract issue.

Comment: We received several comments about the terminology used throughout subpart N. In particular, commenters noted that the terms used in describing the two categories of entities to which the subpart applies, that is, entities that hold M+C contracts and entities that apply to become M+C contractors, vary throughout the subpart. For example, §§ 422.650(c), 422.650(d), 422.656(a), and 422.660 use three different terms to describe contract applicants: "entity," "M+C contract applicant," and "applicant entity." The commenter recommended that we standardize our use of terminology concerning contract applicants.

Response: We agree with the commenter that the varied use of terms to describe contract applicants is confusing and unnecessary. Therefore, we are revising the regulation text throughout subpart N to refer to organizations applying to become M+C organizations as "contract applicants."

Comment: One commenter indicated that in some instances, subpart N refers only to M+C organizations when it presumably should refer to contract applicants as well. For example, § 422.648(b) states that we will reconsider a contract determination if the M+C organization files a written request. Presumably, this provision should likewise apply to contract applicants since we also afford these

organizations reconsideration rights under subpart N.

A similar issue exists at § 422.656 of the interim final rule. Paragraph (a) discusses giving both the M+C organization and the contract applicant written notice of the reconsidered determination, while paragraph (b)(1) refers only to the M+C organization. Paragraph (b)(3) returns to using both M+C organizations and contract applicants.

Response: We agree with the commenter that contract applicants are also entitled to seek reconsideration pursuant to a Medicare contract determination. Thus, we are revising § 422.648(b) to specify that we will reconsider a contract determination if a contract applicant or M+C organization files a written request for one. We likewise agree that § 422.656(b)(1) should be revised to specify that the provision applies to contract applicants as well as existing M+C organizations, and we are making the needed changes to the regulation text.

Comment: One commenter pointed out that subpart N appears to grant different rights to contract applicants than those available to M+C organizations. This is due, in part, to the provision at § 422.648(b) that states—in error—that we will reconsider contract determinations for M+C organizations, but not contract applicants. In conjunction with the § 422.660 citation mentioned above, this section indicates that applicant entities must seek reconsideration before requesting an appeal, while M+C organizations can appeal a termination or nonrenewal without first seeking a reconsideration. This too stands in contrast to the provision at § 422.662 that contemplates hearings taking place after the initial determination and reconsideration occur.

Response: As mentioned earlier, correcting the language at § 422.648(b) to include contract applicants correctly realigns the language in subpart N to convey that applicant entities and M+C organizations must first seek a reconsideration before proceeding to the hearing stage.

Comment: A commenter believes that the language provided at § 422.662(b) is confusing, because it appears to indicate that contract applicants who are denied a contract by us must file a request for a hearing within 15 days of the date of the contract determination without first receiving notice of our initial determination.

Response: We agree that the language at § 422.662(b) confuses our intent to provide for a contract appeals process that includes—in this order—(1) a

contract determination, (2) an opportunity for reconsideration of the initial contract determination, (3) a reconsidered determination, as necessary, (4) the right to a hearing, as applicable, and (5) for contract terminations, a review by our Administrator. We therefore are changing the language at § 422.662(b) to clearly specify that the affected party must file a request for a hearing within 15 days after the date of the reconsidered determination.

Comment: We received one comment on § 422.668 regarding the disqualification of a hearing officer. Paragraph (b) of this section states that the person designated to be the hearing officer must consider objections from any party to the hearing that relates to any potential bias of the hearing officer. The hearing officer may then proceed with the hearing or withdraw. The commenter suggested that allowing a hearing officer whose impartiality has been questioned the discretion to continue with the hearing is ill-advised. The commenter asserted that if a party believes that the officer is biased, it would be more expedient to resolve that issue immediately instead of proceeding with the hearing.

Response: We believe that in selecting an individual to serve as a hearing officer, the individual's ability to be fair and impartial would be taken into account. Should there be a suggestion of a possible bias, we believe that such an individual would be in a position to evaluate the situation, and determine whether he or she in fact could be impartial with regard to the case in question. Vesting the decisionmaker with this authority to make his or her own determination, subject to appeal only after the matter is heard on the merits, is the same approach used with respect to judges in court proceedings, and we believe is appropriate in this context as well. The alternative could permit an appealing party to delay hearings indefinitely by repeatedly challenging the impartiality of the hearing officer and appealing any rejection of such a challenge.

We believe that § 422.668 provides an adequate remedy to situations where bias of the hearing officer is questioned. This section states that the objecting party may, at the close of the hearing, present objections, request that the decision of the hearing officer be revised, or request a new hearing before a different hearing officer.

Comment: Commenters noted that § 422.692 limits the right to a review by our Administrator to situations involving M+C contract terminations. The commenters questioned whether we

intended to deny this level of review in instances in which we nonrenew an M+C contract, or we deny a contract application.

Response: The additional layer of review by our Administrator is intended to apply only to contract termination decisions. This extra level of administrative review was included in the case of termination decisions in order to implement the requirement in section 1857(h)(1)(B) of the Act that M+C organizations have the "right to appeal an initial decision" following a termination decision. In providing for review of a hearing officer's decision by our Administrator, we have adopted procedures similar to those used for the Administrator's review of decisions of the Provider Reimbursement Review Board found at § 405.1875.

Comment: A commenter questioned the provision at § 422.696 under which reopening a contract or reconsideration determination is limited to our discretion, the Administrator, or the hearing officer. The commenter asked if the aggrieved party can petition for reopening in any instance.

Response: If an applicant or M+C organization believes it has a basis for re-opening a decision, it may request that the decisionmaker re-open the matter. The decision whether to act on such a request, however, is committed to the decisionmaker's discretion, and is not subject to appeal or further review of any kind. This is consistent with our general policies on re-opening decisions. See, for example, 42 CFR Part 405, Subpart R.

O. Intermediate Sanctions (§§ 422.750 through 422.760)

As stated in the interim final rule, M+C organization actions that are subject to intermediate sanctions include those specified at § 417.500 for contracts under section 1876 of the Act. The BBA also contained additional sanction authority not found in § 417.500, which we have implemented in subpart O. Specifically, section 1857(g)(3) of the Act provides that the Secretary can impose intermediate sanctions and civil money penalties based on a finding that the grounds in section 1857(c)(2) of the Act for terminating a contract are met. These grounds for termination are reflected in § 422.510(a), and are discussed in section II.K and II.N above. While intermediate sanctions based on the grounds for termination at § 422.510 generally are imposed on the same terms as sanctions for the violations specified in § 422.750(a), in the case of all grounds except a finding of fraud or abuse under § 422.510(a)(4), HCFA,

rather than the OIG, imposes civil money penalties.

We received 3 comments on subpart O.

Comment: A commenter contended that the intermediate sanctions provisions do not provide Medicare contracting organizations with sufficient appeal rights before intermediate sanctions are imposed. Another commenter argued that the Congress originally intended intermediate sanctions to be an intermediate step less severe than a termination, and that instead suspension of payment for enrollees can be a worse penalty than termination. This commenter believes that the use of intermediate sanctions and civil money penalties has been incorporated as a program management tool, rather than an intermediate step to termination, which the commenter believes should follow sanctions.

Response: In the case of the imposition of a civil money penalty, extensive appeal rights are afforded, including the right to a hearing before the departmental appeals board (DAB). In the case of an "intermediate sanction," however, the entire point of this authority is to allow the Secretary to take swift action to respond to a finding of a serious violation of M+C requirements. Since the sanction is temporary, and only remains in place until corrective actions have been taken, elaborate appeal rights were not contemplated by the Congress, and would not be appropriate. The Congress has demonstrated in section 1857(h) of the Act that it knows how to require specific appeal rights when it wishes to do so. We believe that an M+C organization's interests are sufficiently protected by giving the organization an opportunity to seek reconsideration of a decision to impose intermediate sanctions by demonstrating that the basis for the decision is incorrect, and giving the organization an opportunity to have the sanctions lifted when corrective action is taken. This approach is consistent with what is provided with respect to intermediate sanctions in the nursing home enforcement area. With respect to the second comment, we believe that intermediate sanctions are an "intermediate step" between no action and the drastic step of termination, yet do not agree that termination necessarily would follow, unless the organization fails to take corrective action in response to sanctions. Our experience generally has been that organizations respond favorably to sanction letters. The commenter's opinion that an intermediate sanction could be worse than termination may be based on a

misunderstanding of the nature of the sanction referenced by the commenter. The option of suspending payment for enrollees, under section 1857(g)(2)(C) of the Act, applies only to payments for individuals who enroll after the effective date of the sanction. This sanction option, which is available with respect to the violations specified in § 422.752(a), would only apply in a case in which HCFA decided not to impose the sanction of a suspension of enrollment. Finally, the commenter is correct that we view intermediate sanction and civil money penalty authorities as a program management tool that HCFA can employ in the event an organization is not meeting Medicare regulations. Through the use of this tool, HCFA can ensure compliance with regulations without depriving beneficiaries who may be happy with the M+C plan in which they are enrolled of that enrollment option.

Comment: A commenter suggested that HCFA expand intermediate sanctions to include all aspects of grievance and appeals violations.

Response: HCFA has the authority to impose intermediate sanctions for a substantial failure to comply with any grievance and appeal requirement set forth in subpart M. Specifically § 422.752(b) provides that HCFA may impose intermediate sanctions for any violation under § 422.510(a). Section 422.510(a)(6) in turn specifies a substantial failure to “comply with the requirements in subpart M of this part relating to grievances and appeals” as a sanctionable violation.

P. Medicare+Choice MSA Plans

1. Background

Among the types of M+C options authorized under section 1851(a)(2) of the Act is an M+C medical savings account (MSA) option, that is, a combination of a high deductible M+C insurance plan (an M+C plan) and a contribution to an M+C MSA. Section 1859(b)(3)(A) of the Act defines an MSA plan as an M+C plan that:

- Provides reimbursement for at least all Medicare-covered items and services (except hospice services) after an enrollee incurs countable expenses equal to the amount of the plan’s annual deductible.

- Counts for purposes of the annual deductible at least all amounts that would have been payable under original Medicare if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

- After the annual deductible is reached, provides a level of reimbursement equal to at least the lesser of actual expenses or the amount that would have been paid under original Medicare, if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

2. General Provisions (Subpart A)

Sections 422.2 and 422.4 set forth several definitions for terms connected with M+C MSA plans, including “M+C MSA,” “M+C MSA plan,” and “MSA trustee.” We also distinguish between a “network” and a “non-network” M+C MSA plan. These definitions consist of general meanings for these terms as used in the BBA, and do not include specific requirements in the definitions themselves. The definition for an MSA does, however, reference the applicable requirements of sections 138 and 220 of the Internal Revenue Code, while the M+C MSA plan definition references the applicable requirements of part 422.

3. Eligibility, Election, and Enrollment Rules (Subpart B)

a. Eligibility and Enrollment (§ 422.56)

Any individual who is entitled to Medicare under Part A, is enrolled under Part B, and is not otherwise prohibited (such as an ESRD patient), is eligible to enroll in an M+C plan. However, the statute places several limitations on eligibility to enroll in an M+C MSA plan, and these limitations are set forth at § 422.56 of the regulations. Section 422.56(a) indicates that M+C MSA plans are authorized on a limited “demonstration” basis, and incorporates the statutory provisions of section 1851(b)(4), that is:

- No more than 390,000 individuals may enroll in M+C MSA plans.
- No individual may enroll on or after January 1, 2003, unless the enrollment is a continuation of an enrollment already in effect as of that date.
- No individual may enroll or continue enrollment for any year unless he or she can provide assurances of residing in the United States for at least 183 days during that year.

b. Election (§ 422.62)

Section 1851(e) of the Act establishes general rules concerning the time periods when a beneficiary could elect to enroll in an M+C plan (if one is offered in the beneficiary’s area), with special rules for M+C MSA plans set forth at section 1851(e)(5) of the Act. Based on these provisions, § 422.62(d)

specifies that an individual may elect an MSA plan only during one of the following periods:

- An initial election period, that is, the 7-month period beginning 3 months before the individual is first entitled to parts A and B of Medicare.
- The annual coordinated election period in November of each year.

4. Benefits (Subpart C)

a. Basic Benefits Under an M+C MSA Plan (§ 422.103)

Section 422.103 incorporates the statutory requirements for M+C MSA plans defined under section 1859(b)(3) of the Act, as outlined above. Thus, § 422.103(a) specifies that an MSA organization offering an MSA plan must make available to an enrollee, or provide reimbursement for, at least all Medicare-covered services (except for hospice services) after the enrollee’s countable expenses reach the plan’s annual deductible. Further, § 422.103(b) then indicates that countable expenses must include the lesser of actual costs or all the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(c) provides that after the deductible is met, an M+C MSA plan pays the lesser of 100 percent of either the actual expense of the services, or of the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation.

Section 422.103(d), concerning the annual deductible, is based on section 1859(b)(3)(B) of the Act. As the statute specifies, the maximum annual deductible for an MSA plan for contract year 1999 was \$6,000. In subsequent contract years, the maximum deductible may not exceed the maximum deductible for the previous contract year increased by the national per capita M+C growth percentage for the year. Thus, based on a national per capita growth percentage of 5 percent, the maximum deductible for 2000 is \$6,300. In calculating the maximum deductible for future years, HCFA will round the amount to the nearest multiple of \$50.

b. Supplemental Benefits (§§ 422.102 and 422.104)

Section 422.102 addresses the general M+C rules on supplemental benefits.

Unlike other M+C plans, MSA plans are not permitted to include any mandatory supplemental benefits, and are limited in terms of the optional supplementary benefits that can be offered. In accordance with section 1852(a)(3)(B)(ii) of the Act, § 422.104(a) specifies that an M+C MSA plan generally may not provide supplemental benefits that cover expenses that count toward the annual deductible. In addition, section 4003(b) of the BBA added new section 1882 to the Act to prohibit the sale of most supplementary health insurance policies to individuals enrolled in M+C MSA plans. The only exceptions to this rule are spelled out in section 1882(u)(2)(B) of the Act. Further, these exceptions apply both for purposes of the prohibition on selling freestanding supplementary health insurance (or “Medigap” insurance), and for purposes of “optional supplemental benefits” offered under M+C MSA plans. These exceptions are reflected in § 422.103(b)(2).

5. Quality Assurance (Subpart D)

Consistent with section 1852(e)(2) of the Act, a network model M+C MSA plan must meet requirements similar to those that apply to all other M+C coordinated care plans (with the exception of the achievement of minimum performance levels); the statute and regulations establish different requirements for non-network M+C MSA plans. These requirements are discussed in detail in section II.D of this preamble.

6. Relationships With Providers (Subpart E)

For the most part, subpart E of new part 422 does not establish any requirements that are specific to MSA plans. However, § 422.214, “Special rules for services furnished by noncontract providers,” does not apply to enrollees in MSA plans. Section 422.214 implements section 1852(k) of the Act, which contains limits on amounts providers can collect in the case of coordinated care plan enrollees (section 1852(k)(1) of the Act), and private fee-for-service plan enrollees (section 1852(k)(2) of the Act). As explained in the June 1998 interim final rule preamble, it is clear that Congress intended no such limits to apply to services provided to MSA plan enrollees.

7. Payments Under MSA Plans (Subpart F)

Section 1853 of the Act describes the method to be used to calculate the annual M+C capitation rate for a given payment area. We apply the same

methodology in determining the annual capitation rate associated with each M+C MSA plan enrollee, though the actual amount paid to an M+C organization offering an M+C plan is not the amount determined under section 1853 of the Act.

The special rules concerning the allocation of the M+C capitated amount for individuals enrolled in M+C MSA plans are set forth at section 1853. In general, HCFA will allocate the capitated amount associated with each M+C MSA enrollee as follows:

- On a lump-sum basis at the beginning of the calendar year, pay into a beneficiary’s M+C MSA an amount equal to the difference between the annual M+C capitation rate calculated under section 1853(c) of the Act for the county in which the beneficiary resides and the M+C MSA premium filed by the organization offering the MSA plan (this premium is uniform for all enrollees under a single M+C MSA plan, or segment of a plan service area, if authorized under section 1854(h)). (See section I.C.7 for a discussion of the BBRA changes in this regard). This results in a uniform amount being deposited in an M+C MSA plan enrollee’s M+C medical savings account(s) in a given county, since the uniform premium amount will be subtracted from the uniform county-wide capitation rate for every enrollee in that county.

- On a monthly basis, pay to the M+C organization an amount equal to one-twelfth of the difference, either positive or negative, between the risk adjusted annual M+C capitation payment for the individual and the amount deposited in the individual’s M+C MSA.

Section 422.262 contains the regulations concerning the allocation of Medicare trust funds for enrollees in M+C MSA plans.

8. Premiums (Subpart G)

Section 1854 of the Act establishes the requirements for determination of the premiums charged to enrollees by M+C organizations. Like other M+C organizations, organizations offering M+C MSA plans in general must submit by July 1 of each year information concerning enrollment capacity and premiums. For M+C MSA plans, the information to be submitted includes the monthly M+C MSA plan premium for basic benefits and the amount of any beneficiary premium for supplementary benefits. These requirements are set forth under section 1854(a)(3) of the Act and § 422.306(c) of the regulations.

9. Other M+C Requirements

The remaining requirements under subpart 422 have few, if any, implications specific to M+C MSA plans. One issue that we discussed in the interim final rule, however, involves the provision of section 1856(b)(3)(B)(i) of the Act (and § 422.402(b)) that any State standards relating to benefit requirements are superseded. We recognize that this provision means that State benefit rules will not apply (for example, State laws that mandate first dollar coverage for particular benefits such as mammograms or other preventative services). Some States may not license entities to offer catastrophic coverage, and it is possible that M+C MSA plans could not be offered in that State. We invited public comment on this issue.

10. Responses to Comments

Comment: We had requested comments on the establishment of a minimum deductible for MSA plans. We had suggested the possibility of establishing the minimum deductible equal to the projected actuarial value of the average per capita copayment under original Medicare. For 1999, that amount would have been \$1000. In response, we received three comments. One commenter supported a minimum deductible but recommended that it be higher, \$2000—\$3000. Two other commenters opposed the minimum deductible, stating that it would be counterproductive, and would preclude organizations from offering plans feasible for lower income beneficiaries.

Response: Since that there is neither clear consensus on the issue nor any actual experience under the demonstration, we do not believe it would be appropriate at this time to set a minimum deductible. Therefore, we will continue with only a maximum deductible as specified in the Act, but will include an analysis of the deductible issue in the evaluation of this program.

Comment: One commenter requested clarification of § 422.56 specifying how an MSA should be treated in the Medicaid eligibility process.

Response: We are not planning to address the issue of Medicaid eligibility in these regulations. However, this is a valid issue that needs to be addressed in Medicaid eligibility regulations.

Comment: One commenter expressed a concern that MSA enrollees may fail to pay physician claims, based upon experiences with existing deductibles under Medicare. Further, the commenter feared that enrollees might decrease their use of noncovered

elective services, such as elective screening and initial diagnostic examinations.

Response: Assuming that an M+C organization chooses to offer an MSA plan, beneficiaries would be advised before they enroll in the plan that they are responsible for initial medical expenses for the year, and each enrollee would have an MSA account to pay at least part of those expenses. Whether they would be able to meet all of their obligations would be considered in the evaluation. The purpose of the M+C MSA program is to permit beneficiaries to play a greater role in their health care purchasing decisions. The program does provide them with incentives to discourage the overutilization of health care services. We had considered requiring first-dollar coverage for services such as certain screening procedures, but decided that would be contrary to the intent of this demonstration.

Comment: One commenter stated that the maximum enrollment of 390,000 beneficiaries would be a disincentive for organizations to participate in the MSA demonstration. This would be too small a number to permit organizations to devote the resources to developing and marketing a high-deductible MSA policy.

Response: The limit of 390,000 enrollees over the course of the MSA demonstration was specified under section 1851(b)(4) of the Act. We are not at liberty to change that requirement by regulation. Nevertheless, as we previously stated, we do not believe that number would be reached over the course of the demonstration if an M+C organization chose to offer an MSA plan.

Comment: We had solicited comments regarding the issue of whether we should establish sample standardized MSA plans similar to the limited number of Medigap plans. Two organizations commented, both opposing standardized MSA plans as unnecessary and overly restrictive.

Response: We agree with the commenters that there is no need to establish standardized MSA plans under the demonstration.

Comment: Two organizations expressed concern that some States may not license insurers to provide high-deductible policies, thus limiting the availability of MSA plans.

Response: The Act requires that an M+C organization wishing to offer an MSA plan be licensed by the State as a risk-bearing entity, and that the State determine that it can reasonably assume the risk that it would assume under the M+C plan it proposes to offer. It does

not require that the organization be licensed commercially to offer a high deductible policy. Therefore, an M+C organization could offer an MSA plan in a State in which the State does not commercially license high deductible plans. The M+C organization must have the State's approval to do so, however.

Comment: Two commenters asserted that the requirement to submit encounter data would be unduly burdensome for M+C organizations offering MSA plans, particularly for non-network MSA plans. Further, M+C organizations may not have access to claims incurred under the MSA deductible.

Response: This issue was discussed at length during the development of the M+C regulations. Of particular concern was the fact that non-network MSA plans may not see enrollee claims should those claims not exceed the deductible. The possibility of requiring enrollees to submit claims regardless of whether the insurer would have liability was discussed, but dropped as burdensome for enrollees. We believe it is in the interest of the Medicare program that the encounter data submission requirement be maintained for all M+C plans, including MSAs. Should an organization approach HCFA about offering an MSA plan, we would work with the organization on its compliance with these requirements. (For example, enrollees who reach the deductible probably would be required to submit documentation of claims totaling the deductible amount. This documentation might be used to supply encounter data.)

Comment: Four commenters addressed the quality performance measures and the required data submissions. One commenter offered support for the performance improvement projects for MSAs and other M+C plans. Two commenters found the health data requirements for MSAs to be unrealistic, particularly for non-network plans, and likely to deter the offering of MSA and PFFS plans. A fourth commenter recommended that if certain quality assurance data are not available for certain categories for MSAs and PFFS plans, beneficiaries should be made aware of this lack of information.

Response: M+C organizations offering MSA plans are required by statute to adhere to specified quality standards. Quality performance standards in the June 1998 interim final rule have been modified to accommodate the particular characteristics of an MSA, and the fact that a report will be done on the MSA demonstration (assuming that an M+C organization chooses to offer an MSA plan). We recognize the fact that non-

network MSAs may not have access to an enrollee's claims unless that individual's total claims exceed the deductible. In addition, MSAs may not be structured to provide incentives to beneficiaries to obtain preventive and diagnostic services. HCFA is reviewing the quality requirements to make sure that they are feasible for the specific plan for which they are specified.

Comment: One commenter questioned the "community-rated" MSA contributions for all beneficiaries enrolled in an MSA plan, and the lack of balance billing protections for MSA enrollees. Another commenter described the payment methodology as arcane and confusing, and the possibility of a negative premium as absurd.

Response: After lengthy discussions with industry representatives and other officials, the fixed MSA contribution for all beneficiaries in a specific plan in a specific area seemed to be the approach most consistent with legislative intent. Also, HCFA made a point of clarifying that no balance billing restrictions were included in the statute, and that Congress intended that there be none. As has been previously stated, a negative premium is not impossible, but we would expect an MSA plan to set its premium in a given market at a level to avoid such a possibility.

O. M+C Private Fee-for-Service Plans

1. Background and General Comments

As noted above, one type of M+C option available under section 1851(a)(2) of the Act is an M+C private fee-for-service (PFFS) plan. Consistent with the statutory definition of an M+C private fee-for-service plan at 1859(b)(2)(A) of the Act, the regulations state that an M+C PFFS plan is an M+C plan that: Pays providers at a rate determined by the M+C organization offering the PFFS plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide the services, and agree to accept the plan's terms and conditions of payment. The requirements M+C organizations must meet to contract with HCFA to offer an M+C PFFS plan generally are incorporated into the relevant sections of the M+C regulations. An M+C organization wishing to offer a PFFS plan must meet all of the requirements that apply with respect to offering any other type of M+C plan, except to the extent that there are special rules that apply to M+C PFFS plans.

Comment: One commenter contended that HCFA should examine alternatives to the ACR process for ensuring good value under PFFS and MSA plans. The ACR restriction on the premium may conflict with the role envisioned for these plans as paying high fees to providers to ensure unrestricted access.

Response: The commenter is mistaken in the belief that there are restrictions on premiums for M+C MSA and PFFS plans. There is no restriction on the premiums that may be charged for these plans (see § 422.306(e)(2)).

Comment: A commenter noted that the regulations create a loosely defined option in which the organization offering a PFFS plan fills in the details of the plan. The commenter questioned whether many beneficiaries would be motivated to join such a plan, whether insurers would be motivated to offer an option that could have such limited appeal. As currently constructed, the commenter believes that M+C PFFS plans are not likely to be viable, and therefore are not likely to be made available to beneficiaries. This in the commenter's view mitigates against the espoused concept of offering a meaningfully expanded range of options. The commenter suggested that HCFA work with the physician community to do demonstrations to explore what features of the M+C PFFS statute should be changed so that Medicare can offer a viable M+C PFFS defined contribution plan.

Response: We recognize that the statute created a loose structure for M+C PFFS plans, and that therefore M+C plans may vary greatly from one another in how they function. This is a direct consequence of the law. However, we believe that, as currently constituted, M+C PFFS plans are viable. We have received an application for a 30-State, largely rural M+C PFFS plan, and have reason to expect to receive more applications within the next year.

2. Beneficiary Issues

Comment: A commenter objected to the M+C PFFS plan option on the basis that the commenter believes it leaves the beneficiary vulnerable. The commenter's objections included the lack of a quality assurance program to protect beneficiaries, as well as the absence of a cap on premiums or out of pocket expenses, resulting in the possibility that beneficiaries could be charged up to 15 percent over the plan payment amounts. The commenter contended that beneficiaries would be better protected if the PFFS option were not offered.

Response: We recognize that some beneficiary protections provided for

under the coordinated care plan option are not included for M+C PFFS plans. In some cases, such as certain quality assurance requirements, these protections may be less critical in an environment in which the enrollee has complete freedom of choice to use any provider in the country, and is not limited to a defined network of providers. We note that the quality assurance requirements that apply to coordinated care plans do not at this time apply to original Medicare either, which is also a "fee-for-service" arrangement. With regard to the absence of certain limits on beneficiary financial liability, we believe that this makes it particularly important that beneficiaries make a prudent consumer decision when choosing this option. However, we also believe that this alternative can provide a valuable alternative to original Medicare in areas that are not served by coordinated care plans, rural areas in particular. Moreover, we anticipate that, as we gain experience with M+C PFFS contracts, we will determine what changes we need to make to the regulations, or ask Congress to consider improving this M+C option, should we decide that such changes are needed. (We note that we have recently approved the first PFFS plan and intend to monitor its performance closely in order to identify and assess potential beneficiary protection issues.)

Comment: A commenter urged that marketing information to seniors and providers clearly differentiate between traditional Medicare and M+C PFFS plans, as there are substantially different payment schedules, balance billing rules, and premiums that can be charged for M+C PFFS purposes than for original Medicare.

Response: We agree that there is a significant potential for confusion between original Medicare and the M+C PFFS option, and we have tried to clarify the distinction between these options in our 1999 and 2000 Medicare handbooks (Medicare and You). We are also considering the best way to make this distinction clear in our model explanation of coverage for M+C PFFS plans. The model evidence of coverage document is created for an M+C organization to use as a model for the explanation they provide to beneficiaries about the plan's terms and conditions of coverage. We are currently adapting the existing Evidence of Coverage for coordinated care plans for use in the case of PFFS plans.

Comment: A commenter recommended that we require providers furnishing services to PFFS enrollees and MSA enrollees to give notice if they think the plan may not cover a service.

The commenter believes that the same limitations on liability protection that apply in original Medicare should apply to M+C PFFS plans and MSA plan beneficiaries. Moreover, the commenter suggested providers be required to give enrollees of M+C PFFS plans a notice of the expected balance billing amounts that exceed \$250 or more (not just the more than \$500 notice required of hospitals).

Response: Unlike under original Medicare, the statute does not provide any protection against enrollee or provider liability for services that a M+C PFFS plan determines are not medically necessary to treat illness or injury, and the law does not require providers to give an advance notice to enrollees of the likelihood of plan noncoverage. Therefore, there is no basis in law to require an M+C organization to offer such protection in its plan. Of course, the organization may, if it chooses, build such protection into its plan, and we believe that doing so may be necessary to attract and keep enrollees. Moreover, an enrollee and provider clearly may seek an advance determination of coverage from the M+C organization under the organization determination regulations in part 422 subpart M. Thus, the enrollee and provider have the opportunity to seek a plan determination of coverage before receiving the service, and we encourage them to avail themselves of this option.

With respect to the notice of anticipated cost sharing, the law requires such a notice for hospital services, but not for other services. The M+C organization could, however require that contracting and deemed contracting providers of other types furnish such a notice in advance of providing care as a term and condition of payment, and could set whatever tolerance they chose for such a notice.

We chose the \$500 threshold for a notice of out-of-pocket expenses that a hospital may collect from the enrollee because it mirrors the \$500 threshold long established by law at section 1842(m)(1) of the Act. Section 1842(m)(1) of the Act requires that a nonparticipating physician who does not accept assignment on the Medicare claim must give the beneficiary advance notice if the actual charges that will be collected from the beneficiary equal or exceed \$500. While the benefit to which the threshold applies is different, the concept of advance notice of amounts to be collected from the enrollee is the same, and therefore use of the same threshold is justified.

3. Provider Payment Issues

Comment: A commenter urged that HCFA establish standard payment deadlines, and contended that those for M+C PFFS plans should mirror those for original Medicare.

Response: We believe that the prompt payment provisions of § 422.520 largely accomplish this, since they apply to all claims submitted “by, or on behalf of an M+C private fee-for-service enrollee.” Since the benefits under a PFFS plan are the enrollee’s benefits, we believe that any claim submitted on behalf of a PFFS plan enrollee is subject to the clean claim standard in § 422.520. While written agreements with PFFS plan providers must address this issue, and better terms may be negotiated, we have interpreted the reference to fee-for-service enrollees in section 1857(f)(1) of the Act to cover all claims involving PFFS enrollees. Under this standard, the M+C organization must pay 95 percent of the “clean claims” within 30 days of receipt, if they are submitted by or on behalf of an enrollee of the M+C PFFS plan, and are not furnished under a written agreement between the M+C organization and the provider. Moreover, the M+C organization must pay interest on clean claims that are not paid within 30 days as required by sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act for original Medicare.

Comment: A commenter argued that the prompt payment rules at § 422.520 permit payers to “game” the clean claim policy by building in a float between the receipt of Medicare payment and the payment to the providers, and recommended that HCFA establish a standard that would apply for PFFS network providers where an organization offering an M+C PFFS plan effectively imposes a delay as a condition of getting the contract.

Response: The prompt payment provisions that apply to all PFFS plan claims ensure against a float of more than 30 days in the case of a “clean” claim.

Comment: A commenter suggested that HCFA require M+C organizations offering PFFS plans to give physicians 30 days notice of changes to fee schedules, and should require them to follow CPT coding conventions in the same manner as original Medicare.

Response: M+C organizations offering PFFS plans must pay noncontracting providers at least the amounts they would receive under original Medicare (less the enrollee’s cost-sharing); therefore, there is no potential for changes to the payment rates other than through the annual Medicare fee schedule changes. Also, in order to meet

access requirements without having a network in place that satisfies coordinated care plan rules, an M+C organization offering a PFFS plan must pay contracting providers (both those with signed and deemed contracts) at least the Medicare payment rate. In this case, again, providers could count on Medicare payment notices. In all cases, however, providers either will negotiate rates in written and signed contracts, or have the opportunity to learn payment information before providing services under a deemed contract.

4. Noncontracting Provider Issues

Comment: A commenter contended that the regulations should clarify whether a noncontracting provider is precluded from balance billing beneficiaries, and must accept as payment in full rates that are no less than what would be paid under original Medicare. The commenter believes it is not clear: (1) If those rates would include the limiting charge of 115 percent; (2) if noncontracting providers are entitled to direct payment from the M+C organization; or (3) what amounts may be balance billed. The commenter suggested that enhanced balance billing should have been provided as an incentive to sign a contract, but because of the deemed contract provisions, this basic premise for contracting is lost.

Response: The law permits, but does not require, an M+C PFFS plan to permit contracting providers (with both signed and deemed contracts) to balance bill up to 15 percent of the PFFS plan payment rate for the service, in addition to the cost-sharing established under the plan. The statute expressly applies this to deemed contractors as well. Therefore, the balance billing that an M+C plan may permit contracting and deemed contracting providers to collect will be set by the organization offering the plan. The M+C organization will pay under its terms and conditions of payment, and the contracting or deemed contracting provider may collect the cost sharing and any balance billing permitted by the plan (which cannot exceed 15 percent of the PFFS plan payment rate).

In the case of noncontracting providers (that is, providers that neither have a written contract with the M+C organization offering the PFFS plan nor meet the criteria for a deemed contract), there is no balance billing permitted; by law, the provider may collect no more than the plan’s cost sharing. Under section 1852(k)(2)(B) of the Act, the beneficiary liability limits governing payment to noncontracting providers are the same for M+C PFFS plans as for M+C coordinated care plans. We have

clarified this by indicating in § 422.214 that the special rules for payment to noncontracting providers that apply for M+C coordinated care plans also apply for M+C PFFS plans. Specifically, the provider must accept as payment in full the amount that it would be entitled to receive under original Medicare, and the plan must pay the provider the amount that the provider would collect if the beneficiary were enrolled in original Medicare, less the enrollee’s cost-sharing. For example, if the physician participates in Medicare, the plan would pay the noncontracting physician the Medicare allowed amount less the plan’s cost-sharing. In the case of a nonparticipating physician, the plan would pay the Medicare limiting charge less the enrollee’s cost-sharing. In the case of an acute care hospital, the plan would pay the diagnosis-related group (DRG) payment less the enrollee’s cost-sharing. In the case of a nonparticipating durable medical equipment, prosthetic and orthotics (DMEPOS) supplier, the plan would pay actual charges less the enrollee’s cost-sharing.

While the law addresses the payments to providers and the payment liabilities of beneficiaries, it does not specify whether the M+C organization must pay the provider, or whether it may function as an indemnity plan and pay the enrollee, for services for which the enrollee has paid the provider. Moreover, the discussion of prompt payment by M+C plans at section 1857(f) of the Act contemplates that the M+C organization may make payment to the beneficiary. Hence, the M+C organization may determine to whom (provider or beneficiary) it will make payment for covered services. However, we anticipate that M+C organizations will want to make payment to providers of services, rather than to beneficiaries since we believe that minimizing beneficiary paperwork and confusion is necessary to attract and keep enrollees in the plan.

5. Quality Assurance (§§ 422.152 and 422.154)

As discussed in section II.D of this preamble concerning quality assurance requirements, M+C PFFS plans and non-network MSA plans (and now PPO plans) are exempt from some of the quality assurance requirements that apply to network model M+C plans. The statute also exempts these plans from external quality review if they do not have written utilization review protocols. As with all other requirements for M+C organizations and M+C plans, those provisions of regulations that are not identified as

limited to coordinated care plans or MSA plans also apply to M+C PFFS plans.

Comment: Commenters suggested that § 422.154 affirmatively states that M+C organizations, including those offering MSA plans and PFFS plans, must coordinate with an external entity's (that is, a PRO's) investigation of beneficiary quality of care complaints. These commenters believe that beneficiary complaints are an important indicator of quality of care problems, and that all M+C plans should have to cooperate in investigating them.

Response: The statute relieves an M+C organization offering a PFFS plan of responsibility for contracting for external quality review if it does not carry out utilization review with respect to services covered under the plan.

6. Access to Services (§ 422.214)

Like other M+C plans, an M+C private fee-for-service plan must offer sufficient access to health care. Section 422.114(a) specifies that an M+C organization that offers an M+C PFFS plan must demonstrate to HCFA that it has sufficient number and range of health care providers willing to furnish services under the plan. Pursuant to the specific instructions of the law, under § 422.114(a), HCFA will find that an M+C organization meets this requirement if, with respect to a particular category of provider, the plan has: Payment rates that are not less than the rates that apply under original Medicare for the provider in question; contracts or agreements with a sufficient number and range of providers to furnish the services covered under the plan; or a combination of the above. These access tests must be met for each category of service established by HCFA on the M+C organization application. Thus, if an M+C PFFS plan has payment rates that are no lower than Medicare, it need not address if it has a sufficient number of providers of services under written contract. However, where the plan's payment rates are less than the Medicare payment for that type of provider, the M+C organization must demonstrate that the plan has a sufficient number of providers of that type under written contract.

Medicare payment amounts are established in a variety of different ways. For many of the key services for which Medicare pays, Medicare has prospectively set payment amounts or fee schedules that are established by HCFA and published in the **Federal Register** each year. These include, but are not limited to, prospective payment systems for acute care hospital services, and skilled nursing care, and fee

schedules for physician services (which includes care by many nonphysician practitioners and diagnostic tests), durable medical equipment, and clinical laboratory services. Moreover, HCFA is currently developing prospective payment systems or fee schedules for other key services including home health care, ambulance services, and outpatient hospital care, which we expect to be implemented within the next year or two.

However, for some services, Medicare payments are set retrospectively or concurrently by Medicare carriers and intermediaries. For example, until the prospective payment systems or fee schedules are implemented, home health care, outpatient hospital care, and ambulance services will be paid by carriers and intermediaries based upon a HCFA-specified national methodology that they apply either upon receipt of the claim (for example, ambulance services paid on a reasonable charge basis) or long after the service is furnished (for example, retroactive cost report settlement). Moreover, there are some services for which reasonable cost and reasonable charge payment will continue indefinitely. Examples of these services are critical access hospital care (which by law must be paid actual cost without limits) and carrier priced physician services (for which the service is too new or too rare to support a national fee schedule value).

Clearly, where there are national prospective payment systems and fee schedules, M+C organizations offering PFFS plans should have no problem in paying amounts no less than the Medicare payment amount for covered services since those amounts are clearly and prospectively published by HCFA. However, the question arises as to how the access test based on Medicare payment levels can be met with regard to services that are paid by Medicare intermediaries or carriers on a reasonable cost or reasonable charge basis. Moreover, consistent with section 1852(d)(4) of the Act and § 422.214(b), M+C organizations offering PFFS plans cannot restrict providers from whom the beneficiary can acquire care. Therefore, the M+C organization must have the capacity to pay no less than the Medicare-allowed amounts for any Medicare-covered service furnished by any provider in any area of the nation. Acquiring the payment amounts from individual Medicare intermediaries and carriers would be a cumbersome and difficult task, and would be likely to result in unwanted payment delays. Therefore, we have decided to permit M+C organizations offering PFFS plans to establish proxies for use in paying

services for which no Medicare prospective payment system or fee schedule exists.

The law and regulations permit the use of HCFA-approved proxies as long as those proxies result in payment amounts that are "not less than" Medicare payment rates. If the payment amounts to be paid by the M+C organization are equal to or more than the Medicare payment amounts for those services, the requirement of the law and regulations are met and HCFA must find that the PFFS plan provides for adequate access to care for those categories of services. Therefore, in cases of services for which there is no prospective payment system or fee schedule amount, we will permit M+C organizations to pay proxy amounts under certain circumstances. These proxy amounts must be approved by HCFA as approximating as closely as possible what providers as a whole receive for certain services. Because we expect these payment proxies would be estimates, the M+C organization must also have a process for reviewing these amounts, if necessary, on a provider-by-provider basis. If a provider is able to demonstrate that the proxy amount is less than the amount Medicare would actually pay, the M+C organization must pay the latter amount.

Proxies will take different forms, depending upon what makes the most sense for the type of service being paid. For example, a hospital that is paid on reasonable costs subject to a limit may be paid a percent of charges that is taken from the provider's last settled Medicare cost report. Similarly, an ambulance supplier may be paid the prevailing charge adjusted for the IC that applies in the year in which the service is furnished. Where proxies are used, HCFA will require that a description of the proxy methodology must be included in the terms and conditions of plan payment for deemed contractors that must be made available to providers of services before they treat an PFFS enrollee (see § 422.216(h)(2)(iii)(B)). As nationally established prospective payment systems and fee schedules are developed and implemented by HCFA, the use of proxies should diminish. However, at this time, and for the foreseeable future, for a limited subset of Medicare-covered services, proxies will be necessary for organizations offering M+C PFFS plans that choose not to contract directly with providers. For the reasons discussed above, we believe that their use comports with both the spirit and intent of the law and regulations.

7. Physician Incentive Plans (§ 422.208)

In § 422.208(e), we specify that an M+C PFFS plan may not use capitated payment, bonuses, or withholds in the establishment of the terms and conditions of payment. This is necessary to implement that part of the definition of an M+C plan that specifies that the plan must pay without placing the provider at financial risk.

8. Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

As discussed in detail in our June 1998 interim final rule (63 FR 35040), § 422.216(a) addresses payment to providers. Specifically § 422.216(a)(1) provides that the M+C organization offering a PFFS plan must pay all contract providers (including those that are deemed to have contract under § 422.216(f)) on a fee-for-service basis at a rate, determined under the plan, that does not place the provider at financial risk. This reflects the statutory definition of an M+C PFFS plan. We also specify in § 422.216(a)(1) that the payment rate includes any deductibles, coinsurance, and copayment imposed under the plan, and must be the same for all providers paid pursuant to a contract whether or not the contract is signed or deemed to be in place. Section 422.216(a)(3) establishes the payment rate for noncontracting providers.

Section 422.216(b) addresses permissible provider charges to enrollees. Under § 422.216(b)(1), contracting providers (including deemed providers) may charge the enrollee no more than the deductible, coinsurance, copayment, and balance billing amounts permitted under the plan. Like payment rates, the plan deductible, coinsurance or copayments and other beneficiary liability must be uniform for services furnished by all contracting providers, whether contracts are signed or deemed to be in place. These two requirements are closely related, since permissible enrollee liability is linked by statute to the plan's payment rate. These cost-sharing amounts must be specified in the plan contract. The plan must have the same cost-sharing for deemed contract providers as for contract providers, and it may permit balance billing no greater than 15 percent of the payment rate for the service.

Other significant requirements set forth in § 422.216 address monitoring and enforcement of the payment and charge provisions (§ 422.216(c)), notifications to plan members concerning payment liability, including balance billing rules (§ 422.216(d)), and rules covering deemed contract

providers, including enrollee and provider notification requirements associated with these providers regarding payment terms and conditions (§§ 422.216(f), (g), and (h)).

9. Deemed Contracting Providers

Comment: One commenter endorsed having the same standards for deemed and contracting providers so that an M+C PFFS plan does not become a PPO without the quality assurance standards of a PPO. Other commenters objected to the concept of deemed contracting providers, because they believe that it will reduce provider willingness to provide services in these plans, and because they believe it is unfair to physicians, particularly those who provide emergency care.

Specifically, a commenter indicated that M+C organizations offering PFFS plans will not be able to get providers to sign contracts because there is no incentive for a provider to bind itself to a contract when it is not promised a share of the market in the area, and when it will be paid like a contracting provider, whether it signs a contract or not, under the deemed contracting provisions. Commenters indicated that there will be problems determining the "deemed contract" vs. the noncontract status of providers, since it depends on what they knew at the time of service. A commenter said that HCFA should tighten the rules under which deeming can be presumed, and seek statutory modifications to limit the use of deeming.

Some commenters indicated that emergency department physicians should not be deemed contractors because the M+C organization could blanket an area with terms and conditions of plan payment, and thereby force them to accept terms and conditions with which they did not agree, since they must treat all patients who present in the emergency department. They commented that HCFA should stipulate that deeming is never presumed to have occurred when emergency services or urgent care are required, particularly when they are required under the Emergency Medical Treatment and Labor Act. Other commenters recommended that the deemed contract language should be amended to explicitly not apply to out of network service provided in an emergency department, and to require that all physicians who provide services in the emergency department be paid as noncontracting providers. Commenters believe that this is needed because, under the Medicare provider agreement anti-dumping rules, the hospital must ensure that all patients who present in

the emergency room are seen and that, therefore, the physicians on duty have no ability to choose not to provide care to the enrollee. Under the deemed contracting provisions of the law, they are forced to accept the terms and conditions of plan payment when they treat the patient.

Response: We recognize that the law provides little or no incentive for a provider to sign a contract with an M+C PFFS plan because of the deemed contracting provisions. We also agree that the deemed contracting requirements of the law are problematic, particularly in emergency room settings, and will create disputes between M+C organizations and providers about what the provider knew and when it was known.

The statute specifies that the M+C organization must treat providers that do not have a contract with the plan as if they had such a contract, if the provider knew that the beneficiary was enrolled in the plan, and either knew the terms and conditions of plan payment, or had reasonable access to those terms and conditions.

In general, if the beneficiary has advised the provider of his or her plan enrollment (as is often requested by the provider before providing care), and the provider knows the terms and conditions of plan payment (for example, because the physician or the party to whom the physician has reassigned benefits has received the plan terms and conditions in writing), or has a reasonable opportunity to learn the terms and conditions of plan payment (for example, through a toll free phone number, a website, or by having been sent a copy of the terms and conditions of plan payment), in a manner reasonably designed to effect informed agreement by a provider, then the provider meets the statutory test of being a deemed contracting provider, and the law requires that he or she must be treated as such. The law and regulations presume that, if the provider meets the criteria as a deemed contracting provider and subsequently treats the enrollee, then the provider has implicitly demonstrated agreement to the terms and conditions of payment by treating the enrollee.

While the law does not provide an explicit exception to the deemed provider provisions for emergency or urgent care services, we acknowledge that there are special circumstances that surround services in an emergency department of a hospital that justify considering providers who have not signed a contract with the PFFS plan to be noncontracting providers when they furnish services in an emergency

department of a hospital. We have revised § 422.216(f) accordingly.

When a physician or hospital has not signed a contract with a PFFS plan but treats a plan enrollee in an emergency department of a hospital, the physician or hospital has no opportunity to refuse to treat the patient as the deemed contracting provisions of the law anticipate. Hence, we believe that it is appropriate to specify that a physician or hospital that furnishes services in the emergency department of a hospital on behalf of the hospital's obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA) cannot be deemed to be a contracting provider. Of course, if the physician or hospital has previously signed a contract with the PFFS plan, the physician or hospital is a contracting provider, and is bound by the terms and conditions of that contract. Moreover, once the services furnished in the emergency department of a hospital cease to be required under § 489.24, the criteria that determine whether the providers are deemed contracting providers or noncontracting providers would then apply.

III. Provisions of this Final Rule—Changes to the M+C Regulations

For the convenience of the reader, listed below are all significant changes to the M+C regulations that are set forth in this final rule. Please note that changes stemming from the BBRA, which—unlike those changes listed below—are subject to public comment, are all discussed in a discrete section of this preamble (section I.C) and thus are not listed here. In addition, we caution the reader that the list below is intended solely as a reference aid, rather than as a policy summary.

- In § 422.2, we are revising the definition of “service area”, as well as making minor technical changes to several other definitions.
- We are revising § 422.50(a) to allow individuals and employer group members who become entitled to Medicare and live outside of the service area to convert to an M+C plan if they were previously enrolled in a commercial plan offered by the M+C organization, provided these individuals receive full plan benefits and M+C access and availability standards are met.
- To allow us the flexibility to vary the timeframes for the enrollment transmission schedule in the future, we are amending § 422.60(e)(6) to state “upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization

transmits within time frames specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.”

- We are revising § 422.60(f)(3) to state that “upon receipt of the election form from the employer, the M+C organization must submit the enrollment within time frames specified by HCFA.”
- In order to avoid introducing confusion between responsibilities of M+C organizations and HCFA, we have eliminated material in § 422.64 concerning HCFA's information responsibilities and moved necessary material to § 422.111.
- We have modified § 422.66(b)(3)(i) to state that the timeframe to submit disenrollment transactions will be “specified by HCFA,” and have made a conforming change at § 422.66(f)(2), as opposed to within 15 days.
- At § 422.66(d) we are clarifying that an M+C organization must accept any eligible individual who is enrolled in a health plan offered by “an” M+C organization to apply to a specific M+C organization, namely the organization that offers both the commercial health plan in which the individual is enrolled and the M+C plan in which the individual will be enrolling.
- At § 422.74(b)(3)(ii) we are permitting an M+C organization that has reduced an M+C plan's service area to offer continued enrollment in one of its M+C plans to enrollees in all or a portion of the reduced area if enrollees agree to receive “basic benefits” exclusively at designated facilities within the plan's new service area.
- We are adding a provision to § 422.74(d)(1)(iv) that expressly provides an M+C organization the option to discontinue an optional supplemental benefit for which premiums are not paid, while retaining the beneficiary as an M+C enrollee.
- We are changing the requirement at § 422.74(d)(4) to state that the M+C must disenroll an individual, unless he or she chooses the continuation option, if the individual moves out of the plan's service area for over 6 months, rather than 12 months.
- We are adding wallet card instructions to the list of examples of marketing materials at § 422.80(b)(5)(v), to ensure that wallet card instructions to enrollees are consistent with the statute and regulations, particularly requirements that apply to emergency and urgently needed services.
- We are revising § 422.80(e) to permit more flexibility for providers in distributing materials to M+C enrollees.

- We are adding a new § 422.80(e)(1)(viii) that prohibits new M+C plan names that exclude the disabled population.
- We are removing the definition of post-stabilization services in § 422.100(b)(1)(iv) and instead including all post-stabilization requirements in new § 422.113. See section II.C of this preamble for a full discussion of changes in the post-stabilization requirements.
- We are specifying at § 422.100(b)(1)(vi) and § 422.113 that M+C organizations are required to cover ambulance services dispatched through 911 or its local equivalent when use of other forms of transportation would endanger the health of the beneficiary.
- We are adding a provision at § 422.101(a) to state explicitly that services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.
- To promote beneficiary freedom of choice among providers, § 422.105 is revised to permit use of the POS option for in-network providers, rather than only for providers outside the plan network.
- To clarify our existing policy, we are clearly delineating HCFA's review authority in § 422.106 for employer group health plans and Medicaid plans.
- We are adding a new § 422.108(f) to clarify that a State cannot take away an M+C organization's Federal rights to bill or authorize providers to bill for services for which Medicare is not the primary payer.
- We are revising § 422.109(b)(5) to provide that M+C enrollees are responsible only for coinsurance amounts.
- We are revising § 422.111(e) to decouple the enrollee notice time frame from the “issuance or receipt” of a notice of termination and instead require that an M+C organization make a good faith effort to provide written notice at least 30 calendar days before the termination effective date.
- We are revising § 422.112(a)(3) to clarify that an M+C organization shall authorize out-of-network specialty care when its plan network is unavailable or inadequate to meet an enrollee's medical needs.
- At new § 422.113(b) we are specifying that “urgently needed services” are not “emergency services.”
- We are clarifying at § 422.113(b)(2)(ii) that prior authorization may not be required from the beneficiary in wallet card instructions or in other enrollee materials. We are also specifying that instructions on what to do in an emergency should include a statement

specifying that in the event of an immediate and serious threat to health, the enrollee may call 911.

- We are revising § 422.113(b)(2)(iii) to expressly set forth the requirement that M+C organizations assume financial responsibility for services meeting the prudent layperson definition of emergency at § 422.2 regardless of final diagnosis.

- In order to clarify the distinction between a removal of deemed status by HCFA based on HCFA's own survey and a removal based on a determination by an accreditation organization based on its accreditation survey, we are revising § 422.156(a) to separate these two situations.

- We are revising § 422.157(a)(3) to relax the prohibition on the participation of managed care organization representatives in private accreditation organization activities.

- We are revising § 422.158(e) to provide that we will act within the same timeframes that apply to fee-for-service deeming.

- To help clarify that the appeals procedures apply only for adverse participation decisions, we are redesignating the provider appeals procedures from § 422.204(c) to new § 422.202(d).

- Section 422.204 has been re-titled "Provider selection and credentialing" and contains the general rule that an organization must have written policies and procedures for the selection and evaluation of providers.

- We are consolidating the regulations concerning antidiscrimination and choice of providers into new § 422.205. We reaffirm that M+C organizations are prohibited from discriminating against providers based solely on their licensure or certification, and specify that when an M+C organization declines to include a provider in its network, it must notify the provider of the reason for its decision.

- We have revised § 422.214 to clarify the rules concerning payments to noncontracting providers.

- We have revised § 422.216(f) to indicate that, for PFFS purposes, "deemed contract" providers are considered to be noncontracting providers when they furnish services in an emergency department of a hospital.

- We are revising § 422.257 to permit M+C organizations to require that their contractors provide them with complete and accurate encounter data.

- We are adding two terms—"first tier" and "downstream"—to the list of definitions at § 422.500 that we believe clarify the types of entities to which the

M+C contracting requirements described at § 422.502(i) apply.

- We are revising the definition of "clean claim" in § 422.500 to require that claims include data for encounter data submission, and meet the original Medicare "clean claim" requirements in order to be considered a clean claim.

- In consultation with the Office of Inspector General, we are revising the compliance plan requirements under § 422.501 to eliminate mandatory self-reporting.

- In order to ensure that M+C enrollees are not put at financial risk in situations where provider groups or other entities "downstream" from an M+C organization become insolvent, we are revising § 422.502 to strengthen the protections for Medicare enrollees in situations where an M+C organization or its contractors encounter financial difficulties.

- Section 422.502(l), concerning certifications of the accuracy of payment data, has been modified to be consistent with the OIG's "good faith" standard, under which M+C organizations certify the accuracy of payment information to their "best knowledge, information, and belief." We are also permitting the delegation of this responsibility to individuals other than the CEO or CFO of the M+C organization.

- We are revising § 422.506(a)(2)(i) to permit an M+C organization until July 1 to notify us of its intent not to renew its M+C contract for the upcoming contract year.

- We are deleting § 422.506(b)(ii) in response to a concern that the standard for declining to renew an M+C contract was too vague to enforce.

- We are adding a new § 422.510(a)(12) that would specify that a substantial failure to comply with marketing guidelines is grounds for termination, non-renewal, or intermediate sanction.

- We are changing the language at section § 422.520(a)(3) to indicate that non-clean claims and the remaining 5 percent of clean claims not paid within 30 days must be either paid or denied within 60 calendar days from the date of the request.

- We are revising the definition of an organization determination under § 422.566 to provide additional clarity as to the types of situations that constitute an organization determination and thus give rise to the pursuant appeal rights.

- To further clarify the grounds on which an M+C organization may seek an extension, and to ensure an enrollee is adequately advised of the M+C organization's use of an extension, we are adding language to both

§§ 422.568(a) and 422.572(b) that requires an M+C organization to notify the enrollee in writing of the reasons for the extension, and to inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision.

- We are revising § 422.568(c) and (d) to modify the requirement concerning written notification of M+C enrollees when a service is denied in whole in or part.

- We have added new § 422.619 concerning effectuation of expedited reconsideration determinations.

- We have revised § 422.620 to eliminate the requirement that M+C organizations distribute to enrollees the notification of noncoverage of inpatient hospital care.

We have also made many minor technical and conforming changes to the M+C regulations to ensure that citation references are accurate, use more consistent terminology, and correct typographical errors in the current regulations.

IV. Collection of Information Requirements

Under the PRA, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain information collection requirements.

Note: Unless otherwise noted below, all information collection requirements in this rule are currently approved under OMB approval #0938-0753, which currently expires August 31, 2000.

Section 422.60 Election Process

Paragraph (b) of this section states that M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by § 422.306(a)(1). The

burden associated with this reporting provision is captured under § 422.306.

Section 422.74 Disenrollment by the M+C Organization

Paragraph (c) of this section requires that if the disenrollment is for any reason other than death or loss of entitlement to Part A or Part B, the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures. This requirement is currently approved under 0938-0763, which expires March 31, 2003.

Section 422.111 Disclosure Requirements

Paragraph (e) requires the M+C organization to make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days (revised from 15 days) before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating. The burden associated with this requirement has not changed.

Section 422.113 Special Rules for Ambulance Services, Emergency and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services

Paragraph (b)(2) of this section requires that enrollees be informed of their right to call 911.

The burden associated with this disclosure provision is the time it takes an M+C organization to inform each beneficiary of his or her right. In addition, instructions to seek prior authorization for emergency services and/or before the enrollee has been stabilized may not be included in any materials furnished to the enrollee. We anticipate that these requirements will be provided as part of standard enrollment disclosures. Therefore, the burden associated with this requirement is contained in section 422.64.

Section 422.152 Quality Assessment and Performance Improvement Program

Paragraph (e) of this section requires that an organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan to measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified

in uniform data collection and reporting instruments required by HCFA and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this reporting provision is the time it takes an M+C organization to gather and submit the information. "All Medicare+Choice organizations and an organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan will be required to measure performance under their plans, using standard measures required by HCFA, and report their performance to HCFA. Reporting will be required annually. Currently the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB #0938-0701. The currently approved annual per plan burden is estimated to be 400.53 hours. Therefore, the total burden associated with this requirement is 180,239 hours (400.53 hours × 450 plans (100 new/350 current)).

Section 422.202 Participation Procedures

Paragraph (d) of this section requires that an M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees give the affected individual written notice as required by this section.

This section also requires that an M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

The burden associated with these reporting provisions is the time it takes an M+C organization to write the notice and give it to the practitioner and the appropriate licensing, or disciplinary bodies or to other appropriate authorities. We estimate that it will take 450 plans, 10 hours to produce and disclose 10 notices on an annual basis, for a national annual burden of 4,500 hours.

In addition this paragraph requires that an M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

The burden associated with this reporting provision is the time it takes an M+C organization and provider to

write the notice and furnish it to the other party. We estimate that 450 entities will be required to write 10 notices, at 1 hour per notice, for a national annual burden of 4,500 hours.

Section 422.205 Provider Antidiscrimination Rules

The reporting requirement of this section requires that, if an M+C organization declines to include a given provider or group of providers in its network, it furnish written notice to the affected provider(s) of the reason for the decision.

The burden associated with this reporting provision is the time it takes an M+C organization to write and provide the required notice. We estimate that it will take 450 plans, 30 minutes to produce and disclose 20 notices on an annual basis, for a national annual burden of 4,500 hours.

Section 422.206 Interference With Health Care Professionals' Advice to Enrollees Prohibited

The reporting requirement in paragraph (b)(2) requires that, through appropriate written means, an M+C organization make available information on any conscience protected policies to HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111. With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice within 90 days after adopting the policy at issue.

The revision to the information collection provisions requires the M+C organization to make available policy changes. We estimate that it will take 30 minutes for each of the 450 M+C organizations to comply, for a total of 2,225 hours nationally on an annual basis.

Section 422.257 Encounter Data

Paragraph (d)(1) of this section requires that M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service, when appropriate, and to all relevant national standards. M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services. In addition, M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of

complete and accurate encounter data as required by HCFA.

The burden associated with this paragraph is currently approved under OMB approval #0938–0753.

Section 422.568 Standard Timeframes and Notice Requirements for Organization Determinations

Under paragraph (a) of this section, when a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee. When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

The revision to this provision is that requiring the M+C organization to notify the beneficiary of its reasons for delay and of the right to file a grievance.

We estimate that this requirement will add 40 hours for each of the 450 M+C organizations to the burden currently captured under 0938–0753, for an annual addition of 18,000 hours.

Under paragraph (c), at each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed notice from the M+C organization regarding the enrollee's services. The practitioner must provide the enrollee with complete information, using approved notice language in a readable and understandable form, necessary to contact the M+C organization.

The burden associated with this reporting provision is the time it takes a practitioner to notify the beneficiary. We estimate that there will be 160 encounters per entity (450) and that each notification will take an average of 15 minutes to do so, for a national annual burden of 4,500 hours.

Under paragraph (d), if an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization

decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

In addition to the currently approved burden under 0938–0753, the burden associated with this reporting provision is the time it takes to write the detailed decision and provide it to the beneficiary. We estimate that there will be 160 occasions per entity (450) for which a detailed decision must be provided and that each notification will take an average of 15 minutes for a national annual burden of 4,500 hours.

Under paragraph (e), the notice of any denial under paragraph (d) of this section must, in addition to currently approved requirements, (1) for service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and (2) for payment denials, describe the standard reconsideration process and the rest of the appeal process.

The burden associated with this reporting provision is the time it takes an M+C organization to add the required information to a notice. We estimate that it will take 450 plans 1 hour to produce and disclose the necessary language on an annual basis, for a national annual burden of 450 hours.

Section 422.570 Expediting Certain Organization Determinations

The information collection requirement in this section ((d)(2)(iii)) that is not currently approved under 0938–0753 requires that, if an M+C organization denies a request for expedited determination, it must take give the enrollee prompt oral notice of the denial and subsequently deliver, within 2 calendar days (proposed as 2 working days), a written letter that informs the enrollee of the right to resubmit a request for an expedited determination with a physician's support. The currently approved burden, associated with this requirement has not changed.

Section 422.572 Timeframes and Notice Requirements for Expedited Organization Determinations

The information collection requirement change to paragraph (b) requires that, when the M+C organization extends the deadline, it notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension.

The additional burden associated with this requirements set forth in this section is the time it takes an M+C organization to notify the beneficiary of the delay and the reasons for it. We estimate that 450 plans will provide extension notices to approximately 100 of their M+C enrollees on an annual basis and it will take an average of 5 minutes per notification. Therefore, the annual national burden is estimated to be 3,750 hours.

Section 422.584 Expediting Certain Reconsiderations

The information collection change to this section requires that, if an M+C organization denies a request for expedited reconsideration, it must give the enrollee prompt oral notice, and subsequently deliver, within 2 calendar days, a written letter that (in addition to currently approved disclosure requirements) informs the enrollee of the right to resubmit a request for an expedited reconsideration with a physician's support.

The one time burden associated with this disclosure requirement is the time it takes an M+C organization to add the requisite language to the letter it furnishes to the beneficiary. We estimate that it will take each M+C organization (450) an average of 30 minutes to add the language to its current letter for notifying beneficiaries, for a national annual burden of 2,250 hours.

Section 422.620 How Enrollees of M+C Organizations Must Be Notified of Noncoverage of Inpatient Hospital Care.

The information collection change to this section the clarification that in *all* cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, the hospital (as provided under paragraph (d) of this section) or M+C organization must provide written notice to the enrollee that includes the elements described in this section. The burden associated with this requirement is currently approved and captured under 422.622.

We have submitted a copy of this final rule to OMB for its review of the revised information collection requirements in §§ 422.60, 422.74, 422.111, 422.113, 422.152, 422.205, 422.206, 422.257, 422.568, 422.570, 422.572, 422.584, and 422.620. These revised requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and 3 copies within 30 days of

this publication date directly to the following:

Health Care Financing Administration,
Office of Information Services,
Information Technology Investment
Management Group, Division of
HCFA Enterprise Standards, Room
N2-14-26, 7500 Security Boulevard,
Baltimore, MD 21244-1850. Attn:
John Burke HCFA-1030-FC.
and,

Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Allison Heron Eydt,
HCFA Desk Officer.

V. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

As a result of changes to the M+C regulations to reflect provisions of the BBRA, this rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). We consider a major rule to be one with economic effects of \$100 million or more in a given year, and as noted below in section V.B.8 of this regulatory impact analysis, the effects of the BBRA changes reach this threshold. Generally, a major rule takes effect 60 days after the date the rule is published in the **Federal Register**. In this case, however,

as discussed in detail above in section I.C of this preamble, the BBRA included specific effective dates for its various M+C provisions. For the most part, the statutory changes are self-explanatory, and have already taken effect. Thus, except as provided under the BBRA, the provisions of this final rule with comment period take effect 30 days after publication in the **Federal Register**.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more. This final rule with comment period will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below these thresholds as well.

1. Summary of the Final Rule

As discussed in detail above, this rule implements only limited changes in the M+C regulations published June 26, 1998 (and further amended February 17, 1999). While we do not expect the changes contained in this final rule to have a significant economic impact, we believe that we have a responsibility to keep the public informed of the impact of inherent features of the M+C program, such as payment changes and the implementation of risk-adjusted payments. We attempted to describe the impacts of these payment changes in the interim final rule. However, after a year of experience administering the program, we now have a better understanding of the impact of the payment changes. This impact analysis will examine payment effects associated with these two items, and respond to public comments concerning the economic impact of M+C policies.

2. Summary of Comments on Impact of M+C Program

Although commenters on the interim final rule generally recognized that the payment methodology and rates associated with the M+C program were implemented as directed by the BBA, several commenters still expressed concern that resulting payments to M+C organizations were insufficient to keep pace with the costs of providing medical care. These commenters suggested that the new payment methodology, particularly when combined with the implementation of a risk adjustment mechanism in 2000, could have the unintended consequence of limiting, rather than expanding, the health plan choices available to Medicare

beneficiaries. M+C organizations have withdrawn from some areas, and many beneficiaries have experienced growing premium increases or benefit reductions. Commenters also asserted that the M+C regulations contained discretionary provisions that added unnecessarily to the administrative burden on M+C organizations. In particular, commenters identified quality standards, provider participation requirements, and attestation procedures as examples of what they considered overly proscriptive rules that had the potential to raise health plan costs. In general, commenters urged us to evaluate more carefully the cumulative impact of the changes introduced by the M+C program.

We noted in our February 17, 1999 limited M+C final rule that we needed a statistically-based model to evaluate the total impact of payment changes for M+C organizations. We have subsequently developed a model that estimates the impact of risk-adjusted payments on M+C organizations. This impact analysis focuses on results from this model. When possible, we provide detail on impacts by geographic area and by organization size.

We then discuss some of the concerns raised by commenters about likely withdrawals from the M+C program. Finally, our analysis examines available information concerning the administrative burden associated with selected M+C requirements.

B. Payment Changes

1. Background

Prior to the BBA, Medicare's capitation rates for managed care plans had been set at 95 percent of expected costs based on actual fee-for-service costs. Because of the variation in fee-for-service expenditures for different counties due to different utilization patterns and cost structures, the Medicare managed care rates for different counties were also quite divergent. In addition, there was significant evidence that Medicare had paid more for enrollees in the Medicare managed care programs than it would have paid in the fee-for-service program. This was due primarily to the favorable selection that these plans have experienced.

The BBA made a number of changes in Medicare payments to managed care plans including:

- Increasing payments in counties that historically had the lowest payment rates (and generally have not had risk-based Medicare managed care plans) through the use of a payment floor and by introducing a blended payment rate.

- Reducing the rate increases in counties that historically had higher payment rates.

- Reducing M+C capitation rates by phasing in the removal of direct and indirect medical education payments from M+C capitation rates beginning in 1998 (and phasing in direct payment of these “carved out” amounts to the institutions providing care to M+C enrollees).

Payment increases from year to year after 1997 are based on an update factor that is the rate of increase in projected Medicare expenditures each year, less a statutorily specified reduction (reducing the rate to .8 percent less in 1998 and .5 percent less each year thereafter through 2002). However, all counties are guaranteed a minimum payment increase of 2 percent over the preceding year's base rates.

The BBA also mandated the introduction, by the year 2000, of risk-adjusted payments in the M+C program. Risk adjustment will have the effect of reducing payments to plans because, as a number of studies have shown, relatively healthier Medicare beneficiaries enroll in M+C plans. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations

can do better under risk adjustment than they would if case mix stayed the same.

These M+C payment changes were intended to promote the three objectives which we discuss below in V.B.2, 3 and 4.

2. Promote the Availability of M+C Plans in Lower Payment Areas

The introduction of a “floor” on the payment rates for M+C organizations was intended to make the program financially viable in areas where the AAPCC appeared to be too low for any organization to recoup its costs. Beginning in 1998, the floor was set at \$367 and was adjusted annually by the rate of growth of the overall Medicare program. By providing this floor payment level, M+C organizations are paid more than would otherwise be spent on the same beneficiaries in original Medicare.

Some county payment rates are raised through implementation of blended payments. These rates are calculated as a blend of national average rates adjusted for local input prices and area-specific rates. Area-specific rates are 1997 payment rates, adjusted for spending for graduate medical education, and updated using the national M+C update factor.

By raising the M+C payment levels higher than the spending amounts in original Medicare, it was hoped that M+C organizations would be attracted to these lower payment areas. In the chart

below, we have compared the M+C county payment rates for 2001 to the area-specific rate in each county. In 2001, 3,020 counties will receive a payment rate higher than their area-specific rate. The payment rate for Arthur, Nebraska, will be 77 percent or \$175 higher, the greatest improvement for any county.

The payment floor and the phased in blended payments were also designed to raise the payment level for more than just the lowest payment counties. Raising payments above the levels determined by the pre-BBA methodology was intended to give organizations that have operated in lower payment counties the opportunity to enhance their benefit packages, thereby increasing enrollment.

The largest improvements in payments are for areas with relatively small numbers of beneficiaries, and are largely achieved in most cases by applying the payment floor. Many more beneficiaries live in counties where the improvements are more modest (up to a 5 percent difference). These counties were primarily those paid under the blend mechanism in 2000, whose payment improvements were safeguarded by the minimum increase component of the formula for 2001.

Following is a breakout of the 3,147 U.S. counties by percentage improvement over their area specific rate:

TABLE 1.—PERCENT DIFFERENCE BETWEEN M+C PAYMENT RATES AND AREA-SPECIFIC PAYMENT RATES, 2001

Percentage difference	Number of counties	Number of beneficiaries (000s)	Payment is floor	Payment is blend	Payment is minimum increase
Negative	127	1,318	0	0	127
0 to 5	1,000	15,741	0	0	1,000
5 to 10	946	9,848	62	0	884
10 to 20	572	4,133	401	0	171
20 to 30	264	888	264	0	0
30 to 40	131	408	131	0	0
40 to 50	68	142	68	0	0
50 to 60	26	52	26	0	0
60 to 70	9	18	9	0	0
70 to 80	4	5	4	0	0
Total	3,147	32,554	965	0	2,182

Source: HCFA, CHPP.

Counties where M+C payment rates are lower than their area-specific payment rate tend to be those that have received the minimum increase for each of the four years that the M+C payment formula has been in place, and also had relatively little medical education spending. The cumulative four-year increase of the national update was approximately 9.3 percent, only a

percentage point higher than the cumulative four-year increase of 8.2 percent for those counties receiving the minimum update each year. The area-specific payment rate in 2001 reflects a reduction to the 1997 rate of 80 percent of spending attributable to medical education. Thus, a county with relatively high medical education spending will have a higher M+C

payment rate than area-specific payment rate even if it also had received the minimum update each year.

3. Reduce the Wide Disparities in Payments Between High and Low Payment Areas

By changing how payment rates are calculated, the BBA also sought to even out the wide disparity in Medicare managed care payment rates across

counties, an issue that had been a concern for lower-payment areas. Table 2 shows the percentage of counties that

received the floor, a blended rate, or the minimum 2 percent increase for each

year calculated using the BBA methodology.

TABLE 2.—PERCENT OF COUNTIES RECEIVING FLOOR, BLEND, OR 2 PERCENT INCREASE

Year	Floor counties (percent)	Blend counties (percent)	2 percent counties (percent)
1998	33.8	00.0	66.2
1999	39.7	00.0	60.3
2000	29.1	63.1	7.8
2001	30.7	00.0	69.3

Source: HCFA, CHPP.

There were only limited payment increases for 1998 and 1999, with counties receiving either the floor payment or the minimum 2 percent update. This was due primarily to the combined effects of the amount of the national update and the budget neutrality provision affecting calculation of the blended rate. In 2000, however, well over half the counties are receiving the blended rate. The enrollment-weighted average increases in M+C payments nationwide in the year 2000 over 1999 is slightly more than 5 percent. For 2001, all counties will receive the floor payment or the minimum 2 percent update, again

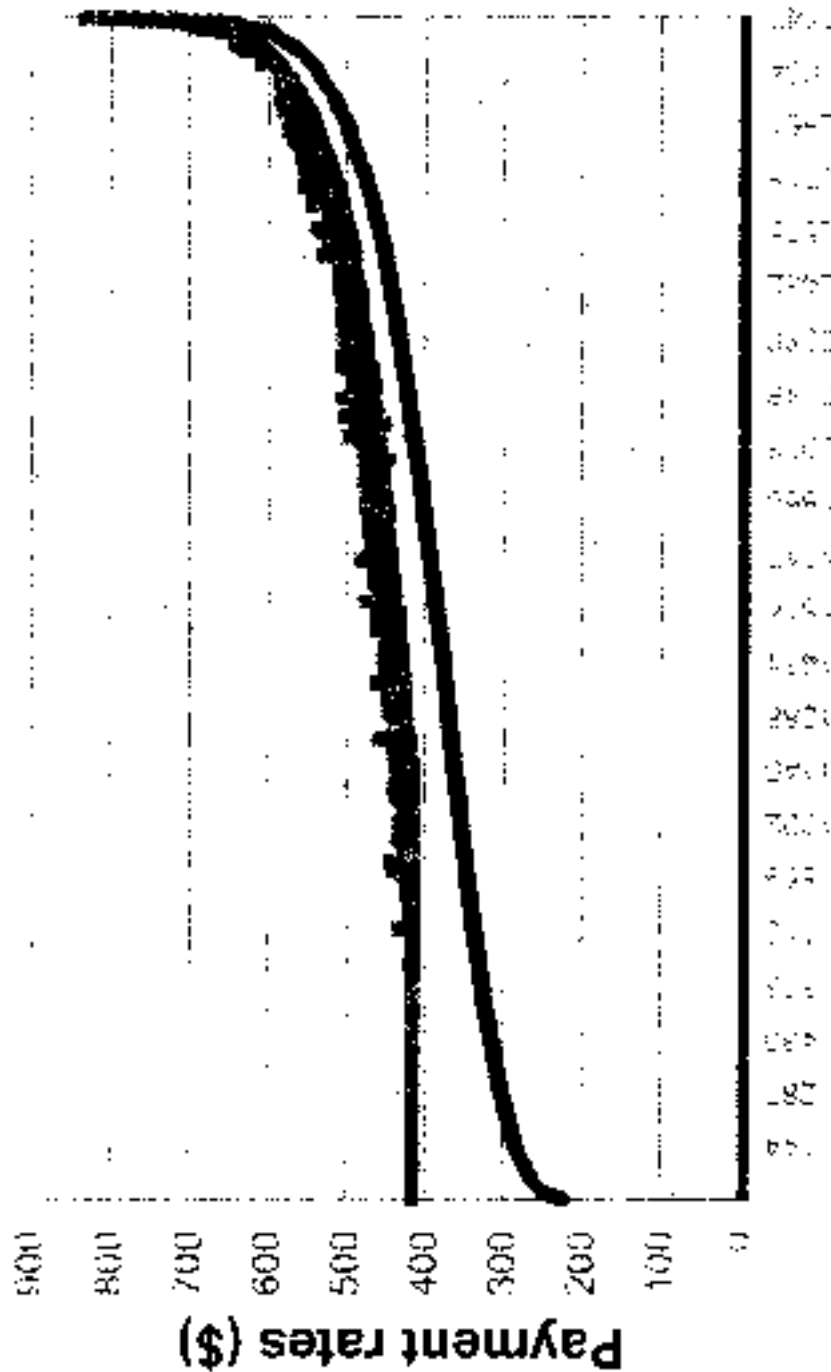
because of the budget neutrality provision and a national update that reflects the extremely low rate of spending in original Medicare in 1999. Although most counties will receive the minimum increase in 2001, many of these had enjoyed relatively large increases due to the blended rates in 2000, which the minimum increase essentially will preserve.

As illustrated in the graph below (1997 Medicare+Choice Payment Rates Compared with 2001 Payment Rates), the new payment formulas have changed the distribution of payment rates across counties, although perhaps not as quickly as the Congress

envisioned because of the unusually low national increases in spending. In 1997, county payment rates for aged beneficiaries ranged from \$221 to \$767. Through the implementation of the payment floor, blended payment rates, and minimum update, payments have increased substantially at the low end of the distribution, and increases at the high end have slowed. The range of payment rates in 2001 is only somewhat smaller: between \$415 and \$831, but the 2001 payment curve is straighter than the 1997 curve, indicating a narrower distribution.

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1997 Medicare+Choice Payment Rates Compared with 2001 Payment Rates



Counties

— 1997 rate • 2001 rate

Source: HCFA, CHPP

While national numbers show the overall pattern, the impact is highlighted when examining the effect of the BBA on the payment rates at the State level. Table 3 shows the effect of the payment changes in two States: Oregon and Florida. Both States have significant M+C enrollment penetration, but Oregon's rates are low, and Florida's are high.

The BBA payment changes have narrowed the regional difference. In 1997, prior to the BBA payment changes, Florida's weighted average payment rates were 149 percent higher than those of Oregon. (Florida's statewide average payments were at 114 percent of the national average, while Oregon's were at 76 percent.) In 2001, Florida's rates will be 136 percent of Oregon's, because many Oregon

counties had benefited from blended payment rates in 2000, while many large Florida counties received the minimum update that year.

Lower-paid States such as Oregon receive relatively higher rates of payment increases than higher-paid States such as Florida. These differential payment increases will bring both States' average payments closer to the national average payment rate.

TABLE 3.—COMPARISON OF MEDICARE+CHOICE PAYMENT RATES IN OREGON AND FLORIDA

State	Weighted average payment rate 2001	Weighted average payment increase 97–01 (percent)	Payment rate as a percent of national 1997 (percent)	Payment rate as a percent of national 2001 (percent)
Oregon	\$435.25	22.5	76	83
Florida	581.15	9.6	114	111
National	523.85	12.4	100	100

Despite the BBA changes, the levels of benefits and premiums between higher and lower payment counties continue to vary in 2000. In Oregon, for example, premiums range from \$35 to \$83 for benefit packages that do not include outpatient drug coverage, and between \$81 and \$123 for packages including drug coverage. In Florida the enrollment-weighted average monthly premium is \$84 per month, and all enrollees in Florida M+C plans have drug coverage in their basic package. Over time, the BBA payment changes may narrow this difference.

4. Establish a Fairer Payment System

The BBA mandated that we “implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment [to M+C organizations] starting no later than January 1, 2000.” The BBA also gives us the authority to collect inpatient hospital data for discharges occurring on or after July 1, 1997, and allows us to require additional data from M+C organizations for services occurring on or after July 1, 1998.

a. Description of the Inpatient Risk Adjustment Model. In implementing the BBA mandate, we selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to implement in 2000. Under the PIP-DCG model, individuals are assigned to a single PIP-DCG group based on the principal inpatient diagnosis they were assigned during an inpatient stay, that has the greatest future cost implications. The model is prospectively based; in other words, base year inpatient diagnoses are used

in the model to predict payment year health expenditures. The model also uses age, sex, original reason for Medicare entitlement (such as age or disability), and entitlement to state payments for Medicaid to derive a predicted expenditure level. This predicted expenditure amount is then converted to beneficiary relative risk factors by dividing an individual's predicted expenditures by the national mean. Because this model was developed and calibrated using a year of inpatient diagnoses, a full year of data is essential for assigning beneficiary risk factors. Beneficiaries “new” to Medicare (for whom no prior diagnosis information exists) have their payments based on the average expenditures for their age group. To determine risk adjusted monthly payment amounts for each M+C enrollee, individual risk factors will be multiplied by the appropriate payment rate for their county of enrollment.

We decided to include a transition period as a component of our risk adjustment methodology, initially using a blend of payment amounts under the current demographic system and the PIP-DCG risk adjustment methodology. Under a blend, payment amounts for each enrollee will be separately determined using the demographic and risk methodologies (that is, taking the separate demographic and risk rate books and applying the demographic and risk adjustments, respectively). These payment amounts would then be blended according to the percentages for the transition year. This transition to full risk adjusted payment will be phased in over 5 years. Following is the transition schedule to comprehensive

risk adjusted payment as mandated by the BBRA:

Calendar year	Demographic method (percent)	PIP-DCG method (percent)
2000	90	10
2001	90	10
2002	80	20

b. Impact of Risk Adjustment. The impact analysis presented here employs a “point in time” approach. To estimate the payment impact of the risk adjustment change, we compared actual demographic-based payments to estimated risk adjusted payments for the exact same enrollees for September 1998. Aggregated to the M+C organization level, the difference in these amounts represents a reasonable estimate of change in payment due to risk adjustment. Projections on reduced payments assume a stable mix of enrollees. However, we assume that organizations will respond appropriately to the incentives to attract more seriously ill beneficiaries. As a result, organizations can do better under risk adjustment than they would if case mix stayed the same.

This analysis uses the best data available at this time. The data to be used for actual payments (beginning January 1, 2000) will be based on hospital discharge data for the calendar year beginning on July 1, 1998 and ending June 30, 1999. The actual impact of the risk adjustment system relative to the current demographic system at the time of implementation may differ, due primarily to potential changes in M+C organization enrollment profiles and possible improvement in the quality and completeness of M+C organization data.

The impacts presented here show estimated figures for both the full effects of the PIP-DCG based payment system (that is, with no transition period), and for the first implementation year during which a 10 percent phase-in was included as part of the methodology. To estimate impacts under phase-in years, full impact results can be multiplied by the appropriate proportion of the risk adjustment payments. For example, the first year risk adjusted payment phase-in level is 10 percent. Therefore, to

estimate the impact under a 10 percent risk adjusted phase-in, the impacts can be multiplied by .10.

If our methodology did not include a transition period, payments to M+C organizations would decrease by approximately 5.7 percent. This is a revision over preliminary estimates of 7.6 percent, which were prepared using an earlier, more limited data set. The majority of M+C organizations would face payment decreases of between five and eight percent.

The table below presents the simulated impacts aggregated to our administrative regions. None of our regions will experience increased payments under the proposed system. The variation between regions is not considerable. Organizations in the Atlanta region will see an average .7 percent reduction, and organizations in the Seattle region will see less than a .4 percent reduction.

TABLE 4.—PAYMENT SUMMARY FOR SELECTED M+C ORGANIZATIONS BY HCFA REGION

Region	Enrollees	Percent difference (phase-in)	Percent difference (full impact)
Boston	359,819	–0.55	–5.50
New York	564,252	–0.35	–3.47
Philadelphia	583,740	–0.66	–6.61
Atlanta	895,021	–0.70	–7.00
Chicago	530,558	–0.50	–4.97
Dallas	472,627	–0.69	–6.93
Kansas City	154,223	–0.61	–6.14
Denver	128,069	–0.62	–6.25
San Francisco	1,710,117	–0.57	–5.69
Seattle	282,765	–0.35	–3.45
Total	5,681,191	–0.57	–5.74

In addition, we simulated impacts by M+C organization enrollment size. Table 5 reveals that the variation in impact between the small M+C

organizations and the large M+C organizations does not appear to be systematic. M+C organizations of all sizes are very close to the national

average, although smaller organizations will experience a slightly higher reduction.

TABLE 5.—PAYMENT SUMMARY FOR SELECTED M+C ORGANIZATIONS BY SIZE OF ENROLLMENT

Enrollment size	Enrollees	Percent difference (phase-in)	Percent difference (full impact)
Less than 500	5,115	–0.71	–7.10
500–2,999	88,594	–0.81	–8.10
3,000–4,999	993,829	–0.69	–6.87
5,000–9,999	354,271	–0.62	–6.22
10,000–24,999	1,177,118	–0.58	–5.79
25,000–49,999	1,029,859	–0.54	–5.41
50,000–99,999	1,471,009	–0.52	–5.23
100,000 or more	1,455,843	–0.61	–6.09
Total	5,681,843	–0.57	–5.74

5. M+C Organization Withdrawals

At the end of 1998, approximately 100 organizations dropped Medicare managed care contracts or reduced the number of counties in which a plan was offered. The result of these withdrawals

was that nearly 50,000 beneficiaries were left with no remaining M+C plan in their county. Likewise, the analysis of 1999 health plan departures shows that approximately 79,000 additional M+C beneficiaries were forced to leave the

program because there was no plan offered in their area.

Table 6 below shows the decline in beneficiaries' access to a M+C plan in their area (declining about 2 percentage points from the 1999 level of almost 70 percent).

TABLE 6.—PERCENT OF BENEFICIARIES WITH ACCESS TO M+C PLANS

1999			2000		
Urban	Rural	Total	Urban	Rural	Total
84.2	22.5	69.7	82.0	20.8	67.7

Of the 71 counties that had an M+C plan in 1999 but will no longer have an M+C option in 2000, 11 were considered high payment counties. In fact, the average increase in 2000 for these 71 counties is 6.2 percent. The county in this situation with the greatest increase was Clallum County, in Washington State, which received a blended rate increase of 12.8 percent over their 1999 rate.

Plan decisions to withdraw from M+C do not appear to be caused only by changes in payment amounts. Payment is rising in all counties this coming year by an average of 5 percent, and will rise by as much as 18 percent in some areas. BBA payment reforms were designed to increase payment in counties that had the lowest rates, and therefore the fewest number of plans. Yet counties receiving the largest increases under the BBA payment system are experiencing

the most disruption. Plan withdrawals are affecting 11.1 percent of enrollees in counties where rates are rising by 10 percent, but affecting only 2.3 percent of enrollees where rates are rising by just 2 percent.

Table 7 shows the States with the largest percentage decrease since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

TABLE 7.—STATES WITH LARGEST PERCENT DECREASE IN ACCESS TO M+C OPTION IN 2000 FROM 1997

State	Total Medicare population	Decrease in beneficiaries	Percent decrease in beneficiaries
Utah	207,838	183,541	88
Louisiana	621,826	175,645	28
Virginia	894,573	246,274	28
New Hampshire	172,069	45,627	27
South Carolina	575,890	130,118	23
Maryland	652,599	119,392	18

While several States have experienced a significant loss of access to M+C plans, other States have seen access to M+C organizations increase. In addition, the M+C program continues to grow despite challenges that parallel those in the larger managed care market in the United States. As of January 2000, there were 6.2 million M+C enrollees representing over 16 percent of the more than 39 million seniors and disabled

Americans in Medicare. Total Medicare managed care enrollment has more than doubled in the past four years from 3.1 million enrollees at the end of 1995 to 6.9 million enrollees as of April 1, 2000. (Total managed care enrollees consist of M+C enrollees and enrollees in Medicare Managed Care Cost Plans, Health Care Prepayment Plans, and managed care demonstrations.) However, the rate of growth has

dropped significantly from earlier periods, and has grown by only 1 percent per month the last several months.

Table 8 below shows the States with the largest percentage increase since 1997 (the start of the M+C program) of Medicare beneficiaries with access to an M+C plan.

TABLE 8.—STATES WITH LARGEST PERCENT INCREASE IN ACCESS TO M+C OPTION IN 2000 FROM 1997

State	Total Medicare population	Increase in beneficiaries	Percent increase in beneficiaries
Maine	219,944	138,067	63
Iowa	488,180	171,017	62
South Dakota	122,220	118,493	29
Oklahoma	519,239	114,185	24
West Virginia	345,587	65,794	20
North Carolina	1,149,374	54,040	18

6. Premium Increases

In our Impact Analysis that accompanied the Interim Final Rule we stated that "Reductions in capitated payment amounts in what are now relatively higher payment areas may result in reduced benefits for beneficiaries." While higher premiums and reduced benefits were not intended effects of the BBA, they are also not surprising given the reduced payment increases in higher cost areas. While benefits, premiums, and cost sharing

remained relatively stable in 1999, year 2000 has been different.

Analysis of the Adjusted Community Rate proposals submitted in July show that premiums for 2000 have increased, especially in rural areas. For example, in 1999, the enrollment-weighted average premium for a basic plan was \$5.35. For 2000, this amount will almost triple to \$15.84.

Table 9 shows the percent of M+C beneficiaries living in the designated areas that have access to a plan with the

associated premium. While the percent of beneficiaries with access to zero dollar premium plans is expected to be reduced by more than 3 percentage points, the percent of beneficiaries that must pay a \$40–\$100 premium has more than doubled. In 1999, only 50,000 Medicare beneficiaries lived in an area where the minimum premium is in the \$80 to \$100 range; however, in 2000, the number will rise to 207,000. The majority of these individuals (60 percent) are residents of rural counties.

TABLE 9.—PERCENT OF BENEFICIARIES LIVING IN DESIGNATED AREAS HAVING ACCESS TO AN M+C PLAN WITH ASSOCIATED PREMIUM 1999

Premium amount	1999			2000			Total percent change
	Urban (percent)	Rural (percent)	Total (percent)	Urban (percent)	Rural (percent)	Total (percent)	
\$0	79	63	78	78	40	75	- 3
\$0.01–\$19.99	1	2	2	3	11	4	2
\$20.00–\$39.99	5	14	5	9	18	9	4
\$40.00–\$59.99	4	11	5	6	17	6	2
\$60.00–\$79.99	1	8	2	1	7	2	0
\$80.00–\$99.99	0	0	0	0	0	1	1

In addition, access to a zero premium plan for rural beneficiaries will be reduced by almost 50 percent. In 1999, 1.3 million rural beneficiaries (63 percent of those with any plan available) live in an area with at least one zero premium plan; in 2000, only 784,000 rural beneficiaries, (40 percent of those with any plan available), will have such an option. One-half million

fewer rural beneficiaries will have access to a zero premium plan.

7. Premiums in Areas With Only One Plan

Medicare beneficiaries who live in areas with only one plan will be particularly affected by premium increases. Approximately 8 percent of M+C beneficiaries (just over three million) live in areas with only one plan. Note also in Table 10 that of the

207,000 beneficiaries who live in areas where the minimum monthly premium available is over \$80, 94 percent (over 195,000) live in areas with only one plan available. There will be a nearly six-fold increase from 1.6 percent to 9.3 percent in the percentage of beneficiaries who live in an area where the sole M+C plan available has a monthly premium in the \$80 to \$100 range.

TABLE 10.—MEDICARE BENEFICIARY POPULATION (TOTAL), ACCESS TO ONLY ONE PLAN

Minimum premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	803,162	31.6	599,553	28.4
\$0.01–\$19.99	17,614	0.7	0	0.0
\$20.00–\$39.99	467,284	18.4	410,662	19.5
\$40.00–\$59.99	716,662	28.2	683,029	32.4
\$60.00–\$79.99	499,095	19.6	220,237	10.4
\$80.00–\$99.99	39,742	1.6	195,432	9.3
Total	2,543,559	100	2,108,913	100

Premium increases in areas with only one plan will have the most pronounced impact in rural areas. From 1999 to 2000, roughly the same percentage of beneficiaries who live in rural areas will

have only one plan available—28.4 percent and 29.6 percent in each year, respectively. However, Table 11 shows that zero premium plans are becoming less widely available in rural areas. It

also shows that there will be a significant increase in the number of rural Medicare beneficiaries whose only M+C option is a relatively high cost plan.

TABLE 11.—MEDICARE BENEFICIARY POPULATION (RURAL ONLY) ACCESS TO ONLY ONE PLAN

Minimum premium	Year 1999		Year 2000	
	Beneficiaries	Percent	Beneficiaries	Percent
Zero	271,833	37.7	174,956	28.1
\$0.01–\$19.99	17,614	2.4	0	0.0
\$20.00–\$39.99	96,131	13.3	104,796	16.8
\$40.00–\$59.99	135,440	18.8	146,425	23.5
\$60.00–\$79.99	160,647	22.3	81,774	13.1
\$80.00–\$99.99	39,742	5.5	115,669	18.5
Total	721,407	100	623,620	100

8. Impact of BBRA

The Balanced Budget Refinement Act (BBRA) made two changes to the payment methodology established by the BBA. First, Section 512 of the BBRA

introduced bonus payments for M+C organizations that enter previously unserved counties. These organizations will receive an additional 5 percent payment for the first 12 months and an

additional 3 percent for the subsequent 12 months. The second change in section 517 of the BBRA was to lower the reduction in the National per Capita Medicare +Choice Growth percentage

from a 5 percent reduction to a 3 percent reduction in calculating the 2002 payment rates.

The Congressional Budget Office (CBO) estimated that the bonus payments would amount to additional payments of \$.1 billion over three years. Our experience to date suggests that this figure may be high, as currently there are only five M+C organizations receiving bonus payments and very few pending applications from prospective M+C organizations that would be eligible for the bonus. However, there is an application on file from a prospective M+C organization that envisions expanding into a large number of previously unserved counties. If this organization is extremely successful in enrolling beneficiaries, the CBO estimate could in fact be a low estimate.

We estimate that lowering the reduction of the National per Capita Medicare+Choice Growth percentage in the year 2002 will provide an additional \$80 million in payments to plans in 2002, and an additional \$560 million over 5 years. Payments to plans in all subsequent years will be higher because of the effect of lowering the reduction on the baseline.

C. Response to Comments on Interim Final Rule

Since the publication of our June 26, 1998 interim final rule, we have implemented several significant changes aimed at alleviating unnecessary administrative burdens. Examples of these changes include the less expansive provider participation requirements adopted in our February

17, 1999 rule, our December 1998 revisions to the QISMIC standards as discussed below, and clarification of the attestation requirements through this final rule. Clearly the cumulative effect of these changes will be to reduce the administrative costs associated with these requirements. Although we continue to solicit quantifiable data that can help us to assess the costs of complying with particular provisions, we have not received any data in this regard. We remain particularly interested in detailed estimates of the administrative costs associated with the QISMIC and HEDIS standards. Research of available literature/studies related to these administrative costs is presented below.

1. Quality Standards

The BBA codified many existing quality assurance requirements that had been established through operational policy letters and other guidance issued under the Medicare risk and cost contracting programs.

On September 28, 1998, we issued interim Quality Improvement Systems for Managed Care (QISMIC) standards and guidance. QISMIC is a system for ensuring that managed care organizations contracting with Medicare and Medicaid protect and improve the health and satisfaction of enrolled beneficiaries. It consists of a set of standards and guidelines developed around four domains—quality assessment and performance improvement, enrollee rights, health services management, and delegation.

QISMIC was developed in conjunction with federal and state officials, beneficiary advocates and the managed care industry to develop a coordinated quality oversight system to reduce duplicative or conflicting efforts, emphasize demonstrable and measurable improvement, and avoid reinventing the wheel. QISMIC standards represent the evolution of existing quality standards being used by commercial, Medicare and Medicaid health plans or managed care organizations. We believe QISMIC incorporates the currently accepted quality assurance elements and provides safeguards for vulnerable Medicare and Medicaid populations enrolled in managed care.

We reviewed NCQA accreditation 1999 standards for their consistency with QISMIC standards. This is an appropriate comparison because the National Committee for Quality Assurance has been recognized as a forerunner in assuring quality assurance in health plans through its accreditation processes, and development and implementation of HEDIS performance data reporting. Also, many Medicare+Choice organizations are NCQA accredited.

Our findings are provided in the table below, which was reviewed by NCQA representatives in order to assure the highest level of technical accuracy. In general, almost two-thirds of NCQA accreditation 1999 standards were determined to be either consistent with variation or highly consistent or identical to QISMIC standards.

TABLE 12
[In percent]

NCQA 1999	Overall	Domain 1	Domain 2	Domain 3	Domain 4
		Quality assessment and performance improvement	Enrollee rights	Health services management	Delegation
Substantially Greater Than QISMIC	12	4	11	17	
Consistent with QISMIC	62	65	68	53	100
Substantially Fewer Requirements	26	30	21	29	

Beneficiaries will benefit significantly from information available to them about the performance of their health plans as well as through improvements in the delivery of care and services that evolve out of on-going quality improvement projects under QISMIC. Beneficiaries already have access to health plan performance and consumer satisfaction measures about the M+C organizations available in their area through our beneficiary education

campaign and individual plan marketing.

We expect that as consumers become increasingly familiar with health plan performance and consumer satisfaction information, it will become an integral part of their decision-making process, in addition to cost and benefits, for selecting their M+C organization. It is our intent that as consumers become better informed and decide not to select plans of lower quality, such plans will

be motivated to initiate improvements in the quality of care they provide.

At the same time, we expect that plan's focus on one national and one plan-specific quality assessment and performance improvement project each year will improve the delivery of services to Medicare beneficiaries, especially beneficiaries suffering from chronic conditions. M+C organizations will need to be proactive in identifying and treating beneficiaries who suffer

from medical conditions which are the focus of their quality assessment and performance improvement projects in addition to their HEDIS measures. This will ultimately lead to improved care and services for Medicare beneficiaries through the institutionalization of these practices.

a. QISM Compliance. Purchaser demands have driven many managed care organizations to become NCQA accredited, implement quality measurement and performance improvement strategies, and report performance and satisfaction data. This has resulted in many managed care organizations becoming NCQA accredited, especially on the east and west coasts. We estimate that the cost of becoming NCQA accredited ranges between \$300,000–\$500,000.

We do not believe that QISM will present significant additional fixed costs for M+C organizations that have already received accreditation from the National Committee for Quality Assurance. While QISM presents some subtle and significant differences from NCQA accreditation, we do not expect that organizations that have prepared for NCQA accreditation will incur significant additional costs to comply with QISM. We recognize that there will be incremental costs associated with QISM, such as costs associated with additional quality assessment and performance improvement projects, internal staff training expenses, and oversight and compliance.

In addition, we expect that some M+C organizations that are not NCQA accredited may incur higher costs to comply with QISM than organizations in other parts of the country.

b. HEDIS Reporting. Since 1997, we have required M+C organizations to report HEDIS and consumer satisfaction data. Beginning in 1998, we required M+C organizations to begin reporting audited HEDIS data as a result of inconsistencies in HEDIS reporting.

We do not expect that requirements for reporting HEDIS and consumer satisfaction measures are inconsistent with expectations that private purchasers have access to health plan performance data (GAO, June 1998). As a result, we do not expect that organizations will incur significant new fixed costs as a result of requirements to report performance measurement and consumer satisfaction data, since we expect that M+C organizations will use audited HEDIS data. However, we do recognize that there may be incremental costs to reporting audited HEDIS data in terms of additional processes, audit fees, etc.

In addition, requirements for M+C organizations to report audit HEDIS data will likely yield improved processes for collecting and reporting complete, accurate and timely data as a result of an independent third party review of their data collection, warehousing and production/reporting processes.

c. Quality Assessment and Performance Improvement Projects. We recognize that a significant difference between QISM and NCQA accreditation 1999 is that QISM is much more prescriptive in defining the type, scope and measurement of quality assessment and performance improvement projects. In response to industry concerns, we have reduced the number and delayed the timeframe for implementing quality assessment and performance improvement projects.

At the same time, specifying beginning and ending dates for QAPIs will ensure that plans do not become mired in projects that do not end. We expect that plans will focus their efforts on achieving results and institutionalizing improvements in the delivery of care, data collection and reporting and information system improvements gained from successful QAPI projects. Even in instances where demonstrable improvements were not obtained, we expect that, in many cases, some improvement will result.

In addition, plans will have added incentives to initiate performance improvement projects that will lead to more cost-effective delivery of health care services, such as influenza immunization. For example, one national managed care organization increased the percentage of Medicare enrollees receiving flu shots from 27 percent to 55 percent in one year. The organization reported a reduction of about 30 percent in hospital admissions for pneumonia, savings of about \$700,000, and fewer lives lost. (GAO, May 1996) We expect that investments in QAPI activities will lead to cost-savings over and above the initial investment.

We recognize that some high-performing managed care organizations will have less ability to achieve additional improvements in some areas. Some organizations will respond to incentives to select projects where results may be more easily obtainable. We continue to believe, however, that there are significant gains that remain to be made in the delivery of quality services.

We concur with industry comments that small plans may have difficulty in complying, since they may not have a statistically credible population for producing reliable and/or comparable

measures. For example, a small plan with a healthier population than average may not have sufficient instances of myocardial infarction for which beta-blocker treatment would be appropriate. We will work with these organizations to address these and other unique issues that may arise.

We believe that requiring plans to participate in at least one national and one plan-specific QAPI project annually and to demonstrate a 10 percent improvement in their QAPI is in the best interest of beneficiaries. These requirements will improve the quality of care and services delivered to Medicare and other populations served by the M+C organization, as performance improvement practices become routine.

d. Deeming. To avoid duplication of effort and unnecessary administrative burdens with respect to internal quality assurance requirements, we are recognizing accrediting by national, private accrediting organizations that we determine to be consistent with our QA requirements. We believe that this will significantly benefit a significant portion of M+C organizations that are already accredited, reducing costs, capitalizing on efficiencies, and avoiding duplicative processes.

2. Provider Procedures

Much less information is available about other requirements cited by some commenters as entailing significant administrative burdens. For example, we received many public comments regarding provider participation requirements. We responded to many of those comments in our February 17, 1999, final rule (64 FR 7968), under which we narrowed many of the requirements set forth in our June 26, 1998 interim final rule (63 FR 34968). Modifications to the interim final rule included:

- Applying the applicable notice and appeal rights and consultation requirements only to physicians, as defined under section 1861 of the Act;
- Adopting a narrower interpretation of what constitute “rules regarding participation” to focus on whether a physician can participate under a given M+C plan;
- Clarifying that an M+C organization need only have reasonable procedures for notifying potential participating physicians of participation rules, which may include providing the information upon request;
- Clarifying that an M+C organization is not required to release information that an organization considers proprietary information;
- Clarifying that in the event that immediate changes are mandated

through Federal law or regulation, an organization should be exempt from the requirement that written notice be provided before the changes are put into effect;

- Clarifying that there is no requirement that an organization obtain signatures acknowledging receipt of a notice of changes;
- Limiting the applicability of the appeals process to appealing adverse participation decisions;
- Clarifying that the availability of the provider appeals process applies only to cases involving suspension or termination of participation privileges, rather than including initial denials of an application to participate; and
- Clarifying that the information to be included in a notification of a decision to suspend or terminate an agreement with a physician is limited to information relevant to the decision.

Since publication of our February 17, 1999 final rule, we have subsequently communicated with several M+C organizations about the costs and benefits associated with the requirements included in this final rule. We believe that the steps taken in our February 17, 1999 final rule significantly reduced the burden on M+C organizations and also ensured that providers and beneficiaries receive the protections intended by Congress under the Act. For example, by narrowing the scope of the requirement for advance notice of changes in participation rules, an M+C organization need not prepare an advance notice for administrative and other changes that do not affect whether a physician can participate in a plan. Notification of most changes made by a M+C organization can be made via usual communication methods, such as regular newsletters, rather than through the preparation of special mailings or other more burdensome methods.

In addition, the M+C organization must consult with the physicians who have agreed to provide services under the M+C plan offered by the organization, regarding the organization's medical policy, quality assurance program, and medical management procedures, and ensure that the following standards are met. We understand that these requirements are consistent with current operational practices by M+C organizations and pose little additional burden, and that the costs associated with incremental changes would be marginal.

We also understand that our requirements concerning credentialing processes and prohibitions on discrimination reflect current practices and similar requirements from other

entities (for example, accrediting bodies) and do not impose additional burden.

3. Attestation Requirements

Similarly, commenters objected to attestation requirements as discussed in detail above (See Subpart K). To receive a monthly payment under subpart F, the chief executive officer (CEO) or chief financial officer (CFO) of a M+C organization must request payment under the contract on a document that certifies the accuracy, completeness, and truthfulness of relevant data that we request. Such data include specified enrollment information, encounter data, and other information that we may specify. The CEO or CFO must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization, and the information relied upon by us in determining payment is accurate. The CEO or CFO must certify that the encounter data it submits under § 422.257 are accurate, complete, and truthful. If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data. In addition, the M+C organization must certify that the information in its ACR submission is accurate and fully conforms to the requirements in § 422.310 in order to retain payment amounts below the amount of its ACR.

We understand that the collection and dissemination of this information by M+C organizations is undertaken in a manner that reflects an M+C organization's best efforts to ensure its accuracy, completeness, and truthfulness. Accordingly, we do not believe that this requirement imposes significant new burdens on an M+C organization that operates in good faith to comply with requirements under the M+C program. We realize that mistakes and errors may occur even under an organization's best efforts, and these attestation requirements are not intended to penalize an M+C organization that operates in good faith. We believe these requirements are important to safeguard the integrity of the M+C program against those few M+C organizations that do not utilize the kind of business and operational practices of most M+C organizations. We also believe the requirements will provide an important tool for seeking out the few bad actors that could harm the M+C program, beneficiaries, providers, and other M+C organizations. As suggested by many commenters, we

have revised the requirements to establish a "good faith" compliance standard as opposed to requiring an attestation of 100 percent accuracy for encounters and enrollment (payment related) data. We believe this change should alleviate commenters concerns over the undue financial burdens associated with attestation requirements.

VI. Other Required Information

A. Federalism Summary Impact Statement

On August 4, 1999, the president signed Executive Order 13132 (effective November 2, 1999) establishing certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have federalism implications. Any such regulations must include a federalism summary impact statement that describes the agency's consultation with State and local officials and summarizes the nature of their concerns, the extent to which these concerns have been met, and the agency's position supporting the need to issue the regulation.

In this final rule, we are not promulgating any changes to the existing M+C regulations that meet any of the criteria mentioned above that would require the inclusion of a federalism impact statement under Executive Order 13132. However, the M+C interim final rule published on June 26, 1998 (63 FR 34968) did contain provisions that have a federalism impact, and we respond to comments on these provisions from States and other interested parties in this rule. Thus, in keeping with the intent of the Executive Order that we closely examine any policies that have federalism implications or would limit the policy making discretion of the States, we have prepared the following voluntary federalism impact statement.

In establishing the M+C program, the BBA included two provisions that have significant implications for States. First, under section 1855(a)(1) of the Act, an organization that wishes to participate in the M+C program generally is required to be organized and licensed under State law as a risk-bearing entity eligible to offer health benefits coverage in each State in which it offers an M+C plan. This statutory requirement is codified at § 422.400(a) and § 422.501(b)(1) of the M+C regulations, and we do not believe it interferes with State functions or limits their policy making discretion. The requirement does not impose any significant

additional burdens on States, who for are already carrying out this licensing function. We received no comments from States on this provision.

The other aspect of the M+C statute and regulations that has significant federalism implications involves the Federal preemption provisions set forth under section 1856(b) of the Act and § 422.402. Section 1856(b)(3)(A) provides for Federal preemption of State laws, regulations, and standards affecting any M+C standard if the state provisions are inconsistent with Federal standards. As discussed in the preamble to the interim final rule (63 FR 35012), and in section II.I of this preamble, we are applying this “general preemption” in much the same way that we previously applied Executive Order 12612 on Federalism. That is, State laws or standards that are more strict than the M+C standards would not be preempted unless they prevented compliance with the M+C requirements.

In addition to this general preemption, the Congress also provided (under section 1856(b)(3)(B) for a “specific preemption” whereby M+C standards supersede any State laws and standards in the following three areas:

- Benefit requirements;
- Requirements relating to the inclusion or treatment of providers; and
- Coverage determinations (including related appeals and grievance processes).

During the development of the June 26, 1998 interim final rule, we consulted with the National Association of Insurance Commissioners (NAIC) regarding the proper interpretation of these provisions. (The NAIC is the organization of the chief insurance regulators from the 50 states, the District of Columbia, and four U.S. territories.) The interim final rule contained an extensive discussion of this subject, including providing examples both of State laws that would be preempted under the M+C statute (such as “any willing provider laws” that would mandate the inclusion of specific types of providers or practitioners) and of State requirements that would continue to apply (such as a requirement that all providers and practitioners be licensed by the State and comply with scope of practice laws). We asserted our intention to adopt a narrow interpretation of the applicability of the three areas of specific preemption in order to ensure that any regulatory preemption of State law would be restricted to the minimum level necessary consistent with the BBA. State and local officials then had an opportunity to participate in the rulemaking process through their public

comments on the M+C interim final rule.

For the most part, commenters representing State governments supported HCFA’s narrow interpretation of the BBA’s specific preemption provisions. (See section II.I of this final rule for a full discussion of comments on these provisions.) The most notable exception to this general support was the contention by one State that its mandatory drug benefit laws should not be preempted by the M+C benefit provisions; but we continue to believe that the specific preemption of “benefit requirements” under section 1856(b)(3)(B) of the Act clearly contradicts the State’s contention. Moreover, we believe that our general approach is fully consistent with the “Special Requirements for Preemption” set forth in section 4 of Executive Order 13132. This section directs that an agency take action to preempt State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under Federal law or there is other clear evidence (such as an express statutory preemption provision) to conclude that Congress intended the agency to have the authority to preempt State law. It also provides that any regulatory preemption of State law be restricted to the minimum level necessary to achieve the objectives of the relevant statute. In conclusion, we believe that the concerns of State and local officials have been met to the greatest possible extent, consistent with the BBA’s preemption provisions.

B. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to afford a period for public comments before issuing a regulation in final form. However, we may waive that procedure if we find good cause that prior notice and comment are impractical, unnecessary, or contrary to the public interest. In addition, section 1871(b)(2)(B) of the Act provides that a notice of proposed rulemaking is not required if a statute establishes a specific deadline for implementation of a provision that is less than 150 days after the enactment of the statute in which the deadline is contained. Finally, Congress provides in certain cases by statute for the publication of a final rule without prior notice and comment.

For the most part, the changes to the M+C regulations set forth in this final rule with comment period result from our review of the public comments on the June 26, 1998 interim final rule that

established the M+C program. Congress expressly authorized the publication of that final rule without prior notice and comment in section 1856(b)(1) of the Act. To the extent the provisions of this final rule respond to comments on that rule, they will have been subjected to prior notice and comment. However, as discussed in detail in section I.C of this preamble, this rule also makes conforming revisions to the regulations that are necessary to reflect changes to the M+C statute resulting from the BBRA (Pub. L. 106–113) which was enacted on November 29, 1999. These changes in requirements and new requirements or provisions were enacted by Congress, and would be in effect without regard to whether they are reflected in conforming changes to the regulations text, since a statute controls over a regulation. In this final rule, we merely have revised the regulations text to reflect these new statutory provisions, as we interpret them. In most cases, the BBRA provisions have merely been incorporated virtually verbatim, with no interpretation necessary. Examples of such provisions include: the earlier availability of alternative Medicare enrollment options and the elimination of the lock-in rules for institutionalized individuals under section 501 of the BBRA, changes in the effective date of elections under section 502, the extension of Medicare cost contracts under section 503, the modification of the 5-year re-entry rule after contract terminations under section 513, flexibility to tailor benefits under an M+C plan under section 515, the delay until July 1 in the deadline for ACR submissions under section 516, the reduction in the adjustment in the national per capita M+C growth percentage under section 517, the new deeming provisions in section 518, the revised quality assurance requirements for PPOs under section 520, and the user fee provisions in section 522. For these types of provisions, we do not believe that publishing a notice of proposed rulemaking is necessary, nor would it be practical given that a number of the provisions have already taken effect consistent with effective dates established under the BBRA. (For example, the changes in the effective date of elections and the new quality assurance requirements for PPOs took effect on January 1, 2000, and several other provisions were effective upon enactment of the BBRA.) In addition, we believe that it would be contrary to the public interest to delay implementation of these provisions until the process of publishing both a proposed and a final

rule could be completed. Finally, we note that the BBRA was enacted on November 29, 1999; thus publication of a notice of proposed rulemaking is not required under section 1871(b) of the Act before implementing any new statutory provisions that took effect upon enactment or on January 1, 2000. Thus, we find good cause to waive proposed rulemaking for these provisions. We are, however, providing a 60-day period for public comment on those provisions.

In the case of two BBRA provisions, we have reflected our interpretation of the provisions in the regulations text. This interpretation is already in effect, and has been applied, as the provisions in question are already in effect. These provisions are section 501(c) of the BBRA, which permits an M+C organization that has reduced a plan service area to offer continued enrollment to current enrollees in all or a portion of the reduced areas, and section 512 that introduces "bonus payments" to encourage organizations to offer M+C plans in areas without such plans. Both of these provisions are discussed in detail in section I.C of this preamble, and both required a limited amount of interpretation of the statute in order to implement the provisions on a timely basis. For example, with regard to the continuation of enrollment option (which was effective upon enactment of the BBRA), we have clarified that an M+C organization may offer enrollment in any plan it offers in the affected area, rather than solely the plan in which an individual was previously enrolled. This clarification results in greater flexibility for M+C enrollees and is consistent with our interpretation of a similar statutory provision affecting individuals with ESRD. Similarly, with regard to the bonus payment provisions (which took effect as of January 1, 2000), we have indicated that if an M+C organization or organizations offers two or more new plans simultaneously in a given area, the organization could receive the bonus payments for each new plan. We believe this interpretation of the statute clearly is consistent with legislative intent to promote the availability of more M+C alternatives for Medicare beneficiaries.

Policy clarifications of this limited nature were essential to implement these BBRA provisions in a clear and timely manner. Again, it would have been impractical and contrary to the public interest to proceed with proposed rulemaking before implementing the interpretive policies linked with these provisions, nor is such rulemaking required under section 1871(b) of the Act. Thus, we believe that

the "good cause" exemption to notice and comment rulemaking is equally applicable for these BBRA provisions as for the others discussed above, and the same 60-day period for public comment applies.

C. Responses to Comments

As discussed above, a limited number of the provisions set forth in this final rule are subject to a 60-day comment period. Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble and, if we proceed with subsequent rulemaking, we will respond to the comments in that document.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare+Choice, Penalties, Privacy, Provider-sponsored organizations (PSO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, HCFA amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (2 U.S.C. 300e, 300e–5, 300e–9), and 31 U.S.C. 9701.

2. Revise § 417.402(b) to read as follows:

§ 417.402 Effective date of initial regulations.

(b) The changes made to section 1876 of the Act by section 4002 of the Balanced Budget Act (BBA) of 1997 are incorporated in section 422 except for 1876 cost contracts. Upon enactment of the BBA (August 5, 1997) no new cost

contracts or service area expansions are accepted by HCFA except for current Health Care Prepayment Plans that may convert to 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2004.

PART 422—MEDICARE+CHOICE PROGRAM

1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102, 1851 through 1857, 1859, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–21 through 1395w–27, and 1395hh).

2. Section 422.2 is amended by:

A. Revising the definitions of "Basic benefits," "Benefits," "M+C plan," "Mandatory supplemental benefits," "Optional supplemental benefits," "Religious and fraternal (RFB) society," "RFB plan," and "Service area."

B. Adding the definition of "National coverage determination."

C. Removing the definitions of "Emergency medical condition," "Emergency services," and "Urgently needed services."

§ 422.2 Definitions.

* * * * *

Basic benefits means all Medicare-covered benefits (except hospice services) and additional benefits.

Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the M+C organization incurs a cost or liability under an M+C plan (not solely an administrative processing cost). Benefits are submitted and approved through the ACR process.

* * * * *

M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan (or in individual segments of a service area, under § 422.304(b)(2)).

* * * * *

Mandatory supplemental benefits are health services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

* * * * *

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service that HCFA makes under section 1862(a)(1) of the

Act, and publishes as a **Federal Register** notice or HCFA ruling. (The term does not include coverage changes mandated by statute.)

* * * * *

Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

* * * * *

Religious and fraternal benefit (RFB) society means an organization that—

(1) Is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of that Act; and

(2) Is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches.

RFB plan means an M+C plan that is offered by an RFB society.

Service area means a geographic area approved by HCFA within which an M+C-eligible individual may enroll in a particular M+C plan offered by an M+C organization. Each M+C plan must be available to all M+C-eligible individuals within the plan's service area. In deciding whether to approve an M+C plan's proposed service area, HCFA considers the following criteria:

(1) Whether the area meets the "county integrity rule" that a service area generally consists of a full county or counties. However, HCFA may approve a service area that includes a portion of a county if it determines that the "partial county" area is necessary, nondiscriminatory, and in the best interests of the beneficiaries.

(2) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or M+C plans offered by the organization.

(3) For M+C coordinated care plans and network M+C MSA plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, HCFA must determine that all services covered under the plan are accessible from the service area.

(4) For non-network M+C MSA plans, HCFA may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

3. In § 422.4, revise paragraph (a)(1)(iii) and add a new paragraph (a)(1)(iv), to read as follows:

§ 422.4 Types of M+C plans.

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs) as specified in paragraph (a)(1)(iv) of this section, RFBs, and other network plans (except network MSA plans).

(iv) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

4. Revise § 422.8 to read as follows:

§ 422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA notifies the contract applicant and allows 60 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, HCFA determines whether the contract applicant's application meets the applicable requirements of § 422.6.

(b) *Use of information from a prior contracting period.* If an M+C organization, HMO, competitive medical plan, or health care prepayment plan has failed to comply with the terms of a previous year's contract with HCFA under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, HCFA may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with HCFA even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* HCFA notifies each applicant that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If HCFA approves the application, it gives

written notice to the contract applicant, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If HCFA finds that the contract applicant does not appear to meet the requirements for an M+C organization and appears to be able to meet those requirements within 60 days, HCFA gives the contract applicant notice of intent to deny the application for an M+C contract and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding and may revise its application to remedy any defects HCFA identified.

(f) *Denial of application.* If HCFA denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under part C of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.* (1) HCFA oversees an M+C organization's continued compliance with the requirements for an M+C organization.

(2) If an M+C organization no longer meets those requirements, HCFA terminates the contract in accordance with § 422.510.

5. Revise § 422.10 to read as follows:

§ 422.10 Cost-sharing in enrollment-related costs (M+C user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that HCFA follows to determine the aggregate annual "user fee" to be contributed by M+C organizations and to assess the required user fees for M+C plans offered by M+C organizations.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes HCFA to charge and collect from each M+C plan offered by an M+C organization its pro rate share of fees for administering section 1851 of the Act, relating to dissemination of enrollment information; and section 4360 of the Omnibus Budget Reconciliation Act of 1990, relating to the health insurance counseling and assistance program.

(c) *Applicability.* The fee assessment also applies to those demonstrations for which enrollment is effected or coordinated under section 1851 of the Act.

(d) *Collection of fees.* (1) *Timing of collection.* HCFA collects the fees over 9 consecutive months beginning with January of each fiscal year.

(2) *Amount to be collected.* The aggregate amount of fees for a fiscal year is the lesser of—

(i) The estimated costs to be incurred by HCFA in that fiscal year to carry out the activities described in paragraph (b) of this section; or

(ii) For fiscal year 2000, \$100 million and for fiscal year 2001 and each succeeding year, the M+C portion (as defined in paragraph (e) of this section) of \$100 million.

(e) *M+C portion.* In this section, the term “M+C portion” means, for a fiscal year, the ratio, as estimated by the Secretary of the average number of individuals enrolled in M+C plans during the fiscal year to the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(f) *Assessment methodology.* (1) The amount of the M+C portion of the user fee each M+C organization must pay is assessed as a percentage of the total Medicare payments to each organization. HCFA determines this percentage rate using the following formula:

A times B divided by C where—

A is the total estimated January payments to all organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year M+C user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) HCFA determines each organization's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. HCFA calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in HCFA's payment system on the first day of the month.

(3) HCFA deducts the organization's fee from the amount of Federal funds otherwise payable to the organization for that month under the M+C program.

(4) If assessments reach the amount authorized for the year before the end of September, HCFA discontinues assessment.

(5) If there are delays in determining the amount of the annual aggregate fees specified in paragraph (d)(2) of this section, or the fee percentage rate specified in paragraph (f)(2), HCFA may adjust the assessment time period and the fee percentage amount.

6. Revise § 422.50(a) to read as follows:

§ 422.50 Eligibility to elect an M+C plan.

(a) An individual is eligible to elect an M+C plan if he or she—

(1) Is entitled to Medicare under Part A and enrolled in Part B (except that an individual entitled only to Part B and who was enrolled in an HMO or CMP with a risk contract under part 417 of this chapter on December 31, 1998 may continue to be enrolled in the M+C organization as an M+C plan enrollee);

(2) Has not been medically determined to have end-stage renal disease, except that an individual who develops end-stage renal disease while enrolled in an M+C plan or in a health plan offered by the M+C organization is eligible to elect an M+C plan offered by that organization;

(3) Meets either of the following residency requirements:

(i) Resides in the service area of the M+C plan.

(ii) Resides outside of the service area of the M+C plan and is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which the individual is entitled to both Medicare Part A and Part B, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements of § 422.112 are met for that individual through the M+C plan's established provider network.

The M+C organization must furnish the same benefits to these enrollees as to enrollees who reside in the service area;

(4) Has been a member of an Employer Group Health Plan (EGHP) that includes the elected M+C plan, even if the individual lives outside of the M+C plan service area, provided that an M+C organization chooses to offer this option and that HCFA determines that all applicable M+C access requirements at § 422.12 are met for that individual through the M+C plan's established provider network. The M+C organization must furnish the same benefits to all enrollees, regardless of whether they reside in the service area;

(5) Completes and signs an election form and gives information required for enrollment; and

(6) Agrees to abide by the rules of the M+C organization after they are

disclosed to him or her in connection with the election process.

* * * * *

7. In § 422.54, the heading of paragraph (b) and paragraphs (c)(2), (d)(1), and (d)(3) are revised to read as follows:

§ 422.54 Continuation of enrollment.

* * * * *

(b) *Basic rule.* * * *

(c) * * *

(2) An enrollee who moves out of the service area into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the plan. The enrollee must make the choice of continuing enrollment in a manner specified by HCFA. If no choice is made, the enrollee must be disenrolled from the plan.

* * * * *

(d) * * *

(1) *Continuation of enrollment benefits.* The M+C organization must, at a minimum, provide or arrange for the Medicare-covered benefits as described in § 422.101(a).

* * * * *

(3) *Reasonable cost-sharing.* For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the M+C plan's service area (in which the enrollee no longer resides).

* * * * *

8. Section § 422.60 is amended by:

A. Revising paragraph (b)(1).

B. Adding paragraph (b)(3).

C. Revising paragraphs (e)(6), (f)(1), and (f)(3).

§ 422.60 Election process.

* * * * *

(b) *Capacity to accept new enrollees.*

(1) M+C organizations may submit information on enrollment capacity of plans they offer by July 1 of each year as provided by § 422.306(a)(1).

* * * * *

(3) HCFA considers enrollment limit requests for an M+C plan service area, other than those submitted with the adjusted community rate proposal, or for a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

* * * * *

(e) * * *

(6) Upon receipt of the election form or from the date a vacancy occurs for an individual who was accepted for future enrollment, the M+C organization transmits, within the timeframes

specified by HCFA, the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

(f) * * *

(1) In cases in which an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members, who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election form from the employer, the M+C organization must submit the enrollment within timeframes specified by HCFA.

9. Section 422.62 is amended by:

A. Removing, in paragraph (a)(3), the phrase “as provide under” and adding in its place the phrase “as provided under”.

B. Revising paragraphs (a)(4)(i) and (a)(5)(i).

C. Adding new paragraph (a)(6).

D. Revising paragraph (b)(1).

§ 422.62 Election of coverage under an M+C plan.

(a) * * *

(4) * * *

(i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan in 2002 may elect an M+C plan or change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 6 months of the year.

* * * * *

(5) * * *

(i) For 2003 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is eligible to elect an M+C plan may elect an M+C plan, change his or her election from an M+C plan to original Medicare or to a different M+C plan, or from original Medicare to an M+C plan, but only once during the first 3 months of the year.

* * * * *

(6) *Open enrollment period for institutionalized individuals.* After 2001, an individual who is eligible to elect an M+C plan and who is institutionalized, as defined by HCFA, is not limited (except as provided for in

paragraph (d) of this section for M+C MSA plans) in the number of elections or changes he or she may make. Subject to the M+C plan being open to enrollees as provided under § 422.60(a)(2), an M+C eligible institutionalized individual may at any time elect an M+C plan or change his or her election from an M+C plan to original Medicare, to a different M+C plan, or from original Medicare to an M+C plan.

(b) * * *

(1) HCFA or the organization has terminated the organization's contract for the plan, discontinued the plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan, or the impending discontinuation of the plan in the area in which the individual resides.

* * * * *

10. Section 422.64 is revised to read as follows:

§ 422.64 Information about the M+C program.

Each M+C organization must provide, on an annual basis, and in a format and using standard terminology that may be specified by HCFA, the information necessary to enable HCFA to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

11. Section § 422.66 is amended by:

A. Republishing the heading of paragraph (b) and the introductory text for paragraph (b)(3).

B. Revising paragraphs (b)(3)(i), (d)(1), (d)(3), the introductory text for paragraph (e), and paragraphs (e)(2), and (f).

§ 422.66 Coordination of enrollment and disenrollment through M+C organizations.

* * * * *

(b) *Disenrollment*—

* * * * *

(3) *Responsibilities of the M+C organization.* The M+C organization must—

(i) Submit a disenrollment notice to HCFA within timeframes specified by HCFA;

* * * * *

(d) * * *

(1) *Basic rule.* An M+C plan offered by an M+C organization must accept any individual (regardless of whether the individual has end-stage renal disease) who is enrolled in a health plan offered by the M+C organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B, and who meets the eligibility requirements at § 422.50.

* * * * *

(3) *Effective date of conversion.* If an individual chooses to remain enrolled with the M+C organization as an M+C enrollee, the individual's conversion to an M+C enrollee is effective the month in which he or she is entitled to both Part A and Part B in accordance with the requirements in paragraph (d)(5) of this section.

* * * * *

(e) *Maintenance of enrollment.* An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

* * * * *

(2) The elected M+C plan is discontinued or no longer serves the area in which the individual resides, the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided under either § 422.54 or § 422.74(b)(3)(ii).

(f) *Exception for employer group health plans.* (1) In cases when an M+C organization has both a Medicare contract and a contract with an employer group health plan, and in which the M+C organization arranges for the employer to process election forms for Medicare-entitled group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election form from the employer, the M+C organization must submit a disenrollment notice to HCFA within timeframes specified by HCFA.

12. Revise § 422.68(c) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period as described in § 422.62(a)(3) through (a)(6), coverage is effective as of the first day of the first calendar month following the month in which the election is made, except that, if the election or change in election is made after the 10th day of any calendar month, then the election shall not take effect until the first day of the second calendar month following the date on which the election is made.

* * * * *

13. Section 422.74 is amended by revising paragraphs (b)(2)(i), (b)(3), (c),

(d)(1), the heading of paragraph (d)(3), (d)(4), and (d)(7) to read as follows:

§ 422.74 Disenrollment by the M+C organization.

* * * * *

(b) * * *
(2) * * *

(i) The individual no longer resides in the M+C plan's service area as specified under paragraph (d)(4) of this section, is no longer eligible under § 422.50(a)(3)(ii), and optional continued enrollment has not been offered or elected under § 422.54.

* * * * *

(3) *Plan termination or reduction of area where plan is available.* (i) *General rule.* An M+C organization that has its contract for an M+C plan terminated, that terminates an M+C plan, or that discontinues offering the plan in any portion of the area where the plan had previously been available, must disenroll affected enrollees in accordance with the procedures for disenrollment set forth at paragraph (d)(7) of this section, unless the exception in paragraph (b)(3)(ii) of this section applies.

(ii) *Exception.* When an M+C organization discontinues offering an M+C plan in a portion of its service area, the M+C organization may elect to offer enrollees residing in all or portions of the affected area the option to continue enrollment in an M+C plan offered by the organization, provided that there is no other M+C plan offered in the affected area at the time of the organization's election. The organization may require an enrollee who chooses to continue enrollment to agree to receive the full range of basic benefits (excluding emergency and urgently needed care) exclusively through facilities designated by the organization within the plan service area.

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) must—

(1) Be mailed to the individual before submission of the disenrollment notice to HCFA; and

(2) Include an explanation of the individual's right to a hearing under the M+C organization's grievance procedures.

(d) * * *

(1) *Monthly basic and supplementary premiums are not paid timely.* An M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums under the following circumstances:

(i) The M+C organization makes a reasonable effort to collect unpaid premium amounts by sending a written notice of nonpayment to the enrollee within 20 days after the date the delinquent charges were due—

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with an explanation of the disenrollment procedures and any lock-in requirements of the M+C plan; and

(C) Advising that failure to pay the premiums within the 90-day grace period will result in termination of M+C coverage;

(ii) The M+C organization only disenrolls a Medicare enrollee when the organization has not received payment within 90 days after the date it has sent the notice of nonpayment to the enrollee.

(iii) The M+C organization gives the individual a written notice of disenrollment that meets the requirement set forth in paragraph (c) of this section.

(iv) If the enrollee fails to pay the premium for optional supplemental benefits (that is, a package of benefits that an enrollee is not required to accept), but pays the basic premium and any mandatory supplemental premium, the M+C organization has the option to discontinue the optional supplemental benefits and retain the individual as an M+C enrollee.

* * * * *

(3) *Individual commits fraud or permits abuse of enrollment card.* * * *

* * * * *

(4) *Individual no longer resides in the M+C plan's service area.* (i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the M+C organization must disenroll an individual if the M+C organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved out of a plan's service area. If the individual has not moved from the M+C plan's service area, but has left the plan's service area for more than 6 months, the M+C organization must disenroll the individual.

(ii) *Special rule.* The M+C organization must disenroll an individual who is enrolled in the M+C

plan, under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4), if the organization establishes, on the basis of a written statement from the individual or other evidence acceptable to HCFA, that the individual has permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, to an area outside the M+C plan service area (unless continuation of enrollment is elected under § 422.54). If the individual has not permanently moved from the residence in which she or he resided at the time of enrollment in the M+C plan, but has left the residence for over 6 months, the M+C organization must disenroll the individual.

(iii) *Notice of disenrollment.* The M+C organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

* * * * *

(7) *Plan termination or area reduction.* (i) When an M+C organization has its contract for an M+C plan terminated, terminates an M+C plan, or discontinues offering the plan in any portion of the area where the plan had previously been available, the M+C organization must give each affected M+C plan enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program.

(ii) The notice must be sent before the effective date of the plan termination or area reduction, and in the timeframes specified in § 422.506(a)(2).

* * * * *

14. Section 422.80 is amended by:
A. Republishing the introductory text in paragraph (b)(5).

B. Revising paragraph (b)(5)(v).

C. Republishing the introductory text in paragraph (c).

D. Revising paragraph (c)(4).

E. Adding new paragraphs (e)(1)(vi), (e)(1)(vii), and (e)(1)(viii).

F. Revising paragraph (f).

§ 422.80 Approval of marketing materials and election forms.

* * * * *

(b) * * *

(5) Examples of marketing materials include, but are not limited to:

* * * * *

(v) Membership communication materials such as membership rules, subscriber agreements (evidence of coverage), member handbooks and wallet card instructions to enrollees.

* * * * *

(c) *Guidelines for HCFA review.* In reviewing marketing material or election

forms under paragraph (a) of this section, HCFA determines that the marketing materials:

* * * * *

(4) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

* * * * *

(e) * * *

(1) * * *

(vi) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the materials have the concurrence of all M+C organizations involved and have received prior approval by HCFA. Physicians or providers may distribute health plan brochures (exclusive of application forms) at a health fair or in their offices. Physicians may discuss, in response to an individual patient's inquiry, the various benefits in different health plans.

(vii) Accept plan applications in provider offices or other places where health care is delivered.

(viii) Employ M+C plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to M+C plan names in effect on July 31, 2000.

* * * * *

(f) *Employer group retiree marketing.* M+C organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the M+C organization, and furnish these materials only to the group members. While the materials must be submitted for approval under paragraph (a) of this section, HCFA will not review portions of these materials that relate to employer group benefits.

15. Revise § 422.100 to read as follows:

§ 422.100 General requirements.

(a) *Basic rule.* Subject to the conditions and limitations set forth in this subpart, an M+C organization offering an M+C plan must provide enrollees in that plan with coverage of the basic benefits described in paragraph (c) of this section (and, to the extent applicable, the benefits described in § 422.102) by furnishing the benefits directly or through arrangements, or by paying for the benefits. HCFA reviews these benefits subject to the requirements of § 422.100(g) and the requirements in subpart G of this part.

(b) *Services of noncontracting providers and suppliers.* (1) An M+C organization must make timely and reasonable payment to or on behalf of the plan enrollee for the following

services obtained from a provider or supplier that does not contract with the M+C organization to provide services covered by the M+C plan:

(i) Ambulance services dispatched through 911 or its local equivalent as provided in § 422.113.

(ii) Emergency and urgently needed services as provided in § 422.113.

(iii) Maintenance and post-stabilization care services as provided in § 422.113.

(iv) Renal dialysis services provided while the enrollee was temporarily outside the plan's service area.

(v) Services for which coverage has been denied by the M+C organization and found (upon appeal under subpart M of this part) to be services the enrollee was entitled to have furnished, or paid for, by the M+C organization.

(2) An M+C plan (other than an M+C MSA plan) offered by an M+C organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that M+C plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) *Types of benefits.* An M+C plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.

(1) Basic benefits are all Medicare-covered services, except hospice services, and additional benefits as defined in § 422.2 and meeting all requirements in § 422.312.

(2) Supplemental benefits, which consist of—

(i) Mandatory supplemental benefits are services not covered by Medicare that an M+C enrollee must purchase as part of an M+C plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost-sharing.

(ii) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the M+C enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. These services may be grouped or offered individually.

(d) *Availability and structure of plans.* An M+C organization offering an M+C plan must offer it—

(1) To all Medicare beneficiaries residing in the service area of the M+C plan;

(2) At a uniform premium, with uniform benefits and cost-sharing throughout the plan's service area, or

segment of service area as provided in § 422.304(b)(2).

(e) *Terms of M+C plans.* Terms of M+C plans described in instructions to beneficiaries, as required by § 422.111, will include basic and supplemental benefits and terms of coverage for those benefits.

(f) *Multiple plans in one service area.* An M+C organization may offer more than one M+C plan in the same service area subject to the conditions and limitations set forth in this subpart for each M+C plan.

(g) *HCFA review and approval of M+C benefits.* HCFA reviews and approves M+C benefits using written policy guidelines and requirements in this part, operational policy letters, and other HCFA instructions to ensure that—

(1) Medicare-covered services meet HCFA fee-for-service guidelines;

(2) M+C organizations are not designing benefits to discriminate against beneficiaries; and

(3) Benefit design meets other M+C program requirements.

(h) *Benefits affecting screening mammography, influenza vaccine, and pneumococcal vaccine.* (1) Enrollees of M+C organizations may directly access (through self-referral) screening mammography and influenza vaccine.

(2) M+C organizations may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their M+C plan enrollees.

(i) *Requirements relating to Medicare conditions of participation.* Basic benefits must be furnished through providers meeting the requirements in § 422.204(b)(3).

(j) *Provider networks.* The M+C plans offered by an M+C organization may share a provider network as long as each M+C plan independently meets the access and availability standards described at § 422.112, as determined by HCFA.

16. Revise § 422.101 to read as follows:

§ 422.101 Requirements relating to basic benefits.

Except as specified in § 422.264 (for entitlement that begins or ends during a hospital stay) and § 422.266 (with respect to hospice care), each M+C organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's

service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) HCFA's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part; and

(3) Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C plan.

17. Revise § 422.102 to read as follows:

§ 422.102 Supplemental benefits.

(a) *Mandatory supplemental benefits.*

(1) Subject to HCFA's approval, an M+C organization may require Medicare enrollees of an M+C plan other than an MSA plan to accept and pay for services in addition to Medicare-covered services described in § 422.101 and additional benefits described in § 422.312.

(2) If the M+C organization imposes mandatory supplemental benefits, it must impose them on all Medicare beneficiaries enrolled in the M+C plan.

(3) HCFA approves mandatory supplemental benefits if the benefits are designed in accordance with HCFA's guidelines and requirements as stated in this part and instructions and operational policy letters.

(b) *Optional supplemental benefits.* Except as provided in § 422.104 in the case of MSA plans, each M+C organization may offer (for election by the enrollee and without regard to health status) services that are not included in the basic benefits as described in § 422.100(c) and any mandatory supplemental benefits described in paragraph (a) of this section. Optional supplemental benefits are purchased at the discretion of the enrollee and must be offered to all Medicare beneficiaries enrolled in the M+C plan.

(c) *Payment for supplemental services.* All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the M+C plan.

(d) *Marketing of supplemental benefits.* M+C organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of groups and individual services.

18. Section 422.105 is amended by:

A. Revising the introductory text for paragraph (a).

B. Revising paragraph (f).

§ 422.105 Special rules for point of service option.

(a) *General rule.* A POS benefit is an option that an M+C organization may offer in an M+C coordinated care plan or network M+C MSA plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer a POS option—

* * * * *

(f) *POS-related data.* An M+C organization that offers a POS benefit through an M+C plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network) and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by HCFA.

19. Revise § 422.106 to read as follows:

§ 422.106 Coordination of benefits with employer group health plans and Medicaid.

(a) *General rule.* If an M+C organization contracts with an employer group health plan (EGHP) that covers enrollees in an M+C plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP or Medicaid benefits supplementing the M+C plan benefits. Jurisdiction regulating benefits under these circumstances is as follows:

(1) All requirements of this part that apply to the M+C program apply to the M+C plan coverage provided to enrollees eligible for benefits under an EGHP or Medicaid contract.

(2) Employer benefits that complement an M+C plan, and the marketing materials associated with the benefits, are not subject to review or approval by HCFA. M+C plan benefits provided to members of the EGHP, and the associated marketing materials, are subject to HCFA review and approval.

(3) Medicaid benefits are not reviewed under this part, but are subject to appropriate HCFA review under the Medicaid program. M+C plan benefits provided to individuals entitled to Medicaid benefits provided by the M+C organization under a contract with the State Medicaid agency are subject to M+C rules and requirements.

(b) *Examples.* Employer/Medicaid benefits, permissible EGHP or Medicaid plan benefits include the following:

(1) Payment of a portion or all of the M+C basic and supplemental premiums.

(2) Payment of a portion or all of other cost-sharing amounts approved for the M+C plan.

(3) Other employer-sponsored benefits that may require additional premium and cost-sharing, or other benefits provided by the organization under a contract with the State Medicaid agency.

20. Section 422.108 is amended by:

A. Republishing the introductory text for paragraph (b).

B. Revising paragraphs (b)(2), (c), the introductory text in paragraph (d), and paragraph (e).

C. Adding a new paragraph (f).

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(b) Responsibilities of the M+C organization. The M+C organization must, for each M+C plan—

* * * * *

(2) Identify the amounts payable by those payers; and * * * * *

* * * * *

(c) *Collecting from other entities.* The M+C organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in paragraphs (d) and (e) of this section.

(d) *Collecting from other insurers or the enrollee.* If a Medicare enrollee receives from an M+C organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may bill, or authorize a provider to bill any of the following—

* * * * *

(e) *Collecting from group health plans (GHPs) and large group health plans (LGHPs).* An M+C organization may bill a GHP or LGHP for services it furnishes to a Medicare enrollee who is also covered under the GHP or LGHP and may bill the Medicare enrollee to the extent that he or she has been paid by the GHP or LGHP.

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C plans only to the extent that those State laws are inconsistent with the standards established under this part. A State cannot take away an M+C organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to

bill, for services for which Medicare is not the primary payer. Section 1852(a)(4) of the Social Security Act does not prohibit a State from limiting the amount of the recovery; thus, State law could modify, but not negate, an M+C organization's rights in this regard.

21. In 422.109, the introductory text for paragraph (b) and paragraph (b)(5) are revised to read as follows:

§ 422.109 Effect of national coverage determinations (NCDs).

* * * * *

(b) The M+C organization must furnish, arrange or pay for an NCD "significant cost" service before the adjustment of the annual M+C capitation rate. The following rules apply to these services:

* * * * *

(5) Beneficiaries are liable for any applicable coinsurance amounts, but are not responsible for the Part A deductible.

* * * * *

22. Revise § 422.110(c) to read as follows:

§ 422.110 Discrimination against beneficiaries prohibited.

* * * * *

(c) *Additional requirements.* An M+C organization is required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act (see § 422.502(h)).

23. Section 422.111 is amended by:

A. Revising the introductory text in paragraph (a).

B. Revising paragraphs (b)(2)(i), (b)(4), and (b)(5)(i).

C. Republishing the introductory text in paragraph (c) and revising paragraph (c)(1).

D. Revising paragraph (e).

E. Adding new paragraph (f).

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An M+C organization must disclose the information specified in paragraph (b) of this section—

* * * * *

(b) * * *

(2) * * *

(i) The benefits offered under original Medicare, including the content specified in paragraph (f)(1) of this section;

* * * * *

(4) Out-of-area coverage provided under the plan, including coverage provided to individuals eligible to enroll in the plan under § 422.50(a)(3)(ii).

(5) * * *

(i) Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at § 422.113;

* * * * *

(c) *Disclosure upon request.* Upon request of an individual eligible to elect an M+C plan, an M+C organization must provide to the individual the following information:

(1) The information required paragraph (f) of this section.

* * * * *

(e) *Changes to provider network.* The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contracted is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) *Disclosable information*—(1) *Benefits under original Medicare.* (i) Covered services.

(ii) Beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts.

(iii) Any beneficiary liability for balance billing.

(2) *Enrollment procedures.* Information and instructions on how to exercise election options under this subpart.

(3) *Rights.* A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the M+C program and the right to be protected against discrimination based on factors related to health status in accordance with § 422.110.

(4) *Medigap and Medicare Select.* A general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under section 1882 of the Act, and provisions relating to Medicare Select policies under section 1882(t) of the Act.

(5) *Potential for contract termination.* The fact that an M+C organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's M+C plan.

(6) *Comparative information.* A list of M+C plans that are or will be available to residents of the service area in the following calendar year, and, for each

available plan, information on the aspects described in paragraphs (c)(7) through (c)(11) of this section, presented in a manner that facilitates comparison among the plans.

(7) *Benefits.* (i) Covered services beyond those provided under original Medicare.

(ii) Any beneficiary cost-sharing.

(iii) Any maximum limitations on out-of-pocket expenses.

(iv) In the case of an M+C MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(v) In the case of an M+C private fee-for-service plan, differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans.

(vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.

(vii) The types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers.

(viii) The coverage of emergency and urgently needed services.

(8) *Premiums.* (i) The M+C monthly basic beneficiary premiums.

(ii) The M+C monthly supplemental beneficiary premium.

(9) *The plan's service area.*

(10) *Quality and performance indicators* for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

(i) Disenrollment rates for Medicare enrollees for the 2 previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to HCFA guidelines.

(ii) Medicare enrollee satisfaction.

(iii) Health outcomes.

(iv) Plan-level appeal data.

(v) The recent record of plan compliance with the requirements of this part, as determined by the Secretary.

(vi) Other performance indicators.

(11) *Supplemental benefits.* Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits.

24. Section 422.112 is amended by:

A. Republishing the introductory text to paragraph (a).

B. Revising paragraphs (a)(2), (a)(3) and (a)(9).

C. Adding new paragraph (a)(10).

D. Removing paragraph (c).

§ 422.112 Access to services.

(a) *Rules for coordinated care plans and network M+C MSA plans.* An M+C

organization that offers an M+C coordinated care plan or network M+C MSA plan may specify the networks of providers from whom enrollees may obtain services if the M+C organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the M+C organization must meet the following requirements:

* * * * *

(2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an M+C organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the M+C organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.

(3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in § 422.2). The M+C organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

* * * * *

(9) *Cultural considerations.* Ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds.

(10) *Ambulance services, emergency and urgently needed services, and post-stabilization care services coverage.* Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with § 422.113.

* * * * *

25. Add new § 422.113 to read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

(a) *Ambulance services.* The M+C organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health.

(b) *Emergency and urgently needed services.* (1) *Definitions.*

(i) *Emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(A) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(ii) *Emergency services* means covered inpatient and outpatient services that are—

(A) Furnished by a provider qualified to furnish emergency services; and

(B) Needed to evaluate or stabilize an emergency medical condition.

(iii) *Urgently needed services* means covered services that are not emergency services as defined this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when the services are medically necessary and immediately required—

(A) As a result of an unforeseen illness, injury, or condition; and

(B) It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

(2) *M+C organization financial responsibility.* The M+C organization is financially responsible for emergency and urgently needed services—

(i) Regardless of whether the services are obtained within or outside the M+C organization;

(ii) Regardless of whether there is prior authorization for the services.

(A) Instructions to seek prior authorization for emergency or urgently needed services may not be included in any materials furnished to enrollees (including wallet card instructions), and enrollees must be informed of their right to call 911.

(B) Instruction to seek prior authorization before the enrollee has been stabilized may not be included in any materials furnished to providers (including contracts with providers);

(iii) In accordance with the prudent layperson definition of *emergency*

medical condition regardless of final diagnosis;

(iv) For which a plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan; and

(v) With a limit on charges to enrollees for emergency services of \$50 or what it would charge the enrollee if he or she obtained the services through the M+C organization, whichever is less.

(3) *Stabilized condition.* The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the M+C organization.

(c) *Maintenance care and post-stabilization care services* (hereafter together referred to as "post-stabilization care services").

(1) *Definition.* *Post-stabilization care services* means covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (c)(2)(iii) of this section, to improve or resolve the enrollee's condition.

(2) *M+C organization financial responsibility.* The M+C organization—

(i) Is financially responsible (consistent with § 422.214) for post-stabilization care services obtained within or outside the M+C organization that are pre-approved by a plan provider or other M+C organization representative;

(ii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain the enrollee's stabilized condition within 1 hour of a request to the M+C organization for pre-approval of further post-stabilization care services;

(iii) Is financially responsible for post-stabilization care services obtained within or outside the M+C organization that are not pre-approved by a plan provider or other M+C organization representative, but administered to maintain, improve, or resolve the enrollee's stabilized condition if—

(A) The M+C organization does not respond to a request for pre-approval within 1 hour;

(B) The M+C organization cannot be contacted; or

(C) The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care and a plan physician is not available for consultation. In this situation, the M+C

organization must give the treating physician the opportunity to consult with a plan physician and the treating physician may continue with care of the patient until a plan physician is reached or one of the criteria in § 422.113(c)(3) is met; and

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the M+C organization.

(3) *End of M+C organization's financial responsibility.* The M+C organization's financial responsibility for post-stabilization care services it has not pre-approved ends when—

(i) A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;

(ii) A plan physician assumes responsibility for the enrollee's care through transfer;

(iii) An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or

(iv) The enrollee is discharged.

26. Revise § 422.118 to read as follows:

§ 422.118 Confidentiality and accuracy of enrollee records.

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish procedures to do the following:

(a) Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The M+C organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify—

(1) For what purposes the information will be used within the organization; and

(2) To whom and for what purposes it will disclose the information outside the organization.

(b) Ensure that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoenas.

(c) Maintain the records and information in an accurate and timely manner.

(d) Ensure timely access by enrollees to the records and information that pertain to them.

27. Section 422.152 is amended by:

A. Revising the heading and introductory text for paragraph (b).

B. Revising the heading and introductory text for paragraph (e).

C. Revising paragraph (e)(1).

D. Republishing the heading of paragraph (f).

E. Adding new paragraph (f)(3).

§ 422.152 Quality assessment and performance improvement program.

* * * * *

(b) *Requirements for network M+C MSA plans and M+C coordinated care plans other than PPO plans.* An organization offering a network M+C MSA plan or M+C coordinated care plan other than a PPO plan must do the following:

* * * * *

(e) *Requirements for M+C PPO plans, non-network MSA plans, and M+C private fee-for-service plans.* An organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan must do the following:

(1) Measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

* * * * *

(f) *Requirements for all types of plans—*

* * * * *

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

28. In § 422.154, the introductory text for paragraph (b) is republished, and paragraph (b)(2) is revised to read as follows:

§ 422.154 External review.

* * * * *

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

* * * * *

(2) Except in the case of complaints about quality, exclude review activities that HCFA determines would duplicate review activities conducted as part of an approved accreditation process or as part of HCFA monitoring.

* * * * *

29. Revise paragraphs (a) and (b) in § 422.156 to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by HCFA; and

(2) The accreditation organization used the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality assurance.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

* * * * *

30. Section 422.157 is amended by republishing the introductory text for paragraph (a) and revising paragraphs (a)(3) and (b)(1) to read as follows:

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* HCFA may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

* * * * *

(3) It ensures that:

(i) Any individual associated with it, who is also associated with an entity it accredits, does not influence the accreditation decision concerning that entity.

(ii) The majority of the membership of its governing body is not comprised of managed care organizations or their representatives.

(iii) Its governing body has a broad and balanced representation of interests and acts without bias.

* * * * *

(b) *Notice and comment—(1)*

Proposed notice. HCFA publishes a notice in the **Federal Register** whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Announces HCFA's receipt of the accreditation organization's application for approval;

(ii) Describes the criteria HCFA will use in evaluating the application; and

(iii) Provides at least a 30-day comment period.

* * * * *

31. Revise the introductory text of § 422.158(e) to read as follows:

§ 422.158 Procedures for approval of accreditation as basis for deeming compliance.

* * * * *

(e) *Notice of determination.* HCFA gives the accreditation organization, within 210 days of receipt of its completed application, a formal notice that—

* * * * *

32. Section 422.202 is amended by:

A. Revising the introductory text of paragraph (b).

B. Adding a heading to paragraph (c).

C. Adding a new paragraph (d)

§ 422.202 Participation procedures.

* * * * *

(b) *Consultation.* The M+C organization must establish a formal mechanism to consult with the physicians who have agreed to provide services under the M+C plan offered by the organization, regarding the organization's medical policy, quality assurance programs and medical management procedures and ensure that the following standards are met:

* * * * *

(c) *Subcontracted groups.* * * *

* * * * *

(d) *Suspension or termination of contract.* An M+C organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An M+C organization that suspends or terminates an agreement under which the physician provides services to M+C plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the M+C organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The M+C organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An M+C organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written

notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An M+C organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

33. Revise § 422.204 to read as follows:

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An M+C organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An M+C organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the application and other information submitted in support of the application;

(ii) Recredentialing at least every 2 years that updates information obtained during initial credentialing and considers performance indicators such as those collected through quality assurance programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals

with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with HCFA permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

34. Add § 422.205 to read as follows:

§ 422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available to M+C plan enrollees, an M+C organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an M+C organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an M+C organization declines to include a given provider or group of providers in its network, it must furnish written notice to the effected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the M+C organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for M+C private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and

control costs consistent with its responsibilities.

35. In § 422.206, the heading for paragraph (b) is republished and paragraph (b)(2) is revised to read as follows:

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

* * * * *

(b) *Conscience protection.* * * *

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To HCFA, with its application for a Medicare contract, within 10 days of submitting its ACR proposal or, for policy changes, in accordance with § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

* * * * *

36. Section 422.208 is amended by:

A. Republishing the introductory text for paragraph (c).

B. Revising paragraph (c)(2).

C. Adding a heading to paragraph (e).

§ 422.208 Physician incentive plans: requirements and limitations.

* * * * *

(c) *Basic requirements.* Any physician incentive plan operated by an M+C organization must meet the following requirements:

* * * * *

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the M+C organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section, and conduct periodic surveys in accordance with paragraph (h) of this section.

* * * * *

(e) *Prohibition for private M+C fee-for-service plans.* * * *

* * * * *

37. In § 422.214, the heading for paragraph (a) is republished and paragraphs (a)(1) and (b) are revised to read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

* * * * *

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C coordinated care plan or M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.86(d)) of this chapter that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct graduate medical education costs.)

38. In § 422.216, paragraphs (a)(4), (b)(2), (c)(2), and the introductory text for paragraph (f) are revised to read as follows:

§ 422.216 Special rules for M+C private fee-for-service plans.

(a) * * *

(4) *Service furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an M+C private fee-for-service plan must accept as payment in full the amounts (less any payments under §§ 412.105(g) and 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) * * *

(2) Noncontract providers. A noncontract provider may not collect from an enrollee more than the cost-sharing established by the M+C private fee-for-service plan as specified in § 422.308(b), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) * * *

(2) *Noncontract providers.* An M+C organization that offers an M+C private

fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA.

* * * * *

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to § 489.24 of this chapter, to an enrollee in an M+C private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

* * * * *

39. Section 422.250 is amended by:

A. In paragraph (a)(1), removing the phrase "in paragraph (a)(2)" and adding in its place the phrase "in paragraphs (a)(2) or (f)".

B. Revising paragraph (a)(2)(i)(B).

C. Adding new paragraph (g).

§ 422.250 General provisions.

(a) * * *

(2) * * *

(i) * * *

(B) HCFA reduces the payment rate for each renal dialysis treatment by the same amount that the Secretary is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 1881(b)(7) of the Act. These funds are to be used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

* * * * *

(g) *Bonus payments.* (1) HCFA provides bonus payments to the M+C organization(s) that first offers a plan in a previously unserved county on or after January 1, 2000 and no later than December 31, 2001. The bonus payment amounts equal—

(i) For the first 12 months after a plan is offered in a previously unserved county, 5 percent of the monthly capitation rate otherwise payable under this section; and

(ii) For the subsequent 12 months, 3 percent of the monthly capitation rate otherwise payable under this section.

(2) A previously unserved county is defined as—

(i) A county in which no M+C plan has been offered; or

(ii) A county in which an M+C plan or plans has been offered, but where any M+C organization offering an M+C plan notified HCFA by October 13, 1999, that it will no longer offer plans in the county as of January 1, 2000.

(3) A plan is considered to be offered when—

(i) The M+C organization sponsoring the plan has a contract in effect to serve beneficiaries in the previously unserved area; and

(ii) The M+C plan is open for enrollment.

40. Revise § 422.254(b)(2) to read as follows:

§ 422.254 Calculation and adjustment factors.

* * * * *

(b) * * *

(2) The percentage points that HCFA uses to reduce its estimates are as follows:

(i) For 1998, 0.8 percentage points.

(ii) For years 1999 through 2001, 0.5 percentage points.

(iii) For 2002, 0.3 percentage points.

(iv) For years after 2002, 0 percentage points.

* * * * *

41. In § 422.257, revise paragraph (d) and add paragraph (g) to read as follows:

§ 422.257 Encounter data.

* * * * *

(d) *Other data requirements.* (1) M+C organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards.

(2) The data must be submitted electronically to the appropriate HCFA contractor.

(3) M+C organizations must obtain the encounter data required by HCFA from the provider, supplier, physician, or other practitioner that rendered the services.

(4) M+C organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate encounter data as required by HCFA. These provisions may include financial penalties for failure to submit complete data, or for failure to submit data that conform to the requirements for equivalent data for Medicare fee-for-service.

* * * * *

(g) *Deadlines for submission of encounter data.* Risk adjustment factors for each payment year are based on

encounter data submitted for services furnished during the 12 month period ending 6 months before to the payment year (for example, risk adjustment factors for CY 2000 are based on data for services furnished during the period July 1, 1998 through June 30, 1999).

(1) The annual deadline for encounter data submission is September 10 for encounter data reflecting services furnished during the 12 month period ending the prior June 30 (for example, the deadline for submission of data for the period July 1, 1998 through June 30, 1999 is September 10, 1999).

(2) HCFA allows a reconciliation process to account for late data submissions. HCFA continues to accept encounter data submitted after the September 10 deadline until June 30 of the payment year (for example, until June 30, 2000 for data from the period July 1, 1998 through June 30, 1999). After the payment year is completed, HCFA recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.

42. Revise § 422.300(b)(2) to read as follows:

§ 422.300 Basis and scope.

* * * * *

(b) * * *

(2) For contracts beginning on a date other than January 1 (according to § 422.504(d)), M+C organizations may submit ACRs on a date other than July 1 approved by HCFA.

43. Revise § 422.304(b) to read as follows:

§ 422.304 Rules governing premiums and cost-sharing.

* * * * *

(b) *Uniformity.* (1) *General rule.* The M+C monthly basic beneficiary premium, the M+C monthly supplemental beneficiary premiums, and the M+C monthly MSA premium of an M+C organization may not vary among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section). In addition, the M+C organization may not vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any), among individuals enrolled in an M+C plan (or segment of the plan as provided under paragraph (b)(2) of this section).

(2) *Segmented service area option.* An M+C organization may apply the uniformity requirements in paragraph (b)(1) of this section to segments of an M+C plan service area (rather than to the entire service area) as long as any such segment is composed of one or more M+C payment areas, and the information specified under § 422.306 is

submitted separately, as provided in that section, for each such segment.

* * * * *

44. Revise the introductory text in § 422.306(a)(1) to read as follows:

§ 422.306 Submission of proposed premiums and related information.

(a) *General rule.* (1) Not later than July 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to HCFA, in the manner and form prescribed by HCFA, for each M+C plan (or service area segment, under § 422.304(b)(2)) it intends to offer in the following year—

* * * * *

45. Section 422.310 is amended by:

A. In the introductory text for paragraph (d), removing the phrase “paragraphs (a)(1) and (a)(2) of this section” and adding in its place the phrase “paragraphs (d)(1) and (d)(2) of this section”.

B. Revising paragraph (c)(3).

§ 422.310 Adjusted community rate (ACR) approval process.

* * * * *

(c) * * *

(3) *Additional revenues.* The relative cost ratio for total revenues for an M+C plan is determined by comparing the total revenues charged on an accrual basis during the most recently ended calendar year prior to submission of the ACR for Medicare enrollees (including payments from HCFA without any needed offsets or reductions, such as, those required by § 422.250(a)(2)(i)(B) for ESRD enrollees) that elected the M+C plan to the total revenues charged for non-Medicare enrollees over the same period. The non-Medicare enrollees included in this computation must be consistent with the non-Medicare enrollees included in the initial rate computation. When the relative cost ratio for total revenues is applied to the total initial rate, the value of additional revenues is the remaining value after removing the value of direct medical costs (as adjusted by paragraph (c)(1) of this section) and the value of Administration (as adjusted by paragraph (c)(2) of this section).

46. In § 422.312, the introductory text for paragraph (b) is republished and paragraph (b)(1) is revised to read as follows:

§ 422.312 Requirement for additional benefits.

* * * * *

(b) *Requirement for additional benefits.* If there is an adjusted excess amount for the plan it offers, the M+C organization must—

(1) Provide additional benefits with an actuarial value (less the actuarial value of any cost-sharing associated with the benefit) which HCFA determines is at least equal to the adjusted excess amount; and

* * * * *

47–50. In § 422.352, the introductory text for paragraph (a) is republished and paragraph (a)(1) is revised to read as follows:

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of an M+C contract if the organization—

(1) Has obtained a waiver of State licensure as provided for under § 422.370;

* * * * *

51. Section 422.500 is amended by:

A. Revising the definition of “clean claim.”

B. Adding definitions for “downstream entity” and “first tier entity.”

§ 422.500 Definitions.

* * * * *

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.257(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

* * * * *

52. Section 422.501 is amended by:

A. Republishing the introductory text in paragraphs (b), (b)(3), and (b)(3)(vi).

B. Revising paragraphs (b)(3)(vi)(G) and (b)(5).

C. Removing paragraph (b)(3)(vi)(H).

D. Republishing the introductory text in (d)(2) and (d)(2)(iii).

E. Revising paragraph (d)(2)(iii)(A).

§ 422.501 General provisions.

* * * * *

(b) *Conditions necessary to contract as an M+C organization.* Any entity seeking to contract as an M+C organization must:

* * * * *

(3) Have administrative and management arrangements satisfactory to HCFA, as demonstrated by at least the following:

* * * * *

(vi) A compliance plan that consists of the following:

* * * * *

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

* * * * *

(5) The M+C organization's contract must not have been terminated by HCFA under § 422.510 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified HCFA of the intention to terminate the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue; or

(ii) HCFA has otherwise determined that circumstances warrant special consideration.

* * * * *

(d) * * *

(2) Each contract under this section must provide that HCFA, or any person or organization designated by HCFA has the right to:

* * * * *

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

* * * * *

53. Section 422.502 is amended by:

A. In paragraph (a)(12), removing the phrase “To comply will all requirements” and adding in its place the phrase “To comply with all requirements”.

B. Republishing the introductory text for paragraph (g).

C. Revising the introductory text for paragraph (g)(1) and the introductory text for paragraph (g)(3).

D. Revising paragraph (i)(3).

E. Revising paragraph (l).

§ 422.502 Contract provisions.

* * * * *

(g) *Beneficiary financial protections.* The M+C organization agrees to comply with the following requirements:

(1) Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the M+C organization. To meet this requirement, the M+C organization must—

* * * * *

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the M+C organization may use—

* * * * *

(i) * * *

(3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C organization.

(ii) Accountability provisions that indicate that—

(A) The M+C organization oversees and is accountable to HCFA for any functions or responsibilities that are described in these standards; and

(B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream entity in accordance with a contract or written agreement are consistent and comply with the M+C organization's contractual obligations.

* * * * *

(1) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy,

completeness, and truthfulness of relevant data that HCFA requests. Such data include specified enrollment information, encounter data, and other information that HCFA may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization and the information relied upon by HCFA in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the encounter data it submits under § 422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its ACR submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.310.

54. In § 422.504, revise paragraph (b) and remove paragraph (d) to read as follows:

§ 422.504 Effective date and term of contract.

* * * * *

(b) *Term of contract.* Each contract is for a period of at least 12 months.

* * * * *

55. Section 422.506 is amended by:

- A. Republishing the introductory text of paragraph (a)(2).
- B. Revising paragraph (a)(2)(i) and the introductory text of paragraph (a)(3).
- C. Removing paragraph (b)(1)(ii).
- D. Redesignating paragraphs (b)(1)(iii) and (b)(1)(iv) as (b)(1)(ii) and (b)(1)(iii), respectively.

§ 422.506 Nonrenewal of contract.

(a) * * *

(2) If an M+C organization does not intend to renew its contract, it must notify—

(i) HCFA in writing, by July 1 of the year in which the contract would end;

* * * * *

(3) HCFA may accept a nonrenewal notice submitted after July 1 if—

* * * * *

56. Section 422.510 is amended by adding paragraph (a)(12) and revising paragraph (c)(1) to read as follows:

§ 422.510 Termination of contract by HCFA.

(a) * * *

(12) The M+C organization substantially fails to comply with the marketing requirements in § 422.80.

* * * * *

(c) * * *

(1) *General.* Before terminating a contract for reasons other than the grounds specified in paragraph (a)(5) of this section, HCFA provides the M+C organization with reasonable opportunity to develop and receive HCFA approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

57. Revise § 422.514(b)(1) to read as follows:

§ 422.514 Minimum enrollment requirements.

* * * * *

(b) * * *

(1) For a contract applicant or M+C organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of the contract, HCFA may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or M+C organization must demonstrate to HCFA's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that HCFA takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or M+C organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or M+C organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, HCFA considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this

section and stop-loss insurance that is adequate and acceptable to HCFA; and

(iii) The contract applicant or M+C organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

* * * * *

58. Revise § 422.520(a)(3) to read as follows:

§ 422.520 Prompt payment by M+C organization.

* * * * *

(a) * * *

(3) All other claims must be paid or denied within 60 calendar days from the date of the request.

* * * * *

§ 422.550 [Amended]

59. In § 422.550(a)(2), the heading "Unincorporated sole proprietor" is removed and the heading "Asset Sale" is added in its place.

60. In § 422.561, the introductory text is republished and the definitions of "Appeal" and "Authorized representative" are revised to read as follows:

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the M+C organization, and if necessary, an independent review entity, hearings before ALJs, review by the Departmental Appeals Board (DAB), and judicial review.

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in 20 CFR part 404, subpart R, unless otherwise stated in this subpart.

* * * * *

61. Section 422.562 is amended by republishing the introductory text for paragraphs (a) and (a)(1) and revising paragraph (a)(1)(ii).

§ 422.562 General provisions.

(a) *Responsibilities of the M+C organization.* (1) An M+C organization, with respect to each M+C plan that it offers, must establish and maintain—

* * * * *

(ii) A procedure for making timely organization determinations;

* * * * *

62. Revise § 422.566(b) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) *Actions that are organization determinations.* An organization determination is any determination made by an M+C organization with respect to any of the following:

(1) Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services.

(2) Payment for any other health services furnished by a provider other than the M+C organization that the enrollee believes—

(i) Are covered under Medicare; or

(ii) If not covered under Medicare, should have been furnished, arranged for, or reimbursed by the M+C organization.

(3) The M+C organization's refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the M+C organization.

(4) Discontinuation of a service if the enrollee believes that continuation of the services is medically necessary.

(5) Failure of the M+C organization to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

* * * * *

63. Section 422.568 is revised to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if

the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(b) *Timeframe for requests for payment.* The M+C organization must process requests for payment according to the "prompt payment" provisions set forth in § 422.520.

(c) *Written notification by practitioners.* At each patient encounter with an M+C enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the M+C organization regarding the enrollee's services, consistent with paragraph (d) of this section. The practitioner's notification must—

(1) Provide the enrollee with the information necessary to contact the M+C organization; and

(2) Comply with any other requirements specified by HCFA.

(d) *Written notice for M+C organization denials.* If an enrollee requests an M+C organization to provide a detailed notice of a practitioner's decision to deny a service in whole or in part, or if an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

(e) *Form and content of the M+C organization notice.* The notice of any denial under paragraph (d) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(4)(i) For service denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

(ii) For payment denials, describe the standard reconsideration process and the rest of the appeal process; and

(5) Comply with any other notice requirements specified by HCFA.

(f) *Effect of failure to provide timely notice.* If the M+C organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.

64. Section 422.570 is amended by:

A. Revising paragraph (a).

B. Republishing the introductory text for paragraph (d).

C. Revising the introductory text to paragraph (d)(2) and revising paragraph (d)(2)(iii).

D. Adding a new paragraph (d)(2)(iv).

§ 422.570 Expediting certain organization determinations.

(a) *Request for expedited*

determination. An enrollee or a physician (regardless of whether the physician is affiliated with the M+C organization) may request that an M+C organization expedite an organization determination involving the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited determination, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that—

* * * * *

(iii) Informs the enrollee of the right to resubmit a request for an expedited determination with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

65. In § 422.572, revise paragraphs (b), (c), and (d) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and

inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(d) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements of this section.

* * * * *

66. Section 422.584 is amended by:

A. Revising paragraph (a).

B. Republishing the introductory text to paragraph (d).

C. Revising paragraph (d)(2).

§ 422.584 Expediting certain reconsiderations.

(a) *Who may request an expedited reconsideration.* An enrollee or a physician (regardless of whether he or she is affiliated with the M+C organization) may request that an M+C organization expedite a reconsideration of a determination that involves the issues described in § 422.566(b)(3) and (b)(4). (This does not include requests for payment of services already furnished.)

* * * * *

(d) *Actions following denial.* If an M+C organization denies a request for expedited reconsideration, it must take the following actions:

* * * * *

(2) Give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the M+C organization will process the enrollee's request using the 30-day timeframe for standard reconsiderations;

(ii) Informs the enrollee of the right to file a grievance if he or she disagrees

with the organization's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited reconsideration with any physician's support; and

(iv) Provides instructions about the grievance process and its timeframes.

* * * * *

67. Section 422.590 is amended by:

A. Republishing the heading for paragraph (a) and revising paragraph (a)(1).

B. Republishing the heading for paragraph (d) and revising paragraphs (d)(2), (d)(3), and (d)(4).

C. Republishing the heading for paragraph (g) and revising paragraph (g)(2).

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the M+C organization makes a reconsidered determination that is completely favorable to the enrollee, the M+C organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration. The M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. For extensions, the M+C organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

(d) *Expedited reconsideration—** * *

(2) *Extensions.* The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). When

the M+C organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision to grant an extension. The M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

(3) *Confirmation of oral notice.* If the M+C organization first notifies an enrollee of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the M+C organization must request information from noncontract providers.* If the M+C organization must receive medical information from noncontract providers, the M+C organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the M+C organization in meeting the required timeframe. Regardless of whether the M+C organization must request information from noncontract providers, the M+C organization is responsible for meeting the timeframe and notice requirements.

* * * * *

(g) *Who must reconsider an adverse organization determination.* * * *

(2) When the issue is the M+C organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

68. In § 422.594, the introductory text for paragraph (b) is republished, and paragraph (b)(1) is revised to read as follows:

§ 422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the entity's decisions in understandable language;

* * * * *

69. Revise § 422.596 to read as follows:

§ 422.596 Effect of a reconsidered determination.

A reconsidered determination is final and binding on all parties unless a party other than the M+C organization files a request for a hearing under the provisions of § 422.602, or unless the reconsidered determination is revised under § 422.616.

70. Revise § 422.612(b) to read as follows:

§ 422.612 Judicial review.

* * * * *

(b) *Review of Board decision.* Any party, including the M+C organization, may request judicial review (upon notifying the other parties) of the Board decision if it is the final decision of HCFA and the amount in controversy is \$ 1,000 or more.

* * * * *

71. Section 422.618 is amended by:

- A. Revising the section heading.
- B. Redesignating paragraph (b) as paragraph (c).
- C. Adding a new paragraph (b).
- D. Revising newly designated paragraph (c).

§ 422.618 How an M+C organization must effectuate standard reconsidered determinations or decisions.

* * * * *

(b) *Reversals by the independent outside entity.* (1) *Requests for service.* If, on reconsideration of a request for service, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize the service under dispute within 72 hours from the date it receives notice reversing the determination, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days from that date. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(2) *Requests for payment.* If, on reconsideration of a request for payment, the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must pay for the service no later than 30 calendar days from the date it receives notice reversing the organization determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent outside entity's determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

72. Add new § 422.619 to read as follows:

§ 422.619 How an M+C organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the M+C organization.* If on reconsideration of an expedited request for service, the M+C organization completely reverses its organization determination, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(d)(2)).

(b) *Reversals by the independent outside entity.* If the M+C organization's determination is reversed in whole or in part by the independent outside entity, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

(c) *Reversals other than by the M+C organization or the independent outside entity.* If the independent review entity's expedited determination is reversed in whole or in part by the ALJ, or at a higher level of appeal, the M+C organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 days from the date it receives notice reversing the determination. The M+C organization must inform the independent outside entity that the organization has effectuated the decision.

73. Section 422.620 is revised to read as follows:

§ 422.620 How enrollees of M+C organizations must be notified of noncoverage of inpatient hospital care.

(a) *Enrollee's entitlement.* Where an M+C organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care, as described in §§ 422.2 and 422.113), written notice of noncoverage under paragraph (c) of this section must be provided to each enrollee. An enrollee is entitled to coverage until at least noon the day after such notice is provided. If PRO review is requested under § 422.622, coverage is extended as provided in that section.

(b) *Physician concurrence required.* Before notice of noncoverage is provided as described in paragraph (c) of this section, the entity that makes the noncoverage/discharge determination (that is, the hospital by delegation or the M+C organization) must obtain the concurrence of the physician who is responsible for the enrollee's hospital care.

(c) *Notice to the enrollee.* In all cases in which a determination is made that inpatient hospital care is no longer necessary, no later than the day before hospital coverage ends, written notice must be provided to the enrollee that includes the following elements:

- (1) The reason why inpatient hospital care is no longer needed.
- (2) The effective date and time of the enrollee's liability for continued inpatient care.
- (3) The enrollee's appeal rights.
- (4) Additional information specified by HCFA.

74. Revise § 422.648(b) to read as follows:

§ 422.648 Reconsideration: Applicability.

* * * * *

(b) HCFA reconsiders the specified determinations if the contract applicant or the M+C organization files a written request in accordance with § 422.650.

75. In § 422.650, paragraphs (c) and (d) are revised to read as follows:

§ 422.650 Request for reconsideration.

* * * * *

(c) *Proper party to file a request.* Only an authorized official of the contract applicant or M+C organization that was the subject of a contract determination may file the request for reconsideration.

(d) *Withdrawal of a request.* The M+C organization or contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for

withdrawal must be in writing and filed with HCFA.

76. Revise § 422.652 to read as follows:

§ 422.652 Opportunity to submit evidence.

HCFA provides the M+C organization or contract applicant and the HCFA official or officials who made the contract determination reasonable opportunity, not to exceed the timeframe in which an M+C organization could choose to request a hearing as described at § 422.662, to present as evidence any documents or written statements that are relevant and material to the matters at issue.

77. Revise § 422.656 to read as follows:

§ 422.656 Notice of reconsidered determination.

(a) HCFA gives the M+C organization or contract applicant written notice of the reconsidered determination.

(b) The notice—

(1) Contains findings with respect to the contract applicant's qualifications to

enter into, or the M+C organization's qualifications to remain under, a contract with HCFA under Part C of title XVIII of the Act;

(2) States the specific reasons for the reconsidered determination; and

(3) Informs the M+C organization or contract applicant of its right to a hearing if it is dissatisfied with the determination.

78. In § 422.660, the introductory text is republished and paragraph (a) is revised to read as follows:

§ 422.660 Right to a hearing.

The following parties are entitled to a hearing:

(a) A contract applicant that has been determined in a reconsidered determination to be unqualified to enter into a contract with HCFA under Part C of title XVIII of the Act.

* * * * *

79. In § 422.662, paragraphs (a) and (b) are revised to read as follows:

§ 422.662 Request for hearing.

(a) *Method and place for filing a request.* A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 days after the date of the reconsidered determination.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 15, 2000.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Approved: June 16, 2000.

Donna E. Shalala,
Secretary.

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 8 OF 14
EXHIBITS D-67 THROUGH D-82
PAGES 2104 THROUGH 2367**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT D-67

What is medical coding?

 aapc.com/resources/what-is-medical-coding



Medical coding is the transformation of healthcare diagnosis, procedures, medical services, and equipment into universal medical alphanumeric codes. The diagnoses and procedure codes are taken from medical record documentation, such as transcription of physician's notes, laboratory and radiologic results, etc. Medical coding professionals help ensure the codes are applied correctly during the medical billing process, which includes abstracting the information from documentation, assigning the appropriate codes, and creating a claim to be paid by insurance carriers.

Medical coding happens every time you see a healthcare provider. The healthcare provider reviews your complaint and medical history, makes an expert assessment of what's wrong and how to treat you, and documents your visit. That documentation is not only the patient's ongoing record, it's how the healthcare provider gets paid.

Medical coders translate documentation into standardized codes that tell payers the following:

- Patient's diagnosis
- Medical necessity for treatments, services, or supplies the patient received
- Treatments, services, and supplies provided to the patient
- Any unusual circumstances or medical condition that affected those treatments and services

EXHIBIT

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~~2105~~

Like a musician who interprets the written music and uses their instrument to produce what's intended, medical coding requires the ability to understand anatomy, physiology, and details of the services, and the rules and regulations of the payers to succeed. Check out our webinar to learn more — [Guidelines: The Foundation of Coding](#).

Medical coding derives from public bills of mortality posted in London in the 18th century. It was through correlating these that doctors determined the cause of a cholera epidemic. It is even more vital now as the data gathered through medical coding is used to improve healthcare overall. The results are submitted to payers for reimbursement, but the data derived from the codes also are used to determine utilization, manage risk, identify resource use, build actuarial tables, and support public health and actions.

Medical coding requires a particular discipline. Medical coders are considered part of the medical team, often working very closely with providers, management, and payers. A scholar, detective, educator, and problem solver, medical coders possess particular skills.

The medical coder and biller process a variety of services and claims on a daily basis. Medical codes must tell the whole story of the patient's encounter with the physician and must be as specific as possible in capturing reimbursement for rendered services. To better understand what a coding transaction looks like, read the article: [What does a medical coder do?](#)

The main task of a medical coder is to review clinical statements and assign standard codes using CPT®, ICD-10-CM, and HCPCS Level II classification systems. Medical billers, on the other hand, process and follow up on claims sent to health insurance companies for reimbursement of services rendered by a healthcare provider.

The medical coder and medical biller may be the same person or may work with each other to ensure invoices are paid properly. To help promote a smooth coding and billing process, the coder checks the patient's medical record (i.e., the transcription of the doctor's notes, ordered laboratory tests, requested imaging studies, and other sources) to verify the work that was done. Both work together to avoid insurance payment denials.

Why is medical coding needed?

The healthcare revenue stream is based on the documentation of what was learned, decided, and performed.

A patient's diagnosis, test results, and treatment must be documented, not only for reimbursement but to guarantee high quality care in future visits. A patient's personal health information follows them through subsequent complaints and treatments, and they must be easily understood. This is especially important considering the hundreds of millions of visits, procedures, and hospitalizations annually in the United States.

The challenge, however, is that there are thousands of conditions, diseases, injuries, and causes of death. There are also thousands of services performed by providers and an equal number of injectable drugs and supplies to be tracked. Medical coding classifies these for easier reporting and tracking. And in healthcare, there are multiple descriptions, acronyms, names, and eponyms for each disease, procedure, and tool. Medical coding standardizes the language and presentation of all these elements so they can be more easily understood, tracked, and modified.

This common language, mandated by the Health Information Portability and Accountability Act (HIPAA), allows hospitals, providers, and payers to communicate easily and consistently. Nearly all private health information is kept digitally and rests on the codes being assigned.

Types of codes used

Medical coding is performed all over the world, with most countries using the International Classification of Diseases (ICD). ICD is maintained by the World Health Organization and modified by each member country to serve its needs. In the United States, there are six official HIPAA-mandated code sets serving different needs.

ICD-10-CM (International Classification of Diseases, 10th Edition, Clinically Modified)

ICD-10-CM includes codes for anything that can make you sick, hurt you, or kill you. The 69,000-code set is made up of codes for conditions and disease, poisons, neoplasms, injuries, causes of injuries, and activities being performed when the injuries were incurred. Codes are “smart codes” of up to seven alphanumeric characters that specifically describe the patient’s complaint.

ICD-10-CM is used to establish medical necessity for services and for tracking. It also makes up the foundation of the MS-DRG system below.

CPT® (Current Procedure Terminology)

This code set, owned and maintained by the American Medical Association, includes more than 8,000 five-character alphanumeric codes describing services provided to patients by physicians, paraprofessionals, therapists, and others. Most outpatient services are reported using the CPT® system. Physicians also use it to report services they perform in inpatient facilities. Here's a little behind the scene on the making of CPT® codes.

ICD-10-PCS (International Classification of Diseases, 10th Edition, Procedural Coding System)

ICD-10-PCS is a 130,000 alphanumeric code set used by hospitals to describe surgical procedures performed in operating, emergency department, and other settings. Don't let the procedural coding intimidate you by taking the right approach to ICD-10-PCS coding.

HCPCS Level II (Health Care Procedural Coding System, Level II)

Developed originally for use by Medicare, Medicaid, Blue Cross/Blue Shield, and other providers to report procedures and bill for supplies, HCPCS Level II's 7,000-plus alphanumeric codes are used for many more purposes, such as quality measure tracking, outpatient surgery billing, and academic studies.

CDT[®] (Code on Dental Procedures and Nomenclature)

CDT[®] codes are owned and maintained by the American Dental Association (ADA). The five-character codes start with the letter D and used to be the dental section of HCPCS Level II. Most dental and oral procedures are billed using CDT[®] codes.

NDC (National Drug Codes)

The Federal Drug Administration's (FDA) code set is used to track and report all packages of drugs. The 10-13 alphanumeric character smart codes allow providers, suppliers, and federal agencies to identify drugs prescribed, sold, and used.

Modifiers

CPT[®] and HCPCS Level II codes use hundreds of alphanumeric two-character modifier codes to add clarity. They may indicate the status of the patient, the part of the body on which a service is being performed, a payment instruction, an occurrence that changed the service the code describes, or a quality element.

MS-DRG and APC

Two federal code sets used to facilitate payment deriving from those above systems are MS-DRG and APCs. They rely on existing codes sets but indicate the resources consumed by the facility to perform the service.

MS-DRG (Medical Severity Diagnosis Related Groups)

MS-DRGs are reported by a hospital to be reimbursed for a patient's stay. The MS-DRG is based on the ICD-10-CM and ICD-10-PCS codes reported. They are defined by a particular set of patient attributes which include principal diagnosis, specific secondary diagnoses, procedures, sex, and discharge status. The Centers for Medicare & Medicaid Services (CMS) work with 3M HIS to maintain this data set.

APC (Ambulatory Payment Categories)

APCs are maintained by the Centers for Medicare & Medicaid Services (CMS) to support the Hospital Outpatient Prospective Payment System (OPPS). Some outpatient services in a hospital, such as minor surgery and other treatments, are reimbursed through this system.

How is medical coding done?

Medical coding is best performed by trained and certified medical coders. The following example outlines what a typical day in the life of a Medical Coder may look like.

After settling into the office and grabbing a cup of coffee, a medical coder usually begins the workday by reviewing the previous day's batch of patient notes for evaluation and coding. The type of records and notes depends on the clinical setting (outpatient or facility) and may require a certain degree of specialization (Healthcare systems may have individuals who focus on medical specialties while coders who work in smaller, or more general offices, may have a broad range of patients and medical conditions.).

Selecting the top patient note or billing sheet on the stack, the coder begins reviewing the documentation to understand the patient's diagnoses assigned and procedures performed during their visit. Coders also abstract other key information from the documentation, including physician names, dates of procedures, and other information.

Coders rely on ICD-10 and CPT® code books to begin translating the physician's notes into useful medical codes. An example of basic procedure documentation and subsequently assigned codes can be seen below.

Many cases are simple to code. Individual medical coders develop a detailed understanding of the procedures and commonality of their specific clinic or facility. Coders occasionally encounter a difficult note requiring in-depth research, taking more time to code correctly. Even among the more commonly used codes are significant gray areas open for examination among coders. With very complex or unusual cases, coding guidelines may be confusing to interpret. Experienced coders will rely on their network of peers and professionals to discuss nuances in online forums, networking with specialists they have met at national conferences, or consulting with co-workers to help understand the issue and determine the proper codes. Ongoing training and current coding-related periodicals such as AAPC the Magazine also provide important opportunities to advance understanding and professionalism.

Finally, the coder completes the chart and begins the next patient record. This cycle of reading, note taking, assigning codes, and computer entry repeats with each chart. Most coders will spend the majority of their day sitting at the computer reading notes and using their computer to enter data into a billing system or search for information to clarify the documentation in the notes.

Here's an example of a case:

This is a 40-year-old male with rectal pain, rectal bleeding, and some left-sided lower abdominal pain. The colonoscopy procedure and the risks, not limited to bleeding, perforation, infection, side effects from medication, need for surgery, etc., and were fully explained to the patient. An informed consent was taken.

Instrument Used: CF-Q160.

Sedation: Versed 5 mg IV in incremental doses and Demerol 100 mg IV in incremental doses performed by the anesthesia team.

Extent of Exam: Up to cecum as identified by ileocecal valve and appendiceal orifice.

Length of Scope Insertion: 110 cm.

Postop Diagnoses/Impression:

1. Moderate-sized, internal hemorrhoids.
2. Mild diverticulosis.

Description of Procedure: With the patient being in the left lateral position, first digital examination of the rectum was done, which was unremarkable. Then, the CF-Q160 was passed through the rectum under direct visualization and advanced all the way to cecum. The cecum was identified by ileocecal valve and appendiceal orifice. There were a couple of tics/diverticula seen on the left side of the colon. A careful look was taken while withdrawing the scope. Retroflex view in the rectum showed moderate-sized internal hemorrhoids.

Plan:

1. Anusol-HC suppositories for hemorrhoids.
2. High-fiber diet.
3. If there is no family history, a follow-up colonoscopy in 10 years.

CPT® Code: 45378

ICD-10-CM Codes: K64.8, K57.30

How do you become a medical coder?

Successful medical coders know anatomy, physiology, medical procedures, and payer rules and policies. To become a medical coder, you must attend training via a coding-specific training program or college. Afterward, finding a job in the field is easier if you have a professional credential, such as AAPC's.

There are several medical coding certifications available, depending on the area of the revenue cycle you wish to pursue. The baseline for most is the Certified Professional Coder (CPC) , which certifies the coder's ability to work in outpatient settings. Facility coders should pursue the Certified Inpatient Coder (CIC) for inpatient coding and Certified Outpatient Coder (COC) for hospital patients receiving in-and-out services. Here's an

infographic to help you chose the right hospital credential. There are several programs available both for online training on medical coding and physical medical coding training classes.

Today more than 200,000 medical professionals are members of AAPC. AAPC elevates the standards of medical coding by developing training, professional certification, opportunities to network with other related medical professionals and providing a variety of job search and career building opportunities.

Professional coders largely work independently. However, interaction with coding staff, medical billers, physicians, and ancillary office staff is essential. Medical coders are usually placed on tight production schedules and expected to complete a determined number of notes each day or to keep their lag days at a specified timeframe. Lag days are the number of days it takes for the notes to be documented to the actual claims submission date. The prime date is usually between two to five days.

Depending on the clinical setting, internal or external auditors periodically perform audits of the coding and documentation for accuracy and completeness. The results of these coding audits are maintained by the compliance department or the department supervisor and are a significant part of job evaluations.

How much does a medical coder make in a year?

AAPC-certified medical coders make \$60,917 per year on average — 29% more than uncertified health information technicians who earn approximately \$47,200 annually. Where you live, what role you play in the revenue cycle, and how much education and credentials you have can influence your pay. Coders who pursue career advancement, earning their Certified Professional Medical Auditor (CPMA), Certified Physician Practice Manager (CPPM), or Certified Documentation Expert Outpatient (CDEO) make average salaries of \$71,646 annually, according to AAPC's 2023 Medical Coding Salary Survey.

Charting your career requires curiosity, continuing education, and imagination. Achieving the credential is the beginning of a lifetime of new experiences and knowledge.

EXHIBIT D-68

Message

To: Cheri.Rice@cms.hhs.gov
CC: Johnson, Thad C [/O=UHG-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=21ebe185-77aa00ab-85256887-56b2c8]; Schumacher, Daniel J [/O=UHG-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=f1aa3511-1c428dc-852567cc-520b3e]; Erickson, Karen L [/O=UHG-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=2f9c139c-fe81e069-85256977-61819f]; Jennifer.harlow@cms.hhs.gov
BCC: Nelson, Steve H [/O=UHG-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=snels59]; Cosgriff, John W [/O=UHG-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=46fd8f6b-8eb0d608-8525702f-68fb35]
Subject: 2012 Attestation and follow-up from yesterday's meeting

Cheri,

Thanks for your email, and please let us know if you need any additional information.

Steve

-----Original Message-----

From: Rice, Cheri M. (CMS/CM) [Cheri.Rice@cms.hhs.gov]
Sent: Friday, May 02, 2014 05:14 PM Central Standard Time
To: Nelson, Steve H
Cc: Johnson, Thad C; Schumacher, Daniel J; Erickson, Karen L; Harlow, Jennifer A. (CMS/CM)
Subject: RE: 2012 Attestation and follow-up from yesterday's meeting

Steve,

Thank you for your email and for our discussion earlier this week. With respect to your fifth point, I would note that regardless of the effective date of the proposed requirement related to medical record reviews, there are other laws that do impose standards, requirements and responsibilities on MA plans in connection with the federal payments they receive from CMS. We cannot provide advice to United about the scope of those other laws. Nor can we provide advice on whether United's plan course of action and/or purported limits on the scope of its attestation are compliant with such other laws. Your statement concerning the data submissions that have already been made and United's plans for future action will be included in our records and we will proceed with our evaluation and use of the risk adjustment data consistent with 42 CFR 422.308, 422.310, and other applicable law.

Thanks again,

Cheri

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Wednesday, April 30, 2014 9:55 AM
To: Rice, Cheri M. (CMS/CM)
Cc: Johnson, Thad C; Schumacher, Daniel J; Erickson, Karen L; Nelson, Steve H
Subject: 2012 Attestation and follow-up from yesterday's meeting

Dear Cheri,

I wanted to thank you and your colleagues for taking the time to meet with us yesterday. We appreciate the time and attention that you and others in CMS leadership have provided on the issue of our 2012 risk adjustment data

EXHIBIT
00324

submissions and our annual risk adjustment data certifications. As we mentioned, prior annual certifications have been on paper, and we have thus had the ability to add notes explaining our understanding of the certifications and our ongoing data remediation efforts. This year, however, the certifications are electronic, and there does not appear to be an opportunity to reflect our understanding. The purpose of our meeting yesterday and this email is to explain our understanding of the certifications.

First, as with our past certifications, the 2012 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.

Second, the certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.

Third, the certifications only cover risk adjustment data for 2012 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.

Fourth, as we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2012 dates of service that we ultimately determine should be deleted consistent with this email.

Fifth, as we discussed yesterday, CMS recently issued a proposed rule that would, if finalized, require MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. During our conversation yesterday and other recent conversations, CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that MA plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. We currently have a process through which we review certain medical records to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes. This process already has resulted in the identification of and, in some instances, the submission of deletes for 2012 dates of service. But based on the proposed rule, including the preamble, and recent conversations with CMS, we suspended that process for 2012 dates of service while we consider whether to make changes. Pursuant to our discussion, however, we will soon submit for deletion those diagnosis codes that have undergone a complete review and that we have therefore identified as appropriate deletes. In the near future, we will determine whether to continue our review process for the diagnosis codes which were still under review at the time we suspended our process. In the meantime, we will not delete these codes.

The certifications that we submit today are made subject to these clarifications. Please let us know if you have any questions. Again, thank you for your time and attention on this matter.

EXHIBIT D-69



Risk Adjustment Team Introductions and Services to M&R

February 12, 2014

EXHIBIT

608

2116

Meeting Agenda

- Introductions / Roles / Areas of Responsibility
 - Paul Barringer (Relationship Office)
 - Kimberly Fadden
 - Jeff Dumcum (Business / Strategy)
 - Patty Brennan
 - Nancy Freeman
 - Ramesh Jayasuriya
 - Tim Trujillo (Operations)
 - Lori Meyer
- Organizational Areas
- Risk Adjustment Overview / 2014 Initiatives: Jeff
- Retrospective Programs: Patty
- Prospective Programs: Nancy
- HEDIS: Jeff / Ramesh
- Medicare Revenue Reconciliation : Lori Meyer

Relationship Office

RELATIONSHIP OFFICE

Relationship Office Team:

RO Leader — David Orbuch
 Clinical/Affordability — Mureen Allen
 Network — Brian Jeffrey
 Stars/Quality — Troy Jelinek
 Benefit Ops — Steve Gelinske
 C&S — Susan Hames
 M&R — Paul Barringer
 M&V — Perry Sekus

Business Solutions:
 Kimberly Fadden
 Alex Kasyjanski
 Paul Kaufman
 Chris Sangster
Physician / Behavioral:
 Ann Swink
Consumer:
 Katie Croxdale

**Optum Support for
 UnitedHealthcare
 Shared Services**

Clinical/Affordability
Network
Stars/Quality
Benefit Operations

- Strategic partners for UnitedHealthcare shared services leaders
- Embedded in UnitedHealthcare and aligned at a senior level
- Expertise and accountability to drive integrated strategy, coordinate resources and provide support
- Ensure tight linkage with Optum Businesses

Optum Support for UnitedHealthcare Business Segments

- | C&S | M&R | M&V | E&I |
|--|-----|-----|-----|
| <ul style="list-style-type: none"> • Strategic partners: single point of accountability • Aligned to and “embedded” in E&I, M&R, C&S, M&V to enable Optum/UnitedHealthcare partnership • Partner with Optum Business Leaders to represent Optum | | | |

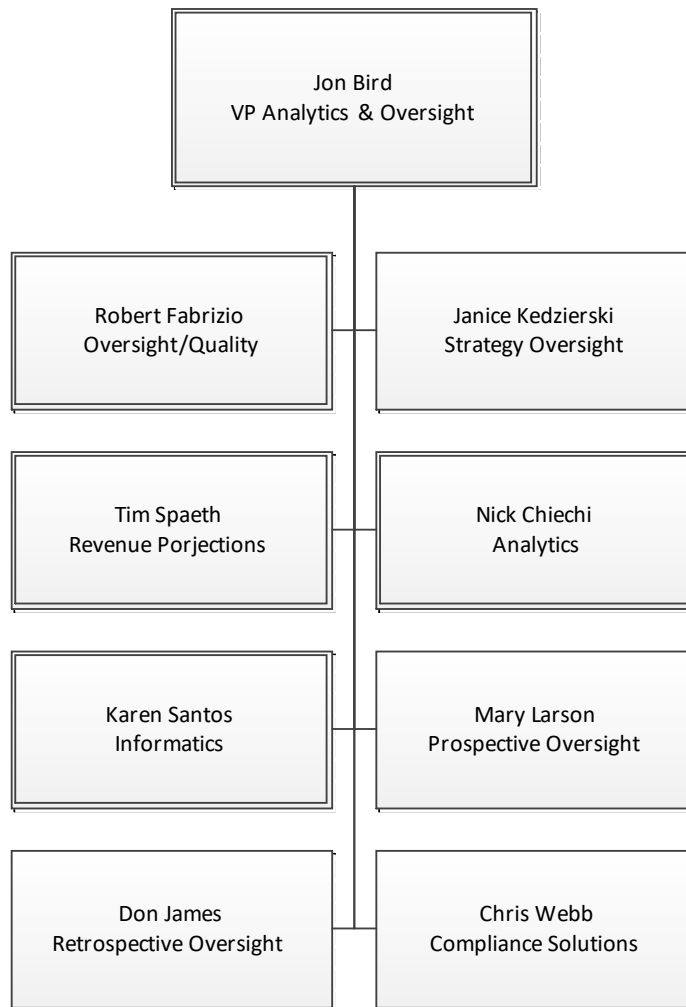
Optum Employer Support

- Large Employer; EGEL;
 Direct/Stop Loss**
- Aligned to UnitedHealthcare to partner more effectively in large employer segment
 - Drive external growth by also serving direct-to-employer

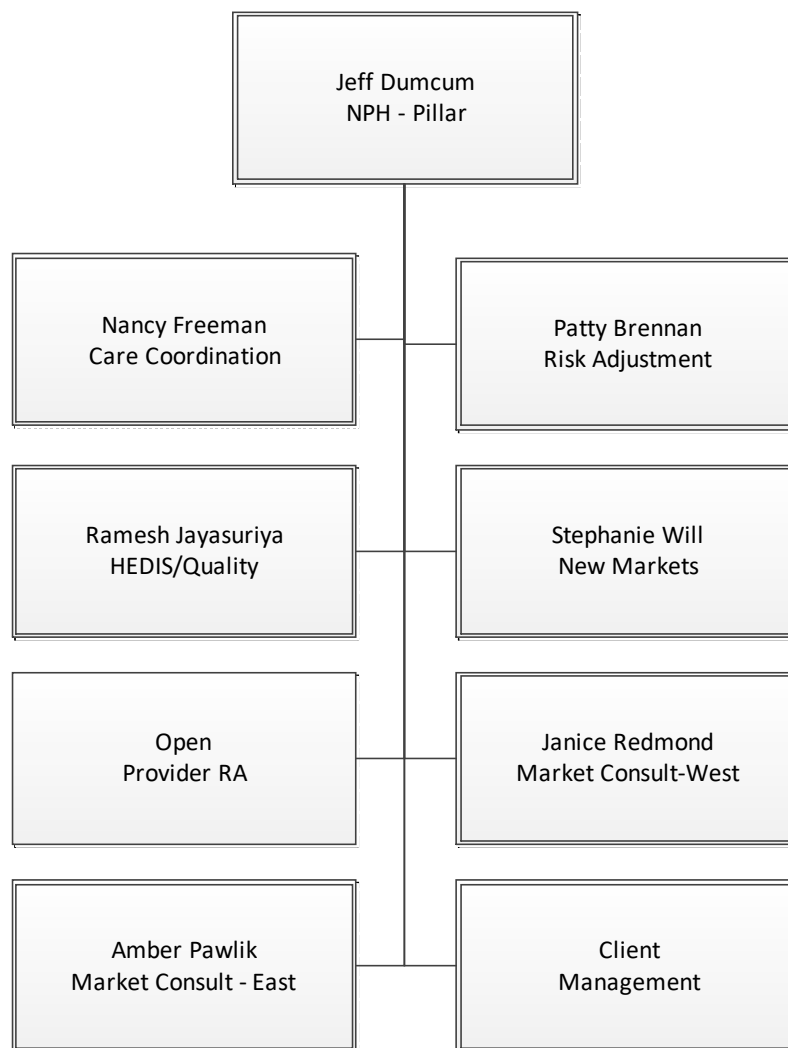
Client Solutions Group

- Non-client facing, highly functional personnel with specialized knowledge, established relationships and appropriate up-training and resources
- Track issues, provide trend analysis and identify root cause
- Coordinate and manage reporting to UnitedHealthcare and employer clients

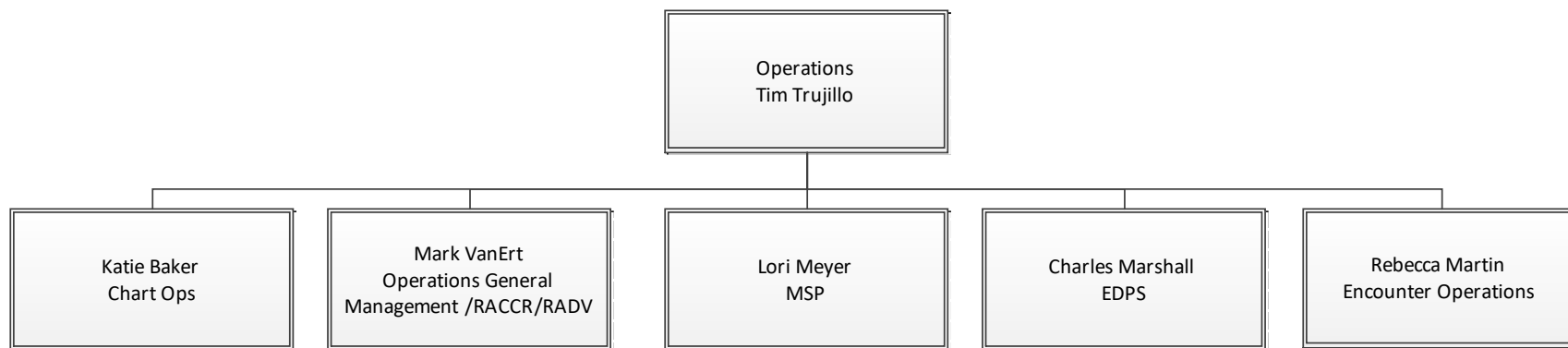
Risk Adjustment Organizational Teams - Bird



Risk Adjustment Organizational Teams - Dumcum



Risk Adjustment Organizational Teams - Trujillo





Risk Adjustment Overview

Jeff Dumcum

Optum: The Health Services Partner

~~Optum is the leading partner for stakeholders across the complex and dynamic health system.~~

One of the largest **health information, technology and consulting** companies in the world



The leader in **population health management** serving the physical, mental and financial needs of both individuals and organizations



The **pharmacy management** leader in service, affordability and clinical quality



Market leaders within a dynamic health services market

Optum Services focused on the Payer Value Chain

The payer value chain serves as a strategic framework to organize ideas and actions in three key areas critical to successfully meeting stakeholder requirements.

Payer Value Chain



Payers are seeing challenges across all aspects

Optum Population Health Management Portfolio

Optum's **population health management solution** addresses quality, risk adjustment and utilization in an integrated manner using a framework that leverages our advanced analytic capabilities to provide a holistic view of a population to provide the right intervention at the right time to drive change in member and provider behavior across lines of business.

Risk Adjustment Solution

Assists in the improvement of accuracy and timeliness of risk adjusted revenue reimbursement.

- Data capture, reconciliation and submission services
- Coordinated chart retrieval and abstraction
- Professionals who engage providers in their offices to improve assessment, documentation and gap closure for members
- Individual assessment services with a unique clinical orientation to improve care management

Medicare/HCC Program

RAPS & Encounter Submission Services

Medicaid/CDPS Program

Exchange HHS/HCC Program

Market/Provider Consultation Representatives

Chart Retrieval Abstraction & Management

Quality Solution

Solution helps to improve quality ratings through a combination of expert consulting, services and technology that support:

- Quality gap identification
- Improvement in Medication Adherence
- Member profiles and registries
- Provider profiles and registries
- Facilitate member and provider outreach & engagement activities
- Capture quality data and submits it with certified software

Stars/HEDIS Gaps in Care

NCQA Certified HEDIS Software

Stars Management and Modeling Software

Evidence Based Medicine Gap ID Software

CAHPS & HOS Surveys and Improvement

Medical Record Abstraction & Management

Integrated Member Support Solution

improves health outcomes, increases member satisfaction, reduces costs and improve retention by:

- Supporting healthy behaviors
- Improving access and setting appointments
- Providing comprehensive HRAs that cover physical, behavioral and environmental assessments
- Providing or partnering in direct care and assessments
- Managing chronic & acute medical, social and behavioral needs
- Medicare, Medicaid, MME, Employer, and Exchange oriented programs

Special Population Management

Transition Management

Complex Care Management

Quality and Risk Assessments (Clinic & Home)

Care Coordination & Facilitation

Medication Adherence

Optum Consulting

Point of View on a Best Practice Framework

There are five key steps that every Plan must consider when running their Risk/Quality Business, each of these steps plays a factor in achieving your desired results.



Population Health Management

Integrated risk adjustment, clinical gaps & performance reporting identify the right intervention strategy



Analytics: Population Metrics and Characteristics

Plan and Provider Level Reports That Address Performance Levels and Identify Opportunities for Intervention and Additional Emphasis

Select Provider Group:

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PCP RAF Report (data last updated 01/26/2023)

The dollar amounts listed in this report are not the actual reimbursement amounts for any MA Plan or participating provider. Rather, the amounts listed are based on a static value formula to assist you with legally appropriate business analysis and NOT for purposes of making any clinical or other determinations affecting a member's course of treatment or medical care.

Available Reports:

Go to Page:

Plan	PCP Name	Total Members	Total RAF
Healthplan 2	PORLO.PORBE	1	0.294
Healthplan 2	PORLP.PORBP	3	0.882
Healthplan 2	PORLP.PORBG	1	0.485
Healthplan 2	PORLP.PORBN	1	0.448
Healthplan 2	PORLP.PORBI	1	0.489
Healthplan 2	PORLP.PORCA	2	1.029
Healthplan 2	PORLP.PORCC	2	0.907
Healthplan 2	PORLP.PORCD	3	0.384
Healthplan 2	PORLP.PORCE	4	0.552
Healthplan 2	PORLP.PORCF	3	0.381
Healthplan 2	PORLP.PORCG	6	0.783
Healthplan 2	PORLP.PORCH	5	0.566
Healthplan 2	PORLP.PORCI	0	0.000
Healthplan 2	PORLP.PORCJ	1	1.365

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Group and Provider Summary View (data last updated 01/26/2023)

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Available Reports:

Group Summary

Payment Year	Total Members	CMS Accepted HCCs Total	CMS Accepted HCCs %	No HCCs Total	No HCCs %	LA WA
2015	142	91	63.2%	71	49.8%	3
2016	6	6	100%	0	0.0%	10

Provider Summary

Go to Page: Page

Plan	PCP Name	Payment Year	Total Members	CMS Accepted HCCs Total
Healthplan 2	PORLO.PORBE	2015	1	0
Healthplan 2	PORLO.PORBE	2016	0	0
Healthplan 2	PORLP.PORBP	2015	3	1
Healthplan 2	PORLP.PORBP	2016	0	0
Healthplan 2	PORLP.PORBG	2015	2	0
Healthplan 2	PORLP.PORBG	2016	0	0
Healthplan 2	PORLP.PORBN	2015	1	0
Healthplan 2	PORLP.PORBN	2016	0	0

Select Provider Group:

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Prevalence Report (data last updated 01/26/2023)

The dollar amounts listed in this report are not the actual reimbursement amounts for any MA Plan or participating provider. Rather, the amounts listed are based on a static value formula to assist you with legally appropriate business analysis and NOT for purposes of making any clinical or other determinations affecting a member's course of treatment or medical care.

Available Reports:

Filter Report By:

Number of Members: 308

HCC	Description	Current PY Relative HCC Factor	1 Year Prior PY Relative HCC Factor	Optum National Prevalence Rate (%)	Current PMPY Revenue (\$)	Prevalence Rate (%) DCS (Current Year) 1/1 - 12/31	Prevalence Rate (%) DCS (1 Year Prior) 1/1 - 12/31	Compare Current RQ% - Optum National%	Net Additional Members	Rank Annual Increase
001	HIV/AIDS	0.4363	0.846	0.19%	\$3,872.00	2.47%	0.0%	3.37%	0	\$0.00
002	Syphilis/Chlamydia	0.7187	0.8794	1.28%	\$5,477.52	0.0%	0.0%	-1.2%	2	\$12,905.90
003	Opportunistic Infections	0.4368	0.2908	0.23%	\$1,902.18	0.0%	0.0%	-0.23%	1	\$1,902.08
007	Metastatic Cancer/Active Leukemia	0.9436	2.6374	1.03%	\$19,360.49	0.0%	0.0%	-1.03%	3	\$36,784.90
008	Lung, Upper Dig. Tract, Other Severe Cancers	0.9035	0.9408	0.61%	\$7,771.52	0.0%	0.0%	-0.61%	1	\$7,771.06
009	Lymphatic/Head/Neck/Brain/DR Major Cancers	0.9034	0.7108	1.42%	\$6,590.15	0.0%	0.0%	-1.42%	2	\$11,948.90
010	Great Prostate/Colonorectal, DR Cancer/Tumors	0.7157	0.7162	7.43%	\$1,581.58	6.78%	7.5%	-0.64%	1	\$1,581.58
015	Diabetes w/Retinal/Peripheral Circulatory/Neuropathy	0.3488	0.4548	5.57%	\$3,137.51	0.62%	3.0%	-4.95%	8	\$25,008.00
016	Diabetes w/Hypertension, Other Spec. Heart	0.3488	0.3052	5.93%	\$3,137.51	1.23%	1.61%	-3.28%	4	\$12,848.90
017	Diabetes w/Kidney Complications	0.3488	0.3052	0.12%	\$3,137.51	0.0%	0.0%	-0.12%	1	\$3,137.08
018	Diabetes w/Cardiomyopathy, Unspecified Heart	0.3488	0.2019	1.62%	\$3,137.51	0.0%	0.0%	-1.62%	3	\$8,411.08

[illegible]

Analytics: Actionable Tools at the Point of Care

Member and Condition Specific Tools Used at the Point of Care

Preventative Screenings to Consider Completing	Reason Suspected	Outcome	Date of Last Screening or Referral	Reason for Exclusion (if applicable)		
Colorectal Cancer Screening	No claims for fecal occult screening in the last 12 months; sigmoidoscopy in last 5 years; nor colonoscopy in the last 10 years	☐ Completed ☐ Referred ☐ Excluded	1 / 1 Screening Type:			
Specification: Yearly fecal occult blood test (FOBT), or every 5 years flexible sigmoidoscopy, or every 10 years colonoscopy.						
Adult Body Mass Index	Recommended for adults 18-74 at each outpatient visit	BMI: _____	Height(in) _____ Weight(lbs) _____			
Specification: Calculate using height & weight to monitor relative body mass over time. BMI = Weight(lbs)/703/Height(in) ²						
Office Visit and Hospitalization History						
Last Office Visit: Office Visits in 2013:		Admit Date	Discharge Date			
Ongoing Assessment and Evaluation						
Instructions: If the suspected condition is being assessed or treated AND IS DOCUMENTED IN THE MEDICAL RECORD, please supply the diagnosis code, the date of service, sign the attestation provided, submit all diagnosis codes.						
Potential Diagnosis	Risk Factors and/or Co-morbid Conditions	Last Reported	Times Reported	Can the Condition be Diagnosed Currently?	DOS	Dx Code
CHF (402.x1, 404.x1, 404.x3, 415.0, 416.x, 417.x, 425.x, 428.x, 429.0, and 429.1)	Previously Coded	2012	13	☐ Yes ☐ No	_____	_____
Diabetes without Complication (250.0x and V58.67)	Previously Coded	2012	12	☐ Yes ☐ No	_____	_____
Disorders of Lipid Metabolism	Previously Coded	2012	4	☐ Yes ☐ No	_____	_____
Hypertension	Previously Coded	2012	13	☐ Yes ☐ No	_____	_____
Specified Heart Arrhythmias (426.0, 427.0 - 427.32, and 427.81)	Previously Coded	2012	16	☐ Yes ☐ No	_____	_____
Supply Indicating Diagnosis	Member is taking LANTUS INJ 100 U/mL	2012	13	☐ Yes ☐ No	_____	_____
Supply Indicating Diagnosis	Member is taking WARFARIN SODIUM TAB 5 MG	2012	12	☐ Yes ☐ No	_____	_____
Vascular Disease	Previously Coded	2012	1	☐ Yes ☐ No	_____	_____
Managing Chronic Illness						



Retrospective Programs

Patty Brennan

Retrospective Services

Chart Review

Claims Verification

RADV

RACCR

Appendix

Submission (EDPS and RAPS)

Hospital Data Capture



Standard Chart Review

Patty Brennan

End-to-End Chart Review Solution

Optum delivers end-to-end services to identify accurate reimbursements & performance.

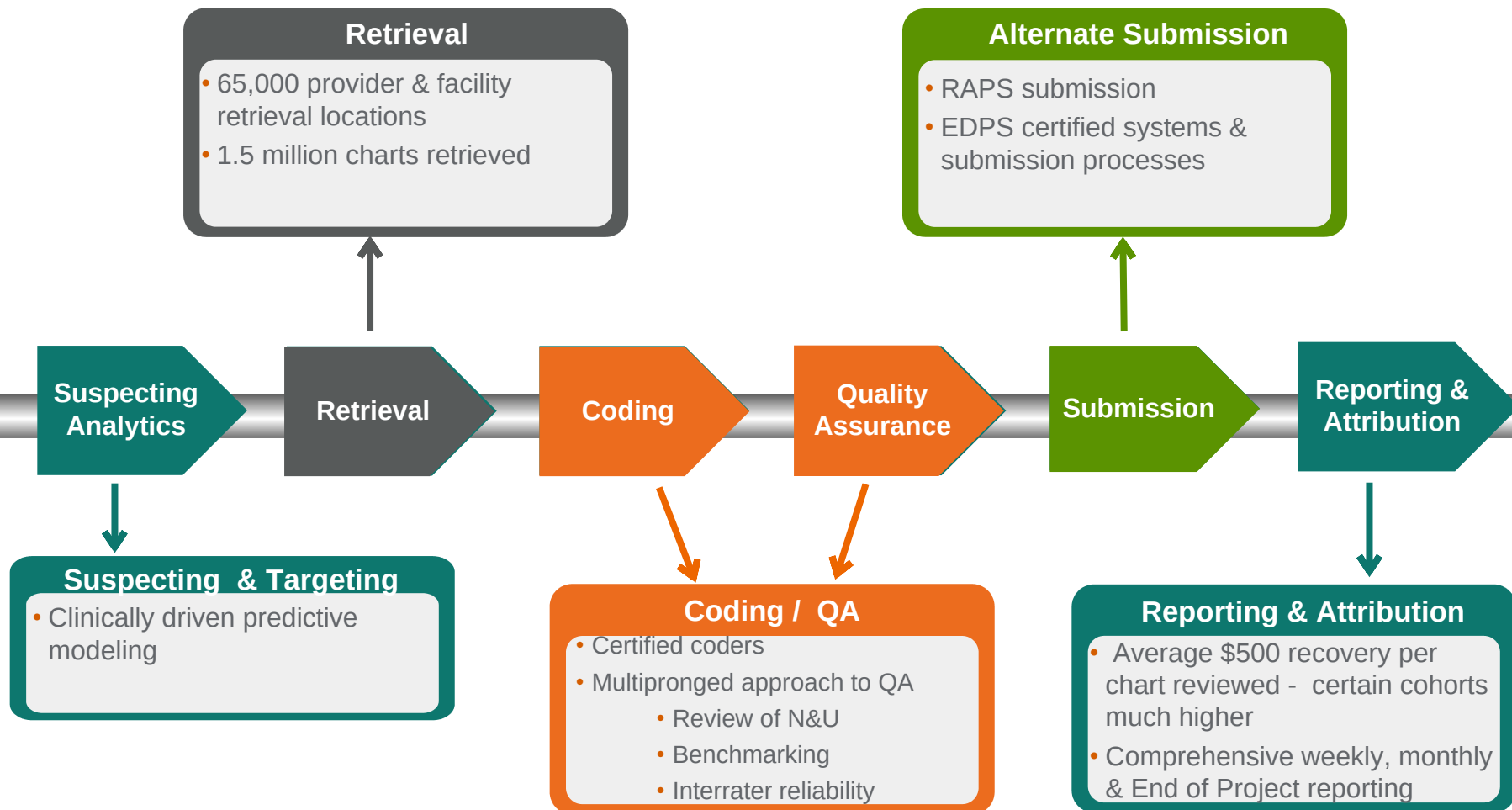


Chart Scoring Example

Mary is an 85 year old, high-risk diabetic. She has had a number of visits with her PCP (Dr. Smith), and one visit with her rheumatologist (Dr. Jones).

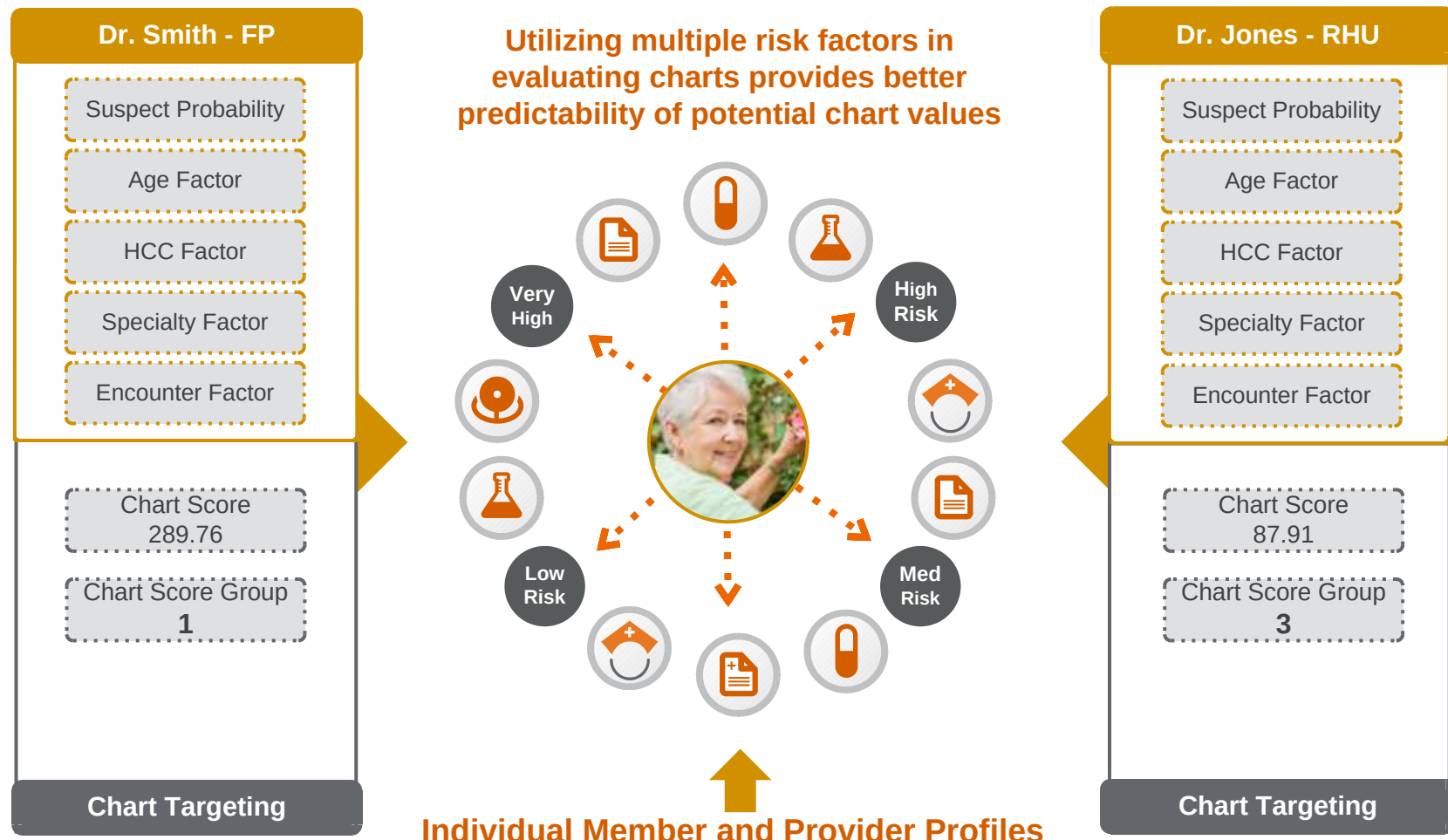


Illustration of 2013 Project/2012 Dates of Service Outcomes

Approach:

- Member profile created for each unique member
- Clinical analysis of each member profile is grouped into 7 stratified priority groups based on level of risk
- Each priority group includes multiple probability factors in addition to the member's clinical risk factors

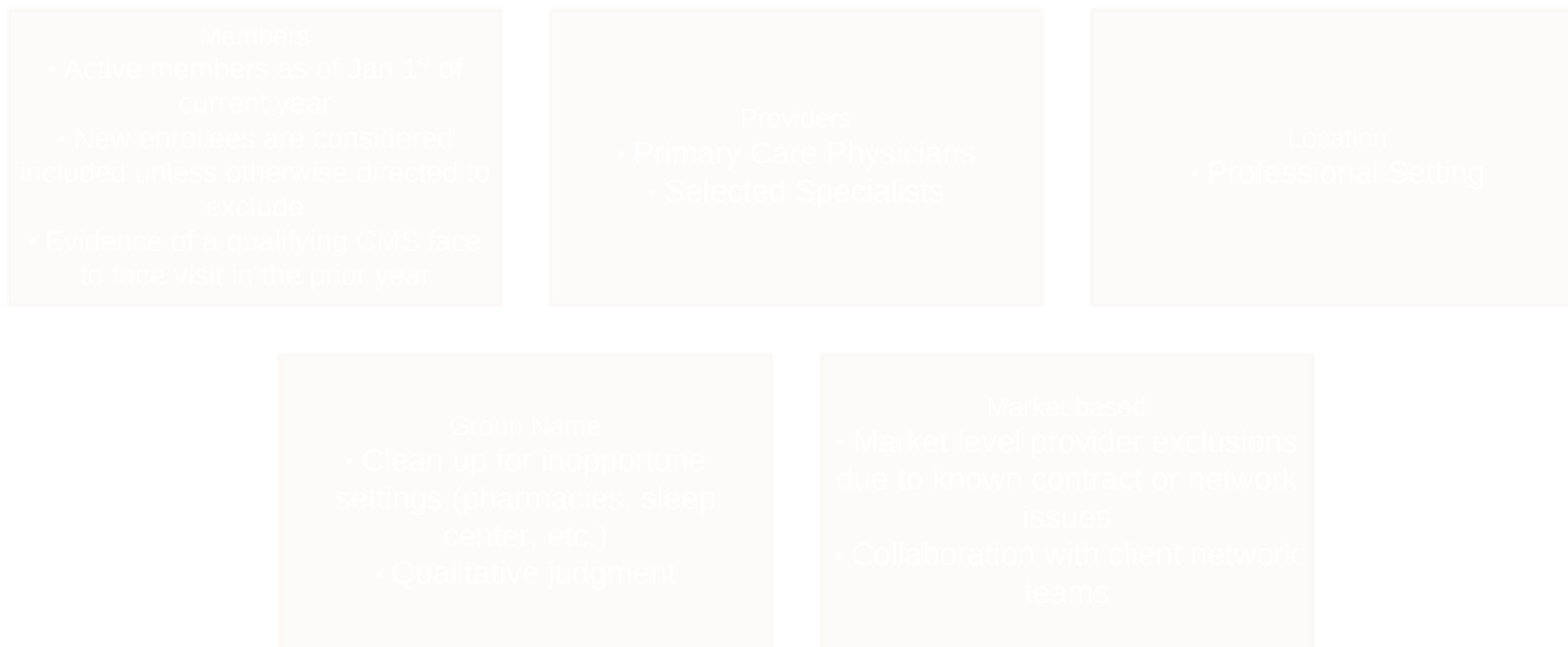
Suspecting Results:

- Detailed front end analysis **driven by data intelligence** that aligns to Health Plan goals & initiatives
- Enhanced focused on clinical & administrative data ensures **greater accuracy & conversion** of suspected charts to actual diagnosis

% of Charts	Average Value Per Chart 1 Year DOS	Priority Grouping
3%	\$714	1
5%	\$463	2
9%	\$400	3
15%	\$330	4
21%	\$242	5
27%	\$190	6
20%	\$57	7

Chart Score Value

2014 Chart Opportunity Logic



Charts to pursue

- Logic applied to remove 'duplicate' charts reviewed in the prior period
- Remaining charts are stratified and prioritized

2013 Filtering & Targeting Waterfall

Total membership active as of 1/1/2013	2,596,515
Cap members	(530,634)
MWOV, or visit at a non-targeted speciality or invalid POS	(436,969)
Net members eligible for Optum coordinated chart review	1,628,912
Available charts	3,122,650
Prioritization of available charts	
(1)	42,730
(2)	192,056
(3)	299,724
(4)	459,142
(5)	418,849
(6)	377,661
(7)	1,332,488
Exclusions	
Charts with no new DOS	(499,563)
Non targeted due to market exclusions	(31,227)
Provider group clean up charts	(48,542)
Low value specialities	(202,704)
Low value charts	(471,847)
Total Exclusions	(1,253,883)
Targeted Charts to Pursue	1,868,768

Medical Record Retrieval Process

✓ Provider pull list is generated by the Health Plan or by Optum using our NCQA certified HEDIS engine.

✓ The pull list is reviewed & approved by the Health Plan in advance of contacting physician offices.

✓ Health Plan is informed of historical accounts of Providers Not Participating (PNPs) & works with Healthcare Advocates to determine retrieval strategies.

✓ Providers approved for inclusion in chart review receive letters by mail or direct delivery.

✓ Provider is contacted by phone to schedule an appointment & discuss preferred method & workflow for retrieving medical record data.

Real-time tracking of record request status via Chart Review Portal. Weekly project tracking, meeting, reporting, and issue resolution reporting provided to Health Plan.

On-site Scanning



Fax & Mail



Secure Email



EMR Retrieval



Direct to Optum

(Provider Submits Electronic Records)



Handling Provider Resistance

Approach:

- Sophisticated management process of identifying Providers Not Participating (PNPs)
- Leverage Healthcare Advocates to engage with providers to resolve issues
- Escalation path defined by Optum & UHC
- Year over year analysis of PNPs & engagement strategies for each Chart Review project period

Results:

- Weekly PNP reporting by reason code including days pending to resolution
- Joint Optum|UHC escalation process to resolve provider PNP's

Provider Not Participating Summary		
PNP Reason Code	Site ID Count	Total Charts
PNP001: Provider Office Not Responding	70	2304
PNP002: Provider Refused Chart Review	24	1303
PNP007: Requesting Chart Reduction	1	488
PNP009: Requesting Payment	37	368
PNP004: Phone/Address Data Invalid	39	134
PNP016: Requesting Legal Consent	1	96
PNP003: Provider No Longer At Address Given	8	36
PNP012: Provider Data Fails Verification	6	32
PNP010: Member Data Fails Verification	4	8
PNP015: Requesting Member Consent	2	6
PNP013: Refusing Provider Verification	2	2
Grand Total	194	4777

Top PNPs By Medical Group	
PRIMECARE MEDICAL	
PNP12: Phone/Address Data Invalid	
PNP13: No Longer at Address	
PNP14: Office Not Responding	
PNP18: Past Due - Provider Unresponsive After Commitment	
PNP4: Refuses to Participate	
PNP6: Requests Payment	
VALLEY PHYSICIANS	
PNP14: Office Not Responding	
PNP18: Past Due - Provider Unresponsive After Commitment	
PNP6: Requests Payment	

Suite of Reports

1. Weekly client dashboard

- UHC M&R C-S Summary
- Provider group drill down
- Plan/PBP drill down

2. PNP reporting

3. Provider End of Project Reporting

Report Date: 3/3/2013 Contract and PBP Summary				
Contract #	PBP	Total Completed	Coding Completed	
H0151	001	20,068	20,068	
H0151	015	7,752	7,752	

PNP Code	PNP Reason Code Description	Site ID Count	Total Charts
PNP001	PNP001: Failed Member Data Verification	27	213
PNP002	PNP002: Refusing Member Verification	134	4,747
PNP003	PNP003: Failed Provider Data Verification	2,181	21,707
PNP004	PNP004: Refuses to Participate	2,579	58,360
PNP005	PNP005: Refuses Provider Verification	469	2,594
PNP006	PNP006: Requests Payment	4,367	76,051
PNP007	PNP007: Requesting Chart Reduction	207	21,976
PNP008	PNP008: Requests Health Plan Confirmation	237	5,335
PNP009	PNP009: Requests On-Site Coding	15	601
PNP010	PNP010: Requires Member Consent	270	2,195
PNP011	PNP011: Requires Legal Contract	63	1,499
PNP012	PNP012: Phone/Address Data Invalid	2,367	16,029
PNP013	PNP013: No Longer at Address	375	2,284
PNP014	PNP014: Office Not Responding	5,786	74,941
PNP015	PNP015: Project Scheduling Issues	182	5,196
PNP016	PNP016: Informed that CR was Cancelled	3,904	99,688
PNP017	PNP017: Prior Year PNP	3,539	87,311
PNP018	PNP018: Past Due - Provider Unresponsive After Commitment	9,907	78,907
PNP019	PNP019: Member's Chart at Different Location	0	0
PNP020	PNP020: Provider Utilizes Copy Service, Requesting Payment	0	0
PNP021	PNP021: Provider Not Participating Due to Health Plan Specific Issue	0	0
Grand Total		36,609	559,634

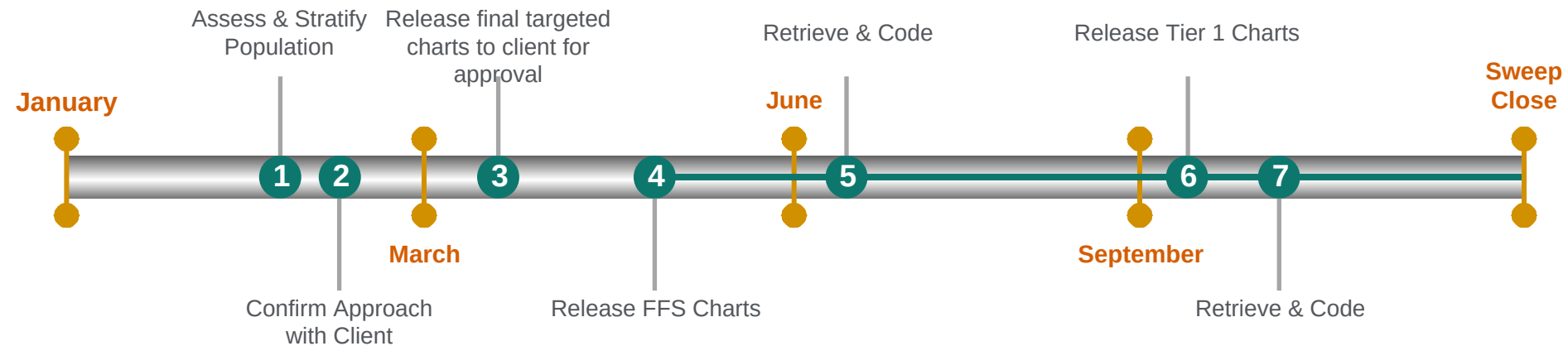
H0543	070	86	86
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Chart Review Service Level Agreement (SLA)

- The **SLA** is the contracted number of charts Optum is obligated to complete for UHC (M&R | C&S) as part of the service pmpm fee
- Measure period is January sweeps to January sweeps
- Charts completed above and beyond the SLA is incremental (buy-up) and charged @ \$30/chart
- M&R and C&S SLA's are derived by taking the September restated membership of the current CY year and running it through a series of specific calculations

Chart Review Project

Chart Review Timing & Targeting:



Drivers of May release

- Necessary runway needed to retrieve and code by sweeps deadline
- Creation and delivery of end of project chart review provider reports
- Early chart entry into claim verification & attestation process
- Coordinate provider chart reviews to minimize provider disruption (attempt chart retrieval for risk adjustment one time per year)

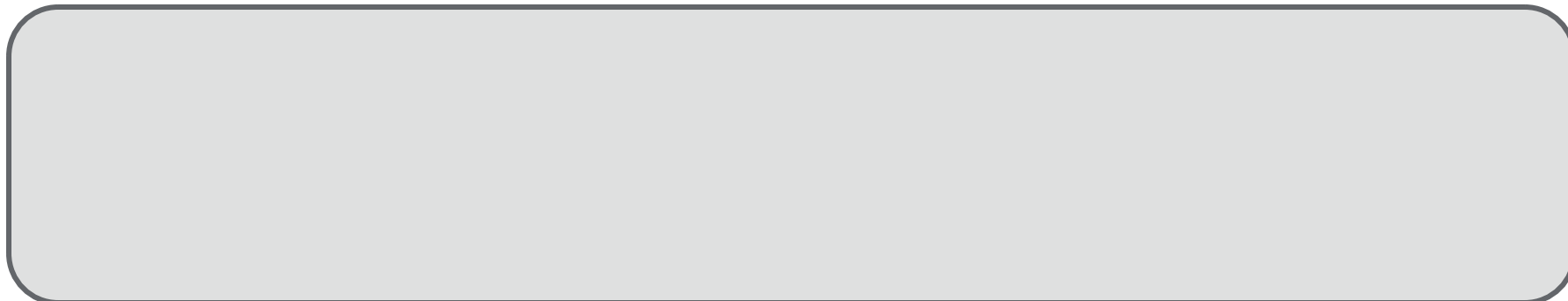


Claims Verification

Patty Brennan

Claims Verification Overview

Reporting	Submission	Coding QA	CVA	System	Chart	Chart
	File		Coding	Matching	Eligibility	Review



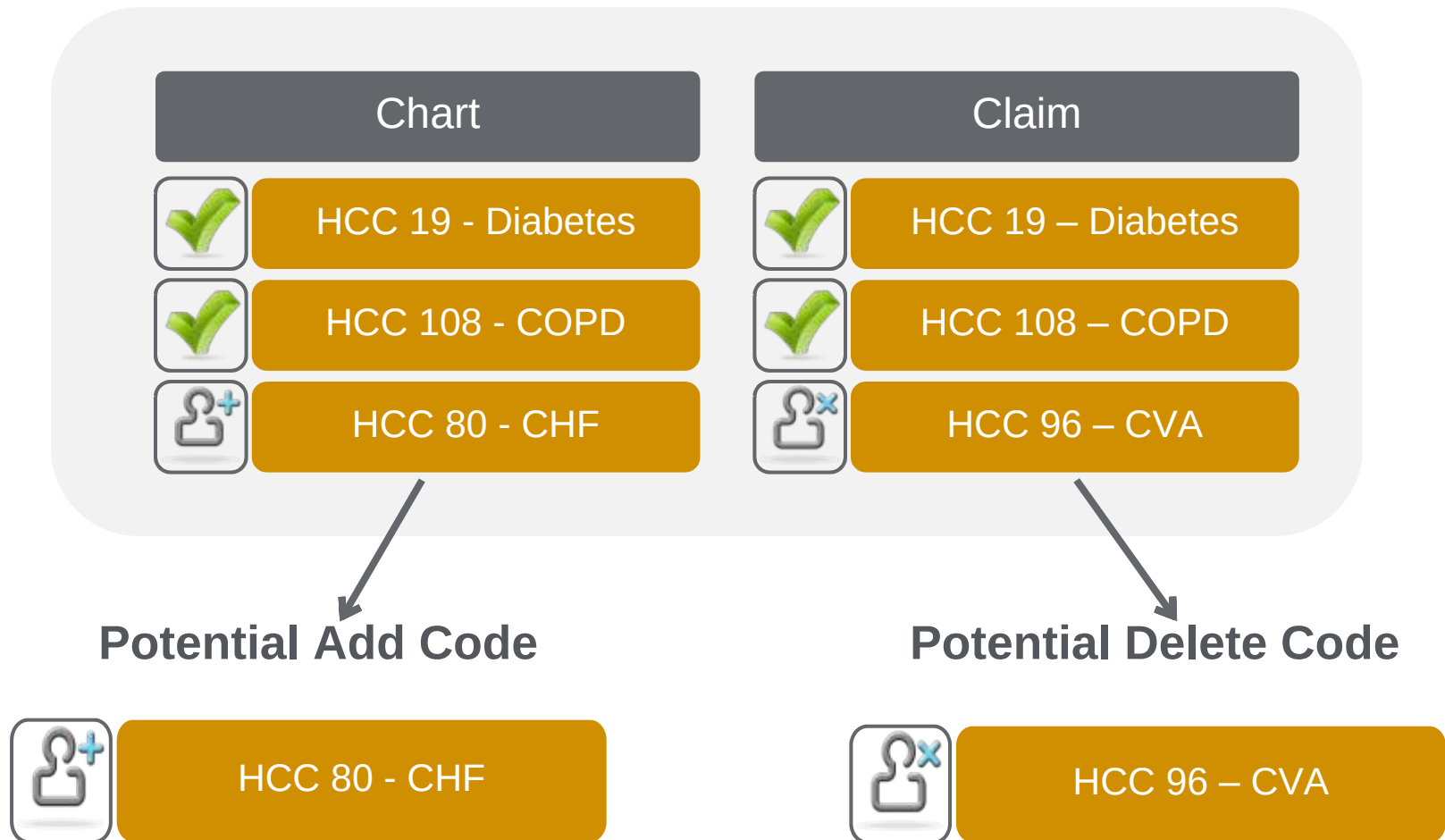
- Process of reviewing claims data with corresponding chart review coding results
- Verifies that the indicated medical record properly documents the condition in accordance with CMS guidelines
- Focused on risk mitigation for single source, single instance HCCs which drive payment

Definition & Methodology of Exclusive HCC

- Defined as an HCC reported by a single provider for a unique member during the collection period.
- Targeting charts that contain only exclusive HCCs allows for:
 - Review of HCC conditions that drive payment
 - Risk Mitigation in case of RADV

Reporting Provider	HCC Reported	Exclusive HCC?
A	HCC 19 HCC 80	NO YES
B	HCC 21	YES
C	HCC 19	NO

Claims Verification – System Matching Overview





RADV

Patty Brennan

CMS RADV – What we know?

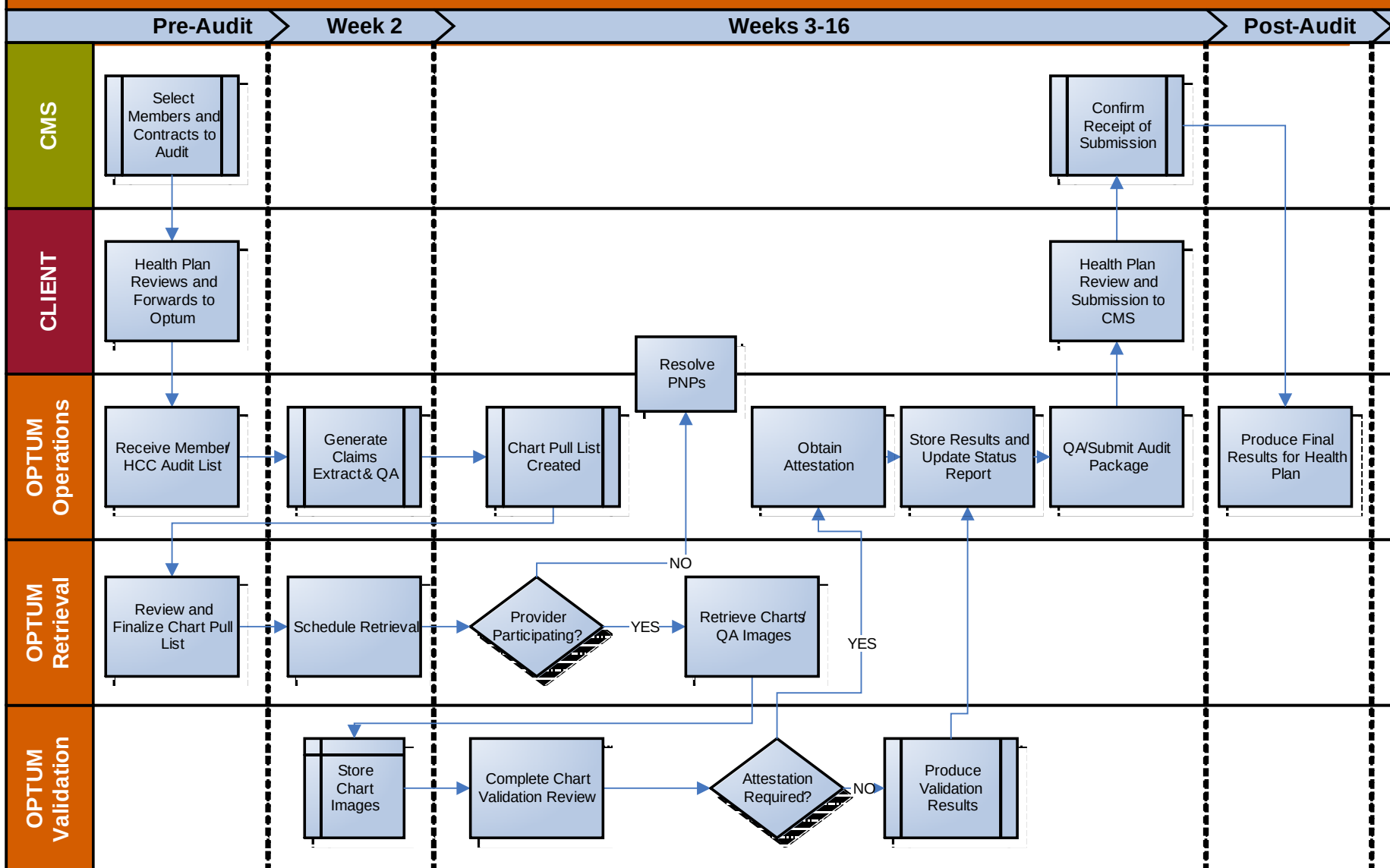
- 30 MA contracts selected
 - M&R four contracts selected.
 - 201 members sampled within each contract selected
- Extrapolation methodology will be applied for next round of RADV - 2011 Payment Year (2010 dates of service)
 - Fee for service adjuster will be applied
- Multiple medical records can be submitted in support of each member/HCC combination (up to five medical records)
- Attestations will be accepted to address signature/credential issues
- Expanded submission deadline to 16 weeks (previously 12 weeks)
- Medical Record Dispute process

CMS Targeted RADV Overview

RADV
End to
End
Support

- Dedicated Project Manager
- Extensive Experience with CMS Targeted RADV, OIG “RADV Like” Reviews, CMS National Sample Reviews
- Expedited retrieval process
- Focused on identifying the best medical records for submission to CMS
- Frequent reporting and status

RADV Workflow





RACCR

Patty Brennan

RACCR Goals

Goals of RACCR Audits

- Identify and test aberrant coding patterns
- Remove errant codes from claims
- Improve accuracy of data submitted by providers via claims and encounters through education

Targeted Provider Groups

- Tier 1 (capitated/gainshare providers)
- Groups with over 500 members
- Groups/HCC combinations that are 2 SD from the mean

Basis for Provider Selection

- Reimbursed on diagnosis code basis
- Large enough for reporting to identify statistically valid patterns
- Greatest likelihood for engagement in improvement efforts

Risk Adjustment Coding and Compliance Reviews

RACCR Process

Analyze prevalence
and compare Tier 1
groups to other tier 1
groups

Select outlier
provider/HCC
combinations

Select a sample of
members

Review medical
records for sampled
members

Produce Validation
reporting/results to
discuss with providers

Coding Training for
providers, when
necessary

Corrective Action
Plans (including 100%
lookback)

Process Deletes to
CMS based on audit
results



Prospective Programs

Nancy Freeman

Program Overview

- Healthcare Quality Patient Assessment Program
 - HQPAF
 - Provider Engagement/Healthcare Advocates
 - Deployment Channels, Provider Compensation, HQPAF Return Management
 - Form Features, History & Enhancements
- Provider Segmentation & Waterfall
- Monthly Program Reporting
- MA-PCPi – Quality Incentive Program

HQPAF – Form History

Member: Member ID: Plan Effective Date: 04/01/2005

Office: Last Office Visit: 03/27/2008 Office Visits in 2500: 3

Diagnosis: Instructions: If the suspected condition RECORD, please supply the diagnosis code to Secure Horizons.

Potential Diagnosis: Diabetes without Complication (250.0x and V58.67) Multiple Sclerosis (340.0, 341.0, 341.1, 341.5, and 341.9)

Additional Conditions: I hereby attest that the above information is true and correct.

Signature: _____

INGENIX
This information is a summary of previously reported diagnoses. For more information, please contact your provider.
Fax completed form to Debbie G.

Patient

Please confirm and document all current conditions and progress notes. All supporting documents must be submitted to the secure fax server. THANK YOU!

Member: MbrLastName, MbrFirstName Member ID: XXXXXX

Diagnosis

Listed in the box below are suspected conditions. Please confirm which suspected conditions are present in the progress notes.

Potential Diagnosis	Reported
Diabetes without Complication (250.0x and V58.67)	Pre
Renal Failure (403.x1, 404.x2, 404.x3, 504.x, 505.x, 506, and 753.14)	Pre
Supply Indicating Diagnosis: Men	TAB
Vascular Disease w/Complications	Pre

Change in Patient Status - Please check any of the member's current status:

☐ Patient does not respond to contact efforts.

☐ Invalid / incomplete contact information.

☐ This member is deceased. Date of expiration: _____

Please submit this coversheet and all supporting documents to the secure fax server. For questions please contact your provider.

999999999, TIN NAME: _____

This information is a summary of previously reported diagnoses. For more information, please contact your provider.

OPTUMinsight™

Healthcare Quality Patient Assessment Form

The Healthcare Quality Patient Assessment Form (HQPAF) questions, please contact 1-877-751-4207.

Instructions

1. Schedule a comprehensive exam for this patient or return only the sections of this form marked with an asterisk.
2. Document in the progress note, including clear progress notes, the results of this form.
3. Submit pages of this form containing the "yes" and "no" factors, documented to the highest level of specificity. Secure Fax Server: 577-660-5747

Administrative reimbursement of \$1K will be paid for each completed form.

Patient & Provider Information

Patient: LAST_NAME1, FIRST_NAME1 Member ID: XXXXXXXX1 DOB: 01/01/1950 Phone: (999)999-9999

Complete this section only if you are not able to complete a full assessment. A reduced reimbursement of \$1K will be paid after submission. Patient does not respond to contact efforts. Invalid / incomplete contact information. This member is deceased, as of MM/DD/YYYY.

Complete this section only if you are not interested in completing a full assessment. No reimbursement will be made. I am not interested in completing this patient.

Early Detection of Chronic Illness

Please consider screening for these chronic illnesses based on conditions and document any confirmed conditions that result in out-of-pocket expense for the patient, depending on the insurance plan.

Chronic Illnesses to Consider	Risk Factors or Co-morbid Conditions
Chronic Kidney Disease	Family History Kidney Disease (V18.01)
Chronic Obstructive Pulmonary Disease	History of Smoking (V15.82)
Diabetes Mellitus	Lower Extremity Ulcer (707.1)
Diabetic Neuropathy	Chronic Bronchitis (491)
Major Depression	Depressive Disorder, not elsewhere classified (311)
Peripheral Arterial Disease	Chronic Pancreatitis (577.1)
Protein Calorie Malnutrition	Cystic Fibrosis (277.0)

Note: Additional information and reference links on risk factors are available in the progress note.

OPTUM™

Health Plan Logo

Healthcare Quality Patient Assessment Form

The HQPAF program is developed and administered by OptumInsight on behalf of [Client]. See page 2 for additional instructions. For questions, visit www.optum.com/HQPAF or call 1-877-751-4207.

Use this form for patient visits between 10/21/12 and 12/31/13 only. Screening documentation may be outside of this date range. Complete form must be submitted with documentation to qualify for \$1K reimbursement. Secure Fax Submission: 1-877-660-5747

► Patient: MbrLastName, MbrFirstName Member ID: XXXXXXXX DOB: MM/DD/YYYY Phone: ###-###-####

► Provider Information: Check box to confirm the provider completing the assessment. Enter name/NPI if not populated. NPI: _____

► Early Detection of Chronic Illness

Chronic Illnesses to Consider	Risk Factors or Co-morbid Conditions	Yes	No
Chronic Kidney Disease	Family History Kidney Disease (V18.01)	☐	☐
Chronic Obstructive Pulmonary Disease	History of Smoking (V15.82)	☐	☐
Diabetes Mellitus	Lower Extremity Ulcer (707.1)	☐	☐
Diabetic Neuropathy	Chronic Bronchitis (491)	☐	☐
Major Depression	Depressive Disorder, not elsewhere classified (311)	☐	☐
Peripheral Arterial Disease	Chronic Pancreatitis (577.1)	☐	☐
Protein Calorie Malnutrition	Cystic Fibrosis (277.0)	☐	☐

► Preventive Medicine Screening

Complete screening/referral(s). Detail in progress note and return with form. The following screening(s) are due or overdue, as indicated by HEDIS & health plan data. Results, referrals, and exclusions must be documented in progress notes and returned with HQPAF.

Screenings to Consider	Outcome	Exclusion
Breast Cancer Screening	☐ Completed ☐ Referred ☐ Refused	☐ Bilateral Mastectomy ☐ Unilateral Mastectomy
Colonorectal Cancer Screening	☐ FOBT ☐ Flex Sig ☐ Colonoscopy	☐ Colorectal Cancer ☐ Total Colectomy
Glaucoma Screening	☐ Completed ☐ Referred ☐ Refused	☐ Glaucoma ☐ Glaucoma suspect
Adult Body Mass Index (BMI)	☐ Completed ☐ Referred ☐ Refused	☐ Pregnant
Cardiovascular Care - Cholesterol Screening	☐ Completed ☐ Referred ☐ Refused	

► Ongoing Assessment & Evaluation

Indicate if condition(s) persist. Detail in progress note and return with form.

Potential Diagnosis	Risk Factors or Co-morbid Conditions	Last Reported	Yes	No
Diabetes without Complication (250.0x and V58.67)	Family History Kidney Disease (V18.01)	2009	☐	☐
Renal Failure (403.x1, 404.x2, 404.x3, 504.x, 505.x, 506, and 753.14)	GFR test value was 57.9	2009	☐	☐
Supply Indicating Diagnosis in Progress Note	Patient is taking BONIVA TAB 150 MG	2010	☐	☐
Vascular Disease w/Complications	Vascular Disease w/Complications	2010	☐	☐

► Managing Chronic Illness

Indicate if suggested actions were completed. Detail in progress note and return with form.

Condition	Suggested Action	Yes	No	N/A
Chronic Obstructive Pulmonary Disease	Spirometry Test	☐	☐	☐
Controlled Blood Pressure	Blood Pressure Evaluation	☐	☐	☐
Diabetes Mellitus	Nephropathy Screening	☐	☐	☐
	Diabetic Eye Exam	☐	☐	☐
	Blood Pressure	☐	☐	☐
	LDL-C Screening	☐	☐	☐
	HbA1c Testing	☐	☐	☐
Depression Management	Bone Density Test (BMD) and/or Rx Treatment	☐	☐	☐
Date of Fracture: xxx/xx/xxxx	Timeframe for completion: xxx/xx/xxxx	☐	☐	☐
Rheumatoid Arthritis	Prescription Treatment	☐	☐	☐

Page 1 of 2

2008

2010

2012

2013



HQPAF – Features

- Risk & Quality Combined
- Member Specific
- Provider Centric
 - Standardized Forms Across Health Plans
 - Typically One Page to Return
 - Maximize Patient Data
 - Relies on Existing Medical Record
 - Limited to Open Suspects & Gaps
- Distribution Channels Tailored to Group Attributes

SAMPLE




Healthcare Quality Patient Assessment Form

The HQPAF program is developed and administered by Optum on behalf of HealthPlan. See page 2 for additional instructions. For questions, please visit www.optum.com/HQPAF or call 1-877-754-0207.

Use this form for patient visits between 8/10/2013 & 04/11/2014 only: Complete form must be submitted with screening documentation may be outside of this date range. documentation to qualify for \$XX. Secure Fax Submission 1-877-889-6147

Patient: LAST_NAME1, FIRST_NAME1
 Member ID: XXXXXXXX1 DOB: 09/09/1999 Phone: (999)999-9999

Provider Information Check box to confirm the provider completing the assessment. Enter name/NPI if not populated.
☐ Provider: PCPName1 NPI: _____
☐ Provider: _____ NPI: _____

Early Detection of Chronic Illness Indicate if at-risk illness(es) were considered and confirm in progress note(s)

Chronic Illness(es) to Consider	Risk Factors or Co-morbid Conditions	Yes	No
Chronic Kidney Disease	Diabetes Mellitus (250.00), Hypertension (401.1)	☐	☐
Chronic Obstructive Pulmonary Disease	History of Smoking (V15.82)	☐	☐
Diabetes Mellitus	Morbid Obesity (278.00)	☐	☐
Diabetic Neuropathy	Diabetes Mellitus (250.00), Peripheral Arterial Disease (443.9)	☐	☐
Major Depression	Long Term Chronic Illness CHF	☐	☐
Peripheral Arterial Disease	Over Age 70, History of Smoking (V15.82), Diabetes Mellitus (250.00)	☐	☐
Protein Calorie Malnutrition	Anemia of Chronic Disease	☐	☐

Preventive Medicine Screening Complete screening/referral(s). Detail in progress note and return with form.
 The following screening(s) are due or overdue, as indicated by HEDIS & health plan data. Results, referrals, and exclusions must be documented in progress notes and returned with HQPAF.

Screenings to Consider	Outcome Document in progress notes	Exclusion Document in progress notes
Breast Cancer Screening	☐ Completed ☐ Referred ☐ Refused	☐ Age/Sex ☐ Bilateral Mastectomy ☐ Unilateral Mastectomies
Colorectal Cancer Screening Indicate type of screening performed	☐ FOBT ☐ Flex Sig ☐ Referred ☐ Refused ☐ Colonoscopy	☐ Age/Sex ☐ Colorectal Cancer ☐ Total Colectomy
Cardiovascular Care - Cholesterol Screening Date of cardiac event: 07/25/2012	☐ Completed ☐ Referred ☐ Refused	
Glaucoma Screening	☐ Completed ☐ Referred ☐ Refused	☐ Age/Sex ☐ Glaucoma ☐ Glaucoma Suspect
Adult Body Mass Index (BMI)	☐ Completed ☐ Refused	☐ Age/Sex ☐ Pregnant

Ongoing Assessment & Evaluation Indicate if condition(s) persist. Detail in progress note and return with form.

Potential Diagnosis	Risk Factors or Co-morbid Conditions	Last Reported	Yes	No
Angina Pectoris/Old MI (412 and 413.x)	Previously Coded	2011	☐	☐
Chronic Kidney Disease Stage 1, 2, or Unspecified	Previously Coded	2011	☐	☐
Coronary Artery Disease	Previously Coded	2012	☐	☐
Depression	Previously Coded	2012	☐	☐
Renal Failure (403.x1, 404.x2, 404.x3, 584.x, 585.x, 586, and 753.14)	Previously Coded	2011	☐	☐

HEALTHPLAN1 Page: 1 PAF V4 Run Date: 02/11/2013
 000001/Group Name PAF ID: HEDIS1PAF_000001/000000000000 PAF_SAMPLE_0013_HQPAF

This information is a summary of previously reported diagnoses, from multiple sources and is not intended to be used in place of medical diagnosis or treatment.
 Any ICD-10 diagnosis and substance abuse conditions, whether present or not, are not part of this Patient Assessment Form.

HQPAF – Form Contents

- Early Detection of Chronic Illness
- Preventive Medicine Screening
- Ongoing Assessment & Evaluation
- Managing Chronic Illness
- Patient Status Exceptions
- Medical History
 - Care Team, ER & Acute visits
 - Three-Year Condition List
 - High-Risk Medications
 - Medication Adherence
 - Other Prescriptions

PATIENT & PROVIDER INFORMATION **SAMPLE**

Patient: LAST NAME1, FIRST NAME1 Provider: PCPName1
Member ID: XXXXXXXX1 DOB: 09/09/1999

Medical History Reported to Health Plan - Retain for Your Records Retain for your records

Information below is based on data received from all providers, including specialists.

Office Visits				ER Visits		Hospitalizations	
2 or more visits in past 24 months				Past 24 months, no admission		Past 36 months	
Physician	Specialty	Visits	Last Visit	Date	Admit	Discharge	
PHYSICIAN_FULLNAME_1	FAMILY PRACTICE	2	10/28/2012	09/15/2011	09/28/2011	09/30/2011	
PHYSICIAN_FULLNAME_2	CARDIOLOGY	2	01/10/2012	12/09/2012	11/03/2011	11/29/2011	
					12/06/2011	02/14/2012	
					05/17/2012	06/20/2012	

*Readmission w/in 30 days

Three-Year Condition List

Place of Service Legend
Inpatient → Provider Office
Outpatient ← Other

Chronic				Non-Chronic					
Diagnosis Coded	HCC if applicable	Year		Diagnosis Coded	HCC if applicable	Year			
		13	12	11			13	12	11
250.00 DM W/O COMP TYPE I/INS NOT UNCNTRL					270.52 HYPOVOLEMIA				
019 Diabetes without Complication					278.9 ELECTROLYTE AND FLUID DISORDERS NEC				
273.8 OTH DIO PLASMA PROTEIN METABOLISM					293.0 DELIRIUM DUE CONDS CLASSIFIED ELSW				
278.00 OBESITY, UNSPECIFIED					518.81 ACUTE RESPIRATORY FAILURE				
278.01 MORBID OBESITY					079 Cardio-Respiratory Failure, Shock				
311 DEPRESSIVE DISORDER NEC					584.9 ACUTE KIDNEY FAILURE UNSPECIFIED				
348.31 METABOLIC ENCEPHALOPATHY					131 Renal Failure				
401.1 ESSENTIAL HYPERTENSION, BENIGN					598.3 LICHENIFICATION/LICHEN SIMPLEX CHRONUS				
401.9 UNSPECIFIED ESSENTIAL HYPERTENSION					734.2 LUMBAGO				
412 OLD MYOCARDIAL INFARCTION					726.5 PAIN IN SOFT TISSUES OF LIMB				
083 Angina Pectoris/Old MI					726.81 SWELLING OF LIMB				
414.01 COR.ATHEROSCLERO NATIVE COR.ART					780.4 DIZZINESS AND GIDDINESS				
416.9 UNSPEC CHRONIC PULM HEART DISEASE					780.8 GENERALIZED HYPERHIDROSIS				
080 CHF					780.87 ALTERED MENTAL STATUS				
443.89 OTHER PERIPHERAL VASCULAR DISEASE					780.03 APNEA				
105 Vascular Disease					786.05 SHORTNESS OF BREATH				
496 CHRONIC AIRWAY OBSTRUCTION NEC					786.3 EXCESSIVE BLOOD LEVEL OF ALCOHOL				
108 COPD					786.11 SOLITARY PULMONARY NODULE				
518.84 ACUTE/CHRONIC RESPIRATORY FAILURE					V04.81 NEED PROPH VACCINATIONS/INOCULAT FLU				
079 Cardio-Respiratory Failure, Shock					V15.62 PERS HX TOBACCO PRS HAZARDS HLTH				
530.81 ESOPHAGEAL REFLUX					V18.0 FAMILY HISTORY OF DIABETES MELLITUS				
585.9 CHRONIC KIDNEY DISEASE UNSPECIFIED					V45.62 POSTSURGICAL PTCA STATUS				
131 Renal Failure									

Note: Chronic determination made by reference to Agency for Healthcare Research and Quality - Healthcare Cost and Utilization Project (HCUP) Chronic Condition Indicator File.

HEALTHPLAN1 Page: 4 RHP V4 Run Date: 02/11/2013
000001/Group Name RHP ID: HFD011PL_010010701000000000 RHP_SAMPLE_1013_HQPAF

This information is a summary of previously reported diagnoses, from multiple sources and is not intended to be used in place of medical diagnosis or treatment. Any ICD-10 diagnosis and substance abuse conditions, whether present or not, are not part of this Patient Assessment Form.

HQPAF – SNP Form

- Care for Older Adults
 - Advanced Care Planning
 - Medication Review
 - Functional Status Review
 - Comprehensive Pain Screening
- Automatically Appears for SNP Member Only
- Production Begins Mid-March

PATIENT & PROVIDER INFORMATION			
Patient:	MbrLastName, MbrFirstName		Provider:
Member ID:	XXXXXX	DOB:	MM/DD/YYYY
		PCPName1	

> Care for Older Adults Complete suggested action(s). Detail in progress note and return with form. According to HEDIS specifications, the following should be completed for members of Special Needs Plans.

Measure	Suggested Action	Outcome Document in progress notes	
Advanced Care Planning	Discussion with patient	☐ Completed	☐ Previously executed
Medication Review	Annual review of medications	☐ Completed	☐ Referred
Functional Status Assessment	Assess Activities of Daily Living	☐ Completed	☐ Referred
	Instrumental Activities Daily Living	☐ Completed	☐ Referred
	Other Standardized assessment	☐ Completed	☐ Referred
Comprehensive Pain Screening	Comprehensive Pain Assessment	☐ Completed	☐ Referred
	And/or Pain Management Plan	☐ Completed	☐ Referred

Note for Advanced Care Planning: Progress notes documenting the discussion with patient (including date) is sufficient to demonstrate the required interaction with the member; progress notes must be returned with HQPAF.

> Additional Instructions

- Schedule** a comprehensive exam for this patient or review HQPAF during the patient's next office visit and complete pages one and two.
- Document** in the progress note, including clear provider signature & credential(s), patient name, and date of service. *This form expires – eligible dates of service for submission limited to MM/DD/YYYY through MM/DD/YYYY.*
- Submit** pages one and two of this form and applicable progress note(s) to support all chronic conditions and co-morbid factors, documented to the highest level of specificity. Submission options:
 - Secure Fax Server: 1-877-889-5747
 - Traceable Carrier: Optum PAF Processing - 1021 Windcross Ct., Franklin, TN 37067

Administrative reimbursement of \$X will be paid for completed forms with progress note(s) that meet CMS documentation requirements.

> Keys to Success

- ✓ Be sure to include the following when submitting an HQPAF:
 - Completed page one
 - All pages of completed progress note for a visit between mm/dd/yy and mm/dd/yy
 - Additional documentation (potentially outside of date range above) supporting past screenings
- ✓ Progress notes must meet Optum coding standards and CMS Documentation requirements, including:
 - Provider name, credentials and signature must appear at the end of each documented patient visit in the progress note
 - Provider signature log should be on file
 - If printing from EMR, appropriate authentication language, such as "Signed by" or "Authenticated by", must be present
 - Member name and date of birth (on all pages)
 - Date of service

> Patient Status Exceptions

Complete this section and return this page only if you are not able to complete the assessment. A reduced reimbursement of \$x will be paid after submission & processing.

☐ Patient does not respond to contact efforts.

☐ Invalid / incomplete contact information.

☐ This patient is deceased, as of MM/DD/YYYY

Complete this section and return this page only if you are not interested in completing the assessment. No reimbursement will be made.

☐ I am not interested in contacting this patient.

HeadPrint	Page 2 of 2	Run Date: 11/3/2012
00001, Group Name	Print ID	Print ID, Review Type
This information is a summary of previously reported diagnoses, from multiple sources and is not intended to be used in place of medical diagnosis or treatment. Any HEDIS diagnosis and substance abuse conditions, whether present or not, are not part of this Patient Assessment Form.		

2014 HQPAF Form Enhancements

Depression Screening	Added to Early Detection of Chronic Illness section	Promotes screening for depression in the primary care setting using readily available formal screening tools	Prompt providers to perform depression screening on all patients
Cognitive Function Screening	Added to Early Detection of Chronic Illness section	Promotes screening for cognitive impairment, in the primary care setting, using readily available formal screening tools	Prompt providers to perform cognitive function screening on all patients
Morbid Obesity	Added to Early Detection of Chronic Illness section	In the CMS V22 HCC model, morbid obesity is a risk-adjusting condition.	Asks provider to consider coding morbid obesity when BMI is >40.
Annual Exam	Added to Office Visits section	Informs provider of the date of the patient's most recent annual exam	Allows providers to easily identify patients who are overdue for an annual exam.
Diabetes Treatment	New section added within the Medication History	Alignment with STAR measure	Alerts providers if patients who are diabetic, and also have high blood pressure, have not been prescribed, or are not taking, an appropriate medication for either condition.
2014 HEDIS and CMS STAR measures	Updating patient identification logic, as appropriate, based on changes to HEDIS and STAR measures		

HQPAF – Provider Segmentation & Waterfall

2014 Modeling

Membership

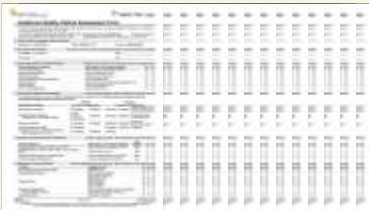
		Tier1	Tier 2	Tier 3	U/U
	Total	Organized & Aligned	High Mbr Density	Low Mbr Density	Unassigned/ Unrendered
Total Members¹	2,507,469	768,398	1,290,080	327,178	121,813
<i>% of Total</i>	100%	31%	51%	13%	5%
Membership Carve-outs					
(1) Provider excluded by client ²	(717,054)	(663,412)	(50,639)	(3,003)	-
(2) Not engaged/escalated to client ³	-	-	-	-	-
(3) No PCP association ⁴	(209,404)	-	(64,504)	(35,268)	(109,632)
(4) Member-level exclusion ⁵	(156,883)	(10,499)	(117,494)	(28,891)	-
Total Carve-outs	(1,083,341)	(673,911)	(232,637)	(67,162)	(109,632)
<i>% Carved-out</i>	43%	88%	18%	21%	90%
Available Members	1,424,128	94,487	1,057,443	260,016	12,181
<i>% Available</i>	57%	12%	82%	79%	10%

PAF Modeling

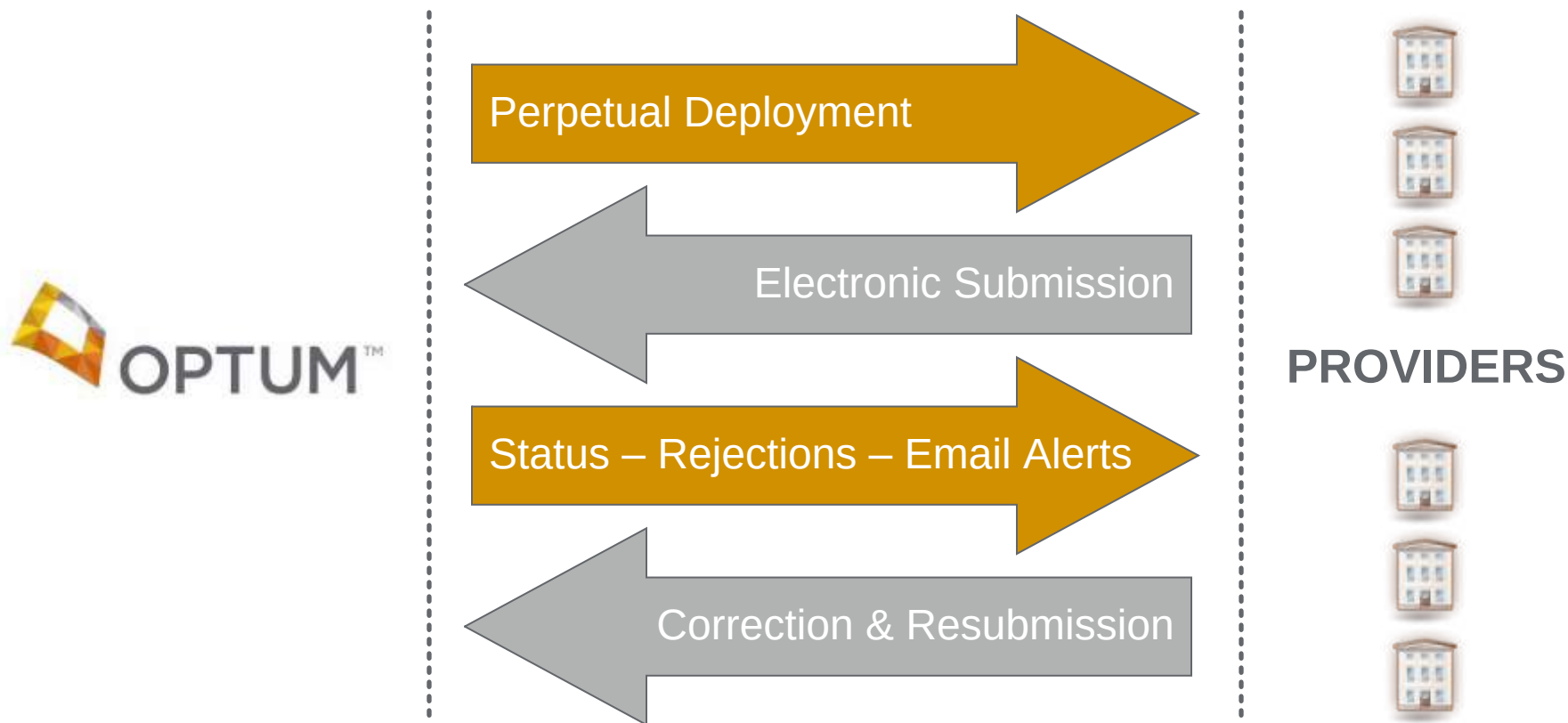
		Tier1	Tier 2	Tier 3	U/U
	Total	Organized & Aligned	High Mbr Density	Low Mbr Density	Unassigned/ Unrendered
Modeled Activity		MC	MC SOPAF Combined	MC SOPAF Combined	
Deployed	1,047,779	31,181	719,061 63,447 782,508	36,402 187,212 223,614	10,476
Deployment Rate	74%	33%	68% 6% 74%	14% 72% 86%	86%
Returned	495,507	16,838	413,460 8,248 421,708	13,469 41,187 54,655	2,305
Return Rate	47%	54%	58% 13% 54%	37% 22% 24%	22%

Deployment – Distribution Channels

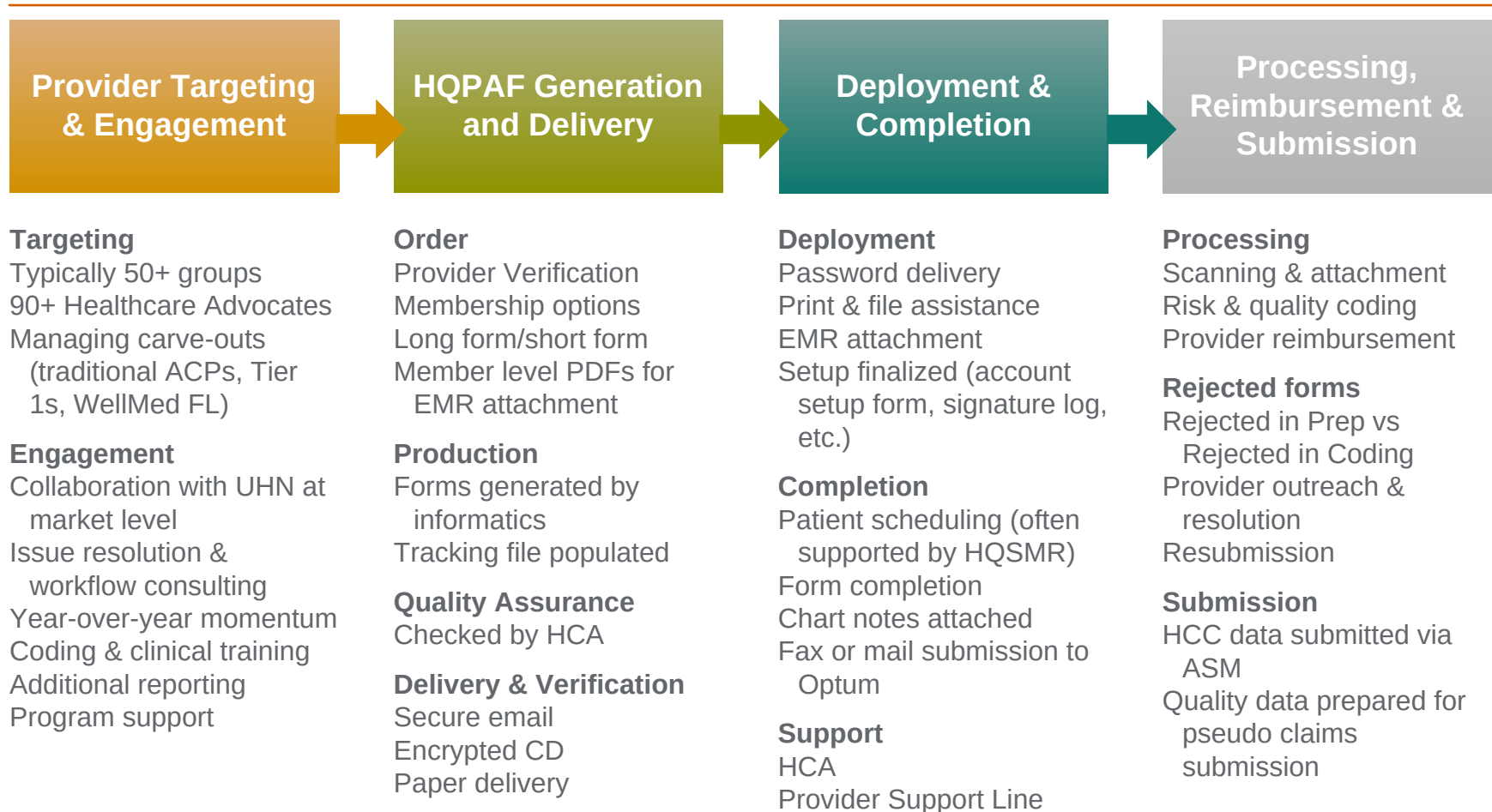
Market Consultation

	MC Ordered	Insite	OptumPAF	Small Office (SOPAF)
				
Targeting	Typically 50+ member groups	Large collaborative & aligned groups	Technology friendly & paperless FFS groups	1 to 49 member groups Outlying groups
Deployment	Annual delivery Secure email, encrypted CD, or paper delivery Face-to-face engagement & training	On-demand access Perpetual deployment Monthly Updates to Suspects & Gaps Download & print Typically face-to-face engagement & training	On-demand access Perpetual deployment Monthly Updates to Suspects & Gaps Download/print options Typically face-to-face engagement & training Tablet or Web completion	Annual delivery Secure email, encrypted CD, or paper delivery Telephonic engagement & training
Submission	Fax or mail	Fax or mail	Online, fax or mail Monitor & manage submitted forms	Fax or mail
2013 Generated	736K (72%)	27K (3%)	27K (3%)	227K (22%)

OptumPAF – Data Flow

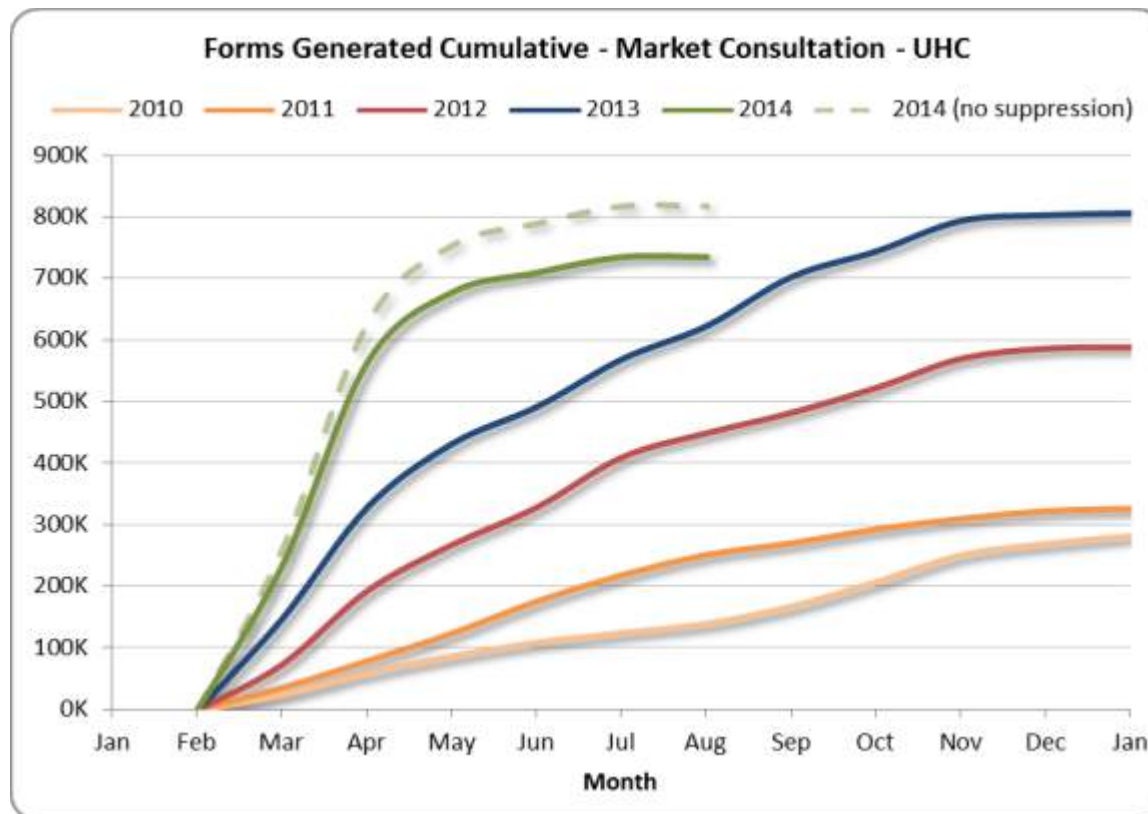


HQPAF – HCA Process



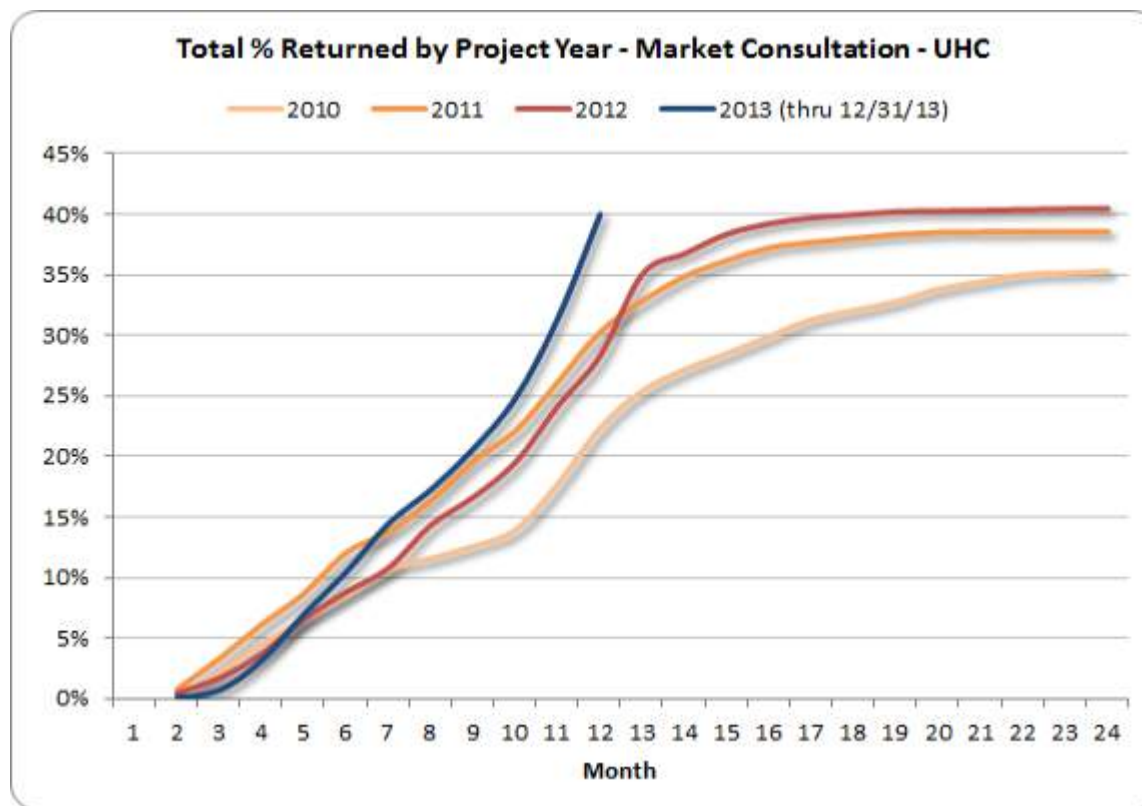
Analytics & Reporting

Deployment – Market Consultation Volume YoY



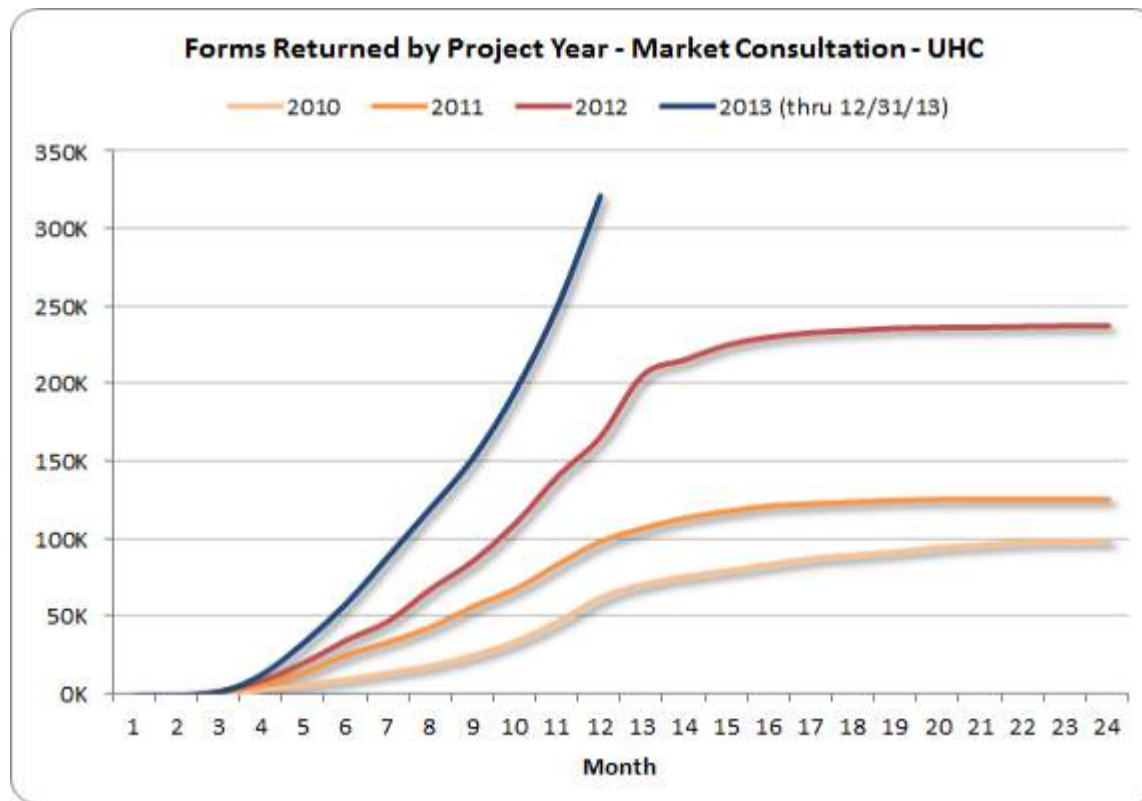
- 2014 Deployment Strategy
 - Early deployment prioritizing based on engagement and volume
 - 2014 initial volumes reduced by blank HQPAF suppression
 - Additional deployments expected in 2014Q3 and Q4

Returns – Market Consultation Return Percentage



- 2013 MC return percentage currently 40%, on track to exceed previous years

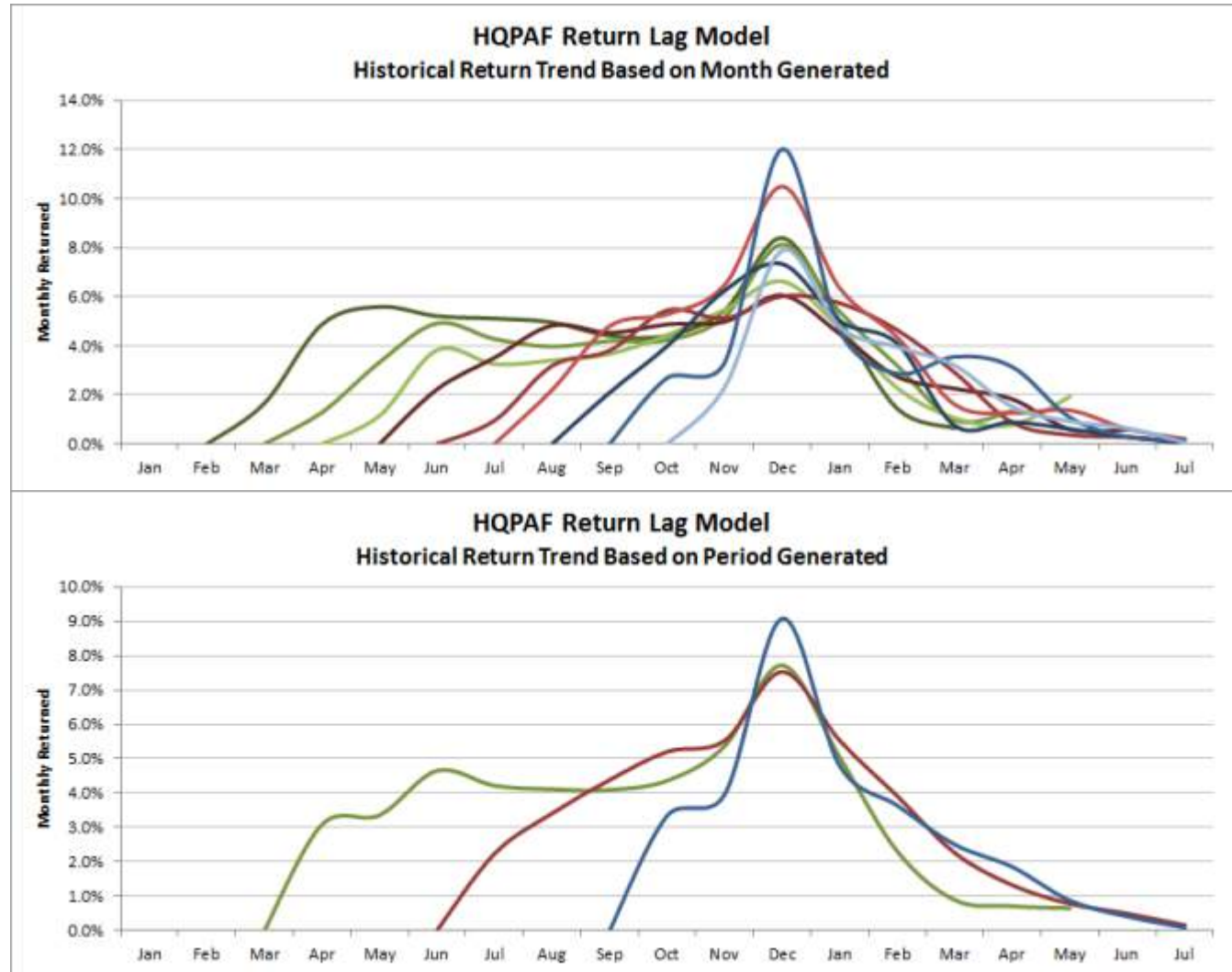
Returns – Market Consultation Volume



- 323K total returned thru 12/31, currently 35% favorable to 2012 project year
 - Significant additional returns expected

Returns – Market Consultation Return Trend

- Early deployments tend to return more consistent volumes each month.
- Returns tend to spike in December regardless of month generated.



HQPAF – Variable Reimbursement

General

- All requests approved by RVPs using standard form
- Approvals expire at year end and must be reviewed & reapproved

State Level

- Permits client to set variable rate for a particular market based on the provider state
- Rate change should be set before deployment begins
- Compatible with all deployment channels
- 2012 Performance – No Variable State level rates for UHC M&R

Group Level

- Permits variable rate for a specific group
- Rate change must be set before deployment
- Currently compatible with PAFs ordered by PVF only
- 2012 Performance
 - 35.8K PAFs generated, 96 orders, June – November
 - 28% returned outperforms 40% model on average (*see graph for variability*)
 - 7% CNA rate (vs 15% average)

HQPAF – Variable Reimbursement

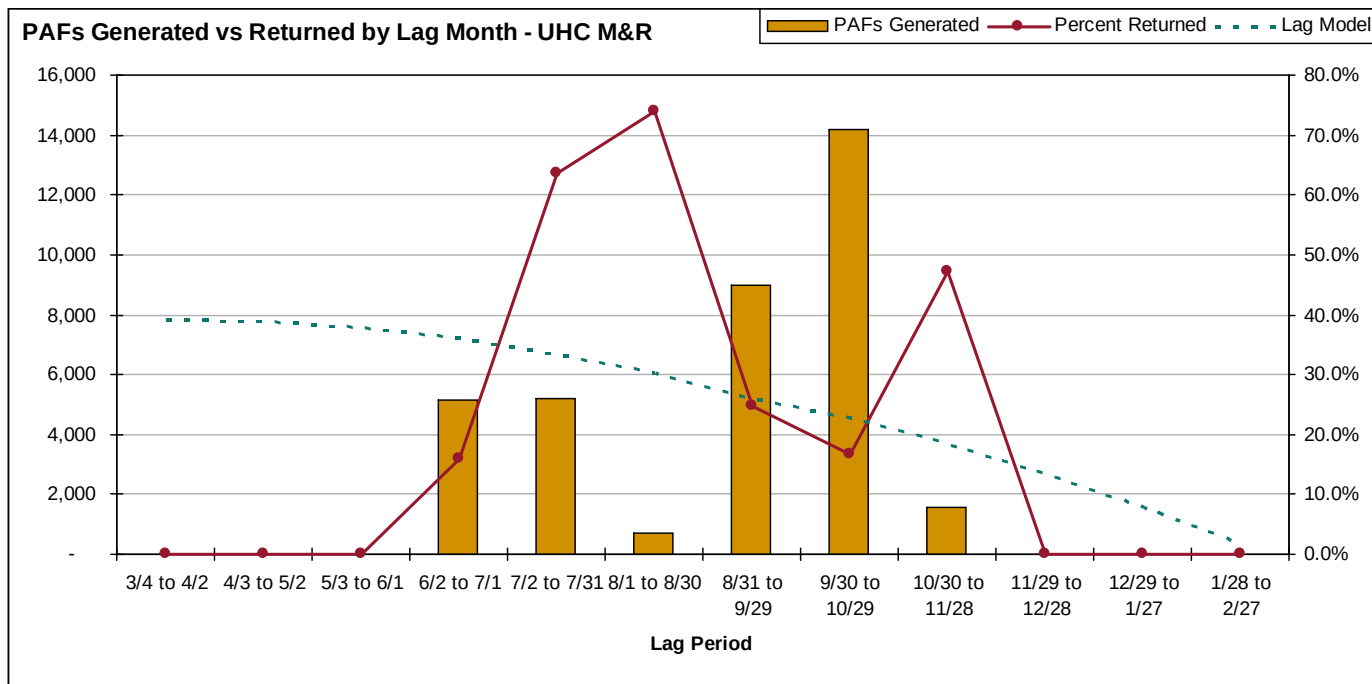
Forms generated

9 States

64% at \$100

State	100	125	150	Total
AZ	13,049			13,049
VA		5,643		5,643
NV	5,055			5,055
OH	3,471			3,471
AL		79	2,950	3,029
TN		2,898		2,898
GA			1,234	1,234
IN	1,177			1,177
NC	258			258
Total	23,010	8,620	4,184	35,814
%	64%	24%	12%	

Performance vs Lag Model



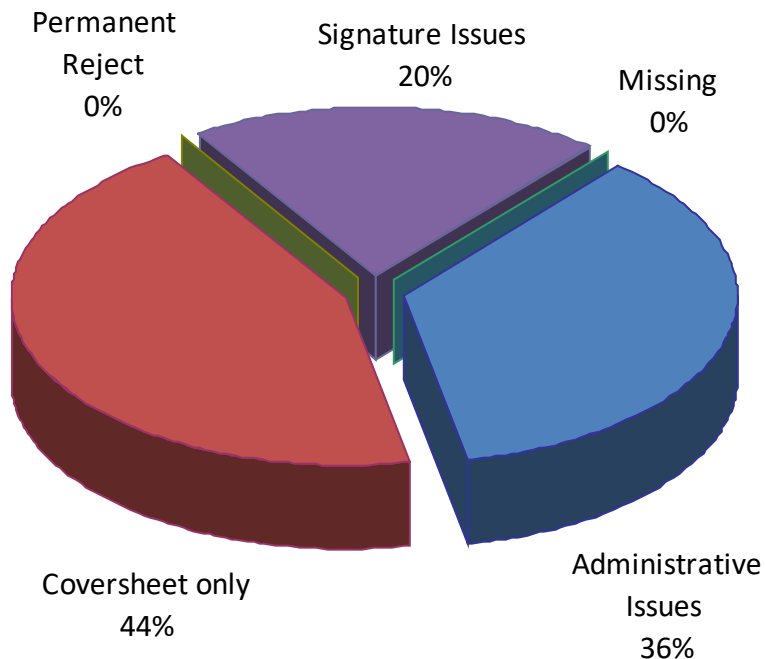
HQPAF – Managing Rejected Forms

Provider reports available for top rejects:

- D02: Provider signature not included in documentation
- D04: Document is partially or totally ineligible
- D05: Date of service not included in documentation
- D06: No patient name on progress note
- D09: Provider credentials missing from documentation
- D14: Chronic Condition Not Documented
- D27: EMR signature verbiage is invalid for authentication

HQPAF – Managing Rejected Forms

UHC Reject Reasons



Administrative Issues

- Member name and DOS visible on all pages of progress note
- DOS exceeds 60 day run date threshold
- Fax viewing error
- Need all pages of progress note
- EMR authentication issues

Signature Issues

- Need signature log
- No provider signature
- EMR signature noncompliant

HQPAF – Monthly Reporting

1. Operational Report

- Provides summary of PAF volumes by channel, including point-in-time generated, returned, and returned disposition (CNA, In Process, Coding Complete)
- Includes catalog of all groups with PAFs generated and early warning engagement indicators

2. Trend Report

- Monthly trend of PAFs generated and returned by channel
- Includes point-in-time breakdown of returned PAF disposition & reject reasons

3. Invoice Support File

- One record per PAF received, including current disposition, provider, group, processing dates, max date of service, and provider reimbursement

4. HQSMR

- Summary and member level detail for early detection and HEDIS/Quality screenings using all claims sources (lab & rx where available) and data coded from medical records returned with HQPAFs
- Includes prospective view of screenings needed
- Member-level data published to Health Plan
- Provider version available

5. Gap Analysis

- Details gap closures resulting from returned HQPAFs based on coding of attached medical records, including gaps triggered, percentage completed
- Shows by measure gaps triggered as well as percentages completed, referred and closed including validly documented numerator-compliant screenings.
- Recent Enhancements
 - Includes additional non-closure reasons (e.g, invalid documentation, numerator specification not met)
 - Provider group version of the report is being developed

MA-PCPi: Overview

- What is MA-PCPi?
 - Medicare Advantage Primary Care Physician Incentive Program
 - Pay for Performance incentive supporting CMS HEDIS & Star Quality Rating programs
 - Requires a contract amendment; automatically renews
 - Utilizes HQPAF
 - Member specific clinical data
 - Captures Risk Adjustment and Stars data
 - Established submission pathways
 - Rapid reimbursement
 - Permits provider control of member population
 - Unprecedented national collaboration between Optum & UHN to engage providers
 - Scalable – deployed to over 1,100 groups in 2013

Stars Measures

2013

	Measure	HEDIS Measure	HEDIS Compliance % Target
1	C01	Breast Cancer Screening	74%
2	C02	Colorectal Cancer Screening	58%
3	C03	Cardiovascular Care - Cholesterol Screening	85%
4	C04	Diabetes Care - Cholesterol Screening	85%
5	C05	Glaucoma Testing	70%
6	DMC12	Access to Primary Care Doctor Visits	85%
7	C14	Osteoporosis Mgt in women w/ fracture	60%
8	C15	Diabetes Care - Eye exam	64%
9	C16	Diabetes Care - Kidney disease monitoring	85%
10	C17	Diabetes Care - Blood sugar controlled	80%
11	C18	Diabetes Care - Cholesterol Controlled	53%
12	C20	Rheumatoid Arthritis Mgt	78%

2014

2013 CMS ID	2014 CMS ID	HEDIS Measure	HEDIS Compliance Target %
C01	C01	Breast Cancer Screening	74%
C02	C02	Colorectal Cancer Screening	58%
C03	C03	Cardiovascular Care - Cholesterol Screening	87%
C04	C04	Diabetes Care - Cholesterol Screening	85%
C05	C05	Glaucoma Testing	70%
C10	C10	Adult BMI Assessment	83%
C14	C14	Osteoporosis Mgt in women w/ fracture	60%
C15	C15	Diabetes Care - Eye exam	64%
C16	C16	Diabetes Care - Kidney disease monitoring	85%
C20	C20	Rheumatoid Arthritis Mgt	78%
D14	D11	High Risk Medication	<12%
D15	D12	Diabetes Treatment	87%
D16	D13	Medication Adherence for Diabetes Medications	78%
D17	D14	Medication Adherence for Hypertension (RAS antagonists)	79%
D18	D15	Medication Adherence for Cholesterol (Statins)	74%
C17	C17	Diabetes Care - Blood sugar controlled	80%
C18	C18	Diabetes Care - Cholesterol Controlled	53%

Incentives

2013

# of MA-PCPi Measures Met	Bonus Amount per Assessed MA-PCPi Customer
12	\$100
11	\$90
10	\$80
9	\$70
8	\$60
7	\$50
6	\$40

2014

# of MA-PCPi Measures Met	Bonus Amount per Assessed MA-PCPi Customer		
	Met Requirements for <u>both</u> C17 and C18	Met Requirements for <u>either</u> C17 or C18	Did Not Meet Requirements for either C17 or C18
17	\$300	n/a	n/a
16	\$230	\$215	n/a
15	\$215	\$200	\$185
14	\$200	\$185	\$175
13	\$185	\$175	\$130
12	\$175	\$130	\$120
11	\$130	\$120	\$110
10	\$120	\$110	\$100
9	\$110	\$100	\$90
8	\$100	\$90	\$80
7	\$90	\$80	\$70
6	\$80	\$70	\$60

In addition to the inclusion of the pharmacy measures, we will double the payment for achieving 4 Star on the outcomes measures (C17 and C18) and include an additional \$10 per assessed customer for each measure where the provider hits the 5 Star stretch goal.

Example, if they hit 12 measures including C17 and C18, they would earn \$175 per Assessed Customer. If they hit the stretch goal on 3 measures, we would add an additional \$30 for a total of $(\$175 + (\$10 * 3)) = \$205$ per assessed customer.

Data & Reporting: 2014

MA-PCPi Database

- UHN SharePoint
- Provider Targeting
- HQPAF Weekly Dataset
- HQSMR Monthly Dataset
- Pharmacy Data



Program
Reporting

PCOR
Baseline/Interim
Reporting

MA-PCPi: Provider Engagement

North Carolina	Select Market	Color Key:	On Track for 60% completion rate	Off Track for 60% completion rate	New deployment	Point-in-time achieved 6+ measures	Measure Achieving Target																			Count of Health Systems: 25					
Top 50 Health Systems by Status																															
Health System Data			HQPAF & Measure Data																		UHN/Contract Data										
Name	ID	Target Mbrs	MaxRunDate	Generated	Returned	CNA+Comp	On Track	Measures	DMC12	C01	C05	C02	C20	C14	C03	C17	C04	C18	C15	C16	Owner	Type	Mailed	Delivered	Executed	Effective	Baseline				
Kernodle Clinic Inc	560520990	2,727	02/13/13	2,839	1,839	1,766	552	6	100%	83%	62%	46%	72%	3%	8%	90%	87%	73%	45%	89%	Deitz, William R	Bilateral		07/16/13		08/06/13					
Bethany Medical Center Pa	561564485	940	04/08/13	879	786	600	253	6	100%	70%	46%	47%	59%	0%	44%	88%	97%	87%	38%	95%	Taft, Deborah D	Bilateral		07/02/13	09/01/13	09/01/13	07/26/13				
Regional Physicians Uc	562120765	1,217	03/28/13	874	621	565	214	6	100%	79%	64%	52%	75%	11%	0%	84%	93%	80%	62%	97%	Edgar, Julie D	Bilateral		06/25/13	10/28/13	09/01/13	07/17/13				
Blue Ridge Cardiology & Int Med	561907582	850	02/21/13	855	587	579	217	5	100%	75%	56%	44%	78%	43%	8%	87%	78%	69%	36%	87%	Deitz, William R	Bilateral		08/20/13	08/29/13	08/20/13	08/06/13				
Whitley Lothian Mcgough Cresenzo	560860057	541	02/21/13	597	551	537	284	6	100%	79%	63%	41%	100%	50%	4%	90%	82%	75%	48%	91%	Haakins, Marian N	Bilateral		09/01/13		09/01/13	08/20/13				
Raleigh Durham Med Grp Pa	201582408	751	03/13/13	577	316	253	15	7	100%	71%	62%	40%	100%	100%	100%	97%	83%	69%	51%	91%	Sturdevant, Seth	Bilateral		07/17/13	09/17/13	09/01/13	09/02/13				
Pardee	999999035	589	09/16/13	464	171	136	82	9	100%	78%	55%	26%	100%	100%	100%	100%	89%	78%	39%	86%	Harmon, Charita	Bilateral		06/28/13		08/01/13	10/17/13				
Northwest Medical Partners Pa	562194655	428	02/21/13	416	277	211	35	5	100%	70%	62%	49%	67%	50%	20%	86%	92%	76%	62%	95%	Haakins, Marian N	Bilateral		07/07/13	09/06/13	09/01/13	08/20/13				
Midway Medical Center Pa	561903161	299	02/20/13	403	363	304	133	5	100%	49%	50%	37%	100%	0%	33%	88%	69%	58%	27%	96%	Orlino-Crowe, Yvony	Bilateral		07/22/13							
High Rock Internal Medicine Pa	562185972	305	02/22/13	327	311	309	171	7	100%	87%	62%	73%	43%	25%	25%	83%	89%	67%	56%	95%	Harmon, Charita	Bilateral		07/12/13	08/29/13	09/01/13	08/08/13				
Rockingham Internal Med Assoc	561309131	267	02/21/13	248	206	194	89	6	100%	61%	73%	56%	100%	50%	73%	63%	92%	61%	47%	92%	Edgar, Julie D	Bilateral		06/24/13	09/16/13	08/01/13	08/14/13				
Internal Medicine Asc/raleigh	562266181	193	03/04/13	187	139	130	52	8	100%	33%	78%	58%	100%	0%	100%	88%	88%	50%	63%	88%	Edgar, Julie D	Bilateral		07/25/13	10/28/13	09/01/13	08/09/13				
Piedmont Health Services Inc	560952737	738	08/27/13	694	13	1	(128)														Edgar, Julie D	Bilateral		07/22/13	10/28/13	10/21/13	10/28/13				
Uncpa	999999039	3,048	07/26/13	443	27	20	(101)	11	100%	100%	71%	88%	100%	100%	100%	100%	100%	100%	33%	100%	Edgar, Julie D	Bilateral		09/12/13							
Eden Internal Medicine Assoc Pilc	561208305	451	07/16/13	440	10	9	(115)	11	100%	100%	0%	100%	100%	100%	100%	100%	100%	100%	100%	100%	Taft, Deborah D	Bilateral		07/09/13		09/01/13	08/13/13				
Bomray	561976679	339	02/21/13	354	172	144	(6)	6	100%	90%	33%	33%	75%	50%	0%	84%	95%	84%	32%	100%	Alcott, Sandra B	Bilateral		06/27/13	09/01/13	09/01/13	08/06/13				
Pleasant Garden Family Practice	561107828	273	02/27/13	325	-	-	(136)														Edgar, Julie D	Bilateral		07/15/13							
Blue Ridge Family Physicians P	562280794	325	05/30/13	320	-	-	(111)														Edgar, Julie D	Bilateral		07/15/13							
Rowan Diagnostic Clinic Pa	560988429	297	09/16/13	298	30	-	(35)														Harmon, Charita	Bilateral		08/02/13	09/23/13	10/01/13	10/29/13				
Alpha Medical Clinics Pa	030428236	238	03/15/13	271	50	46	(65)	9	100%	100%	20%	29%	100%	100%	100%	100%	100%	100%	0%	100%	Taft, Deborah D	Unilateral	06/28/13								
Cedar Creek Family Med Pilc	562197985	228	02/22/13	228	67	32	(64)	8	100%	57%	63%	68%	100%	100%	0%	100%	100%	100%	57%	86%	Harmon, Charita	Bilateral		07/22/13	10/17/13	09/01/13	08/12/13				
Angus G Mcinnis Md	562001846	203	02/20/13	214	106	79	(12)	5	100%	82%	32%	46%	0%	0%	0%	92%	77%	62%	23%	92%	Edgar, Julie D	Bilateral		06/25/13	08/01/13	08/01/13					
Piedmont Healthcare	561965983	321	10/28/13	319	-	-	-														York, Michele D	Bilateral		07/24/13	10/16/13	11/01/13					
Hma	999999030	306	10/16/13	289	-	-	-														Harmon, Charita	Bilateral		07/25/13	10/17/13						
Novant	999999034	9,415	10/24/13	89	-	-	-														Murthy, Mala K										

- Provider status key to prioritization, engagement, performance under the program
- Provider on-track status, measures achieved, and UHN engagement

Baseline & Interim Report - Summary

•HQPAF Summary

- Status of total HQPAF activity including
 - Forms Generated
 - Status of Forms Submitted
 - % Completed vs Incentive Threshold
 - Indicators for Diabetic Forms

•Incomplete Forms

- Summary of Stars performance to target for members where HQPAF has not been completed.

• Complete Forms

- Summary of Stars performance for completed HQPAFs. If 60% total completion thresholds met, indicates measures “on track” to meet target.

MA-PCPI Baseline & Interim Report

Group ID: 0123456789
Group: Sample Family Practice

HQPAF Summary		Diabetic	
	Actual	Threshold	Actual
Latest Date Generated	02/28/13		
Forms Generated	932		145
Forms Returned	636		101
Rejected	8		3
Processing	16		3
Forms in Interim Status	24		3
Patient Status Exceptions - Can Not Assess	34		1
Completed	578		87
PSE/CNA + Completed	612	558	88
Percent PSE/CNA + Completed	65.7%	60%	97.6%

Incomplete Forms [Forms Generated - (PSE/CNA + Completed)]					
#	Measure	Eligible	Needs	Completed	Target %
	Total Members	320			
DMC12	Access to Primary Care Doctor Visits				
C01	Breast Cancer Screening	102	79	23	23%
C05	Glaucoma Testing	204	123	81	40%
C02	Colorectal Cancer Screening	228	168	60	26%
C20	Rheumatoid Arthritis Mgt	8	-	8	100%
C14	Osteoporosis Mgt in Women w/Fracture	5	4	1	20%
C03	Cardiovascular Care - Cholesterol Screening	11	11	-	0%
C17	Diabetes Care - Blood Sugar Controlled	47	-	47	100%
C04	Diabetes Care - Cholesterol Screening	66	24	42	64%
C18	Diabetes Care - Cholesterol Controlled	66	24	42	64%
C15	Diabetes Care - Eye Exam	66	43	23	35%
C16	Diabetes Care - Kidney Disease Monitoring	66	11	55	83%

Completed Forms					
#	Measure	Eligible	Needs	Completed	Target %
	Total Members	578			
DMC12	Access to Primary Care Doctor Visits	578	-	578	100%
C01	Breast Cancer Screening	154	29	85	75%
C05	Glaucoma Testing	406	182	224	55%
C02	Colorectal Cancer Screening	395	169	216	56%
C20	Rheumatoid Arthritis Mgt	7	2	5	71%
C14	Osteoporosis Mgt in Women w/Fracture	54	10	4	29%
C03	Cardiovascular Care - Cholesterol Screening	23	23	-	0%
C17	Diabetes Care - Blood Sugar Controlled	97	-	97	100%
C04	Diabetes Care - Cholesterol Screening	122	19	103	84%
C18	Diabetes Care - Cholesterol Controlled	122	21	101	83%
C15	Diabetes Care - Eye Exam	122	67	55	45%
C16	Diabetes Care - Kidney Disease Monitoring	122	8	114	93%

Yes/No - After percent PSE/CNA + Completed threshold met, indicates whether On Track by measure.

These rates are based on criteria that is meant to be achievable in a prospective subyear program.

Figures are directional and will not match actual HEDIS measurements.

These screenings are recommendations based on previously reported risk factors and/or co-morbid conditions and may have already been performed.

Report Run Date: 10/10/13 HQPAF Activity Refreshed: 10/09/13 Screening Data Refreshed: 09/11/13

Baseline & Interim Report - Detail

MA-PCPI Member Detail																									
Group ID:		0123456789																							
Group:		Sample Family Practice																							
Report Run Date:		10/10/13																							
PAF Activity Refreshed:		10/09/13																							
Clinical Data Refreshed:		09/15/13																							
PAF Status: PSE/CNA=Patient Status Exceptions - Can Not Assess																									
X=Needs Screening / Test																									
C=Screening Completed: For HbA1c, DM LDL-C, Cardiovascular LDL-C, CBP & DM HTN: Completed w/normal result, or value not available																									
H=High HbA1c, DM LDL-C, Cardiovascular LDL-C, CBP & DM HTN value																									
Blank=Not Applicable																									
						HQPAF Activity							Measures							Measures - Diabetes					
PCP Name	Member Name	Member ID	DOB	Phone	Diabetic	Last Clinical Measure Refresh	Generated	Returned	Status	Date Rejected	Rejection Reason	Date Completed	Access to Care	Breast Cancer	Glucose ma	Colorectal Cancer	RA/DMA RD	Osteo/B MD or Rx	Cardio LDL	HbA1c	LDL-C	Eye Exam	Nephropathy		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13									C	X								
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	9/19/2013	Completed			09/23/13	C												
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13								X										
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	7/23/2013	Completed			08/01/13	C		X	C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	6/18/2013	Completed			06/25/13	C			C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	6/11/2013	Completed			06/22/13	C	C		C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13								C	C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####	Y	09/11/13	02/26/13	7/23/2013	Completed			08/01/13	C			X				C	C	X	C		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	8/30/2013	Completed			09/05/13	C		C	C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####	Y	09/11/13	02/26/13	7/23/2013	Completed			08/01/13	C		X	X				C	C	X	C		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####	Y	09/11/13	02/26/13	6/18/2013	Completed			06/25/13	C	C		C				C	C	C	C		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13									X									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13								X	X	X								
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	6/19/2013	Completed			06/25/13	C		C	X			X						
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####	Y	09/11/13	02/26/13	5/23/2013	Completed			06/13/13	C			C				C	C	X	C		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	9/19/2013	Completed			09/23/13	C			X									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13								C	C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	7/25/2013	Completed			08/04/13	C	C	C	X									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	7/25/2013	Completed			08/04/13	C		X	C									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####	Y	09/11/13	02/26/13									X				C	X	C	C		
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13								X		X								
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13									X									
Sample, Sample MD	Sample, Sample	123456789	MM/DD/YY	###-###-####		09/11/13	02/26/13	6/19/2013	Completed			06/25/13	C		C	C									

- Member Identifiers & Contact Info
- Diabetic Status
- HQPAF Activity Data
- Stars Measure Status

2013 Early Indicators – Incentive Estimates

Accrual Summary

PAF activity thru: 01/08/2014

HQSMR updated thru: 12/13/2013

Incentive Accrual (\$) - Point-In-Time Model

Total	
#	%

\$ 1,978,270

Incentive Accrual (\$) - End-of-Year Model

\$ 2,804,876

Projects forms completed at end of measurement period based on current completion rates, holding all other variables constant.

Incremental Potential #1 (\$) - End-of-Year Model

\$ 2,129,614

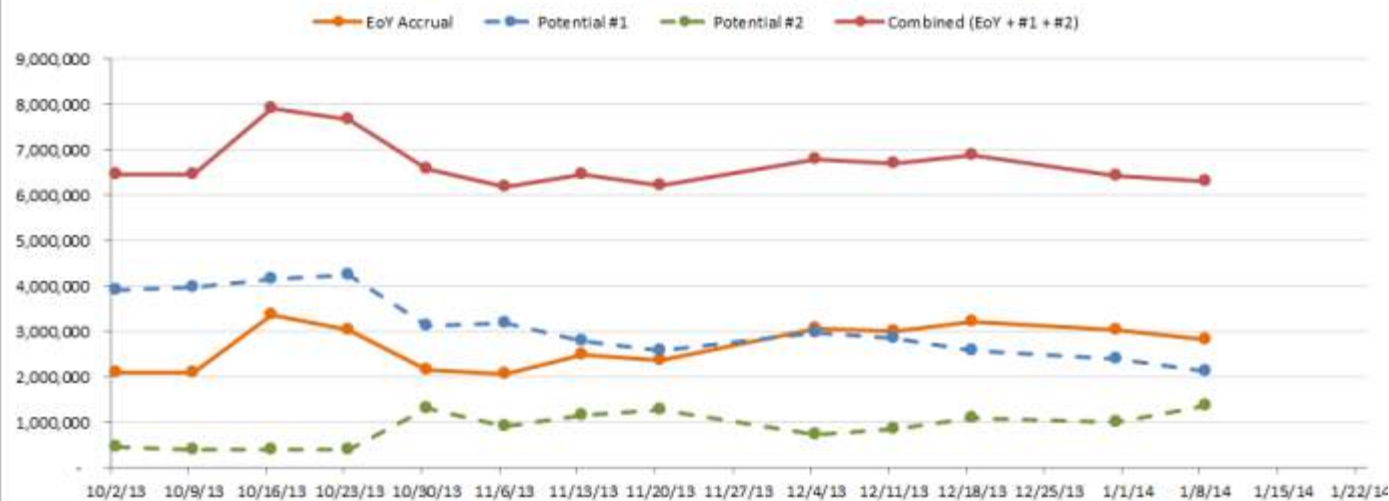
Estimates incremental incentive potential if On-Track HS's close gaps at a higher rate (+2 measures).

Incremental Potential #2 (\$) - End-of-Year Model

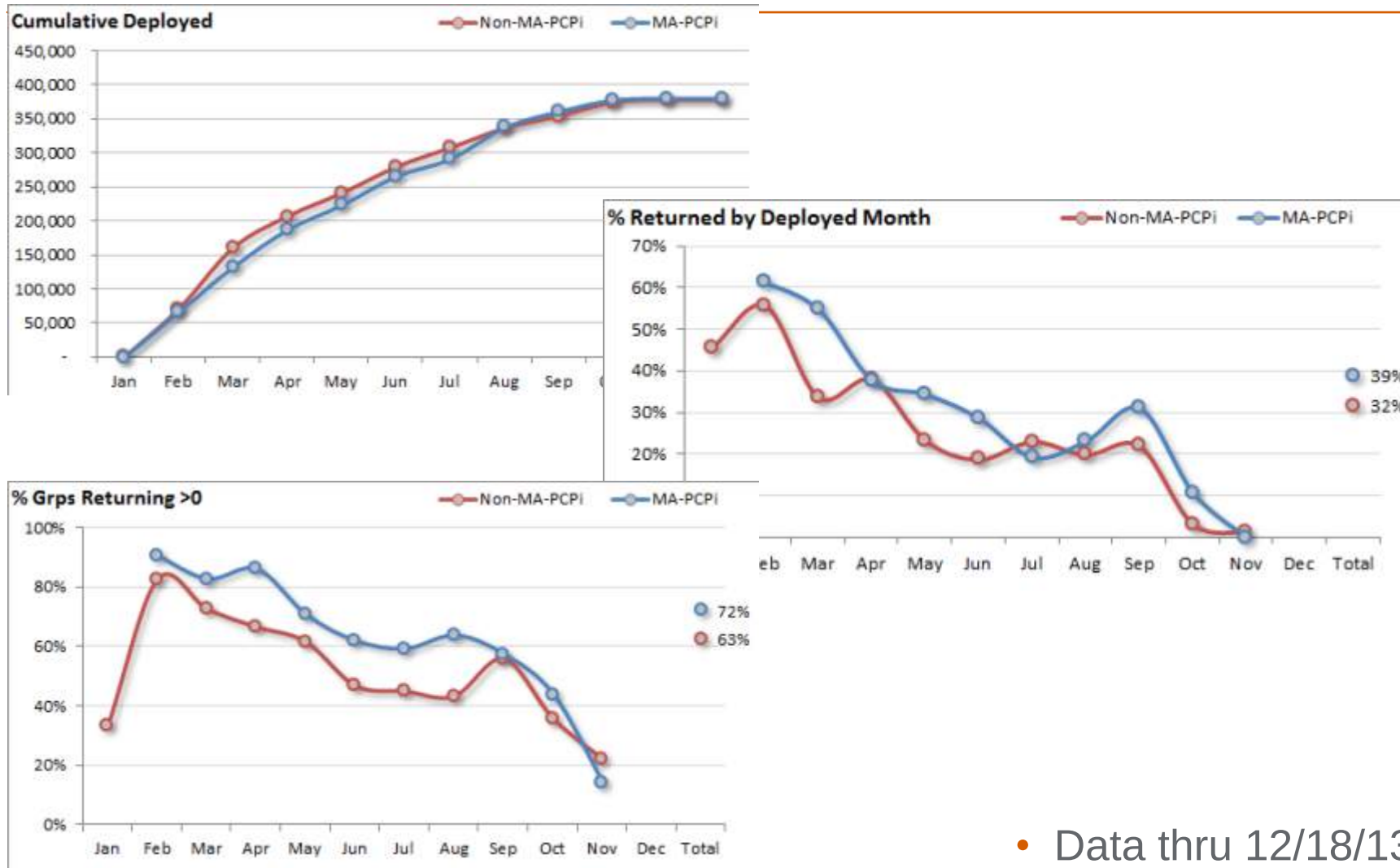
\$ 1,352,844

Estimates incremental incentive potential if slightly Off-Track HS's shift to On-Track & close gaps at a higher rate (+2 measures).

MA-PCPi Incentive Accrual Tracking (M&R + C&S)



2013 Early Indicators – HQPAF performance & MA-PCPi



- Data thru 12/18/13

MA-PCPi 2014 – Changes

1. Earlier Deployment

- Targeting by Tier based on 2013 engagement

2. New Measures

- Remove Access to Care
- Add BMI
- Add Rx Measures

3. New Incentive Model

- Higher potential payout
- More complex tiers to drive provider behavior

4. Reporting thru PCOR

- Client requests integration with PCOR as report delivery engine

HQPAF & MA-PCPi 2014 – Opportunities & Challenges

OPPORTUNITIES

1. Growth in Engagement, Volumes, Outcomes

- Enhanced Provider Targeting
- YoY engagement growth at the provider level
- Incentives for quality submission
- Blank PAF suppression
- Earlier SOPAF deployment (17% of M&R mbrs associate with small groups)

2. Continued RA & Stars Impact

3. Supplemental Submission

- Provider ability to close gaps with submission subsequent to HQPAF

4. Full Year MA-PCPi Campaign

CHALLENGES

1. Compressed Production/Deployment Calendar

2. Enticing Providers to Portals

- Insite
- OptumPAF

3. PCOR Alignment/Integration

4. Provider Data Alignment w/ UHN

- Alignment between Contracted Entities (Health Systems) & Point-of-Care Providers



HEDIS Programs

Ramesh Jayasuriya

Clinical Quality – Financial Impact

Financial performance of payers are increasingly dependent on the ability to accurately **measure** and **improve** quality of care

Healthcare reform has attached a significant dollar value to quality of care

- ❖ Increased use of sanctions with stringent corrective action plans
- ❖ The industry as a whole has transitioned from routine retrospective measurements to real-time data driven issue identification and follow-through to operations
- ❖ Focus on the member experience when interacting with the health plan, its delegates and its network

Quality-based bonus payments are increasingly important to operating margins

- ❖ STARS
- ❖ State bonuses
- ❖ ACO
- ❖ PCMH

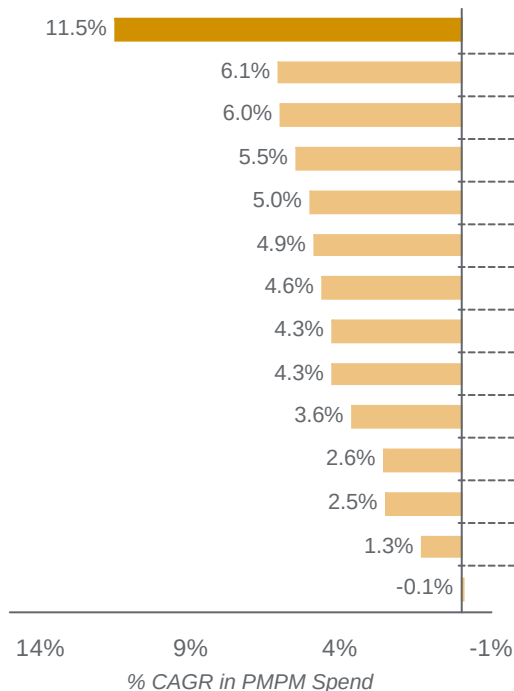


Quality Spending has Grown Dramatically

Payers have demonstrated a financial commitment to quality, increasing their investment in this area at nearly double the rate of the next closest administrative spend category

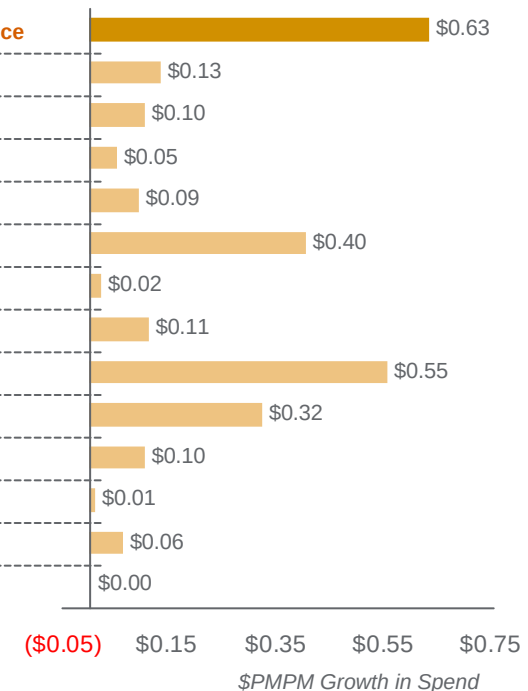
Growth Rate of Admin Spend

Blue Cross Blue Shield Admin Spend Benchmark
CAGR of Admin Spend Category from 2005 to 2008



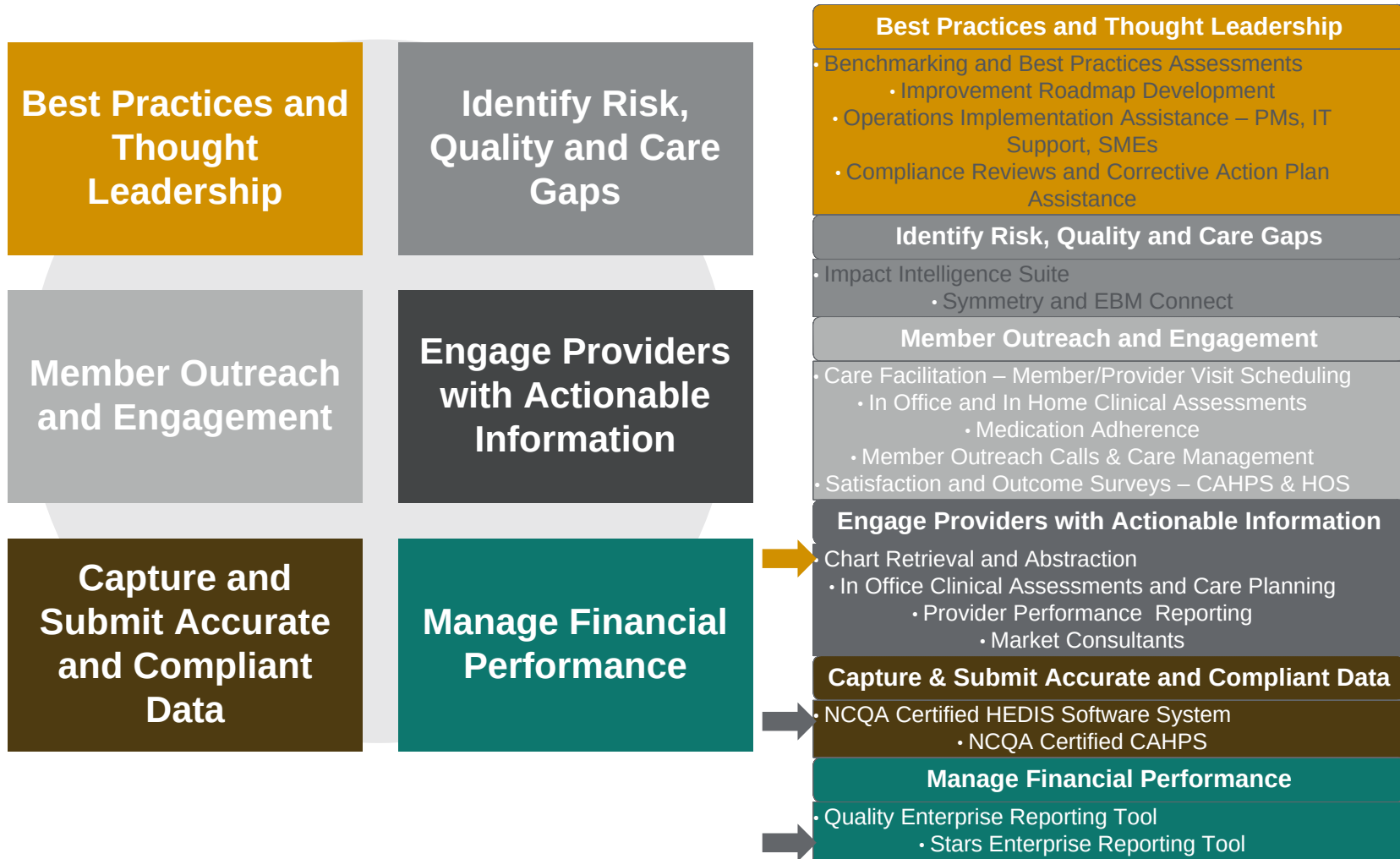
PMPM Growth in Admin Spend

Blue Cross Blue Shield Admin Spend Benchmark
Increase in PMPM Spend from 2005 to 2008



Notes: Based on Median PMPM expense level of surveyed BCBS plans from 2005 to 2008.
Source: Sherlock SEER Data- 2009; Optum Analysis

Our Solution At-A-Glance



HEDIS Medical Record Review

Key highlights:

- ✓ Year 1 of a 2-3 year plan to in-source HEDIS medical record review
- ✓ In 2014 we will handle about 30% of total volume – about 150k charts between all 3 lines of business
- ✓ Goal is to offer a high quality internal solution & minimize the reliance on external vendors

Key Components to Optum's HEDIS solutions

- Efficient Record Retrieval
- High Quality Abstraction
- Dynamic Reporting and Monitoring
- NCQA Certified Engine and Reporting Front End
- Best in class team that has ample industry and direct UHC experience

Key Business Benefits

- Internal solution that has a proven track record of supporting large projects & maintaining high quality standards
- Minimize the reliance on external vendors
- Working with a trusted and experienced team that is directly impacted by, and committed to, the success of UHC

UHC/Optum HEDIS MRR Partnership

- ✓ Opportunity to insource medical record review for HEDIS within UHG
- ✓ Rely on trusted HEDIS professionals to carry the burden of HEDIS medical record review
- ✓ Align QMP & Optum quality goals

Award Winning Certified HEDIS Reporting



Gartner Appoints Optum HEDIS Reporting

*“Best in Class
Healthcare Payer Dashboards”*



World's leading information technology research and advisory company.

Author of the “Magic Quadrant”



Internal Announcement: <http://inside.optum.com/data/news-articles/optum/payer-market-news/12102013-hedis>

2191

Stars Management Reporting – Intent of Design

To empower the client/user with a “**prospective**” solution that allows them to make informed decisions regarding “**where**” their organization can affect the care, services and satisfaction being received “**today**” by their members/provider in order to achieve their “**goal(s)**” - Evaluate the response to their intervention on those services that will be measured and reimbursed in the future thru the CMS 5 Star Rating program

- Business goals:
 - Evaluate progression to the plan’s goal “are we on track”
 - Where are we strong, where do we have opportunities to improve
 - Project the impact if the plan’s goal were achieved
 - Drill into identify and priorities area of focus – who to engage
 - Measure response to intervention
 - Promote a easy, intuitive and mature reporting solution the analyzes across all Stars domains and measures





Medicare Revenue Reconciliation Programs

Lori Meyer

What we do

The key objective of the MRR Team is to ensure CMS has the most accurate and complete information for special status categories for each member that impact payment.

MRR Reconciliation Processes

- **Current Medicaid Status**
 - To ensure plan and CMS records are as accurate as possible, the MRR Team identifies Medicaid suspects; verifies the member's eligibility with state data; reconciles the Medicaid and Medicaid Add-On statuses with CMS; submits status adjustments if needed; and tracks until resolved.
- **MAO (Medicaid Add On)**
 - All members with at least one month of Medicaid status in the prior year are identified on an annual basis. This list is compared to the MMR payment dates for the following year. Any member without the expected MAO flag or payment adjustment is sent to CMS for correction and tracked until resolved.
- **ESRD (End Stage Renal Disease)**
 - To ensure plan and CMS records are as accurate as possible, the MRR Team identifies ESRD enrollees; verifies the enrollees' status with Dialysis Facilities or with the Renal Networks; reconciles the ESRD status with the CMS Monthly Membership Report (MMR); submits status adjustment requests; and tracks until resolved.
- **ESRD MSP (End Stage Renal Disease, Medicare as Secondary Payer)**
 - The MRR team identifies ESRD Members with other health insurance that is primary to Medicare and works directly with the Coordination of Benefits Contractor (COBC) to ensure CMS records are accurate.

MRR Reconciliation Processes

- MSP (Medicare as Secondary Payer)

- To ensure plan and CMS records are as accurate as possible, the MRR Team identifies MSP members; verifies the members' status with member, employer and/or other insurer; reconciles the MSP status with the CMS Monthly Membership Report (MMR); submits status adjustment requests; and tracks until resolved.

- Hospice

- To ensure plan and CMS records are as accurate as possible, the MRR Team identifies hospice members; verifies status with hospice agencies; reconciles the hospice flag with the Daily Transaction Reply Report (DTRR), Monthly Membership Report (MMR), and internal systems; works with agencies to ensure they submit status adjustment requests to CMS timely; and tracks until resolved.

Appendix

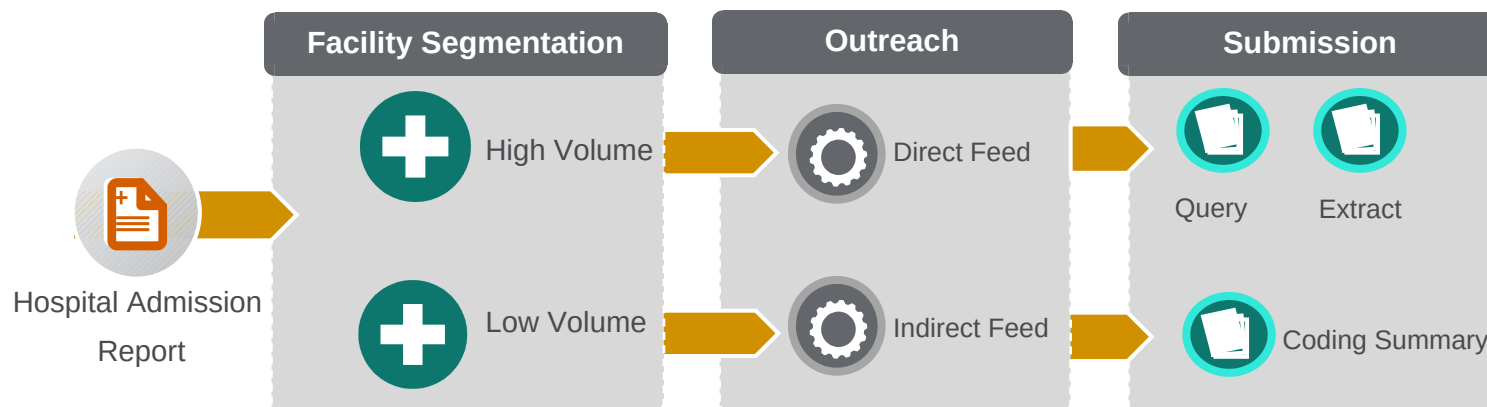
Hospital Data Capture

Submissions

Hospital Data Capture Solution Overview

Hospital Data Capture

CPC retrospective service designed to capture additional member diagnoses codes from hospitals not submitted through the normal claim/encounter process. Due to both payer and hospital system limitations, some hospital diagnoses may be omitted via the normal claim stream.



Hospital Data Capture Logic



2012 Preliminary results

- 2,466 facilities identified w/an admit to pursue
- 1,746 facilities w / a submission to Optum

Outreach Timing

Q1	Q2	Q3	Q4
• Create hospital admission reports • Review program collateral • Analyze prior year results • Enhance operational reporting • Assess 2013 and 2014 strategy	• UHC review of plan • Segment facilities • Provide list of outreach facilities • Initiate facility outreach	• Process hospital submissions • Track returns vs. plan • Follow up on non-engaged facilities	

2013 Strategy

Market Opportunity

Health Plan Business Challenge

- Hospitals capture and submit to Health Plans between 18 - 24 Dx Codes during an inpatient encounter when in fact a patient may have as many as 80 Dx Codes during the encounter.
- This presents a gap in the number of Dx Codes being documented in the Hospital's Health Information System and the number of codes that are being transmitted to the Health Plan.
- Health Plans need to ensure complete and accurate coding is represented in the risk adjustment data submissions to CMS.

Business Opportunity & Client Value

- Currently, Optum offers a **Hospital Data Capture** service as part of the retrospective risk adjustment service offering. According to Optum's interpretation of the CMS EPDS guidelines, CMS will not accept hospital based diagnoses codes submitted as part of Optum's 'current' Hospital Data Capture (HDC)
- Only 'chart review type' data will be accepted by CMS as part of the EDPS submission.
- In order to maintain customer expectations, we are evaluating the HDC service under EDPS

CMS definition of ‘chart review type’

August 2012 CMS Participation Guide:

3.5.7 Chart Reviews

Historically, chart reviews have been performed by MAOs and other entities for the purpose of obtaining diagnosis codes that were either not originally submitted by the provider or were submitted by the provider in error. Based on this information, CMS collects chart review data as a part of the encounter data process. All chart review encounter data must be from an appropriate provider “specialty,” from an allowed provider type (inpatient, outpatient, physician), and within 25 months of the data collection period. Further, all diagnoses codes submitted through chart review must be based on a face-to-face visit and supported by a medical record.

Because not all chart reviews are able to be linked back to a previously adjudicated claim in the MAOs adjudication system, CMS allows for MAOs and other entities to submit chart review encounters that are linked to a previously submitted and accepted encounter (linked ICN) and chart review encounters that are not linked to a previously submitted and accepted encounter (unlinked ICN). All chart reviews, whether linked to an ICN or unlinked, must be able to be validated through the medical record.



The term “chart review” refers to all medical reviews

2013 Strategy

- Continue with HDC 'business as usual' as follows:
 - Target 2012 DOS and submit via RAPS to drive CY 2013 payment
 - Evaluate the Optum HDC service in the context of EPDS submission guidelines
- Consider how **Optum's** HDC program will co-exist with **XL Health's** hospital abstract program (Hospital Chart Review)
 - Coordinated approach
 - Identify overlapping facilities & members
 - Information sharing between XL hospital abstract program and Optum HDC program

EXHIBIT D-70

29

TUESDAY

APRIL, 2014 • 119th Day, 246 Days Left • 18th Week

APPOINTMENTS & SCHEDULED EVENTS

DIARY AND WORK RECORD

Steve
Miles
Don Shulman
J. C. P. O.
U. H. C. + M. A. C.
Threats
United

8
9
10
11
12
1
2
3
4
5
6
7
8

No preventive
to confirm
accuracy of dx
Claims over
deleted 13k
from 2012
8k - completed
steps - will
delete
unrise in process
41k
various
steps
not finished.

2012 - client
review, "Stoppy"
to sign attestations

TO BE DONE TODAY (ACTION LIST)

Obligations to
Stop review or
tell us about
what they find.
"Addition" - accuracy
Stop work.

EXPENSE & REIMBURSEMENT RECORD

Imp

EXHIBIT

1062

2205

EXHIBIT D-71

To: Burke, Sherry Lynn (HHS/OGC)[SherryLynn.Burke@hhs.gov]; Uehersax, Julie (CMS/CM)[Julie.Uehersax@cms.hhs.gov]; Harlow, Jennifer A. (CMS/CM)[Jennifer.Harlow@cms.hhs.gov]; Paul, Rebecca (CMS/CM)[REBECCA.PAUL@CMS.HHS.GOV]; Chaudhuri, Ilina (CMS/CM)[Ilina.Chaudhuri@cms.hhs.gov]; Nolan, Janet (HHS/OGC)[Janet.Nolan@hhs.gov]; Kornfield, Thomas (CMS/CM)[Thomas.Kornfeld@cms.hhs.gov]; Abrams, Jill (HHS/OGC)[Jill.Abrams@HHS.GOV]; Tudor, Cynthia G. (CMS/CM)[cynthia.tudor@cms.hhs.gov]; Cavanaugh, Sean (CMS/CM)[Sean.Cavanaugh@cms.hhs.gov]
From: Rice, Cheri M. (CMS/CM)
Sent: Fri 5/2/2014 10:16:17 PM
Importance: Normal
Subject: FW: 2012 Attestation and follow-up from yesterday's meeting
Received: Fri 5/2/2014 10:16:19 PM

FY.

From: Rice, Cheri M. (CMS/CM)
Sent: Friday, May 02, 2014 6:15 PM
To: 'Nelson, Steve H'
Cc: Johnson, Thad C; Schumacher, Darie J; Erickson, Karen L; Harlow, Jennifer A. (CMS/CM)
Subject: RE: 2012 Attestation and follow-up from yesterday's meeting

Steve,

Thank you for your email and for our discussion earlier this week. With respect to your fifth point, I would note that regardless of the effective date of the proposed requirement related to medical record reviews, there are other laws that do impose standards, requirements and responsibilities on MA plans in connection with the federal payments they receive from CMS. We cannot provide advice to United about the scope of those other laws. Nor can we provide advice on whether United's plan course of action and/or purported limits on the scope of its attestation are compliant with such other laws. Your statement concerning the data submissions that have already been made and United's plans for future action will be included in our records and we will proceed with our evaluation and use of the risk adjustment data consistent with 42 CFR § 422.308, § 422.310, and other applicable law.

Thanks again,

Cheri

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Wednesday, April 30, 2014 9:55 AM
To: Rice, Cheri M. (CMS/CM)
Cc: Johnson, Thad C; Schumacher, Darie J; Erickson, Karen L; Nelson, Steve H
Subject: 2012 Attestation and follow-up from yesterday's meeting

Dear Cheri,

I wanted to thank you and your colleagues for taking the time to meet with us yesterday. We appreciate the time and attention that you and others in CMS leadership have provided on the issue of our 2012 risk adjustment data submissions and our annual risk adjustment data certifications. As we mentioned, prior annual certifications have been on paper, and we have thus had the ability to add notes explaining our understanding of the certifications and our ongoing data remediation efforts. This year, however, the certifications are electronic, and there does not appear to be an opportunity to reflect our understanding. The purpose of our meeting yesterday and this email is to explain our understanding of the certifications.

First, as with our past certifications, the 2012 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.

Second, the certifications use the phrase "best knowledge, information, and belief," which is based on our practices.

Third, the certifications only cover risk adjustment data for 2012 dates of service that were submitted to CMS and subsequently deleted prior to the date of the certifications.

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Fourth, as we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2012 dates of service that we ultimately determine should be deleted consistent with this email.

Fifth, as we discussed yesterday, CMS recently issued a proposed rule that would, if finalized, require MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. During our conversation yesterday and other recent conversations, CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that MA plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. We currently have a process through which we review certain medical records to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes. This process already has resulted in the identification of and, in some instances, the submission of deletes for 2012 dates of service. But based on the proposed rule, including the preamble, and recent conversations with CMS, we suspended that process for 2012 dates of service while we consider whether to make changes. Pursuant to our discussion, however, we will soon submit for deletion those diagnosis codes that have undergone a complete review and that we have therefore identified as appropriate deletes. In the near future, we will determine whether to continue our review process for the diagnosis codes which were still under review at the time we suspended our process. In the meantime, we will not delete these codes.

The certifications that we submit today are made subject to these clarifications. Please let us know if you have any questions. Again, thank you for your time and attention on this matter.

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EXHIBIT D-72

Message

From: Rice, Cheri M. (CMS/CM) [/O=HHS EES/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CHERI.RICE.CMS59728027]
Sent: 10/26/2015 4:05:26 PM
To: Cavanaugh, Sean (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Sean.Cavanaugh.CMS]; Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=jennifer.harlow.cms20728073]
CC: Tudor, Cynthia G. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=cynthia.tudor.cms06246732]
Subject: RE: RADV

Another thought is getting more help supporting DOJ whistleblower activity. The volume of these cases is increasing and they often need significant technical assistance from MPPG to evaluate whether to intervene and to support cases they choose to prosecute. We think the whistleblower activity could be as effective – or even more effective – than CMS audits in getting plans to do more to prevent and identify risk adjustment overpayments.

From: Rice, Cheri M. (CMS/CM)
Sent: Monday, October 26, 2015 12:01 PM
To: Cavanaugh, Sean (CMS/CM); Harlow, Jennifer A. (CMS/CM)
Cc: Tudor, Cynthia G. (CMS/CM)
Subject: RE: RADV

Our regs say that plans must use reasonable diligence to identify overpayments. We have not yet defined what that means.

We could, through regulation, define specific steps a plan must take, at a minimum, to meet that requirement. For example, we could require them to self-audit (i.e., their own RADV audits). We could also revive the NPRM proposal we had that if a plan is checking a medical record for underpayments, they must also look for overpayments.

On the attestation language, we are working now to tighten it up. But without a reg change (as described above), we are limited in how high we set the bar.

We're developing contract-specific coding adjustor options, but those don't address diagnosis error.

From: Cavanaugh, Sean (CMS/CM)
Sent: Monday, October 26, 2015 11:36 AM
To: Rice, Cheri M. (CMS/CM); Harlow, Jennifer A. (CMS/CM)
Cc: Tudor, Cynthia G. (CMS/CM)
Subject: RADV

What would a list of proposals to strengthen RADV include?

1. Stronger attestation language.
2. Limitations around home visits.
3. Anything else?

Sean Cavanaugh
Center for Medicare
202-690-6301|sean.cavanaugh@cms.hhs.gov

EXHIBIT

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EXHIBIT D-73

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EXECUTIVE SUMMARY
[Please see body of report.]

BACKGROUND

The Unfunded Budget Act of 1997, P.L. No. 105-33, established Medicare Part C to allow beneficiaries managed care options through the Medicare Choice program. Section 227 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, revised Medicare Part C and renamed the program the Medicare Advantage (MA) program. Organizations that participate in the MA program (MA organizations) include health maintenance organizations, preferred provider organizations, provider-sponsored organizations, and private fee-for-service plans.

Section 1833(a)(4) of the Social Security Act requires that the Secretary of Health and Human Services adjust payments to MA organizations based on the health status of beneficiaries. As a result, the Centers for Medicare and Medicaid Services (CMS) pays MA organizations less for beneficiaries who are expected to incur lower health care costs and more for beneficiaries who are expected to incur higher health care costs.

Pursuant to 42 CFR § 422.30(d), “Each MA organization must submit to CMS for reconciliation with CMS instructions of the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional capabilities of enrollees of each MA organization.” The 2007 *MA Reimbursement Data: Overview* (hereinafter *Reimbursement Data*) states that “MA organizations are responsible for the accuracy of the data submitted to CMS.” These data are commonly known as risk adjustment data. Among other information, risk adjustment data include beneficiaries’ diagnoses.

CMS calculates risk-adjusted payments to MA organizations using the CMS Hierarchical Condition Category model (the model). Under the model, MA organizations collect beneficiary diagnoses from hospital inpatient facilities, hospital outpatient facilities, and physicians during a data collection period. MA organizations review the data, identify diagnoses relevant to the model, and submit the relevant diagnoses to CMS. CMS categorizes these diagnoses into groups of clinically related diseases called Hierarchical Condition Categories (HCCs). CMS uses these HCCs and demographic characteristics to calculate a risk score for each MA organization beneficiary. Benchmark risk scores are used to adjust the monthly capitated payments that CMS makes to MA organizations.

Pacificare of Texas (Pacificare), an indirect, wholly owned subsidiary of UnitedHealth Group located in Cypress, California, is an MA organization. For calendar year (CY) 2007, Pacificare had multiple contracts with CMS, including contract number H4590, which we refer to in this report as “the contract.” Under the contract, CMS paid Pacificare approximately \$1.2 billion to administer health care plans for approximately 118,000 beneficiaries.

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OBJECTIVE

Our objective was to determine whether the risk adjustment data that PacificCare submitted to CMS complied with requirements set forth in the Participant Guide.

SUMMARY OF FINDINGS

The risk adjustment data that PacificCare submitted to CMS did not always comply with requirements set forth in the Participant Guide. As a result, PacificCare did not always receive accurate payments from CMS. Risk scores calculated using the diagnosis codes for 56 of the 100 beneficiaries in our sample were valid. The risk scores for the remaining beneficiaries were invalid because each of the 44 beneficiaries had at least 1 HC Code that was not supported by documentation. Based on our sample results, we estimated that PacificCare was overpaid at least \$69,549,120.

PacificCare did not have written policies and procedures in place for obtaining, processing, and submitting risk adjustment data to CMS. Furthermore, PacificCare's quality assurance practices focused primarily on ensuring that all relevant risk adjustment data were submitted to CMS, rather than ensuring that the data it submitted were accurate. Contrary to CMS requirements, UnitedHealth Group officials stated that providers are responsible for the accuracy of risk adjustment data that PacificCare submitted to CMS.

RECOMMENDATIONS

We recommend that PacificCare:

- return to the Medicare program \$69,549,120 in overpayments;
- implement formal policies and procedures for obtaining, processing, and submitting risk adjustment data; and
- create a more robust claim validation process by periodically selecting a random sample of all providers and using this data to ensure that PacificCare is in compliance with the requirements set forth in the Participant Guide.

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D REASONS FOR INVALID SAMPLES

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INTRODUCTION

BACKGROUND

Welsh: A Language Programme

The Unfunded Budget Act of 1997, P.L. No. 105-33, established Medicare Part C to offer beneficiaries managed care options through the Medicare+Choice program. Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, revised Medicare Part C and renamed the program the Medicare Advantage (MA) program. Organizations that participate in the MA program (MA-sponsors) include health maintenance organizations, preferred provider organizations, private-sponsored organizations, and private fee-for-service plans. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, makes monthly capitated payments to MA organizations for services provided to Medicare beneficiaries enrolled in their plans.

Section 13(1) of the Social Security Act requires that the Secretary of the Department of Human Resources Development Canada, in his or her discretion, may award an award of compassionate allowances to persons who are unable to work because of a long-term illness or disability. The regulations also contain provisions for awards of compassionate allowances to persons who are unable to work because of a long-term illness or disability. The regulations also contain provisions for awards of compassionate allowances to persons who are unable to work because of a long-term illness or disability.

Pharmacologic [2, 3] and clinical [4, 5] data have shown that smoking status plays a significant role in the development of AIDS and that the data necessary to characterize the complex role of patients of certain ethnic groups due to a variety of factors for the development of AIDS are still incomplete. The CDC has also collected data necessary to characterize the functional interactions and mechanisms of ethnicity, migration, and other factors [6]. The 1987 *First National Survey of Drug-Using Populations: Characteristics, Health Status, and Health Care Needs* [7] presents information that will be used to select, evaluate, and develop interventions and programs for drug-using populations and to develop strategies for the prevention of AIDS. The survey was nationally known as the risk reduction study. Among other information, the risk reduction study includes information on the following:

The Risk-Adjusted Process Risk-Adjusted Payoffs

As stated in section 1832 of the Social Security Act, CMS is required to "first attempt to pay" organizational claims for the health care of eligible individuals. In January 1994, CMS implemented the following risk-adjusted payments to MA organizations offering the CMS financial risk-adjustment eligibility model (the model for a state to use as a model payment):

Under the model, MA organizations collect skill and/or data including beneficiary diagnoses, length of stay, employment activities, hospital or patient activities, and physicians during a

Φ is a positive real function, $\Phi(\lambda) = 0$ if and only if $\lambda = 0$, $\Phi(\lambda) \rightarrow \infty$ as $|\lambda| \rightarrow \infty$, and $\Phi(\lambda)$ is bounded on the unit circle.

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data collection period.¹ MA organizations review the data, identify diagnoses relevant to the model, and submit the relevant diagnoses to CMS. CMS categorizes these diagnoses into groups of clinically related diseases called Hierarchical Condition Categories (HCCs). CMS uses HCCs and demographic characteristics to calculate a risk score for each MA organization beneficiary. CMS then uses the risk score to adjust the monthly capitation payment to the MA organization for the next payment period.²

Risk Adjustment Data Requirements

CPHQ's 2007 *Final Guidance on Data Submission to Medicare Coverage Eligibility Contractors* (hereby the Part 499 guidance) and the Medicare Claims & MS established guidelines regarding the valid risk adjustment data. Diagnoses included in risk adjustment data must be "based on clinical medical record documentation from a face-to-face encounter coded according to the ICD-9-CM coding manual." *Consistency in Reporting, Subsequent, Complete Identification, Good Care, the Coding and Reporting*. A stipulated based on dates of service within the data collection period, and submitted to the RFA region, not from an appropriate risk adjustment provider type and an appropriate risk adjustment physician data source." The Part 499 guidance addresses the following points: (1) face hospital inpatient documentation and hospital outpatient and physician documentation; (2) source of data as a claim starts for a claim; (3) signatures and credentials and the approval of a certified medical agencies; (4) the Part 499 guidance also specifies unacceptable sources of medical records (such as medical records from skilled nursing facilities and long-term care facilities); (5) patients' records and unacceptable medical records; (6) records that are not used for purposes beyond the intended use of the data; and (7) the Part 499 guidance also specifies that the data must be submitted to the RFA region in a timely manner.

CMS engages providers in a risk adjustment data validation process in which it verifies that the diagnosis codes that inform a by MSA organization's submission to CMS are supported by beneficiaries' medical record documentation. The purpose of risk adjustment data validation is to ensure payment integrity and accuracy.

PacificCare of Texas

Pacific Air of Texas (Pacific Air) is an NVO company that is not subject to the proposed rules. The UnitedHealth Group is not an express contracting or an NVO company. For FY 2013 Pacific Air had multiple contracts with UHS, including contract number H-1590, which we refer to in this report as "the contract." Under the contract, UHS paid Pacific Air approximately \$1.3 billion to administer health care plans for approximately 1.3 million beneficiaries.

and service team and business units.

for example, a MS used diagnoses that KX is given, was submitted for the calendar year X . On data collection, prices for determining payments for the FY 2007 payment prices.

and then a further refinement will likely produce the optimal set $\hat{M}_k$ and interest in high-order discontinuous reconstructions is increasing. In fact, previous work would allow us to conjecture that $\hat{M}_k$ may converge to a set $\hat{M}_\infty$ which is independent of k .

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OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the risk adjustment data that PacificCare submitted to CMS for FY 2010 risk adjustment complied with the requirements set forth in the Participant Guide.

Scope

Our review covered \$827 million of CY 2010 MA payments that CMS made to PacificCare on behalf of 57,373 beneficiaries. These payments were based on risk adjustment data that PacificCare submitted to CMS for FY 2010 dates of service for beneficiaries who were aged 18 to 64, with a primary diagnosis of mental illness, 20% of the ages 65 to 64, with a primary diagnosis of mental illness, and 10% of the ages 65 to 64, with a primary diagnosis of mental illness. We limited our objective and no-assignment survey review of PacificCare's overall internal control structure to gathering evidence on the collection process for the risk adjustment data.

We reviewed CMS's risk adjustment validation process, which did not request all medical records associated with a beneficiary. Instead, we limited our request to the portion of the sampled beneficiary's medical record associated with an encounter that, in PacificCare's judgment, best supported the risk adjustment diagnosis that was submitted to CMS. To verify that risk adjustment diagnosis information was accurate, we selected the data on two representative sample beneficiaries to review documentation for the purpose of this report; we refer to this medical record assessment throughout the report as "review" and as "documentation."

We did not calculate the entropy of the assignment of the risk scores.

We performed our fieldwork at 11 medical clinics in Minnesota, Minnesota, and at CMS in Baltimore, Maryland, from October 2018 through December 2019.

Methodology

To accomplish our objective, we did the following:

- We reviewed applicable Federal laws, regulations, and guidance regarding payments to MA organizations.
- We interviewed CMS officials to obtain an understanding of the model.
- We obtained the services of a medical review contractor to determine whether the documentation that PacificCare submitted supported the HCCs in our sample.

¹ We limited our sampling frame to continuously enrolled beneficiaries to ensure that PacificCare was responsible for obtaining the risk adjustment data for the risk scores subject to our review.

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- We retrieved UnitedHealth Group's efforts to guarantee standardizing of EHR data via its internal controls for obtaining risk adjustment data from providers, processing the data, and submitting the data to CMS.
- We obtained enrollment data (i.e. 2017 beneficiary risk score data) and 2018 risk adjustment data from CMS.
- We first identified 62,987 beneficiaries associated with the Saxton Insurance network. These beneficiaries were continuously enrolled under the contract during all of CY 2016 and January of CY 2017, and (2) had a risk score that is below the top 25% of first-line HC.
- We selected a simple random sample of 100 beneficiaries with 25 HC's (see Appendix B.4 for more information about our sample design and methodology). For each sample beneficiary, we:

We revised our sampling frame to exclusively include hotel chains in cities that they are responsible for admitting the risk assessment data that resulted in the risk scores subject to our review.

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highly specific (e.g., S. 2.2.2.1.2, paragraph 1). For the sampled jurisdictions that we determined to have implemented one or more effective risk controls, we identified a set of jurisdictions whose practices were based on the model of existing guidance to the pertinent controls or regulation. These jurisdictions are "Y" jurisdictions, as they published risk scores, and "E" or "overpayments in delay" jurisdictions, which are based on the difference between the old and new risk scores. (Although the language we suggested is more detailed, we believe it is not inquisitive. As indicated, we recommend revision to the more general language included in the prior version. If you disagree, let's discuss.)

- We estimated the total seasonal wage of overpayments based on our sample results. (See Appendix E) to our survey results and to Figure 1.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

FINDINGS AND RECOMMENDATIONS

The risk-adjustment standard requires that Panel 56, as submitted, not include a case (JO) whose risk score (level 1 or 2) did not always comply with the requirements set forth in the Participant Guide. (12) As a result, Panel 56 did not always reserve adequate payment (in \$ MS). Risk scores calculated using the diagnosis codes for the Participant's data for 56 of the 100 beneficiaries in our sample were valid. The risk scores for the remaining 44 beneficiaries were invalid because, for diagnosis 1, the Patient's submission was not appropriate because each of the 44 beneficiaries had at least one risk 1 that was not supported by documentation. (13) The 44 beneficiaries were placed in the risk category of level 2 because they had at least one risk 2 that was not supported. Because in our sample results, we determined that Panel 56 was supported at rate 86% (46/53).

Each of the 62 unsupplied EUs identified in my review was determined to be unsupplied for one or more of the following reasons:⁴

- The documentation did not support the associated diagnosis; also, were there dependent on HCC?
- The documentation did not include an appropriate: Was our issue whether the signature and credentials were appropriate, or was it that they were missing? If the latter, we suggest changing "an" to "a" and deleting inappropriate "[provider [physician]] signature and credentials."
- The diagnosis submitted for this was unacceptable for use and ten proposed corrections.

* The null hypothesis is: the proportion of the sample that says "yes" is less than or equal to the proportion in the population. The alternative hypothesis is: the proportion of the sample that says "yes" is greater than the proportion in the population.

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- The *Diagnostic Coding Manual* (“DCM”) is a 1992 document that is not an update to a

“book of codes” and is not a “text” that is “used” to “code” or “translate” physical conditions.¹⁴

As a result of these unapproved diagnoses, Pacificare received \$ 790.12 million overpayment from CMS per Appendix C.1. In 2003, in response to this, we learned that Pacificare was overpaid at least \$55,546,130. See Appendix D for an analysis of the unapproved ICD-9-CM coding and response to each error.

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Pacificare did not have written policies and procedures in place for coding, processing, and submitting new diagnosis-based claims to CMS. Furthermore, Pacificare’s quality assurance practices were not effective in ensuring that the diagnoses it submitted to CMS compared with the most recent *ICD-9-CM Coding Manual*. As a result, on occasions that all new risk adjustment data were submitted to CMS either the information that the data contained were accurate. UnitedHealth Group officials stated that providers were responsible for the accuracy of the diagnosis-based charges, those that Pacificare submitted to CMS, which is contrary to CMS’ position.

RISK ADJUSTMENT DATA VALIDATION REQUIREMENTS

On September 17, 2008, *ICD-9-CM Coding Manual* (“ICD-9-CM”) was updated to ICD-9-CM, version 9. The *ICD-9-CM* is a book that contains the codes and descriptions of the diseases, injuries, and conditions that are used to code medical services provided to a patient and is used by a provider, supplier, physician, or other professional. CMS may adjust the data necessary and appropriate for determining the accuracy of each ICD-9-CM diagnosis. The *ICD-9-CM* is a book that contains the codes and descriptions of the diseases, injuries, and conditions that are used to code medical services provided to a patient and is used by a provider, supplier, physician, or other professional. CMS may adjust the data necessary and appropriate for determining the accuracy of each ICD-9-CM diagnosis.

Diagnosis Coding

Pursuant to section 7.1.4 of the *Participated Guide*, a diagnosis submitted to CMS for risk adjustment purposes must be coded according to the *International Classification of Diseases, 9th Revision, Clinical Modification Guidelines for Coding and Reporting* (the “Coding Guidelines”). According to Section 2.1 of the *Coding Guidelines*, states that for each hospital inpatient stay, the hospital’s medical record reviewer should code the principal diagnosis and “... all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded.”

In *UnitedHealth Group v. UnitedHealthcare*, Section IV of the *Coding Guidelines* states that “[e]ach hospital’s medical record reviewer should “[e]xclude all documented conditions that

¹⁴ A typical example is that a provider does not apply and the two patients mean to be treated typically provided by a physician, usually a nurse practitioner or physician assistant.

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coexist at the time of the encounter visit, and require or affect patient care/treatment or management.” The Coding Guidelines also state that conditions should not be coded “if they” were previously treated and no longer exist. However, “history codes” may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment.” Additionally, diagnoses that are “probable,” “suspected,” “questionable,” “working,” or “trial and,” should not be coded.

Medical Record Documentation

The Participant Guide requires that documentation support the MRA assessment as described in the various Part IV components and direct the use of CMS’s manual coding criteria.

Specifically, the Participant Guide requires (emphasis supplied) the following with respect to documentation for MRA component’s related to CMS’s valuation: “benefiting risk scores—regardless of:”

- The documentation must be based on a face-to-face visit with one of the three provider types associated with the adjustment. Benefiting risk scores are applied without a compliance check.
- The documentation must include an acceptable physician signature and specialty credentials. Examples of acceptable physician signatures include handwritten signatures or initials, signature stamps that comply with State regulations, and electronic signatures with authentication by the respective providers. Typed names or printouts of nonphysicians or nonphysician extenders (e.g., medical students), and signatures without credentials are unacceptable for risk adjustment purposes (section 7.2.4.2.1).
- Documentation must be in a form of acceptable type. Acceptable types of documentation include physician or registered nurse notes of patient encounters, diagnosis reports, discharge notes, consult notes, and any documentation or data collected via services outside the claim collection period (section 7.2.4.2.2).

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Additionally, the Participant Guide (section 7.2.4.4) specifies several sources of documentation that are not acceptable for risk adjustment data collection:

- skilled nursing facilities;
- direct support organizations or group homes;
- ambulatory care centers or pharmacies;
- other physician extenders (e.g., nurse practitioners);

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- For one beneficiary, PacificCare submitted a diagnosis code indicating for "malignant neoplasm of the brain, cerebrum, except for lobes and ventricles." As a result, CMS associated with the HCUP system and the diagnosis associated HCUP code to the beneficiary's risk score. However, the documentation that PacificCare provided regarding the diagnosis of benign prostatic hypertrophy. The documentation did not mention the beneficiary's brain cancer or indicate that brain cancer had affected the care, treatment, or management provided during the encounter.

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Missing Signatures and Credentials

Fourteen HCUs were unsupported because the documentation that PacificCare provided did not include the physician's signatures and credentials.

For example, for one beneficiary PacificCare submitted a diagnosis code for congestive heart failure, unspecified. As a result, CMS associated with the HCUP system and the diagnosis associated HCUP code to the beneficiary's risk score. However, the documentation that PacificCare submitted was not signed by the physician. The documentation stated, "This report has been dictated but not proofread and is subject to correction of transcription variances & edit."

Unconfirmed Diagnoses

Three HCUs were unsupported because the diagnoses submitted to CMS were unconfirmed.

For example, for one beneficiary PacificCare submitted a diagnosis code for cardiovascular disease, obstructive pulmonary disease, not elsewhere specified. As a result, CMS associated with the HCUP system and the diagnosis associated HCUP code to the beneficiary's risk score. The physician's impression was documented that the patient had a long history of smoking with possible mild chronic obstructive pulmonary disease. (For this example, please confirm and indicate that this was a physician or outpatient/hospital encounter. (The criteria do not apply to inpatient encounters.) Diagnoses that are "probable," "suspected," "questionable," or "working" or "crossed out" should not have been assigned.

No Face-to-Face Visits: Unreliable Documentation

Two HCUs were unsupported because the documentation provided in support of the diagnosis (heart failure) was not signed by a physician. No other documentation was provided in support of these two HCUs. Another unsupported diagnosis was a patient diagnosis that type of documentation required support from a physician or other healthcare provider who is not a physician.

For example, for one beneficiary PacificCare submitted a diagnosis code for one beneficiary out-patient, inflammation and toxic neuropathy, unspecified. As a result, CMS associated with the HCUP system and the diagnosis associated HCUP code to the beneficiary's risk score. The physician's impression was documented that the patient had a long history of smoking. However, the

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documentation about the file are provided regardless of native connection protocol and file location (local or remote) and the location path is resolved by global type for the specific host (e.g., `http://www.example.com`).

CAUSES OF OVERPAYMENTS

As a result of the above, the following theorem holds.

During our audit period, Pacificare did not have written policies and procedures for obtaining, processing, and submitting risk adjustment data. Pacificare informed us that it had since developed formal policies and procedures, but had not implemented them as of December 2, 2019.

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Although 2-year-life expectancy was used as a proxy for survival, it is likely that this measure is not a perfect proxy for quality of life. Furthermore, quality of life may be affected by the timing of the diagnosis, the extent of the disease, and the effectiveness of the treatment. Although the accuracy of the diagnosis, the extent of the disease, and the effectiveness of the treatment were not directly measured, they were indirectly measured by the use of the following variables: (1) the extent of the disease was measured by the use of the extent of the disease at the time of diagnosis; (2) the effectiveness of the treatment was measured by the use of the extent of the disease at the time of diagnosis; and (3) the extent of the disease was measured by the use of the extent of the disease at the time of diagnosis. The use of these variables as proxies for survival is likely to be biased, but the bias is likely to be in the same direction for all groups, and thus the relative ranking of the groups is likely to be preserved.

[illegible]

Participants were informed by the research provider that the diagnosis was possible if their codes corresponded to valid ICD-9 diagnosis codes.¹¹ Any error that one did not respond to valid diagnosis codes was the responsibility of the participants because the purpose was to test their ability to work specific without medical diagnosis. *Example:* These errors were first reviewed by a board of ethics and clinical analysts who determined whether the errors could be corrected by reviewing the original clinical notes entry, if not the provider corrected. A board of ethics and clinical analysts determined whether the errors could be corrected. The research group was not informed of this. Overall, one-fifth of the misclassified in 2008 and 2009, 19.4 percent of diagnosis errors were rejected as invalid and manually corrected. The article also said that they thought the 2007 internet report was incorrect. The study's error control checklist was also incorrect identifying and correcting invalid diagnosis codes. However, as pointed out by the low percentage of invalid diagnosis codes, Pacific Eye identified invalid codes were a minor source of risk (as mentioned in 2008).

* The 1996 prevalence of childhood overweight and obesity is based on information from the publication period standard classification of diseases as health records. Current circumstances are determined by extrapolation of 2% annual decrease in prevalence from 1996 to childhood year 2000.

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(4) $\text{H}^1(\mathbb{R}^n, \mathbb{R}) \cong \mathbb{R}$.

existing self-reported survey data and were linked as much as possible to data on the subject countries' income per capita. The results may, however, be properly tested against a parallel, substantial clearing of other self-reported data, including beneficiaries' drug use. The pursuit of the research was consistent with the objectives that were established in the identification and field-based evaluation of DHS. The research design reviewed and ensured the accuracy of the data.

$$\dot{z} = \dot{z}_p + \dot{z}^* = \dot{z}_p + \frac{1}{\tau} (z^* - z)$$

During chart abstraction, the diagnosis codes submitted by providers were reviewed to determine whether they were supported and valid. Part 10 was used when it fit into the chart abstraction to represent ICD-9 codes in terms of codes and Outpatient use for internal audit purposes. Part 10 and its chart utilization was not formally used for quality assurance purposes. When chart abstractions were used for quality assurance purposes, the chart abstractions included only those diagnoses that received a financial payment. Of the practice, we selected a series of 100 patients as a point of entry to the significant data to be analyzed, namely, Part 10 only, provided we could find the patients, date of diagnosis, and date of ICD-9 coded with the diagnosis of the dominant trade. For *accuracy*, it is only stated that Part 10 is not a source of a complete picture of the patient's care, they have a limited Part 10 only.

ESTIMATE OF UNRECOVERABLE PAYMENTS

Based on our sample results, we estimated that Pacifica are was compensated at least \$89,546,120 for a ton of the fish it sees the Pacific states discarded but MSW is not a good fit.

RECOMMENDATIONS

We assumed that β is 0.05.

- return to the Federal Government \$88,546,120 in overpayments;
 - implement formal policies and procedures for obtaining, processing, and submitting payed risk adjusting data; and
 - create a review and more robust cost-containment review process by periodically selecting and displaying a random sample of all providers' applied records to compare if the numerical difference between cost-bills are acceptable and why any cost data overruns that do occur are in compliance with the requirements set forth in the Partic-part rule.
- Let's discuss whether we can support this recommendation.

¹ For details see e.g. [15] for a review of the various theoretical approaches to the problem.

[P 45]

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APPENDIXES

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APPENDIX AC: SAMPLE RISK-ADJUSTED PAYMENTS TO PACIFICARE, ACTUAL AMOUNTS OWED, AND OVERPAYMENTS/UNDERPAYMENT

[Please rearrange the appendices for consistency with the way they are introduced in the report.]

Sample Number	Payments to Pacificare	Adjusted Amount	Overpayment (Underpayment)
2	520,007.10	517,958.67	\$6,942.47
4	21,421.06	14,574.48	6,947.20
5	10,714.07	7,138.37	3,575.60
7	3,095.68	2,992.70	1,101.16
8	1,475.48	1,015.06	460.42
10	55,115.16	54,106.64	1,412.52
11	25,768.57	7,778.40	18,310.02
13	15,202.70	12,528.70	3,570.00
15	11,127.12	8,581.66	2,545.66
17	29,002.84	25,244.70	2,979.00
18	8,265.00	4,706.40	3,576.60
20	12,881.52	7,242.48	5,639.04
21	10,081.28	8,523.84	1,557.44
25	6,431.36	4,392.48	2,038.88
26	17,858.78	17,061.64	3,897.24
27	16,210.16	9,487.84	6,722.32
29	12,308.16	9,021.24	3,286.92
35	10,127.24	6,052.64	4,074.00
38	7,241.58	5,555.96	1,586.40
39	12,580.07	7,243.44	5,337.48
41	5,156.60	2,026.09	2,512.71
42	7,664.24	4,200.96	3,050.28
45	6,411.32	5,132.70	2,279.16
48	7,810.64	5,583.60	2,406.04
50	9,144.00	4,943.76	3,500.84
51	0,234.04	7,497.84	730.20
53	11,021.00	6,036.64	2,309.50
54	15,678.70	7,347.84	8,710.68
55	6,270.80	4,943.64	2,376.16
57	39,051.52	28,044.84	9,106.68
62	40,112.40	27,879.70	12,234.24
65	8,162.70	6,697.18	2,565.44
66	14,808.24	11,779.00	3,030.24
68	26,076.12	17,595.76	9,480.36
74	29,050.44	6,036.70	20,492.20
76	8,430.20	4,515.04	1,595.16
77	10,712.12	3,771.00	6,941.12
81	36,744.84	37,700.62	1061.081
85	15,843.00	15,014.28	828.72
88	8,634.36	6,429.02	1,404.91
91	6,193.52	4,274.64	2,918.88
92	7,536.32	5,038.64	2,899.68
94	16,055.64	11,112.24	4,943.40

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	33	12,650.04	5,040.00	7,907.04
Total	44	56,79,280.25	54,75,624.10	5,199,572.15

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APPENDIX B.1: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population included beneficiaries who were continuously enrolled under H4590 during all of calendar year (CY) 2006 (the data collection period) and January of CY 2007 (CY 2007 was the payment period) and (2) had at least one diagnosis relevant to the CY 2007 Centers for Medicare & Medicaid Services Therapeutic Condition Category payment model (the model).

SAMPLING FRAME

The sampling frame included 52,987 beneficiaries on whose behalf CMS paid Part D out of Texas approximately \$877 million for CY 2007.

SAMPLE UNIT

The sample unit is a continuously enrolled beneficiary who had one or more diagnoses relevant to the model.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 890 beneficiaries.

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services, RAT-STATS statistical sampling software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the frame from 1 to 12,987. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used RAT-STATS to estimate the amount of incorrect payments.

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APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Results				
Sampling Frame Size	Sample Size	Value of Sample	Number of Beneficiaries with Unmet Payments	Value of Overpayments
62,961	100	\$1,143,621	44	\$199,612

Estimates
(Limits Calculated for a 90-Percent Confidence Interval)

	Estimated Overpayments
Point estimate	\$125,767,226
Lower Limit	\$59,546,120
Upper Limit	\$192,988,333

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APPENDIX D: REASONS FOR INVALID SAMPLES

(Please delete columns 2, 3, 5, 7, and 9 and adjust the Ns such that the total number of Ns =
in each of the remaining four columns agree with the number of unsupported HCCs in
each of the four findings. Also, please add a column at the right indicating the total
number of deficiencies for each HCC.)

[Formatted: 10h]

- 1 Unsupp'd Diagnostic Code
- 2 Unsupp'd Diagnostic Code and Other Reason
- 3 Unsupp'd Diagnostic Code Category (Obtain the actual number of diagnoses)
- 4 Missing signature on test column
- 5 Missing signature on test column and Other Reason
- 6 Unidentified Diagnosis
- 7 Unidentified Signature and Other Reason
- 8 No analysis (see Validation report) - *Refused* or *Not*
- 9 No data to use for analysis (see Validation)

Sample No. Hierarchical Condition Category	1	2	3	4	5	6	7	8	9
2-21	N								
2-105		N			N				N
4-55		N			N				
4-105		N			N				
5-80	N								
7-96		N					N		
7-105	N								
8-74	N								
10-15	N								
11-55		N			N				
11-80				N					
11-83				N					
11-108				N					
13-80		N					N		
14-10				N					
17-71	N								
18-80	N								
20-16	N								
20-55		N			N				
21-10	N								
25-71	N								
26-80	N								

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Sample No. - Hierarchical Condition Category	1	2	3	4	5	6	7	8	9
27-80	X								
27-96	X								
27-105	X								
28-35		X			X				
35-158	X								
38-19	X								
39-15	X		X						
39-132	X								
41-55	X								
42-55	X								
45-85		X			X				
49-10	X								
50-108	X								
51-18	X		X						
53-96	X								
54-15	X		X						
54-71		X							X
54-108	X								
55-10		X			X				
57-80	X								
57-105	X								
62-96	X								
62-108						X			
65-71	X								
66-92	X								
68-105	X								
68-108	X								
74-8	X								
74-71		X			X				
75-152	X								
77-9	X								
81-96	X								
85-15	X								
86-37	X								
86-105		X			X				
86-159	X								

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Sample No. - Hierarchical Condition Category	1	2	3	4	5	6	7	8	9
Q1:018	2								
Q2:018	2								
Q1:17	8								
Q6:9	5								
Totals	44	15	5	4	10	1	2	0	2

EXHIBIT D-74

Risk Adjustment Data Validation (RADV) Contract-Level Audits

Center for Medicare
January 13, 2012

EXHIBIT
1143-1

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

Agenda

- Background on RADV audits
- Current status of audits
- Policy issues
 1. Timing of audits
 2. Model Calibration Factor
 3. Number of annual audits and selection criteria [[reversed #3 and #4]]
 4. Audit documentation standards – One Best Medical Record policy

Background

- Of approximately \$112.2 billion in Medicare Advantage payments in CY 2009, approximately 11.0%, or \$12.4 billion are estimated to be improper payments (gross dollars in error, as reported in FY 2011 AFR for CY 2009 payment year).
- Most of the CY 2009 improper payments are due to MA organizations' submitting diagnoses to CMS for enhanced payment and not being able to document these diagnoses in a medical record.
- CMS developed its Risk Adjustment Data Validation (RADV) audits as its primary corrective action to recoup these improper payments.

Basic RADV Audit Methodology

- Sample beneficiaries enrolled in MA plans
- Request medical records for their Hierarchical Condition Codes (HCCs)
- Review medical records for supporting diagnosis information
- Correct HCCs and risk score
- Recalculate correct payment
- Estimate contract-level error using extrapolation

Current Status

- On December 21, 2010, CMS released a proposed RADV contract-level audit methodology for public comment.
- CMS solicited comments on two issues in particular:
 - RADV sampling methodology
 - RADV payment error calculation methodology
- CMS received over 500 comments from health plans, trade associations, law firms, and the public.
- Health plan industry is eagerly awaiting CMS's final methodology, and has raised significant concerns with CMS's proposed methodology.
- CMS plans to publish the final RADV methodology at the time the MA/Part D Advance Notice is released (February 2012).

Policy Issue #1: Timing of First RADV Audits Using Payment Recovery Based on Extrapolation

- Issue: Medicare Advantage plans most recently have argued that RADV payment recovery based on extrapolation should begin with plan year 2011 rather than 2007 as CMS originally proposed.

Plans argue they did not have sufficient information on RADV audits to 1) understand the implications of RADV and build their plan operations accordingly; or 2) bid appropriately.

- CMS Recommendation:
 - RADV audits start with payment year 2011 and will be conducted every calendar year thereafter. Recovery would start in Jan. 2014.

Note that the RADV proposal in the President's Plan for Economic Growth and Deficit Reduction begins with payment year 2008.

Policy Issue #2: Model Calibration Factor (MCF)

- Issue: Medicare Advantage plans argue that they are being held to a standard of coding perfection that is greater than observed for the traditional fee-for-service program.
- CMS Recommendation: CMS will apply an MCF adjustment to payment error estimates to account for the underlying error in the traditional fee-for-service program.

Applying the MCF adjustment accounts for the fact that the documentation standard used in RADV audits to determine a plan's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims).

Policy Issue #3: Number of Plans to Audit and Selection Criteria

Issue: How many plans should be subject to RADV audits each year, and what criteria should be used to select plans for audit?

CMS Recommendation:

- CMS should audit 30 plans per year. [deleted other text]
- Select plans for audit based on their coding intensity scores, targeting more plans with higher levels of coding intensity.

Policy Issue #4: Audit Documentation Standards

- Issue: Medicare Advantage plans object to CMS's current documentation standards for plans to select the "one best medical record" to validate their risk adjustment scores.
 - Plans want to submit more than one medical record, documentation other than medical records, and documentation from outside of the collection period to validate HCCs.
- CMS Recommendation:
 - Allow unlimited submission of medical records. Recognize underpayment from the first medical record that validates the diagnosis being audited.
 - (Alternative) Maintain current policy, recently modified in response to industry comments (with a proposed increase for submission time, medical record selection support, and interactive submission process) while still requiring plans to document a patient's risk score with at least one medical record from the collection period.
 - (Alternative) Increase the number of medical records the plan can submit, e.g., to two records, and recognize underpayment on all medical records submitted.

CMS Responses to Industry Concerns about RADV Policies

CMS' previous responses to industry concerns:

- Permit attestations to allow for physicians signatures and credentials in instances where medical records lacked either for outpatient and physician records
- Provide specific guidance in the form of Best Practices to Medicare Advantage plans to help MA contracts identify valid medical records for submission and address problems regarding diagnosis documentation
- Provide additional time to gather and submit medical records, representing a change in policy from 12 to 16 weeks
- Provide an interactive electronic CMS-HCC coversheet to prompt MA contract to confirm that medical record meets RADV guidelines and to guide the MA contracts through the submission process
- Credit additional identified during medical record review
- Medical Record Dispute process permits plan to request subsequent review of medical record and may reduce payment error

CMS continues to demonstrate its willingness to assist the industry in conducting RADV audit activity:

- Begin with CY2011 audit year allows plan/provider more timely access to medical records
- Allow multiple records to assist MA contract with selection of OBMR
- Apply Model Calibration Factor (FFS Adjustor) to account for appropriate level of coding accuracy

EXHIBIT D-75

**REDACTED VERSION OF
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FILED UNDER SEAL**



CON11 RADV Results



MPPG

May 26, 2016

EXHIBIT

1187-1

2247

Introduction

- Today we present preliminary results of the CON11 RADV audit.
- We audited 201 enrollees in each of 30 MA contracts for PY 2011 (2010 dates of service). Contracts were selected based on coding intensity: 20 from the “High” group, 5 from “Medium,” and 5 from “Low.”
- MAOs were allowed 20 weeks to submit medical records, and we received over 42,000 submissions for over 6,000 beneficiaries.
- Certified medical record coders review and code the medical records, with independent verification of the results by other coders.
- Payment error amounts are reduced by:
 - “Additional,” which are HCCs found during medical record review that are not among the audited HCC(s) for the enrollee.
 - RADV finding a more severe manifestation of an audited HCC than what the MAO submitted for payment.
- The total preliminary CON11 recovery amount is \$98,178,040 (lower bound of a 99% confidence interval [CI]) without a Fee-for-Service Adjuster (FFSA).
 - “Preliminary” means before a FFSA and before appeals.

Audit Methodology

- Our audit methodology for CON11 is detailed in a publicly available white paper.
- We select 201 enrollees from the RADV-eligible population in each contract: 67 from each of three strata based on risk scores for the payment year.
- After medical record review, we determine preliminary recovery amounts by calculating a point estimate of the payment error for each contract and then computing a 99% confidence interval (CI) around the point estimate. The lower bound of the confidence interval for each contract is the recovery amount unless the lower bound is negative, in which case the recovery amount is constrained to \$0.
 - Preliminary recovery amounts are subject to change based on the FFSA and appeals, which are triggered by regulation upon release of the audit reports.
 - Using the lower bound of a 95% confidence interval would increase recoveries by about 40%, from \$98,178,040 to \$138,238,562. This would constitute a methodological change.
 - Using the lower bound of a 90% confidence interval would increase recoveries by about 66%, from \$98,178,040 to \$163,363,801. This would also constitute a methodological change.

Preliminary Recovery Amounts

Contract ID	Parent Org	Total PY 2011 Contract Payment	Weighted Net Payment Error (Point Estimate)	Recovery Amount (99% CI)	Recovery Amount (95% CI)	Recovery Amount (90% CI)
-------------	------------	--------------------------------	---	--------------------------	--------------------------	--------------------------

Preliminary Recovery Amounts (cont.)

Contract ID	Parent Org	Total PY 2011 Contract Payment	Weighted Net Payment Error (Point Estimate)	Recovery Amount (99% CI)	Recovery Amount (95% CI)	Recovery Amount (90% CI)
H0543	UnitedHealth Group, Inc.	\$3,606,115,507	\$32,363,041	-	-	-
H2226	UnitedHealth Group, Inc.	\$94,201,539	\$524,117	-	-	-
H4522	UnitedHealth Group, Inc.	\$132,156,899	(\$1,142,040)	-	-	-
H4590	UnitedHealth Group, Inc.	\$2,002,635,960	(\$3,943,825)	-	-	-

Contracts with Net Underpayments

At 99% CI	At 95% CI	At 90% CI
16	13	11

- Per our published methodology, a contract has a net underpayment if the lower bound of the confidence interval around the payment error point estimate is a negative amount.
- Based on point estimates of payment error alone, six CON11 contracts had net underpayments.
 - Compare this with TAR07, which had two contracts with net underpayments based on point estimates and four contracts with net underpayments based on the lower bound of the 99% CI.

Contracts with Net Underpayments at 99% CI

Contract ID	Parent Org	Total PY 2011 Contract Payment	Lower Bound of 99% CI	Underpayment as % of Total Payment	HCC Discrepancy Rate ³
				-6.15%	17.60%
				-5.60%	17.50%
				-4.79%	16.00%
H4522	UnitedHealth Group, Inc.	\$132,156,899	(\$4,622,640)	-3.50%	19.00%
H0543	UnitedHealth Group, Inc.	\$3,606,115,507	(\$91,884,129)	-2.55%	16.20%
H4590	UnitedHealth Group, Inc.	\$2,002,635,960	(\$51,017,738)	-2.55%	11.90%
				-2.53%	12.90%
				-2.20%	16.80%
				-1.65%	17.70%
				-1.58%	14.10%
				-1.52%	20.70%
				-1.49%	22.50%
				-1.15%	19.70%
				-0.73%	21.90%
				-0.59%	16.90%
				-0.44%	13.80%

¹ Contract does not have a net underpayment at the 95% CI

² Contract does not have a net underpayment at the 90% CI

³ Discrepancy rate is calculated as (discrepant HCCs for sampled enrollees / total audited HCCs for sampled enrollees)

Notes on Underpayments

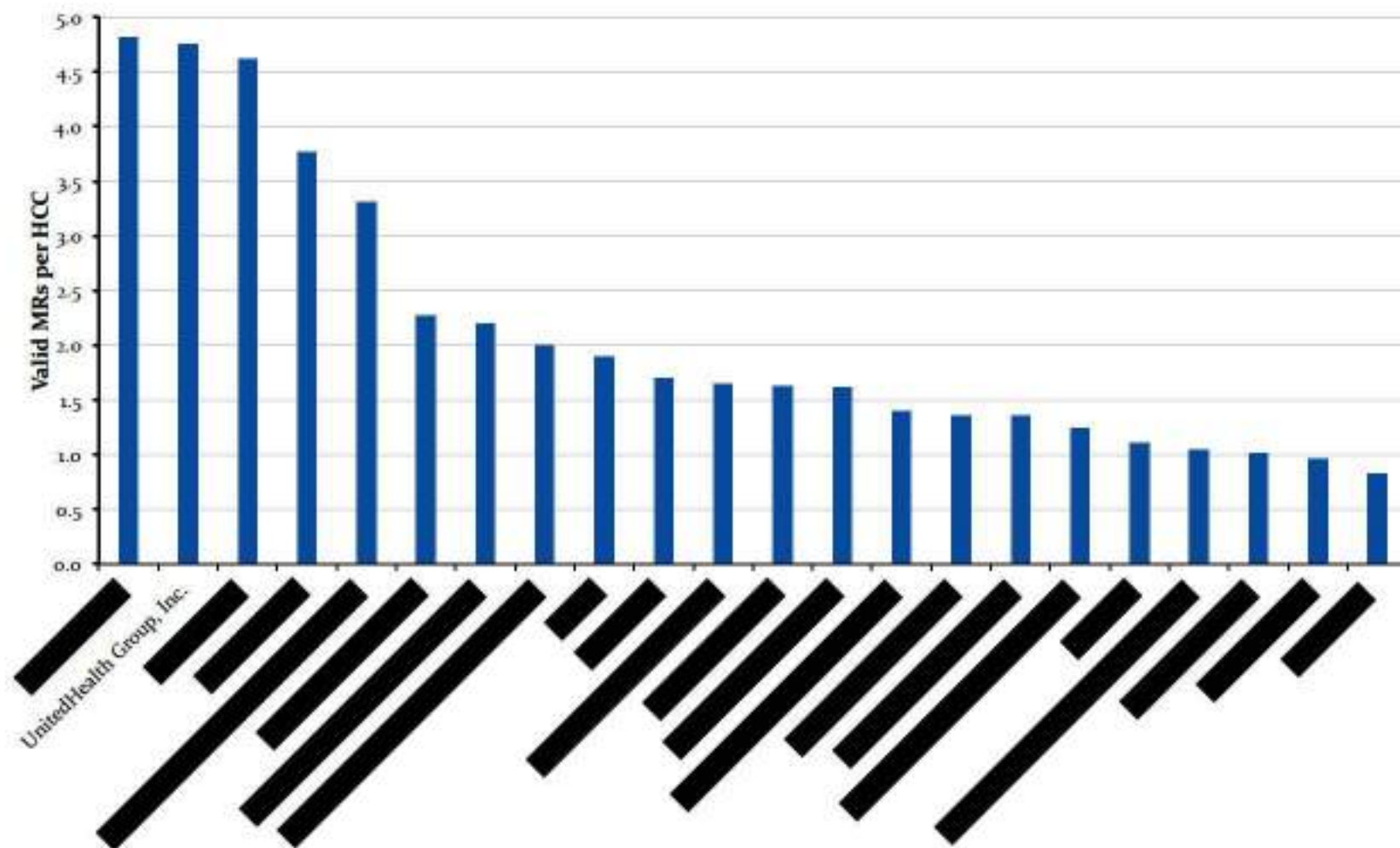
- All four (4) UnitedHealth Group contracts have net underpayments at the 99%, 95%, and 90% CI.
- Total PY 2011 payments to the 16 contracts on the previous slide were \$10,347,596,161, which is 67.8% of total PY 2011 payments to all 30 selected contracts.

-

-

Outliers
include H2226 (UnitedHealth Group) with 99 additional,

Average Number of Valid MRs per HCC*



* Valid MRs are those not invalidated due to missing DOS, missing signature/credential, or other issues. RADV policy generally allows up to five medical records per HCC.

HCC Discrepancy Rates for Major Parent Orgs

Parent Org	CON11 Discrepancy Rate	TAR07 Discrepancy Rate
	25.8%	45.3%
	23.5%	32.0%
	20.5%	30.7%
	15.0%	—
UnitedHealth Group	12.3%	38.7%

Note: Discrepancy rate is calculated as (discrepant HCCs for sampled enrollees / total audited HCCs for sampled enrollees)

HCC Discrepancies by Final Error Type

Final Error Type	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Coding/Incomplete	2,424	79.11%	2,424	79.11%
Invalid (non-Signature/non-Credential)	136	4.44%	2,560	83.55%
Missing	248	8.09%	2,808	91.64%
Invalid (Signature/Credential)	256	8.36%	3,064	100%

Coding/Incomplete: The medical record(s) reviewed for the audited CMS-HCC did not provide sufficient documentation of a diagnosis, in accordance with ICD-9 coding guidelines, to support the CMS-HCC being audited.

Invalid (non-Signature/non-Credential): The medical record(s) submitted for the audited CMS-HCC were invalid for reasons other than signature/credential issues.

Missing: No medical record was submitted for the audited CMS-HCC, and no other record submitted for the enrollee could confirm the CMS-HCC.

Invalid (Signature/Credential): The medical record submitted was ruled invalid because it did not contain a valid signature and/or credential.

Top 10 HCCs by Discrepancy Rate*

HCC	HCC Name	HCCs Sampled	Discrepancy Rate
HCC96	Ischemic or Unspecified Stroke	286	62.6%
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	28	57.1%
HCC82	Unstable Angina and Other Acute Ischemic Heart Disease	166	53.6%
HCC69	Spinal Cord Disorders/Injuries	41	46.3%
HCC104	Vascular Disease with Complications	179	44.7%
HCC51	Drug/Alcohol Psychosis	35	42.9%
HCC95	Cerebral Hemorrhage	26	42.3%
HCC37	Bone/Joint/Muscle Infections/Necrosis	73	38.4%
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	189	37.6%
HCC101	Cerebral Palsy and Other Paralytic Syndromes	24	37.5%
ALL[†]	—	16,263	18.8%

* Includes only HCCs sampled for at least 20 enrollees

† Includes all HCCs sampled for CON11

Top 10 Additional HCCs by Frequency

HCC	HCC Name	CON11 Rank	Mean Rank*
HCC19	Diabetes without Complication	1	1.5
HCC105	Vascular Disease	2	2.5
HCC71	Polyneuropathy	4 [†]	3.7
HCC83	Angina Pectoris/Old Myocardial Infarction	4 [†]	2.7
HCC16	Diabetes with Neurologic or Other Specified Manifestation	5	5.7
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	6	8
HCC80	Congestive Heart Failure	7	7.3
HCC108	Chronic Obstructive Pulmonary Disease	8	7.8
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	9	9
HCC131	Renal Failure	10	9

* Average rank across NAT08–NAT12 and CON11

[†] Tie

Top 10 Additional by Total Underpayment Amount

HCC	HCC Name	CON11 Rank	Mean Rank*
HCC7	Metastatic Cancer and Acute Leukemia	1	4.8
HCC105	Vascular Disease	2	1.7
HCC71	Polyneuropathy	3	3.8
HCC16	Diabetes with Neurologic or Other Specified Manifestation	4	5
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	5	6
HCC19	Diabetes without Complication	6	6
HCC77	Respirator Dependence/ Tracheostomy Status	7	8.5
HCC83	Angina Pectoris/Old Myocardial Infarction	8	4.2
HCC104	Vascular Disease with Complications	9	9
HCC80	Congestive Heart Failure	10	7.6

* Average rank across NAT08–NAT12 and CON11

Top 10 Additionalals by Average Underpayment Amount per HCC

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HCC	HCC Name	CON11 Average	Average for all Samples *
HCC7	Respirator Dependence/Tracheostomy Status	\$18,131	\$17,388
HCC77	Lung, Upper Digestive Tract, and Other Severe Cancers	\$15,457	\$10,914
HCC130	Dialysis Status	\$10,171	\$10,721
HCC8	Decubitus Ulcer of Skin	\$9,204	\$9,029
HCC25	End-Stage Liver Disease	\$8,970	\$8,259
HCC1	HIV/AIDS	\$8,308	\$8,308
HCC44	Severe Hematological Disorders	\$8,006	\$8,339
HCC68	Metastatic Cancer and Acute Leukemia	\$7,809	\$8,134
HCC45	Paraplegia	\$7,796	\$8,198
HCC148	Decubitus Ulcer of Skin	\$7,583	\$7,139

* Average underpayment amount per HCC across NAT08–NAT12 and CON11

OIG 2007 Audit Results vs. CON11 Results

Contract ID	Parent Org	OIG 2007 Payment Error Point Estimate *	OIG 2007 Lower Bound of 99% CI	CON11 Payment Error Point Estimate *	CON11 Lower Bound of 99% CI
H0543	UnitedHealth Group, Inc.	\$423,709,068	\$288,232,331	\$32,363,041	(\$91,884,129)
H4590	UnitedHealth Group, Inc.	\$115,422,084	\$82,129,887	(\$3,943,825)	(\$51,017,738)

* Point estimate is calculated as (payment error for sampled enrollees / sampling weight)

- In 2007, HHS OIG audited six contracts to estimate the payment error. All six of these contracts were also selected for CON11.
- All but one of the six contracts had a net underpayment for CON11 at the 99% CI. This may have been due to internal plan measures taken to delete inaccurate diagnoses in response to the OIG 2007 audit.

TAR07 Recovery Amounts

Contract ID	Parent Org	Recovery Amount
[REDACTED]		
H0609	UnitedHealth Group, Inc.	\$406,738
[REDACTED]		
H0151	UnitedHealth Group, Inc.	\$362,527
[REDACTED]		

Contract ID	Parent Org	Recovery Amount
[REDACTED]		

Key Differences Between CON11 and TAR07

- CMS' February 24, 2012, press release estimated the CON11 recovery amount at \$370M, based on extrapolating TAR07 results with a Fee-for-Service Adjuster applied.
- Unlike in TAR07, MAOs used routine CMS processes to self-report and return overpayments for PY 2011 data, which may have impacted overpayments identified by RADV. Total deletes submitted for PY 2011 for all contracts are (\$227,246,080.99).
- Five medical records per HCC were allowed for CON11, providing more opportunity for validating the audited HCC and finding additional HCCs; only one medical record per HCC was allowed for TAR07 (actual CON11 average was 2.5 records/HCC)
- Submissions for TAR07 occurred outside CDAT (MAOs filled out hardcopy Coversheets)
- Greater use of EMRs during time of CON11

Next Steps

- Issue proposed FFSA methodology for comment
- Issue CON11 audit reports to MAOs
 - Triggers the first set of administrative appeals, known as Reconsideration, which is comprised of re-reviewing medical records for disputed HCCs and the payment error calculation appeal
 - Using the extrapolated estimates at the lower bound of the 99% CI, about 10% of HCCs are eligible for the reconsideration phase of appeals (1,644 of ~16,000)
 - Next phase of appeals is with the Office of Hearings, and the third and final phase of appeals is with the Administrator

EXHIBIT D-76

DOJ's February 11, 2022 Attachment B: The United States' Custodians Employment Chart

Jennifer Harlow	CM/MPPG	Deputy Director	July 2012-present
		Division Director	Feb. 2007-July 2012
	CM/Medicare Plan Policy Group	Special Assistant and Senior Advisor	Sept. 2005-Feb. 2007
	CM/Health Plan Policy Group	Social Science Research Analyst	2000-2004
		Social Science Research Analyst	1998-2000

EXHIBIT

1253

2267

EXHIBIT D-77



CY 2011 CMS Risk Adjustment Data Validation Overview

October 9, 2012

EXHIBIT

1306

2268

Welcome

- Introductions

- o Cheri Rice

- Director, Medicare Plan Payment Group

- o Jonathan Smith

- Director, Division of Payment Validation

- o Tobi Pulley

- Acting Deputy Director, Division of Payment Validation

RADV Team Members

Maricruz Bonfante

Stacey Deiter

Esmail Essajee

Ashley Franzel

Kellie Gombeski

Carolyn Kapustij

Steve Ludwig

Objectives

- Presentation will provide information about the risk adjustment data validation (RADV) contract-level audits for payment year 2011
- Information geared toward the contract-level sample, not the national sample conducted annually for error rate reporting
- At the conclusion of the presentation, CMS will respond to questions that have been submitted in advance

Agenda

- What is RADV?
- Final Payment Error Calculation Methodology
- RADV Process: Selection for Audit through Appeals
- What Happens After My Contract is Selected for an Audit?
- Answers to Submitted Questions

CY 2011 CMS Risk Adjustment Data Validation Overview

What Is RADV?

Terminology

- AROF – Audit Report of Findings
- CDAT - Central Data Abstraction Tool
- CMS - HCC – Center for Medicare and Medicaid Services Hierarchical Condition Category
- INV - Invalid
- MRD - Medical Record Dispute
- MRR - Medical Record Review
- RADV - Risk Adjustment Data Validation
- RAPS – Risk Adjustment Processing System

Risk Adjustment Data Validation (RADV)

Overview

- RADV validates diagnoses submitted for payment.
- RADV is a corrective action to help reduce the Part C error rate.
 - Each year CMS reports a National Payment Error Estimate to comply with the Improper Payments Elimination and Recovery Act (IPERA) of 2010
- CMS expects that RADV will have a sentinel effect on quality of risk adjustment data submitted for payment going forward.

Risk Adjustment and Data Accuracy

- MA organizations are responsible for submitting accurate data to CMS for payment
- RADV is a method of evaluating the accuracy of the diagnoses submitted for payment

RADV Verifies Diagnoses Submitted for Payment

- MAO-submitted risk adjustment diagnoses must be:
 - Based on clinical medical record documentation from a face-to-face encounter (patient and provider)
 - Coded in accordance with the *ICD-9-CM Guidelines for Coding and Reporting*
 - Assigned based on dates of service within the data collection period
 - Submitted to the MA contracts by acceptable:
 - RA provider type
 - RA provider data source

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CY 2011 CMS Risk Adjustment Data Validation Overview

Final Payment Error Calculation Methodology

Final Payment Error Calculation Methodology

- On Feb 24, 2012 CMS released the

Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits.

- Notice available at: www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/PaymentValidation.html/

- Revised from the December 20, 2010 document CMS released for comment entitled

Medicare Advantage Risk Adjustment Data Validation Notice of Payment Error Calculation Methodology for Part C Organizations Selected for Contract-Level RADV Audits- Request for Comment

- CMS reviewed all comments received and considered them when finalizing the methodology

Final Payment Error Calculation Methodology

- Methodology will be applied to next round of contract level audits conducted on payment year 2011
- Extrapolation will begin with payment year 2011
- Approximately 30 contracts will be selected for audit
- Contracts will be able to submit multiple medical records per CMS-HCC
- Fee-for-Service Adjuster will be applied to payment recovery amounts

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CY 2011 CMS Risk Adjustment Data Validation Overview

RADV Process:
Selection for Audit through
Appeals

RADV Process -Sampling

- Step 1: Select MA Contracts eligible for RADV audits
 - Active contracts that received risk adjusted payments
- Step 2: Select enrollees eligible for sampling
 - Selection based on enrollment data for January of the payment year
 - Eligible enrollees:
 - 12 months of Part B during data collection year (i.e., Full Risk)
 - Continuously enrolled in the same contract from January of the data collection year through January of the payment year
 - Non-ESRD in status from January of the data collection year through January of the payment year;
 - No hospice-only status from January of the data collection year through January of the payment year;
 - At least one CMS-HCC assigned
 - All CMS-HCCs for selected enrollees will be reviewed

RADV Process – Sampling Size and Strata

- 201 enrollees will be selected from the contract's RADV eligible population
- Stratified, random sample
 - o 67 in each stratum
- Sampling weights
 - o Enrollee sample weight computed as the total number divided by the number of enrollees sampled from that stratum (N/n).
 - For RADV contract level samples $n = 67$

RADV Process – Medical Record Review

- Every valid submitted record is evaluated by coders according to the *ICD-9-CM Guidelines for Coding and Reporting*
- Contracts should adhere to the RADV rules and provide documentation as prescribed in the audit instructions
 - Failure to do so may render the contract's subsequent appeals invalid and impact the payment recovery amount.
- CMS uses the Central Data Abstraction Tool (CDAT) to facilitate the RADV process

RADV Process – Medical Record Review

- Effective with the CY 2011 RADV audits, CMS will allow audited MA contracts to submit up to five medical records for each audited CMS-HCC per enrollee.
- A CDAT management function will allow MA contracts to add, re-order, and delete medical records for each enrollee up until the submission deadline.
- CMS will consider individual hardship requests if an MA contract identifies the need to submit more than five medical records per sampled CMS - HCC.

RADV Process – Medical Record Review

- CMS will consider hardship requests in the extraordinary circumstance that a contract will need to submit more than five medical records to support a CMS-HCC for an enrollee
- Guidance pertaining to the hardship request will be included in the instructions packet issued to audited contracts

RADV Process – Medical Record Review

- Records submitted for RADV first undergo an intake evaluation
- For outpatient and physician records, a CMS-Generated Attestation may be submitted with a record that is missing a provider's signature and/or credential
- Only valid records go forward for coding

RADV Process – Medical Record Review

- CMS created the *Risk Adjustment Data Validation (RADV) Medical Record Checklist and Guidance* to assist contracts in selecting appropriate medical records
 - o The guidance is based on issues CMS observed with medical records submitted for previous RADV audits
 - o The guidance addresses issues observed during intake (incorrect date of service, unacceptable provider type, etc) and coding (diagnosis cannot be verified using ICD-9 guidelines).
- List available at <http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/radvchecklist.pdf>

RADV Process – Medical Record Review

- All diagnoses will be abstracted from the priority medical record that supports the CMS-HCC under review.
- Priority is based on the order in which medical records are arranged by the MA contract.

RADV Process - Payment Error Estimate and Payment Recovery Amount

- The medical record review (MRR) results feed the payment error estimate
- Enrollee Level Error = Original Payment – Post RADV Payment
- Apply the sampling weights to the enrollee level payment error to determine contract level error

RADV Process: Payment Error Estimate and Payment Recovery Amount

- Total all enrollee payment errors
- Calculate 99% confidence interval
- Payment Error Estimate is lower bound of 99% confidence interval
- Application of FFS Adjuster
- Payment Recovery Amount
 - Payment recovery will occur after all steps of medical record review have been completed, including medical record dispute
 - Recovery amounts will be deducted from a contract's monthly payment

RADV Process - Payment Error Estimate and Payment Recovery Amount

- Step One: calculate difference in payment based on MRR results for each sampled enrollee.

Actual payment – Post MRR payment = Enrollee level payment error

- Step two: apply sampling weights.

Un-weighted payment error X strata specific sampling weight (N/n) =
Extrapolated payment error for MA contract (point estimate)

RADV Process - Payment Error Estimate and Payment Recovery Amount

- Step three: calculate 99% confidence interval (CI) around payment error estimate
- Step four: determine payment recovery amount
 - If the CI for the point estimate includes zero or is below zero, payment recovery amount is constrained to zero
 - If CI is above zero, preliminary payment recovery amount is set at lower bound of 99% CI
 - Final payment recovery amount determined by applying a fee-for-service (FFS) adjuster to lower bound
 - If FFS adjuster amount is greater than preliminary payment recovery amount, final recovery is constrained to zero
 - Details on the FFS Adjuster will be shared in the future
 - Calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

RADV Process - Findings

- At the conclusion of the initial medical record review process, results will be issued to audited contracts
- Contracts will receive their Preliminary Audit Report of Findings (AROF)
 - For each audited CMS- HCC the Preliminary AROF will detail the validation outcome, error type (if applicable), and eligibility for medical record dispute
 - For each enrollee, the preliminary AROF will detail calculation of the corrected risk score and payment, based on initial medical record review results
- Contracts will receive information and instructions on medical record dispute (MRD) with the preliminary AROF

RADV Process - Medical Record Dispute

- MRD occurs after the initial medical record review results have been released to contracts
- Allows MA contracts an opportunity to dispute certain types of RADV-related errors
- Errors may be overturned through the MRD process
- For MRD, MA contracts will be allowed to select the “one best medical record” from the medical records it previously submitted for each audited CMS-HCC

RADV Process – MRD Findings

- At the conclusion of MRD, audited contracts will receive their finding through the Audit Report Post Medical Record Review
- Similar to the Preliminary AROF, the Audit Report Post Medical Record Review will detail CMS - HCC validation outcomes, error types, eligibility for appeal, as well as payment error recovery amounts
- Contracts will also receive instructions on filing appeals

Appeals

- Per 42 CFR § 422.311, MA contracts are afforded two types of appeals:
 - Medical Record Review Determination Appeal
 - Payment Error Calculation Appeal
- Full appeal rights are detailed in the regulation

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CY 2011 CMS Risk Adjustment Data Validation Overview

What Happens After My
Contract Is Selected for an
Audit?

What happens after my contract is selected for audit?

- The CEO and MCO for your MA contract will:
 - o Receive a CMS notification message via email containing:
 - Information about training and instructions availability
 - Directions on establishing three users for the Central Data Abstraction Tool (CDAT)
- Training will include
 - o CDAT Access Training Teleconference
 - o CMS Audit-Specific Teleconference, including CDAT submission training

What happens after my contract is selected for audit?

- CDAT is the secure system through which data related to RADV audits is transferred.
 - o MA contracts download enrollee data and audit instructions
 - o MA contracts upload medical records to CDAT
 - o Medical record review is conducted within the CDAT

What happens after my contract is selected for audit?

- Two types of training will be held prior to the start of the audit
 - o CDAT access training
 - Will instruct users on how to access and login to the system
 - o Audit specific training
 - Will instruct users on how to upload records to CDAT
 - Will also provide information and instructions for the audit

What happens after my contract is selected for audit?

- Enrollee data is available on CDAT following the CMS Audit-Specific Teleconference
- Medical record submission deadline will be 16 weeks after the data identifying sampled enrollees is released to contracts
- CMS will provide technical assistance regarding the submission process

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CY 2011 CMS Risk Adjustment Data Validation Overview

Answers to Submitted Questions

Questions and Answers

- CMS will answer questions that were submitted through radv@cms.hhs.gov
- If you have additional questions, please submit them to the RADV mailbox

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EXHIBIT D-79

June 4, 2013

DRAFT
Affordable Care Act Section 6402(a):
Reporting and Returning Overpayments
by Medicare Advantage Organizations and Part D Sponsors

PURPOSE:

The goal of the proposed regulatory changes described in this paper is to codify the Affordable Care Act requirement that Medicare Advantage organizations and Part D sponsors identify and return Medicare overpayments. This paper addresses six key issues related to this report and repay requirement.

BACKGROUND:

The Affordable Care Act (the Act) makes a number of changes to the Medicare program that enhance CMS' efforts to recover overpayments and combat fraud, waste and abuse. Section 6402(a) of the Act established 1128J(d) of the Social Security Act entitled "Reporting and Returning of Overpayments." Section 1128J(d)(1) of the Social Security Act requires a person who has received an overpayment under Titles XVIII and XIX to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor and to provide written documentation explaining the reason for the overpayment.

Section 1128J(d)(2) of the Social Security Act further requires that an overpayment must be reported and returned by the later of -- (1) the date which is 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable.

The Center for Program Integrity (CPI) issued a proposed rule in February 2012 that proposed several provisions regarding reporting and returning overpayments under section 6402 by providers in FFS Medicare. We propose to use the upcoming proposed Part C and D regulation for plan year 2015, which will be published this fall, as the vehicle for codifying the report and return requirement for MA organizations and Part D sponsors.

DISCUSSION:

This paper discusses six issues that will be addressed in the upcoming regulation and where decisions are needed for Medicare Parts C and D:

- **Issue 1.** Defining *Overpayment* for Medicare Parts C and D;
- **Issue 2.** Defining *Identified* for Medicare Parts C and D;
- **Issue 3.** Determining what the term *Applicable Reconciliation* means for Medicare Parts C and D;
- **Issue 4:** Determining the process for reporting and returning overpayments;
- **Issue 5:** Establish a look-back period for reporting Medicare Parts C and D overpayments; and
- **Issue 6:** Amending current payment regulations for Parts C and D to align with the new overpayment provisions.

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June 4, 2013

A number of the overpayment decisions apply equally to Part C and Part D payments; however, in several places a separate approach is needed for each program.

Due to the fact that this proposed overpayment rule will be released before CPI's final rule on overpayments, we must be cognizant not to refer in preamble to any element of our proposed policies as a CPI or Parts A and B final policy. Throughout this paper, differences and similarities in the two sets of proposals are noted.

ISSUE 1: Defining Overpayment for Medicare Part C and Medicare Part D

Section 1128J(d)(4)(B) of the Act defines the term "*overpayment*" as "any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title." (In this paper we use the term entity instead of person.) In the regulation text, should CMS adhere to the more general statutory definition of an *overpayment* in implementing this provision for Parts C and D or should CMS tailor the definition to Medicare Parts C and D?

OPTIONS:

Option 1: Propose the statutory definition. Under this approach, CMS would propose the statutory definition of *overpayment*, which provides CMS with maximum flexibility, and then provide in preamble some examples of overpayments specific to Medicare Parts C and D. CMS would further specify in sub-regulatory documents what constitutes Medicare Parts C and D overpayments. However, the downside to adopting this approach is that MA organizations and Part D sponsors may argue that the broad statutory definition of *overpayment* is not specific enough to be actionable. Of note, CPI proposed adopting the statutory definition of overpayment in their proposed rule, and received very few comments objecting to this definition.

Option 2: Further specify the statutory definition by incorporating parameters unique to Medicare Parts C and D. Under this approach, CMS would identify the universe of examples that would constitute an overpayment. The advantage in adopting this approach is that it clarifies in more detail what is and is not an overpayment in Medicare Parts C and D. The disadvantage with taking a more specific approach in defining overpayment in the regulations text is that CMS could unintentionally fail to cover all possibilities, thus creating exceptions that the industry could exploit, and the need for ongoing updates to regulation.

RECOMMENDATION:

Adopt the more general statutory definition of an *overpayment*. This would avoid the situation where we unintentionally omit from regulation an area of Medicare Part C or D payment for which MA organizations and Part D sponsors would have responsibility, thus creating loopholes. Also, in the event new laws change Medicare Parts C or D payment provisions in a way that impacts the regulation, we would not have to amend the definition of *overpayment*. We understand that CPI intends to utilize the statutory definition of *overpayment* in the Medicare Parts A and B final rule.

[PAGE 1* MERGEFORMAT]

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We would, however, recommend that we discuss in the preamble the general principle that the obligation to report and repay overpayments under Section 6402 applies in those circumstances in which the overpayment is the result of the use of data submitted to CMS by the plans. Plan-submitted payment data generally fall into three categories: enrollment transactions, risk adjustment data, and Prescription Drug Event/ Direct and Indirect Remuneration data. Plans have complete control over submitting and then correcting data that fall into these three categories.

There are other payment data that could lead to an overpayment that MA organizations and Part D sponsors do not control because these elements are submitted to CMS by the SSA, States, and other sources such as ESRD dialysis networks. The accuracy of these other data are ultimately the responsibility of the entity that controls the relevant system of record. We would clarify in preamble that plans have an obligation to report what they believe might be errors in these data, but the final determination of the accuracy of the data is responsibility of the entity that controls the system of record. As a result, we would clarify that, in these situations, a determination by the plan of whether an overpayment occurred is not possible and, therefore, would not be governed by Section 6402.

ISSUE 2. Defining *Identified* for Medicare Parts C and D

Section 1128J of the Act does not include a definition of the term "*identified*." Our understanding from CPI is that the definition of "*identified*" proposed in their proposed rule will likely be amended for the final rule, in response to public comments¹. The Center for Program Integrity's final definition of "identification" of overpayments may be refined to indicate that the person/entity has identified an overpayment if there was (or should have been) an exercise of "reasonable diligence" to determine whether they did receive an overpayment and if so, to quantify the amount with a reasonable degree of certainty. Further, we understand that CPI's approach to defining "reasonable diligence" is to indicate it includes both proactive activities to monitor payments and reactive activities to investigate a possible overpayment based on credible information the person/entity received about an overpayment.

RECOMMENDATION:

Redacted

¹ In CPI's NPRM, identified means that "a person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment." CPI mentioned that commenters indicated confusion about this definition (e.g., how persons are to identify potential overpayments and whether persons must take proactive steps).

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June 4, 2013

Redacted

ISSUE 3. Determining what the term “*applicable reconciliation*” means for Medicare Part C and D

Applicable Reconciliation. Section 1128J(d)(4)(B) of the Act defines the term *overpayment* as “any funds that a person receives or retains under title XVIII or XIX to which the person, after *applicable reconciliation*, is not entitled under such title.” Since Medicare Parts C and D payments go through elaborate reconciliation processes, CMS must determine what the term means within the context of the definition of *overpayment*, for MA organizations and Part D sponsors.

Risk Adjustment Reconciliation. Medicare makes “estimated” interim capitated payments to MA organizations and Part D sponsors for each enrollee each month with the knowledge that a reconciliation of those payments will be done when the actual costs or correct payment information, such as risk adjustment data, becomes available, usually at a later date. The initial “estimated” payments are based on the approved bids and preliminary risk adjustment data submitted by MA organizations and Part D sponsors. CMS makes prepayments at the beginning of the month based on the most current information available. Over time, as additional payment information becomes available, interim payments that were made throughout the payment year are reconciled. Final risk adjustment data are due by January 31st following the payment year. Overpayments are currently recognized and accepted after this point, but MA organizations cannot submit additional diagnoses for additional payment after the January 31st deadline. Therefore, January 31st provides a logical *applicable reconciliation*.

Annual Part D Reconciliation. In addition to the direct subsidy, Medicare Part D makes prospective payments to plans that cover the low-income cost-sharing subsidy (LICS) and the reinsurance subsidy. During the annual Part D payment reconciliation, CMS compares the finalized prospective payments and the corresponding actual costs reported on prescription drug events (PDEs) and makes payment adjustment according to the rules for LICS and reinsurance. In addition, after year-end (and after reconciliation of the direct subsidy payment), CMS compares actual covered drug costs to direct subsidy payments, and if they differ by legislatively specified percentages, CMS calculates a risk sharing payment adjustment. Plans have an additional reporting requirement to submit DIR data for the year-end reconciliation. Prior to performing the reinsurance reconciliation and risk sharing, the Net Part D Covered DIR amount is determined. The cost-based reconciliations for the LICS and the reinsurance subsidy (described at 42 CFR 423.343 (c) and (d), respectively) are the last reconciliation processes for the annual Part D payment reconciliation, and therefore provide a logical *applicable reconciliation* for Medicare Part D.

RECOMMENDATION:

We recommend adopting separate definitions of *applicable reconciliation* for risk adjustment data and for Part D payment data.

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Risk Adjustment: For risk adjustment data, *applicable reconciliation*, for the purposes of this rule, means

- *after the deadline for submitting diagnoses that will be used to calculate the risk scores that will be used in the final reconciliation of risk adjusted payments to MA organizations within the timeframes established within applicable MA regulations or other sub-regulatory guidance. See 42 CFR 310 (g) (2) for the annual deadline for risk adjustment data submission.*

Part D: For Medicare Part D, *applicable reconciliation*, for the purposes of this rule, means

- *The annual Part D payment reconciliation referred to in 42 CFR 423.343 (c) and (d).*

ISSUE 4. Determining the process for reporting and returning overpayments.

Section 1128J(d)(1) of the Social Security Act requires a person who has received an overpayment to report and return the overpayment. Section 1128J of the Act also provides that an overpayment must be reported and returned by the later of (i) the date which is 60 days after the date on which the overpayment was identified; or (ii) the date any corresponding cost report is due, if applicable. The statute does not define what *return* means in terms of the Secretary's responsibility. We believe the statute provides flexibility in the length of time, within reason, for CMS to process the overpayment returned by the MA organization or Part D sponsor. We do not believe the statute requires CMS to process the overpayment in the system within the 60 days after the date on which the overpayment was identified. This would be impossible to accomplish due to operational resource constraints. We would discuss this in the preamble.

RECOMMENDATION:

We recommend generally that MA organizations and Part D sponsors submit corrected data related to overpayments to CMS and that CMS then recoup overpayments through the routine payment adjustment processes. Therefore, a plan's obligation to "return" the overpayment would be met by reporting corrected data related to the overpayment and the timing of the actual overpayment recoupment would depend on the timing of when CMS performs the relevant payment update or reconciliation.

ISSUE 5. Look-back Period for Reporting Medicare Parts C and D Overpayments

After the applicable reconciliation, the look-back period is the timeframe within which MA organizations and Part D sponsors will be held accountable for both identifying and reporting overpayments. The question is how long should the look-back period be.

Current Policy for Finalizing Medicare Part C Payments. The applicable reconciliation and deadline for finalizing Medicare Part C payments is final risk adjustment reconciliation. However, payment adjustments are routinely conducted after this reconciliation in order to incorporate changes to plan and beneficiary information which impact the payment calculation. These changes to plan and beneficiary information can be discovered well after the final payment reconciliation and some necessitate special system runs to accommodate payment recalculations. Changes to beneficiaries risk score information generally trigger the larger payment adjustments.

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Recently, with RADV, plans have been paying more attention to submitting 'deletes' which essentially remove diagnoses from risk scores and result in payments being recouped from plans. Once risk adjusted payment are finalized, CMS only updates risk scores to address overpayments (e.g., "adds" are not taken and there are no "underpayments"). The timeframe for conducting a final risk adjustment reconciliation is established at 42 CFR 422.310(g) (2) as January 31st after the payment year. Payment adjustments based on final risk scores are typically made in August after the payment year has ended.

Current Policy for Finalizing Medicare Part D Payments. The timing for when the direct subsidy part of the Medicare Part D payment is final follows that for the Medicare Part C risk score final reconciliation, and the discussion above generally applies to the Medicare Part D direct subsidy payments. Medicare Part D regulations and Medicare Part D guidance do not define a time at which the cost-based reconciliations for a given contract year is considered final. To the contrary, 42 CFR 423.346(a) (2) contemplates a reopening 4 years after the date of the notice of the initial or reconsidered determination and 42 CFR 423.346(a) (3) contemplate a reopening at *any time* for fraud or similar fault of the Part D sponsor.

Multiple factors can cause overpayment related to the cost-based reconciliations, such as:

- An overstatement in the LICR, covered plan-paid amounts (CPP), Gross Covered Drug Cost Above the OOP Threshold (GDCA);
- An overstatement in of the TrOOP eligible fields (e.g., patient pay, LICR, reported gap discount, other TrOOP amount), which can lead to an overstatement in GDCA;
- Beneficiary is retroactively disenrolled, and the plan fails to delete the PDEs;
- Plan submitted a claim as if Medicare was primary when they were secondary;
- Underlying claim issue where the plan should have never submitted a PDE in the first place;
- Plan submits a duplicate PDE;
- Plan under-reports DIR, which could result in inflated reinsurance and risk-sharing payments; and
- Inaccuracies in bid data resulting in a plan being miscategorized for reconciliation

As stated in Issue 3 above, the proposed "*applicable reconciliation*" for Medicare Part D is to be the annual Part D payment reconciliations referred to in 42 CFR 423.343 (e) and (d). Part D sponsors will continue to submit PDEs and DIR data after the applicable reconciliation due to audit and other post reconciliation oversight activity. As a result, CMS will perform global reopenings of the reconciled contract years to reconcile payments with the new data received. To date, contract years 2006, 2007, and 2008 have been reopened, and CMS has released guidance stating that we intend to eventually perform a global reopening of 2011 once there is stability in the data for that year. This experience indicates to us that we will likely have to perform a reopening for every contract year. However, in light of the statutory overpayment provision that we plan to codify in this regulation, we do not believe that it is necessary do a reopening for a contract year anymore than once. We, therefore, propose that CMS may do one reopening 5 years from the initial cost-based reconciliations. This is approximately 6 years from the close of a contract year.

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June 4, 2013

CPI Proposed Rule for FFS. In CMS-6037-P, CPI proposed a 10 year look-back period. However, it is expected that the final regulation will move to a 6 year look-back period. This is because a 6 year period will not pose enforcement obstacles for the Department of Justice, and is consistent with the statute of limitations related to the False Claims Act and Civil Monetary Penalty provisions.

OPTIONS:

The following options address the look-back period for which MA organizations and Part D sponsors will need to ensure accurate payments.

Option 1: 10 year lookback period- MA organizations and Part D sponsors would be required to ensure accurate payments for 10 years after applicable reconciliation. This timeframe is consistent with the outer limit of the False Claims Act statute of limitations. This is also consistent with the record keeping requirements for the MA and Part D contracts and allows MA organizations and Part D sponsors to close their books and not have ongoing liability associated with an overpayment.

Option 2: 6 year lookback period- MA organizations and Part D sponsors would be required to ensure accurate payments for 6 years after applicable reconciliation. This option would be consistent with what we understand will be the final FFS policy. In CMS-6037-P, CPI proposed a 10 year look-back period. However, it is expected that the final regulation will move to a 6 year look-back period. This is because a 6 year period will not pose enforcement obstacles for the Department of Justice, and is consistent with the statute of limitations related to the False Claims Act and Civil Monetary Penalty provisions.

RECOMMENDATIONS:

We recommend Option 2. The 6 year look-back period allows MA organizations and Part D sponsors to ensure accurate payments within a reasonable amount of time. It takes into consideration the resource burden on MA organizations, Part D sponsors and CMS. For Part D sponsors, a 6 year look-back period also makes sense in light of the proposed changes to the reopening provision.

This approach is consistent with the maintenance of records requirements in MA and Part D contracts. There would be exceptions pertaining to fraud-related overpayments.

ISSUE 6. Amending current payment regulations for Parts C and D to align with the new overpayment provisions.

Issue 6.A. Currently the Part C regulation at 422.310(g)(2) states that CMS will not accept risk adjustment data after the annual January 31 late data submission deadline:

CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data.... until January 31 of the year following the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data

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June 4, 2013

that are received after the annual January 31 late data submission deadline will not be accepted for the purposes of reconciliation.

This paragraph also applies to Part D, by reference at 423.343(b), which states that adjustments to payments to account for updated risk adjustment data are made as provided in the Part C regulation at 422.310(g)(2).

CMS has not enforced this late deadline, especially given numerous requests in recent years from MA organizations that CMS allow them to submit updated risk adjustment records that delete diagnoses previously submitted for payment. Adjustments for overpayments after the deadline have been allowed, but not for underpayments (except in a very limited number of circumstances).

The proposed overpayment regulation will require organizations that identify overpayments under a look-back period of six years to submit corrected data to allow CMS to correct payment amounts.

RECOMMENDATION: We would propose to replace the final sentence in paragraph 422.310(g)(2) with the following sentence that references 422.326, the proposed new section with the Part C overpayment provisions.

CMS will determine the timeline and conditions under which risk adjustment data can be corrected for purposes of 422.326. However, additional diagnoses for the payment year cannot be submitted after the annual late data submission deadline.

Issue 6.B. Amend §422.310 to require MA organizations conducting medical record reviews to focus not only on identifying underpayments.

Under existing regulation, there is no requirement to for plans to audit medical records for overpayments. If a plan is conducting medical record reviews to identify underpayments, we recommend that they be required to audit as well for overpayments. We believe that CMS should codify this requirement, and now would be an effective time to make this change, as part of implementing the overpayment provisions of Section 6402(a) of the Act.

Redacted

(1) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive

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June 4, 2013

officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.....

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the data it submits under §422.310 are accurate, complete, and truthful.

The requirement would apply to those MA organizations that conduct medical record reviews for the purpose of evaluating their payments (i.e., evaluating the diagnosis data that they submit to CMS for payment). "Accurate and complete" risk adjustment data for a beneficiary should obligate an MA organization to identify and delete diagnoses it submitted to CMS systems but later found to not be supported by the medical record, as a part of any medical record review it undertakes.

RECOMMENDATION:

We recommend adding a new paragraph §422.310(c)(1)², stating:

"For any MA organization that conducts reviews of enrollee medical records (including reviews conducted by a related entity, contractor, or subcontractor), if any aspect of such reviews informs the MA organization's decisions on what risk adjustment data to submit or resubmit to CMS (including encounter data) for purposes of amending CMS' payments to the MA organization under §422.304, the methodology and implementation of such reviews cannot focus only on identification of underpayments. Such reviews must focus on the identification of any payment that was made by CMS in an incorrect amount, including both underpayments and overpayments."

² We would propose to renumber current 422.310(c)(1), which addresses RADV audits, as (c)(2), and then add this paragraph as (c)(1).

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EXHIBIT D-80

February 24, 2012

**Notice of Final Payment Error Calculation Methodology for
Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits**

Introduction

On December 21, 2010 the Centers for Medicare and Medicaid Services (CMS) posted on its website the "Medicare Advantage Risk Adjustment Data Validation (RADV) Notice of Payment Error Calculation Methodology for Part C Organizations Selected for RADV Audit – Request for Comment". CMS invited public comment on the proposed methodology, with such comments to be submitted in writing by Friday, January 21, 2011.

CMS carefully reviewed the more than 500 comments received on the draft methodology. This Notice responds to the analytic concerns raised relating to extrapolation and payment recovery and presents the final methodology for the RADV payment error calculation.

Following the background section, this Notice provides a general walkthrough of the RADV payment error calculation methodology in two sections: (A) sampling; and (B) payment error calculation.

This methodology will be applied to the next round of RADV contract-level audits, which will be conducted on payment year 2011. Payment year 2011 is the first year for which payment recovery based on extrapolated estimates will be conducted for Medicare Advantage (MA). Note that sampling for RADV audits will occur after the close of final reconciliation for the payment year being audited.

CMS' RADV audit initiative is the Agency's primary strategy to address the national payment error rate for the MA program, which is currently estimated to be 11 percent for FY 2011. In addition to recovery of overpayments through RADV audits, CMS also expects that these contract-level audits will have a sentinel effect on the quality of risk adjustment data submitted for payment by MA organizations.

Background

Section 1853(a)(3) of the Social Security Act requires that CMS risk adjust payments to Medicare Advantage (MA) organizations. In general, the current risk adjustment methodology relies on enrollee diagnoses, as specified by the International Classification of Disease, Ninth Revision Clinical Modification guidelines (ICD-9-CM), to prospectively adjust capitation payments for a given enrollee based on the health status of the enrollee. Diagnosis codes submitted by MA organizations are used to determine beneficiary risk scores, which in turn determine the risk-adjusted reimbursement.

RADV audits determine whether the diagnosis codes submitted by MA organizations can be validated by supporting medical record documentation. This medical record documentation must meet certain criteria and standards specified in RADV materials that CMS provides to audited contracts. Diagnoses that cannot be validated contribute to a payment error rate. This document describes the sampling methodology that CMS will use for RADV audits and the methodology for calculating the payment error for each audited Medicare Advantage contract.

EXHIBIT

1497-10
2318

A. Sampling

To conduct these audits, CMS selects a set of MA contracts for each RADV audit cycle. Enrollees are sampled from each selected MA contract for the purpose of estimating payment error related to risk adjustment.

Sampling Frame

First, CMS identifies all beneficiaries under each MA contract who are “RADV-eligible” because they meet the following criteria:

1. Enrolled in an MA contract (H-number, E-number, or R-number) in January of the payment year— based on CMS’ monthly member enrollment files;
2. Continuously enrolled in the same MA contract (as identified in step (1) above) from January of the data collection year through January of the payment year;
3. Non-End Stage Renal Disease (non-ESRD) status from January of the data collection year through January of the payment year;
4. Non-hospice status from January of the data collection year through January of the payment year;
5. Enrolled in Medicare Part B coverage for all 12 months during the data collection year (i.e., defined as full risk enrollees for risk adjusted payment); and
6. Had at least one risk adjustment diagnosis (ICD-9-CM code) submitted during the data collection year that led to at least one CMS-Hierarchical Condition Category (HCC) assignment for the payment year.

Sample Size and Strata

Next, CMS selects a sample of beneficiaries from each contract’s cohort of RADV-eligible enrollees. Enrollee-based stratification will be used in the process of sampling enrollees. In order to derive the strata, the RADV-eligible enrollees in each contract will be ranked from lowest to highest based on their community risk score. The enrollees will then be divided into three equal groups based on the total number of eligible enrollees, where the first group will include the third of enrollees with the highest risk scores and the third group will include the third of enrollees with the lowest risk scores. The remaining enrollees will be in the middle stratum.

CMS will select up to 201 enrollees for medical record review from each contract selected for a contract-level audit. For smaller contracts, i.e., those with fewer than 1,000 RADV-eligible enrollees, CMS will individually adjust their sample sizes by using the finite population correction factor. The sample sizes for these smaller contracts will be 201 or fewer enrollees.

To achieve a sample size of 201 enrollees per contract, sixty-seven (67) enrollees will be randomly sampled from each group or stratum. The corresponding stratum-based enrollee weights will be computed as the number of RADV-eligible enrollees in the population grouping (or stratum) divided by the number of enrollees selected from that grouping for the sample, i.e., N_h/n_h , where h represents the corresponding stratum.

For example, if a contract has 3,000 RADV-eligible enrollees, the enrollees would be ranked by risk score, then divided into three equal groups of 1,000 enrollees each (to represent high, medium, and low strata). An equal number of enrollees will be randomly selected from each group. The weight for each sampled enrollee will equal 14.925 (i.e., 1,000/67).

For small contracts with fewer than 1,000 RADV-eligible enrollees, the same enrollee-based stratification process will be applied; however, a proportionally smaller number of enrollees will be randomly sampled from each group or stratum.

The enrollee sampling weights will be used as multipliers to scale-up (or extrapolate) the sample payment error findings to the population it represents.

Once enrollees have been selected, the MA contract will be required to submit medical records to support all CMS-HCCs represented in the sampled beneficiaries' risk scores for the payment year.

Effective with the CY 2011 RADV audit, CMS will allow audited MA contracts to submit multiple medical records for each CMS-HCC being validated. All diagnoses will be abstracted from the first medical record that validates the CMS-HCC under review. The one best medical record policy will continue to apply to the RADV audit dispute and appeal processes outlined in 42 CFR §422.311. CMS will provide more detailed information in the RADV audit procedures that will be distributed to audited MA contracts.

B. Payment Error Calculation

Enrollee-level Payment Error Calculation

CMS will calculate each contract's payment error based on the validation results. For each sampled enrollee, the RADV-corrected risk score and corrected payment will be calculated based on the CMS-HCCs that are supported by RADV medical record review findings for the enrollee. Enrollee-level payment errors will be defined as the difference between the original payment and the RADV-corrected payment (per member per month). The payment error for each enrollee will be either positive (representing a net overpayment), or negative (representing a net underpayment). An annual payment error amount will be calculated for each sampled enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year.

Payment Error Extrapolation Calculation

To derive the payment error estimate for each MA contract, the annual payment error for each sampled enrollee will be multiplied by the enrollee's sampling weight (computed for each stratum [h] during the sampling phase as N_h/n_h , where N represents the number of enrollees in the RADV-eligible population and n is the number of enrollees sampled). The weighted enrollee annual payment error will be summed across all enrollees in the sample to determine an estimated payment error for the MA contract (the "point estimate"). A 99 percent confidence interval (CI) will then be calculated for the estimated payment error for each audited MA contract.

The following formulas illustrate computation of a 99 percent CI around the payment error estimate for one contract, assuming a sample size of 201, with 67 enrollees selected from each of three strata groupings.

The lower bound of the 99 percent CI is computed as the estimated payment error for the contract (PE) minus (2.575 multiplied by the standard error), or (PE – (2.575 * SE)). The standard error (SE) can be calculated as follows:

1. Derive the variance, v_h , (standard deviation squared) of the unweighted enrollee payment errors across the sample enrollees within each of the three strata (h).
2. Calculate the variance of the estimated total ($V_{\hat{\tau}}$) payment error, where N represents the number of enrollees in the RADV-eligible population of the h^{th} (1st, 2nd, 3rd) stratum:

$$V_{\hat{\tau}} = \sum_{h=1}^3 \frac{N_h^2}{67} v_h$$

3. The standard error is $SE_{\hat{\tau}} = \sqrt{V_{\hat{\tau}}}$

Payment Recovery Amount and the Fee-For-Service Adjuster

If the CI for the point estimate includes zero or is below zero, the contract will have the payment recovery amount constrained to zero.

If the CI for the point estimate is above zero, the payment recovery amount for the contract will be determined as follows. First, a preliminary payment recovery amount will be set at the lower bound of the 99 percent CI for the contract's point estimate. Second, to determine the final payment recovery amount, CMS will apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount. If the FFS Adjuster amount is greater than the preliminary recovery amount, the final recovery amount is equal to zero.

The FFS adjuster accounts for the fact that the documentation standard used in RADV audits to determine a contract's payment error (medical records) is different from the documentation standard used to develop the Part C risk-adjustment model (FFS claims). The actual amount of the adjuster will be calculated by CMS based on a RADV-like review of records submitted to support FFS claims data.

EXHIBIT D-81

**REDACTED VERSION OF
DOCUMENT PROPOSED TO BE
FILED UNDER SEAL**

PRODUCED IN NATIVE FORMAT

EXHIBIT

1497-18

2323

CONFIDENTIAL

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CMS RADV

– Comparison and Analysis of CON11, CON12 & CON13

December 8, 2017

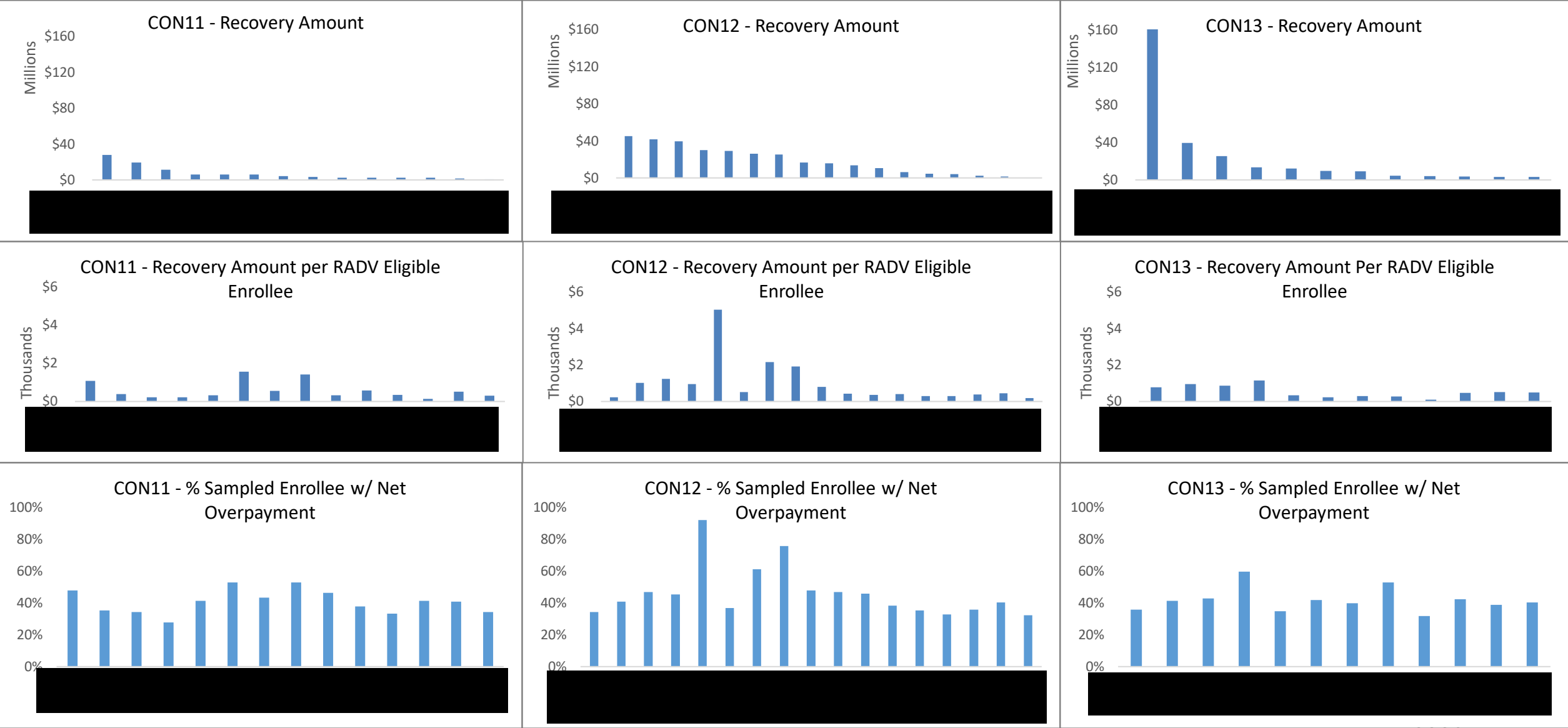
Sampling Differences for Contract Samples

	CON11	CON12	CON13
RADV-eligible enrollee threshold	1,000	2,000	5,000
Number of Contracts selected:	30	30	30
High Coding Intensity Stratum	20*	20	25
Medium Coding Intensity Stratum	5**	5	5
Low Coding Intensity Stratum	5	5	0
Number of RADV-eligible enrollees in 30 Sampled Contracts	778,808	838,373	902,451
Parent Organization Analysis			
4 United HealthGroup plans account for 0.0% of total recovery amount			6 United Health Group plans account for 1.4% of total recovery amount
5 United HealthGroup plans account for 5.0% of total recovery amount			

* includes 5 OIG-selected plans

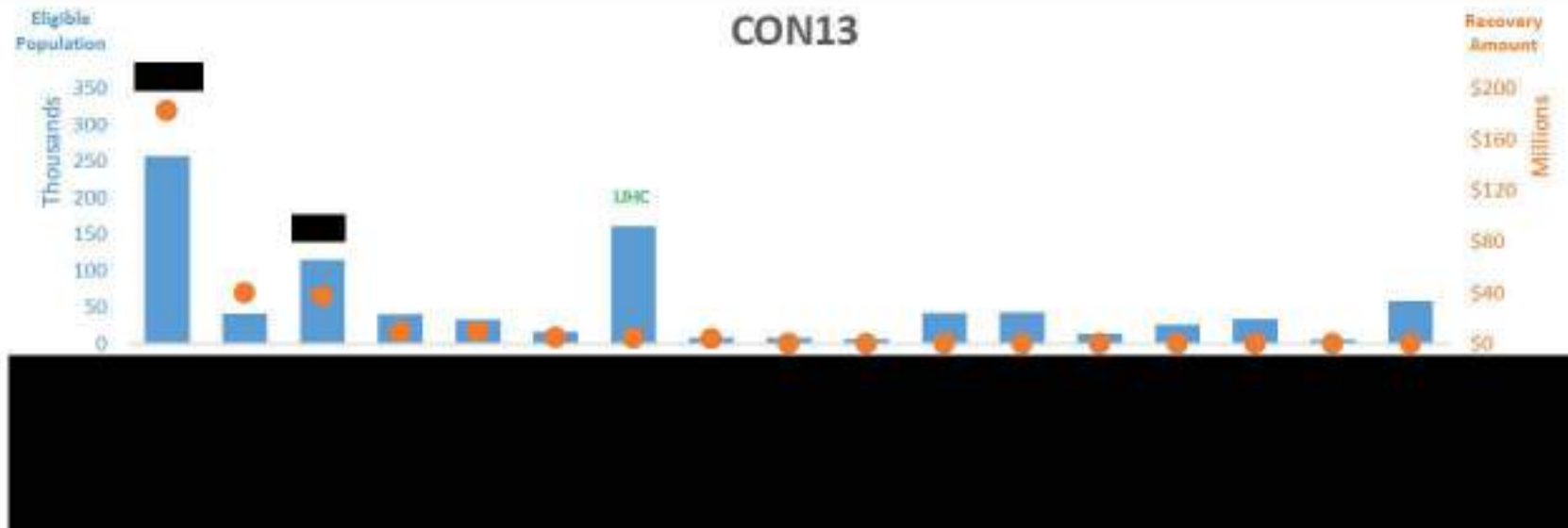
** includes 1 OIG-selected plan

Recovery Amount/Eligible Population



*Recovery amount is the extrapolated payment error amount based on the lower bound of the 99% confidence interval for the total.
*Only those MA contracts with greater than \$0 recovery amount are included; there were 14 such contracts in CON11, 17 contracts in CON12 and 12 contracts in CON13.

Recovery Amount and Eligible Population by Parent Organization



*Recovery amount is the extrapolated payment error incorporating the lower bound of the 99% confidence interval.

*All MA contracts in the sample are included in this analysis.

Medical Record Submission Summary

Medical Record (MR) Submission per CMS-HCC- Overall

MR validity	CON11					CON12					CON13				
	Total MRs	MEAN	STD	MIN	MAX	Total MRs	MEAN	STD	MIN	MAX	Total MRs	MEAN	STD	MIN	MAX
Invalid	1,805	1.38	0.79	1	6	1,842	1.47	1.01	1	5	1,426	1.46	0.98	1	5
Valid	35,499	2.91	2.13	1	26	37,979	2.75	1.76	1	13	41,203	2.78	1.85	1	15
Overall	37,304	2.99	2.21	1	26	39,821	2.81	1.8	1	13	42,629	2.83	1.88	1	15

- The number of MRs submitted increased year over year, with CON13 having the most submissions
- The average number of MR submission per CMS-HCC is similar between CON12 and CON13, and slightly higher in CON11
- There were ~400 fewer invalid records submitted in CON13 compared to CON11 and CON12

Summary of Valid MRs Used for MRR CMS-HCC by Contract

Sample	Total Valid MRs submitted	MRs used after applying MRR result selection logic*			
		MRs - additional allowed	MRs - additional Not allowed	Total	Percentage
CON11	35,499	8,679	212	8,891	25.05%
CON12	37,979	8,364	213	8,577	22.58%
CON13	41,203	8,849	168	9,017	21.88%

*MRR Result Selection Logic:

- For each non-hierarchical audited CMS-HCC: The highest ranked MR that confirmed the audited CMS-HCC is selected. Any additional found on the selected MR are used.

- For each hierarchical audited CMS-HCC: The highest ranked MR that had a higher manifestation of the audited CMS-HCC is selected. If the selected MR confirm/confirm higher then additional found on the MR, if any, are used. If the selected MR confirmed-lower then additional found on the MR, if any, are not used.

**Full details of MRR results selection criteria can be found in LAC-Oriented data creation document.

- The percentage of total valid MRs used for MRR decreased year over year with the lowest percentage of valid MR used in CON13

HCC Discrepancy Rate Summary

Discrepancy Rate by Sample - Overall

Sample	Audited HCCs	Confirmed* HCCs	Discrepant** HCCs	Additional HCCs					Discrepancy Rate
				Confirmed Higher	Confirmed Lower	New Hierarchy	Non Hierarchy	Total	
CON11	16,263	13,199	3,064	439	475	678	462	2,054	18.84%
CON12	16,842	13,241	3,601	329	473	696	414	1,912	21.38%
CON13	17,863	15,099	2,764	362	393	710	410	1,875	15.47%

* Discrepant confirmed higher CMS-HCCs were counted as confirmed.

** Discrepant confirmed lower CMS-HCCs were counted as discrepant.

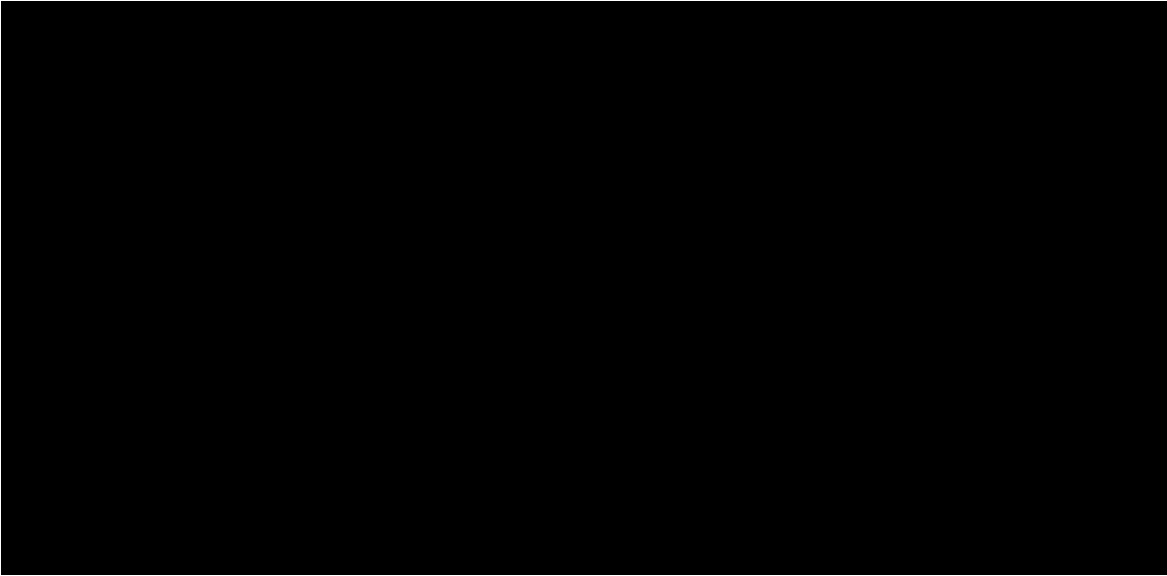
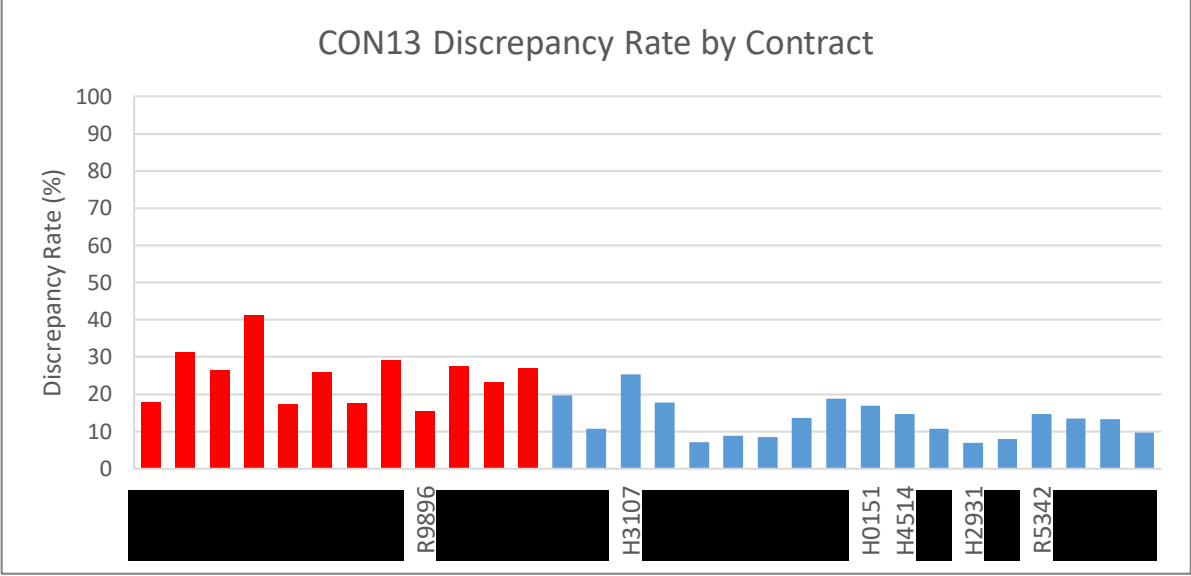
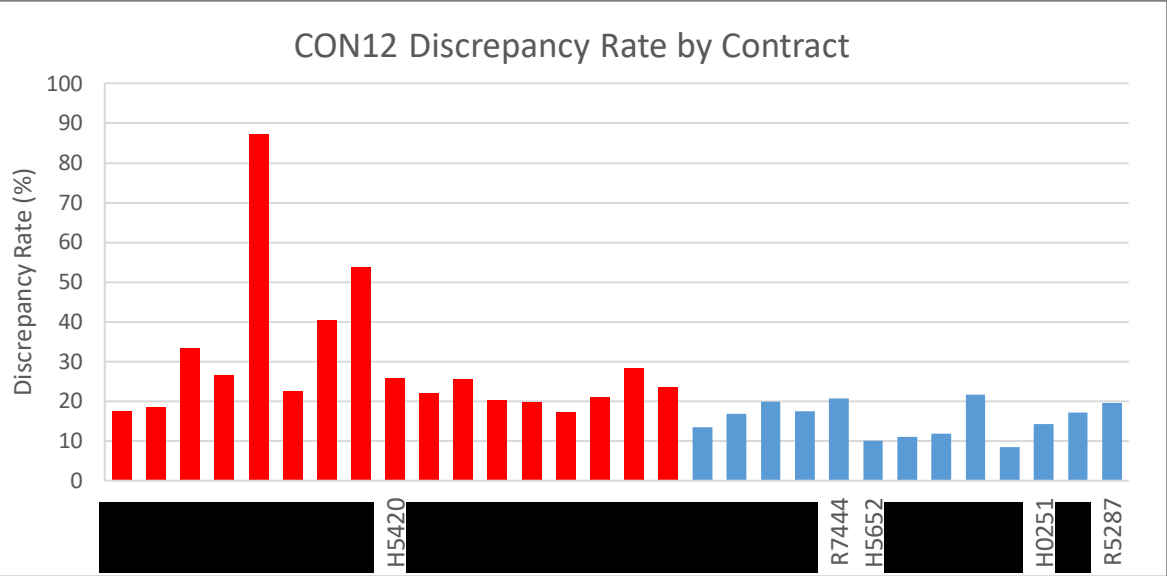
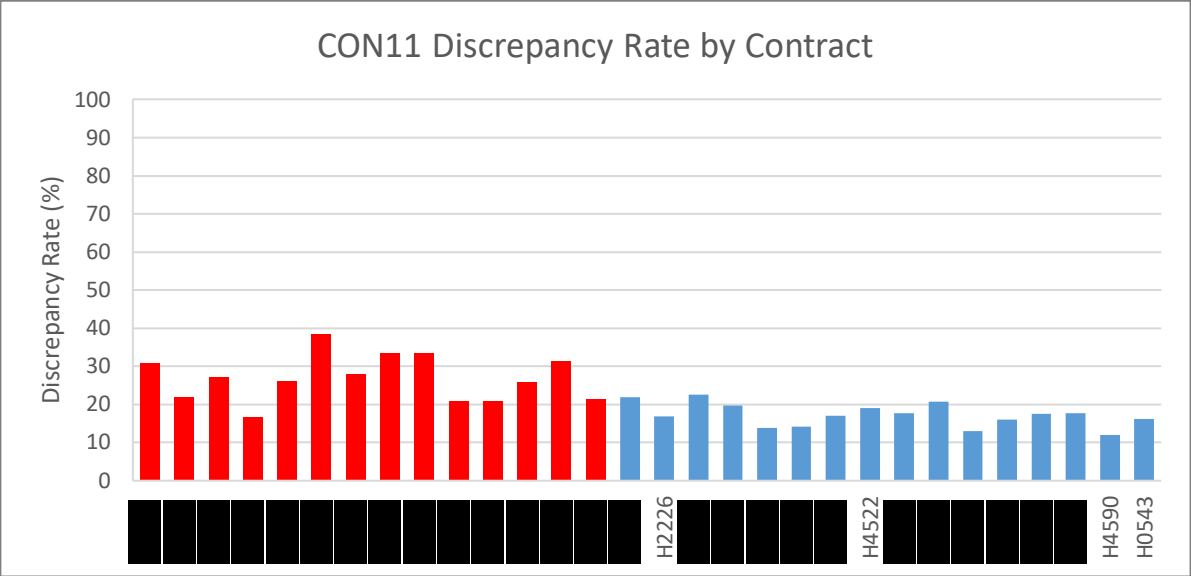
- CON13 has lowest discrepancy rate
 - Highest number of audited HCCs
 - ~900 fewer discrepant HCCs compared to CON12
- CON13 has fewer additional HCCs

Discrepant CMS-HCC Summary by Error Type - Overall

Sample	Discrepant HCCs	Error Type							
		Coding Incomplete		Signature Credential Issues		Invalid		Missing	
		Count	Percent	Count	Percent	Count	Percent	Count	Percent
CON11	3,064	2,424	79.11%	256	8.36%	136	4.44%	248	8.09%
CON12	3,601	2,764	76.76%	303	8.41%	161	4.47%	373	10.35%
CON13	2,764	2,344	84.80%	162	5.86%	105	3.80%	153	5.54%

- Percentage of discrepant HCCs due to incomplete coding is higher in CON13
- Percentage of discrepant HCCs due to signature credential issues, invalid MR, and missing MR is lower in CON13

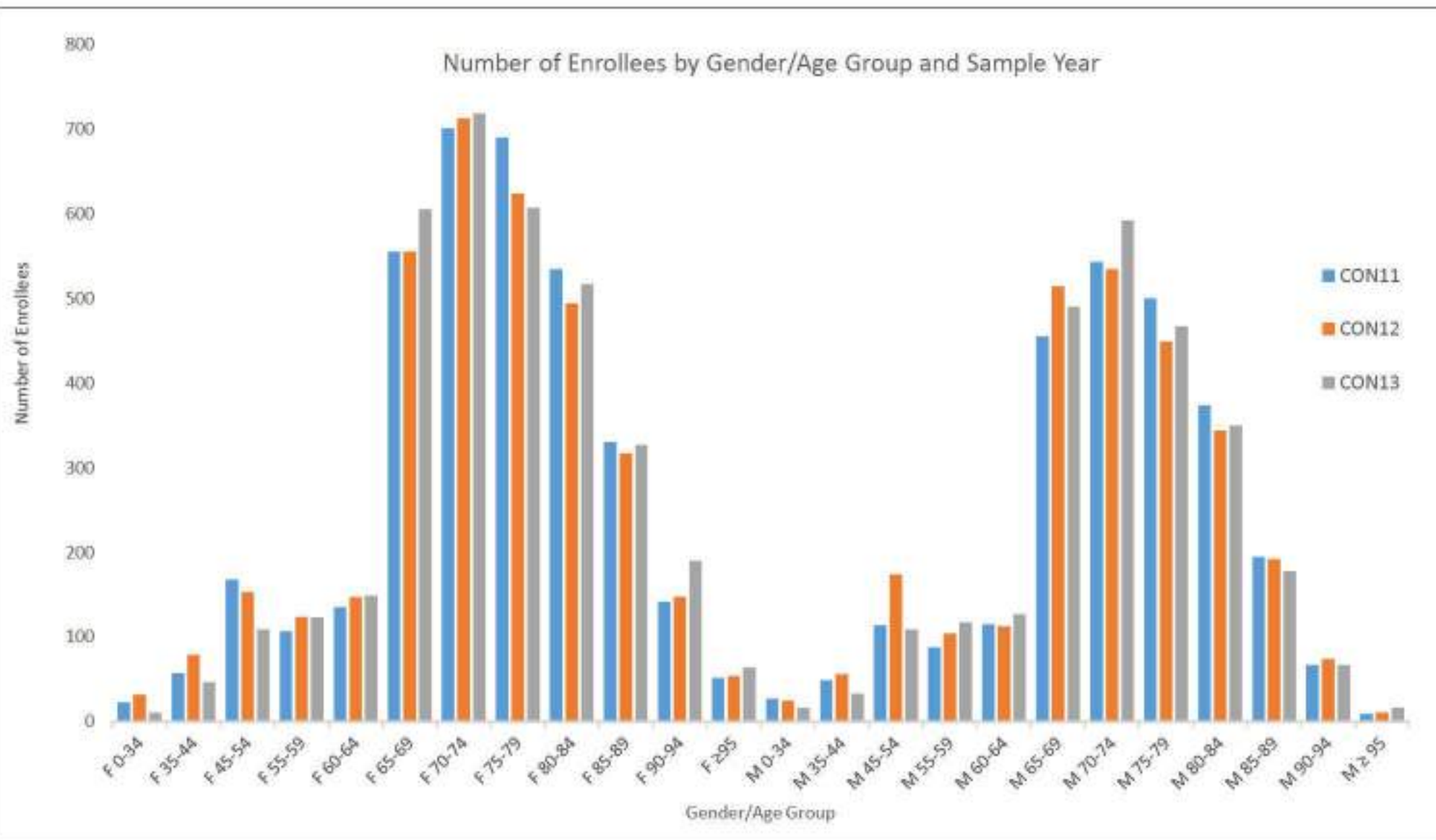
HCC Discrepancy Rate by Contract



*MA contracts are in the descending order (from left to right) by recovery amount (based on lower 99% Confidence Interval).

** Discrepant confirmed higher CMS-HCCs were counted as discrepant.

Sampled Enrollees Distribution by Gender/Age Group

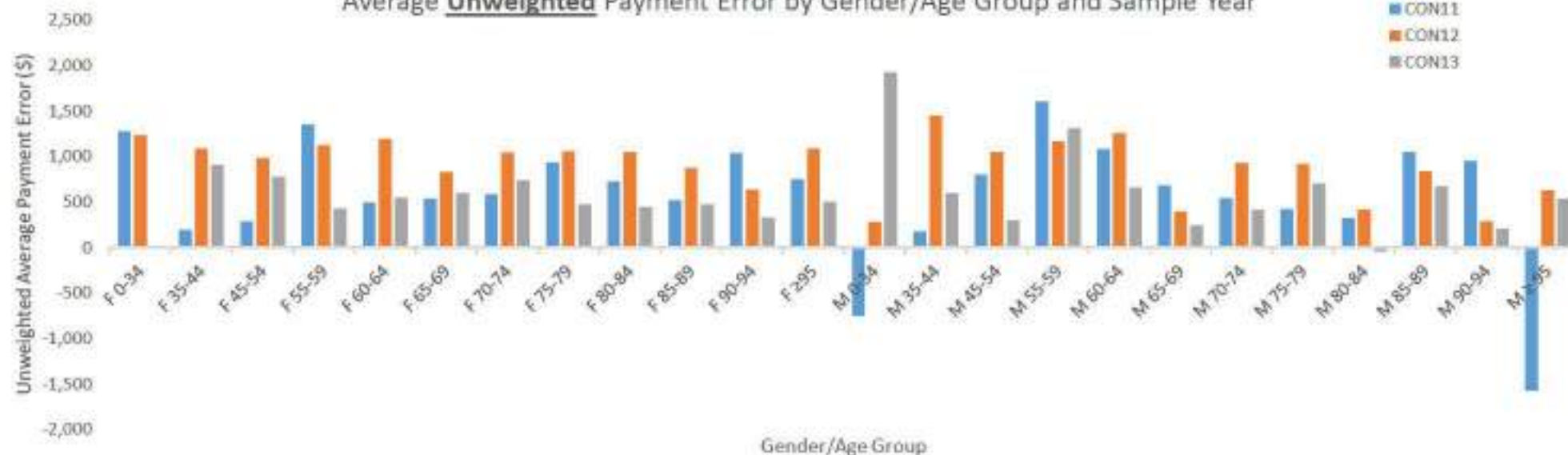


➤ The number of sampled enrollees per group appears to be close among the three samples

*All MA contracts in the sample are included in this analysis.

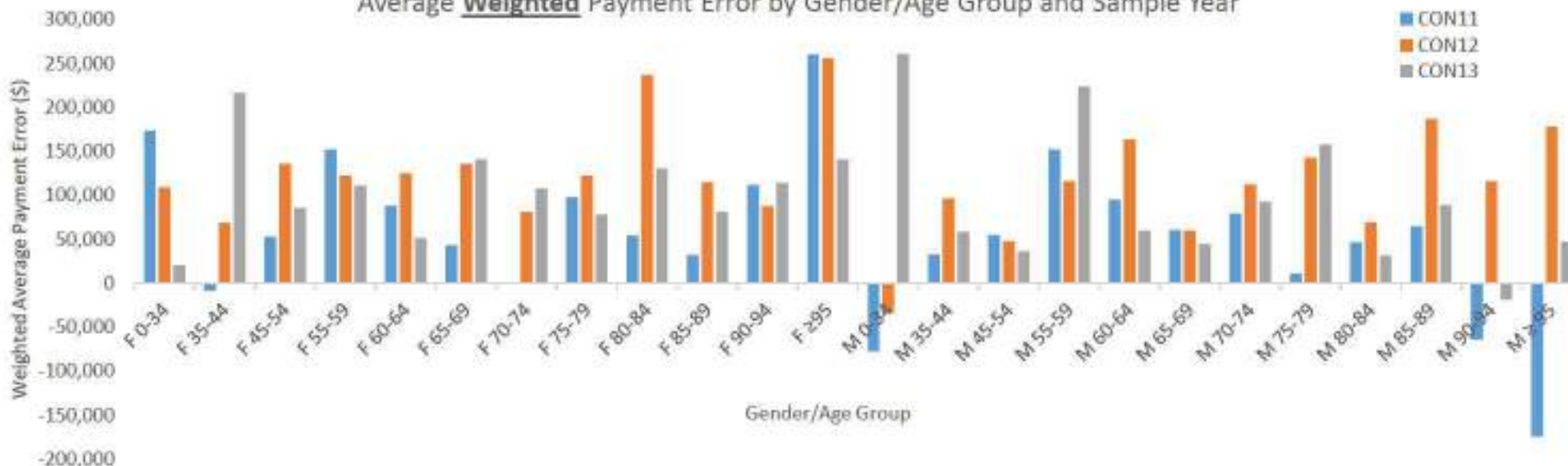
Sampled Enrollees Payment Error by Gender/Age Group

Average Unweighted Payment Error by Gender/Age Group and Sample Year



- The average **unweighted** payment error is lower for CON13 in many of the groups
- The Male 0-34 yrs and Male ≥95 yrs groups show underpayments on average for CON11

Average Weighted Payment Error by Gender/Age Group and Sample Year

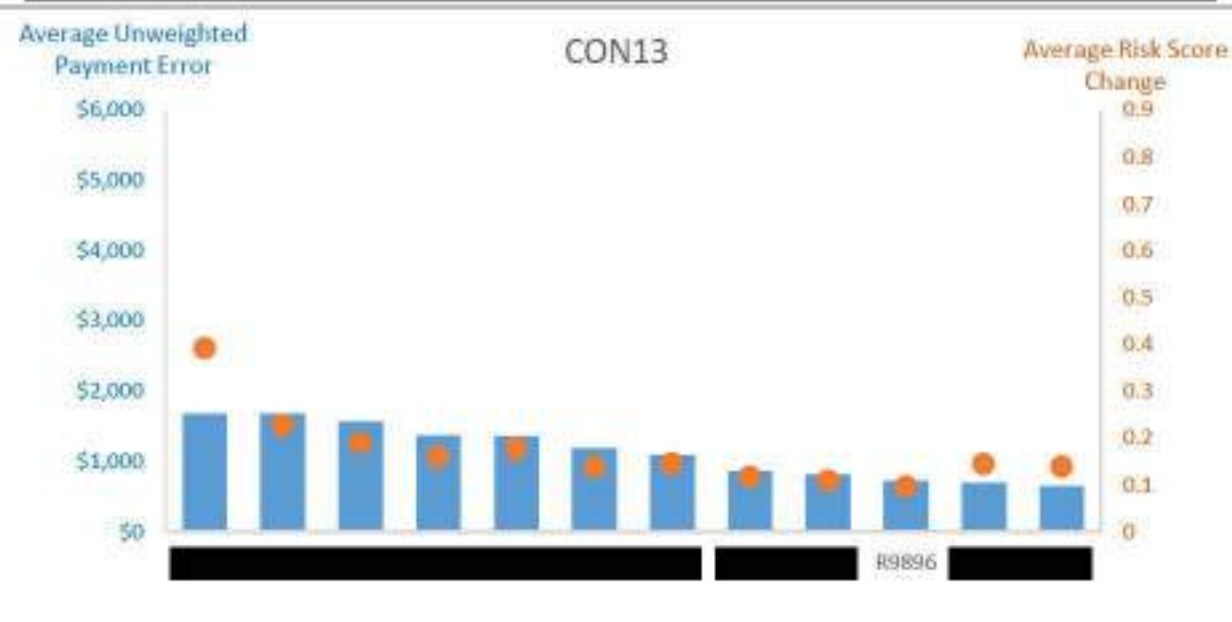
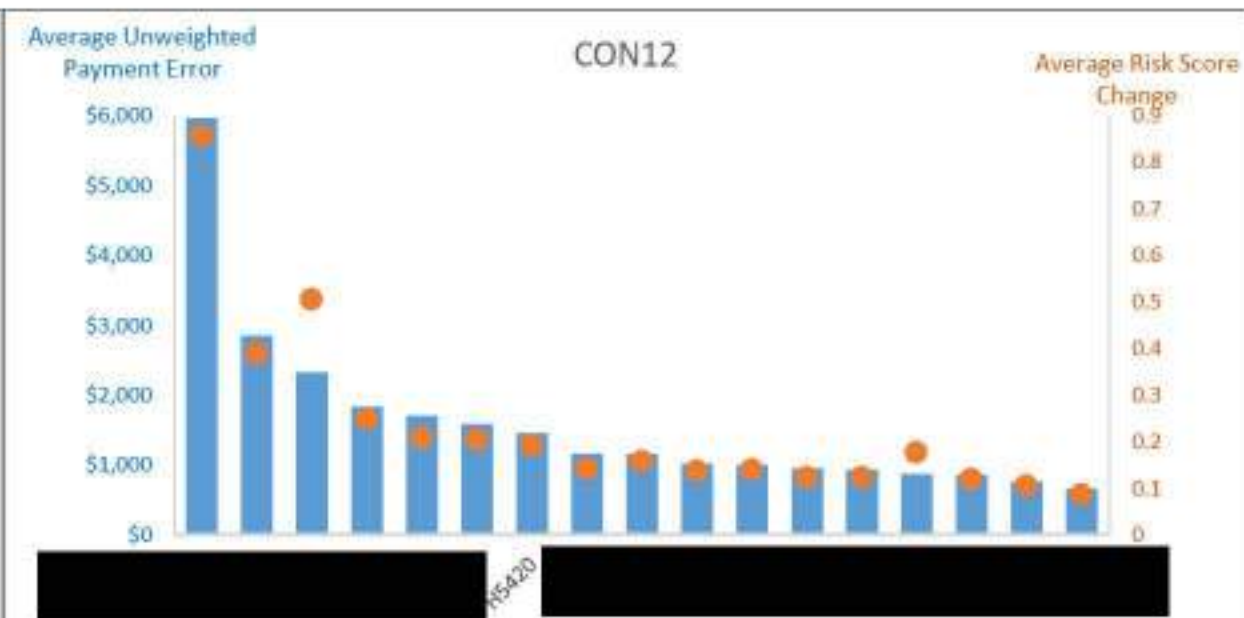
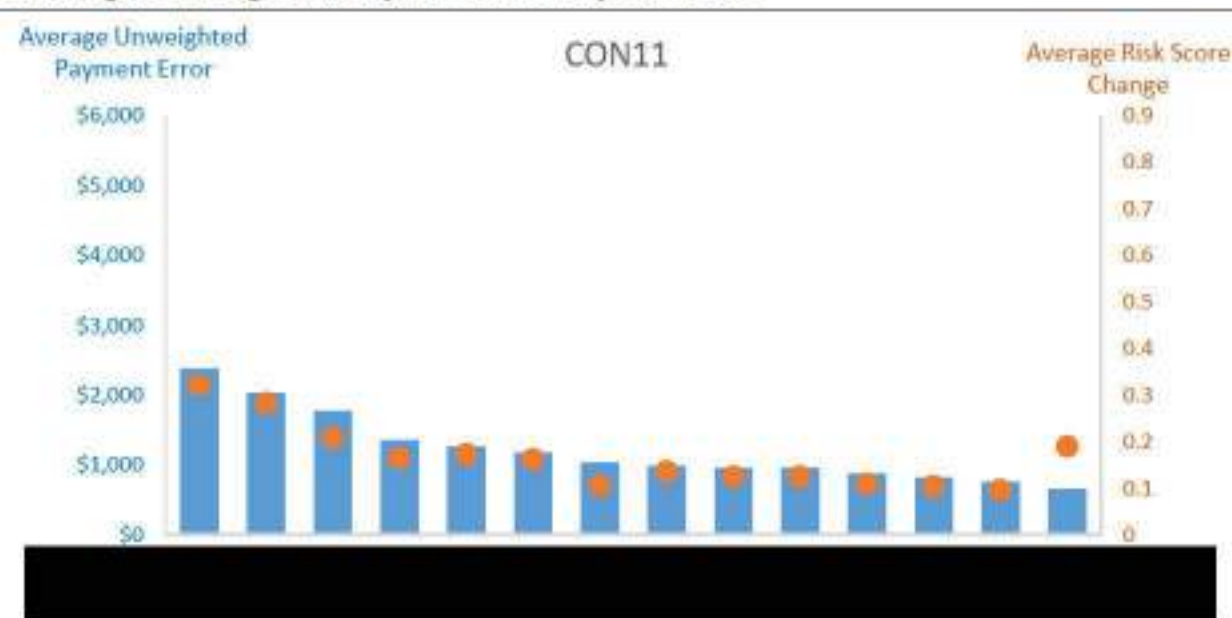


- CON11 has more groups with average **weighted** underpayments

Sampled Enrollees Average Unweighted Payment Error and Risk Score Change by Contract

Case 2:16-cv-08697-FMO-PVC Document 616-9 Filed 08/06/24 Page 233 of 267 Page ID
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Average Unweighted Payment Error by Contract



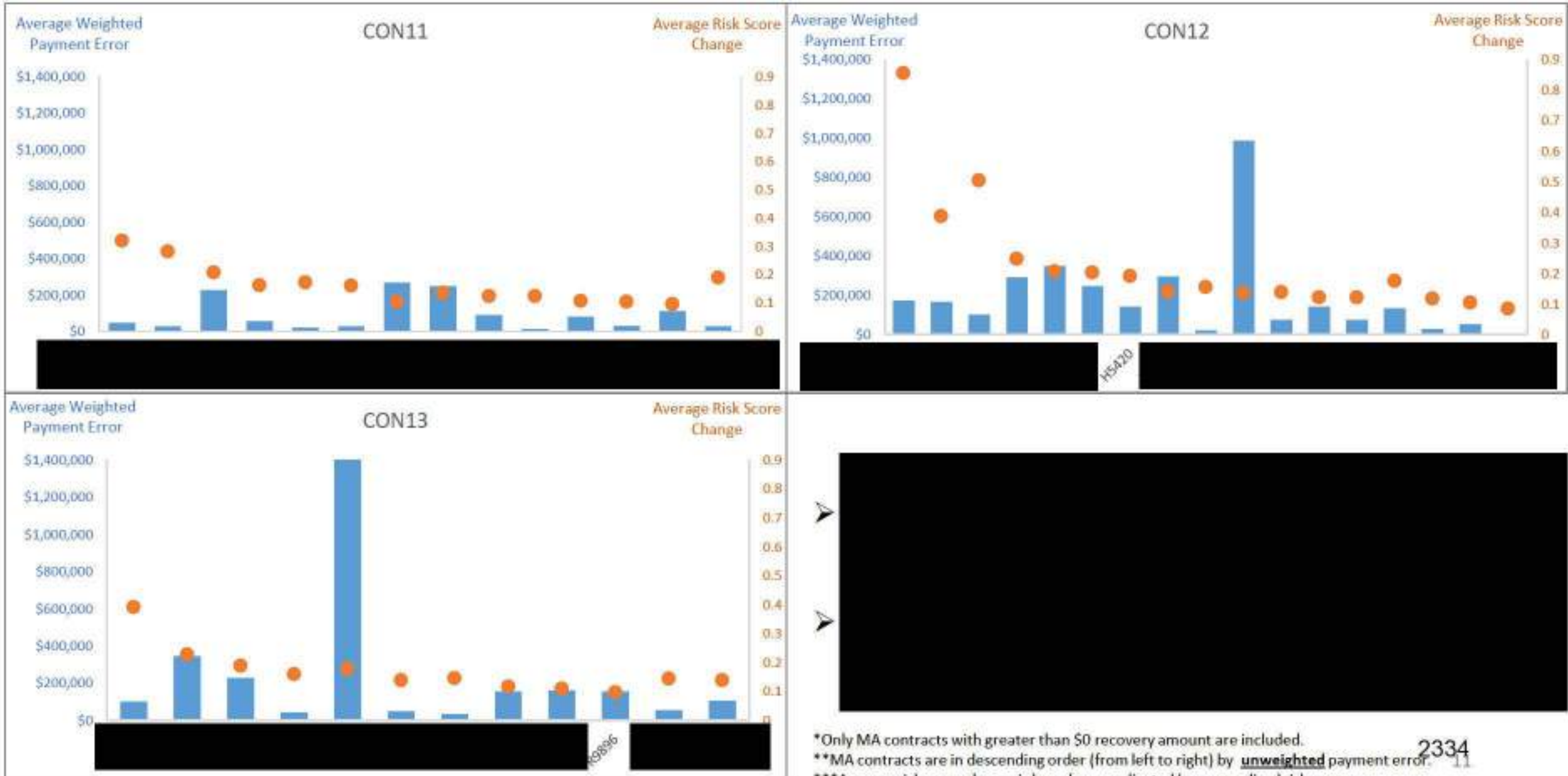
- [Redacted]
- Higher average risk score changes are aligned with the higher average unweighted payment errors

*Only MA contracts with greater than \$0 recovery amount are included.

**Average Risk Score Change is based on unadjusted/un-normalized risk scores.

Sampled Enrollees Average Weighted Payment Error and Risk Score Change by Contract

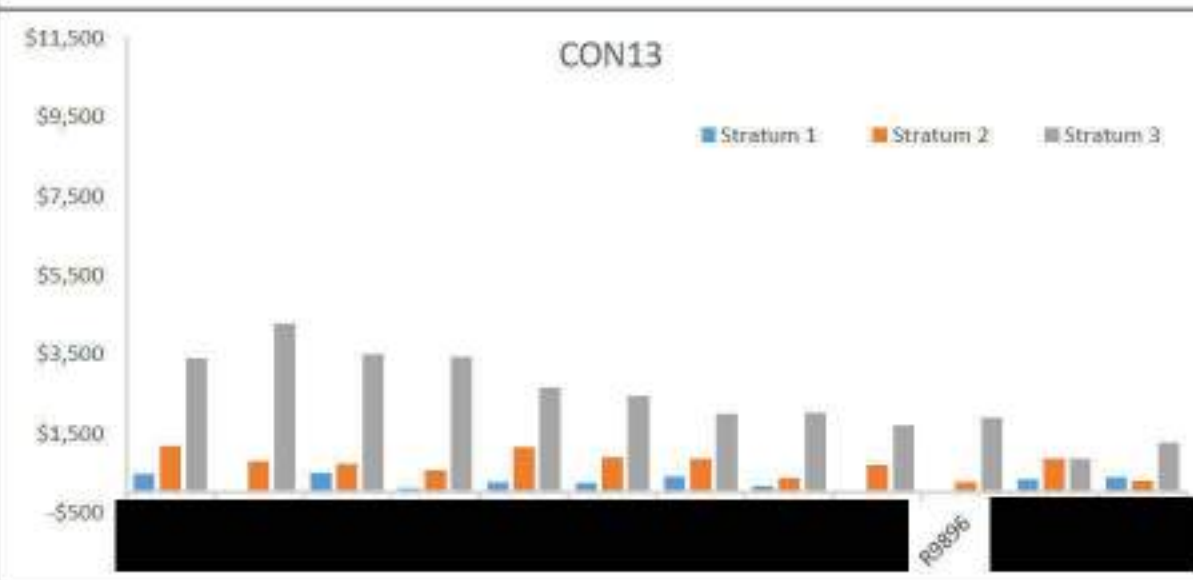
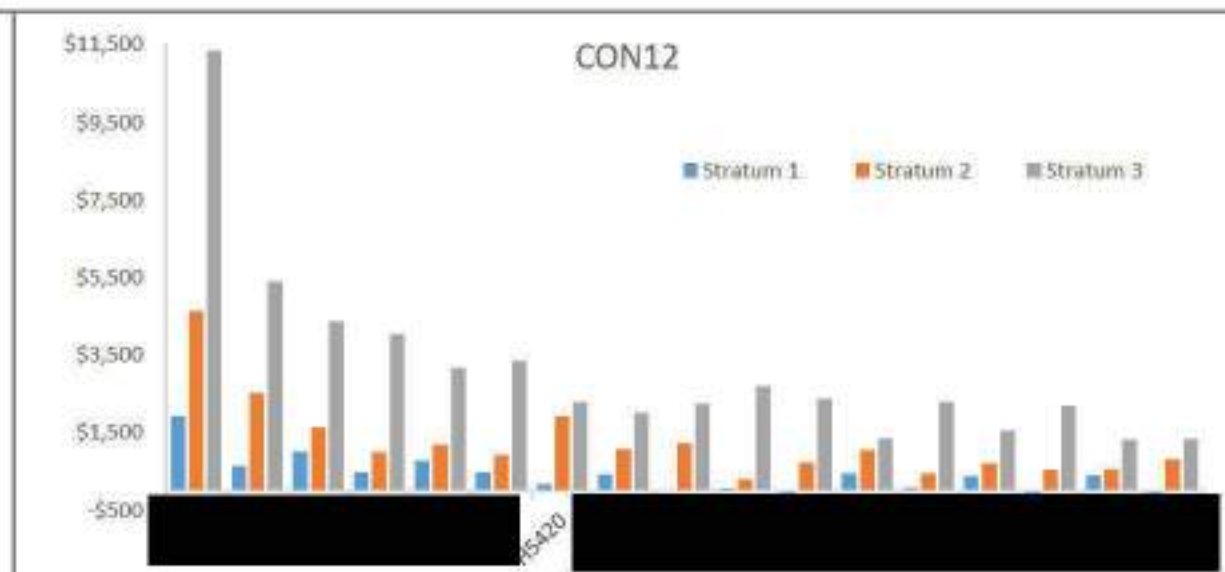
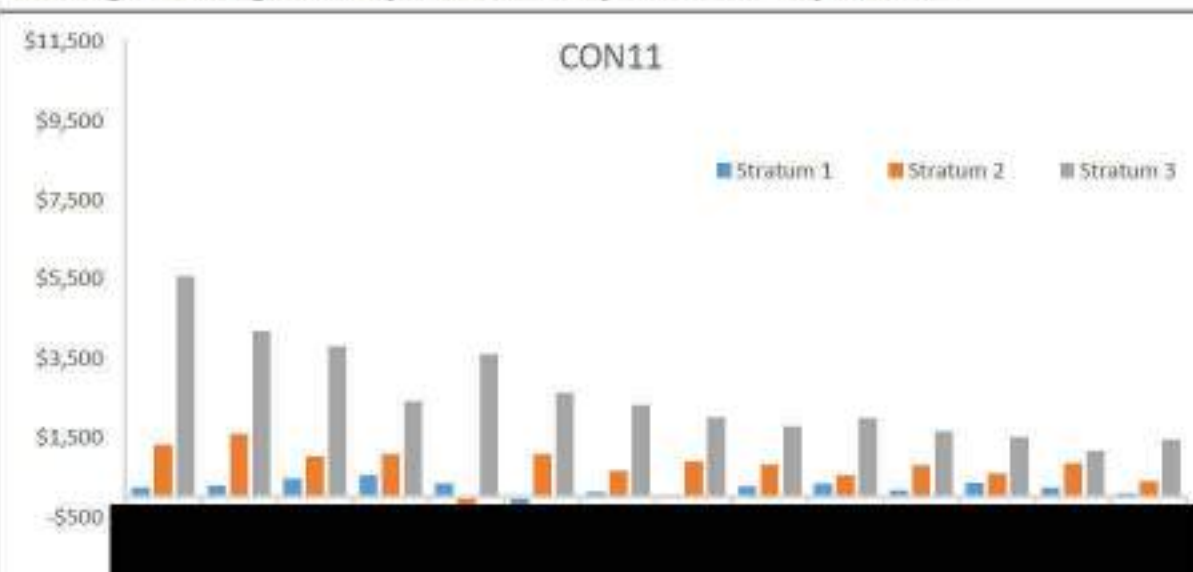
Average Weighted Payment Error by Contract



*Only MA contracts with greater than \$0 recovery amount are included.
 **MA contracts are in descending order (from left to right) by unweighted payment error.
 ***Average risk score change is based on unadjusted/un-normalized risk scores.

Sampled Enrollees Average Unweighted Payment Error by Contract

Average Unweighted Payment Error by Contract – by Stratum

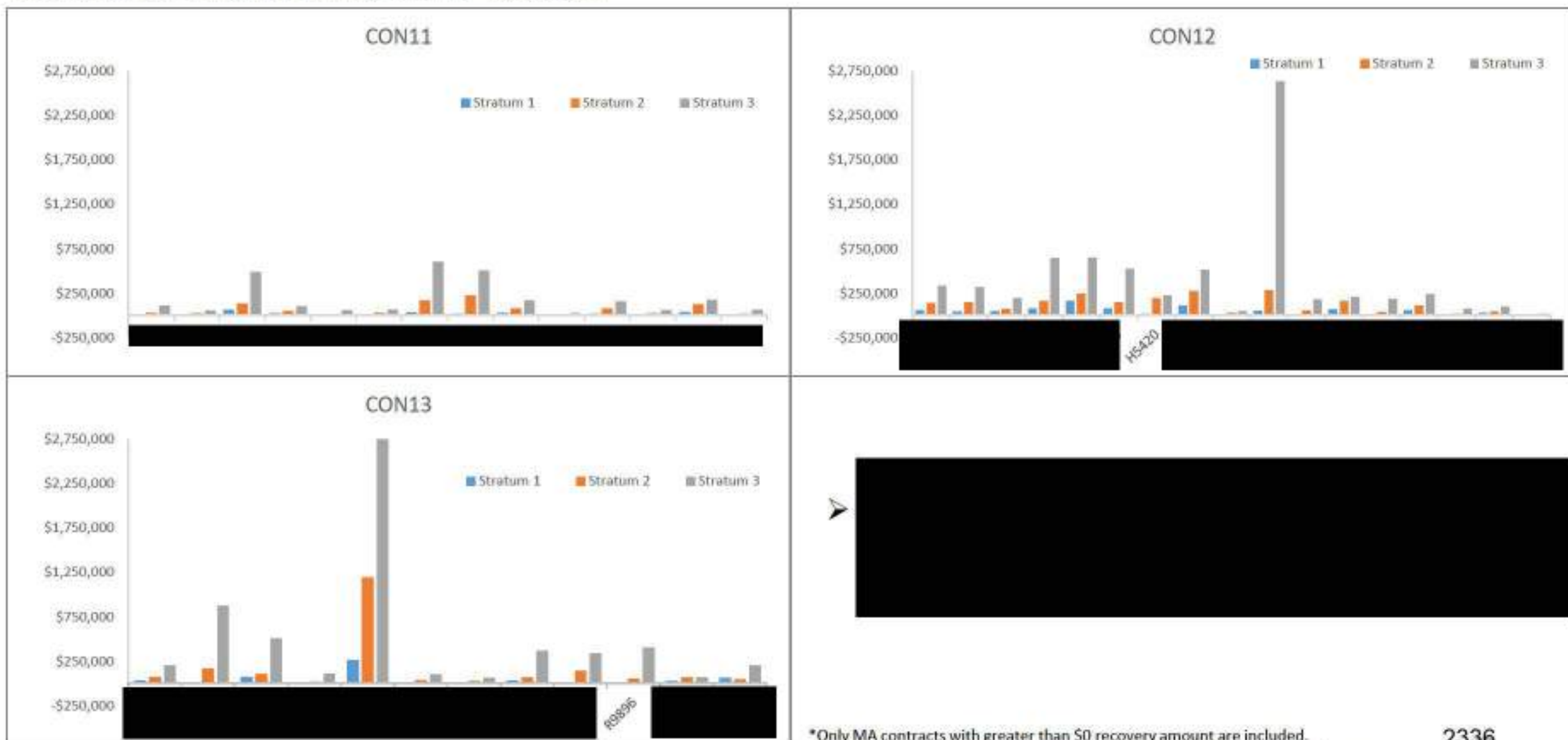


- Average unweighted payment error is lower in Stratum 1 for most contracts
- Average unweighted payment error is higher in Stratum 3 for all contracts

➤ [Redacted text block]

Sampled Enrollees Average Weighted Payment Error by Contract

Average Weighted Payment Error by Contract – by Stratum

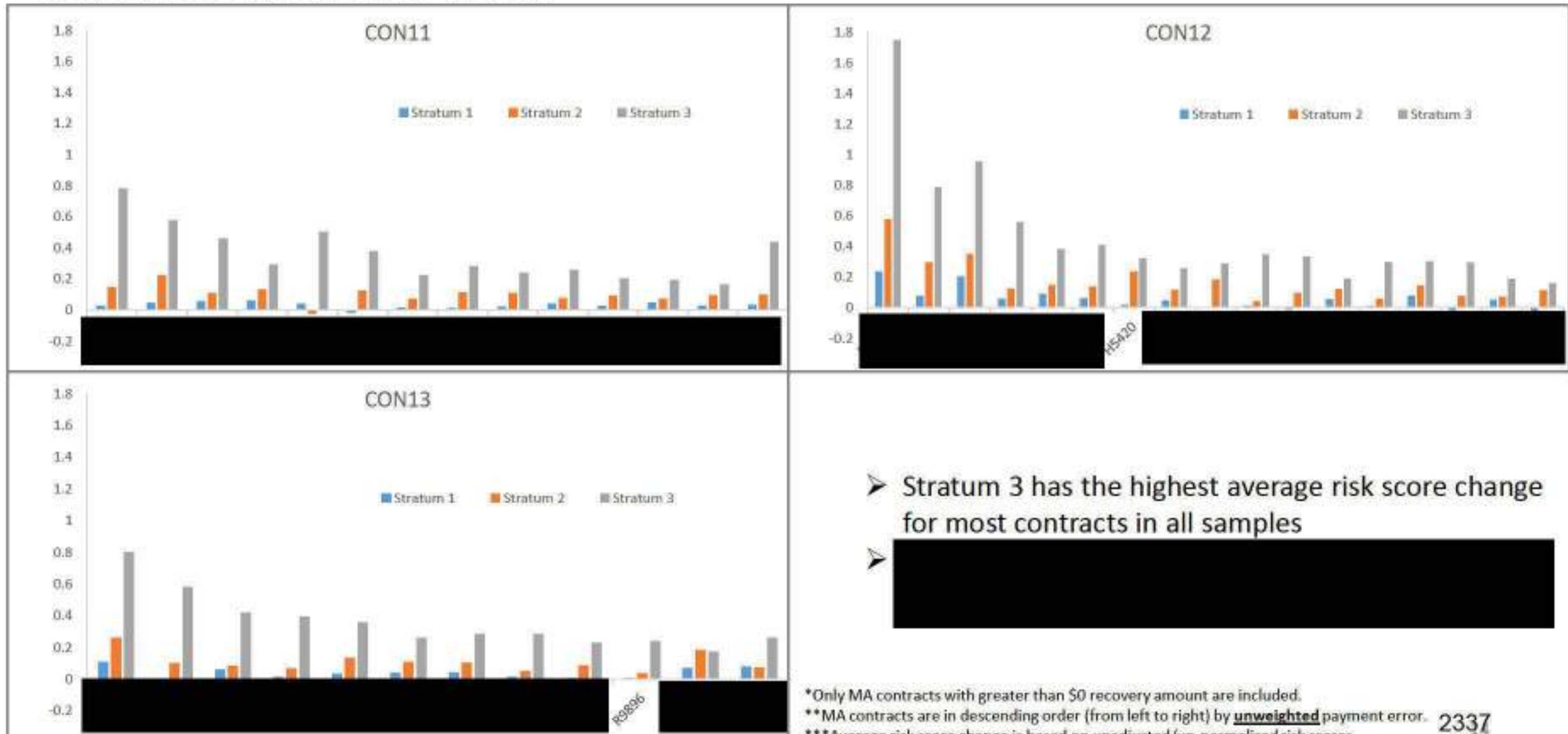


*Only MA contracts with greater than \$0 recovery amount are included.

**MA contracts are in descending order (from left to right) by unweighted payment error.

Sampled Enrollees Average Risk Score Change by Contract

Average Risk Score Change by Contract – by Stratum



➤ Stratum 3 has the highest average risk score change for most contracts in all samples

➤ [Redacted]

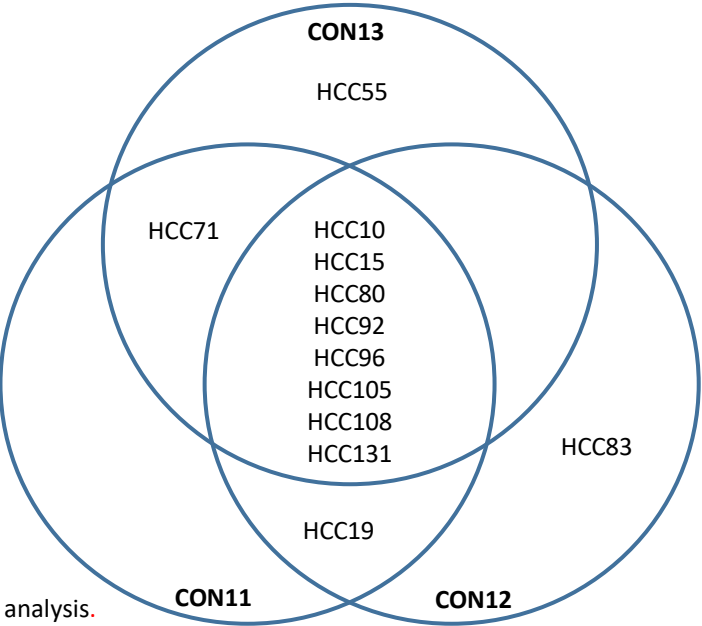
*Only MA contracts with greater than \$0 recovery amount are included.

**MA contracts are in descending order (from left to right) by unweighted payment error.

***Average risk score change is based on unadjusted/un-normalized risk scores.

Top 10 CMS-HCCs by Discrepancy Count*

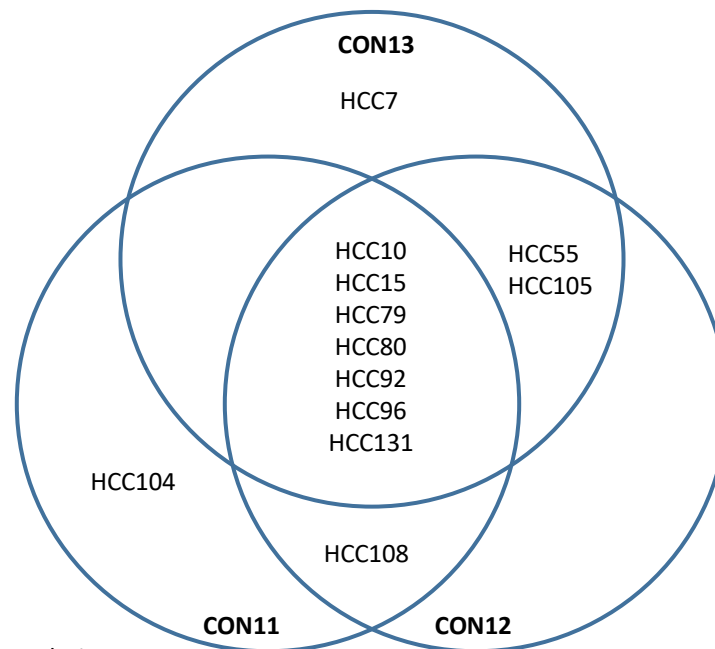
Top 10 Discrepant HCCs									
CON11				CON12			CON13		
#	HCC	# Discrepant	% Total Discrepant	HCC	# Discrepant	% Total Discrepant	HCC	# Discrepant	% Total Discrepant
1	HCC105	139	7.54%	HCC105	234	8.70%	HCC105	139	8.59%
2	HCC10	104	5.64%	HCC80	165	6.13%	HCC96	98	6.06%
3	HCC80	104	5.64%	HCC108	153	5.69%	HCC92	91	5.62%
4	HCC96	101	5.48%	HCC92	150	5.57%	HCC131	88	5.44%
5	HCC108	100	5.43%	HCC10	141	5.24%	HCC15	87	5.38%
6	HCC92	85	4.61%	HCC96	135	5.02%	HCC10	85	5.25%
7	HCC15	81	4.40%	HCC15	130	4.83%	HCC80	85	5.25%
8	HCC71	77	4.18%	HCC19	125	4.65%	HCC55	68	4.20%
9	HCC131	74	4.02%	HCC83	117	4.35%	HCC108	67	4.14%
10	HCC19	71	3.85%	HCC131	114	4.24%	HCC71	67	4.14%



* Only MA contracts with greater than \$0 recovery amount are included in this analysis.

Top 10 CMS-HCCs by Payment Error*

Top 10 Discrepant HCCs									
CON11				CON12			CON13		
#	HCC	Payment Error	PE Rate	HCC	Payment Error	PE Rate	HCC	Payment Error	PE Rate
1	HCC80	\$ 232,768	6.23%	HCC80	\$ 432,535	7.14%	HCC92	\$ 197,608	6.78%
2	HCC96	\$ 224,810	6.02%	HCC108	\$ 399,938	6.60%	HCC96	\$ 190,097	6.52%
3	HCC15	\$ 222,912	5.97%	HCC105	\$ 391,275	6.46%	HCC105	\$ 173,185	5.94%
4	HCC108	\$ 209,896	5.62%	HCC15	\$ 387,222	6.39%	HCC131	\$ 153,303	5.26%
5	HCC79	\$ 206,924	5.54%	HCC92	\$ 320,202	5.29%	HCC7	\$ 132,003	4.53%
6	HCC104	\$ 196,807	5.27%	HCC96	\$ 278,847	4.60%	HCC10	\$ 122,055	4.19%
7	HCC10	\$ 177,664	4.75%	HCC131	\$ 262,446	4.33%	HCC80	\$ 121,007	4.15%
8	HCC92	\$ 172,308	4.61%	HCC55	\$ 256,185	4.23%	HCC55	\$ 118,243	4.06%
9	HCC38	\$ 149,132	3.99%	HCC79	\$ 240,443	3.97%	HCC15	\$ 115,827	3.97%
10	HCC131	\$ 140,375	3.76%	HCC10	\$ 238,194	3.93%	HCC79	\$ 114,663	3.93%

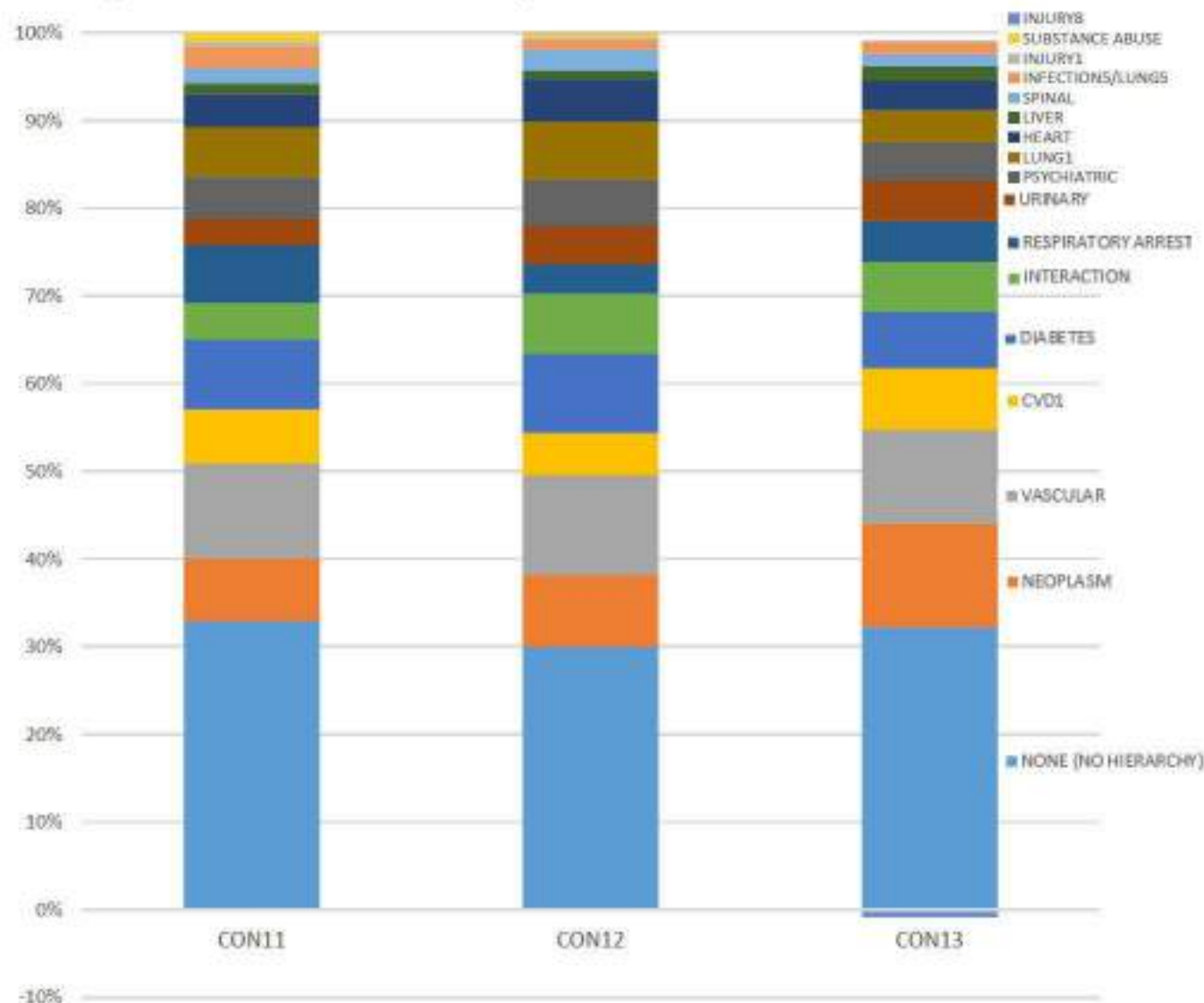


* Non-normalized, unadjusted, unweighted payment error

* Only MA contracts with greater than \$0 recovery amount are included in this analysis.

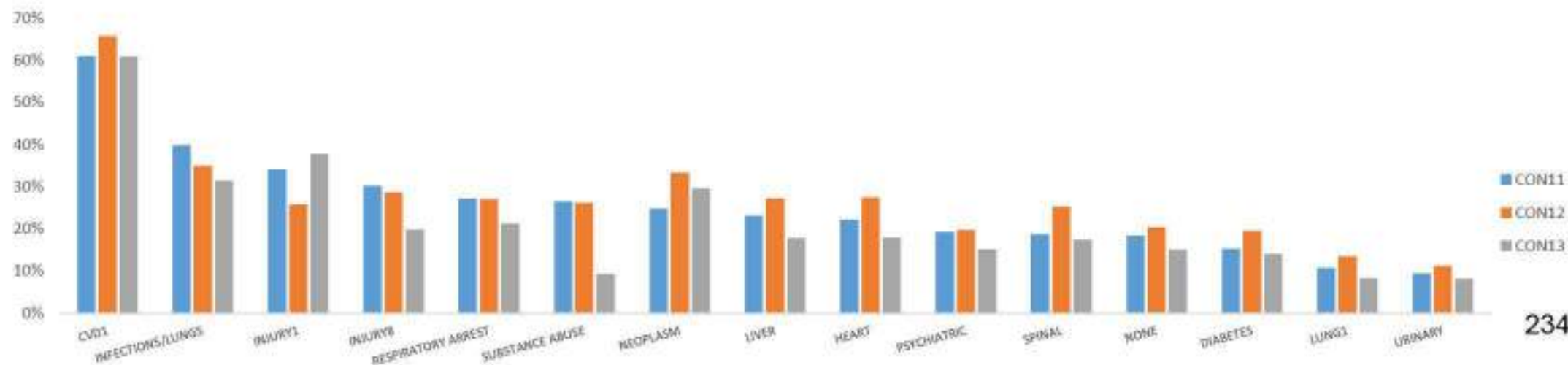
Payment Error by Disease Group*

Hierarchy	Payment Error		
	CON11	CON12	CON13
TOTAL	\$ 3,736,489	\$ 6,056,084	\$ 2,914,685
NONE (NO HIERARCHY)	\$ 1,230,887	\$ 1,815,030	\$ 955,665
VASCULAR	\$ 405,410	\$ 691,622	\$ 318,243
DIABETES	\$ 297,372	\$ 547,968	\$ 189,497
NEOPLASM	\$ 265,759	\$ 494,770	\$ 348,527
RESPIRATORY ARREST	\$ 246,532	\$ 199,874	\$ 138,367
CVD1	\$ 232,485	\$ 290,707	\$ 209,308
LUNG1	\$ 213,696	\$ 396,702	\$ 109,617
PSYCHIATRIC	\$ 178,582	\$ 323,112	\$ 130,216
INTERACTION	\$ 156,607	\$ 414,685	\$ 168,605
HEART	\$ 139,357	\$ 295,718	\$ 98,325
URINARY	\$ 109,679	\$ 267,122	\$ 134,561
INFECTION5/LUNG5	\$ 89,442	\$ 68,666	\$ 37,412
SPINAL	\$ 68,441	\$ 147,447	\$ 40,329
LIVER	\$ 45,436	\$ 55,658	\$ 51,715
SUBSTANCE ABUSE	\$ 39,979	\$ 29,194	\$ 2,226
INJURY1	\$ 18,168	\$ 14,429	\$ 6,930
INJURY8	\$ (1,344)	\$ 3,381	\$ (24,857)



Discrepancy Rates by Disease Group

Disease Group	CON11			CON12			CON13		
	Sampled	Discrepant	Discrepancy Rate	Sampled	Discrepant	Discrepancy Rate	Sampled	Discrepant	Discrepancy Rate
CVD1	312	190	60.90%	311	204	65.59%	298	181	60.74%
DIABETES	2,583	392	15.18%	2,625	510	19.43%	2,733	383	14.01%
HEART	951	210	22.08%	1,019	279	27.38%	1,012	181	17.89%
INFECTIONS/LUNG5	123	49	39.84%	89	31	34.83%	86	27	31.40%
INJURY1	50	17	34.00%	70	18	25.71%	53	20	37.74%
INJURY8	53	16	30.19%	42	12	28.57%	66	13	19.70%
LIVER	126	29	23.02%	114	31	27.19%	113	20	17.70%
LUNG1	1,399	149	10.65%	1,460	196	13.42%	1,466	120	8.19%
NEOPLASM	990	245	24.75%	829	276	33.29%	840	248	29.52%
NONE (NO HIERARCHY)	5,145	942	18.31%	5,099	1,034	20.28%	5,578	836	14.99%
PSYCHIATRIC	689	132	19.16%	918	180	19.61%	895	135	15.08%
RESPIRATORY ARREST	369	100	27.10%	330	89	26.97%	349	74	21.20%
SPINAL	316	59	18.67%	346	87	25.14%	363	63	17.36%
SUBSTANCE ABUSE	186	49	26.34%	203	53	26.11%	250	23	9.20%
URINARY	1,251	117	9.35%	1,538	171	11.12%	1,760	143	8.13%
VASCULAR	1,720	368	21.40%	1,849	430	23.26%	2,001	297	14.84%



Summary Statistics CON11 (Sorted by Descending Recovery Amount)

CON11						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$355,028			
			\$198,283			
			\$206,760			
			\$151,598			
			\$192,131			
			\$477,849			
			\$271,056			
			\$408,266			
			\$130,357			
			\$235,896			
			\$164,324			
			\$175,719			
			\$251,829			
			\$192,128			
			\$76,998			
H2226	UnitedHealth Group, Inc.	HI	\$37,933	2,773	(\$2,068,360.00)	(\$745.89)
			\$88,994			
			\$113,827			
			\$81,595			
			\$45,006			
			\$89,809			
H4522	UnitedHealth Group, Inc.	LOW	(\$38,104)	6,023	(\$4,622,640.00)	(\$767.50)
			\$47,311			
			\$76,600			
			(\$1,662)			
			(\$39,035)			
			(\$53,277)			
			(\$54,856)			
H4590	UnitedHealth Group, Inc.	HI	(\$8,630)	91,850	(\$51,017,738.00)	(\$555.45)
H0543	UnitedHealth Group, Inc.	HI	\$35,126	185,186	(\$91,884,129.00)	(\$496.17)

Summary Statistics CON12 (Sorted by Descending Recovery Amount)

CON12						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$202,609			
			\$341,198			
			\$367,086			
			\$316,883			
			\$1,197,584			
			\$232,536			
			\$571,738			
			\$466,263			
H5420	UnitedHealth Group, Inc.	HI	\$290,803	19,923	\$15,735,769	\$789.83
			\$174,147			
			\$189,414			
			\$199,820			
			\$187,043			
			\$150,526			
			\$171,730			
			\$230,838			
			\$131,073			
			\$1,902			
			\$103,752			
			\$54,707			
			\$11,023			
R7444	UnitedHealth Group, Inc.	HI	\$40,516	9,559	(\$3,962,831)	(\$414.57)
H5652	UnitedHealth Group, Inc.	HI	(\$141,220)	3,414	(\$4,740,216)	(\$1,388.46)
			(\$22,584)			
			\$20,132			
			\$133,204			
			(\$155,487)			
H0251	UnitedHealth Group, Inc.	HI	(\$73,921)	11,352	(\$10,348,919)	(\$911.24)
			(\$8,445)			
			(\$32,705)			
R5287	UnitedHealth Group, Inc.	HI	(\$32,705)	84,014	(\$69,295,194)	(\$824.81)

Summary Statistics CON13 (Sorted by Descending Recovery Amount)

CON13						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$272,003			
			\$337,112			
			\$315,529			
			\$337,267			
			\$171,454			
			\$162,436			
			\$129,630			
			\$138,336			
R9896	UnitedHealth Group, Inc.	HI	\$144,939	43,114	\$4,065,269	\$94.29
			\$238,417			
			\$274,061			
			\$217,529			
			\$98,606			
			\$64,631			
H3107	UnitedHealth Group, Inc.	HI	\$107,627	27,753	(\$1,581,972)	(\$57.00)
			\$55,312			
			\$51,785			
			\$13,962			
			\$66,409			
			(\$59,194)			
			\$94,339			
H0151	UnitedHealth Group, Inc.	HI	\$47,142	21,671	(\$7,790,780)	(\$359.50)
H4514	UnitedHealth Group, Inc.	HI	(\$5,954)	13,265	(\$9,302,996)	(\$701.32)
			\$24,887			
			\$15,457			
H2931	UnitedHealth Group, Inc.	HI	(\$34,668)	31,364	(\$10,078,497)	(\$321.34)
			\$32,110			
			(\$32,110)			
			(\$52,137)			
			(\$33,582)			
R5342	UnitedHealth Group, Inc.	HI	(\$125,921)	23,226	(\$14,309,264)	(\$616.09)

EXHIBIT D-82

**REDACTED VERSION OF
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PRODUCED IN NATIVE FORMAT

EXHIBIT

1498

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CMS RADV

– Comparison and Analysis of CON11, CON12 & CON13

December 8, 2017

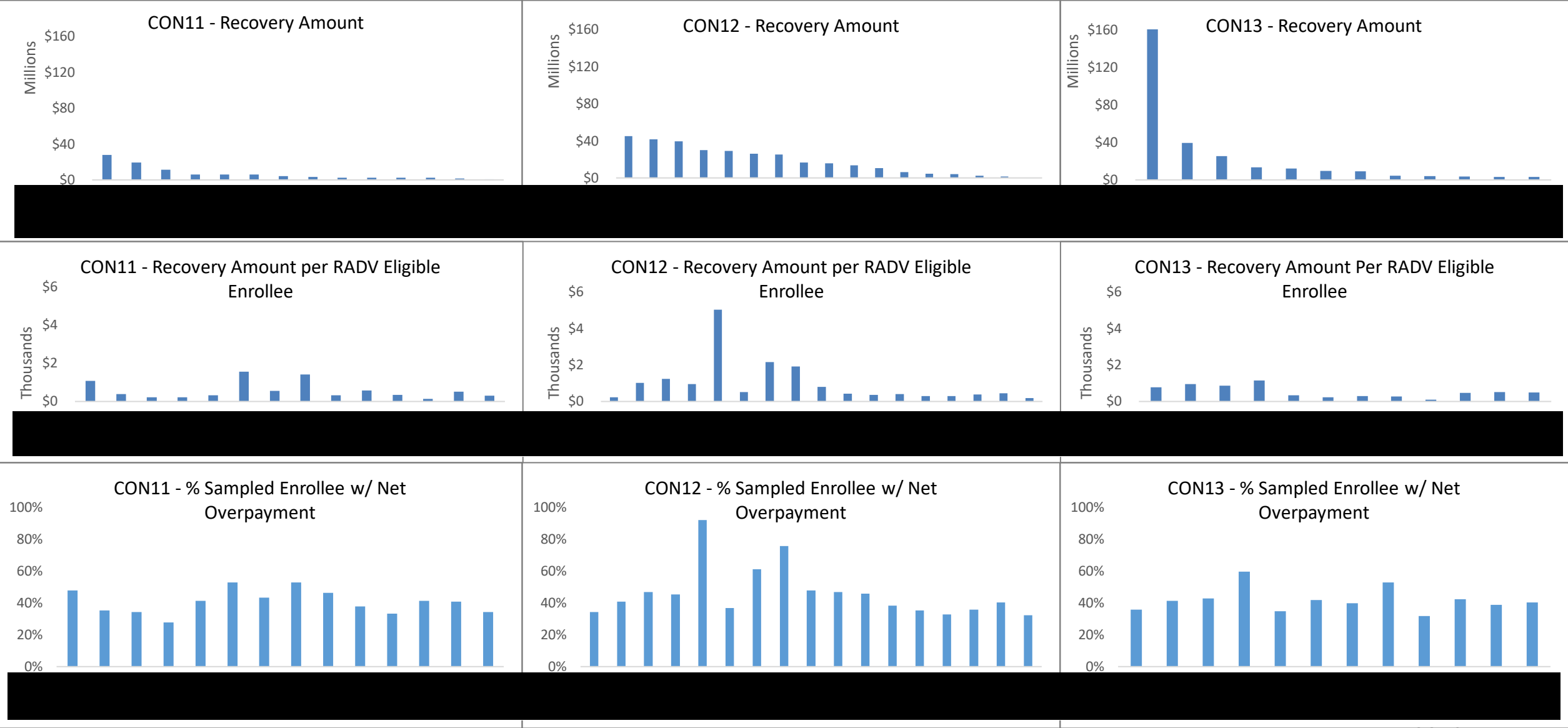
Sampling Differences for Contract Samples

	CON11	CON12	CON13
RADV-eligible enrollee threshold	1,000	2,000	5,000
Number of Contracts selected:	30	30	30
High Coding Intensity Stratum	20*	20	25
Medium Coding Intensity Stratum	5**	5	5
Low Coding Intensity Stratum	5	5	0
Number of RADV-eligible enrollees in 30 Sampled Contracts	778,808	838,373	902,451
Parent Organization Analysis			
	4 United HealthGroup plans account for 0.0% of total recovery amount	5 United HealthGroup plans account for 5.0% of total recovery amount	6 United Health Group plans account for 1.4% of total recovery amount

* includes 5 OIG-selected plans

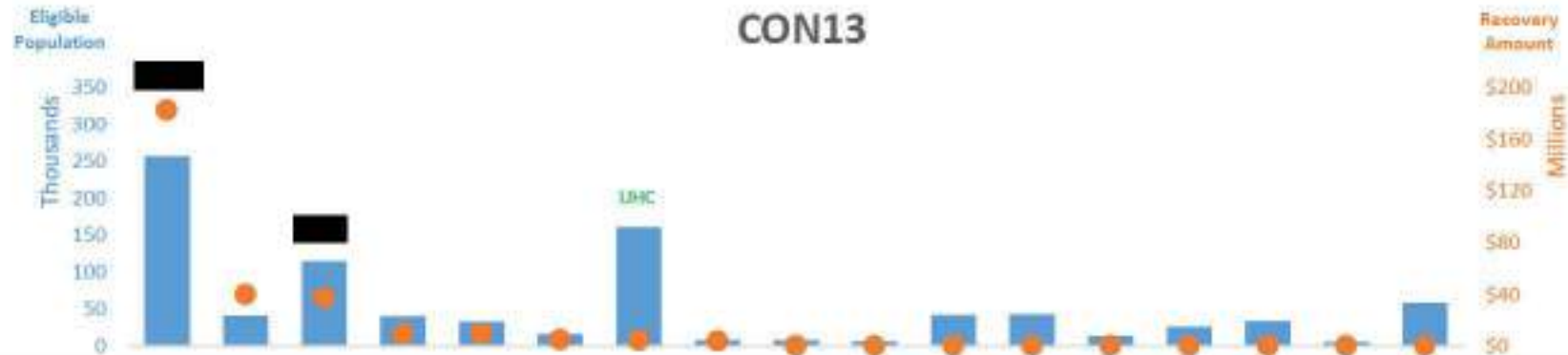
** includes 1 OIG-selected plan

Recovery Amount/Eligible Population



*Recovery amount is the extrapolated payment error amount based on the lower bound of the 99% confidence interval for the total.
*Only those MA contracts with greater than \$0 recovery amount are included; there were 14 such contracts in CON11, 17 contracts in CON12 and 12 contracts in CON13.

Recovery Amount and Eligible Population by Parent Organization



*Recovery amount is the extrapolated payment error incorporating the lower bound of the 99% confidence interval.
*All MA contracts in the sample are included in this analysis.

Medical Record Submission Summary

Medical Record (MR) Submission per CMS-HCC- Overall

MR validity	CON11					CON12					CON13				
	Total MRs	MEAN	STD	MIN	MAX	Total MRs	MEAN	STD	MIN	MAX	Total MRs	MEAN	STD	MIN	MAX
Invalid	1,805	1.38	0.79	1	6	1,842	1.47	1.01	1	5	1,426	1.46	0.98	1	5
Valid	35,499	2.91	2.13	1	26	37,979	2.75	1.76	1	13	41,203	2.78	1.85	1	15
Overall	37,304	2.99	2.21	1	26	39,821	2.81	1.8	1	13	42,629	2.83	1.88	1	15

- The number of MRs submitted increased year over year, with CON13 having the most submissions
- The average number of MR submission per CMS-HCC is similar between CON12 and CON13, and slightly higher in CON11
- There were ~400 fewer invalid records submitted in CON13 compared to CON11 and CON12

Summary of Valid MRs Used for MRR CMS-HCC by Contract

Sample	Total Valid MRs submitted	MRs used after applying MRR result selection logic*			
		MRs - additional allowed	MRs - additional Not allowed	Total	Percentage
CON11	35,499	8,679	212	8,891	25.05%
CON12	37,979	8,364	213	8,577	22.58%
CON13	41,203	8,849	168	9,017	21.88%

*MRR Result Selection Logic:

- For each non-hierarchical audited CMS-HCC: The highest ranked MR that confirmed the audited CMS-HCC is selected. Any additional found on the selected MR are used.

- For each hierarchical audited CMS-HCC: The highest ranked MR that had a higher manifestation of the audited CMS-HCC is selected. If the selected MR confirm/confirm higher then additional found on the MR, if any, are used. If the selected MR confirmed-lower then additional found on the MR, if any, are not used.

**Full details of MRR results selection criteria can be found in LAC-Oriented data creation document.

- The percentage of total valid MRs used for MRR decreased year over year with the lowest percentage of valid MR used in CON13

HCC Discrepancy Rate Summary

Discrepancy Rate by Sample - Overall

Sample	Audited HCCs	Confirmed* HCCs	Discrepant** HCCs	Additional HCCs					Discrepancy Rate
				Confirmed Higher	Confirmed Lower	New Hierarchy	Non Hierarchy	Total	
CON11	16,263	13,199	3,064	439	475	678	462	2,054	18.84%
CON12	16,842	13,241	3,601	329	473	696	414	1,912	21.38%
CON13	17,863	15,099	2,764	362	393	710	410	1,875	15.47%

* Discrepant confirmed higher CMS-HCCs were counted as confirmed.

** Discrepant confirmed lower CMS-HCCs were counted as discrepant.

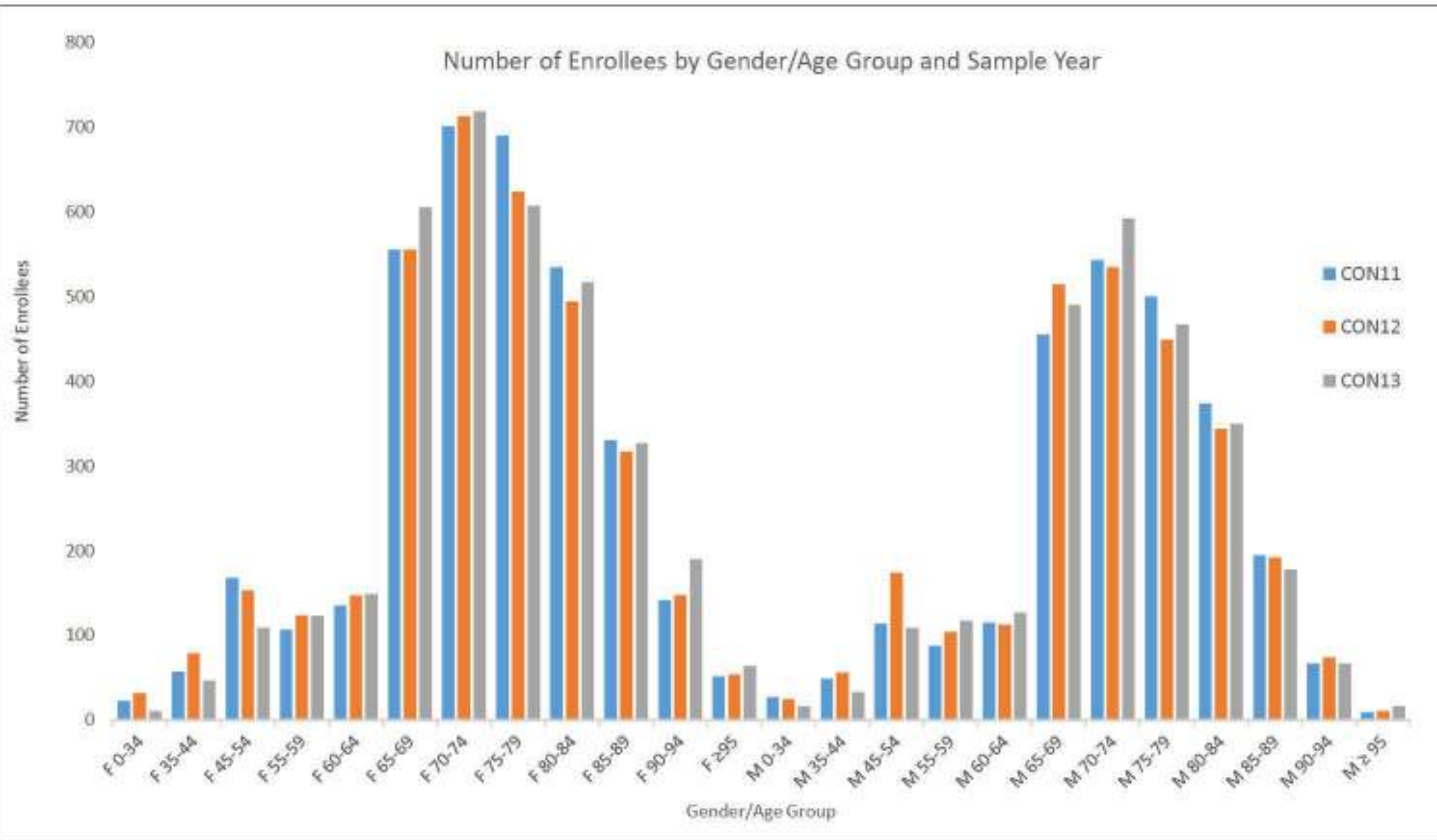
- CON13 has lowest discrepancy rate
 - Highest number of audited HCCs
 - ~900 fewer discrepant HCCs compared to CON12
- CON13 has fewer additional HCCs

Discrepant CMS-HCC Summary by Error Type - Overall

Sample	Discrepant HCCs	Error Type							
		Coding Incomplete		Signature Credential Issues		Invalid		Missing	
		Count	Percent	Count	Percent	Count	Percent	Count	Percent
CON11	3,064	2,424	79.11%	256	8.36%	136	4.44%	248	8.09%
CON12	3,601	2,764	76.76%	303	8.41%	161	4.47%	373	10.35%
CON13	2,764	2,344	84.80%	162	5.86%	105	3.80%	153	5.54%

- Percentage of discrepant HCCs due to incomplete coding is higher in CON13
- Percentage of discrepant HCCs due to signature credential issues, invalid MR, and missing MR is lower in CON13

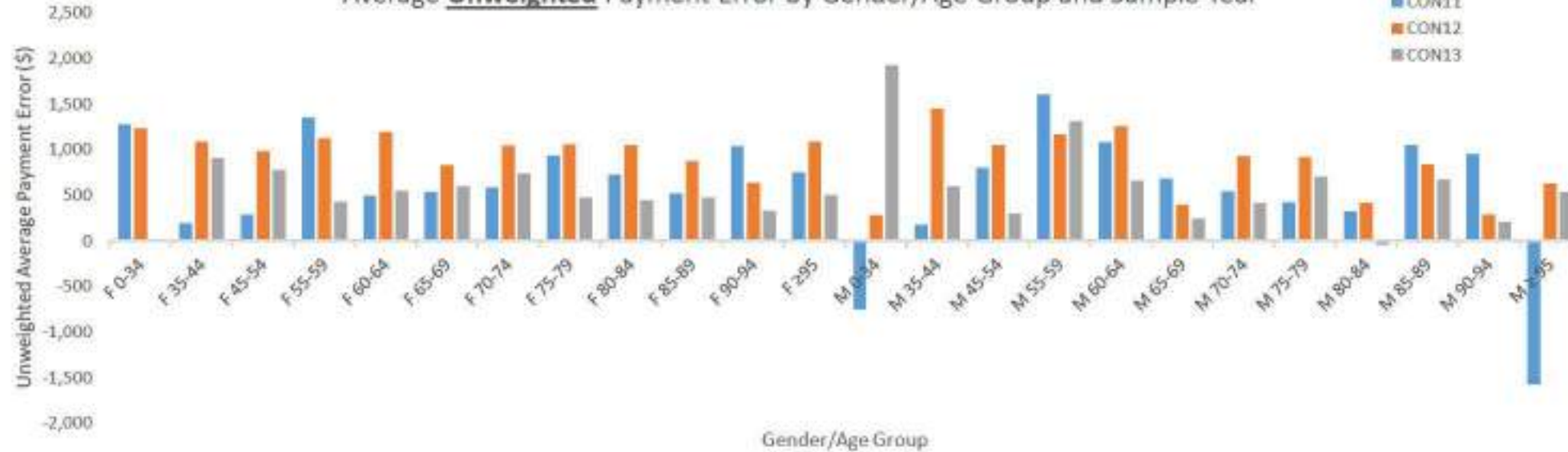
Sampled Enrollees Distribution by Gender/Age Group



➤ The number of sampled enrollees per group appears to be close among the three samples

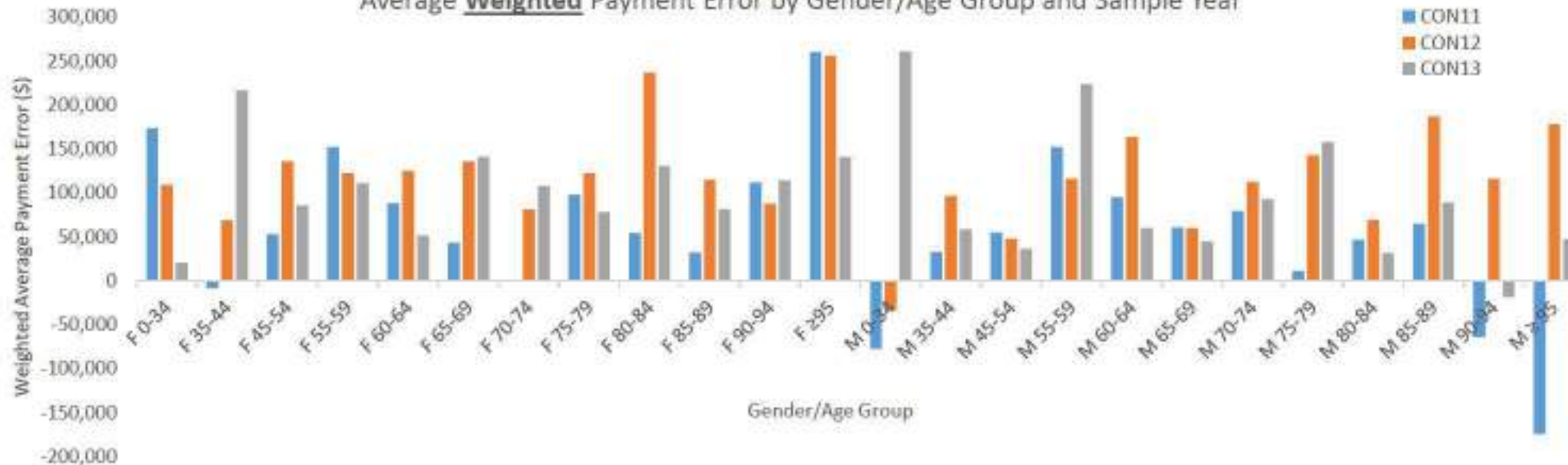
Sampled Enrollees Payment Error by Gender/Age Group

Average Unweighted Payment Error by Gender/Age Group and Sample Year



- The average **unweighted** payment error is lower for CON13 in many of the groups
- The Male 0-34 yrs and Male ≥95 yrs groups show underpayments on average for CON11

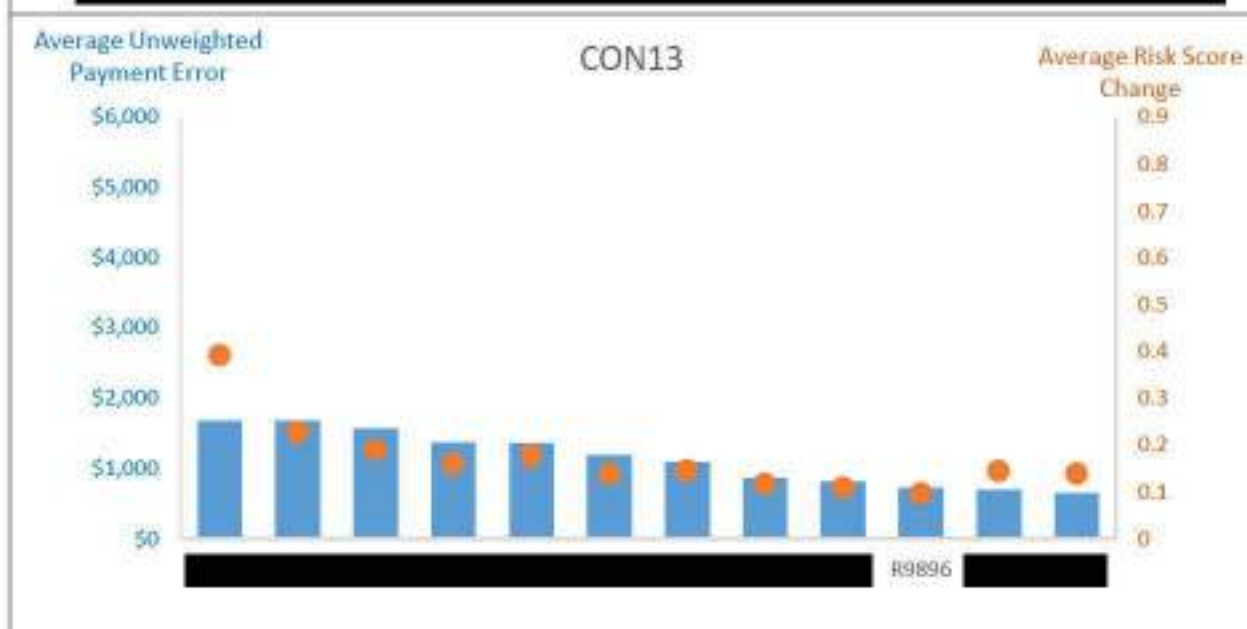
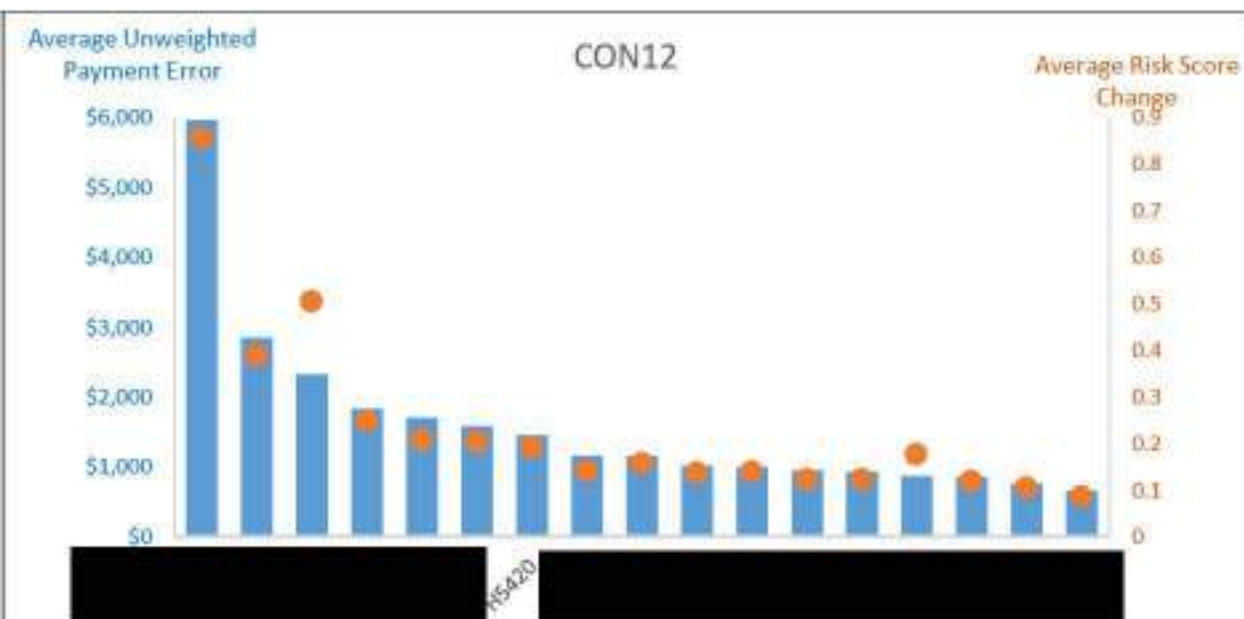
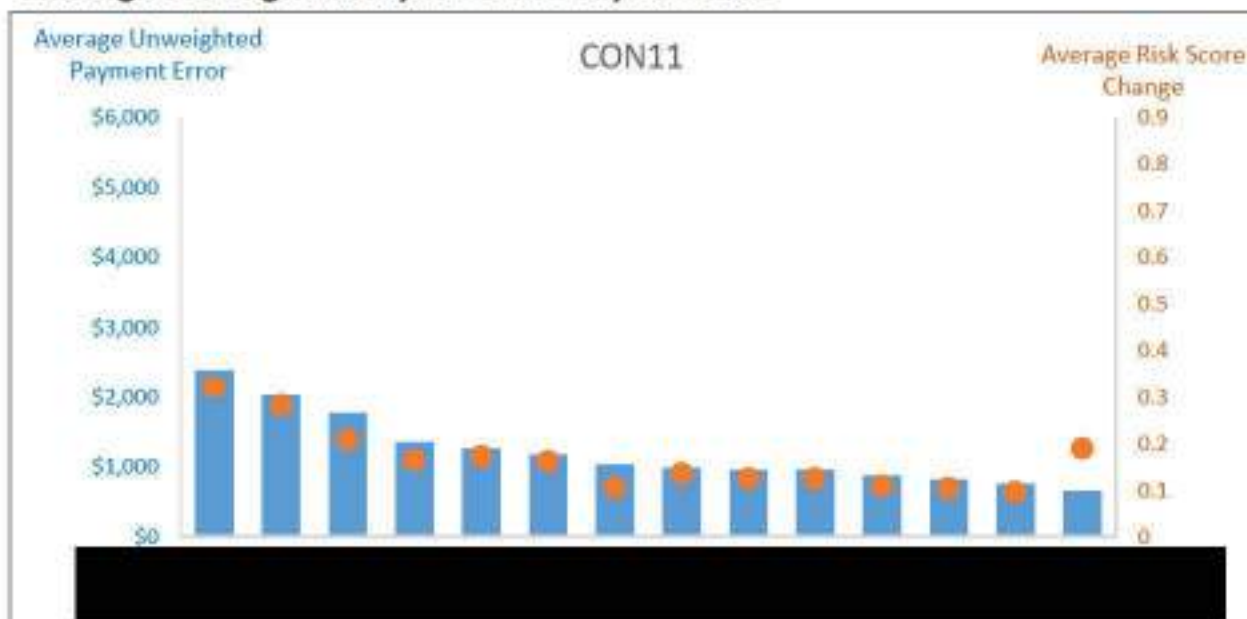
Average Weighted Payment Error by Gender/Age Group and Sample Year



- CON11 has more groups with average **weighted** underpayments

Sampled Enrollees Average Unweighted Payment Error and Risk Score Change by Contract

Average Unweighted Payment Error by Contract



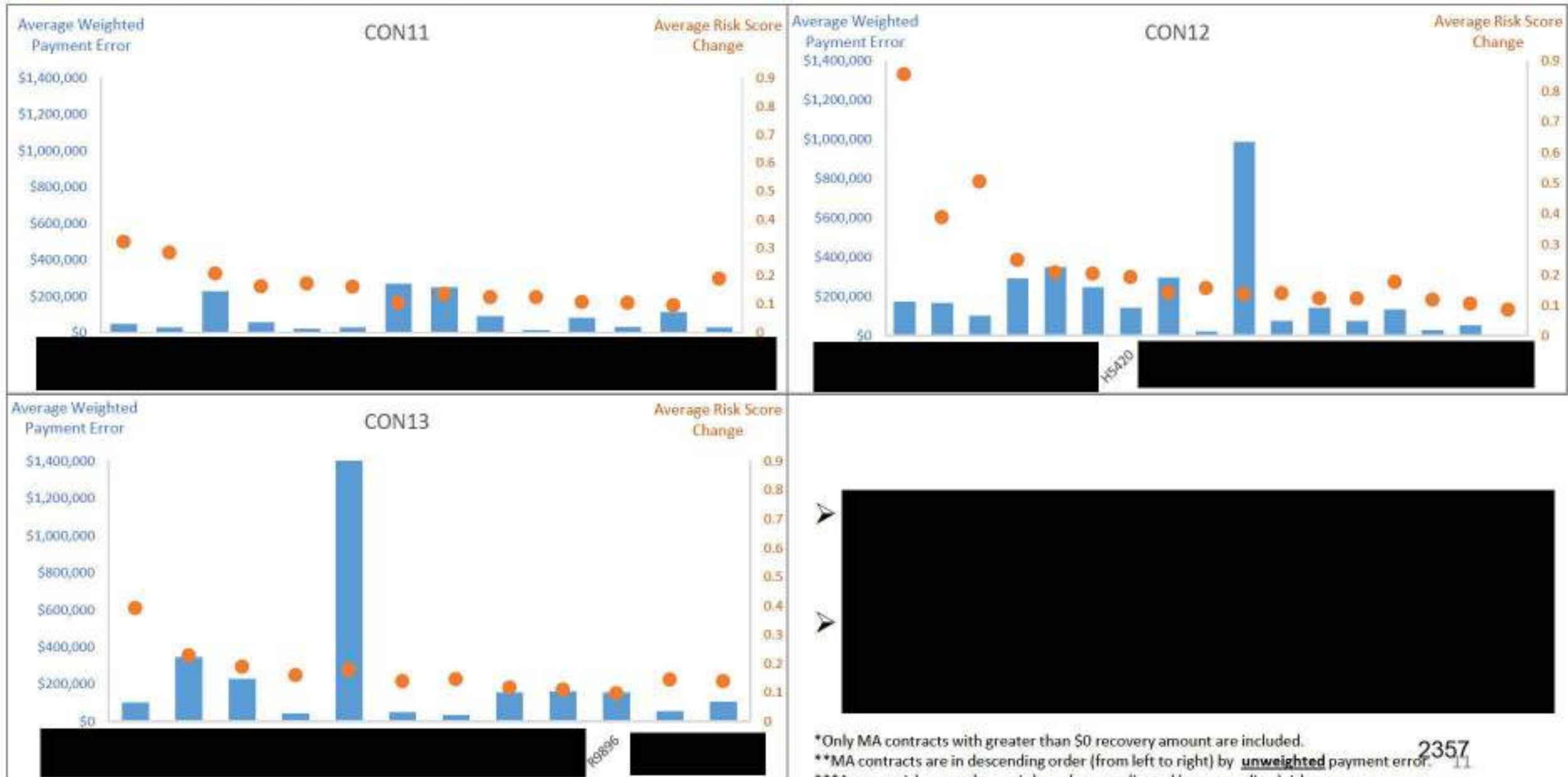
➤ Higher average risk score changes are aligned with the higher average unweighted payment errors

*Only MA contracts with greater than \$0 recovery amount are included.

**Average Risk Score Change is based on unadjusted/un-normalized risk scores.

Sampled Enrollees Average Weighted Payment Error and Risk Score Change by Contract

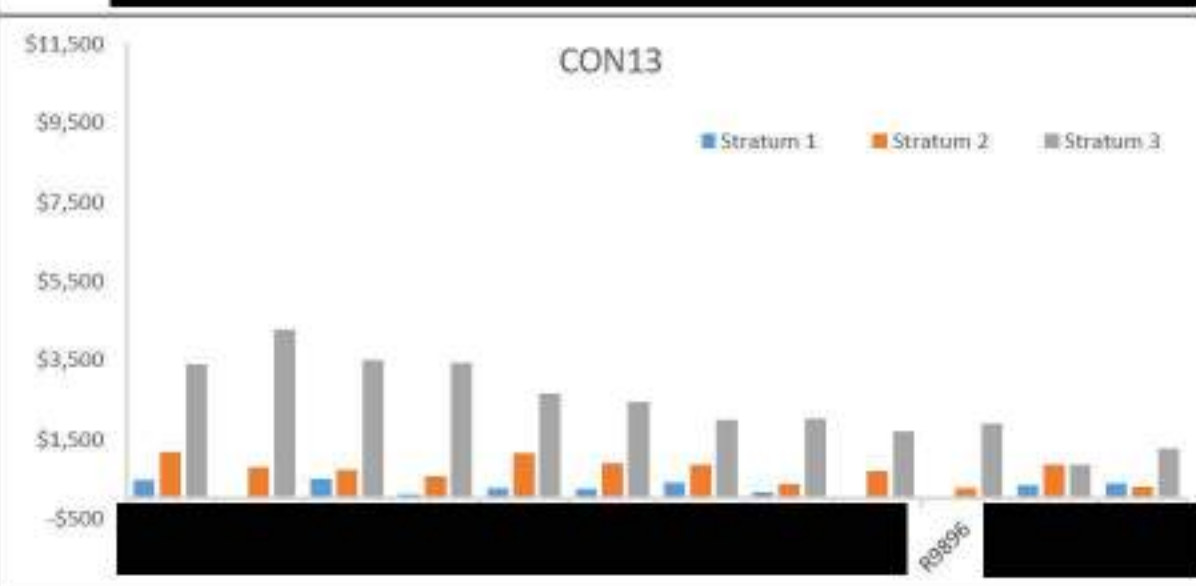
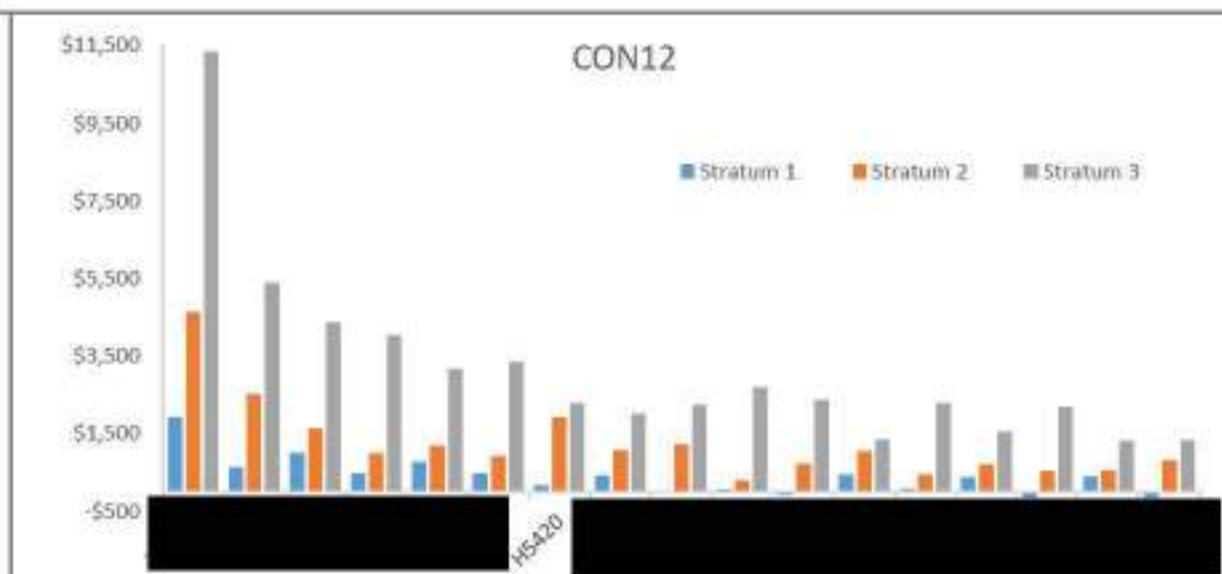
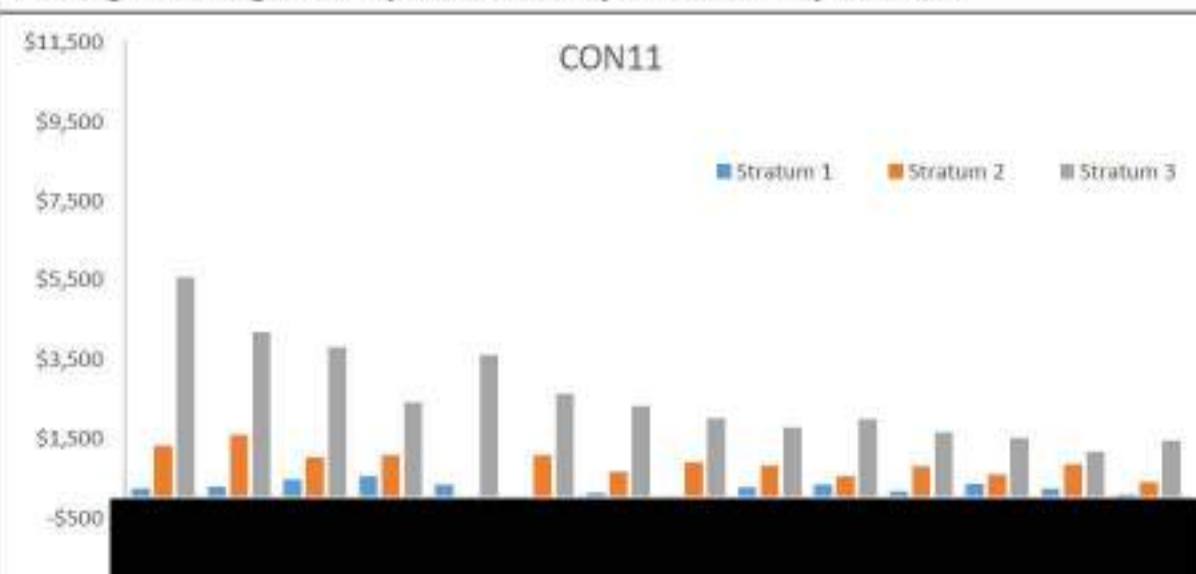
Average Weighted Payment Error by Contract



*Only MA contracts with greater than \$0 recovery amount are included.
 **MA contracts are in descending order (from left to right) by unweighted payment error.
 ***Average risk score change is based on unadjusted/un-normalized risk scores.

Sampled Enrollees Average Unweighted Payment Error by Contract

Average Unweighted Payment Error by Contract – by Stratum

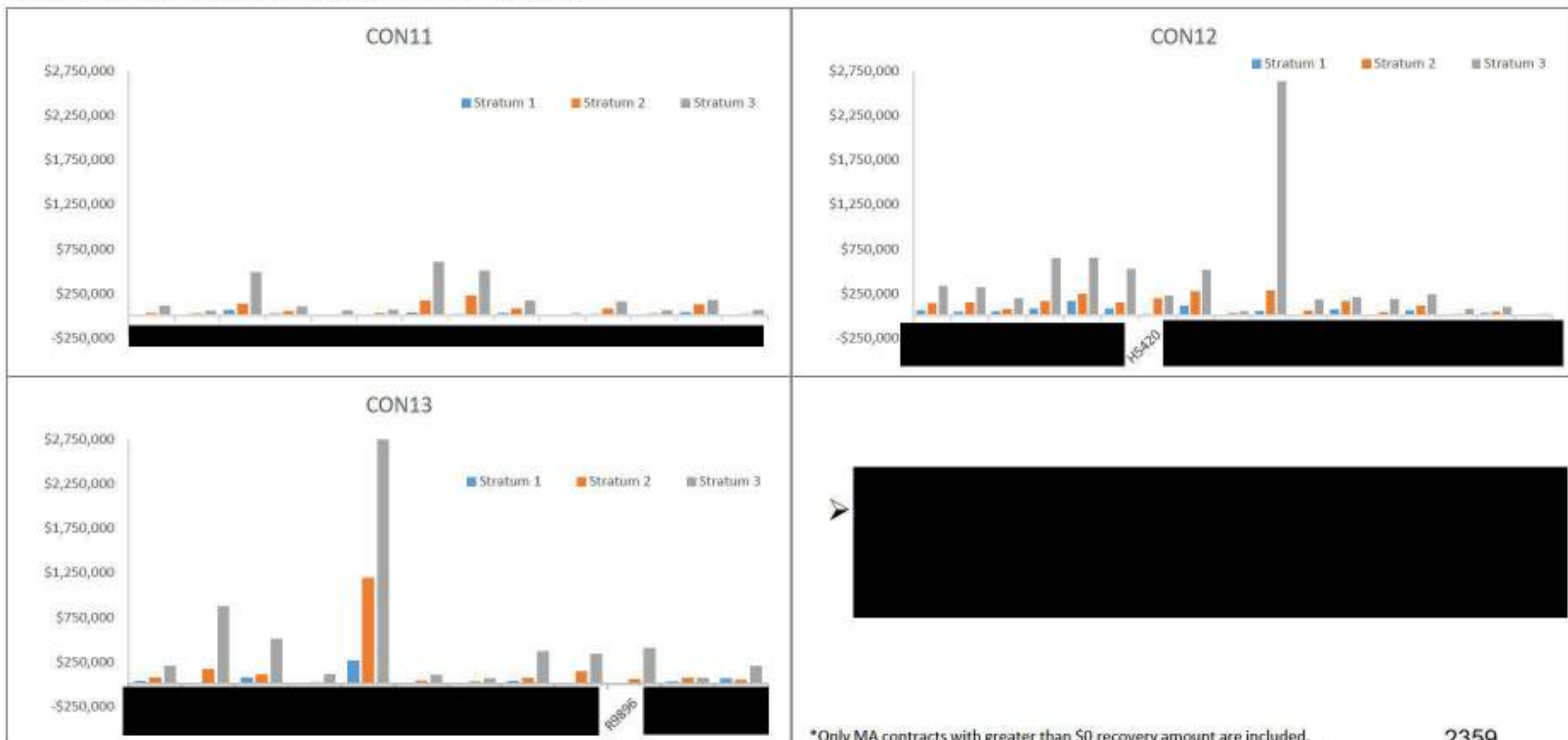


- Average unweighted payment error is lower in Stratum 1 for most contracts
- Average unweighted payment error is higher in Stratum 3 for all contracts

➤ [Redacted]

Sampled Enrollees Average Weighted Payment Error by Contract

Average Weighted Payment Error by Contract – by Stratum

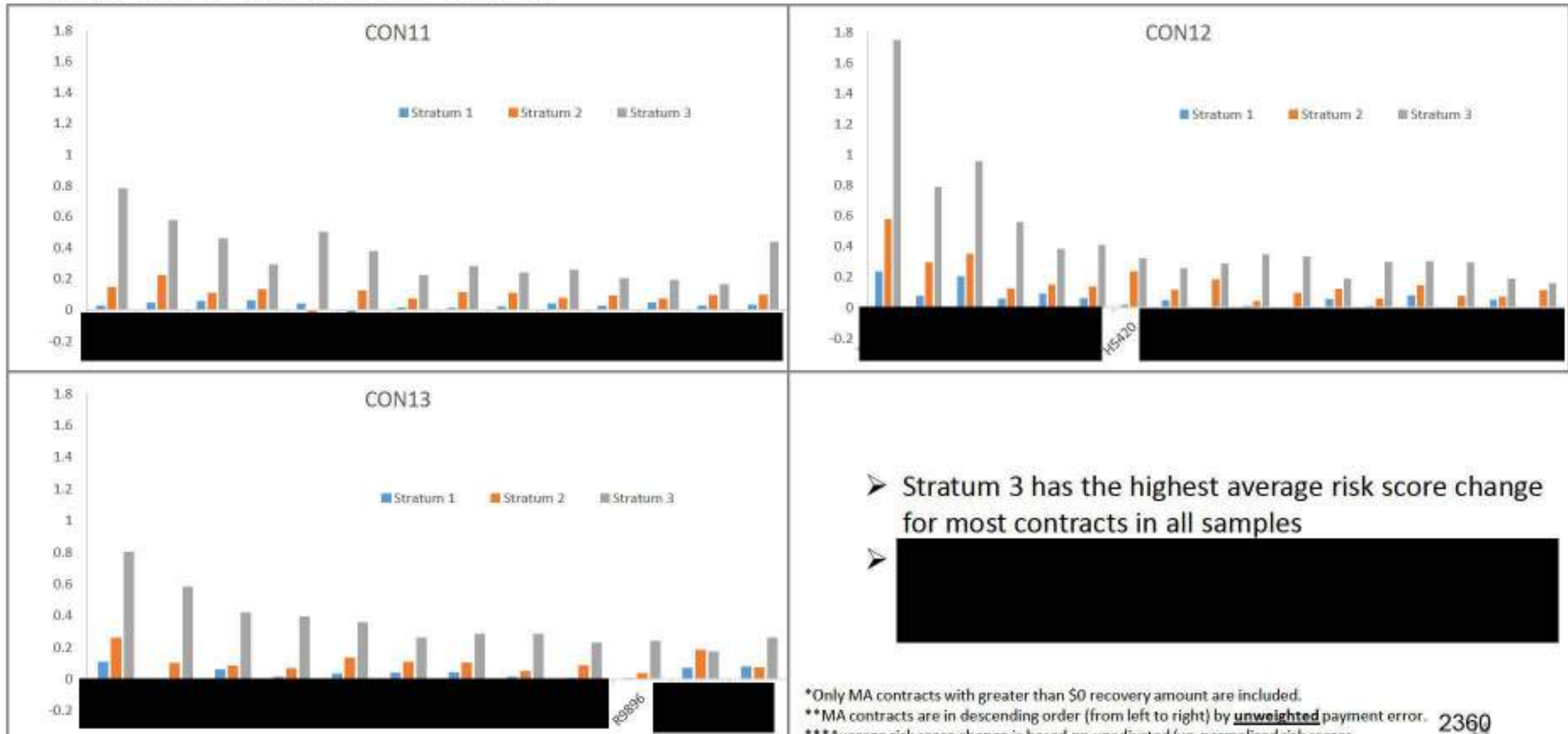


*Only MA contracts with greater than \$0 recovery amount are included.

**MA contracts are in descending order (from left to right) by unweighted payment error.

Sampled Enrollees Average Risk Score Change by Contract

Average Risk Score Change by Contract – by Stratum



➤ Stratum 3 has the highest average risk score change for most contracts in all samples

➤ [Redacted]

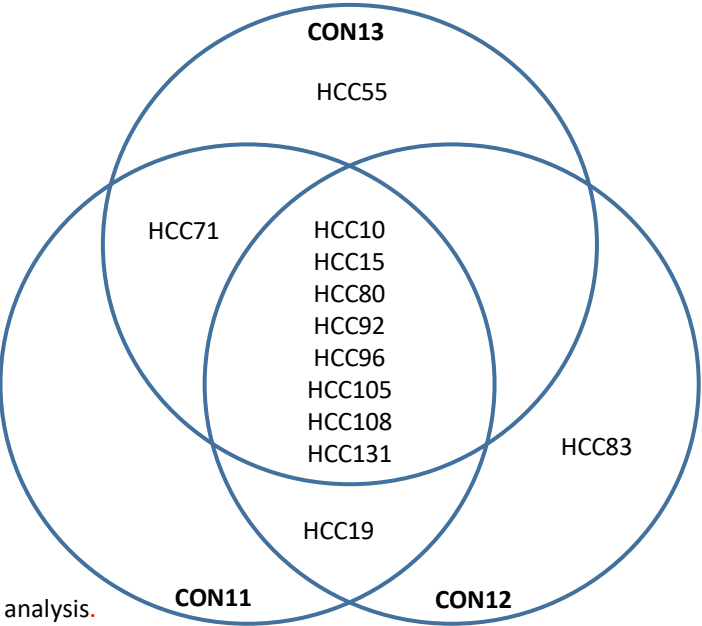
*Only MA contracts with greater than \$0 recovery amount are included.

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Top 10 CMS-HCCs by Discrepancy Count*

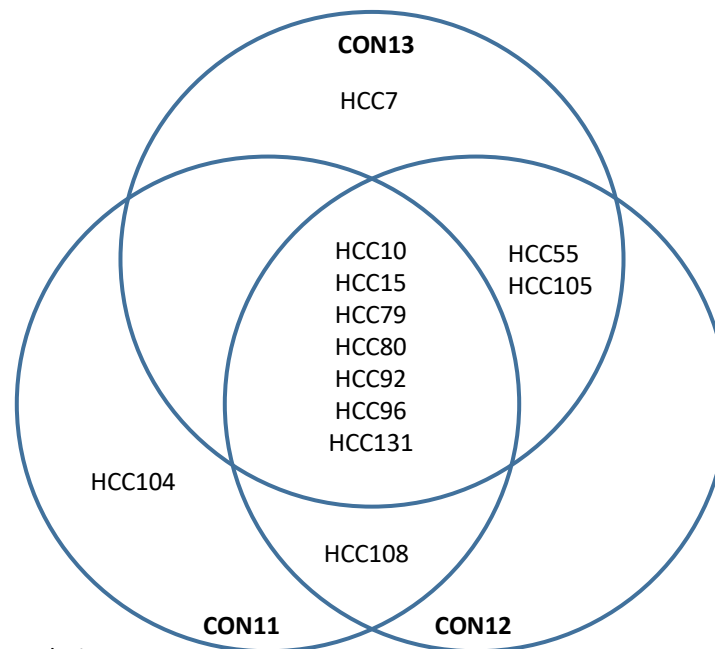
Top 10 Discrepant HCCs									
CON11				CON12			CON13		
#	HCC	# Discrepant	% Total Discrepant	HCC	# Discrepant	% Total Discrepant	HCC	# Discrepant	% Total Discrepant
1	HCC105	139	7.54%	HCC105	234	8.70%	HCC105	139	8.59%
2	HCC10	104	5.64%	HCC80	165	6.13%	HCC96	98	6.06%
3	HCC80	104	5.64%	HCC108	153	5.69%	HCC92	91	5.62%
4	HCC96	101	5.48%	HCC92	150	5.57%	HCC131	88	5.44%
5	HCC108	100	5.43%	HCC10	141	5.24%	HCC15	87	5.38%
6	HCC92	85	4.61%	HCC96	135	5.02%	HCC10	85	5.25%
7	HCC15	81	4.40%	HCC15	130	4.83%	HCC80	85	5.25%
8	HCC71	77	4.18%	HCC19	125	4.65%	HCC55	68	4.20%
9	HCC131	74	4.02%	HCC83	117	4.35%	HCC108	67	4.14%
10	HCC19	71	3.85%	HCC131	114	4.24%	HCC71	67	4.14%



* Only MA contracts with greater than \$0 recovery amount are included in this analysis.

Top 10 CMS-HCCs by Payment Error*

Top 10 Discrepant HCCs									
CON11				CON12			CON13		
#	HCC	Payment Error	PE Rate	HCC	Payment Error	PE Rate	HCC	Payment Error	PE Rate
1	HCC80	\$ 232,768	6.23%	HCC80	\$ 432,535	7.14%	HCC92	\$ 197,608	6.78%
2	HCC96	\$ 224,810	6.02%	HCC108	\$ 399,938	6.60%	HCC96	\$ 190,097	6.52%
3	HCC15	\$ 222,912	5.97%	HCC105	\$ 391,275	6.46%	HCC105	\$ 173,185	5.94%
4	HCC108	\$ 209,896	5.62%	HCC15	\$ 387,222	6.39%	HCC131	\$ 153,303	5.26%
5	HCC79	\$ 206,924	5.54%	HCC92	\$ 320,202	5.29%	HCC7	\$ 132,003	4.53%
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8	HCC92	\$ 172,308	4.61%	HCC55	\$ 256,185	4.23%	HCC55	\$ 118,243	4.06%
9	HCC38	\$ 149,132	3.99%	HCC79	\$ 240,443	3.97%	HCC15	\$ 115,827	3.97%
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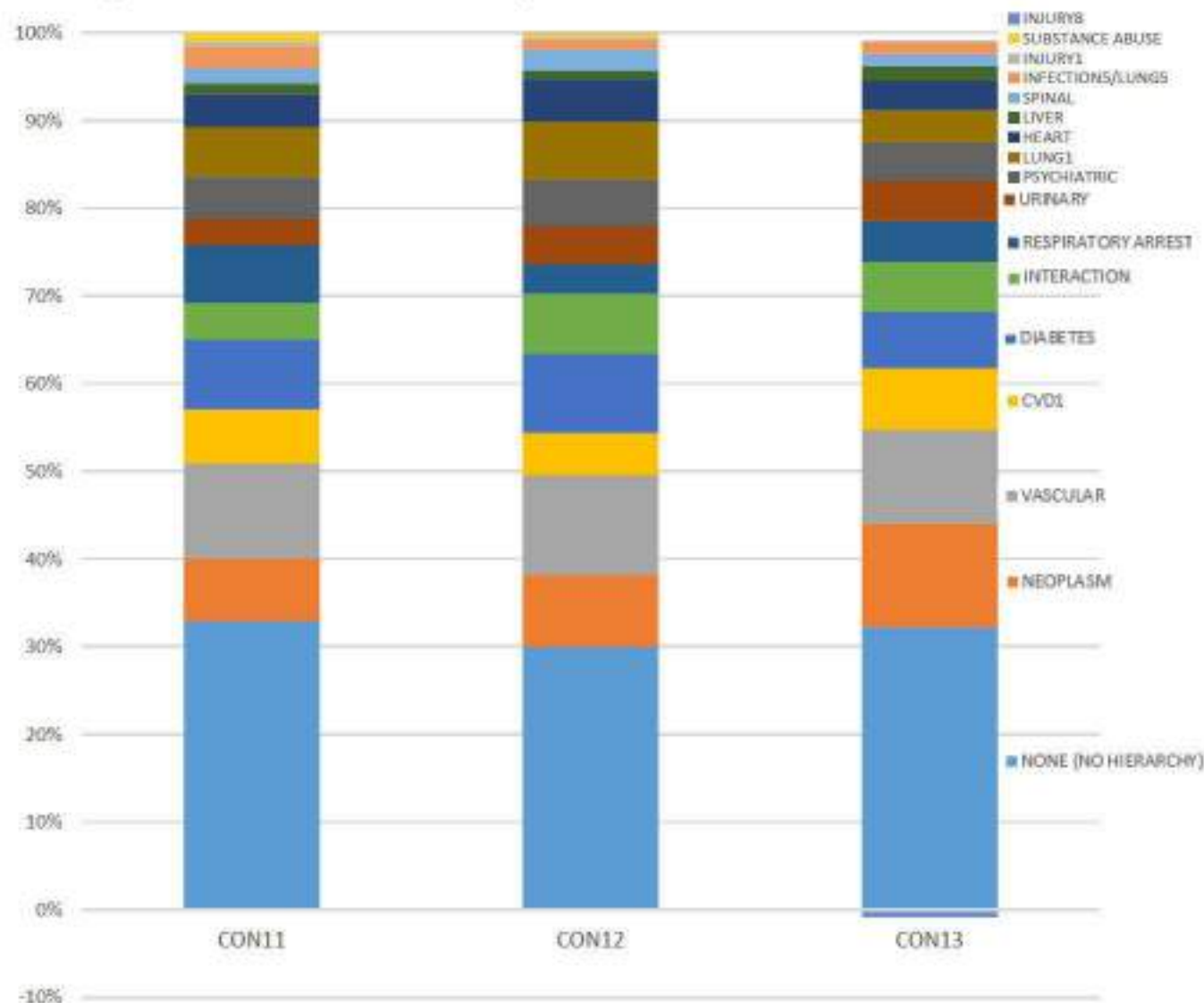


* Non-normalized, unadjusted, unweighted payment error

* Only MA contracts with greater than \$0 recovery amount are included in this analysis.

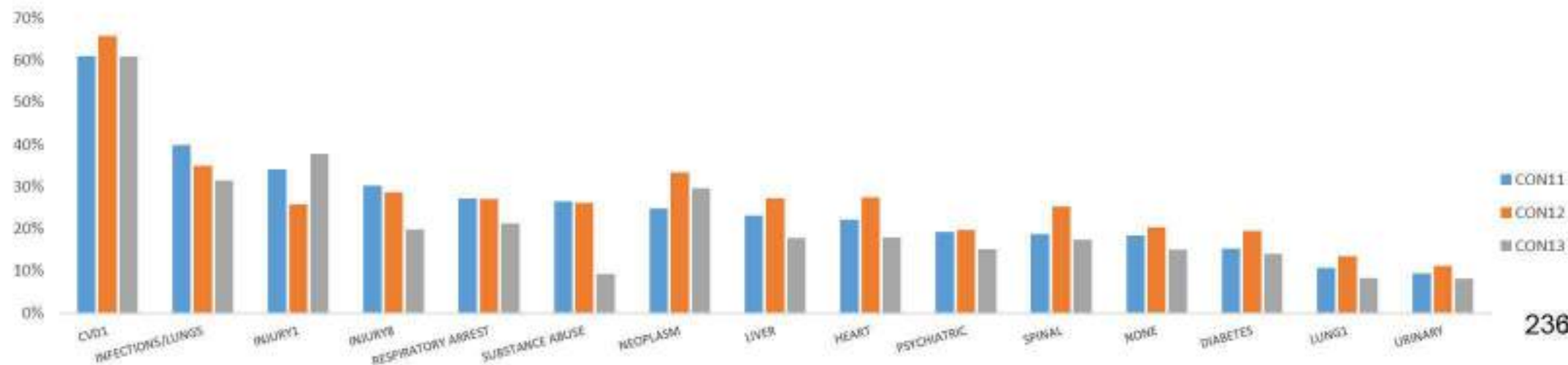
Payment Error by Disease Group*

Hierarchy	Payment Error		
	CON11	CON12	CON13
TOTAL	\$ 3,736,489	\$ 6,056,084	\$ 2,914,685
NONE (NO HIERARCHY)	\$ 1,230,887	\$ 1,815,030	\$ 955,665
VASCULAR	\$ 405,410	\$ 691,622	\$ 318,243
DIABETES	\$ 297,372	\$ 547,968	\$ 189,497
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HEART	\$ 139,357	\$ 295,718	\$ 98,325
URINARY	\$ 109,679	\$ 267,122	\$ 134,561
INFECTION5/LUNG5	\$ 89,442	\$ 68,666	\$ 37,412
SPINAL	\$ 68,441	\$ 147,447	\$ 40,329
LIVER	\$ 45,436	\$ 55,658	\$ 51,715
SUBSTANCE ABUSE	\$ 39,979	\$ 29,194	\$ 2,226
INJURY1	\$ 18,168	\$ 14,429	\$ 6,930
INJURY8	\$ (1,344)	\$ 3,381	\$ (24,857)



Discrepancy Rates by Disease Group

Disease Group	CON11			CON12			CON13		
	Sampled	Discrepant	Discrepancy Rate	Sampled	Discrepant	Discrepancy Rate	Sampled	Discrepant	Discrepancy Rate
CVD1	312	190	60.90%	311	204	65.59%	298	181	60.74%
DIABETES	2,583	392	15.18%	2,625	510	19.43%	2,733	383	14.01%
HEART	951	210	22.08%	1,019	279	27.38%	1,012	181	17.89%
INFECTIONS/LUNG5	123	49	39.84%	89	31	34.83%	86	27	31.40%
INJURY1	50	17	34.00%	70	18	25.71%	53	20	37.74%
INJURY8	53	16	30.19%	42	12	28.57%	66	13	19.70%
LIVER	126	29	23.02%	114	31	27.19%	113	20	17.70%
LUNG1	1,399	149	10.65%	1,460	196	13.42%	1,466	120	8.19%
NEOPLASM	990	245	24.75%	829	276	33.29%	840	248	29.52%
NONE (NO HIERARCHY)	5,145	942	18.31%	5,099	1,034	20.28%	5,578	836	14.99%
PSYCHIATRIC	689	132	19.16%	918	180	19.61%	895	135	15.08%
RESPIRATORY ARREST	369	100	27.10%	330	89	26.97%	349	74	21.20%
SPINAL	316	59	18.67%	346	87	25.14%	363	63	17.36%
SUBSTANCE ABUSE	186	49	26.34%	203	53	26.11%	250	23	9.20%
URINARY	1,251	117	9.35%	1,538	171	11.12%	1,760	143	8.13%
VASCULAR	1,720	368	21.40%	1,849	430	23.26%	2,001	297	14.84%



Summary Statistics CON11 (Sorted by Descending Recovery Amount)

CON11						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$355,028			
			\$198,283			
			\$206,760			
			\$151,598			
			\$192,131			
			\$477,849			
			\$271,056			
			\$408,266			
			\$130,357			
			\$235,896			
			\$164,324			
			\$175,719			
			\$251,829			
			\$192,128			
			\$76,998			
H2226	UnitedHealth Group, Inc.	HI	\$37,933	2,773	(\$2,068,360.00)	(\$745.89)
			\$88,994			
			\$113,827			
			\$81,595			
			\$45,006			
			\$89,809			
H4522	UnitedHealth Group, Inc.	LOW	(\$38,104)	6,023	(\$4,622,640.00)	(\$767.50)
			\$47,311			
			\$76,600			
			(\$1,662)			
			(\$39,035)			
			(\$53,277)			
			(\$54,856)			
H4590	UnitedHealth Group, Inc.	HI	(\$8,630)	91,850	(\$51,017,738.00)	(\$555.45)
H0543	UnitedHealth Group, Inc.	HI	\$35,126	185,186	(\$91,884,129.00)	(\$496.17)

Summary Statistics CON12 (Sorted by Descending Recovery Amount)

CON12						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$202,609			
			\$341,198			
			\$367,086			
			\$316,883			
			\$1,197,584			
			\$232,536			
			\$571,738			
			\$466,263			
H5420	UnitedHealth Group, Inc.	HI	\$290,803	19,923	\$15,735,769	\$789.83
			\$174,147			
			\$189,414			
			\$199,820			
			\$187,043			
			\$150,526			
			\$171,730			
			\$230,838			
			\$131,073			
			\$1,902			
			\$103,752			
			\$54,707			
			\$11,023			
R7444	UnitedHealth Group, Inc.	HI	\$40,516	9,559	(\$3,962,831)	(\$414.57)
H5652	UnitedHealth Group, Inc.	HI	(\$141,220)	3,414	(\$4,740,216)	(\$1,388.46)
			(\$22,584)			
			\$20,132			
			\$133,204			
			(\$155,487)			
H0251	UnitedHealth Group, Inc.	HI	(\$73,921)	11,357	(\$10,348,919)	(\$911.24)
			(\$8,445)			
R5287	UnitedHealth Group, Inc.	HI	(\$32,705)	84,014	(\$69,295,194)	(\$824.81)

Summary Statistics CON13 (Sorted by Descending Recovery Amount)

CON13						
HMOID	Parent Org	Coding Intensity Group	Net Payment Error	RADV Eligible Population	Recovery Amount	Recovery Amount Per RADV Eligible Enrollee
			\$272,003			
			\$337,112			
			\$315,529			
			\$337,267			
			\$171,454			
			\$162,436			
			\$129,630			
			\$138,336			
R9896	UnitedHealth Group, Inc.	HI	\$144,939	43,114	\$4,065,269	\$94.29
			\$238,417			
			\$274,061			
			\$217,529			
			\$98,606			
			\$64,631			
H3107	UnitedHealth Group, Inc.	HI	\$107,627	27,753	(\$1,581,972)	(\$57.00)
			\$55,312			
			\$51,785			
			\$13,962			
			\$66,409			
			(\$59,194)			
			\$94,339			
H0151	UnitedHealth Group, Inc.	HI	\$47,142	21,671	(\$7,790,780)	(\$359.50)
H4514	UnitedHealth Group, Inc.	HI	(\$5,954)	13,265	(\$9,302,996)	(\$701.32)
			\$24,887			
H2931	UnitedHealth Group, Inc.	HI	\$15,457	31,364	(\$10,078,497)	(\$321.34)
			(\$34,668)			
R5342	UnitedHealth Group, Inc.	HI	(\$32,110)	23,226	(\$14,309,264)	(\$616.09)
			(\$52,137)			
			(\$33,582)			
			(\$125,921)			

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 9 OF 14
EXHIBITS D-83 THROUGH D-110
PAGES 2368 THROUGH 2878**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT D-83

HMOID	CON Year	Parent Org	Coding Intensity Group	Recovery Amount
H0543	11	UnitedHealth Group, Inc.	HI	(\$91,884,129.00)
R5287	12	UnitedHealth Group, Inc.	HI	(\$69,295,194.00)
H4590	11	UnitedHealth Group, Inc.	HI	(\$51,017,738.00)
R5342	13	UnitedHealth Group, Inc.	HI	(\$14,309,264.00)
H0251	12	UnitedHealth Group, Inc.	HI	(\$10,348,919.00)
H2931	13	UnitedHealth Group, Inc.	HI	(\$10,078,497.00)
H4514	13	UnitedHealth Group, Inc.	HI	(\$9,302,996.00)
H0151	13	UnitedHealth Group, Inc.	HI	(\$7,790,780.00)
H5652	12	UnitedHealth Group, Inc.	HI	(\$4,740,216.00)
H4522	11	UnitedHealth Group, Inc.	LOW	(\$4,622,640.00)
R7444	12	UnitedHealth Group, Inc.	HI	(\$3,962,831.00)
H2226	11	UnitedHealth Group, Inc.	HI	(\$2,068,360.00)
H3107	13	UnitedHealth Group, Inc.	HI	(\$1,581,972.00)
R9896	13	UnitedHealth Group, Inc.	HI	\$4,065,269.00
H5420	12	UnitedHealth Group, Inc.	HI	\$15,735,769.00

(\$261,202,498.00)

Total UHG Net
Underpayment for
PYs 2011 to 2013

EXHIBIT

1501

EXHIBIT D-84

UNITED STATE EX REL. POEHLING V. UNITEDHEALTH GROUP, INC. [LATHAM & WATKINS]

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File Type: application/vnd.openxmlformats-officedocument.spreadsheetml.sheet

File Size: 4,055 KB

File Name: CON14 CMS RADV Results Summary.xlsx

MD5 Checksum[†]: 78764c73e9b849a4c2569978e79e24b3

File attachment[‡]:



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EXHIBIT

1521

2371

EXHIBIT D-85

UNITED STATE EX REL. POEHLING V. UNITEDHEALTH GROUP. INC. [LATHAM & WATKINS]

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File Type: application/vnd.openxmlformats-officedocument.spreadsheetml.sheet

File Size: 5,704 KB

File Name: CON15_CDAT_Detail Report_01092023.xlsx

MD5 Checksum[†]: c22471eb9c7451ed6305e4ec5d81230e

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Why Medicare Advantage Plans Are Being Overpaid By \$200 Billion And What To Do About It

[Richard Kronick](#)

JANUARY 29, 2020 10.1377/forefront.20200127.293799



In the Deficit Reduction Act of 2005, Congress gave the Centers for Medicare and Medicaid Services (CMS) the statutory authority and obligation to implement a “coding intensity adjustment” for Medicare Advantage (MA) plans, to adjust for differences in patterns of diagnosis coding between MA and traditional Medicare.

Under both the Obama and Trump administrations, the coding intensity adjustment implemented by CMS has consistently been substantially smaller than justified by the data. The fiscal problem created by inadequate adjustment for coding intensity is large. Under reasonable assumptions about the rate of growth of MA coding, [CMS will overpay MA plans by \\$200 billion](#) over the next decade if the coding intensity adjustment remains at 5.91 percent, its current level.

Why does this overpayment persist? The annual decision about the size of the coding intensity adjustment is made by political appointees at CMS, the Department of Health and Human Services, and the White House, and the political benefits from implementing a smaller than empirically justified coding intensity adjustment far outweigh the potential political gains from protecting the taxpayers and creating a stable and level playing field between MA and traditional Medicare. To fix this problem, Congress should remove discretion from CMS and specify in statute an even-handed method of computing coding intensity. A statutory formula for measuring coding intensity would bring MA payment more in line with payment for other providers, in which Congress, not CMS, decides how much providers will be paid.

Below, I offer suggestions regarding what a statutory coding intensity adjustment formula should look like. Of course, Congress, like CMS, is subject to political pressures that will make enacting such a formula difficult. But unlike CMS, Congress could use the \$200 billion in

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293799

avoided MA overpayments to fund other priorities, offering countervailing political incentives for legislators to save taxpayer money and level the playing field between MA and traditional Medicare by adopting a statutory measure of relative coding intensity.

The Problem

CMS pays MA plans based on the health status of the beneficiaries who enroll, paying more for older and sicker enrollees and less for younger and healthier enrollees. This "risk adjusted" payment mechanism is intended to encourage MA plans to develop systems of care that are attractive to beneficiaries most in need and to prevent MA plans from profiting by attracting only good risks.

The health status of MA enrollees is measured using diagnostic information submitted by the MA plans themselves. As a result, MA plans have strong incentives to identify and report as many diagnoses as can be supported by the medical record, incentives that are not present in traditional Medicare. Although some MA plans may have used fraudulent strategies to inflate enrollee risk scores, many legitimate strategies are available to MA to increase risk scores. The incompleteness of diagnostic coding in traditional Medicare provides ample opportunities for MA plans to increase the identification and reporting of diagnoses. For example, in traditional Medicare, approximately 40 percent of beneficiaries coded with quadriplegia in a 12-month period do not have a diagnosis of quadriplegia appear on any claim in the subsequent 12 months.

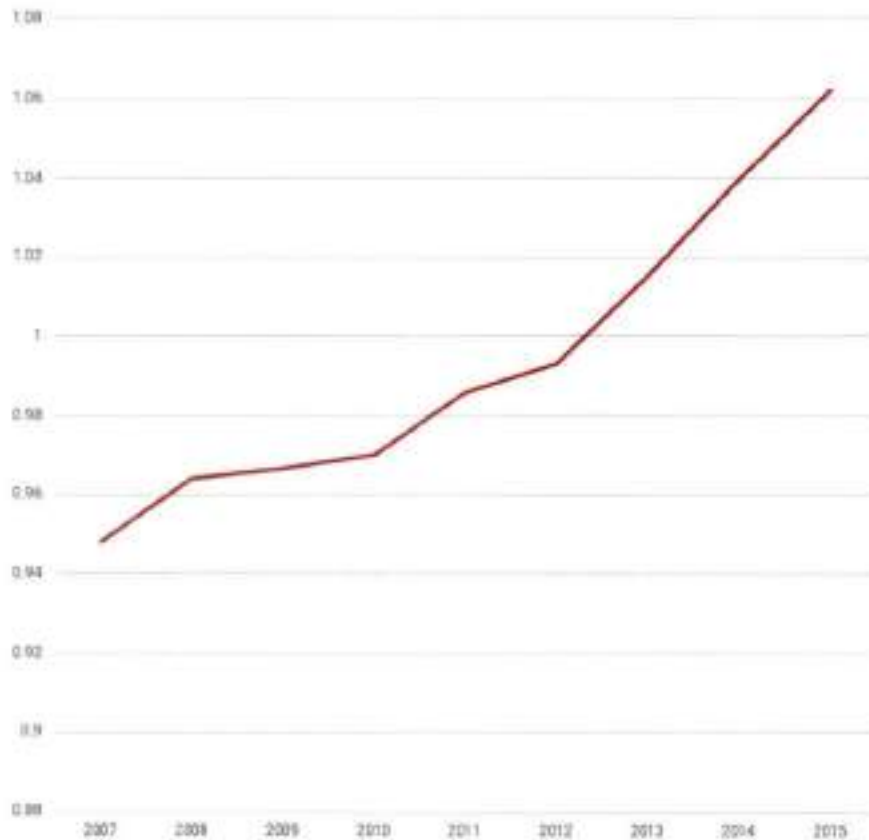
Discretion For CMS

Recognizing the likelihood that MA plans will report diagnostic information differently than is reported in traditional Medicare, in the Deficit Reduction Act of 2005, Congress gave CMS the authority to implement a "coding

intensity adjustment” to adjust for differences in coding patterns between MA and traditional Medicare. In 2010, CMS implemented a 3.41 percent coding intensity adjustment, reducing MA risk scores by that amount. The Affordable Care Act, and subsequently the American Taxpayers Relief Act of 2012, created a schedule of minimum adjustments, starting at 4.71 percent in 2014, increasing to 5.91 percent in 2018.

CMS retained the authority and obligation to implement adjustments larger than the statutory minimum if the data indicated that a larger adjustment was needed. However, it has not yet done so, despite strong evidence that a larger adjustment is needed to compensate for differences between MA and traditional Medicare in coding patterns. The measured risk of MA enrollees relative to traditional Medicare increased from 95.0 percent in 2007 to 106.2 percent in 2015 (exhibit 1).

Exhibit 1: Average risk score of Medicare Advantage enrollees as a percentage of average risk score of traditional Medicare beneficiaries, 2007-15



Source: [Richard Kronick and Pete Welch, 2014](#); [Paul Jacobs and Richard Kronick, 2018](#).

MA enrollment grew substantially from 2007 to 2015, and it is theoretically possible that the increase in relative risk reflects real changes in the relative health of MA enrollees. However, analyses of other data sources—including [mortality rates](#), [survey data from the Medicare Current Beneficiary Survey](#), [data on switchers from traditional Medicare to MA](#), and [prescription drug use data](#)—show conclusively that there was little, if any, change in real relative risk over this time period. The 11-percentage-point increase in measured relative risk from 2007 to 2015 appears largely to be the result of differences in coding patterns between MA and traditional Medicare.

Perverse Political Incentives

The main reason that CMS has not implemented a larger

coding intensity adjustment is that there is little political gain from doing so, and the decision about the coding intensity adjustment is, ultimately, made by political appointees. If CMS were to implement an adjustment that is larger than the statutory minimum, MA plans would make their displeasure known to members of Congress. Furthermore, an adjustment larger than the statutory minimum might result in higher MA premiums or fewer extra benefits for enrollees, raising the likelihood of constituent dissatisfaction.

In even numbered years, information on MA premiums and benefits is made public soon before the November elections. Members of Congress (and, every four years, the president) are concerned that voters, likely encouraged by information fed to them by MA plans, may blame incumbents for increased premiums or reduced benefits. This is not a merely theoretical argument. Federal legislators have repeatedly exerted strong bipartisan pressure on CMS in response to industry and constituent concerns about MA payment policy.

The political cost of more aggressive action by CMS on coding intensity is clear. The political benefits are much less clear: The deficit would be slightly smaller but not enough to change interest rates or anything else that voters would notice. Given this imbalance between political costs and benefits, it is not surprising that CMS has stuck with the statutory minimum, despite strong evidence that larger adjustments are warranted.

Proposed Solution: Specify The Coding Intensity Adjustment Formula By Statute

This problem could be solved by removing discretion from CMS when calculating the coding intensity adjustment, which Congress could do by writing a method for calculating the adjustment into statute. This approach would make payment for MA plans more like

payment for other providers—Congress typically tells CMS how to set payment rates, leaving relatively little discretion to CMS.

MedPAC's Method

There are several reasonable options for specification of a formula to calculate the coding intensity adjustment. For example, Congress could direct CMS to adopt the [approach used by the Medicare Payment Advisory Commission](#) (MedPAC) in the past few years to estimate the magnitude of differential MA coding. That method compares the rate of growth in risk scores for MA enrollees with the rate of growth in risk scores for similar beneficiaries in traditional Medicare. For 2015, MedPAC estimated coding intensity increased MA risk scores by 10 percent. The MedPAC estimates for 2016 and 2017 are slightly lower—8 percent and 7 percent respectively—largely because of changes in the model used to calculate beneficiary risk scores. However, further changes in that model in 2018 and subsequent years are likely to increase the estimated coding intensity effect.

The MedPAC method is reasonable but requires complex calculations, would be difficult to audit, and is somewhat difficult to explain. It would be extraordinarily difficult to write into statute in enough detail to remove discretion from CMS in implementation.

A Better, More Practical Approach

An alternative, and, in my view, preferable approach would be to require CMS to calculate the coding intensity adjustment using a method that CMS floated as a trial balloon in the [Advance Notice for 2016 MA rates](#). First, CMS would calculate the relative risk of MA using the diagnostic risk adjustment system, which, as noted above, was 106.2 percent in 2015.

Second, CMS would calculate the relative risk of MA

using information on the age, gender, Medicaid status, and institutional status of enrollees—that is, using the Adjusted Area Per Capita Cost (AAPCC) system that was used prior to the introduction of diagnosis-based risk adjustment. In 2015, MA relative risk using these four factors was 97 percent. That statistic is less than 100 percent primarily because MA enrollees were less likely than traditional Medicare beneficiaries to be institutionalized, and institutionalized enrollees have high risk scores.

Third, CMS would divide the second number by the first, and subtract the quotient from 1.0. The result, which would have been 8.7 percent in 2015, would be the coding intensity adjustment.

This is a simple approach to explain and write into statute. It assumes that MA enrollees are no healthier and no sicker than demographically similar traditional Medicare beneficiaries. This assumption of no favorable or adverse selection is likely still a bit generous to MA—although the extent of favorable selection for MA appears to have declined over the past decade, [there is no evidence](#) to suggest that MA enrollees are, on average, sicker than demographically similar traditional Medicare beneficiaries, and some evidence to suggest they are a bit healthier.

The method of calculating coding intensity suggested above would return to the “budget neutrality” method that CMS, under the leadership of Tom Scully, implemented when the CMS-HCC (hierarchical condition category) risk adjustment model began to be phased in in 2004. At that time, MA relative risk, using the CMS-HCC model, was well below 1.0, and MA revenues would have been reduced if the CMS-HCC model had been implemented without adjustment. To avoid this outcome, CMS implemented a “budget neutrality adjustment,” increasing CMS-HCC scores by the ratio suggested above. In the

Deficit Reduction Act of 2005, Congress directed CMS to phase out the budget neutrality adjustment by 2008. Ironically, in 2008, the measured relative risk of MA using the CMS-HCC model became greater than the measured relative risk using the AAPCC model, so if budget neutrality had been left in place, it would have resulted in decreases in payments to MA.

One potential substantive disadvantage to this approach is that at some point in the future it is theoretically possible that MA enrollees will, on average, be sicker than demographically similar traditional Medicare beneficiaries, and that the formula will unfairly penalize MA contracts. At the risk of giving CMS discretion that might be abused, CMS could be given the authority to use other data—such as data on mortality rates, prescription drug use, and the Medicare Current Beneficiary Survey—to analyze whether there is adverse selection against MA. Under this option, if CMS certifies that there is strong evidence of adverse selection against MA, then it would have the authority to adjust the statutory formula to reflect that adverse selection. Political influence on this decision could be lessened by requiring the CMS Office of the Actuary (OACT), not the agency's Center for Medicare, to make the certification. OACT has traditionally been less responsive than other parts of CMS to the preferences of political appointees.

A second potential concern about the proposed approach, as well as about the status quo adjustment of 5.91 percent, is that there is [substantial variation across MA plans in how aggressively they have increased risk scores](#). Any industrywide adjustment will pay too much to plans that have been most aggressive in coding, too little to plans that have been least aggressive, and leave in place the incentive to code as many diagnoses as legally permissible. Consideration could be given to contract-specific adjustments, but it is far more important to first get the coding intensity adjustment, on average, correct.

- After first fixing the \$200 billion problem, Congress and CMS could then consider whether and how to implement contract-specific adjustments.

Summing Up

Under reasonably conservative assumptions about the rate of growth of coding intensity, using the budget neutrality method to calculate coding intensity would likely result in approximately \$200 billion in savings to Medicare over the next decade compared to current policy in which the coding intensity adjustment remains at 5.91 percent. Just as CMS is reluctant to anger the MA industry and its enrollees, members of Congress will be reluctant as well. However, unlike CMS, which does not get to spend any of the savings generated by more appropriate actions on coding intensity, Congress can choose to use the \$200 billion in savings for additional spending or tax cuts, providing reason to hope that legislators will, at some point, do the right thing.

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EXHIBIT D-87

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex :
rel., BENJAMIN POEHLING, :
Plaintiffs, : Case No.:
VS. : CV-16-08697 FMO
UNITED HEALTH GROUP, INC., :
et al., :
Defendants. : Page 1-362

- - -

Friday, March 22, 2024

- - -

Videotaped deposition of JEAN ACEVEDO
taken at Latham & Watkins, 555 Eleventh Street, Suite
1000, Washington, DC commencing at 9:50 a.m., before
Sherry L. Brooks, Certified LiveNote Reporter and
Notary Public, in and for the District of Columbia.

- - -

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1 A. Correct.

2 Q. You have not reviewed the details of
3 United Health Group's chart review programs, correct?

4 A. Correct.

5 Q. You're not familiar with the details of
6 those -- of United Health's chart review programs,
7 correct?

8 A. Correct.

9 Q. In connection with the expert testimony
10 you're offering in this case, you have not reviewed
11 any of the medical records underlying the diagnosis
12 codes that are in dispute between the Department of
13 Justice and United Health Group, right?

14 A. Correct.

15 MS. KRIEG: Object to form.

16 BY MR. BAAK:

17 Q. And, in fact, you have not reviewed any
18 specific medical records in connection with the
19 expert testimony you're offering in this case,
20 correct?

21 MS. KRIEG: Object to form. Foundation.

22 A. Correct.

1 BY MR. BAAK:

2 Q. If you had been asked by the Department of
3 Justice to review the medical records underlying the
4 diagnosis codes that the two parties are disagreeing
5 about to see whether the codes were, in fact,
6 supported, would you have been qualified to do so?

7 A. Yes.

8 Q. The Department of Justice, though,
9 however, has not asked you to do so, correct?

10 A. Correct.

11 MS. KRIEG: Object to form. And, again, I
12 caution the witness not to reveal any attorney/client
13 privileged communications.

14 BY MR. BAAK:

15 Q. I mentioned earlier an expert for the
16 Department of Justice, Craig Garthwaite. And I think
17 you indicated you had not looked at his report; is
18 that correct?

19 A. That's correct.

20 Q. Have you heard of Mr. Garthwaite?

21 A. No.

22 Q. I don't want to march through his report.

1 So I'm just going to represent a couple things to
2 you, and I trust your counsel will object if I get
3 them wrong.

4 Mr. Garthwaite offers an opinion on a list
5 of diagnosis codes that he refers to as his potential
6 deletes. You have not reviewed any medical records
7 related to Professor Garthwaite's potential deletes
8 list, right?

9 A. Correct.

10 Q. Similarly, you have not reviewed any
11 medical records related to Professor Garthwaite's
12 final delete list, right?

13 A. Correct.

14 Q. And you're not offering any opinions, one
15 way or the other, on whether or not the diagnosis
16 codes on Dr. Garthwaite's final deletes list are, in
17 fact, supported, right?

18 A. Correct.

19 Q. Let's come back to paragraph 26 of your
20 report. You're discussing the purpose of the
21 Medicare Advantage risk adjustment payment model in
22 paragraph 26.

1 A. Correct.

2 Q. So, for example, in my blood draw
3 hypothetical they may say that I was having certain
4 routine blood testing done, for example, correct?

5 A. Yes.

6 Q. Or part of an annual exam?

7 A. Yes, and there would be an ICD code for
8 that.

9 Q. In your experience what are providers
10 typically paid for, the CPT codes, the procedures
11 they've done, or the diagnosis codes that are
12 submitted?

13 A. So in a non -- in an organization that is
14 not primarily Medicare Advantage risk basis, it's the
15 CPT and HCPCS codes.

16 Even in a risk environment they're
17 actually not paid on the diagnosis. The diagnosis
18 can have an impact on their payment, which does not
19 typically happen -- I have to say typically -- in a
20 fee-for-service environment where the physician is
21 billing -- being paid for the CPT or HCPCS codes.

22 Q. Outside of the circumstances where the

1 provider is sharing in risk adjustment payments, the
2 providers are typically being paid instead for the
3 procedures they perform; is that correct?

4 A. Correct.

5 Q. In your experience, is that the vast
6 majority of providers?

7 MS. KRIEG: Object to form.

8 A. It depends on where you are in the
9 country.

10 BY MR. BAAK:

11 Q. What about the providers you consult for?
12 Are they primarily compensated for the procedures
13 they perform?

14 A. Some yes; some no.

15 Q. If a provider is being compensated based
16 solely on the procedures they submit, they would not
17 have a financial incentive to submit a complete set
18 of diagnosis codes, right?

19 A. Right.

20 MS. KRIEG: Object to form.

21 BY MR. BAAK:

22 Q. That's one reason why providers sometimes

1 fail to submit a complete set of the diagnosis codes
2 that are, in fact, supported by the medical record,
3 right?

4 MS. KRIEG: Object to form.

5 A. Failed to submit or submit codes that
6 aren't supported, sure.

7 BY MR. BAAK:

8 Q. Well, that wasn't my question. We'll get
9 to that in a second. But since providers are often
10 not paid for the diagnosis codes, that's one reason
11 why -- and are instead paid for the procedures,
12 that's one reason that providers often fail to submit
13 a complete set of the diagnosis codes that are
14 supported by the medical records, right?

15 A. Correct.

16 MS. KRIEG: Object to form.

17 BY MR. BAAK:

18 Q. And I think you suggested that there are
19 also cases where the providers submit codes that you
20 believe that are unsupported. That also is something
21 that you've seen in your practice, correct?

22 A. Correct.

1 Q. And, again, it's because the providers are
2 maybe having a little less attention to detail on the
3 diagnosis codes if it's not impacting their pay,
4 correct?

5 A. Yes.

6 Q. Would you agree with me that it's
7 beneficial from a patient management standpoint to
8 have an accurate capture of what the patient's
9 diagnoses are?

10 MS. KRIEG: Object to form.

11 A. What do you mean by patient management
12 perspective?

13 BY MR. BAAK:

14 Q. Just care for the patient, to have an
15 accurate picture of which diagnosis codes have
16 actually been assigned. Does that help the care of
17 the patient?

18 A. Care of the patient by their provider?

19 Q. By the provider or by the plan.

20 MS. KRIEG: Object to form.

21 A. It's two very different circumstances. So
22 for the provider having an accurate list of the

1 MS. KRIEG: Object to form.

2 A. Yes. My certified coders are expected to
3 get it right almost all the time, and they do nicely.

4 BY MR. BAAK:

5 Q. So you used the phrase in your opinion
6 that there should be little variance between two
7 coders.

8 What does almost 100 percent mean in your
9 view? Do you have a benchmark you use internally
10 that you grade your coders against?

11 A. As a small organization -- you know, as
12 you can imagine, we don't have a big formal program
13 -- everybody is -- is counseled on any errors, and
14 any errors or disagreements are extremely rare.

15 So if I had to create a benchmark, I'd
16 probably use for diagnosis coding the 95 percent.

17 Q. So just to make sure I understand that,
18 you don't have a numerical internal benchmark for
19 measuring whether your coders should agree with one
20 another that you use internally at Acevedo
21 Consulting?

22 A. No. As part of a formal program, no.

1 Q. Are you aware of any formal studies that
2 show that two experienced coders when looking at the
3 same medical record should reach the same conclusion
4 about the appropriate diagnosis codes 95 percent of
5 the time?

6 A. Formal studies, no.

7 Q. Not aware of any studies showing that
8 that's realistic or that -- or any CMS guidance
9 saying that's the requirement, correct?

10 MS. KRIEG: Object to form.

11 A. Not that I'm aware of.

12 BY MR. BAAK:

13 Q. I want to talk about some of the reasons
14 that two coders reviewing the same medical record --
15 and I'm going to set aside circumstances where
16 they're reviewing different medical records and come
17 back to that.

18 So I want to talk about the circumstances
19 where two experienced coders reviewing the same
20 medical record might disagree about the appropriate
21 diagnosis codes. Okay?

22 A. Okay.

1 Q. You've touched on one of these already.

2 But one reason two medical -- two coders might reach
3 different conclusions about what diagnosis codes to
4 assign to a given medical record could be impacted by
5 the particular coder's level of experience, correct?

6 A. Correct.

7 Q. Another reason that two experience coders
8 could reach different conclusions about what
9 diagnosis codes to assign to a given medical record
10 is the particular skill of the coder, correct?

11 MS. KRIEG: Object to form.

12 A. I would put skill and experience in the
13 same bucket.

14 BY MR. BAAK:

15 Q. But you can be experienced and bad at
16 life, unfortunately. So just -- I want to separate
17 them for a second.

18 A. Aha.

19 Q. So some people are just better at the
20 coding exercise than others, right?

21 A. Oh, I'm sure.

22 Q. So that's what I mean by skill. So in

1 addition to experience, skill is another factor that
2 can affect whether -- sorry -- can create a
3 circumstance where two coders might disagree on
4 whether to assign a diagnosis code, right?

5 A. I'm sure that would be the case, a good
6 reason for certification.

7 Q. I noticed that you have a certification
8 specific to ENT; is that correct?

9 A. Correct.

10 Q. What is ENT?

11 A. Otolaryngology. Did that help? Ear,
12 nose, and throat.

13 Q. Ear, nose, and throat. Okay. What was
14 the purpose of obtaining your certification in ear,
15 nose, and throat?

16 A. So, actually, the AAPC had reached out to
17 me when they wanted to develop a certification for
18 ENT coders because I have quite a bit of experience
19 in that specialty area.

20 And I was one of the members of the
21 steering committee that then wrote the national exam.
22 So I didn't desire or have an intent or a goal to

1 become certified as an ENT coder. But I was
2 understandably, I think, given the designation since
3 I couldn't take the test that I helped to write.

4 Q. Does the AAPC, the coding organization we
5 talked about earlier -- does it offer certification
6 specific to other medical clinical subspecialties?

7 A. Yes.

8 Q. How many, approximately, certifications
9 for particular areas of medicine do they offer
10 certifications?

11 A. So it's a fairly lengthy list. I'm going
12 to say conservatively probably ten.

13 Q. Why does AAPC offer these certifications
14 that are specific to particular clinical specialties?

15 A. So I've not been part of their thought
16 process, but I do know that I have actually
17 recommended to some single specialty practices that I
18 work with who want to get one or more of their coders
19 who are not yet certified certified.

20 I've recommended that they not take a CPC
21 exam, that maybe they take if it's an orthopedic
22 practice an orthopedic coding exam because they

1 wouldn't have the depth of knowledge or experience to
2 pass the CPC.

3 So I'm sure that was part of the thought
4 process in the AAPC in having specialty designations
5 in addition to the CPC.

6 Q. Coming back to my scenarios where two
7 experienced coders might reach a different conclusion
8 on whether to assign a diagnosis code, you agree, I
9 think based on what you said in your report, that
10 experience in a particular clinical specialty can
11 impact why two coders might reach different
12 conclusions, right?

13 MS. KRIEG: Object to form.

14 A. Yeah, because the one in a specialty that
15 isn't what he or she is looking at wouldn't have the
16 experience for that.

17 BY MR. BAAK:

18 Q. I think you touch on this, if you want to
19 look at paragraph 55 of your report. You say at the
20 end of paragraph 55: "Coders should be exposed to
21 different medical specialties during training if they
22 previously only worked in one specialty."

1 Do you see that?

2 A. Yes.

3 Q. And why is -- why do you think that's
4 preferable?

5 A. So that they gain experience and as part
6 of their training if they have questions, and you can
7 more closely check their accuracy. I do that myself
8 since -- if I have someone that's working and has not
9 worked with, say, just to use orthopedics again, an
10 orthopedic practice.

11 Even if they're an experienced coder but
12 they have not worked with an orthopedist, they're
13 going to be closely monitored and mentored until they
14 have the knowledge necessary to be on their own.

15 Q. Whether the particular coder has expertise
16 in a particular clinical area can impact whether or
17 not they assign the appropriate diagnosis codes,
18 right?

19 MS. KRIEG: Object to form.

20 A. Yeah, it could. It could, because even
21 though the rules are the same, regardless of what
22 area of the code book they're looking at, they may

1 experienced coders might assign different diagnosis
2 codes based on the same medical record, another
3 reason is the ability to read the handwriting on a
4 medical record, right?

5 A. Correct.

6 Q. Do you agree, Ms. Acevedo, that we can
7 have a circumstance where you might be able to read
8 someone's handwriting but I cannot?

9 A. Oh, yes.

10 Q. A coder in a provider group who has
11 familiarity with a doctor's handwriting might be more
12 able to read the handwriting than someone who does
13 not have that familiarity, correct?

14 A. Yes.

15 Q. A coder in a doctor's office might also
16 have greater familiarity with the particular
17 abbreviations that a doctor uses, correct?

18 MS. KRIEG: Object to form.

19 A. They might.

20 BY MR. BAAK:

21 Q. For example, if I'm a coder in a doctor's
22 office and I know that the particular doctor always

1 uses PE to mean physical exam, that familiarity might
2 allow me to understand what a particular abbreviation
3 meant, correct?

4 MS. KRIEG: Object. Object to form.

5 A. That familiarity will allow you to assume
6 what that meant in that instance and you might be
7 correct because of your knowledge.

8 BY MR. BAAK:

9 Q. Well, it might not necessarily be an
10 assumption. If I know the doctor always uses PE to
11 be physical exam, that might allow me to understand
12 that the medical record reflected that a physical
13 examination occurred, correct?

14 MS. KRIEG: Object to form.

15 A. So I'm going to assume that the PE then
16 has a colon after it and is followed by the actual
17 physical exam and that, yes, she might make a correct
18 assumption that the PE in that instance relates to a
19 physical exam.

20 BY MR. BAAK:

21 Q. So ability to read handwriting is another
22 reason that two experienced coders might reach

1 different conclusions based on the same medical
2 record, correct?

3 A. Correct.

4 Q. We've talked a little bit about judgment
5 calls. You agree that judgment calls for what I
6 think you referred to as difficult cases also might
7 be another reason that two experienced coders assign
8 different diagnosis codes based on the same medical
9 record, right?

10 A. Different levels of experience of the
11 coders, yes.

12 Q. Human error, the fact that people make
13 mistakes, is another reason that two experienced
14 coders could assign different diagnosis codes based
15 on the same medical record, right?

16 A. Of course.

17 Q. Everybody makes mistakes, right?

18 A. Yes.

19 MS. KRIEG: Object to form.

20 BY MR. BAAK:

21 Q. That's true of experienced certified
22 coders, correct?

1 MS. KRIEG: Object to form.

2 A. Yes.

3 BY MR. BAAK:

4 Q. Coders encounter situations that require
5 in-depth research and take more time to code
6 correctly on occasion, correct?

7 A. I'm sure, yes. Um-hum.

8 Q. Even among the more commonly used codes
9 are significant gray areas open for examination among
10 coders, right?

11 MS. KRIEG: Object to form.

12 A. I don't think I agree with that. Can you
13 give me an example of a significant gray area?

14 BY MR. BAAK:

15 Q. Well, you know what the phrase "gray area"
16 means, right?

17 A. Yes.

18 Q. So let me just ask my question again. How
19 would you define gray area?

20 A. So I really don't find gray areas in
21 diagnosis coding. That's why I asked and I couldn't
22 agree with your question. I was hoping that maybe

1 there was something else that you could add to that.

2 So to me the requirements -- the
3 guidelines are pretty straightforward and objective.
4 The gray areas have to do with clinical
5 documentation, the handwriting that's illegible that
6 you just mentioned, et cetera.

7 Q. Let me come back to my question: Even
8 among the more commonly used codes are significant
9 gray areas open for examination among coders.

10 Do you agree?

11 MS. KRIEG: Object to form.

12 A. No.

13 BY MR. BAAK:

14 Q. With very complex or unusual cases, coding
15 guidelines may be confusing to interpret --

16 MS. KRIEG: Object to form.

17 BY MR. BAAK:

18 Q. -- correct?

19 A. To an inexperienced coder who hasn't come
20 across that before, quite possibly sure.

21 BY MR. BAAK:

22 Q. What about to an experienced coder?

1 that does not mean the code is, in fact, unsupported
2 in the medical record, right?

3 MS. KRIEG: Object to form.

4 A. So I don't agree with the totality of your
5 -- how you're phrasing it. So from my perspective as
6 all the guidelines are really clear, it has to be
7 documented in the medical record for anybody to see
8 it. Any coder should be able to find it.

9 One coder may have missed it for one
10 reason or another, but if it's not in the medical
11 record, then it's not been missed and it should not
12 be coded.

13 BY MR. BAAK:

14 Q. I may have made my hypothetical more
15 confusing than I intended it to be, in part because
16 people make mistakes as we talked about a second ago.
17 Also because of potential errors of disagreement.
18 But just because a diagnosis code isn't found by a
19 coder in a blind review that doesn't mean with 100
20 percent certainty that the code is, in fact, not
21 supported in the medical record, right?

22 MS. KRIEG: Object to form.

1 A. Yeah, because in the way you phrase it now
2 the coder missed it.

3 BY MR. BAAK:

4 Q. Have you ever been involved in your
5 consulting practice doing chart retrieval, whether
6 it's for plans or for providers?

7 A. Define "chart retrieval."

8 Q. The act of obtaining medical records from
9 providers.

10 A. So electronically we do that all the time
11 now. I have access to more electronic medical
12 records, as do my team, than we care to ever have.
13 And we often are the ones that will go in and find
14 the records.

15 There haven't been many paper records
16 since about 2011, but I can picture myself standing
17 in a primary care office and literally going and
18 pulling the charts off the shelves myself, so yes.

19 Q. In what context does Acevedo Consulting do
20 the actual retrieval of the medical records? Is this
21 in advance of your chart audits?

22 A. So it's part of the chart audit.

1 Q. When you go to retrieve medical records as
2 part of the chart audit, it is not always possible to
3 obtain a complete set of the medical records, right?

4 MS. KRIEG: Object to form.

5 A. It depends on how you define a complete
6 set of the medical records.

7 BY MR. BAAK:

8 Q. Right. You talked about the difficulty of
9 paper records. But sometimes providers don't
10 respond. Sometimes they don't have the full record.
11 These are all things that can happen in the real
12 world when you try to go retrieve medical records,
13 right?

14 A. Yes, any of that could happen.

15 Q. If a blind -- if in a blind review a coder
16 is only looking at a portion of the patient's medical
17 records, would that allow them to draw any
18 conclusions about what was in other medical records
19 that are not in front of them?

20 A. No.

21 Q. In a blind chart review if the coder only
22 has a portion of the patient's medical records in

1 front of them, that would not allow them to draw a
2 conclusion about the totality of the appropriate
3 diagnosis codes for that given patient, correct?

4 A. Correct. They could only assign diagnosis
5 codes for the medical records they had at hand.

6 Q. Do you have any experience with what -- or
7 do you track what percentage of time in the chart
8 retrieval process you're able to obtain a complete
9 set of the patient's medical records?

10 A. I don't track it, but I will tell you that
11 it's the overwhelming majority of the time with
12 electronic medical records.

13 Q. When did most practices switch to
14 electronic medical records?

15 A. Beginning in 2011, probably the majority
16 of -- because that's when the meaningful use program
17 and some government funding for implementing
18 electronic medical records started. And the adoption
19 -- I'm trying to think when seeing paper charts at
20 all for medical records was suddenly so very uncommon
21 for us. I can't picture when.

22 Q. Can you estimate just approximately when

1 -- you know, the transition started in 2011 -- but
2 when most providers had moved from paper records to
3 electronic medical records in your experience?

4 A. So by most you mean more than half. Yes?

5 Q. Yes.

6 A. So I'm going to hazard a pretty probably
7 informed guess that by 2015, 2016 more than half of
8 providers were on electronic medical records. If
9 we're talking hospital providers, it's probably
10 higher. But for physician -- community-based
11 physician practices, probably sometime around there.

12 Q. If you look at your opening report -- give
13 me a second to find the right section. Paragraph 8,
14 the scope of your assignment, you state that the
15 relevant time period from the report covers dates of
16 service 2008 through 2016, correct?

17 A. Yes.

18 Q. Given the testimony you just gave me about
19 the adoption of medical records, it sounds --
20 electronic medical records, rather, for most of the
21 relevant time period for your report paper medical
22 records were more commonly used than electronic

1 medical records, right?

2 MS. KRIEG: Object to form.

3 A. Well, I mean in the community-based
4 provider setting that I really referred to, so from
5 2008, 2011 would be three years, another two, five,
6 11 -- so it's about half and half -- no, no. No, no.
7 I take it back. Bad math. Bad math.

8 So, yeah, probably the last maybe three
9 years would have been more EMRs, around 2013, yeah.

10 Q. You said as late as 2015 or 2016 in the
11 provider space it was still around -- was it around
12 50/50 between paper and electronic?

13 A. No. By 2015 and '16 most providers were
14 on electronic medical records.

15 Q. But having done the math again it sounds
16 like that paper records were predominant -- more than
17 half --

18 A. Yeah, a little more than half --

19 Q. -- for the relevant period for your report
20 in this case, right?

21 A. Yes, um-hum.

22 Q. In your experience is it more difficult to

360

C E R T I F I C A T E

I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this

_____ day of _____, 2024.


Notary Public



EXHIBIT D-88

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
vs.	)	CASE NO.
	)	CV 16-08697 FMO
UNITEDHEALTH GROUP, INC. et	)	
al.,	)	
	)	
Defendants.	)	

VIDEOTAPED DEPOSITION of KATHLEEN BAKER
taken by Plaintiffs, held at Riley, Warnock &
Jacobson, 1906 West End Avenue, Nashville,
Tennessee, commencing at 8:19 A.M., on July 12,
2022, before Gary Schneider, RPR, CRR, RMR, TLCR
and Notary Public within and for the State of
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Counsel (remotely)

1 A. Yes.

2 Q. Okay. And how is Optum
3 affiliated with UnitedHealth Group?

4 MS. MADDUX: Objection. Form.
5 You can answer.

6 THE WITNESS: Sorry. I just --
7 it is a subsidiary of UnitedHealth
8 Group.

9 BY MS. ZUPAC:

10 Q. And before Ingenix purchased
11 Aim, so actually I'm going back to your time at
12 Aim, did you work for UnitedHealth Group or any
13 United subsidiaries?

14 A. Like, can you -- meaning, like,
15 was I employed by them?

16 Q. No. I just mean did you do any
17 work for United and any United subsidiary as a
18 client of yours when you were employed by Aim?

19 A. I don't recall personally
20 working on any UHC subsidiaries, but Aim had UHC
21 business.

22 Q. Okay. All right. So then
23 turning back to Exhibit 261. So your LinkedIn
24 profile states that you were the vice president,
25 risk adjustment and STARS operations from

1 December 2004 to February 2016. So I just want to
2 make sure that we're all on the same page. That
3 particular entry covers your work with Aim,
4 Ingenix, and Optum during those years, correct?

5 A. It does. And it only signifies
6 that last role versus all of the roles --

7 Q. Right.

8 A. -- that I had at the time.

9 Q. Okay. So focusing on the first
10 paragraph under that entry, though, the middle of
11 page 2, it mentions here responsible for 800
12 million dollar plus global coding operation with
13 \$150 million plus expense budget. Lead, 2300 plus
14 global resources including FTEs and contractors.

15 Is that right?

16 A. That is what it states.

17 Q. Is this referring to Optum's
18 medical coders?

19 MS. MADDUX: Objection. Form.

20 BY MS. ZUPAC:

21 Q. You can answer.

22 A. It -- in part.

23 Q. Okay. So I guess I'll ask it a
24 different way. What -- what are you referring to
25 here with the \$800 million plus global coding

1 operation?

2 A. I can't recall the \$800 million
3 plus, what that tied to.

4 Q. What about the global coding
5 operation?

6 A. That would be the having coders
7 in US, India, and Philippines.

8 Q. Okay. And did the coders in
9 India and Philippines, were they also referred to
10 as offshore coders?

11 A. Yes.

12 Q. And did they include medical
13 coders employed directly by Optum as well as by
14 vendors?

15 MS. MADDUX: Objection. Form.

16 BY MS. ZUPAC:

17 Q. You can answer.

18 A. Yes.

19 Q. And what were the vendors that
20 employed certain of those coders?

21 A. PI International.

22 Q. Okay. Is PI the only one?

23 A. It's the only one -- it's the
24 only one I recall.

25 Q. Do you recall working with a

1 vendor or contractor called "iCodify"?

2 A. Yes.

3 Q. Okay. And were you responsible
4 for overseeing Optum's relationship with iCodify?

5 A. No.

6 Q. Do you recall who was
7 responsible for that relationship?

8 A. I do not.

9 Q. So we'll come back to discussing
10 this role, but I just want to quickly address the
11 other more recent entries on your LinkedIn.

12 So it looks like it states that
13 you were the senior director of compliance program
14 operations from February 2016 to July 2021,
15 correct?

16 A. Correct.

17 Q. Okay. And what was the nature
18 of that role at Optum?

19 A. I led the external audit team
20 for regulatory or client audits, the internal
21 compliance audit team in the risk assessment
22 program.

23 Q. And in this role, did you have
24 oversight over Optum's risk adjustment programs?

25 A. No.

1 Q. And it looks like your current
2 role at Optum, which you began in August 2021, is
3 vice president, risk adjustment operations and
4 transformation, correct?

5 A. Correct.

6 Q. Is that, in fact, your current
7 role at Optum?

8 A. Yes.

9 Q. And what are your
10 responsibilities in this role?

11 A. I manage the retrospective chart
12 review program, lead, I should probably say, the
13 national coding team for risk adjustment, and the
14 AS submissions team.

15 Q. And how is this role different
16 from the one you served in previously, the vice
17 president of risk adjustment and STARS operations?

18 A. It's in a different business
19 unit, and so, you know, it's kind of a
20 different -- it's on the provider's side, and it's
21 a broader role from the perspective that working
22 with coders that do more than just retrospective
23 chart review. They're doing other types of
24 programs.

25 Q. All right. And who do you

1 report to now?

2 A. Jon Bird.

3 Q. Jon Bird?

4 Okay. All right. So as
5 promised, I'm going to go back to your prior role.
6 So at some point in your prior role, this 2004 to
7 2016 role, did you begin working with Optum's
8 chart review operations?

9 A. Yes.

10 Q. Okay. So we've been using the
11 term "chart review" or discussing it, so I just
12 want to stop and ask what your understanding of
13 the term "chart review" is.

14 A. It's retrospective chart review
15 of a member's chart where you retrieve and code
16 the chart.

17 Q. And what is the purpose of doing
18 chart review?

19 MS. MADDUX: Objection. Form.

20 BY MS. ZUPAC:

21 Q. You can answer.

22 A. It is to code diagnosis codes
23 that are documented within the medical record that
24 were previously not submitted.

25 Q. Would you agree that the purpose

1 of chart review is to provide a complete and
2 accurate recording of a member's diagnosis codes
3 to CMS?

4 MS. MADDUX: Objection. Form.

5 THE WITNESS: That is not my
6 understanding.

7 BY MS. ZUPAC:

8 Q. Okay. So can you go back to
9 Exhibit 258.

10 A. I am there.

11 Q. Okay. All right. Can you go to
12 PDF page 8. And you can get there by clicking on
13 the gray box at the bottom.

14 A. Mm-hmm.

15 Q. And typing it "8." That might
16 be easier than scrolling.

17 A. I am there.

18 Q. Okay. And so I am on deposition
19 page 24, and you'll probably see a highlighted
20 section which starts on line 11 reading "Q: Okay.
21 What is your understanding of the purpose of chart
22 review?"

23 "Answer: Chart review is to
24 provide a complete and accurate reporting of a
25 member's diagnosis codes to CMS."

1 Do you recall previously
2 testifying that the purpose of chart review was to
3 provide a complete and accurate recording of a
4 member's diagnosis codes to CMS?

5 MS. MADDUX: Objection. Form.

6 BY MS. ZUPAC:

7 Q. You can answer.

8 A. I see it written in this
9 document.

10 Q. Okay. And is your testimony
11 today that you disagree with your prior testimony?

12 A. I think my thoughts on that is
13 that there should have been additional words after
14 "to CMS."

15 Q. Okay. And what are those
16 additional words?

17 A. It's to provide a complete and
18 accurate recording of member diagnosis code to CMS
19 that have been coded from the retrospective chart
20 review.

21 MS. MADDUX: And, Wendy, the
22 yellow highlighting, are you
23 representing this was added --

24 MS. ZUPAC: Yes.

25 MS. MADDUX: -- by the

1 frame in which you worked in operations, so I'm
2 focusing on 2012 to 2014.

3 A. It depends. Like, meaning at
4 that time we had a dependency on vendors, PI, like
5 we referenced earlier.

6 Q. Sure.

7 A. And then I was given the
8 instruction to start building out an internal
9 coding competency. And so if you ask me the
10 question of during that time frame did Optum
11 employ coders, it would be yes and no.

12 Q. Okay.

13 A. Or maybe, more importantly, no
14 and yes --

15 Q. Okay. Sure, sure.

16 A. -- to some the extent.

17 Q. Sure.

18 A. So it kind of depends.

19 Q. Yeah, so I can step back and
20 just ask it a different way.

21 At different points in time,
22 Optum utilized coders employed by vendors,
23 correct, including PI, correct?

24 A. Correct.

25 Q. And then at other points in

1 time, Optum also directly employed coders,
2 correct?

3 A. Yes.

4 Q. Okay. And are you aware if at
5 any point Optum used coders either employed by a
6 vendor or internally that were not certified
7 medical coders?

8 A. I don't recall that
9 specifically, but I do recall having conversations
10 around making sure that the coders were certified.

11 Q. Okay. And did you believe that
12 Optum's medical coders, whether the ones employed
13 internally or by a vendor, were skilled medical
14 coders?

15 MS. MADDUX: Objection. Form.
16 Calls for speculation.

17 BY MS. ZUPAC:

18 Q. And to be clear, I'm asking for
19 your belief.

20 A. Skilled in what?

21 Q. Skilled in medical coding.

22 A. They -- if a coder is certified
23 and met the requirements of certification, so,
24 yes.

25 Q. And did you believe that the

1 coders that Optum used, whether employed by a
2 vendor or by Optum directly, had the appropriate
3 level of training?

4 MS. MADDUX: Objection. Form.

5 BY MS. ZUPAC:

6 Q. You can answer.

7 A. Our coders were given training,
8 and our training was consistent with our policies
9 and practices, and so yes.

10 Q. Okay. And did you have
11 confidence in Optum's coders' ability to code
12 charts accurately?

13 MS. MADDUX: Objection. Form.

14 BY MS. ZUPAC:

15 Q. You can answer.

16 A. Can you repeat the question
17 again, please?

18 Q. Sure.

19 Did you have confidence in
20 Optum's coders' ability to code charts accurately?

21 MS. MADDUX: Same objection.

22 THE WITNESS: I had confidence
23 that every coder was competent in doing
24 their role. Does that mean that every
25 coder was right 100 percent of the

1 3:49.)

2 THE VIDEOGRAPHER: The time is
3 now 3:49 and we are back on the record.

4 E X A M I N A T I O N

5 BY MS. MADDUX:

6 Q. So, Ms. Baker, we have a few
7 questions for you. Earlier today do you recall
8 testifying about claims verification?

9 A. Yes.

10 Q. What was your involvement in
11 designing the scope of Optum's claims verification
12 program?

13 A. I did not have involvement in
14 designing it.

15 Q. What was your involvement in
16 managing Optum's claims verification program?

17 A. I had people within my hierarchy
18 that worked on the claims verification program,
19 but I was not necessarily involved day to day in
20 it.

21 Q. What was your involvement in
22 making decisions about Optum's claims verification
23 program?

24 A. I had no decision-making in
25 that.

1 Q. What was your involvement in
2 making decisions about whether to submit deletes
3 from Optum's CV program?

4 A. I made no decisions regarding
5 that.

6 Q. What was your involvement in
7 decisions regarding whether a claims verification
8 program should be implemented?

9 A. I was not involved in those
10 conversations or decisions.

11 Q. Earlier today do you recall that
12 you testified that you used chart retrieval
13 vendors to retrieve charts for Optum's
14 retrospective chart review program?

15 A. Yes.

16 Q. In your experience, did these
17 chart retrieval vendors retrieve all charts for a
18 member for a given date of service year?

19 A. No, that's not possible.

20 Q. When you say it's not possible,
21 what do you mean?

22 A. Meaning there's just so many
23 charts for members. So, like, you know, if we go
24 back to, like, my -- well, actually, where we're
25 positioned right now, like, my cancer diagnosis is

1 that, you know, a member can have multiple charts
2 across different locations, across different
3 providers. So, like, here we sit in -- you know,
4 I had services done at Saint Thomas Ascension that
5 also has a private ambulatory surgery center that
6 also houses a medical -- a medical building that
7 housed my breast surgeon and my plastic surgeon,
8 and then also Vanderbilt where I had some
9 procedures done.

10 You know, even if I just go back
11 to the date where I had, you know, surgery done at
12 the ASC, I would have, you know, four different
13 visits from separate doctors regarding my date of
14 service that day, but they're all different charts
15 or, you know, Vanderbilt's in their charts. If I
16 would go to one location to grab a chart, it
17 doesn't mean I would have grabbed all charts for
18 that member because it would've only been what was
19 available that day. But even if I -- you know,
20 for instance, for Vanderbilt or maybe personal
21 experience, we've all been to doctors, where
22 Monday -- well, here, I mean, I'll say Vanderbilt,
23 like, Monday and Wednesdays they're here downtown
24 or Midtown here at Vanderbilt. But then on, you
25 know, Tuesdays and Thursdays, they're out in

1 Franklin office location. And so depending upon
2 how their medical charts are, those could be
3 different locations for charts for that member.
4 And so, you know, it's just charts -- a chart for
5 a member doesn't contain every single encounter
6 that that member has had, nor is it possible to
7 say whether or not it's always a complete chart
8 because it's based upon what was available at that
9 time or if the provider sent it and what the
10 provider sent to us.

11 Q. Did Optum review all of the
12 charts for a member in a particular date of
13 service year in its retrospective chart review
14 program?

15 A. Did we review all? No, it's
16 not -- I mean, we didn't have all of the data. We
17 didn't have all of the medical charts for them.

18 Q. Earlier today do you recall
19 testifying about blind -- blind chart reviews?

20 A. Yes.

21 Q. Do you know what a blind chart
22 review is?

23 A. Yes.

24 Q. What is it?

25 A. It's when the coders are not

1 given any information about that member at a
2 member level.

3 Q. So does the coder conducting a
4 blind review of a chart know what diagnosis codes
5 the provider reported on the claim for that
6 beneficiary?

7 A. No. It's not possible to tie it
8 back because we don't know what the chart
9 contains.

10 Q. So, hypothetically, a provider
11 submits diagnosis codes A, B, and C on the claim
12 for a beneficiary, the coder conducting a blind
13 review of the chart for that beneficiary
14 identifies codes B, C, and D. Do you understand
15 the hypothetical?

16 A. I do.

17 Q. If a coder conducting a blind
18 review of the chart identifies diagnosis codes B,
19 C, and D, does that mean that code A is not
20 documented in the medical record?

21 MS. ZUPAC: Object to form.

22 BY MS. MADDUX:

23 Q. You can answer.

24 A. No. I mean, it means -- it
25 could mean that we don't have all of the pages in

1 that chart. It could be that that chart -- that
2 chart was in circulation and, therefore, what we
3 were -- that what we had is not complete. It
4 could be that that happens to be a practice where
5 it multiple chart locations. And so, you know,
6 out of convenience, sometimes you go to the 100
7 Oaks location, and another time you go to the
8 Franklin Road location. It's just kind of
9 dependent upon where that chart is. And so
10 it's -- it's possible to not have the full chart
11 when you're reviewing it.

12 Q. What would Optum need to do to
13 determine whether or not code A may, in fact, be
14 documented in the medical record?

15 MS. ZUPAC: Object to form.

16 BY MS. MADDUX:

17 Q. You can answer.

18 A. To be able to take a look at --
19 say that again, please.

20 Q. What would Optum need to do to
21 determine whether or not code A may, in fact, be
22 documented in the medical record?

23 MS. ZUPAC: Object to form.

24 Calls for speculation.

25

1 BY MS. MADDUX:

2 Q. You can answer.

3 A. You know, a lot of research, a
4 lot of rework, being able to open up the chart to
5 see do we have the right rendering provider,
6 did -- do we have the right -- does that provider
7 have any other locations, does that provider
8 have -- going through an EMR transition, do we
9 think we have all that information. I mean,
10 it's -- it's -- you got to be able to do a lot of
11 research and opening up that chart, none of which
12 is insignificant tasks.

13 Q. Earlier today do you recall
14 Ms. Zupac asked you some questions about
15 completeness as it relates to retrospective chart
16 reviews?

17 A. Yes.

18 Q. Do you recall testifying about
19 how chart review coders may not identify every
20 diagnosis code that is documented in the medical
21 record?

22 A. Yes.

23 Q. In your experience, what are
24 some reasons for this?

25 A. Some reasons for that just have

1 to do with specialties in terms of what you're
2 coding. Like, you may have the right -- may have
3 all the same training, but, like, you're all, I
4 think, litigators here, you wouldn't necessarily
5 go to an environmental lawyer for litigation,
6 right? So -- or it could be experience. It could
7 be coding direction or coding policy applications.
8 It could be skill sets, you know, because there is
9 a variation of coding across 95 percent accuracy,
10 right? But, you know, a lot of it has to do with
11 how you look at the application.

12 Again, I'd go back to my example
13 where I was diagnosed with cancer. I had the same
14 set of data presented to two oncologists, and I
15 got one answer from one oncologist that didn't
16 have something, we can't -- with the same
17 training, everything. Another one had more
18 experience doing it and interpreted it another way
19 for me to be able to say that the application of
20 what the chemotherapy I needed had to be X, Y, and
21 Z.

22 In case you're wondering, this
23 is 16 months of hair growth, so...

24 Q. In your experience, how does the
25 legibility of a medical record impact whether a

1 coder may miss a diagnosis code that's supported
2 in the medical record?

3 MS. ZUPAC: Object to the form.

4 Calls for speculation. Ms. Baker
5 testified that she has no training in
6 medical coding.

7 BY MS. MADDUX:

8 Q. You can answer.

9 A. I mean, legibility, forms,
10 templates. I mean, a lot of times if a doctor --
11 I mean, we've all heard the joke about, you know,
12 a doctor's handwriting signature and it being
13 rough to read, right? But, like, it's really --
14 you know, if you're looking at the differences in
15 medications and trying to understand when the one
16 adherence, you know, the difference between having
17 an E there or an A there, you know, and being able
18 to look at what type of wording it is is really
19 important. And so, again, depending upon an
20 individual's skill set being able to read
21 handwritten charts, it would certainly make a
22 difference.

23 Q. In your experience, how does the
24 length of the medical record impact whether a
25 coder may miss a diagnosis code that is supported

1 on medical record?

2 MS. ZUPAC: Object to form.

3 Calls for speculation. Again,

4 Ms. Baker testified that she does not

5 have training in medical coding.

6 BY MS. MADDUX:

7 Q. You can answer.

8 A. I mean, operationally, I would
9 say, and we -- just like we would do anything is,
10 like, as you read a document that maybe is, you
11 know, ten pages, that's different that reading a
12 document that's 200 pages, that by the time you
13 get to -- you know, midway, a quarter way, you get
14 some level of fatigue in there. And so, you know,
15 the length of a medical record does have to do
16 with it. I mean, we -- we all probably personally
17 experience reading longer documents and -- and
18 remember what that fatigue looks like.

19 Q. And in your role working in
20 chart operations, did you oversee medical record
21 coders?

22 A. Yes, I had medical coders on my
23 team.

24 Q. And did you through overseeing
25 the medical record coders, did you learn of

1 different reasons that coders may miss diagnosis
2 codes that are supported in the medical records?

3 MS. ZUPAC: Object to form.

4 BY MS. MADDUX:

5 Q. You can answer.

6 A. Yes.

7 Q. Earlier today do you recall
8 testifying regarding informed coding?

9 A. Yes.

10 Q. What do you understand informed
11 coding to mean?

12 MS. ZUPAC: Objection. Asked
13 and answered.

14 BY MS. MADDUX:

15 Q. You can answer.

16 A. Informed coding means diagnosis
17 codes collected from multiple or any data sources
18 that we had that were at a member level, so not at
19 a provider level or not a provider date of service
20 level, but a member level and presenting that to
21 the coder in order to improve efficiency and
22 productivity.

23 Q. So when you say they're not at a
24 provider date of service level, what do you mean
25 by that?

1 A. The information is aggregated
2 across from multiple data sources and presented.
3 It's not -- I mean, when you open up a chart, you
4 don't know what's in the chart. I mean, you don't
5 know what date of service it is there. You don't
6 know what information was there exactly. And so
7 when we're looking at it, we're trying -- when
8 we're doing informed coding from a productivity
9 perspective, we're trying to provide a large data
10 set to the coders in order to improve their
11 productivity.

12 Q. Earlier today do you recall
13 testifying about a CAT form?

14 A. Yes.

15 Q. What do you understand the CAT
16 form to be?

17 MS. ZUPAC: Objection. Asked
18 and answered.

19 BY MS. MADDUX:

20 Q. You can answer.

21 A. The CAT form was a template that
22 we used to -- for the coders to handwrite in their
23 coding results because ChartSync was slow.

24 Q. Do you recall testifying that
25 the CAT form was used for the recode project

1 conducted for charts in 2012 and 2013?

2 A. Yes.

3 Q. Can you describe how the coders
4 were instructed to use the CAT form as part of the
5 recode project?

6 A. They were instructed to -- well,
7 we gave them informed coding, and they were
8 instructed to not have to document those HCCs on
9 the form in order to speed them up from a
10 production perspective, and then they were to
11 document the dates of services and HCC or
12 diagnosis codes that they saw in there.

13 Q. Earlier today do you recall
14 testifying that the CAT forms included information
15 regarding previously reported HCCs for a member?

16 A. As part of that informed coding,
17 yes.

18 Q. Were the HCCs listed on the CAT
19 forms specific to the chart being reviewed?

20 A. They were not. It wouldn't be
21 possible to know everything that was in that
22 chart.

23 Q. And is that for the reason you
24 gave earlier, that you don't know what information
25 is in the chart?

1 A. Correct.

2 MS. ZUPAC: Object to form.

3 BY MS. MADDUX:

4 Q. Were the diagnosis codes listed
5 on the CAT forms specific to the date of service
6 being reviewed in the chart?

7 A. I'm sorry. Can you repeat that
8 question?

9 Q. Were the diagnosis codes listed
10 on the CAT forms specific to the date of service
11 being reviewed in the chart?

12 A. The coders would -- would
13 document the dates of services that were in the
14 chart. But when you open the chart, you have no
15 idea what's in there until you go through it.

16 Q. So did the HCCs provided to the
17 coder on the CAT form before they started coding
18 the chart, were they specific to a date of service
19 that was also in the chart?

20 MS. ZUPAC: Object to form.

21 THE WITNESS: No.

22 BY MS. MADDUX:

23 Q. Why did you provide the
24 previously reported HCCs to the coders?

25 MS. ZUPAC: Object to form.

1 STATE OF TENNESSEE)
2 COUNTY OF DAVIDSON) SS:

3 I, Gary Schneider, TLCR No. 676, in and
4 for the State of Tennessee, do hereby certify:

5 That, prior to being examined, the
6 witness named in the foregoing deposition was by
7 me duly sworn to testify the truth, the whole
8 truth and nothing but the truth;

9 That said deposition was taken down by
10 me stenographically at the time and place therein
11 named, and thereafter transcribed via
12 computer-aided transcription under my direction,
13 and the same is a true, correct and complete
14 transcript of said proceedings;

15 Before completion of the deposition,
16 review of the transcript was not requested. If
17 requested, any changes made by the deponent (and
18 provided to the reporter) during the period
19 allowed are appended hereto.

20 I further certify that I am not
21 interested in the outcome of the action.

22 Witness my hand this July 15, 2022.

23
24 
GARY SCHNEIDER, TLCR No. 676

25 Certified Shorthand Reporter
State of Tennessee
State of Tennessee

EXHIBIT D-89

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

- - - - -X
:
UNITED STATES OF AMERICA, ex rel.:
BENJAMIN POEHLING, :
:
Plaintiff, :
: Case No.
vs. : 2:16-cv-08697-FMO-SS
:
UNITEDHEALTH GROUP, INC., et al., :
:
Defendants. :
:
- - - - -X

VOLUME I
VIDEOTAPED RULE 30(b)(6) DEPOSITION OF
OPTUMINSIGHT, INC. AND UNITEDHEALTHCARE, INC.,
BY THEIR DESIGNEE, KATHLEEN O. BAKER

Washington, D.C.
May 30, 2023

Reported by:
Misty Klapper, RMR, CRR
Job No.: 982005

1 are you referring to?

2 A. UnitedHealthcare's risk adjustment
3 health plan members, Medicare Advantage health
4 plan members.

5 Q. And you're here today to testify
6 about certain aspects of Optum's chart review
7 program; is that right?

8 A. The retrospective chart review
9 program, yes.

10 Q. Okay. So broadly speaking, what is
11 Optum's retrospective chart review program?

12 A. Optum's retrospective chart review
13 program is a program where we submit a more
14 complete health status from medical records
15 collected on a member for appropriate payment
16 from CMS.

17 Q. Okay. So what is the purpose of
18 Optum's chart review program?

19 A. To submit more complete health
20 statuses to CMS on risk adjustment members.

21 Q. Okay. And what do you -- what do you
22 mean when you say more complete risk adjustment

1 information?

2 A. So members, Medicare Advantage
3 members, can see multiple different providers,
4 either in network, out of network,
5 fee-for-service, non-fee-for-service.

6 Data can be submitted to CMS, you
7 know, through various different channels, claims,
8 encounter. And all of that data from different
9 sources at different points of time, you know,
10 potentially at different health plan memberships
11 with different providers are consolidated by CMS
12 to create a full health status. But that health
13 status is never, ever fully complete. So with
14 retrospective chart review, we're trying to
15 provide more complete health status for
16 appropriate payment.

17 Q. Okay. And when you see -- when you
18 say more complete health status, do you mean that
19 Optum tries to submit all of the risk
20 adjustment -- risk adjusting diagnosis codes
21 supported by the member's medical record?

22 MS. MADDUX: Objection, form.

1 THE WITNESS: So in my personal
2 opinion, when I say more complete health
3 status, it's the recognition that
4 there's -- we may not ever be able to
5 submit 100 percent of a person's medical
6 status, but it's -- in context of the
7 retrospective chart review program, it's
8 being able to say based upon a chart that
9 we have on a member, knowing that a member
10 may have multiple charts from different
11 providers that contain different providers
12 within those charts on different dates of
13 services that we're, you know, attempting
14 for one of those charts to provide
15 information.

16 BY MS. ZUPAC:

17 Q. So Ms. Baker, you understand that
18 you're here today to testify on behalf of Optum
19 and UnitedHealthcare, Inc., correct?

20 A. Yes.

21 Q. And you understand that one of the
22 topics that you've been designated on to testify

1 on behalf of these entities is the purpose of the
2 chart review program, correct?

3 A. Yes.

4 Q. Okay. When I'm asking you questions
5 about the purpose of Optum and UnitedHealthcare
6 Inc.'s chart review program, you understand that
7 you need to answer on behalf of the entities,
8 correct?

9 A. Yes.

10 Q. Okay. So let's try this question
11 again.

12 Was the purpose -- was one of the
13 purposes of Optum's chart review program to
14 submit complete diagnosis data for Medicare
15 Advantage members to CMS?

16 A. No.

17 Q. Okay. Why not?

18 A. It's not possible to do so for
19 several reasons. And some of the reasons include
20 things such as when we are looking at a medical
21 record, a coder could have different experiences,
22 different levels of ability to be able to code

1 that chart.

2 They may have a background in
3 cardiology, but they're looking at an oncology
4 chart. They could be looking at a chart that is
5 handwritten in cursive and font smaller than
6 college ruled paper and are unable to be able to
7 be able to make all those connections.

8 There could be other components of
9 the chart where it is, again, based upon a
10 coder's experience and decision making,
11 potentially unable to be able to make those
12 connections. It could be that, you know, when
13 we're looking at the chart itself, we're only
14 looking at the pieces of information that are in
15 front of them at that time.

16 And there's -- you know, on that
17 piece of paper it could have been a three-page
18 date of service and it may not have had all the
19 pieces of data from that date of service in front
20 of them.

21 Q. All right. So Ms. Baker, you've
22 offered a laundry list of reasons why a member's

1 health information may not be 100 percent
2 complete, correct?

3 MS. MADDUX: Objection,
4 mischaracterizes testimony.

5 THE WITNESS: I've offered some
6 reasons that I can recall right now on --
7 on when we're looking at a chart why
8 not -- why not 100 percent of what's on
9 that chart could be captured.

10 BY MS. ZUPAC:

11 Q. Okay. But that's not quite getting
12 at the -- my question, which my question is
13 whether it was the purpose of Optum and
14 UnitedHealthcare's Inc.'s chart review programs
15 to submit complete diagnosis data for Medicare
16 Advantage members.

17 MS. MADDUX: Objection, asked and
18 answered.

19 BY MS. ZUPAC:

20 Q. You can answer.

21 A. I would refer back to my prior
22 statement then, where we -- it, as part of

1 retrospective chart review, look to -- look to be
2 able to collect more complete health status on a
3 member to -- for submission.

4 Q. Okay. And when you say more complete
5 health status information, what are you referring
6 to?

7 A. The recognition that it may not be
8 100 percent complete. I mean, from the
9 perspective that even from an industry standard,
10 we say that coders should be 95 percent accurate.
11 Right? And that's a standard that is permeated
12 throughout the industry and it's just part of the
13 going in position when looking at work.

14 Q. Okay. Was one purpose of Optum's
15 chart review program to submit accurate diagnosis
16 data for Medicare Advantage members to CMS?

17 A. For retrospective chart review our QA
18 program is designed around what the QA of what
19 our coders coded from that and it would never be
20 100 percent -- was the term used complete or
21 accurate?

22 Q. Accurate.

1 A. -- accurate, again with the
2 understanding that the industry standard is
3 95 percent.

4 Q. Okay. So is it fair to say that
5 Optum's purpose in its retrospective chart review
6 program is to submit accurate data to CMS, but
7 there may be reasons why the information
8 submitted may not be 100 percent accurate?

9 MS. MADDUX: Objection, form.

10 THE WITNESS: I think, as I was
11 stating previously, you know, the -- did
12 you say purpose?

13 BY MS. ZUPAC:

14 Q. The purpose, yes.

15 A. The purpose of retrospective chart
16 review is to submit more complete health statuses
17 on our members from medical records.

18 Q. So is it your testimony on behalf of
19 Optum and UnitedHealthcare, Inc. today that the
20 purpose of these entities' chart review programs
21 does not include the submission of accurate
22 diagnosis information to CMS?

1 MS. MADDUX: Objection,
2 mischaracterizes testimony.

3 THE WITNESS: As part of the
4 retrospective chart review program we have
5 quality assurance's programs that look at
6 what our coders code and ensure -- to
7 ensure or to work towards a 95 percent
8 industry standard, which is what we all
9 do.

10 BY MS. ZUPAC:

11 Q. A 95 industry -- a 95 percent
12 industry standard in terms of accuracy?

13 A. Correct.

14 Q. Okay.

15 A. For what our coders code.

16 Q. Okay. I just want to make sure that
17 we're operating under the same definition of
18 accurate.

19 What is -- what is Optum's
20 understanding of the term accurate?

21 A. For -- for -- well, it -- it would
22 vary. And if I could go to my --

1 Q. Sure.

2 A. -- binder, if that's okay.

3 Q. Just let me know what tab you're
4 going to --

5 A. Yep.

6 Q. -- look at.

7 A. Okay. Just for expediency, accurate
8 can mean different things in different levels.
9 And so in risk adjustment, you know, depending
10 upon the time -- and this is just an
11 approximate -- you know, there were about, like,
12 15,000, I think, like ICD-9 codes that mapped to
13 approximately 70-something HCC codes at some
14 point in time, right? So just using that kind of
15 as my example.

16 And in doing that, we were looking at
17 QA. There are different ways to look at QA. And
18 so you could look at QA on an HCC level where,
19 you know, our coder may have said something like
20 the -- said a diagnosis code that mapped an HCC
21 to a -- or with a diagnosis code to, like, the
22 lower arm, but really, when they're looking at

1 Q. Right.

2 A. -- it -- it's approximate. About
3 15,000 ICD-9 codes map to 70-something HCC codes.

4 Q. Okay.

5 A. But not all ICD-9 codes map to a risk
6 adjustment code.

7 Q. Okay. And so then I'm focusing now
8 on the HCC accuracy piece that you testified
9 about. Okay?

10 A. Okay.

11 Q. Okay. So is it fair to say that an
12 HCC submitted to CMS is accurate if the HCC maps
13 to an ICD-9 diagnosis code that is, in fact,
14 supported by that member's medical record?

15 MS. MADDUX: Objection, form.

16 THE WITNESS: Can you please
17 restate that.

18 MS. ZUPAC: Can you read back my
19 question, please.

20 (The record was read as requested.)

21 MS. MADDUX: Same objection.

22 THE WITNESS: From -- I'm sorry.

1 Can you just read the last part of that
2 again.

3 MS. ZUPAC: Yes.

4 (The record was read as requested.)

5 MS. MADDUX: And same objection.

6 THE WITNESS: So our chart review
7 program and its quality assurance program
8 is designed around our looking at what our
9 coders are coding at 95 percent accuracy.
10 It's not designed around looking at what
11 the provider may have coded within that
12 medical record itself.

13 So when we're looking at
14 submissions as result chart review, our
15 quality assurance program is looking at
16 a -- is designed for looking at the codes
17 that our coders are looking at to make
18 sure that we're meeting the 95 percent
19 HCC.

20 BY MS. ZUPAC:

21 Q. All right. So I don't believe that
22 that was responsive to my question. So let me

1 try to --

2 A. Okay.

3 Q. -- rephrase this.

4 You testified earlier that one
5 measure of accuracy is the accuracy of HCCs; is
6 that right?

7 MS. MADDUX: Objection,
8 mischaracterizes testimony.

9 THE WITNESS: That one measure for
10 our chart review program and the codes
11 that our -- that our coders code from the
12 chart is HCC accuracy, yes.

13 BY MS. ZUPAC:

14 Q. So then what are you measuring
15 when -- what is Optum measuring when it is
16 measuring HCC accuracy?

17 A. It is measuring whether the diagnosis
18 code that our coder inputted into our coding tool
19 is accurate at the HCC level based upon their
20 understanding of how they're looking at the
21 chart.

22 Q. And what does it mean for a code to

1 Then, when we send it over to the
2 retrieval provider, the retrieval -- or the
3 retrieval vendor, the vendor will -- could
4 further consolidate. They could find that maybe
5 this chart, as far as we knew, belonged to three
6 locations, but really, as part of a supergroup
7 that had seven other locations for ten locations.
8 So then they combined them into a site ID. So
9 then all of a sudden you have this provider
10 consolidation effect, where you keep rolling up
11 charts associated with the retrieval of a chart
12 underneath one provider, right, but you just keep
13 consolidating because you just know it's there
14 and typically it is.

15 And then as you're retrieving the
16 chart, what the vendor will do is they'll call up
17 the provider. They'll do some sort of provider
18 verification, like asking are there X number of
19 providers and their ID there to make sure they've
20 got the right area. Then they'll go through a
21 member verification to say hey, do you have these
22 members with this information.

1 And then once we get validation from
2 there, typically we either fax or we would secure
3 E-mail the complete list of the members. And
4 then, based upon the number, we'd work with them
5 to schedule either on site or they could
6 themselves decide to send us the charts them --
7 back because they don't want people -- or they
8 wouldn't want somebody on site or various
9 permutations of that.

10 Q. Okay. And prior to this retrieval
11 process that you just described, there is a chart
12 targeting process, correct?

13 A. Correct.

14 Q. Okay. So Optum began by targeting
15 certain charts to pull, correct?

16 A. Began chart review?

17 Q. Yes.

18 A. We would -- actually, as part of the
19 targeting -- targeting was one of the first
20 steps, yes, not the -- not the first, first step,
21 because there's suspecting that you have to do
22 and then out of suspecting you go into targeting.

1 But, yes, it was part of that.

2 Q. Okay. So we can actually go
3 backwards in time.

4 You mentioned that the first step
5 that Optum did was suspecting.

6 A. Um-hmm.

7 Q. And what is suspecting?

8 A. You know, part of suspecting was just
9 taking a look at the whole universe of -- of
10 members. And so you think about that, it's like
11 the whole universe and then targeting as you're
12 picking specific ones, right?

13 And so, like, from a suspecting
14 perspective, we'd take a look at information that
15 we have from CMS on -- on -- like, for instance
16 from the MOR, the Model Output Report, or other
17 CMS documentation that would tell us what health
18 statuses a member has, had either in the prior
19 year or the current year.

20 We would look at lab information.
21 We'd look at medications. We'd look at encounter
22 information or claims information if we had it,

1 knowing that, again, this information, especially
2 if it comes from an MOR, could have come from
3 other health plans, right, because the member
4 could have not been in our health plan the prior
5 year.

6 You know, we take a look at
7 information such as, like, disease management
8 programs that our members belong to. So, like,
9 you know, if someone was in diabetes, they would
10 probably be in a diabetes program; cancer, an
11 oncology program. You know we take a look at
12 certain information like that.

13 And then, you know, as we look at
14 information regarding the different types of --
15 of health statuses that member either previously
16 had or currently has or how they interact with
17 one another, we would then compare that to the
18 claims information that we would have.

19 Or, in some cases, if we didn't have
20 claims information -- because, again -- I mean,
21 again, we -- we may not -- get a capitated
22 provider, a provider that -- or somehow we don't

1 have information on that member, we may have just
2 made a request to a -- an assigned provider
3 panel, if that makes sense, patient panel to a
4 provider.

5 And then once we get to the universe
6 of what member-provider combinations there could
7 be, then we would go through a -- a -- you know,
8 a targeting process of saying okay, let's look
9 for these member-provider combinations based upon
10 health statuses, based upon their -- their health
11 risk status.

12 Q. Okay.

13 MS. ZUPAC: I'm going to pull up a
14 new exhibit, Tab 4. So this exhibit will
15 be marked 608.

16 (Exhibit 608 was marked for
17 identification.)

18 THE WITNESS: Thank you.

19 BY MS. ZUPAC:

20 Q. So this exhibit was produced in
21 native, so the individual slides don't have Bates
22 numbers. But the Bates number of the document is

1 MAPL000684019.

2 And I'll give you a chance to review
3 the slide deck, but I'll be directing you to
4 specific pages. And for the record, I'll go
5 ahead and identify that this is a slide deck with
6 the cover slide showing the Optum logo and the
7 title Risk Adjustment Team Introductions and
8 Services to M&R, dated February 12th 2014. And
9 my first question is simply a clarification:

10 Does M&R refer to Medicare and
11 Retirement?

12 A. It does.

13 Q. And what was Medicare and Retirement?

14 A. Medicare and Retirement is the
15 business unit within UnitedHealthcare that
16 provides health insurance benefits to Medicare
17 Advantage or Medicare patients.

18 Q. And that included Medicare Advantage
19 members?

20 A. Yes.

21 Q. Okay. So I'll direct your attention
22 to slide 17. So the slide number is on the

1 Q. Okay. And so go ahead and look at
2 that chart on the right. This lays out the
3 percentage of charts that fall within each chart
4 score group, correct?

5 A. Yes. That's what it says.

6 Q. And then there is a heading on --
7 under the next -- or over the next column stating
8 Average Value Per Chart, 1 Year Date of Service,
9 correct?

10 A. That is what is written, yes.

11 Q. Okay. So what is this average value
12 per chart, 1 year date of service measuring?

13 A. It -- it's measuring the -- once
14 HCCs -- it's measuring the -- the -- all of the
15 different HCCs on a member and after hierarchical
16 conditions are -- are taken into account.

17 And so it's the average number of
18 HCCs and their corresponding value.

19 Q. And by value, do you mean the payment
20 that the Medicare Advantage organization receives
21 for that member from CMS?

22 A. The -- the appropriate reimbursement

1 from CMS.

2 Q. And we've been discussing Optum's
3 suspecting and targeting processes, correct?

4 A. Yes.

5 Q. Okay. Did -- did UnitedHealthcare,
6 Inc. -- was UnitedHealthcare, Inc. aware that
7 Optum was using suspecting logic to target
8 particular charts for retrieval?

9 A. We would have conversations with
10 UnitedHealthcare on the logic we would use and
11 targeting to make sure we were generally aligned.

12 Q. Okay. And did UnitedHealthcare, Inc.
13 sign off on or approve the suspect logic that
14 Optum used?

15 A. We would have conversations with them
16 and we would generally receive their approval on
17 the -- on the logic that we would deploy.

18 Q. Okay. And did Optum decide which
19 charts to target for retrieval based on their
20 chart score group?

21 A. Chart score group was a consideration
22 on doing retrievals, but it was not the only

1 consideration.

2 So, for instance, timing was a
3 consideration, like meaning -- the way the risk
4 adjustment program works, you have only until
5 January of the following year after the year that
6 the data collection period ended to submit that.
7 So you have about 13 months, you know, to submit
8 it.

9 And so with claims, if we're using it
10 for targeting and claims lag and -- and run out,
11 sometimes targeting wouldn't start until May of a
12 year and retrievals wouldn't start until summer.
13 So you had less time to do retrievals. Right?
14 So just the timing of things would have had a
15 consideration. Other things would have been
16 operational capacity.

17 So, you know, you could retrieve all
18 the charts you want, but if you can't code the
19 charts, then there's no -- you can't -- you can't
20 code them. And so we would also have to take a
21 look at seeing if we only had the ability to code
22 1,000 charts, you know, you know, which 1,000

1 does it make sense for us to look after.

2 And there could have been other
3 constraints, such as onshore/offshore
4 restrictions. So not all charts could be sent
5 offshore for coding. And so there is kind of
6 business rules that we had to take a look at, if
7 that makes sense.

8 So there's other things that we took
9 a look at as well.

10 Q. Um-hmm. The one thing you mentioned
11 is that Optum may have limited resources or
12 certain resources to code charts, correct?

13 A. We have -- we had operational
14 considerations when you're looking at it,
15 production plans and operational capacity plans,
16 yes.

17 Q. Okay. So did Optum use the chart
18 score group information as part of its
19 consideration for which charts to retrieve?

20 A. We -- chart score group was one of
21 the considerations, but not the only
22 consideration.

1 Q. And was that true for the entirety of
2 the period for 2008 to 2016 date of service chart
3 review?

4 A. No. Chart score group generally came
5 into consideration around this time frame of this
6 presentation.

7 Q. Meaning February 2014?

8 A. We piloted it in, like, 2013 and --
9 and took a look at it, but 2013, 2014.

10 Q. Okay. And what date of service
11 years, then, was -- did chart score groups start
12 to be a -- a consideration for chart retrieval?

13 A. In a kind of rudimentary form in
14 20 -- in 2012 we -- which is -- ran into that
15 January time frame, if we -- kind of
16 December/January would have been 2011 dates of
17 services and then 2013 would have been 2012. And
18 I think these here are -- yeah. Actually, that's
19 what it says. It's 2013 project/2012.

20 Q. So then before the 2012 date of
21 service chart review, did Optum use suspect
22 logic?

1 A. In a -- yes. But, again, you -- you
2 evolve suspect logic over time but recapture.

3 So again, using this example of Mary,
4 it could have been that Mary's information from
5 the prior year said she was diabetic, right? And
6 so in the current data collection period, the
7 suspect logic was more like a recapture, if that
8 makes sense, and that's the predominant.

9 Q. Okay. So was the policy before the
10 2012 date of service chart review to review a
11 chart for each member every two years?

12 A. Can you restate that? I -- I -- I
13 think I know what you're saying, but I just want
14 to make sure I understand, so ...

15 Q. Okay. So before the chart review for
16 the 2012 date of service, was Optum's policy to
17 review member charts every two years?

18 A. And so I -- I believe that we started
19 changing the targeting approach -- so really, the
20 targeting approach of looking at a member once
21 every two years -- sorry, just saying it a little
22 bit differently -- like starting in 2011-ish.

1 So -- so we would -- we -- we started
2 making that change then.

3 Q. And I just want to clarify, since we
4 are obviously talking about date of service years
5 and calendar years.

6 A. Yeah. Yeah.

7 Q. So when you say 2011-ish, are you
8 referring to the 2011 date of service or are you
9 referring to the 2011 calendar year?

10 A. I'm -- the -- talking about the --
11 about the 2011 -- as -- as I recall, about the
12 2011 project year, which would have been 2010
13 dates of services.

14 Q. Okay. So what was Optum's approach
15 for targeting charts for the 2008 to 2011 date of
16 service chart reviews?

17 A. It -- it was what you just described,
18 which was looking at about half of the membership
19 every other year.

20 Q. Okay. And so then is it accurate to
21 say that for the 2012 date of service, Optum
22 shifted to an approach that used suspect logic?

1 MS. MADDUX: Objection, form.

2 THE WITNESS: So we always use
3 suspect logic. It just evolves over time,
4 you know, if you would. So, you know,
5 here we're taking a look at -- as you can
6 see, back in 20, on slide 20, looking at
7 specialties and encounters.

8 BY MS. ZUPAC:

9 Q. Um-hmm.

10 A. And so it's, you know, based upon the
11 fact that we were seeing information that -- that
12 members that maybe would have only been looked at
13 every other year were still being looked at
14 within that same -- sorry -- would -- had an
15 encounter in the data collection period in
16 question for that submission year and so there
17 was information here to say it would make sense
18 to retrieve a chart.

19 Q. So then am I understanding you
20 correctly that the sorting of charts into --
21 chart into the seven chart score groups that
22 we've been discussing started with the 2012 date

1 of service chart review?

2 A. That is where I'd say it was
3 productionalized.

4 Q. Okay. And so then can you describe
5 the -- the way suspect logic was used from the
6 2008 to 2011 date of service chart reviews?

7 A. Sure. It -- you know, it was -- you
8 know, suspect logic is a very wide term. Right?

9 Q. Um-hmm.

10 A. So, you know, it would have included
11 things such as, you know, membership in the
12 current year, membership in the data collection
13 period year. It could have included information
14 such as -- and you're only asking suspecting now,
15 right?

16 Q. Yes.

17 A. Okay. Suspecting.

18 You know, if we had information on
19 a -- again, a -- some sort of CMS report saying
20 that the member had a disease condition the prior
21 year and looking to see if there is any other
22 information that had that disease progression or

1 correlation. So, like, some diseases happen in
2 correlation with one another. And so -- and
3 those are listed also on the -- on the actual HCC
4 categories, the interactions, I think.

5 Q. Are you referring to comorbidities?

6 A. I would refer to them as
7 interactions.

8 Q. And then is it accurate that for each
9 of the years, each of the date of service years
10 from 2008 to 20 -- to 2016, UnitedHealthcare was
11 aware of the suspect logic that Optum was using
12 to target charts?

13 MS. MADDUX: Objection, form.

14 THE WITNESS: We would discuss with
15 UnitedHealthcare our suspect logic that we
16 used and, you know, generally talk about
17 process improvements or -- and then we
18 would get general approval on what we were
19 going to implement for that current year.

20 BY MS. ZUPAC:

21 Q. Okay. And did ever -- did Optum ever
22 proceed with a suspect logic program that

1 UnitedHealthcare did not agree with?

2 MS. MADDUX: Objection, form.

3 THE WITNESS: Not that I recall,
4 but let me research that and get back to
5 you on that.

6 BY MS. ZUPAC:

7 Q. You're not aware of an instance in
8 which -- sitting here today, in which Optum
9 proceeded with a --

10 A. I am not. Your -- the way you asked
11 that question I was like, I -- no, I -- I am not
12 aware of that.

13 Q. Okay. And so at any point was the --
14 at -- at any point between the 2008 and 2016 date
15 of service years, was the chart targeting process
16 in the -- that Optum used seeking charts
17 randomly?

18 A. Can you say that one more time?

19 Q. Sure. I can try to rephrase.

20 At any point did -- between the 2008
21 to 2016 date of service years did Optum use chart
22 targeting to target charts at random?

1 MS. MADDUX: Objection, form.

2 THE WITNESS: It is retrieval
3 provider information that has been
4 consolidated to avoid provider abrasion
5 based upon the provider information that
6 we had on hand.

7 MS. MADDUX: Counsel, we've been
8 going for a little over an hour, so I
9 don't know if there's a good breaking
10 point soon.

11 MS. ZUPAC: Yeah, I can --

12 Ms. Baker, do you need a break
13 right now?

14 THE WITNESS: Sure.

15 MS. ZUPAC: Okay. Why don't we
16 take a five-minute break.

17 MS. MADDUX: Okay.

18 VIDEO OPERATOR: Off the record.
19 The time is 11:20.

20 (Thereupon, a brief recess was
21 taken.)

22 VIDEO OPERATOR: On the record.

1 The time is 11:35.

2 MS. ZUPAC: Okay.

3 BY MS. ZUPAC:

4 Q. So, Ms. Baker, we were talking about
5 the -- about Optum's consolidation process with
6 respect to provider ID, correct?

7 A. In respect to retrieval provider
8 associated with a chart.

9 Q. Yes. And all of my questions today
10 about this topic are -- are related to the
11 retrospective chart review program, to be clear.

12 A. Okay.

13 Q. Okay. So as a result of Optum's
14 consolidation process for that retrieval --
15 retrieval provider ID, was it possible to collect
16 charts for members that included encounters with
17 multiple providers?

18 MS. MADDUX: Objection, form.

19 THE WITNESS: So after we -- after
20 we released the charts to the retrieval
21 vendor and they did their consolidation
22 and they did their validation and we

1 retrieved the chart under that method, it
2 could include multiple providers. But we
3 don't know which providers they are --

4 BY MS. ZUPAC:

5 Q. Um-hmm.

6 A. -- and we also can't tell you if it's
7 complete.

8 So, like, for example, you know, if
9 it was a -- a site that had paper-based charts
10 and we only went to, you know, Site 1 and it was
11 a two-site one, we would only receive the part of
12 the chart that was there for the doctors that saw
13 there -- there. But that doctor, let's say --
14 call it Dr. A, could have been at Site 1 on
15 Monday, Wednesday, Friday but went to Site 2 on
16 Thursday -- Tuesday and Thursday and we didn't
17 have that component of the chart.

18 Or, you know, another example could
19 be that the provider themselves, the
20 representative at the provider, right, could have
21 said I want to send you the chart. And so at
22 that point in time we catch the ball of whatever

1 information that they send --

2 Q. Um-hmm.

3 A. -- right?

4 And so it -- the chart itself could
5 have multiple information, but we also wouldn't
6 know for sure if it was complete.

7 Q. Sure. Sure. But the -- my question
8 basically was whether or not that -- whether or
9 not a chart retrieved for a particular member
10 could include encounters with, for example,
11 Dr. A., as you noted, but also Dr. B. and maybe
12 also Dr. C.

13 MS. MADDUX: Objection, asked and
14 answered.

15 THE WITNESS: To -- to clarify on
16 that one, we wouldn't know if the chart
17 was supposed to have Drs. A, B and C in
18 your example in that one. But, you know,
19 if -- if we, you know, retrieve the chart
20 or if they sent us a chart, it could
21 contain multiple providers. But, again,
22 we wouldn't be able to tell you if that

1 chart should be A, B or C.

2 BY MS. ZUPAC:

3 Q. Okay. But the -- the chart that
4 included the encounters with potentially multiple
5 providers would all be -- would be assigned one
6 retrieval provider ID, correct?

7 A. It would be assigned one retrieval
8 provider ID for that specific member-provider
9 group location, but that member could have seen,
10 you know, five different doctors. So, like, for
11 instance, like in Nashville, you could see
12 Vanderbilt Health group, which is distinctly
13 different than the -- you know, the St. Thomas
14 Health group, right, which is distinctly
15 different than the Heritage Medical group.

16 And so that example, that's three
17 different charts, but within Vanderbilt you could
18 have seen, you know, five doctors. At Heritage
19 you could have seen two. At St. Thomas you've
20 seen seven. So you have had consolidation within
21 those three, but you'd still have three different
22 charts --

1 QA coders provided?

2 A. The -- again, it -- it -- it was date
3 of service, the chart information, the member
4 information, the date of service, the diagnosis,
5 any E0 codes. But, you know, rendering provider
6 wasn't picked up, so there -- no information on
7 rendering provider.

8 Q. The QA coders were informed, though,
9 or given information about what the production
10 coder had coded, correct, the ICD-9 and E0 codes
11 that the production coder had coded?

12 MS. MADDUX: Objection, form.

13 THE WITNESS: The QA coder --
14 coders were given the coding results from
15 a production coder.

16 BY MS. ZUPAC:

17 Q. QA coders were not informed of what
18 diagnosis codes had been submitted by the
19 provider for a particular member, correct?

20 A. That's not possible as part of the
21 retrospective chart review program because, for
22 most of those years described, rendering provider

1 was not picked up. It wasn't a -- it was not
2 a -- a data element for -- for RAPS and the -- I
3 mean, closer to, I think, the 2013 -- or no.
4 Actually, I think it was more like the 2014 year
5 we started saying does rendering provider equal
6 retrieval provider and then we started building
7 that out.

8 Q. Um-hmm.

9 A. But most of those years there's no
10 way -- we didn't pick up rendering provider.

11 Q. So I just have a couple more
12 questions. Then we'll take a break.

13 A. Okay.

14 Q. So we have been talking about
15 ChartSync a lot. ChartSync's gotten a lot of
16 attention. But at some point ChartSync was
17 phased out, correct?

18 A. Yes.

19 Q. Okay. And it was replaced with a
20 tool called the Medical Record Manager or MRM?

21 MS. MADDUX: Objection, out of
22 scope.

1 THE WITNESS: Um-hmm.

2 BY MS. ZUPAC:

3 Q. And was MRM also referred to as
4 Emerald?

5 MS. MADDUX: Objection, out of
6 scope.

7 THE WITNESS: In the beginning,
8 yes.

9 BY MS. ZUPAC:

10 Q. Okay. So what date of service years
11 was the Medical Record Manager operational?

12 MS. MADDUX: Objection, out of
13 scope.

14 THE WITNESS: MRM was implemented
15 in the 2014 calendar year and so that
16 would have contained some 2013 dates of
17 services.

18 BY MS. ZUPAC:

19 Q. Okay. And then was it operational
20 for the 2014, 2015 and 2016 dates of service?

21 MS. MADDUX: Objection, out of
22 scope.

1 You can answer.

2 THE WITNESS: Yes.

3 BY MS. ZUPAC:

4 Q. Okay. And did MRM have certain
5 features that were unavailable in ChartSync?

6 MS. MADDUX: Objection, out of
7 scope.

8 THE WITNESS: It started off with
9 being able to collect information on
10 rendering provider. It had some
11 additional work queues where -- I think
12 earlier I gave the example you'd give them
13 a member ID and say go do this. Like we
14 were able to do that. It had some
15 additional capabilities regarding coding
16 organizations to be able to say who was
17 going to code the chart, who's going to
18 retrieve the chart.

19 So a lot of the capabilities were,
20 like, kind of systematic like that. Also
21 the ability to save a chart -- no, that
22 was on -- yeah. No, that was the -- a

1 summary of some of them.

2 BY MS. ZUPAC:

3 Q. Okay. And did MRM include the
4 capability of conducting Q -- QA processes within
5 MRM?

6 MS. MADDUX: Objection, out of
7 scope.

8 MS. ZUPAC: So I'll just note for
9 the out-of-scope objections related to
10 questions about QA that one of the
11 subtopics that this witness is designated
12 on is additional reviews of charts
13 reviewed in the program, including recode,
14 second level review, quality assurance and
15 overread.

16 MS. MADDUX: And I'll also note
17 for the record that the government
18 actually noticed separate topics around
19 databases and use of databases. I mean,
20 they also have a topic around databases
21 used for specific programs but did not
22 include that in the scope of the quality

1 assurance topic, so it is clearly out of
2 scope.

3 MS. ZUPAC: Okay. So it's the --
4 it's defendants' position that a topic
5 about quality assurance cannot include any
6 questions about any programs used to
7 conduct quality assurance?

8 MS. MADDUX: The government knows
9 how to write a topic when it wants to ask
10 about databases or --

11 MS. ZUPAC: That's a yes or --

12 MS. MADDUX: -- programs used.

13 MS. ZUPAC: -- question, Counsel.

14 MS. MADDUX: I'm answering your
15 question, Ms. Zupac.

16 The government knows how to write a
17 topic. When they want to ask about the
18 database of the programs used for a
19 program, they did it in topic 12 slash --
20 or I guess 13 slash 18 from the combined
21 notice and they didn't do it here.

22 MS. ZUPAC: Okay. So I'm asking

1 about QA processes and certain QA
2 processes are different, depending on the
3 date of service here. And the -- that is
4 in part because the programs used for
5 those date of service years were
6 different. So I'm trying to get
7 clarification so that the record is clear
8 as to which program was in effect for a
9 date of service year and, therefore, how
10 that affected the QA processes used for
11 that date of service year.

12 MS. MADDUX: Except you're asking
13 very broad questions about what different
14 databases are without tying it to QA and
15 then trying to tie it to QA. They're out
16 of scope.

17 MS. ZUPAC: I am currently asking
18 the witness whether Medical Record Manager
19 included the ability to conduct QA within
20 Medical Record Manager.

21 MS. MADDUX: And I will maintain
22 my objection out of scope.

1 MS. ZUPAC: Okay. And we disagree.

2 BY MS. ZUPAC:

3 Q. Go ahead.

4 MS. MADDUX: You can answer.

5 THE WITNESS: We tried to build out
6 QA within Medical Record Manager. But
7 ultimately it wasn't possible to do in a
8 timely manner, so we continued with new --
9 because at that -- by that point in time
10 we were moving to new and unique QA --
11 unique QA outside of --

12 MS. REPORTER: Moving to what?
13 Sorry.

14 THE WITNESS: New and unique QA
15 outside of MRM.

16 BY MS. ZUPAC:

17 Q. Okay. So let's go on a break and
18 when we come back we will discuss new and unique
19 QA.

20 VIDEO OPERATOR: Off the record.

21 The time is 2:57.

22

1 (Thereupon, a brief recess was
2 taken.)

3 VIDEO OPERATOR: On the record.
4 The time is 3:21.

5 BY MS. ZUPAC:

6 Q. Okay. Welcome back, Ms. Baker.

7 So certain of the topics that you are
8 designated on relate to blind coding versus
9 informed coding, correct?

10 A. Yes.

11 Q. And so I asked you earlier about your
12 understanding of the term blind coding, correct?

13 A. Yes.

14 Q. Okay. And what -- what is your
15 understanding of the term blind coding?

16 A. It's where a coder codes a -- the
17 medical record in front of them.

18 Q. And that coder is not provided with
19 any information about that member outside of
20 what's in the chart, correct?

21 A. They're -- about that member?

22 Q. Um-hmm.

1 A. I mean, the member name and that --
2 that -- correct. I mean, it's industry standard
3 to start with blind coding.

4 Q. But I just want to make sure I
5 understand what exactly blind coding entails.

6 A. Um-hmm.

7 Q. So -- so in blind coding a coder
8 would not be informed, for example, about
9 diagnoses that the member is suspected to have,
10 correct?

11 MS. MADDUX: Objection, form.

12 THE WITNESS: The -- in blind
13 coding a coder's given no additional
14 information, other than the image of the
15 chart to -- to code to the best of their
16 ability.

17 BY MS. ZUPAC:

18 Q. And in blind coding a coder would not
19 be informed about diagnosis codes previously
20 submitted by a provider for that member, correct?

21 A. The -- the -- in blind coding a
22 coder's is given no information.

1 Q. And so in contrast to blind coding,
2 there's informed coding, correct?

3 A. Yes.

4 Q. Okay. And so what is your
5 understanding of the term informed coding?

6 A. I just want to read the definition,
7 if that's okay. See if I can find it.

8 Q. Are you referring to a particular
9 tab, Ms. Baker?

10 A. I will be.

11 Q. Okay. Just let me know the tab --

12 A. Yep.

13 Q. -- when you get to it.

14 A. Still looking. Sorry.

15 Q. Okay. Are you by any chance looking
16 for United's first supplemental responses and
17 objections to the sixth set of interrogatories --

18 A. I -- I think --

19 Q. -- Tab 23?

20 A. Is it Tab 23? Thank you.

21 Q. If that's what you're looking for.

22 A. Let me look.

1 Q. Suggesting.

2 A. I -- I may be too far back.

3 Yes. Thank you very much.

4 Q. All right.

5 MS. ZUPAC: So I'll go ahead and
6 reveal that as -- or mark that as
7 Exhibit 611.

8 (Exhibit 611 was marked for
9 identification.)

10 BY MS. ZUPAC:

11 Q. And are you on page 10 of
12 Exhibit 611?

13 A. I am.

14 Q. Okay. And so what part are you
15 looking at now?

16 A. Line 21, starting with line 21.

17 Q. Okay. So I'm looking -- I'm looking
18 at line 20 where it states, For the purposes of
19 responding to this interrogatory, UnitedHealth
20 interprets the term informed manner to refer to
21 an informed coding process whereby the coder
22 conducting a review of a medical record as part

1 of UnitedHealth's chart review program was
2 provided with diagnoses previously coded or
3 received from an acceptable data source across
4 all providers associated with the member and/or
5 non-UnitedHealth MA plan submissions for the
6 member associated with the appropriate data
7 collection period.

8 Do you see those lines?

9 A. I do.

10 Q. Is -- is that what you were referring
11 to?

12 A. That was what I was -- thank you very
13 much.

14 Q. Good, because it was a very long
15 sentence to read if that wasn't what you were
16 referring to.

17 Okay. So --

18 A. I mean, I would maybe also just
19 continue that further informed coding, as
20 UnitedHealth uses the term to respond to this
21 interrogatory was not specific to the rendering
22 provider or date of service as the charts

1 denotes whether a chart was coded in
2 UnitedHealth's chart reviewing using informed
3 coding, as UnitedHealth interprets this term.

4 Correct?

5 A. I see that.

6 Q. Okay. And so is it your
7 understanding that the only charts that were
8 coded in the defendants' chart review program
9 using informed coding are those that are marked
10 with the recode flag discussed in this response?

11 A. Yes.

12 Q. Okay. And so you're not aware of any
13 other instances of charts coded using informed
14 coding that have not been marked with the recode
15 flag discussed in this response?

16 A. As part of the chart -- retrospective
17 chart review program?

18 Q. Correct.

19 A. We tried to do it in the -- to do it
20 again in the project year 2013, but it was not
21 successful.

22 Q. Right. And so the -- so the charts

1 that you're mentioning that you tried to do
2 informed coding on in the 2013 date of service
3 year were not ultimately coded using informed
4 coding, correct?

5 A. Correct.

6 Q. Okay. So then -- so then I -- I
7 guess I can modify my question to ask, are there
8 any other instances of charts successfully coded
9 using informed coding in the retrospective chart
10 review program that have not been marked with the
11 recode flag?

12 MS. MADDUX: Objection, form.

13 THE WITNESS: Not that I'm aware of
14 in regards to the retrospective chart
15 review program.

16 BY MS. ZUPAC:

17 Q. Okay. Okay. So aside from the
18 charts marked with the recode flag discussed
19 here, Optum coded charts for UnitedHealthcare's
20 chart review program using blind coding for the
21 2008 to 2016 dates of service, correct?

22 A. Yes.

1 Q. Okay. And why is that? Why were
2 the -- why were charts other than those subject
3 to the recode program coded using blind coding?

4 A. It's just how it organically evolved.
5 I mean, from the very beginning, there weren't --
6 there wasn't tools or processes or even claims
7 information available to be able to provide that
8 information from a blind -- or sorry -- from a --
9 from a -- a -- from a non-blind perspective.

10 And then as chart review --
11 retrospective chart review became industry
12 standard, it also just became industry standard
13 to do blind coding as part of its natural method
14 for doing it.

15 Q. I believe you testified about --
16 at -- at the beginning there wasn't -- there
17 weren't other data sources to -- used to use
18 informed coding, correct?

19 MS. MADDUX: Objection, form.

20 THE WITNESS: There weren't --
21 there wasn't an ability to tie, you know,
22 a -- like a -- a claim to a -- a chart,

1 because when you do a chart, you don't
2 know what's in the chart until you, you
3 know, see what's in the chart. And even
4 then, once we saw it, you're -- we didn't
5 have the ability to pick up a rendering
6 provider information until further on in
7 the program.

8 BY MS. ZUPAC:

9 Q. Okay. So what date of service years
10 are your -- are -- are you referring to, during
11 that time period when it wasn't possible to pick
12 up this information?

13 MS. MADDUX: Objection, form.

14 THE WITNESS: What information?

15 BY MS. ZUPAC:

16 Q. The information that you testified to
17 as being required to perform informed coding.

18 MS. MADDUX: Objection, form.

19 THE WITNESS: Informed coding where
20 its diagnosis previously coded or received
21 from acceptable data source across all
22 providers?

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CERTIFICATE OF NOTARY

I, MISTY KLAPPER, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to typewriting by me; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Misty Klapper

Misty Klapper, RMR, CRR
Notary Public in and for
the District of Columbia

EXHIBIT D-90

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

- - - - -X

:

UNITED STATES OF AMERICA, ex rel.:

BENJAMIN POEHLING, :

:

Plaintiff, :

: Case No.

vs. : 2:16-cv-08697-FMO-SS

:

UNITEDHEALTH GROUP, INC., et al., :

:

Defendants. :

:

- - - - -X

VOLUME II
CONTINUATION OF VIDEOTAPED
RULE 30(b)(6)DEPOSITION OF
OPTUMINSIGHT, INC. AND UNITEDHEALTHCARE, INC.,
BY THEIR DESIGNEE, KATHLEEN O. BAKER

Washington, D.C.

May 31, 2023

Reported by:
Misty Klapper, RMR, CRR
Job No.: 982006

1 P R O C E E D I N G S

2 VIDEO OPERATOR: We are on the
3 record. This begins videotape number 1 in
4 the deposition of Katie Baker in the
5 matter of United States of America,
6 ex rel. Benjamin Poehling, Plaintiff,
7 versus UnitedHealth Group, Inc., et al.
8 Defendants, Case Number CV 16-08697-FMO,
9 in the United States District Court for
10 the Central District of California,
11 Western Division.

12 Today's -- is May 31st 2023, and
13 the time on the monitor is 9:13 a.m.

14 This deposition is being taken at
15 555 11th Street, Northwest, Washington,
16 D.C. 20004, at the request of Department
17 of Justice. The videographer is Robyn
18 Ellis of Magna Legal Services and the
19 court reporter is Misty Klapper of Magna
20 Legal Services.

21 Counsel appearances will be on
22 stenographic record only.

1 Will the court reporter please
2 swear in the witness.

3 MS. REPORTER: One moment.

4 KATHLEEN O. BAKER, AS DESIGNEE

5 The witness herein, called for
6 further examination by counsel for the
7 Plaintiffs, having been duly sworn, was
8 further examined and further testified as
9 follows:

10 FURTHER EXAMINATION BY COUNSEL FOR PLAINTIFFS

11 BY MS. ZUPAC:

12 Q. All right. Welcome back, Ms. Baker.

13 I'm going to start by following up on
14 some items that we discussed yesterday, starting
15 with the question of whether coders were
16 instructed to record all RxHCCs in the medical
17 records.

18 Do you recall that we discussed this
19 yesterday?

20 A. I do.

21 Q. Okay. And do you recall that you did
22 not remember at the time whether or not that

1 instruction changed over the years for the chart
2 review projects for dates of service 2008-2016?

3 MS. MADDUX: Objection, form.

4 THE WITNESS: I -- I wanted to
5 clarify.

6 BY MS. ZUPAC:

7 Q. Sure. Go ahead and give that
8 clarification.

9 A. So we did not do RxHCCs during recode
10 and for part of 2013, but then we started doing
11 RxHCCs again.

12 Q. Okay. So let's start with the recode
13 project. So this is the recode project that we
14 discussed yesterday that covered dates of service
15 2011?

16 A. Yes.

17 Q. Okay. And so during the recode
18 project were the recode coders instructed not to
19 record ICD-9 diagnosis codes that mapped only to
20 an RxHCC?

21 A. They were instructed to pick up --
22 well, they -- they could write down RxHCCs.

1 If, in fact, the factual basis
2 underlying the denial includes facts drawn
3 from the medical records, then I am
4 entitled to know that. And so I'm asking
5 as a yes or no question whether the
6 factual basis underlying the denial
7 includes any review of the underlying
8 medical records. I'm not asking for the
9 details of -- of that review. I'm just
10 asking the yes or no question.

11 MS. MADDUX: And we -- we'll still
12 instruct the witness not to answer. It's
13 outside the scope and premature expert
14 discovery and it is not properly within
15 the topic that you noticed nor within the
16 parties' agreement.

17 MS. ZUPAC: Okay.

18 BY MS. ZUPAC:

19 Q. So are you going to follow
20 instruction -- your counsel's instruction not to
21 answer my question?

22 A. I am.

1 Q. Okay. And so then I believe that you
2 do have some information underlying the factual
3 basis for the denial or refutation by you of the
4 United States' contention that the diagnosis
5 codes identified by the United States in its
6 response to UHC of California's interrogatory
7 response -- Interrogatory 1 are not supported by
8 charts, correct?

9 A. I have information, yes.

10 Q. Okay. And so would you like to
11 provide that information now?

12 A. Please.

13 Q. Go ahead.

14 A. Okay. Thanks.

15 You know, there are several parts of
16 the process where there -- about completeness and
17 about whether or not we have adequate data
18 elements.

19 So, for instance, within the chart
20 targeting process, we talked about the fact that
21 providers are consolidated at different levels.
22 And so the retrieval providers' information gets

1 consolidated based upon locations, groups, the --
2 based on number of providers, and then when we
3 send that information over to the provider
4 vendors, that there could be further provider
5 consolidations.

6 And so charts could be located at
7 multiple different locations. Charts could be --
8 for different providers could be at different
9 locations. Some charts may be provider specific.

10 And when we go to retrieve that
11 chart, not all dates of services or encounters
12 for that provider or provider group are able to
13 be picked up. When the -- some other items could
14 also include if the provider themselves sent us
15 the chart, they could have not included all of
16 the dates of services. And a member has multiple
17 different charts across different locations and
18 we may not have all that information.

19 You know, if we also just step -- as
20 we talked about in this process, just within
21 coding that coders have different types of skill
22 sets and different types of experiences, that

1 they have -- you know, that they have different
2 levels of problem-solving skills and ability to
3 make connections within chart.

4 Coders could have, again, different
5 background experiences. They could have a -- one
6 type of specialty experience like cardiology.
7 They could be looking at an oncology chart. And
8 those personal experiences do also influence the
9 type of different problem-solving and ability to
10 look at the chart.

11 We also have, you know, other
12 information that, you know, coding clinics have
13 changed over time, that we, you know, looked at
14 that information and that we also look at, you
15 know, other metrics such as RADV results and
16 other types of audits like that where our overall
17 results have been generally aligned with the
18 expectations of the government.

19 Q. Okay. And so, Ms. Baker, is that a
20 complete description of the factual basis
21 underlying any denial or refutation by you of the
22 United States' contention that the diagnosis

1 CERTIFICATE OF NOTARY

2 I, MISTY KLAPPER, the officer before whom
3 the foregoing deposition was taken, do hereby
4 certify that the witness whose testimony appears in
5 the foregoing deposition was duly sworn by me; that
6 the testimony of said witness was taken by me in
7 shorthand and thereafter reduced to typewriting by
8 me; that said deposition is a true record of the
9 testimony given by said witness; that I am neither
10 counsel for, related to, nor employed by any of the
11 parties to the action in which this deposition was
12 taken; and, further, that I am not a relative or
13 employee of any attorney or counsel employed by the
14 parties hereto, nor financially or otherwise
15 interested in the outcome of this action.

16

17



Misty Klapper, RMR, CRR

18

Notary Public in and for
the District of Columbia

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EXHIBIT D-91

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 1
DEPOSITION OF JON H. BIRD
As 30(b)(6) Designee 2 of
OptumInsight, Inc.
UnitedHealthcare, Inc.
Washington, DC
June 22, 2023

Reported by: John L. Harmonson, RPR
Job No. 988356

1 you abstracted. Can you clarify what you mean by
2 that?

3 MR. QURESHI: Objection to form. This
4 continues to be outside the scope.

5 THE WITNESS: The actual diagnosis/date
6 of service combinations would have been documented
7 based on a review of the medical record.

8 BY MR. MASON:

9 Q. But is abstracting -- when you're saying
10 abstracting, is that different than the activity
11 done by the coder?

12 A. No, it's the same thing. It's just a
13 term that's used.

14 Q. And so you're saying that for a period
15 of time, the coders were instructed not to identify
16 all of the diagnoses documented in the medical
17 record but only to identify diagnosis codes that
18 were new for that six-month period for that
19 beneficiary?

20 MR. QURESHI: Objection to form.
21 Mischaracterizes testimony. And remains out of
22 scope for this designee.

23 You can answer in your personal
24 capacity, Mr. Bird.

25 THE WITNESS: Not necessarily new. I

1 mean the way the payment process works, as you
2 know, it's really every six months. So one code
3 per six months is sufficient. So if a -- if an
4 individual saw the doctor ten times and had
5 diabetes documented ten times during the six-month
6 period, you would only need one code to be
7 submitted to CMS for that to map to an HCC.

8 So in the early stages of the program,
9 which I think was the early stages -- and again
10 this is my personal capacity and is based upon my
11 recollection -- it wasn't a requirement to code
12 everything that was in the medical record.

13 BY MR. MASON:

14 Q. Okay. And when you're saying that this
15 was in the early stages of the chart review
16 program, what time period are you talking about?

17 A. I can't remember when everything
18 changed. You know, I think -- and I think the
19 scope covers what, 2008 through 2016. So probably
20 in that 2008 to 2010, '11 time frame.

21 Q. During that three-year time period,
22 you're saying the coders were instructed to only
23 find a code once per six months?

24 MR. QURESHI: Objection to form.

25 Mischaracterizes testimony. And outside of scope

1 for this designee.

2 You can answer in your personal
3 capacity.

4 THE WITNESS: For some of that period.
5 I don't know exactly what, whether it was our
6 coders or whether it was external coders. But I
7 just recall that being part of the program for a
8 period of time.

9 BY MR. MASON:

10 Q. And so -- why don't we move on.

11 But just to recap, aside from those two
12 clarifications, then, my description previously
13 about the chart review program is accurate; right?

14 MR. QURESHI: Objection to form.
15 Mischaracterizes testimony, and ignores the last
16 five minutes of responses. Outside the scope as
17 well.

18 THE WITNESS: Subject to the corrections
19 that I made, then I think the rest of your
20 description around retrieve, codes, that is -- it's
21 fair.

22 BY MR. MASON:

23 Q. Okay. And Optum performed the chart
24 review program for its clients which were MAO --
25 Medicare Advantage organizations; is that right?

1 A. For certain clients, correct.

2 Q. Okay. Optum didn't perform it for all
3 of its clients, but it did perform it for some of
4 its Medicare Advantage organization clients?

5 A. Correct.

6 Q. And one of those Medicare Advantage
7 organization clients was UnitedHealthcare; right?

8 MR. QURESHI: Objection to form.
9 Outside of scope.

10 THE WITNESS: That's correct.

11 BY MR. MASON:

12 Q. And during what time period did Optum
13 perform the chart review program for
14 UnitedHealthcare?

15 MR. QURESHI: Objection to form.
16 Outside of scope for this designee.

17 You can answer in your personal
18 capacity, Mr. Bird.

19 THE WITNESS: I know it does today. I
20 don't know which year it started doing that. I
21 mean the earliest I saw in my personal capacity,
22 chart review results, would have been around the
23 2008 date of service time frame. That's not to say
24 that it wasn't done prior to that, but that's when
25 I started with the organization.

1 workstream owner of this attribution process;
2 right?

3 MR. QURESHI: Objection to form.

4 THE WITNESS: My name is listed in
5 "Workstream Owner," correct.

6 BY MR. MASON:

7 Q. And the target completion dates for the
8 retrospective attribution dataset analysis is
9 October 29th, and then the target completion date
10 for the attribution logic validation analysis is
11 November 2nd. Do you see that?

12 A. I do.

13 Q. And is that consistent with your
14 testimony about when the attribution process was
15 developed and implemented?

16 A. I don't see a year. What year is this?

17 Q. Fair enough. Let's go back to 713A,
18 which is the cover email. Do you see that this was
19 sent on October 29, 2012?

20 A. I see that.

21 Q. And so is this essentially a task
22 manager for the process of developing the
23 attribution logic and attribution analysis that
24 you've testified about?

25 MR. QURESHI: Objection to form.

1 THE WITNESS: Yeah, I think I indicated
2 earlier the process evolved over time. So it looks
3 like there was additional analysis and logic being
4 developed in this time frame of October of 2012. I
5 think the documentation that we looked at earlier
6 indicated that that began earlier in 2012.

7 BY MR. MASON:

8 Q. Okay. And then for the -- following the
9 development of the attribution process, attribution
10 analysis was done consistently since then?

11 MR. QURESHI: Objection to form.

12 THE WITNESS: You mean that attribution
13 process we described has continued in some form
14 since then?

15 BY MR. MASON:

16 Q. Yeah.

17 A. Yeah, I believe so. Yes.

18 Q. And you're saying in some form. Are you
19 referencing that it's changed?

20 A. You have a culture of continuous
21 improvement, so I'm sure the platforms have
22 probably changed since this early time. There's
23 perhaps different kinds of features and functions
24 that are part of the product. But I think the
25 essence of establishing valuation related to

1 programs continues.

2 Q. Okay.

3 MR. MASON: Why don't we go off the
4 record and take a break.

5 THE VIDEOGRAPHER: Going off the record
6 at 11:53.

7 (Recess taken.)

8 THE VIDEOGRAPHER: We are back on the
9 record at 12:11.

10 BY MR. MASON:

11 Q. Mr. Bird, another risk adjustment
12 program that Optum performed for UnitedHealthcare
13 was called claims verification; right?

14 A. Correct.

15 Q. Can you explain what the claims
16 verification program is?

17 A. It was a program that we operated during
18 a certain time frame that identified and reviewed
19 exclusive HCCs that were submitted by providers
20 that were part of the chart review program.

21 Q. And Optum performed that program for
22 UnitedHealthcare?

23 A. That's correct.

24 Q. When?

25 A. The program was in phases. The first

1 phase of the program was 2010 calendar year for
2 2009 dates of service that was limited to Ovations,
3 which was UnitedHealthcare population, and also
4 limited to one member one provider.

5 The second phase was a similar one
6 member one provider. It was moved from a manual
7 process into one that was within a system, and that
8 was in 2011 for 2010 dates of service.

9 And then Phase 3 of CV was for 2011 and
10 '12 dates of service. And that was looking at
11 multiple provider as opposed to one member one
12 provider criteria.

13 Q. And when was Phase 3 conducted?

14 A. Phase 3 -- and I may need to refer to
15 kind of a timeline on that. But typically it would
16 be done on a retrospective basis. So if we're
17 looking at 2011 dates of service, we would have
18 commenced that in 2012. And then it was ongoing
19 for 2011 and in 2012 until the program was
20 suspended and ultimately discontinued, which was
21 the spring of 2014.

22 Q. When specifically was it suspended?

23 A. There was -- so there was operational
24 suspensions from time to time based upon -- but in
25 terms of suspension leading to discontinuation of

1 the program, my understanding is it was around the
2 middle of April that there was -- I think I've seen
3 within the documentation I reviewed some
4 notification for the delete process to be put on
5 hold around April of -- on or around April 18th of
6 2014.

7 Q. And when you say suspended, you just
8 said that you suspended the delete process. Did
9 you suspend all of CV, or just the delete process?

10 A. The notification that I saw was in
11 relation to deletes. But my understanding is the
12 entire CV process was suspended at or around that
13 time.

14 Q. And it was terminated when?

15 A. The decision for termination, which is
16 based on the memorandum that came from Steve Nelson
17 to Scott Theisen, I think that was dated on
18 June 11th, and he references in there the decision
19 for termination of the program was made on
20 May 27th.

21 Q. And so is that your testimony as the
22 designee for UnitedHealthcare and Optum, that the
23 suspension of CV went into place on April 18, 2014,
24 and the termination of CV went into place on
25 May 27, 2014?

1 A. Yeah, my testimony is on or around
2 April 18th is when I saw notification of delete
3 processing, and I believe the program was also
4 suspended on or around that date.

5 And yeah, based upon the -- we have the
6 exhibit in here which is Steve Nelson's email or
7 memorandum to Scott Theisen. He indicates in there
8 that the decision was made to terminate on
9 May 27th, and then that memorandum was dated with
10 notification to Scott and others that was on
11 June 11th.

12 Q. And the dates that you were just
13 speaking of are in regards to the CV program that
14 Optum performed for UnitedHealthcare; right?

15 A. That's correct.

16 Q. Optum also performed CV for other MAO
17 clients; right?

18 A. That is correct.

19 Q. During what time period?

20 A. I don't actually -- within the materials
21 that I kind of reviewed, I didn't look at the
22 specific timelines related to commercial customers
23 or non-UHC customers. There were claims
24 verification processes in place for some MAO
25 clients as well as some HHS, you know, ACA risk

1 adjustment services also. Unfortunately, I don't
2 think I have materials that set out the time frame
3 of which those services were provided to
4 commercial.

5 Q. Okay. And to be clear, today I'm not
6 asking you anything about ACA -- you're referring
7 to the Affordable Care Act -- plans or services
8 that were performed for any of those plans. I'm
9 only talking about Medicare Advantage. Okay?

10 A. Okay.

11 Q. So with that in mind, can you tell me
12 during what time period Optum performed claims
13 verification for MA organization clients other than
14 UnitedHealthcare?

15 MR. QURESHI: Objection to form. And
16 it's also outside the scope of the designated
17 topics for this particular witness.

18 THE WITNESS: I don't have exact dates.
19 And I did, through the process of my review, I did
20 look at some internal presentations to external
21 customers, I think one of which was Aetna at the
22 time. I just can't say with any certainty at what
23 point, if any, the services were actually delivered
24 to that customer.

25 I've also seen reference in my research

1 on Health Net of California as one of the clients
2 that at least the service was discussed with.

3 But unfortunately, I can't determine for
4 what time frame and what dates of service the
5 service would have been provided to those external
6 clients.

7 BY MR. MASON:

8 Q. Do you know whether Optum ever actually
9 performed CV for any commercial -- when I say
10 commercial clients, I mean MA organizations other
11 than UnitedHealth?

12 MR. QURESHI: Same objection. This is
13 outside the scope of the topics on which this
14 witness has been designated.

15 THE WITNESS: I believe we did.

16 BY MR. MASON:

17 Q. And what can you tell me about when that
18 occurred?

19 MR. QURESHI: Objection; asked and
20 answered. And this is outside the scope.

21 THE WITNESS: Yeah, I don't --
22 unfortunately, I don't know the dates.

23 BY MR. MASON:

24 Q. Okay. Did Optum stop offering claims
25 verification as a service at some point?

1 MR. QURESHI: Objection to form. To
2 United or to other commercial clients?

3 BY MR. MASON:

4 Q. Do you understand my question?

5 A. I understand your question. You know,
6 it's not part of the review I did and I wasn't
7 personally involved in selling services to external
8 customers. So yeah, I know it was an offering for
9 a period of time. Yeah, I believe at least one
10 commercial client took those services. I don't
11 know how those services evolved when I was not part
12 of that organization.

13 Q. So you don't know the answer to my
14 question?

15 A. I don't know --

16 MR. QURESHI: Objection to form.

17 THE WITNESS: I don't know the answer.

18 MR. QURESHI: Objection to form. Your
19 question, if you were asking about commercial
20 clients, is outside the scope.

21 BY MR. MASON:

22 Q. You don't know the answer to my
23 question?

24 A. I don't know the service offering to
25 commercial clients at this time.

1 Q. What's the purpose of the claims
2 verification program?

3 A. The purpose is to identify exclusive
4 HCCs and review those that were submitted by
5 providers that were part of the chart review
6 program.

7 Q. What do you mean, and review them?

8 A. They would be subject to medical coder
9 review. So the CVA people that we spoke about
10 earlier, CV analysts.

11 Q. And when you say the purpose was to
12 identify exclusive -- did you say exclusive HCCs or
13 exclusive codes?

14 A. Exclusive HCCs.

15 Q. And what do you mean by that?

16 A. It would be an HCC or diagnoses that
17 mapped to an HCC and that HCC is submitted by one
18 and only one provider.

19 Q. So why?

20 MR. QURESHI: Objection to form.

21 BY MR. MASON:

22 Q. I was asking the purpose; right? And
23 you're telling me what CV did. CV looked at
24 exclusive codes and then had a CV analyst review
25 the chart associated with it to determine if it was

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that JON H. BIRD, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was not requested.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 26th day of June, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT D-92

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
-----	)	

Videotaped Deposition of
JON HARVEY BIRD
Given Remotely
Wednesday, August 10, 2022

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 piece in here which -- I probably wouldn't use
2 exactly the same words today -- is for accounts
3 to be acceptable for risk adjustment, the
4 documentation needs to meet certain standards.

5 The -- I think, for risk adjustment
6 purposes, you know, with information encounters
7 received directly from providers, they need to
8 meet submission criteria, which is a
9 face-to-face encounter with an acceptable
10 provider, and we develop filter logic in our
11 submission platforms to ensure that.

12 I think in the context of the claims
13 verification program, we are looking for the
14 appropriate support in the -- in the medical
15 record. And to the extent that it was not
16 found, and we concluded that the condition was
17 not supported in the medical record, we did
18 process deletes.

19 BY MR. MASON:

20 Q. So you agree that -- that the claims
21 verification program, when you say "validated," it
22 was looking to see whether the conditions were
23 appropriately documented in the medical record.
24 Correct?

25 MR. QURESHI: Objection. Asked and

1 answered.

2 THE WITNESS: The way the claims
3 verification program was designed was to look
4 for the appropriate documentation in the medical
5 record, and feel certain we would be able to
6 conclude that that document -- documentation
7 does not exist. And to the extent that it
8 didn't, then deletes were processed.

9 BY MR. MASON:

10 Q. Okay. In other words -- well, I won't say
11 another word. Strike that.

12 So if Optum determined that it had
13 submitted diagnosis codes that were not appropriately
14 documented in the medical record, it -- it deleted
15 them from CMS's risk adjustment system; is that what
16 you're saying?

17 MR. QURESHI: Objection to form.
18 Mischaracterizes testimony.

19 THE WITNESS: I say a year through to
20 process, if Optum was able to conclude that the
21 record is not -- that diagnosis is not supported
22 in the available -- in all the medical records.

23 You know, so there's -- yeah, there's
24 complexity, right, in terms of whether you got
25 the right medical record, whether you got the

1 entire medical record, you know, and
2 obviously -- you know, to process a delete,
3 we're overturning what a provider has actually
4 submitted for their patient.

5 So that's why I use the word "conclude."
6 You know, there's a -- a level of diligence
7 required to draw that conclusion. But when that
8 conclusion is drawn, then the delete is
9 processed.

10 BY MR. MASON:

11 Q. Okay. And throughout the deposition, I
12 might refer to that type of delete as a "CV delete,"
13 or a "claims verification delete." Do you understand
14 that terminology?

15 A. I do.

16 Q. And you've described the claims
17 verification process. Do you have any understanding
18 of -- of why Optum submitted claims verification
19 deletes?

20 A. It was not part of the decision to
21 implement the program or to design the initial
22 program.

23 And I apologize, but could you repeat the
24 second -- so any understanding of --

25 Q. Yes. Sorry.

1 A. I -- I don't -- yeah, was it why we
2 implemented the program, or why we processed the
3 deletes?

4 Q. Let's start with -- do you have any
5 understanding of why Optum implemented the claims
6 verification program?

7 A. Yeah. Yeah. Like I previously testified,
8 I was not involved in the decision to implement the
9 program. But, you know, my understanding is we were
10 operating, you know, in an environment of -- a
11 regulatory environment that was unclear and
12 ambiguous. And you know, to err on the side of
13 caution, United decided to implement the CV program.

14 I think, as far as processing deletes
15 related to the CV program, it was our policy to do
16 so. So, you know, our policy is when we concluded
17 that a code was not supported in the medical record,
18 we would delete. And we did in this program along
19 with other programs as well.

20 Q. And do you have any understanding of why
21 that was the policy?

22 A. Yeah. I'm no lawyer, and I don't read the
23 regulations or determine obligations, but I do
24 understand the policy that we had in place at that
25 time.

1 Q. So is the answer you don't -- you don't
2 have an understanding of why it was the policy?

3 MR. QURESHI: Objection. Asked and
4 answered.

5 THE WITNESS: I don't.

6 BY MR. MASON:

7 Q. And when you said that your understanding
8 for why the claims verification program was
9 implemented was related to your understanding that
10 you were operating in a regulatory program that was
11 unclear and ambiguous -- did I hear that right?

12 MR. QURESHI: Objection to form.

13 BY MR. MASON:

14 Q. Sorry. I didn't hear your answer.

15 A. You did hear that correctly.

16 Q. And what was the basis for that
17 understanding?

18 A. It was kind of general vibe within the
19 organization, discussions with people that -- that
20 may have been associated with compliance, or people
21 discussing, yeah, requirements for the organization.

22 Q. Did you say it was the "general vibe"?
23 Did I hear that right?

24 A. Correct.

25 Q. So you can't remember specifically anybody

1 telling you that, but it was something that you just
2 generally understood?

3 A. I'd say something I generally understood.

4 Q. And -- okay. And can you explain how
5 CV deletes reduced the amount of revenue that
6 MA plans received from CMS?

7 MR. QURESHI: Objection to form.

8 THE WITNESS: So CV deletes don't always
9 impact the revenue that the health plan will
10 receive. CV deletes are taken into
11 consideration with all other submission data by
12 CMS in order to calculate a risk score. And the
13 risk score is the basis for the payment to the
14 health plan.

15 So some CV deletes will have no impact.
16 They could be nonrisk-adjusting diagnoses. They
17 could be multiple diagnosis of whatever the HCC
18 is seeing. There could be other HCCs in the
19 hierarchy that trump the deleted code.

20 So really, it just depends on -- on the
21 data, and how the data impacts the model.

22 BY MR. MASON:

23 Q. So it's not as simple as saying if
24 there's, you know, X number of deletes, and each
25 delete costs Y dollars, so then the total reduction

1 in revenue is X times Y dollars; it's not that
2 simple?

3 MR. QURESHI: Objection to form.

4 THE WITNESS: It's not that simple to do
5 a -- an accurate calculation of the impact of
6 the program. There could be models created that
7 might estimate potential impacts used in a more
8 simplistic approach.

9 BY MR. MASON:

10 Q. At OptumInsight, you and your team had a
11 way of -- of doing that type of modeling, right?

12 MR. QURESHI: Objection to form.

13 THE WITNESS: My team developed models
14 that we designed to try and estimate impacts for
15 the purpose of informing accrual estimates with
16 M&R.

17 BY MR. MASON:

18 Q. Did anyone at -- did anyone at M&R ever
19 express concern about the revenue that M&R was losing
20 due to the claims verification deletes?

21 MR. QURESHI: Objection to form.

22 THE WITNESS: I don't recall.

23 BY MR. MASON:

24 Q. You don't recall anyone at M&R ever
25 expressing concern about the revenue that it was

1 In the meantime, I'd ask that no one look
2 at this document, and for us to take it off the
3 screen.

4 But with that, yes, may we go off the
5 record?

6 MR. MASON: We'll go off the record.

7 VIDEOGRAPHER: We are off the record at
8 1:50 p.m.

9 (A recess transpired from 1:50 p.m. until
10 1:55 p.m.)

11 VIDEOGRAPHER: We're back on the record
12 at 1:55 p.m.

13 MR. QURESHI: After conferring, Mr. Mason,
14 the Defendants are clawing back the document
15 that had been designated Exhibit 404, on the
16 basis of it's privileged; and as I remarked
17 before the break, we believe that the United
18 States should have alerted to its existence as a
19 potential clawback.

20 MR. MASON: And -- and as I said during
21 the break, we disagree with United's position,
22 and -- and we'll reserve rights to handle this
23 after the deposition. And if -- if we need to
24 leave it open after this deposition, then we
25 will.

1 MR. QURESHI: Okay. Well, I understand.

2 MR. MASON: Okay.

3 BY MR. MASON:

4 Q. Mr. Bird, we've testified a little bit
5 about the CV program -- or, sorry, "we've testified";
6 sorry about that.

7 You've testified a little bit about the CV
8 program, and we've talked about the CV financial
9 projections that you did. I'd like to ask you if you
10 can explain, as best you can, how the CV program
11 worked.

12 A. Any particular aspects of the program?

13 Q. Just -- why don't you start with just a
14 high level of how the CV program worked, from start
15 to finish.

16 A. So my -- you know, my understanding -- I
17 didn't, you know, design the program; I was involved
18 in certain operational analytic components, so I can
19 provide, you know, my understanding.

20 There -- it's -- for the providers that
21 were engaged in the chart review program, we -- the
22 organization sought to identify claims that were --
23 and encounters that were submitted by those same
24 providers.

25 There was a very complex process to try

1 and link provider information from a -- chart review
2 data and from the provider data, the existed -- the
3 claim data that existed -- that existed within the
4 various claim systems.

5 When that process was -- you know, when
6 the -- the match was attempted, there would be a
7 comparison of what was in a claim to what was in the
8 initial chart review information. Anything that met
9 a certain criteria around not matching would go
10 through a process of review with medical coders, and
11 an expert level of review also.

12 And then, after the expert-level review
13 was complete, any codes where the organization
14 concluded that support was not in the medical record,
15 a delete would be processed.

16 Q. When you said "anything that met a
17 criteria of not matching," you're referring to
18 diagnosis codes there; is that right?

19 A. The -- I don't recall actually whether the
20 matching process was at the diagnosis or the HCC
21 level.

22 Q. Okay. You don't recall if it was at
23 the -- the dx level or the HCC level, but in -- but
24 in either case, it was matching the conditions shown
25 on both sides. Is that right?

1 A. Correct.

2 Q. Okay. Can I show you the next exhibit.

3 MR. MASON: This is Tab N, Jesse. And so
4 I suppose this will be -- I don't know if this
5 is going to come up -- okay. Exhibit 405. So
6 we have a -- we have a blank there, due to the
7 clawback document from before.

8 BY MR. MASON:

9 Q. So Exhibit 405 should now be in front of
10 you. Let me know when you see that.

11 (Exhibit 405 was marked for identification.)

12 MR. MASON: And -- and Tab N1 can go up,
13 too, which will be Exhibit 405-1.

14 (Exhibit 405-1 was marked for identification.)

15 BY MR. MASON:

16 Q. And do you see Exhibit 405, Mr. Bird?

17 A. I do.

18 Q. And this is an e-mail from Chris Webb to
19 yourself, dated February 20th, 2014, with the subject
20 "Claims Verification Overview for MBM." Right?

21 A. Yeah.

22 Q. And Mr. Webb was one of your team members
23 at OptumInsight who reported to you at the time?

24 A. He was, yes.

25 Q. And "MBM" there, do you understand that to

1 Q. And if we look at the attachment, and in
2 407 -- sorry, 407-1 is the attachment. And do you
3 see there were some changes to the "Overview"
4 section, at the top?

5 MR. QURESHI: Objection to form.

6 THE WITNESS: I'd need to read and
7 compare.

8 BY MR. MASON:

9 Q. Yeah, can you compare this with
10 Exhibit 405-1, and see if there are any differences
11 in the "Overview" section?

12 You don't need to look at the whole
13 document; I'm just asking about the "Overview"
14 section.

15 A. I didn't review it word for word, but I
16 can see where there's differences.

17 Q. And one of the differences is that in
18 407-1, the section ends by saying, "Claims associated
19 with exclusive HCCs not supported in the
20 corresponding medical record are deleted." Right?

21 That was an addition that was made after
22 your feedback; is that correct?

23 MR. QURESHI: Objection to form.

24 THE WITNESS: So, I mean, the original
25 document said, "This service will also include a

1 submission of deletes to CMS, where
2 appropriate."

3 BY MR. MASON:

4 Q. Right. The original document said it will
5 include submission of deletes wherever appropriate;
6 but the final document, that was sent to Marybeth
7 Meyer, after your feedback, says, "Claims associated
8 with exclusive HCCs not supported in the
9 corresponding medical record are deleted."

10 Is that correct?

11 MR. QURESHI: Objection to form. Document
12 speaks for itself.

13 THE WITNESS: Yeah, that's what the
14 document says.

15 You know, what I can't determine from the
16 previous exhibit, if I was the only person to
17 provide feedback. You know, or how that
18 feedback was delivered, whether it was me or
19 inclusion of other people.

20 I can see the -- the language has changed
21 in the second version.

22 BY MR. MASON:

23 Q. And -- and the language being changed, you
24 agree that that sentence is -- is different?

25 MR. QURESHI: Objection to form. The

1 document speaks for itself.

2 MR. MASON: Withdrawn.

3 BY MR. MASON:

4 Q. Another thing, you'll notice that in
5 Exhibit 405-1, you drew attention to the language
6 that gave you some pause, I think you said, which was
7 where it says, "in accordance with CMS guidelines."

8 Do you see that that language is still
9 in 407-1?

10 A. I see that.

11 MR. QURESHI: Objection to form.

12 Mischaracterizes testimony.

13 THE WITNESS: I see that.

14 BY MR. MASON:

15 Q. Do you see --

16 And is it fair to conclude, then, that in
17 2014, when you reviewed this document, you didn't
18 have any concerns with the language "in accordance
19 with CMS guidelines"?

20 MR. QURESHI: Objection to form.

21 THE WITNESS: I don't know what I can
22 conclude from -- from that. You know, reading
23 it today, I think there's lack of clarity around
24 what "CMS guidelines" would mean, whether that's
25 coding or something other. So I don't know

1 whether I had those same -- exact same concerns
2 back in 2014, or whether I would have voiced
3 them.

4 But I can see that the document didn't
5 change.

6 MR. MASON: We -- you know, we've been
7 going for a little over an hour. Why don't we
8 go off the record for a break?

9 MR. QURESHI: Okay. Thank you.

10 VIDEOGRAPHER: We are off the record at
11 2:25 p.m.

12 (A recess transpired from 2:25 p.m. until
13 2:37 p.m.)

14 VIDEOGRAPHER: We are back on the record
15 at 2:37 p.m.

16 BY MR. MASON:

17 Q. Mr. Bird, you're familiar with a group at
18 UHG referred to as the UHG Risk Adjustment Advisory
19 Board?

20 A. I am.

21 Q. What is it?

22 A. In my understanding, recollection of that
23 group was it was a kind of legal-led organized group
24 of people that were involved in risk, and it also
25 included individuals that were involved in risk

1 MR. MASON: We need to go off the record
2 so that the witness can discuss an issue of
3 privilege with counsel.

4 VIDEOGRAPHER: We are off the record at
5 2:42 p.m.

6 (A recess transpired from 2:42 p.m. until
7 2:44 p.m.)

8 VIDEOGRAPHER: We are back on the record
9 at 2:44 p.m.

10 BY MR. MASON:

11 Q. Mr. Bird, do you remember my pending
12 question?

13 A. Could you repeat it for me, please?

14 Q. Sure. And I wasn't asking about any
15 specific request, but just trying to understand the
16 general nature of your role on the board.

17 And is it accurate to say that the board
18 would ask you specific requests for information; you
19 would use your data and analytics at OptumInsight to
20 provide information to inform the board in response
21 to those requests?

22 A. So from my recollection, there was no role
23 and responsibility specifically assigned to people
24 within the -- within the group. It's my
25 understanding I was invited to attend the meetings

1 based upon my knowledge of risk adjustment, and --
2 yeah, the programs that we ran, and analytics.

3 I -- you know, I believe the request would
4 have come -- come to me, but I don't recall any
5 specific request that came to me during that period,
6 or whether indeed any request came to me during that
7 period.

8 Q. Will you agree that your role on the board
9 was to use data and analytics to respond to specific
10 requests for information from the board? Right?

11 MR. QURESHI: Objection. Asked and
12 answered.

13 THE WITNESS: I don't -- we didn't have --
14 I didn't have a role description provided. My
15 understanding is, you know, the knowledge and
16 skills I brought to the -- the team was around
17 analytics and program knowledge.

18 BY MR. MASON:

19 Q. Analytics and program knowledge regarding
20 risk adjustment?

21 A. That's correct.

22 Q. And whether you had a specific defined
23 role or not, the way that you understood your role
24 was it to use those data and analytics related to
25 risk adjustment to respond to specific requests from

1 the board?

2 MR. QURESHI: Objection to form. Asked
3 and answered.

4 THE WITNESS: That -- that sounds very
5 specific, and I -- I don't recall that they had
6 any specific description of role.

7 BY MR. MASON:

8 Q. Okay. Can we go back to Exhibit 399,
9 which you'll recall was your CID transcript? And I'd
10 like you to go to page 52. And you recall you can do
11 that just by punching in the number "52" in that
12 little box?

13 And I'd like you to go to line 22.

14 Oh, I might be on the wrong -- sorry, it
15 should be on page -- oh, you know, it's confusing,
16 because -- it's page 52 of the transcript, but you
17 actually have to type in -- you have to type in the
18 number "53." There's an extra page in the PDF.

19 So if you type in 53, you'll see it says
20 "page 52" at the very top. Do you see that?

21 A. Yeah.

22 Q. Yeah. And then if you scroll down to
23 line 22.

24 And it says: "Did you have any particular
25 responsibilities on the board?"

1 MR. QURESHI: I'm sorry. United's counsel
2 has some redirect, please.

3 VIDEOGRAPHER: Apologies.

4 EXAMINATION

5 BY MR. QURESHI:

6 Q. Good afternoon, Mr. Bird.

7 A. Good afternoon.

8 Q. Earlier today you discussed your
9 background briefly. Please remind us how long you've
10 worked for the UnitedHealth Group group of companies.

11 A. So I -- I commenced an appointment with
12 Ingenix in October of 2008, so approximately
13 14 years.

14 Q. And in the time period that has been under
15 focus of the government's questions, 2010 to
16 approximately 2015, what role did you hold?

17 A. So, you know, my role changed over time.
18 Initially it was a -- a financial role, including
19 kind of some pricing exercises. And, you know, over
20 time, I took on additional responsibility for kind of
21 program analytics and some kind of operational
22 responsibility also.

23 Q. And in these various responsibilities that
24 you have described, how have you approached these
25 responsibilities throughout your tenure?

1 A. You know, with -- really doing the best
2 job I can, you know, with integrity. My background,
3 chartered accountant; we have strong, you know,
4 professional ethics, and I abide by them, and I
5 definitely take them seriously and -- into the --
6 into work I do.

7 Q. Throughout the day you testified about a
8 few different risk adjustment programs. I'd like to
9 understand what role you played in each of those
10 programs.

11 I'll start with chart review: What is
12 chart review?

13 A. So chart review is a -- a program that
14 involves the retrieval of medical records, the
15 extraction of codes from those medical records, and
16 submission of those codes to CMS.

17 Q. In your role at Ingenix, and later Optum,
18 what was your understanding of the purpose of chart
19 review?

20 A. So my -- my understanding of the -- the
21 purpose of chart review was to enable us to report
22 the complete health status of the member.

23 Q. And in order to report the complete health
24 status of the member, what process was used by
25 individuals involved in chart review?

1 A. Typically we would target certain medical
2 records for retrieval. You know, once those medical
3 records are retrieved, they would be reviewed by
4 certified coders. There would be QA processes in
5 place to ensure the -- the codes are appropriately
6 supported in the medical record. And then those
7 codes would be submitted.

8 Q. You talked about certified coders who
9 abstracted medical records. What was the entire
10 universe of information provided to the certified
11 coders who abstract the medical records?

12 A. Yeah, those reviews would have been --
13 yeah, so the information that would have been
14 provided to the -- the coders at the time would be an
15 image of the -- the medical record, so it is what we
16 would refer to as a blind interview, you know, where
17 we're not getting any additional information related
18 to codes that were previously submitted; just a blind
19 abstraction, looking at the documentation provided in
20 the record, and assigning the appropriate ICD
21 diagnosis codes to that documentation.

22 Q. In this chart review process that you've
23 described, what attempt was made to compare diagnoses
24 codes abstracted by certified coders with diagnoses
25 codes that might have been identified by a coder

1 working for a hospital or a provider?

2 A. That -- that comparison would not have
3 been completed at, you know, through the chart review
4 program, but, you know, as we, you know, as I
5 testified earlier, there was a claims verification
6 process, you know, where there was an attempt to
7 match the diagnosis submitted by providers; they're
8 also part of the chart review program.

9 You know, I call it an attempt because it
10 a very complex process; it has, you know, several
11 challenges, you know, in particular related to the
12 quality of data around the provider IDs across
13 various systems. And also, you know, the
14 completeness of the medical records that would have
15 been reviewed as part of the chart review process.

16 Q. You talked a little bit about the
17 complexity of the process. What additional
18 information would be required in order to undertake a
19 comparison between diagnoses codes identified by
20 United's certified coders with codes that might have
21 been identified by coders working for a hospital or a
22 provider?

23 MR. MASON: Objection to form.

24 Foundation.

25 THE WITNESS: So, you know, the first

1 thing is understanding that you have a match
2 between the -- you know, the same provider in
3 the claims system is the same provider in the
4 medical record review system.

5 And that's always a challenge within the
6 industry around the quality of provider data, in
7 particular with, you know, providers; they may
8 be assigned an ID. They could have multiple
9 IDs, based on where they may -- which locations
10 they practice in, or which IPA they're part of,
11 or which provider group they may be part of.
12 Those IDs would typically change over time.
13 They may not be unique.

14 And then the same applies in the health
15 plan side. You know, typically health plans
16 grow through acquisition. There's multiple
17 claims platforms. The same providers may
18 have -- they may need to present in multiple
19 systems, you know, with different IDs.

20 So that's the -- that's the big -- you
21 know, one of the big challenges, you know,
22 related to matching, you know, the data.

23 BY MR. QURESHI:

24 Q. Mr. Bird, what conclusions, if any, would
25 you draw from a circumstance in which a certified

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

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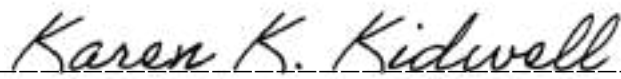

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-93

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CASE NO. CV 16-08697 FMO

UNITED STATES OF AMERICA ex rel.,
BENJAMIN POEHLING,
Plaintiffs,

vs.

UNITED HEALTH GROUP, INC., et al.,
Defendants.

-----/

DEPOSITION OF BARBARA BLAIR
WEDNESDAY, APRIL 3, 2024
9:48 a.m. - 7:37 p.m.

TWO SOUTH BISCAYNE BOULEVARD, SUITE 1850
MIAMI, FLORIDA

- - -

Reported By:
Katiana Louis
Notary Public, State of Florida
Miami Office #1100998
Magna Legal Services
866-624-6221
www.MagnaLS.com

1 others at FTI in publications related to any of
2 these topics?

3 A. I may have. I may have been asked about
4 a specific subject, but I can't specifically
5 point to any publisher.

6 Q. And you also did not list any
7 presentations from the past 10 years relevant to
8 the issues in your expert report; is that
9 correct?

10 A. That is correct.

11 Q. So, in the past 10 years, you have not
12 made or drafted any presentations related to
13 diagnosis coding; is that correct?

14 A. I performed internal presentations to
15 clients pretty regularly, but they are all under
16 privilege.

17 Q. But no external presentations?

18 A. No external.

19 MS. LIKOFF: Okay. I think we can
20 go ahead and take a break.

21 (A brief break was had.)

22 BY MS. LIKOFF:

23 Q. Ms. Blair, in connection with the
24 opinions you're offering in this case, you have
25 not reviewed any medical records; is that

1 correct?

2 A. That is correct.

3 Q. So, I'd like to now turn back to
4 Exhibit 812, which is a copy of your expert
5 report. We can keep this out because we'll spend
6 time going through it now.

7 You offer two main opinions in your
8 report; is that correct?

9 A. That is correct.

10 Q. And we'll discuss them in detail, but I
11 just want to start off with making sure I
12 understand at a high level the two opinions that
13 you are offering. You first opine that the
14 identification of diagnosis codes supported by
15 documentation in a medical record is a complex
16 process, informed by a variety of coding guidance
17 dependent on the coder's training, experience,
18 and judgment; is that correct?

19 A. That is correct.

20 Q. And what is the basis for this opinion?

21 A. My 25-plus years of working in the
22 diagnosis and coding space, as well as my
23 education and experience that I've had in the
24 industry.

25 Q. Is there anything else that you're

1 relying on as the basis for this opinion?

2 A. The resources as I've quoted them.

3 Q. We'll discuss some of those as we go
4 throughout the day.

5 And then you offer a second opinion;
6 correct?

7 A. I do.

8 Q. And I think that appears on -- that
9 appears on page 27 of your report; correct?

10 A. Correct.

11 Q. And what's the basis for this second
12 opinion that you offer?

13 A. This is based on my 25 years of
14 experience in looking at many, many medical
15 records.

16 Q. Is it based on anything else?

17 A. No, it is not.

18 Q. And I think we may have covered this,
19 but I just want to make sure the record is clear,
20 what information were you given in order to form
21 your opinions in this case?

22 A. These are my opinions.

23 Q. Were you given any information or
24 resources on which to base your opinions?

25 A. No. The resources are mine and this is

1 education, but I don't believe I talk about
2 undercoding or overcoding. I talk about
3 potentially missed because of their background
4 or, you know, that -- that's the reason for the
5 additional reviews. But undercoding, overcoding,
6 that is all just part of my discussion on the
7 complexity of coding.

8 Q. Well, I recognize that, I don't believe,
9 you used the words "undercoding" or "overcoding"
10 in your report, but as we just talked about, I
11 believe there are a number of examples, but I'll
12 point to the one again in paragraph 24 you do
13 ultimately describe a scenario in which
14 undercoding might take place due to coder
15 experience and training?

16 A. They may be less effective, yes, in
17 identifying all the diagnosis codes.

18 Q. So, I'm just trying to understand
19 whether you believe that those same concerns with
20 respect to coder experience, coder training could
21 lead to overcoding or miscoding?

22 A. Again, in my report, I do speak to that.
23 I speak to human error. I speak to miscoding. I
24 speak to that.

25 Q. Do you agree that coder certification,

1 ongoing coder training and quality control
2 results in coding that is more accurate?

3 A. I can opine to training, certifications
4 that may -- as you can see, that may assist a
5 coder in being more proficient in their job. As
6 to accurate, I can't truly assign what accuracy
7 is, but I can say that training and certification
8 does assist the coder as a rule into better being
9 able to identify diagnoses in the record.

10 Q. I'd like to move on to the next sort of
11 six points that you make which relate to the
12 availability, legibility, and variability of
13 provider documentation. In paragraph 26 you
14 state, "In addition to varied coder backgrounds,
15 the provider documentation available to coders
16 during chart review varies greatly."

17 Is that your opinion?

18 A. It is.

19 Q. And what is the basis for your opinion
20 that provider documentation during chart review
21 varies greatly?

22 A. In any type of chart review, I will say
23 that in my experience, that's been one of the
24 more challenging aspects of chart review is
25 getting a complete record and all the record that

1 you request.

2 Q. Are you basing your opinion on anything
3 other than your experience?

4 A. No, that is my experience.

5 Q. Can you point to any studies or
6 published articles that support your opinion that
7 provider documentation available to coders during
8 chart review varies greatly?

9 A. No, I cannot.

10 Q. So, I'd like to specifically focus for a
11 couple of minutes on paragraph 29 in which I
12 believe you discuss the legibility and clarity of
13 available documentation. And you opine that this
14 can also "affect a coder's ability to identify
15 diagnosis codes." Is that correct? Is that your
16 opinion?

17 A. Yes, that is my opinion.

18 Q. And what is the basis for your opinion
19 that "the legibility and clarity of documentation
20 can affect a coder's ability to identify
21 diagnosis codes"?

22 A. As you can see, a coder who can't read a
23 provider's handwriting may not identify the
24 diagnosis code during a chart review. But
25 another coder who is in the provider's office is

1 familiar with that documentation and knows that
2 that says "diabetes" and they assign the diabetes
3 code.

4 Q. Do you believe that there is any
5 requirement for documentation to be legible to
6 the extent that it is readable to any coder
7 looking at the documentation?

8 A. I believe, based on the role of a coder,
9 is if you know what that documentation is, you
10 assign the code appropriately. If someone else
11 is unable to read that record, that coder that
12 assigned that code who can, assigned it
13 appropriately.

14 MS. LIKOFF: All right. I'd like
15 to take a look at another exhibit. And
16 I think this will be Exhibit 815.

17 And Lauren, this is Tab 11. And
18 I'll note that there is some yellow
19 highlighting -- it's not even
20 highlighting. It's yellowness that
21 appears on the document. And just on
22 the courtesy copy that we're going to
23 provide on hard copy, but this is not
24 highlighting that we made and it does
25 not have any significance and I don't

1 believe it appears on the official
2 exhibit on AgileLaw.

3 MS. SOBEL: So just to confirm, the
4 exhibit in AgileLaw is the same as the
5 exhibit that we're seeing here?

6 MS. LIKOFF: It is.

7 MS. SOBEL: Just without the yellow
8 highlights?

9 MS. LIKOFF: It is, yes. And I
10 believe it's now up in AgileLaw as 815,
11 if you want to take a look at it.

12 (Defendant's Exhibit No. 815 was
13 marked for identification.)

14 BY MS. LIKOFF:

15 Q. So, I'm handing you, Ms. Blair, an
16 article from AAPC entitled, "Medical Record
17 Entries: What Is Timely and Reasonable?" And I
18 believe this was cited in footnote 16 of your
19 report.

20 MS. SOBEL: Take your time to
21 review it.

22 BY MS. LIKOFF:

23 Q. My first question will just be: Whether
24 this article is familiar to you?

25 MS. SOBEL: You said it was

1 REPORTER'S DEPOSITION CERTIFICATE
2 STATE OF FLORIDA
COUNTY OF MIAMI-DADE

3
4 I, Katiana Louis, do hereby certify that
5 I was authorized to and did stenographically
6 report the foregoing deposition; and that the
7 transcript is a true and correct transcription of
8 the testimony given by the witness; and that the
9 reading and signing of the deposition were not
10 waived.

11
12 I further certify that I am not a
13 relative, employee, attorney or counsel of any of
14 the parties, nor am I a relative or employee of
15 any of the parties' attorney or counsel connected
16 with the action, nor am I financially interested
17 in the action.

18
19 Dated this 8th day of April 2024.

20
21 

22 Katiana Louis

23
24
25

EXHIBIT D-94

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
MARY BONNER
Given Remotely
Friday, May 13, 2022

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. Is this often referred to as "MA"?

2 A. Yes.

3 Q. What is Medicare Advantage?

4 A. It's Part C of the Medicare program.

5 Q. And how did you learn about Medicare
6 Advantage?

7 A. I learned about it just before I worked at
8 CMS, just through general awareness of Medicare
9 programs. And then I've learned about it directly
10 through my work on the RADV project.

11 Q. And while at CMS, did you receive any
12 specific training related to Medicare Advantage and
13 how it worked?

14 A. No. Not formal training, no.

15 Q. So you -- more of a learn-on-the-job type
16 thing?

17 A. Yes. About the program, yes.

18 Q. And what is your current job title at CMS?

19 A. I'm a communications specialist.

20 Q. And how long have you had that position?

21 A. Since 2013.

22 Q. Okay. And if you scroll back up to page 1
23 of Exhibit 1196, next to "Work Experience," it lists
24 "Communications Specialist." Is that your current
25 position?

1 A. Yes.

2 Q. And what do you do in this role?

3 A. I do writing and editing related to
4 Medicare, and marketplace messaging, mainly for
5 beneficiaries and consumers, those programs.

6 Q. And is it related to Medicare Advantage?

7 A. There are references to Medicare Advantage
8 in the work that I do, yes.

9 Q. Is it also related to the Affordable Care
10 Act?

11 A. Yes.

12 Q. Is it related to the RADV project that you
13 mentioned earlier?

14 A. No.

15 Q. Okay. And who do you report to now?

16 A. Valerie Perkins is the director at the
17 Division of Content Development.

18 Q. And just -- did you say "Perkins"?

19 A. Yes. Valerie Perkins.

20 Q. Okay. Great. Thank you. I wanted to
21 make sure I heard correctly.

22 Did anything that you -- does anything in
23 your current role relate to audits of Medicare
24 Advantage plans?

25 A. No.

1 Calls for speculation.

2 THE WITNESS: Could I ask you to repeat
3 the question again?

4 BY MS. MADDUX:

5 Q. Would the senior coder review 100 percent
6 of the additional HCCs because the primary coder may
7 have erroneously identified it during their review?

8 MS. OBEREMBT: Objection. Foundation.
9 Calls for speculation.

10 THE WITNESS: No, I think that it would be
11 for -- they would be reviewing for an IC- -- you
12 know, a missing ICD-9 code -- an ICD-9 code that
13 wasn't identified.

14 BY MS. MADDUX:

15 Q. So the senior -- yeah, go ahead.

16 A. No, no, go ahead.

17 Q. The senior coder was conducting a review
18 of 100 percent of both the discrepant and additional
19 HCCs to check the primary coder's work?

20 MS. OBEREMBT: Objection. Foundation.
21 Calls for speculation.

22 THE WITNESS: That's not my memory, that
23 they were checking their work. They were --
24 they were checking to see -- they were checking
25 to see if there was an ICD-9 code present that

1 would validate an HCC, requested HCC.

2 BY MS. MADDUX:

3 Q. The senior coder was?

4 A. Yes.

5 Q. So if the primary coder had not identified
6 it, the senior coder was doing a second review to
7 confirm if it was in fact there?

8 A. Correct.

9 MS. OBEREMBT: Objection. Foundation.
10 Calls for speculation.

11 BY MS. MADDUX:

12 Q. Number 5 on page 25 of Exhibit 1197 says,
13 "Initial review of approximately 25 medical records
14 prior to beginning 'live' review of medical records
15 for any coders." Do you see that?

16 A. Yes.

17 Q. A few sentences later, it says, "An IRR
18 report generated by the Tool will indicate
19 proficiency at 95 percent or greater; in the event
20 that the coder achieves less than 95 percent
21 proficiency, that coder shall be restricted from
22 coding of the live medical records until a subsequent
23 review of another 25 medical records results in
24 proficiency of 95 percent or greater."

25 Do you see that?

1 A. I do.

2 Q. Is this the IRR process we discussed
3 earlier?

4 A. Yes.

5 Q. It then says, "The contractor shall
6 continue to monitor IRR of all coders and provide
7 appropriate remediation or dismissal."

8 Do you see that?

9 A. Yes.

10 Q. Did the IRR evaluation take place on a
11 continual basis throughout the medical record review
12 process?

13 MS. OBEREMBT: Objection. Vague.

14 THE WITNESS: I'm taking a minute just to
15 reread this and try to remember if it -- if it
16 did continue.

17 BY MS. MADDUX:

18 Q. Take as much time as you need.

19 A. I -- I clearly remember the initial IRR
20 period. I believe that it continued throughout, you
21 know, a specific coding period, but I can't remember
22 details about that.

23 Q. And what is a 95 percent proficiency?

24 A. My memory is that -- that coders would
25 accurately code the record 95 percent of the time.

1 Q. Do you know why the standard was
2 95 percent?

3 A. No.

4 Q. The IRR activity described here, would
5 that involve comparing the diagnosis codes identified
6 by the primary coder to the diagnosis codes
7 identified by the senior coder?

8 A. I don't remember that.

9 Q. Does it involve a situation where one
10 coder said the -- the other code was not supported by
11 the medical record, but the senior coder said that
12 the code is supported by medical record?

13 MS. OBEREMBT: Objection. Foundation.
14 Calls for speculation.

15 THE WITNESS: That's a reasonable way to
16 describe the -- that check.

17 BY MS. MADDUX:

18 Q. Does the 95 percent threshold acknowledge
19 that coders may not agree about whether a diagnosis
20 code is supported by medical record?

21 MS. OBEREMBT: Objection. Foundation.
22 Calls for speculation.

23 THE WITNESS: I don't know the answer to
24 that.

25

1 BY MS. MADDUX:

2 Q. In your experience as the government task
3 leader or contracting officer's representative, were
4 you aware that coders did not always agree about what
5 other diagnosis code was supported by medical record?

6 A. Yes.

7 Q. Does the 95 percent threshold acknowledge
8 that coders may make mistakes?

9 MS. OBEREMBT: Objection. Foundation.
10 Calls for speculation. Asked and answered, too.

11 THE WITNESS: I don't remember that
12 definition, that the IRR step acknowledges that
13 coders might make mistakes. But it's -- so I
14 kind of don't have more to say there.

15 BY MS. MADDUX:

16 Q. Why not have a 100 percent standard?

17 MS. OBEREMBT: Objection. Foundation.
18 Calls for speculation.

19 THE WITNESS: I don't remember ever
20 talking about -- or talking to my colleagues
21 about the percent -- the acceptable percentage
22 for the standard.

23 BY MS. MADDUX:

24 Q. What are some reasons why a primary
25 coder's IRR may be 95 percent or less?

1 Do you see that?

2 A. Yes.

3 Q. If you skip to the second paragraph, it
4 says, "The contractor's team of certified trained
5 medical record reviewers shall" -- excuse me. Strike
6 that.

7 Do you see -- do you see the paragraph
8 that starts, "The contractor's team of certified
9 trained medical record reviewers"?

10 A. Yes.

11 Q. Midway through this paragraph, it says,
12 "There shall be one lead (senior coder) reviewer for
13 every five primary reviewers, and the lead reviewer
14 shall be qualified to mediate coding decisions as
15 appropriate between senior and primary coders."

16 Do you see this?

17 A. Yes.

18 Q. What does "mediate coding decisions" mean?

19 A. So the record would go to the senior coder
20 if the primary review didn't show the ICD-9 code.
21 And so if the senior coder could find it and the
22 primary coder would disagree, there would be an
23 opportunity to -- to mediate that decision.

24 I think that's one example of the
25 mediation of a coding decision. And that's not

1 something that I would have -- yeah, I -- and -- and
2 that would be work that's happening on their end. So
3 that's my memory of it.

4 Q. So one scenario may be -- one scenario
5 necessitating a mediation of coding decision may be
6 where the two coders, the primary and senior coder,
7 disagreed about whether it was supported by the
8 medical record?

9 A. Yes.

10 Q. In your experience as the contracting
11 officer's representative, or the -- the government
12 task leader provide the audit, did you have an
13 understanding that coding was subjective?

14 MS. OBEREMBT: Objection. Vague.

15 THE WITNESS: I don't know that that's a
16 term I would have heard used to describe coding,
17 but -- yeah, I -- I don't know -- I don't know
18 the answer to that, but it's not -- I don't
19 remember it being a term that would be used.

20 BY MS. MADDUX:

21 Q. In your experience as the contracting
22 officer representative or government task leader
23 provide the audit, do you agree that two coders may
24 have different interpretations of the coding
25 guidance?

1 MS. OBEREMBT: Objection. Calls for
2 speculation.

3 THE WITNESS: I think that's accurate, to
4 say that coders could have different
5 interpretations of the coding guidance.

6 BY MS. MADDUX:

7 Q. In your experience working with trained
8 coders, did you think it was not uncommon for two
9 certified coders to disagree on whether or not a
10 particular diagnosis code was supported by a medical
11 record?

12 MS. OBEREMBT: Objection. Foundation.

13 THE WITNESS: I don't remember that it was
14 common. But again --

15 BY MS. MADDUX:

16 Q. Do you recall --

17 A. Sorry. I was going to say, again, it's
18 been a long time since I've worked on that. But I
19 don't remember that it was common.

20 Q. Do you recall that disagreements among two
21 certified coders occurred?

22 MS. OBEREMBT: Objection. Foundation.

23 THE WITNESS: I don't remember specific
24 instances, but I do know that, yes, there could
25 be disagreements about coding.

1 BY MS. MADDUX:

2 Q. And do you know why two certified coders
3 could reach different results?

4 MS. OBEREMBT: Objection. Foundation.
5 Calls for speculation.

6 THE WITNESS: No. It's something that I
7 would have been more aware of when I was working
8 on this project, and I -- I don't remember that
9 right now.

10 BY MS. MADDUX:

11 Q. In situations where two certified coders
12 disagreed, would the mediation exercise work to
13 resolve those disagreements?

14 MS. OBEREMBT: Objection. Calls for
15 speculation.

16 THE WITNESS: I -- I don't remember the
17 outcome of that kind of mediation.

18 BY MS. MADDUX:

19 Q. In the situation where two certified
20 coders have a difference of opinion, would you agree
21 that neither one is right or wrong?

22 MS. OBEREMBT: Objection. Vague. Calls
23 for speculation. Lack of foundation.

24 THE WITNESS: Sorry, can you repeat the
25 question?

1 BY MS. MADDUX:

2 Q. In a situation where two certified coders
3 have a difference of opinion about whether or not a
4 diagnosis code is supported by the medical record,
5 would you agree that neither one is necessarily right
6 or wrong?

7 MS. OBEREMBT: Repeat the objections.

8 THE WITNESS: I -- I don't think I know
9 enough about coding to answer that question. I
10 think it would depend on the coders and the code
11 in question.

12 BY MS. MADDUX:

13 Q. The last sentence --

14 MS. OBEREMBT: We've been -- excuse me.

15 We've been going another hour, and I think
16 it's time for a break.

17 MS. MADDUX: Yeah, I just have one more
18 question on this document. If we can just
19 finish this page, it should take less than two
20 minutes --

21 MS. OBEREMBT: Sure.

22 MS. MADDUX: -- if that's okay, Laurie.

23 MS. OBEREMBT: Yeah. Sounds good.

24 BY MS. MADDUX:

25 Q. So the last sentence of -- if you turn --

1 A. Yes.

2 Q. Do you know if this document was submitted
3 to you as the contracting officer's representative,
4 or COTR, for HMS's contract for payment year 2009
5 RADV audit?

6 MS. OBEREMBT: Objection. Asked and
7 answered.

8 THE WITNESS: We -- we saw an earlier
9 document that showed Sam Jenkins as the COR for
10 the contract. I -- I don't remember if this
11 predates or -- predates that.

12 BY MS. MADDUX:

13 Q. Under the "Submitted By," it says it was
14 submitted by Jeanne Cress, or Jeanne Cress, at HMS.
15 Do you see that?

16 A. I do, yes.

17 Q. And then this is a monthly progress report
18 for the time period August 1st, 2011, to August 30th,
19 2011, correct?

20 A. Yes.

21 Q. Do you know what the purpose of this
22 document is?

23 A. The progress report for the work that HMS
24 had done in August.

25 Q. Were you responsible for reviewing the

1 monthly progress report?

2 A. Yes. I usually shared them with others on
3 our team as well.

4 Q. I want to direct you to page 4 of
5 Exhibit 1198.

6 A. Mm-hmm.

7 Q. In the last row, it says "3.B.5." Do you
8 see that?

9 A. I do.

10 Q. And that says "Medical record review
11 (second level initial validation review) including
12 weekly IRR testing, coding discussions, and findings
13 reports." Do you see that?

14 A. I do, yes.

15 Q. And then in the next box, if you scroll to
16 page 5, the box continues, and it says, "The final
17 overall HMS IRR is 94.97 percent for the national
18 2009 audit." Do you see that?

19 A. I do.

20 Q. Does this suggest that the IRR was lower
21 than the 95 percent threshold we talked about
22 earlier?

23 A. It's not 95 percent. I don't know -- yes,
24 it's a different number than 95 percent.

25 Q. Does the fact that the agreement rate is

1 lower than 95 percent surprise you?

2 A. Does it surprise me? It's -- it's notable
3 here that it's different. But I -- I don't remember
4 how -- how it was addressed in 2011.

5 MS. MADDUX: And we're going to post a
6 new document to AgileLaw: Tab 37, please. And
7 this document, for the record, is Bates-labeled
8 USBP000045745.

9 And this will be Exhibit 1199.

10 (Exhibit 1199 was marked for identification.)

11 BY MS. MADDUX:

12 Q. Do you see this document up on the screen?

13 A. I do.

14 Q. And this appears to be a June 22nd, 2010,
15 e-mail from you to Lateefah Hughes, copying Jennifer
16 Harlow and Bryant Hall at HMS. Is that correct?

17 A. Yes.

18 Q. And the "Subject" line reads, "Primary
19 coder inability to view coversheet." Do you see
20 that?

21 A. Yes.

22 Q. Do you know what the coversheet is?

23 A. I don't remember now. I -- I would
24 have -- I don't remember now, and in this context.
25 It's something I would have known then.

1 Q. In the second paragraph of your e-mail, it
2 says, "Primary coders have no access to coversheets,
3 which may otherwise help lead them to the HCC being
4 validated." Do you see that?

5 A. Yes.

6 Q. Do you recall if the coversheets included
7 information about what HCC the plan had submitted?

8 A. I don't recall what the coversheet
9 displayed.

10 Q. Do you remember this issue with the
11 primary coders not having access to the coversheets?

12 A. I don't recall it.

13 Q. You then write: "Example: At first
14 glance, a record was illegible to the primary coder,
15 escalation reviewer, and senior coder. However, when
16 the senior coder checked the cover sheet she or he
17 was able to locate the HCC on the record." Do you
18 see that?

19 A. I do.

20 Q. Do you recall what you mean by this?

21 A. I don't recall this specific episode.
22 I -- I think the sentence seems self-explanatory.

23 Q. So does this mean that the primary coder,
24 doing their blind review of the record, was unable to
25 find the diagnosis code in the medical record?

1 CERTIFICATE OF REPORTER

2 I, Karen K. Kidwell, Registered Merit Reporter
3 and Notary Public for the State of Maryland at Large,
4 do hereby certify:

5 That the foregoing deposition was taken
6 remotely before me on the date and at the time stated
7 on page 1 of this transcript; that the deponent was
8 duly sworn to testify to the truth, the whole truth
9 and nothing but the truth; that the testimony of the
10 deponent and all objections made at the time of the
11 examination were recorded stenographically by me and
12 were thereafter transcribed; that the foregoing
13 deposition as typed is a true, accurate and complete
14 record of the testimony of the deponent and of all
15 objections made at the time of the examination to the
16 best of my ability.

17 I further certify that I am neither related to
18 nor counsel for any party to the cause pending or
19 interested in the events thereof.

20 Witness my hand this 17th day of May, 2022.

21

22

23

24

25


Karen K. Kidwell,
Registered Merit Reporter
Notary Public
State of Maryland at Large
My Commission expires:
April 14, 2025

EXHIBIT D-95

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.,)
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
vs.) Civil Action No.
) 16-08697 FMO
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----/

VIDEOTAPED DEPOSITION OF PATRICIA BRENNAN
(Taken Virtually by Plaintiff)
Tuesday, September 12th, 2023
11:34 a.m. EDT

Reported Stenographically by

1 Q. What is IRADS?

2 A. It was Optum's submission system for
3 RAPS submissions.

4 Q. And was this also the system to which
5 providers would submit claims data to Optum?

6 A. I don't think that's accurate. I think
7 the claims data that providers submitted went to
8 the plan, and then the plan submitted that data to
9 Optum, which then got put into IRADS.

10 Q. Okay. And then Optum would use IRADS
11 to submit that data through RAPS to CMS?

12 A. Correct.

13 Q. And you never would refer to these as
14 "provider-reported diagnosis codes"; is that
15 correct?

16 A. I don't know what that refers to.

17 Q. Okay. Beyond diagnosis codes that came
18 to the plan from providers, were there other
19 sources of diagnosis codes submitted by Optum on
20 behalf of M&R?

21 A. Yes.

22 Q. And what other sources of -- what were
23 the other sources of diagnosis codes that Optum
24 submitted on behalf of M&R to CMS?

25 A. Codes that came from retrospective

1 chart review and codes that came from prospective
2 programs.

3 Q. Okay.

4 MS. LIKOFF: Since we promised our
5 videographer that we would take a break, and
6 I don't want to sort of move into a whole new
7 topic, this may be a good time for us to
8 break for lunch. So if we could go off the
9 record.

10 THE VIDEOGRAPHER: Off the record,
11 2:54 p.m.

12 (Recess taken.)

13 THE VIDEOGRAPHER: On the record,
14 3:42 p.m.

15 MS. LIKOFF: Thank you.

16 BY MS. LIKOFF:

17 Q. Welcome back, Ms. Brennan.

18 We were just starting -- before the
19 break, I was just starting to ask you about Optum's
20 chart review program.

21 Is it correct that chart review is a
22 process that Optum employed to collect medical
23 records from providers, employ coders to review
24 those medical records to identify all diagnoses
25 documented in those medical records, and then

1 submit additional diagnoses to CMS for risk
2 adjustment payments?

3 Is that an accurate description of the
4 chart review process?

5 A. Yes.

6 Q. And throughout our conversation this
7 afternoon, I may refer to the chart review program
8 as "CR." You'll understand that I'm talking about
9 the chart review program?

10 A. Yes.

11 Q. Great.

12 And you'd agree that the goal of the
13 chart review program was to identify additional
14 diagnosis codes in beneficiaries' medical records
15 to submit to CMS?

16 A. Yes.

17 Q. And it's correct that those additional
18 diagnosis codes would lead to increased
19 reimbursement from CMS to the MAO?

20 A. In some instances, yes.

21 Q. Were there instances in which those
22 additional diagnosis codes would not increase
23 reimbursement to the MAO?

24 A. Yeah. Sometimes you could find a code
25 and it would already be reported somewhere else, so

1 then it wouldn't generate any additional revenue.

2 Q. Okay.

3 A. Only if it was new.

4 Q. And Optum performed the chart review
5 program for its clients; is that correct?

6 A. Yes, if a client purchased that
7 service, yes.

8 Q. And one of those clients was M&R,
9 correct?

10 A. Correct.

11 Q. Do you remember what time period Optum
12 performed the chart review program for M&R?

13 A. I mean, since I started until I left.

14 Q. Okay. And did Optum perform chart
15 review for any non-UnitedHealth claims?

16 A. Yes.

17 Q. I know that when we were speaking about
18 your background earlier this morning, you explained
19 that there was a time period in which you had
20 involvement with the chart review program.

21 Can you explain in a little bit more
22 detail what your involvement with the chart review
23 program was?

24 A. You mean when I was leading
25 retrospective chart review, is that what you're

1 referring to?

2 Q. Let's start there.

3 A. Yes. So my involvement was, you know,
4 as I mentioned earlier, like working with our
5 existing clients on launching their program because
6 it was an annual program that happened every year,
7 and I would work with them on launching, talk to
8 them about what they wanted to achieve, and present
9 options to them. They would select what they
10 wanted to pursue, and then we would launch the
11 program. And then I would monitor the program to
12 see if it was in line with what we expected it to
13 be and report out to them periodically on the
14 program performance.

15 Oh, sorry.

16 Q. No, no, please finish your answer.

17 A. That was for existing clients that
18 already purchased the service.

19 And then I would also go out with our
20 sales team to prospective clients and explain the
21 program to them, how it worked, because they were
22 interested in potentially purchasing the program.

23 Q. I'd like to break down what you just
24 said a little bit. When we were talking about your
25 work with respect to existing clients, you

1 recall for sure.

2 Q. Okay. During your time at Optum, did
3 you come to have any understanding regarding the
4 general rate of unsupported codes and diagnostic
5 data submitted by providers?

6 MR. ABASCAL: Object to form.

7 THE WITNESS: I think that the general
8 error rate was published by CMS as part of
9 the national sample of the -- what they call
10 the "IPM audit" that they did across plans.
11 So I remember being aware of that at the
12 time.

13 BY MS. LIKOFF:

14 Q. Do you recall what that sort of
15 published rate was?

16 A. I don't recall what the rate was.

17 Q. Do you recall whether there were any
18 other sources for your understanding regarding the
19 general rate of unsupported codes in diagnostic
20 data submitted by providers?

21 A. No, I don't recall.

22 Q. Another one of the risk adjustment
23 programs that Optum performed, at least for a
24 period of time, was a program called "claims
25 verification," correct?

1 A. Correct.

2 Q. And you're familiar with claims
3 verification?

4 A. Yes.

5 Q. And today I may refer to the claims
6 verification as "CV." If I refer to it as "CV" or
7 the "CV program," you'll understand that I'm
8 referring to claims verification?

9 A. Yes.

10 Q. Great.

11 And claims verification was a program
12 that was implemented to identify diagnosis codes
13 that were previously submitted to CMS but were not
14 documented in the medical record for that
15 corresponding date of service for charts reviewed
16 as part of the chart review program. Is that an
17 accurate description?

18 A. Yes.

19 Q. And ultimately, if a code, a diagnosis
20 code went through the CV process and a CV coder did
21 not find support for the code in the medical
22 record, then Optum would submit those codes as "CV
23 deletes"; is that correct?

24 A. Correct.

25 Q. I'd like to understand a little bit

1 more about what your role was with respect to the
2 claims verification program.

3 A. So I participated in the development
4 and enhancements that came with Phase II and III,
5 and then discussing it with clients, reporting out
6 on the results and monitoring the program.

7 Q. Would you describe yourself as the
8 leader on CV during at least some period of time?

9 A. I would say I was working with our
10 legal team on developing the program, continuing to
11 enhance and develop the program.

12 Q. Do you recall who from the legal team?

13 THE WITNESS: Can I answer that?

14 MR. ABASCAL: You can just provide the
15 names. Just don't provide any substance of
16 communications.

17 THE WITNESS: So Tim Trujillo,
18 Keith Dobbins, Dave Thomas.

19 BY MS. LIKOFF:

20 Q. Were there nonlawyers that you were
21 working with in developing the CV program?

22 A. Not in developing it, but in
23 communicating, you know, the approach. Once we
24 finalized an approach, then I would work with our
25 other teams to develop the process and what needed

1 CERTIFICATE OF NOTARY PUBLIC

2

3 I, Amy A. Brauser, RPR RMR CRR, the officer
4 before whom the foregoing deposition was taken, do
5 hereby certify that the witness was duly sworn by me
6 prior to the taking of the foregoing deposition; that
7 the testimony of said witness was taken by me to the
8 best of my ability and thereafter reduced to
9 typewriting under my direction; that I am neither
10 counsel for, related to, nor employed by any of the
11 parties to the action in which this deposition was
12 taken, and further that I am not a relative or
13 employee of any attorney or counsel employed by the
14 parties thereto, nor financially or otherwise interest
15 in the outcome of the action.

16

17 This is the 15th day of September, 2023.

18

19 Amy A Brauser

20

Amy A. Brauser, RPR RMR CRR

Notary Public

21

for the Commonwealth of Virginia

22

23 Notary Registration No.: 7675529

24 My Commission Expires: January 31, 2024

25

EXHIBIT D-96

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL

Videotaped Rule 30(b)(6) Deposition of United States
Designee 5 by CHRISTOPHER GILES BRESETTE

Given Remotely

Wednesday, May 31, 2023

10:34 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. Okay. And you're prepared to testify
2 about Topic 19 on behalf of the government today?

3 A. Yes.

4 Q. If you move down to page 27 of the PDF, I
5 want you to take a look at Topic 22, please.

6 And do you recognize Topic 22 as one of
7 the topics you've been designated to testify on
8 behalf of the OIG today?

9 A. Yes.

10 Q. And you're prepared to testify on that
11 topic on OIG's behalf?

12 A. I am.

13 Q. So, Mr. Bresette, you have not been
14 deposed in this litigation -- or at all, correct?

15 A. Correct.

16 Q. Just want to do a little bit -- get a
17 little bit of background on your -- your role. What
18 is your -- what is your current role, your current
19 position?

20 A. My current role with OIG, I am the
21 director of Medicare Part C audits.

22 Q. And who are your -- what are your
23 responsibilities as it relates to the topics that
24 you're prepared to testify about today?

25 A. I have to ask you --

1 MS. OBEREMBT: Objection. Vague.

2 BY MS. SCHEFFLER DO:

3 Q. What are some of your responsibilities as
4 the OIG director of Medicare Part C audits at OIG?

5 A. All of the audits for Medicare Part C,
6 from beginning to end. I hope --

7 Q. That would -- I'm sorry. Go ahead.

8 A. No, I got ahead of myself. My apologies.

9 Q. And that would include the OIG RADV,
10 audits as that's term's been defined in Exhibit 1435?

11 A. Yes.

12 Q. Who are your direct reports, if any?

13 A. You said director before me?

14 Q. I'm sorry. Your direct reports?

15 A. And my apologies. I honestly have bad
16 ears, so I do not mean any offense. Could you
17 rerepeat that question again, please? We're going to
18 turn up the volume a little too.

19 Q. Sure. And I'll try to keep my voice up as
20 well.

21 Who are your direct reports, if any?

22 A. Who I report to?

23 Q. Who reports to you?

24 A. Reports to me? Steve Garrison reports to
25 me.

1 am not aware of any CMS requirement to -- for
2 the MAOs to review all of the diagnosis codes
3 prior to submission.

4 BY MS. SCHEFFLER D0:

5 Q. Let's move on to Topic 18. And if it's
6 helpful, you can look at Exhibit 1435, which is again
7 the amended notice, 30(b)(6) notice that you are
8 testifying pursuant to today.

9 Topic 18 is on page 25 of the PDF of
10 Exhibit 1435.

11 A. Okay.

12 Q. Okay. Are you prepared to testify on
13 behalf of OIG on Topic 18 today?

14 A. Is your understanding that Topic 18
15 conforms to the relevant time period of 2004 to May
16 of 2017? May 16th of 2017?

17 Q. It does, yes.

18 A. Yes, I am prepared to testify on that.

19 Q. You understand what Topic 18 covers?

20 A. I believe I do.

21 Q. We've already confirmed that "MAOs" stands
22 for Medicare Advantage Organizations, right?

23 A. Could you repeat that, please? My bad
24 ears again, please. Sorry.

25 Q. We've already established that "MAOs"

1 refers to Medicare Advantage Organizations, right?

2 A. Yes. Yes.

3 Q. And do you understand that "diagnosis
4 codes" refers to ICD-9 or ICD-10 diagnosis codes?

5 A. I'm -- I thank you for your patience.
6 It's -- I'm having -- there's a -- it's on me; it's
7 on my ears. Could you say that question one more
8 time, please? I don't mean any offense.

9 Q. No problem.

10 Do you understand that "diagnosis codes,"
11 as used in Topic 18, refers to ICD-9 or ICD-10 --

12 A. Yes, I do.

13 Q. -- diagnosis codes?

14 A. Yes.

15 Q. So outside of the audits discussed
16 earlier, has the OIG analyzed whether the diagnosis
17 codes reported by providers, the MAOs, are supported
18 by medical records in the relevant time period?

19 A. Outside of the audits that we performed,
20 that we've discussed, am I aware -- is the OIG aware
21 that -- about the accuracy of diagnosis codes as
22 reported by providers? In order to do that, we would
23 have to review the medical records supporting them to
24 determine whether they are accurate or not. And
25 outside of those audits, we did not perform reviews

1 of medical records to determine whether diagnosis
2 were supported or not.

3 At least I'm not aware of any.

4 Q. Okay. So the answer to my question
5 is "no," then?

6 A. The answer to your question is -- is no.

7 Q. Okay.

8 A. Based upon the answer -- the qualification
9 that I provided.

10 Q. And apart from, again, the audits we've
11 already discussed, the RADV audits we've already
12 discussed, did OIG consider any analysis of whether
13 the diagnoses codes reported by providers to MAOs are
14 supported by medical records?

15 A. Did we consider -- did you ask, did we
16 consider whether the -- the diagnosis were reported
17 by MAOs -- reported by providers to MAOs were
18 accurate?

19 Q. I asked whether OIG considered any
20 analysis of whether the diagnosis codes reported by
21 providers to MAOs are supported by medical records.

22 A. Make sure I answer this correctly, and all
23 questions.

24 Q. Appreciate that.

25 A. -- regarding the accuracy.

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CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

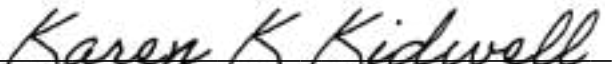

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-96A

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 2
DEPOSITION OF CHRISTOPHER BRESETTE
As 30(b)(6) Designee 5 of
The United States

(Via Zoom Videoconference)
August 9, 2023

Reported by: John L. Harmonson, RPR
Job No. 1001591

1 coder to take another look to determine whether
2 they agreed with the first senior coder who
3 identified a new HCC that had not been submitted by
4 the MAO; correct?

5 A. Correct.

6 Q. Why was the second senior coder -- why
7 wasn't that reviewed blind as well?

8 A. This was a process that we believed was
9 reasonable to accomplish our audit objective.

10 Q. Would you agree that coders can
11 sometimes miss diagnosis codes on a blind review?

12 MS. OBEREMBT: Objection; calls for
13 speculation.

14 THE WITNESS: I would have to speculate
15 on that. We've asked the senior coders to
16 determine whether they believe something is -- if a
17 diagnosis is supported or not.

18 BY MS. SCHEFFLER DO:

19 Q. In your preparation for today and
20 reviewing all of these audits, you're not aware of
21 any instances where the first senior coder
22 conducting a blind review determined that an HCC

1 was not validated but OIG ultimately determined
2 that it in fact was validated?

3 A. I'm not going to say that it did or did
4 not happen. It very well may have happened. I did
5 not study the results of the first senior coder and
6 the second senior coder.

7 Q. We can go back to that and look at some
8 specific examples to refresh your recollection.

9 A. Absolutely.

10 Q. So if the second senior coder determines
11 that the HCC that the first senior coder -- let me
12 restart that.

13 If the second senior coder determines
14 that a particular HCC is validated despite the
15 first senior coder determining that it was not
16 supported, then it escalated to a physician to
17 independently review the medical record and make a
18 final determination. Is that right?

19 A. It's mostly correct. There were
20 oftentimes where the senior coders -- I shouldn't
21 say often. There was the opportunity and there
22 were times that existed that either the first

1 senior coder or the second senior coder asked for
2 assistance with that physician reviewer to make the
3 determination.

4 There were, as you say, instances in
5 which the physician reviewer would review that. I
6 believe independently, but I don't want to say that
7 it was exclusively independently. A lot of times I
8 believe it was in consultation with the senior
9 coder to make that determination.

10 Q. So are you saying that the example that
11 I gave, that's not the only time a physician would
12 weigh in?

13 A. Correct.

14 Q. But you're not -- you're agreeing that
15 if the second senior coder found support in that
16 example, then a physician would independently
17 review the medical record to make the final
18 determination?

19 A. I would agree with that.

20 Q. Was the physician review blind as well?

21 A. No, it was not. And independently is
22 correct. So my apologies. I see "independently"

1 written in the report. There's a lot of steps to
2 this, and so I did not want to mislead you by any
3 means. So my apologies.

4 Q. No problem.

5 Okay. I'm going to shift gears just a
6 little bit. So in May, you had testified that for
7 each OIG audit, OIG issues a draft report to the
8 MAO being audited. Is that correct?

9 A. That is correct.

10 Q. And OIG permits the MAO to point to
11 documentation that it believes supports the HCCs at
12 issue. Is that right?

13 A. That is correct.

14 Q. And OIG also allows the MAOs to submit
15 additional medical records or documentation that it
16 believes supports the HCCs. Is that right?

17 A. Yes, that is correct. They can
18 submit --

19 Q. And is it correct --

20 A. I'm sorry. I did not mean to speak over
21 you.

22 Yeah, it is correct that we allow the

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that CHRISTOPHER BRESETTE, the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

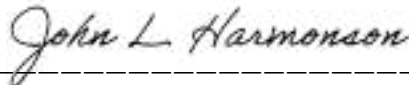
10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 11th day of August, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

EXHIBIT D-97

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

CONTAINS PORTIONS OF ATTORNEYS' EYES ONLY

Videotaped Deposition of
SEAN CAVANAUGH
Given Remotely
Thursday, February 17, 2022
9:02 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Medicare Advantage plans?

2 A. No.

3 Q. Nothing to do with what's known as the
4 coding intensity adjustment, the -- or the
5 fee-for-service adjustment for the RADV audits? None
6 of that was within your purview at the Innovation
7 Center?

8 A. No.

9 Q. How long were you at the Innovation
10 Center?

11 A. February 2011 to March or April of 2014.

12 Q. What was your next role -- what was the --
13 what was the role that you took in March or April of
14 2014 at CMS?

15 A. I became deputy administrator and director
16 of the Center for Medicare.

17 Q. What is the Center for Medicare?

18 MS. KRIEG: Object to form.

19 THE WITNESS: Center for Medicare is one
20 of several centers within CMS. It specifically
21 has responsibility for the rule-making around
22 payment and regulation of Part A, B, C, and D of
23 Medicare.

24 BY MR. GALLAGHER:

25 Q. Who was your predecessor as the director

1 of the Center for Medicare?

2 A. Jon Blum.

3 (Reporter requests clarification.

4 A. Jon Blum, J-o-n, B-l-u-m.

5 Q. And did you take over directly for him, or
6 was there an interim director between you?

7 A. I believe the -- a woman named Elizabeth
8 Richter, who was a career civil servant, acted as the
9 acting center director between when Jon was appointed
10 and when I was appointed.

11 Q. Okay. Explain how it is you made the move
12 to be the director of the Center for Medicare. What
13 was the reason for that change in position?

14 A. Jon had been promoted from his position at
15 the Center for Medicare, so it created a vacancy. As
16 I said, it is common, if there isn't an immediate
17 successor -- these are political -- excuse me --
18 politically appointed positions. If there's not an
19 immediate successor, it's often common to have a
20 career civil servant fill in, which is what happened.

21 I threw my name in the hat, and I
22 interviewed with the administrator, Secretary's
23 Office with the White House, and I was selected for
24 the position.

25 Q. So your position as the director of the

1 Center for Medicare was a political appointment,
2 essentially, from the president, right?

3 A. That's correct. The presidential --
4 Presidential Personnel Office had to approve it, yes.

5 Q. And then you were confirmed by the Senate?

6 A. No, it's not a Senate confirm. It's
7 political, but not Senate confirm.

8 Q. As the director for the Center for
9 Medicare, were you responsible for overseeing the
10 regulation and payment of Medicare fee-for-service
11 providers, privately administered Medicare health
12 plans, and the Medicare prescription drug program?

13 A. Yes.

14 MS. KRIEG: Object to form.

15 THE WITNESS: Sorry.

16 Yes.

17 BY MR. GALLAGHER:

18 Q. And basically -- I listened to a podcast
19 you did at Aledade, and I think you described your
20 job as essentially running Medicare. Is that how you
21 would describe it?

22 A. That's how I describe it to lay people.
23 Technically, there are other aspects of the program.
24 There's a Center for Program Integrity, a Center for
25 Clinical Standards and Quality. But what most people

1 perceive as Medicare was mostly under my
2 jurisdiction.

3 Q. And as the director for the Center for
4 Medicare, there you did have responsibility for
5 regulation and oversight of the payment mechanisms
6 for Medicare Advantage plans, that's the subject of
7 this litigation. Right?

8 A. Yes.

9 Q. Things like risk adjustment, and the
10 models that are used to achieve it?

11 A. Yes.

12 Q. When did you leave government employment
13 at the Center -- at CMS?

14 A. January of 2017, whatever date was
15 inauguration date. Noon on the day of inauguration
16 date, January 2017.

17 Q. As a -- as a political appointment, your
18 appointment ended with the administration?

19 A. That's correct.

20 Q. So some of your colleagues have returned
21 to CMS under the new administration. Have you
22 considered doing that? Or do you have any plans to
23 do that?

24 A. I did consider it. I no longer have
25 plans.

1 Q. So you're happy at Aledade, and that's
2 where you are going to stay for the near term?

3 A. Yes.

4 Q. When you took the position as the -- as
5 the director for the Center for Medicare, did you
6 receive any kind of transition briefing on things
7 like the -- the risk-adjustment audits that are
8 conducted by the Center for Medicare, or CMS, or --
9 or the coding intensity, or coding intensity
10 adjustment, or things like that?

11 MS. KRIEG: Object to form.

12 THE WITNESS: Yes.

13 BY MR. GALLAGHER:

14 Q. What was the nature of that -- that
15 transition briefing? Who gave it to you, and what
16 form did it take?

17 A. Specifically on those issues you
18 enumerated? Because I had numerous transitional
19 briefings.

20 Q. Yes. Specifically on issues around the
21 payment programs for Medicare Advantage plan and --
22 and things associated with risk adjustment.

23 MS. KRIEG: Object to form.

24 THE WITNESS: They would have been
25 organized by my back then acting deputy director

1 on that side, Cynthia Tudor. So she would have
2 scheduled and arranged them and prepared them.

3 Most things related to Medicare Advantage
4 payment, the actual briefing would have been
5 conducted by Cheri Rice, or one of her staff
6 under her direction.

7 BY MR. GALLAGHER:

8 Q. And would the briefing -- or did the
9 briefing involve, you know, PowerPoint presentations,
10 or written briefing memos?

11 A. I have no specific recollection, but it --
12 yes.

13 Q. Just to get a sense of the -- of the
14 organizational structure you had at the Center for
15 Medicare, you were the director, and then you had
16 some deputy directors who served with you that had
17 specific areas of responsibility; is that right?

18 A. Yes.

19 Q. And you mentioned Cynthia Tudor. What was
20 her area of responsibility at the deputy director?

21 A. Everything under Part C and Part D.

22 Q. So that would include everything that had
23 to do with payment programs for Medicare Advantage
24 plans under Part C?

25 A. Yes.

1 Q. And then you mentioned that Cheri Rice is
2 somebody who had some responsibility for payment
3 programs for Medicare Advantage plans. What was her
4 role?

5 A. She was a group director for MPPG,
6 which -- I don't remember what it stands for exactly,
7 but it's Medicare Plan Payment Group, or something
8 like that -- under Cynthia Tudor.

9 Q. So in terms of direct responsibility for
10 payment programs, that really fell to Cheri Rice?

11 A. Yes.

12 Q. While you were at CMS, did you have any
13 responsibilities in connection with lawsuits like
14 this one?

15 MS. KRIEG: Object to form.

16 THE WITNESS: I'm not sure what you
17 meant -- what you mean. Did I have
18 responsibilities for them? I'm not an attorney,
19 if that's what you're asking.

20 BY MR. GALLAGHER:

21 Q. Well, while you were at CMS -- and in
22 particular, I'll focus on your -- your tenure as the
23 director of the Center for Medicare -- did you have
24 any responsibility for coordinating with the lawyers
25 who are pursuing this litigation on behalf of the

1 government?

2 A. Again, I'm not sure I understand the
3 question. I didn't -- I did -- I was informed of the
4 litigation by counsel.

5 Q. And as the director for the Center for
6 Medicare from 2014 to early 2017, did you coordinate
7 with the lawyers handling this litigation for the
8 government?

9 MS. KRIEG: Object to form.

10 THE WITNESS: Yeah. I apologize. I'm
11 struggling with the word "coordinate." I'm not
12 an attorney. I would not have coordinated a
13 litigation strategy, if that's what you're
14 asking.

15 BY MR. GALLAGHER:

16 Q. Let me ask a related question, then.

17 As the director for the Center for
18 Medicare from 2014 to early 2017, did you meet with
19 the lawyers who were handling this litigation for the
20 government?

21 A. I do recall having met with attorneys from
22 DOJ to be informed of this litigation, yes.

23 Q. And did you provide support or materials
24 to the lawyers handling this litigation for the
25 government?

1 A. I -- I believe -- so I don't --

2 MS. KRIEG: I'm just going to again
3 caution you not to reveal any privileged
4 information that was sought or received from
5 counsel.

6 THE WITNESS: Thank you.

7 I will solely say that my understanding
8 was any records I had were to be made available,
9 to be retained and made available for the
10 litigation. But I didn't need to do anything in
11 that regard. I never destroyed records, so I
12 never had to provide things. I think they
13 had -- they or the agency had access to them
14 without me -- my -- my intervening.

15 BY MR. GALLAGHER:

16 Q. I'm asking a slightly different question,
17 and it may be that I -- that I wasn't -- wasn't clear
18 about it.

19 What I'd like to know is, you know, during
20 your tenure as the director for the Center for
21 Medicare, did you meet with the lawyers who are
22 pursuing this litigation on behalf of the government
23 and provide them with support, whether it was
24 briefings on the underlying payment programs, or CMS
25 policies and procedures, or CMS plans for

1 rule-making, or anything to support them in the
2 litigation effort?

3 (Instruction not to answer.)

4 MS. KRIEG: I'm going to object and
5 instruct him not to answer any privileged
6 information sought or received with counsel.

7 And object to form also.

8 THE WITNESS: So I'm going to answer the
9 first half again, and on advice of counsel not
10 answer the second half.

11 Yes, I met with counsel. But as far as
12 what we discussed or provided, I'm going to
13 follow my counsel's advice and not to go
14 further.

15 BY MR. GALLAGHER:

16 Q. Did you have -- as the director for the
17 Center for Medicare, did you have any decision-making
18 authority with respect to this litigation, positions
19 that would be taken or arguments that would be made?

20 A. No, not that I was aware of.

21 Q. You indicated that you were briefed, while
22 you were at CMS as the director for the Center for
23 Medicare, on the nature of the case and the claims
24 being asserted. Is that correct?

25 MS. KRIEG: Object to form. Misstates

1 A. Yes.

2 Q. So to walk through how the program works,
3 at a high level, am I right that CMS first
4 establishes a benchmark, the highest monthly payment
5 that CMS will pay for an average fee-for-service
6 beneficiary?

7 A. I'd characterize it somewhat differently.
8 It is -- it is a benchmark up against which health
9 plans will -- Medicare Advantage plans will bid.

10 Q. And is that benchmark based on -- is it in
11 fact the highest monthly payment that CMS will pay
12 for an average beneficiary, using the fee-for-service
13 data as the basis for that determination?

14 A. Yes.

15 Q. And then plans bid. And does that bid
16 establish their base rate per beneficiary?

17 A. Yes. I mean, we're simplifying here, but
18 yes.

19 Q. And then the -- and then the plans are
20 paid either the base rate or the benchmark, whichever
21 is lower, right?

22 A. Well, they're paid their bid plus the --
23 you know, there's a rebate function, or -- skipping
24 that part, or --

25 Q. Let me be more specific. Before taking

1 into account risk adjustment or rebates or other
2 considerations, the plans are paid a base rate --

3 A. Okay.

4 Q. -- that is equal to their base rate or the
5 benchmark, whichever is lower, right?

6 A. Correct.

7 Q. I'm sorry. I couldn't hear you.
8 "Correct"?

9 A. Correct.

10 Q. Okay. And then CMS makes some adjustments
11 to that base rate, including an adjustment to reflect
12 enrollees' risk scores. Right?

13 A. That's correct.

14 Q. So there are various risk adjustments that
15 are taken into account, including demographic
16 information and where people live. But what we're
17 going to be talking about here is the adjustment
18 that's made based on diagnostic coding.

19 Is that one of the risk adjustments that
20 CMS makes to the base rate?

21 A. It is.

22 Q. Okay. And that risk adjustment, based on
23 diagnostic coding, is meant to ensure that Medicare
24 Advantage plans are paid more for beneficiaries with
25 conditions that are -- that make them riskier or

1 higher-cost, and less for beneficiaries that are
2 relatively less risky than the average
3 fee-for-service beneficiary. Is that a fair
4 statement?

5 A. That is.

6 Q. And the risk adjustment, the diagnostic
7 coding risk adjustment, is based on the hierarchical
8 condition categories that we discussed earlier,
9 right?

10 A. Correct.

11 Q. So just to use some examples, a
12 beneficiary with diabetes is likely to require more
13 medical care, and therefore will cost more than
14 someone who does not have diabetes; and they would
15 therefore have a higher risk score and a higher
16 risk-adjustment factor in the model. Right?

17 A. Yes.

18 Q. And the same thing would be --

19 A. All -- all other things held equal, yes.

20 Q. Right. So there would be a factor, a
21 risk-adjustment factor, associated with just the fact
22 you have diabetes. And then you would add that
23 factor to all the others for the beneficiary to come
24 to their total risk score. Right?

25 A. That's right.

1 Q. And the same thing is true for other
2 conditions that signal higher health care costs for a
3 beneficiary, like hypertension, or cancer, or heart
4 failure, or the fact that they're a quadriplegic.
5 Right?

6 MS. KRIEG: Object to form.

7 THE WITNESS: That's correct.

8 BY MR. GALLAGHER:

9 Q. All of those things would have a
10 risk-adjustment factor associated with them, if that
11 condition existed for a beneficiary and was actually
12 included in their records. Right?

13 A. That's correct.

14 Q. Or associated with them in the -- in the
15 database at CMS, right?

16 A. I'm not sure what you mean by "associated
17 with them in the database."

18 Q. Well, there's two steps that are involved,
19 right? First, somebody has to -- has to determine
20 that the beneficiary has the condition, whether it be
21 diabetes or hypertension or cancer, and actually code
22 that in the claims data that's submitted for the
23 beneficiary, right?

24 A. Yes. First, it -- it should be reflected
25 appropriately in the medical record. Then make

1 fee-for-service providers and Medicare Advantage
2 plan?

3 MS. KRIEG: Object to form.

4 THE WITNESS: I did.

5 BY MR. GALLAGHER:

6 Q. And did you understand that both the
7 fee-for-service claims data and the Medicare
8 Advantage plans submitted data that was -- was
9 incomplete, because providers missed diagnostic codes
10 that were appropriately associated with the
11 beneficiary?

12 MS. KRIEG: Object to form.

13 THE WITNESS: Are you asking in the
14 traditional Medicare side, or the Medicare
15 Advantage side at this point?

16 BY MR. GALLAGHER:

17 Q. I'm asking both, basically, unless there's
18 a difference between them, in your recollection.

19 A. Yes, I'm sure I was aware at the time that
20 there were often omitted diagnoses. I think I was
21 also aware that at times, since we're talking about
22 both sides of the diagnosis that had been supported,
23 that submitted that maybe could not be supported in
24 the medical record.

25 Q. And that was true for both the

1 fee-for-service, traditional claims data, and the
2 Medicare Advantage plans data, right?

3 A. Well, I think it was much more common, if
4 it was unsupported, to be on the side where it drove
5 financial advantage and Medicare Advantage. And if
6 it was omitted, it was much more likely to happen on
7 the fee-for-service side, where it didn't cause any
8 financial harm.

9 Q. Setting aside your belief about the extent
10 to which it occurred, you agree that both fee for
11 service and Medicare Advantage, you know, submitted
12 data included codes that were not supported by the
13 medical records, and omitted diagnostic codes that
14 would be supported by the medical records? Right?

15 MS. KRIEG: Object to form.

16 THE WITNESS: Yes, it was my understanding
17 that that was true.

18 BY MR. GALLAGHER:

19 Q. And you could refer to that as overcoding
20 and undercoding, right? Overcoding being assigning
21 codes that are not supported by the medical record,
22 and undercoding being omitting codes that would be
23 supported by the medical records. Fair?

24 A. Yes. They frequently -- they are
25 frequently referred to that way.

1 Q. And it was your understanding, as the
2 director for the Center for Medicare in 2014, 2017,
3 in that time frame, that overcoding and undercoding
4 was to some degree an issue with both traditional,
5 fee-for-service data and the data submitted by
6 Medicare Advantage plans. Right?

7 MS. KRIEG: Object to form.

8 THE WITNESS: Yes.

9 BY MR. GALLAGHER:

10 Q. Bear with me one second. I have an
11 outline, and I've covered some of it already. I
12 don't want to waste time, so -- just bear with me one
13 second.

14 So I want to direct your attention to the
15 article that we've marked as Exhibit 1002, and in
16 particular to page 5, at the top.

17 Are you on page 5?

18 A. I am.

19 Q. So do you see at the top, where
20 Mr. Kronick and Mr. Welch write in their article that
21 "However, fee-for-service coding is known to be both
22 incomplete and variable." Do you see that?

23 A. Yes.

24 Q. And this article was written in two
25 thousand -- or published in 2014. Do you agree with

1 their statement?

2 MS. KRIEG: Object to form.

3 THE WITNESS: Yes, that's my
4 understanding, fee-for-service coding.

5 BY MR. GALLAGHER:

6 Q. And did you understand that back in 2014,
7 when you were the -- after you were the director for
8 the Center for Medicare?

9 A. Yes.

10 Q. All right. Now, the article gives an
11 example that I'd like to ask you about. It's on
12 page 3.

13 Actually, before we go to page 3, stay on
14 page 5. I apologize.

15 A. Uh-huh.

16 Q. So on page 5 of the Kronick and Welch
17 article, under the statement we just looked at, where
18 it says: "Fee-for-service coding is known to be both
19 incomplete and variable" --

20 A. Uh-huh.

21 Q. -- they write: "For instance, among
22 Medicare beneficiaries diagnosed with quadriplegia in
23 one year, only 61 percent had a diagnosis of
24 quadriplegia reported in the subsequent year."

25 Do you see that?

1 A. Yes.

2 Q. And that would -- that would have the
3 effect of ensuring a complete record of diagnostic
4 codes, and also increasing the risk score for
5 beneficiaries and payment under the program, right?

6 A. Well, I want to be clear that that's the
7 only thing that happened. The question is, you know,
8 in my mind, were they looking to make sure things
9 were not just complete, but complete and fully
10 accurate?

11 So yes, if the only thing they found was a
12 condition that hadn't been properly documented, and
13 they did document it, that would be appropriate. If
14 they found things that had -- had been
15 inappropriately documented and -- and didn't follow
16 through on that, I don't think it would be
17 appropriate.

18 Q. On your example there, first just let me
19 break it down. If the medical record review
20 conducted by a Medicare Advantage plan found a
21 diagnostic condition that was not reflected in the
22 claims data, there was no code reflected in the
23 claims data, perfectly appropriate to supplement with
24 that diagnostic code in order to have a complete
25 record of supported conditions for the beneficiary,

1 right?

2 A. Yes.

3 Q. And what you're talking about is a
4 situation where in conducting that review, if a
5 Medicare Advantage plan discovered that there were --
6 there were codes that were not supported, you had
7 questions about what they should do in that
8 situation. Right?

9 A. No, I had no questions. I think they had
10 an affirmative obligation to correct the records and
11 not be paid inappropriately.

12 Q. Right. So if they knew that the code was
13 not supported, they should withdraw it, right?

14 A. Yes.

15 Q. When you took over as the director for the
16 Center for Medicare, was there any rule or regulation
17 in place that affirmatively required Medicare
18 Advantage plans to proactively review medical
19 records, to audit them, and determine which, if any,
20 codes were not supported?

21 A. Not that I'm aware of.

22 Q. So what you're talking about is if they
23 did review the medical records and discover that the
24 codes were not supported, then the plans had an
25 obligation to withdraw them. Right?

1 A. If in any way a plan was aware of
2 inaccurate data, they had an obligation, because
3 their obligation was to submit complete and accurate
4 data.

5 Q. Well, everyone knew -- including you,
6 right? -- that the data submitted for fee-for-service
7 under traditional -- traditional model, and for
8 Medicare Advantage plans, had some errors and
9 inaccuracies in it, right?

10 MS. KRIEG: Object to form.

11 THE WITNESS: Yes.

12 BY MR. GALLAGHER:

13 Q. That was your baseline understanding at
14 CMS when you took over as the director for the Center
15 for Medicare, and it was widely understood that the
16 data had inaccuracies in it, because of the way
17 coding is done at the point of care. Right?

18 MS. KRIEG: Object to form.

19 THE WITNESS: Yes, we understood that.

20 BY MR. GALLAGHER:

21 Q. So it wasn't the case that -- that if you
22 had some idea that there might be a code in there
23 somewhere that was not supported, that you, as a
24 Medicare Advantage plan, had to do something. It was
25 that if you knew that a specific code was not

1 the -- at the -- at the administrator's office level?

2 A. Yes.

3 Q. Did anybody on your team have input on
4 whether to finalize this rule? Like Cheri Rice or
5 Cynthia Tudor, who we discussed earlier?

6 A. I wouldn't think so.

7 Q. Can you describe the purpose and intent of
8 this proposed rule, as you understood it?

9 MS. KRIEG: Object to form.

10 THE WITNESS: When I was briefed on the
11 provision, it seemed redundant to me, as why are
12 we doing this? You know. Don't the plans
13 already have an affirmative obligation to attest
14 that the data are complete and accurate?

15 And I was told this is being done in an
16 excess of -- "caution" is the wrong word -- you
17 know, to go above and beyond on clarity. And I
18 thought that seemed harmless enough.

19 BY MR. GALLAGHER:

20 Q. So you're saying you thought that this
21 rule specifically requiring that any medical record
22 review conducted by an organization must be designed
23 to determine the accuracy of diagnoses -- diagnoses
24 submitted, you're saying you thought that was
25 redundant --

1 A. Yeah, it was --

2 Q. -- to the attestation requirement?

3 A. At that time, I'm not sure I would have
4 cited necessarily the attestation requirement. My
5 belief at the time, and it was not contradicted by
6 the staff, that they must have an obligation to
7 make -- you know, to -- to affirm that to the best of
8 their belief and knowledge, these data are accurate,
9 and they're like, "They do."

10 And I said, "Okay. I'm not sure why we're
11 doing this, but it's out there. It's fine with me."

12 Q. Can you point to any existing regulation
13 or rule that predates this proposed rule that
14 specifically dictated the form of the medical record
15 review that Medicare Advantage plans would conduct?
16 Or had to conduct?

17 A. No, I can't do that.

18 Q. Is there anything in the attestation
19 requirement that creates a proactive obligation for a
20 Medicare Advantage plan to audit the claims data
21 provided -- the coding provided in the claims data
22 that providers have keyed in?

23 A. Just to be clear, my thinking at the time,
24 and remains to be so today, is that if they're
25 engaged in any activity where they come upon

1 knowledge of something that's inaccurate, to be
2 compliant with their attestation, they have to
3 correct that. It just seemed plain on its face.

4 Q. Well, so let's -- let's explore that.

5 We discussed earlier that everybody knew
6 that the data submitted by Medicare Advantage plans
7 and by fee-for-service providers and the claims data,
8 everybody knew that there was some degree of
9 inaccuracy in that data. Right?

10 MS. KRIEG: Object to form.

11 THE WITNESS: Yes.

12 BY MR. GALLAGHER:

13 Q. You certainly knew it, as the director of
14 the Center for Medicare, that that was the case,
15 right?

16 A. We understood it. But everything we did
17 sought to eliminate it. And, you know, I used to
18 work in a hospital. We submitted cost reports. We
19 made an attestation that we did the best we could,
20 that -- you know, not that -- that everything we were
21 submitting was true and accurate, and we tried hard
22 to make sure that was true.

23 Q. When you say that there was a requirement
24 of attestation that -- that if you came across
25 knowledge that a code was not supported, or that it

1 was inaccurate, you had to do something, what did you
2 mean by "came across that knowledge"?

3 A. If by any mechanism, whether it's medical
4 record review or other -- I don't want to run through
5 hypothetical scenarios. I don't know everything that
6 goes into how they run their plans and their audits
7 and so forth. But they had an affirmative obligation
8 to make it correct.

9 Q. So are you saying that an affirmative
10 obligation, if they knew, from whatever mechanism,
11 that a code was not supported, to withdraw it?

12 A. Absolutely if they knew. I'm
13 less conversant in law and regulation on if they had
14 an affirmative obligation to take reasonable steps to
15 find out.

16 Q. Sitting here today, you can't identify any
17 rule or regulation that created an affirmative
18 obligation to audit the claims data submitted by
19 providers, or to proactively review medical records,
20 to ensure that the codes selected by providers were
21 supported?

22 A. I cannot. But I'm not an expert in the
23 area and don't work in that area.

24 Q. This rule that we're looking at in
25 Exhibit 1006, the medical records review rule that

1 was proposed and withdrawn, that would have created a
2 proactive obligation on the part of Medicare
3 Advantage plans to conduct medical record reviews in
4 a particular way. Right?

5 A. I mean, it -- to my reading of it is
6 that -- yeah, that you had to -- you had to be, you
7 know, looking for "adds and deletes," is the
8 shorthand we used. You couldn't turn a blind eye to
9 data just because it disadvantaged you.

10 Q. And you say you withdrew; that one of the
11 reasons that this was withdrawn is that you believed
12 it was redundant?

13 MS. KRIEG: Object to form. I think that
14 misstates prior testimony.

15 THE WITNESS: Yeah. I was going to say, I
16 didn't say that. What I said was my
17 understanding, from the directions I received
18 from the administrator's office, was the rule
19 writ large, meaning all the other -- not just
20 this, but all the other provisions had drawn
21 significant flak, and that a decision had been
22 made to pare it down significantly and only
23 finalize certain provisions.

24 And that's the -- those are the marching
25 orders that I executed.

1 specifically comply with the law, that's more
2 appropriately posed to your own counsel.

3 Q. Do you recall that there was -- there were
4 actually a couple of issues raised by United about
5 their -- about what the rule -- what the rules were;
6 that it wasn't just whether the medical record review
7 rule would be finalized, but also what to do with
8 their as-yet-not-completed medical record review that
9 they had been conducting for the 2012 year?

10 A. I -- in the vaguest sense, I do recall
11 something like that, yes.

12 Q. So you recall that there was discussion
13 about how United had been -- unlike other plans, had
14 been conducting medical record reviews and looking
15 for deletes, that they had a whole process around
16 that, and that they had not yet really completed it?

17 MR. LANGHAM: Objection. Form.

18 BY MR. GALLAGHER:

19 Q. Do you recall that?

20 A. I have a recollection that they did
21 describe their medical record review process in
22 some -- I forget how much detail, but they were
23 describing it.

24 Q. If you would look at Exhibit 1060, which
25 is the exchange you had with Cynthia Tudor and

1 Cheri Rice in advance of the meeting on April 28th,
2 2014.

3 Do you see where in her e-mail in the
4 middle of the page on page 1, Cynthia Tudor says,
5 "However, we now have a disclosure that says they
6 have wrongly sent some diagnoses. So legally I think
7 they need to carry through on this regardless of the
8 rule, if the attestation does not give them an out."

9 Do you see that?

10 A. I see that.

11 Q. And do you recall that what she was
12 referring to there was United's disclosure, in
13 Mr. Renfro's e-mail on page 2 of this exhibit, that
14 they had a medical record review under way that had
15 looked for deletes and not just things to add?

16 MS. KRIEG: Object to form.

17 THE WITNESS: I would not say, then or
18 now, that I knew that that's what she was
19 referring to.

20 BY MR. GALLAGHER:

21 Q. All right. And so -- and we talked about
22 this earlier, but to refer you to Ms. Rice's e-mail,
23 where she says that there's an obligation for
24 correcting data that they know is wrong, did you
25 understand that to be a reference to the disclosure

1 by Mr. Renfro, in his opening e-mail on this topic,
2 that United had conducted medical record reviews,
3 looked for deletes, and at some stage of the
4 proceedings, found some things that might need to be
5 deleted?

6 MS. KRIEG: Object to form.

7 THE WITNESS: That's how I read Cheri's
8 e-mail.

9 BY MR. GALLAGHER:

10 Q. Right. So there was on the one hand the
11 issue of what to do, given that United had
12 conducted -- had conducted a medical record review
13 looking for deletes for the 2012 year, and a separate
14 question about whether they were required to conduct
15 that type of medical record review under the rules.

16 Do you recall that being a distinction
17 drawn in the conversation you had with United?

18 MS. KRIEG: Objection. Form.

19 THE WITNESS: I do not have a
20 recollection.

21 BY MR. GALLAGHER:

22 Q. Do you recall that in the meeting, United
23 did describe its medical record review program that
24 it had been following for the 2012 year, specifically
25 in response to questions from Cheri Rice?

1 A. I do recall them describing the program.
2 I do not recall whether it was in response to Cheri's
3 questions or whether they volunteered.

4 Q. Do you recall that United described for
5 you the status of their medical record review,
6 including, you know, how many documents had
7 progressed to the final stage and how many were still
8 being -- how many medical records had progressed to
9 the final stage and how many were still being
10 reviewed at the various levels of review that were in
11 place?

12 A. I don't recall.

13 MS. KRIEG: Object to form.

14 THE WITNESS: I don't recall.

15 BY MR. GALLAGHER:

16 Q. Do you recall you or Ms. Rice saying, in
17 sum and substance, that under current rules, you
18 don't have to delete diagnostic codes unless you know
19 they are inaccurate?

20 A. I don't recall anybody saying that. And
21 again, we had agreed ahead of time to stay -- say the
22 thing I've been telling you, so that seems
23 inconsistent with what we agreed to say.

24 Q. So you deny saying that?

25 A. I certainly did not say it.

1 Q. And you deny that Cheri Rice said that?

2 A. I -- yes. I deny that she said that. It
3 seems -- it's totally inconsistent with the approach
4 we took into that meeting, and what we agreed to say.

5 Q. So you claim that rather than saying that,
6 you stuck to the script that you gave us earlier, and
7 just repeated that mantra?

8 A. When it came to articulating any
9 obligation and duty, or duty they had, that was the
10 response we gave.

11 Q. Did you give that response more than once
12 in the meeting? Like multiple times?

13 A. Oh, yes. Yes.

14 Q. So it was a mantra that you repeated, you
15 claim, multiple times in response to questions from
16 United?

17 A. Yes.

18 Q. And you deny saying anything else besides
19 the mantra on the subject of what United's
20 obligations were before finalization of the medical
21 record review rule?

22 MR. LANGHAM: Objection. Form.

23 THE WITNESS: I deny saying anything else
24 about what their obligations were under either
25 the probes reg or existing requirements.

1 BY MR. GALLAGHER:

2 Q. Did you or Ms. Rice say, in the meeting
3 with United, that until the proposed rule on medical
4 record review is finalized, Medicare Advantage plans
5 do not have a -- any proactive obligation to confirm
6 whether diagnosis codes submitted by physicians are
7 correct?

8 A. I don't recall anybody saying that.

9 Q. Do you deny that that was said by you or
10 Ms. Rice?

11 A. I deny it was said by me, certainly. And
12 I'll stop just short of denying Cheri said it. It
13 just seems so inconceivable. But I -- my
14 recollection of the meeting is, you know, eight years
15 ago.

16 Q. You don't -- you don't actually recall one
17 way or the other whether Ms. Rice said it?

18 A. Not with certainty.

19 MR. GALLAGHER: Let's -- let's share

20 Tab 22.

21 (Exhibit 1061 was marked for identification.)

22 BY MR. GALLAGHER:

23 Q. Do you have that, Document 13?

24 I'm sorry, Mr. Cavanaugh. I think you're
25 on mute.

1 A. I'm sorry. By accident.

2 Yes, I have the document.

3 Q. Okay. So Exhibit 1061 is a two-page
4 document that has Bates number starting with MARA and
5 ending with 57039. It's a set of notes entitled "CMS
6 Meeting Notes," dated -- and has the date in the
7 upper right-hand corner, under attorney stamp
8 April 29th, 2014. Do you see that?

9 A. I see that.

10 Q. Do you recall or -- or could you tell,
11 during the meeting you had over video with United,
12 could you tell whether they, the United participants,
13 were taking notes?

14 A. I do recall someone on the United side was
15 taking notes.

16 Q. You don't recall anybody on your side
17 taking notes, but you do recall folks on the United
18 side taking notes during the meeting, right?

19 MS. KRIEG: Object to form.

20 THE WITNESS: That is -- that is how I
21 recall. I do not recall whether someone on our
22 side took notes. I do specifically recall
23 seeing someone on their side taking notes,
24 though.

25

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, SEAN CAVANAUGH was remotely sworn to testify to the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.



Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

Dated: February 28, 2022

EXHIBIT D-98

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
-----	)	

*** CONFIDENTIAL ***

CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videoconference Videotaped Deposition OF
ILINA CHAUDHURI
(Taken virtually)
10:34 a.m. Eastern
Wednesday, August 10, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 approximately three years and eight months; is
2 that correct?

3 A. That's correct.

4 Q. Can you please describe at a general
5 level what kind of work is handled by the Division
6 of Payment Validation?

7 MR. BULAND: Object to form.

8 THE WITNESS: This was one of the
9 divisions that made up the Medicare Plan
10 Payment Group, and it was responsible for a
11 number of items related to payment
12 validation for Medicare Advantage and the
13 Part D program.

14 BY MS. KOPPEL:

15 Q. By Medicare Advantage, you mean
16 Medicare Part C?

17 A. Medicare Part C.

18 Q. And you said it was responsible for a
19 number of items relating to payment validation.
20 Can you describe those items? What was the
21 Division of Payment Validation responsible for?

22 MS. KRIEG: Object to form. Vague.

23 THE WITNESS: So one of the items was
24 validating through a process called
25 beneficiary payment validation. It was

1 recalculating at a beneficiary level agreed
2 prospective payments that we were going to
3 make that was routine work that recurred
4 every month.

5 That division at that time was
6 responsible for two types of risk
7 adjustment data validation activities. It
8 was responsible -- and this is going back a
9 number of years now. And it was
10 responsible for coordinating and
11 collaborating with the -- with the other
12 divisions in the group or, you know, as
13 needed outside of the group as well in the
14 agency.

15 BY MS. KOPPEL:

16 Q. You said the division at that time was
17 responsible for two types of risk adjustment data
18 validation activities. What were those
19 activities?

20 A. One was a contract-level RADV audit
21 and the other one was for the purpose of
22 calculating a national error estimate for the
23 Part C and the Part D program.

24 Q. What is a RADV audit?

25 A. I'm sorry. So which RADV activity are

1 you referring to?

2 Q. You said one of the activities of the
3 Division of Payment Validation was responsible for
4 was a contract-level RADV audit. And I'm
5 wondering what you meant by contract-level RADV
6 audit.

7 A. Sure. So the contract-level RADV
8 audits were the primary corrective action in order
9 to address the Part C payment error.

10 Q. What do you mean by the Part C payment
11 error?

12 A. So from what I recall there's an
13 improper payment reporting statute. So by law,
14 CMS is required to estimate what a payment error
15 rate is every year and -- and to report that
16 amount. So that's what I was referring to.

17 Q. We're going to come back to RADV
18 audits in a bit. But I'm wondering as the
19 director of this division, what were your
20 responsibilities?

21 MS. KRIEG: Object to form.

22 THE WITNESS: So I was responsible for
23 managing the team of people who was in my
24 division. So doing all of that managerial
25 work. And then whatever items were in

1 my -- in my portfolio. I was also, you
2 know, responsible for managing and
3 shepherding the work to help further that
4 work.

5 BY MS. KOPPEL:

6 Q. What items were in your portfolio?

7 A. Some of the main ones that I recall
8 are the ones that I just mentioned, the
9 beneficiary payment validation work, payment error
10 work, contract-level RADV work.

11 Q. Thank you.

12 So you meant beneficiary payment
13 validation work. By payment error work, you mean
14 the national payment error?

15 A. Yes.

16 Q. As director, who did you report to?

17 MS. KRIEG: Object to form.
18 Foundation.

19 BY MS. KOPPEL:

20 Q. You can answer.

21 A. My -- I reported to Cheri Rice.

22 Q. And she was your direct report? There
23 was no one in between you and Ms. Rice?

24 A. I was her direct report. There was
25 nobody between me and her.

1 Q. Thank you. Thank you.

2 How long did you work directly for
3 Ms. Rice?

4 A. Directly, it would have been from 2015
5 until I left that position.

6 Q. Okay. So the entire time you were
7 director of division -- of the Division for
8 Payment Validation, Ms. Rice -- you reported to
9 Ms. Rice directly?

10 A. That's correct.

11 Q. You said you were responsible for
12 managing your team as the Division of Payment --
13 at the Division of Payment Validation. Who was
14 your team? What were their names?

15 A. I'm not going to be able to remember
16 all of them, and over the course of that time
17 people came and went as well. So I don't -- I
18 don't recall all of their names.

19 Q. Do you recall some of their names?

20 A. Yes.

21 Q. Who do you recall being a member of
22 your team?

23 A. Okay. So at some point during my time
24 managing that division I remember Sue Billet,
25 David Winchell, Carolyn Kapustij, Mary Anne

1 Brewer, Esmail Essajee.

2 Q. I'm sorry, I'm getting a video error.
3 Is anyone else seeing that as well?

4 A. No.

5 MS. KRIEG: I think there's a little
6 bit of a delay.

7 MS. KOPPEL: Okay. If the --

8 THE VIDEOGRAPHER: I have her frozen on
9 my screen.

10 THE WITNESS: It looks like my
11 connection -- my video connection came out,
12 but it sounds like you can hear me okay.

13 MS. KOPPEL: Yeah. Can we go off the
14 record while we see if we can get
15 Ms. Chaudhuri's video back?

16 THE VIDEOGRAPHER: Sure. The time is
17 11:01 a.m. We're going off the record.

18 (Recess taken from 11:01 a.m. until 11:06 a.m.)

19 THE VIDEOGRAPHER: The time is
20 11:06 a.m. We are back on the record.

21 MS. KOPPEL: While we were off the
22 record, defendants asked the government to
23 produce Ms. Chaudhuri's notes, and I
24 understand that they are objecting on the
25 basis of privilege. Is that correct,

1 Ms. Krieg?

2 MS. KRIEG: That's correct. The notes
3 are attorney-client privileged, and we are
4 not going to produce the notes taken during
5 Ms. Chaudhuri's meeting with her attorneys.
6 So they are attorney-client privileged and
7 we are not going to produce them.

8 MS. KOPPEL: Thank you for your
9 objection. That's noted. Just objecting
10 on the basis of privilege is fine.

11 MS. KRIEG: Okay.

12 BY MS. KOPPEL:

13 Q. Ms. Chaudhuri, before we popped off
14 the record for the technical problem, you were
15 listing the individuals who worked for you when
16 you were a director of the Division of Payment
17 Validation. I think the last name I was able to
18 get was Esmail Essajee?

19 A. Yes, that's right.

20 Q. Who else worked for you while you were
21 a director of the Division of Payment Validation?

22 A. Ron Thompson, Ronald Thompson. I
23 think Maricruz Bonfante, Joanne Davis. I may have
24 said that already. I don't recall. Those are the
25 names that are coming to mind right now.

1 Q. That first name I think you said was
2 Dew Billet -- Drew Billet, is that correct?

3 A. Sue. S-u-e.

4 Q. S-u-e. Thank you for that.

5 Okay. And before you were the
6 director for Division of Payment Validation, you
7 were the deputy director of the Division of
8 Payment Policy; is that correct?

9 A. That's correct.

10 Q. How long did you work as the deputy
11 director for the Division of Payment Policy?

12 A. From 2012 to 2015.

13 Q. So three years? Two, three years?

14 A. Yes.

15 Q. Can you describe what kind of work is
16 handled by the Division of Payment Policy?

17 A. They are responsible for the risk
18 adjustment payment policy.

19 Q. What do you mean by risk adjustment
20 payment policy?

21 A. So for both the Part C and the Part D
22 programs, they're paid based on risk adjustment,
23 and the Division of Payment Policy oversees that
24 work.

25 Q. What is risk adjustment?

1 MS. KRIEG: Object to form.

2 THE WITNESS: It's a payment
3 methodology.

4 BY MS. KOPPEL:

5 Q. Okay. Payment methodology based on
6 what?

7 MS. KRIEG: Object to form.

8 THE WITNESS: Yeah, could you make that
9 question a little more specific, please?

10 BY MS. KOPPEL:

11 Q. Sure. You said that the Division of
12 Payment Policy is responsible for the risk
13 adjustment payment policy. And I am trying to
14 figure out what you mean when you say risk
15 adjustment.

16 MR. BULAND: Objection. If that's a
17 question.

18 MS. KRIEG: Yeah. I join that
19 objection.

20 BY MS. KOPPEL:

21 Q. What do you mean by risk adjustment?

22 MS. KRIEG: Object to form. Vague.

23 THE WITNESS: I mean it's a broad
24 question. It's a payment methodology
25 that's used in many areas including in

1 Part C and D.

2 BY MS. KOPPEL:

3 Q. How is it used in Medicare Part C?

4 MS. KRIEG: Object to form. Vague.

5 THE WITNESS: Really broadly speaking,
6 it's -- it's used to calculate how payments
7 are made to Medicare Advantage plans and
8 Part D sponsors.

9 BY MS. KOPPEL:

10 Q. How does it calculate payment for
11 Medicare Advantage plans?

12 MR. BULAND: Objection.

13 MS. KOPPEL: You can answer.

14 THE WITNESS: So, sorry, can you repeat
15 or specify what -- what exactly you're
16 asking?

17 BY MS. KOPPEL:

18 Q. Yeah. So you said the risk
19 adjustment -- risk adjustment is used to calculate
20 how plans -- how payments are made to Medicare
21 Advantage plans and Part D sponsors. And I'm
22 asking you how does it calculate payment?

23 MS. KRIEG: Object to form.

24 THE WITNESS: Yeah, I mean, it's a
25 really big question that, you know, one --

1 one could take years to study and to
2 explain. So I'm unsure how to like answer
3 that question completely right now.

4 BY MS. KOPPEL:

5 Q. Okay. Let me try a different way.
6 What is your understanding of the methodology used
7 to pay Medicare Advantage organizations in the
8 risk adjustment system?

9 MS. KRIEG: Object to form.

10 THE WITNESS: Well, again, that's --
11 that's a hard question to answer in a sound
12 byte. Every single year CMS proposes the
13 specific payment policies for a particular
14 year and then finalizes them. So --

15 BY MS. KOPPEL:

16 Q. Okay.

17 A. The broad parameters are set out in
18 statutes, you know, the specifics of the
19 methodology are laid out every single year.

20 Q. Okay. Sorry for stepping on you
21 there. I didn't realize you hadn't finished your
22 question.

23 I'm going to ask my colleague to pull
24 up what's been previously marked as Exhibit 1174.
25 I'm going to state for the record that

1 Exhibit 1174 is Bates Stamped USBP069103470.

2 Let me know when that's visible to
3 you.

4 A. Yes, I can see it.

5 Q. Okay. And that's -- that first page
6 of Exhibit 1174, you see your name listed there?

7 A. Yes, I do.

8 Q. And do you recognize this document?

9 A. I recognize some of the content of it.
10 I don't know about like the specific, you know,
11 version of the specific document.

12 Q. Sure. What is it?

13 MS. KRIEG: Object to form.

14 THE WITNESS: The -- the title reads
15 "Medicare Part C Payment Training."

16 BY MS. KOPPEL:

17 Q. Do you recall providing trainings when
18 you were the deputy director of the Division of
19 Payment Policy?

20 A. I do.

21 Q. Was this -- to whom was this training
22 directed?

23 A. Give me a second. Let me see if it
24 says.

25 I flipped through the slides quickly,

1 and I don't see that the slides specify to whom
2 this training was directed.

3 Q. Well, when you provided trainings as
4 the deputy director of the Division of Payment
5 Policy, who did you provide those trainings to?

6 A. I don't recall specifically the
7 trainings, but, generally speaking, we would train
8 internally to the division, to the group, other
9 areas in the agency. We would train -- we would
10 conduct like learning type sessions, I don't know,
11 training sessions I suppose is fine, to, you know,
12 others also in the plan community.

13 Q. When you say others in the plan
14 community, who do you mean?

15 A. Plans primarily.

16 Q. I'm going to ask you to turn to
17 slide 14 of Exhibit 1174.

18 A. Yes.

19 Q. And the slide is titled "Risk
20 Adjustment," and it says, "A method used to adjust
21 payment based on the health status and demographic
22 characteristics of an enrollee."

23 Do you see that?

24 A. Yes.

25 Q. Is that true? Risk adjustment is a

1 method used to adjust payment based on the health
2 status and demographic characteristics of an
3 enrollee?

4 A. Yes.

5 Q. Okay. And CMS uses diagnoses to
6 measure health status; is that accurate?

7 MR. BULAND: Objection.

8 MS. KRIEG: Objection. Object to form.

9 BY MS. KOPPEL:

10 Q. You can answer.

11 A. Yes, CMS does use diagnostic data.

12 Q. It does use diagnostic data to measure
13 the health status of enrollees?

14 A. Yes. I mean, on this slide I just
15 think it's -- I'm not entirely sure what is
16 entirely encapsulated by health status. So what I
17 can say for sure is that diagnostic data is used
18 in risk adjustment.

19 Q. To adjust payment?

20 A. To calculate the payment, yes.

21 Q. Okay. Thank you.

22 What is a risk score?

23 MS. KRIEG: Object to form.

24 THE WITNESS: A risk score is a sum of
25 individual coefficients that is roughly --

1 the text as it's written that there is a
2 documentation standard of the medical
3 record, it's set forth in the regulation,
4 it's consistent with other Medicare
5 prospective payment systems. And that the
6 number of diagnoses may not indicate --
7 what does it say? Are not sufficient for
8 indicating the plan has undertaken the risk
9 of incurring expected costs.

10 BY MS. KOPPEL:

11 Q. So that's in MA. And the next
12 sentence starts with "In FFS Medicare, the actual
13 risk of providing a benefit is assumed regardless
14 of its -- of the diagnosis indicated by the
15 claim -- or on a claim"; is that correct?

16 A. That's what it says, yes.

17 Q. And "Providers are reimbursed for the
18 services provided, which are dictated by the
19 beneficiary's actual condition"; correct?

20 A. That's what it says, yes.

21 Q. Okay. This is what we were discussing
22 earlier the differences between the payment
23 mechanisms between Medicare Advantage and
24 fee-for-service Medicare; is that correct?

25 A. Yes.

1 Q. Okay. So the next paragraph says
2 "Study Approach" -- or actually --

3 A. Yes.

4 Q. Sorry. I want to go up for a second.
5 After this paragraph discusses how fee-for-service
6 claims are paid, it says, "The claim may or may
7 not indicate the diagnosis code for which the
8 beneficiary was treated, but regardless, the
9 annual cost of treating the beneficiary is
10 accurately captured."

11 Do you see that?

12 A. I see that, yes.

13 Q. Do you agree with that statement?

14 A. I had a little bit of trouble
15 following it. So "Providers are reimbursed for
16 services provided which are dictated by the
17 beneficiary's actual conditions. The claim may or
18 may not indicate the diagnosis code for which the
19 beneficiary was treated, but regardless, the
20 annual cost of treating the beneficiary is
21 accurately captured."

22 Yeah, I mean I understand this to
23 say -- when it's talking about the claim, I'm
24 understanding it to mean the claim from the
25 provider to the plan. I'm not 100 percent sure

1 I'm interpreting the way that the author intended.
2 That's the way I would interpret this.

3 Q. So this is in FFS Medicare, so this
4 would be from the provider to CMS?

5 MS. KRIEG: Object to form.

6 THE WITNESS: Okay. So read in that
7 way seem -- yeah, that the claim may or may
8 not -- this is -- again, I have some
9 limitations in terms of my understanding in
10 how things work in fee-for-service. But
11 the way I understand the sentence is that
12 when the provider is seeking reimbursement
13 in fee-for-service that the diagnosis code
14 may or may not be on there, but their costs
15 are.

16 BY MS. KOPPEL:

17 Q. And that's because they're reimbursed
18 for the actual services, so the services have to
19 be represented on the claim?

20 A. That makes sense to me.

21 Q. Okay. The next sentence says, "Thus,
22 we can assume that the CMS risk adjustment model
23 is predicting the average cost for beneficiary
24 accurately."

25 Do you see that?

1 A. I do.

2 Q. Do you agree that the CMS risk
3 adjustment model is predicting the average cost
4 for beneficiary accurately?

5 A. I think that the CMS risk adjustment
6 model does what it is intended to do of predicting
7 the average cost per beneficiary, and I do believe
8 that it does -- it does that accurately.

9 Q. Okay. Says, "Any variation in cost
10 not explained by the HCCs and interaction terms
11 will be explained by the demographic factors -- or
12 sorry -- demographic components of the model."

13 Do you see that?

14 A. I do.

15 Q. Says, "By changing the documentation
16 standards for FFS data from claim to the medical
17 record, the expected costs of each model component
18 would change, but the annual cost for beneficiary
19 would not change."

20 Do you see that?

21 A. I do.

22 Q. Do you agree with that statement?

23 A. I'm not 100 percent sure here in terms
24 of what model component is being referred to.
25 I -- I do agree -- to the extent that this

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CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 14th day of August, 2022.


Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-99

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel. BENJAMIN POEHLING,

Plaintiff,

VS.

UNITEDHEALTH GROUP, INC.,
et al.,

Defendants.

No. CV 16-08697 FMO

SUBJECT TO PROTECTIVE ORDER

Volume 1

DEPOSITION OF SEAN CREIGHTON

Washington, DC

March 23, 2022

Reported by: John L. Harmonson, RPR

Job No. 798205

1 services akin to what was happening at Verscend?

2 A. No. They're very different companies.
3 Avalere is -- I don't know -- more akin to a think
4 tank than an operational organization.

5 Q. Got it.

6 A. You know, it only has 240 employees.
7 It's a very different organization than Verscend.

8 Q. So when you mention a think tank,
9 Avalere from time to time would produce work
10 product that was designed to advise the industry
11 or provide commentary associated with issues that
12 were relevant to the Medicare Advantage insurance
13 plans, for example?

14 A. Sure. There's a couple ways that
15 happens. A primary one is on a routine basis we
16 produce something called Avalere insights which
17 are publicly available, they're on the website,
18 where we will have looked at a particular issuance
19 from the government, a policy pronouncement or
20 proposed rule or so on. We would offer our
21 summary of it, and then some indication of what it
22 might imply for those businesses on a go-forward
23 basis. And generally the purpose of that is to
24 elicit further conversation and more in-depth
25 conversation.

1 But then, of course, the second part is
2 when that actually happens with our clients, we do
3 dive pretty deep into those issues and advise them
4 on the impact of regulatory events on their
5 business.

6 Q. Got it.

7 So let's circle back now and talk a
8 little bit about your time at CMS. Okay? And
9 we're going to get in a few moments to some of the
10 concepts that you talked about when you were
11 giving us your background before. But I really
12 just want to start with some structure.

13 During that time frame from 2000 to
14 2012, I think I heard you say that you were the
15 director for payment policy and risk adjustment.
16 Was that your title?

17 A. The division went through a number of
18 title changes during my time there. First we were
19 the Division of Risk Adjustment Operations, DRAO I
20 believe. And then at some point we became the
21 Division of Payment Policy and Risk Adjustment or
22 something like that. So we had a variety of
23 titles.

24 But the bottom line was from -- I don't
25 remember the exact date. Sometime around 2006 or

1 2007 I became the division director, and we were
2 given responsibility for putting together the
3 advance notice, which is the governing document
4 for payment to MA and Part D plans for the
5 forthcoming year. And at that point, yeah, I
6 suppose that defined the job from there on out.

7 Q. Okay. And as director, who did you
8 report to?

9 A. I reported to the director of our
10 group, which is the Medicare Plan Payment Group.

11 Q. And who was the director of the
12 Medicare Plan Payment Group?

13 A. Initially in that formulation, it was
14 Tom Hutchinson, and then later on Cheri Rice.

15 Q. And I gather that either Mr. Hutchinson
16 or Ms. Rice in turn reported up.

17 A. Sure. All the group directors report
18 directly to the center director for the Center for
19 Medicare which is responsible for both
20 fee-for-service and Medicare Advantage.

21 Q. Okay. And you mentioned the expression
22 "fee-for-service." And for purposes of the court
23 and jury, what do you mean by fee-for-service?

24 A. Fee-for-service, sometimes referred to
25 as traditional Medicare or original Medicare, is

1 the system which Medicare started out with,
2 essentially where CMS is the direct payer to
3 providers, hospitals, physicians, durable medical
4 equipment, you know, the whole gamut, hospice and
5 so on, home health.

6 So in that instance, typically the
7 government puts out a fee schedule which these
8 providers agree to abide by. They provide
9 services to beneficiaries who are enrolled in
10 Medicare. They bill the government directly, and
11 those bills are paid directly by the government.

12 Q. And so when you say "fee-for-service,"
13 is it fair to say that what you're referring to is
14 the fact that providers are paid for a particular
15 service rather than based upon the illness that
16 the particular patient might have?

17 A. Yes.

18 MS. McMAHON: Objection; vague.

19 You can answer.

20 THE WITNESS: Yes. I mean the way the
21 system evolved is that each -- excuse me. Each
22 procedure is codified that the providers do, I
23 suppose for want of a better term, and then a
24 payment rate that's associated with that procedure
25 once it's conducted during the course of a visit

1 and doing procedures on their various parts.

2 Q. What are the other advantages to the
3 Medicare Advantage, to the MA plan program as a
4 whole that you are familiar with?

5 A. My understanding, it's gone -- it's a
6 historical arc. Right? So in the early days, the
7 advantage for companies like Kaiser in the West
8 or --

9 Q. Let me stop you. I want to focus on
10 advantages to patients as well.

11 A. Yeah, that's where I was going.

12 The idea was obviously you are looking
13 after your enrolled population holistically and
14 providing all the services, and you could do that
15 in a more coordinated way within this managed care
16 environment. And there were companies on the East
17 Coast doing the same kind of thing too.

18 I think at that point managed care was
19 relatively small but it had a model of looking
20 after the whole patient and providing all these
21 services, sometimes at the same site. They would
22 have everything available so the person didn't
23 have to run all over the place going to 20
24 different procedures and testing facilities and so
25 on and so forth.

1 I think at some point the managed care
2 model grew or it became more, I would say,
3 insurance-oriented. It was more a risk-taking
4 exercise where the companies were, I think to be
5 frank, more in the business of controlling
6 utilization than holistically managing care. I
7 think now it's evolved again to where the
8 companies have become pretty sophisticated in
9 terms of analytics around the patient. Right?
10 How is the patient interacting with the
11 organization? Has the patient interacted with the
12 healthcare system? They've become sophisticated
13 in analytics in terms of signaling where things
14 might be going wrong and closing gaps for people.
15 And they provide a whole range of supplemental
16 services that you can't get in fee-for-service.

17 So I would say there has been an arc
18 here. We're not quite at the end of the patient's
19 interest of the arc yet but we're getting there,
20 you know.

21 Q. So if you were going to identify for us
22 the advantages to the patients, you mentioned the
23 fact that there are some services that are
24 available on the Medicare Advantage side that are
25 not available in fee-for-service. What are some

1 other advantages?

2 A. Yeah, there are lots of other ones
3 beyond that. One of the big ones, obviously, from
4 the early days was paperwork. Right? Simple as
5 that. You know, people were getting all sorts of
6 statements and explanations of benefits and so on
7 and so forth, getting bills they didn't understand
8 from multiple providers and so on and so forth.
9 Typically that doesn't happen in the managed care
10 environment. So the healthcare company -- so
11 that's one major advantage.

12 Another one is Medicare Advantage has a
13 concept called the maximum out-of-pocket, which
14 means that in any given year the amount that a
15 beneficiary can spend out of pocket is capped. It
16 was around 6,800 recently, like that; it might be
17 a little higher now.

18 That does not exist in fee-for-service.
19 There's unlimited liability. So in
20 fee-for-service, Medicare people either have to
21 buy a supplemental insurance to cap their
22 liability, or a lot of people in traditional
23 fee-for-service still have supplemental insurance
24 through either a Medicaid program or an employer
25 program. So about 80 percent of

1 fee-for-service -- people in fee-for-service have
2 or must have -- you know, kind of have to have
3 some other program to control the cost. You don't
4 need that in Medicare Advantage because of this
5 concept of the maximum out-of-pocket.

6 Q. Got it.

7 A. The other advantage is obviously that
8 the medical and the drug benefit are integrated
9 typically in Medicare Advantage. So these plans
10 are both Part C, meaning Part A plus B equals C
11 plans, and Part D plans. And within that there is
12 a whole other level of advantage, too, because the
13 Part C plans can use their rebate to reduce cost
14 sharing for drugs under Part D, and generally do,
15 and generally have better -- they typically have
16 co-pays rather than coinsurance for drugs under
17 Part D, particularly for preferred drugs, generics
18 or preferred brands.

19 So there's a whole range of additional
20 benefits that accrue from joining a Medicare
21 Advantage plan for a beneficiary.

22 Q. So senior citizens will potentially get
23 their drugs at a cheaper cost under the MA plan?

24 A. Absolutely.

25 Q. Okay. Any other advantages to the

1 patients that you can think of as you sit here?

2 A. Well, the other big one in more recent
3 times has been an explosion in what are called
4 supplemental benefits. There are different
5 categories of supplemental benefits ranging -- so
6 supplemental benefits can be categorized in a
7 number of different ways. So there's five
8 different types of supplemental benefit that
9 people get access to.

10 The first one is a reduced Part C
11 premium, but to actually activate this Part C
12 plans typically don't have any premiums so that's
13 not a biggy.

14 You can also use the -- Part C plans
15 can use their money to reduce Part D premium.

16 They can provide Part C supplemental
17 benefits, which means in addition to everything
18 else, they can provide preferential cost sharing
19 for medical benefits relative to fee-for-service.
20 In fee-for-service, typically cost sharing, unless
21 it's capped in some other way, is typically
22 20 percent. That could be a coinsurance rate. So
23 they can reduce that.

24 They can, as I said, do the Part D
25 cost-sharing reductions. And then there are other

1 supplemental benefits which can be mandatory or --
2 mandatory or optional supplemental benefits which
3 can comprise things such as transportation to
4 medical visits, housing, gym membership. There's
5 social isolation programs. But the big ones, the
6 three biggies which people take advantage of
7 typically are dental, vision and hearing, which
8 are not provided in traditional fee-for-service
9 and are routine at this point. I mean some kind
10 of dental benefit is almost table stakes for a
11 Medicare Advantage plan.

12 Q. Okay. So just to summarize,
13 beneficiaries or senior citizens who participate
14 in Medicare Advantage programs have an array of
15 additional benefits that are not available to them
16 in fee-for-service, and a number of those include
17 reduced costs and additional benefits that you
18 have been describing to us. Is that a fair
19 summary, Mr. Creighton?

20 A. That is. And if I have time to put
21 notes together, I could lay it out more
22 systematically, but I think I covered most of
23 them.

24 Q. Thank you. Okay.

25 Now, sticking with your time at CMS,

1 you mentioned that part of your responsibility was
2 developing something called the risk adjustment
3 model. And if you could explain to us, what do
4 you mean by the risk adjustment model?

5 A. Sure. Risk adjustment models are
6 models that essentially predict a number of
7 outcomes. Right? So you can have risk adjustment
8 models that predict mortality, probability of a
9 hospital visit, or cost, right, among other
10 outcomes.

11 So any model that's used to predict
12 some level of risk in the population can be
13 referred to as a risk adjustment model. So the
14 ones that we're talking about here, right, there
15 are a range of risk adjustment models that are
16 constructed or calibrated to estimate predicted
17 cost, healthcare cost. Right? And there are a
18 variety of these models. Some of them are used
19 more commonly in one sphere rather than another.

20 So there is one called CDPS that's most
21 common in Medicaid. There's an ACG model that's
22 sometimes used in Medicaid as well. There's the
23 DXCG which is the parent of the CMS HCC model
24 that's used in Medicare. 3M has a model.

25 So there are a variety of these models

1 this fact that in the fee-for-service side there
2 is not as an incentive to find and report all of
3 the diagnoses associated with a particular
4 patient. Is that a fair statement?

5 A. That's fair.

6 Q. And he goes on to write: "If, for
7 example, a fee-for-service patient with
8 quadriplegia and a urinary tract infection has an
9 office visit for treatment of the UTI, the payment
10 to the physician will be no more if the UTI and
11 quadriplegia are reported on the claim than if
12 only the UTI is reported. Coding guidelines
13 specify that the quadriplegia can legitimately be
14 coded if it contributes to the complexity of care,
15 but unlike the situation for MA plans, in
16 fee-for-service there is no incentive to report
17 more than one diagnosis."

18 Do you agree with that?

19 A. Correct.

20 Q. Okay. It goes on to say: "In
21 contrast, MA plans have a strong incentive to do
22 so." And it says that "In addition to the
23 incentives to report more completely, the method
24 of collecting diagnostic information also provides
25 MA plans additional opportunities to increase risk

1 scores."

2 Do you agree with that proposition?

3 A. If you incorporate sort of what he's
4 written below. You know, MA plans may also review
5 medical records and can report all diagnoses that
6 are supported in the record.

7 So I think what it really probably
8 should say is that the allowed methods of
9 collecting the allowed and sort of, if you like, I
10 don't know, routine methods of collecting
11 diagnoses. But yeah, obviously these mechanisms
12 are actually available in fee-for-service too. So
13 a physician could potentially review a medical
14 record and submit an amended claim even if their
15 first claim only said UTI. If they wanted to put
16 in paraplegia on it, they could submit an amended
17 Part B claim too, but there is no incentive to do
18 so.

19 Q. Okay. And you were going exactly to
20 the portion of this paragraph that I wanted to get
21 to, Mr. Creighton, which is that the notion that
22 MA plans may also review medical records and can
23 report all diagnoses that are supported in the
24 record, including those that were not reported by
25 physicians on any healthcare claim or Encounter

1 record. Right?

2 A. Correct.

3 Q. And there is nothing illegal or
4 improper about that, is there?

5 A. No.

6 Q. Okay. And in fact, when you were at
7 Verscend, I think you were testifying earlier that
8 part of the coding review that Verscend provided
9 to its clients was that exact exercise, reviewing
10 medical records to report additional diagnosis
11 codes that appeared on those medical records;
12 correct?

13 A. Correct.

14 Q. Okay. And nothing fraudulent about
15 that exercise, was there?

16 A. No, it's standard. It's fairly
17 standard industry procedure.

18 Q. Okay. Now, if we go to the next page,
19 E4, Dr. Kronick writes: "As noted" -- on the top
20 of E4. "As noted, payment to MA plans is
21 calibrated based on coding patterns in
22 fee-for-service. If, for example, Jane Doe would
23 have a risk score of 1.0 if she were in
24 fee-for-service, the implicit assumption in the
25 design of the MA payment system is that she would

1 therefore the pattern, the relationship between
2 particular factors in the model, particularly
3 diseases, and the incremental cost would be the
4 same in MA as in fee-for-service.

5 BY MR. SCHINDLER:

6 Q. Okay.

7 A. Yeah.

8 Q. And he goes on to say in that second
9 paragraph on that left column there on page E4, if
10 you go towards the bottom, the last sentence,
11 Dr. Kronick writes: "The goal of the risk
12 adjustment system is to assure that MA plans that
13 enroll sicker-than-average beneficiaries are paid
14 appropriately, but not to increase payment for an
15 average beneficiary."

16 Do you see that?

17 A. Yes.

18 Q. And would you agree with that, that the
19 goal of the risk adjustment system is to do what
20 Dr. Kronick has outlined here?

21 A. Except that I would say it's not just
22 to ensure that plans that enrolled
23 sicker-than-average beneficiaries are paid
24 appropriately, it's to ensure that plans that
25 enroll any beneficiary whether they're sicker or

1 healthier are paid appropriately.

2 Q. Okay, that's fair. And that's based
3 upon what you've testified earlier, that part of
4 the goal of this whole risk adjustment model was
5 designed to achieve; correct?

6 A. Correct.

7 Q. Okay. Now, if you note over on
8 page E5, at the top of E5, at the very beginning
9 there is a sentence that begins: "However,
10 fee-for-service coding is known to be both
11 incomplete and variable."

12 Do you see that?

13 A. Yes, indeed.

14 Q. Okay. And that's consistent with what
15 you testified about earlier, that you discovered
16 at CMS that this fee-for-service coding was in
17 fact both incomplete and variable. That's what
18 you told us about earlier; correct?

19 A. Correct.

20 Q. Okay. And he noticed -- he notes that
21 "Incomplete coding is evidenced by lack of
22 persistence in coding of chronic conditions." And
23 he gives an example that "For instance, among
24 Medicare beneficiaries diagnosed with quadriplegia
25 in one year, only 61 percent had a diagnosis of

1 quadriplegia reported in the subsequent year."

2 Do you see that?

3 A. Yeah.

4 Q. What he's saying is that a person who
5 was a quadriplegic in one year likely does not
6 magically not become a quadriplegic in the next
7 year, that nevertheless, only 61 percent of them
8 end up with that diagnosis in the following year;
9 correct?

10 A. Correct.

11 Q. And in the context of this
12 fee-for-service model we've been talking about,
13 what would be the payment impact in terms of --
14 for the MA plan that insured this population of
15 quadriplegics if in the subsequent year 61 --
16 almost 40 percent of them effectively no longer
17 appeared as quadriplegics? What would that impact
18 be?

19 MS. McMAHON: Objection; calls for
20 speculation.

21 THE WITNESS: So when the model is
22 calibrated, it's calibrated on the 61 percent of
23 fee-for-service beneficiaries who are coded.
24 Right? So that means that the costs associated
25 with that incremental coefficient, you know,

1 really are the costs for this 61 percent and the
2 other 39 percent aren't there. Right? Their
3 costs are not -- they're there, they're in the
4 model, they're just somewhere else. They're in a
5 different coefficient, they're in a different
6 disease.

7 So really the answer to that question,
8 it's a rate question. So if you've got a health
9 plan, and let's say it's got a thousand
10 quadriplegics, which would be a lot but let's say
11 it did. If 610 of them are diagnosed as
12 quadriplegics, that plan would generally be okay.

13 So it's not just the coefficient. It's
14 the proportion of -- you know. Now, if the
15 implied rate -- as I say, it's just not that
16 incremental coefficient. It's the implied
17 proportion of quadriplegics. If the health plan
18 essentially has the same proportion in reality as
19 fee-for-service and codes more than 61 percent,
20 they will do better. If they find less than that
21 rate, they will do worse.

22 BY MR. SCHINDLER:

23 Q. Okay. So let's talk about this in the
24 context of over-coding.

25 A. Sure.

1 those available to the public. Okay? So
2 obviously the advance notice is one. The rate
3 announcement itself. Sometimes prior to that,
4 based on consultation with industry or depending
5 on whether we want to -- we at the time being
6 CMS -- elicit comment, there might be white papers
7 put out in advance, so on and so forth.

8 In this case, what had happened here I
9 believe is that we had gone out with a proposal
10 for coding intensity I believe in 2008, '09. We
11 did not finalize that if memory serves me
12 correctly.

13 But the purpose of this paper would
14 have been to fully elucidate the methodology
15 behind the development of the coding intensity
16 factor and let people know -- give people more
17 detail on how it was done.

18 And publishing this type of
19 information, the Healthcare Financing Review,
20 which previously had been in paper format as well
21 as electronic, was sort of just a fairly standard
22 way of doing this, the same as any number of
23 articles in this journal over the years, just
24 elaborating on methodological changes.

25 Q. Okay. Got it.

1 If you turn to what's been marked at
2 the bottom, the last three digits 588, the
3 introduction page.

4 A. Okay, here we go.

5 Q. And this is the introductory paragraph
6 of this paper. And you wrote, or you and your
7 colleagues wrote: "Payments to Medicare Advantage
8 plans are risk adjusted to account for the
9 relative health resources needed to provide care
10 for each beneficiary." And there is a citation
11 there to somebody named Pope. I take it, is that
12 Greg Pope?

13 A. That is Greg Pope.

14 Q. And who was Greg Pope?

15 A. Greg Pope worked for a company I
16 mentioned earlier, RTI, which back in the day was
17 called Health Economics Research. He is one of
18 the original developers of the DXCG model which is
19 the forerunner of the CMS HCC model and a major
20 figure in risk adjustment, pay-for-performance,
21 all things payment-related when it comes to the
22 fee-for-service system.

23 Q. Got it.

24 And you go on to write: "Payment for
25 MA enrollees is based on the diagnoses that are

1 reported for them by the plans in which they are
2 enrolled. If an MA plan reports more or more
3 serious diagnoses for a beneficiary, the plan is
4 paid more than if fewer or less serious diagnoses
5 are reported."

6 I take it you agree with that
7 statement.

8 A. That is correct in general.

9 Q. Okay. And then you write: "The
10 Medicare payment system provides strong incentives
11 for MA plans to identify and report diagnostic
12 information as completely as possible."

13 Now, you and your colleagues recognized
14 that the MA plans had an incentive to ensure that
15 all diagnoses for the beneficiaries they insured
16 were captured; right?

17 A. Absolutely.

18 Q. And you understood that the MA plans
19 were engaged in these reviews of medical records
20 to look for additional diagnoses codes; right?

21 A. True.

22 Q. And that was something that was
23 generally known within your division at CMS; is
24 that correct?

25 A. Yes.

1 MS. McMAHON: Objection; calls for
2 speculation.

3 BY MR. SCHINDLER:

4 Q. And there was nothing illegal or
5 improper about plans looking for additional codes
6 to ensure that the risk scores for the
7 beneficiaries accurately reflected their true
8 medical conditions; right?

9 MS. McMAHON: Objection to extent it
10 calls for a legal conclusion.

11 BY MR. SCHINDLER:

12 Q. You can answer.

13 A. The activity on its face is not
14 contrary to statute or regulation as far as I
15 could tell. Whether every element of it was
16 proper or not, I couldn't opine on.

17 Q. Okay. Well, for purposes of the jury
18 and laymen right here, when you say that "the
19 activity on its face is not contrary to statute or
20 regulation as far as I could tell," is that just
21 another way of saying that the conduct was not
22 illegal as far as you knew?

23 MS. McMAHON: Objection; calls for a
24 legal conclusion.

25 THE WITNESS: I think it's another way

1 of saying that doing this -- or engaging in these
2 type of activities was perfectly proper. However,
3 I have no knowledge at that time that every aspect
4 of what each company out there in the marketplace
5 was doing was either legal or proper.

6 BY MR. SCHINDLER:

7 Q. Okay, fair enough. You weren't privy
8 to all the different review exercises?

9 A. Correct.

10 Q. But the concept itself of MA plans
11 looking for additional diagnosis codes for the
12 beneficiaries to augment their risk scores itself
13 was not improper, to use your words?

14 A. No, it was not improper, and it was
15 most likely a foreseeable consequence of the
16 incentives built into the model.

17 Q. Just give me one second here.

18 If you turn to page 589, the next page,
19 this is a carryover of the "Background" section of
20 the paper, if you will, that starts on 588.

21 A. Sure.

22 Q. And I will start on page 588,
23 Mr. Creighton. You'll see that last paragraph
24 says: "The critical question in determining
25 whether MA risk scores are calculated

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that SEAN CREIGHTON, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the
12 transcript was requested.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in
16 the outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 29th day of March, 2022.

19

20

21 _____
JOHN L. HARMONSON, RPR

22 My commission expires: 04/14/26

23

24

25

EXHIBIT D-100

UNITED STATES DISTRICT COURT
FOR THE CENTAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

United States of America, ex rel.

Benjamin Poehling,

Plaintiffs,

vs.

No. 16-08697

UnitedHealth Group, Inc., et al.,

Defendants.

DEPOSITION

of Sean Creighton, taken pursuant to
notice to take oral deposition, given
remotely on the 4th day of October,
2022, before Nathan D. Engen, a notary
public in and for the State of
Minnesota.

1 Fee-for-Service Adjuster accounts for
2 difference in documentation
3 standards..." Do you see that?

4 A Yes.

5 Q All right. And that's the -- it is
6 your summary of what the
7 Fee-for-Service Adjuster accounts for;
8 is that correct?

9 MS. MCMAHON: Objection.

10 THE WITNESS: That is
11 correct.

12

13 By Mr. Schindler:

14 Q And as you note here, "Because
15 Fee-for-Service claims data are not
16 audited to determine if the diagnosis
17 are supported by medical record, there
18 are undocumented errors in
19 Fee-for-Service data as research
20 shows." Do you see that?

21 A Yes.

22 Q And that's something that you believed
23 in 2019; correct?

24 A That is correct.

25 Q And still believe today; correct?

1 A That's correct.

2 Q Okay. And you indicate that, "Absent
3 an adjuster to account for such errors,
4 RADV audits would be contrary to the
5 statutory requirements."

6 And then you cite to statute
7 provision of Title 42 the United States
8 Code. And I'm quoting you here,
9 "...which states that risk adjustment
10 must achieve actuarial equivalence
11 between Fee-for-Service and Medicare
12 Advantage." Correct?

13 A That's correct.

14 Q All right. And you still believe that
15 today; correct?

16 A Yes.

17 Q Okay. And at the -- toward the top of
18 Page 3 of your article, it's a carry-on
19 paragraph from the bottom of Page 2
20 which talks about the revised payment
21 methodology that would remove the
22 Fee-for-Service Adjuster -- if you look
23 on the carry-on.

24 A (Indicating).

25 Q And at the top of Page 3 you note that

1 "...that you, we..." this is in the
2 context of this article at Avalere
3 "...have previously critiqued." Is
4 that correct?

5 MS. MCMAHON: Objection.

6 THE WITNESS: So...

7 MR. SCHINDLER: Let me
8 correct.

9 THE WITNESS: Yeah.

10

11 By Mr. Schindler:

12 Q Let me rephrase. Let me rephrase.
13 Let's go back to the bottom of Page 2,
14 to make this easier.

15 At the bottom of Page 2 you
16 wrote, "CMS has proposed that the
17 Fee-for-Service Adjuster is not
18 warranted based on the study." Then
19 there's a long citation --

20 A Sure.

21 Q -- for the study. And it continues,
22 "That we," and the 'we' here is
23 Avalere; correct?

24 A (Indicating).

25 Q "...have previously critiqued." And

1 there's citations to some other Avalere
2 publications. Is that an accurate
3 description?

4 MS. MCMAHON: Objection --

5 THE WITNESS: Give me one
6 moment.

7 MS. MCMAHON: -- vague.

8 THE WITNESS: (Witness
9 reading to self). (Chuckling). It's
10 actually correct. What I don't see is
11 where it says, "We previously
12 critiqued." I may be --

13

14 By Mr. Schindler:

15 Q -- it's at the bottom of --

16 A -- missing that.

17 Q -- Page 2.

18 A Bottom of Page 2.

19 Q "The revised payment methodology..."

20 Do you see the paragraph at the bottom
21 of Page 2?

22 A Yeah, yeah.

23 Q Okay. "The revised payment

24 methodology..." continues, "CMS has

25 proposed that the Fee-for-Service --

1 A Correct.

2 Q -- is not warranted based on a study,"
3 that's in bold. Do you --

4 A Yeah, yeah.

5 Q -- see that?

6 A Sure.

7 Q And there's a reference to the -- to
8 the --

9 A Yep.

10 Q -- and then at the bottom, "That we,"
11 and it carries over to Page 3, "...have
12 previously critiqued."

13 A I'm gonna show you Page 2 and if you
14 would be so kind to show me where it
15 says, "We," because I am missing it
16 entirely.

17 REPORTER'S NOTE: Whereupon,
18 a discussion is conducted
19 off the record.

20 MS. MCMAHON: I'm actually
21 missing it, too, in fairness.
22 (Laughing).

23

24 By Mr. Schindler:

25 Q In -- in your -- okay. It's because --

1 I'm sorry, if you look a little further
2 up in the paragraph --

3 A Okay. Got it.

4 Q -- it's not a carryover to Page 2 or 3.
5 For some reason my version of the
6 printout is printed differently.

7 A Okay.

8 Q At the bottom full paragraph on Page 2.

9 A Okay.

10 Q Okay? And it starts with, "The revised
11 payment methodology..." Right?

12 A Yep.

13 Q Are we together now?

14 A We have been except for the bit about
15 the, "We."

16 Q (Laughing).

17 MS. MCMAHON: (Laughing).

18

19 By Mr. Schindler:

20 Q I'm the one -- I'm one who wasn't
21 there, so apologies, Mr. Creighton.
22 All right.

23 So you indicate there that
24 Avalere has previously critiqued that
25 study; is that an accurate description

1 of what you wrote there?

2 A It's an accurate description; I don't
3 know what I wrote there because it's
4 not on the piece of paper. (Laughing)
5 Sorry to be a pain. (Laughing).

6 Q (Laughing).

7 A Oh, geez.

8 Q All right. Let's get to the same
9 place. If you go to --

10 A (Indicating).

11 Q -- bottom paragraph, Paragraph 2?

12 A (Indicating).

13 Q The first sentence, "The revised --

14 A Yeah.

15 Q -- methodology..."

16 A Yeah, yeah. Got all that.

17 Q Okay. And it continues in the middle
18 there, "The revised payment
19 methodology --"

20 A -- ah, "that we have previously
21 critiqued." Okay. Got it. We're on
22 the same page.

23 REPORTER'S NOTE: Whereupon,
24 a discussion is conducted
25 off the record.

1 By Mr. Schindler:

2 Q Let's slow down and though we've had
3 confusion, let's clear it up.

4 You wrote at the bottom of
5 Page 2 that, "The revised payment
6 methodology removed the Fee-for-Service
7 Adjuster, CMS has proposed that the
8 Fee-for-Service Adjuster is not
9 warranted based on the study," which
10 you cite there, "that we, and the 'we'
11 here is Avalere, have previously
12 critiqued," and that's in bold, in
13 reference to some other studies.

14 Is that an accurate
15 description of what you wrote?

16 A Absolutely.

17 Q Okay. All right. Now, you go on to
18 write that, "CMS suggests that it
19 assessed" -- sorry. Let me start
20 again.

21 "CMS suggests it assessed
22 the difference in risk scores that
23 would occur from a model based on
24 unaudited Fee-for-Service data (the
25 current model), versus a model

1 group HCCs, and the costs; right?

2 So you would expect, at a
3 minimum, if you -- the -- the general
4 expectation would be if you take out
5 diagnosis that are in error, you have
6 the true population.

7 So the co -- the -- the
8 prediction for the true population
9 should differ from the prediction with
10 the population that says, "Error
11 embedded."

12 Q Okay. Can I stop you? Because I want
13 to break that down. When you say 'if
14 you remove the errors --

15 A Right.

16 Q -- and have the true population,' is
17 what you're saying that if you remove
18 the errors, you will have the true
19 population of the beneficiaries who
20 suffer from that condition?

21 A Correct.

22 Q And you, therefore, would have the
23 accurate population upon which to
24 distribute the cost associated -- the
25 incremental costs associated.

1 A Ab -- absolutely, yeah.

2 Q Okay. And -- go ahead and continue.

3 A So when that happens you expect either
4 (chuckling), you're gonna take out
5 people most likely who differ from the
6 population with the error.

7 And there's all sorts of
8 reasons for that, but, you know. So it
9 can cause coefficients to either go up
10 or go down, but the chances they stay
11 more or less exactly the same seems
12 pretty low; right?

13 Q And going back to that notion of
14 removing from the population the
15 erroneous diagnosis codes so that you
16 have the true population that suffer
17 from the conditions, you would expect
18 the costs, the incremental costs, of
19 caring for that condition to rise?

20 A That has --

21 MS. MCMAHON: -- objection
22 to form. You can go ahead.

23 THE WITNESS: That -- that
24 has been my expectation. The -- our
25 study showed that it was a bit more

1 complicate than that.

2 So, yeah, that's normally
3 the expectation. If you think about a
4 population who actually have cancer,
5 you know, and you measure them very
6 accurately and you look of the cost
7 versus somehow you've got a bunch of
8 miscodes and they really have something
9 else.

10 Cancer is expensive, so you
11 would expect the coefficients for the
12 true population to be higher than one
13 with a bunch of other miscellaneous
14 stuff mixed in there.

15 However, it turns out it's
16 not, like a lot of statistical stuff,
17 it's not quite as simple as that. So
18 we found in our studies, sometimes they
19 rise, sometimes they go down.

20 But on -- on average what
21 you do know is they're gonna be
22 different, they're... You know. So I
23 agree with your initial hypothesis, it
24 was my hypothesis, too.

25 Turns out it's not true for

1 all conditions across the model.

2 MR. SCHINDLER: Okay.

3

4 By Mr. Schindler:

5 Q But -- but fundamentally the concern
6 you had here with the study that CMS
7 had conducted is that ultimately the
8 methodology they employed seemed to be
9 flawed to you; correct?

10 A That is correct.

11 MS. MCMAHON: Objection.

12 THE WITNESS: And I can tell
13 you why.

14 MR. SCHINDLER: All right.

15 THE WITNESS: If you want.

16

17 By Mr. Schindler:

18 Q In fact, I want to -- if you go a
19 couple pages back, you'll get to a -- a
20 section, and unfortunately your -- it's
21 -- it's not numbered.

22 But if you continue back to
23 probably about the 6th page, you'll get
24 to a section where the header that says,
25 "The methodology includes steps that

1 minimize the impact of the
2 Fee-for-Service Adjuster regardless of
3 the error rate in the underlying data."

4 A Right.

5 Q Tell me when you're there.

6 A I'm there.

7 Q Okay. And you wrote here that, "CMS
8 applied the IPARS adjustment factor."

9 And let's stop for a moment.

10 What -- what is IPARS adjustment factor
11 in -- in plain English?

12 A That is a great question. I'm not sure
13 that even to this day I can explain
14 what it is in plain English, or any
15 other language really. Um...
16 (Laughing).

17 You know, essentially it was
18 an adjustment factor that once the
19 initial study had been critiqued, CMS
20 went back and, you know, they had to re
21 -- reestimate their initial study
22 because they'd lost the initial data
23 sets.

24 But they went back and they
25 did that. And then they came up with

1 this other factor which is based on
2 some theory I still, for the life of
3 me, don't understand.

4 Um... But, basically, there
5 needed to be a correction to the model
6 coefficients that essentially removed
7 their own finding of the necessity for
8 a Fee-for-Service Adjuster.

9 And they called this thing
10 the IPARS. I'm -- I'm gonna tell you
11 this is some differential between the
12 corrected and uncorrected models.

13 I still don't understand
14 what this thing is. All I know is that
15 it basically mathematically reversed
16 the finding that they had just created,
17 magically, and they called it the IPARS
18 adjuster.

19 Q Okay. Let's go on and talk more about
20 that. You wrote that the IPARS
21 adjustment factor -- that, "CMS applied
22 the IPARS adjustment factor to the
23 coefficients of each of the 50 model
24 simulations, normalizing them such that
25 the average predicted risk from each of

1 whatever number you pick, but to 1.0
2 typically, you just divide through by
3 the mean.

4 You divide everything -- all
5 these coefficients through by the
6 average and then it turns the dollars
7 into, you know, they're based on 1 and
8 if something's higher than 1 it's
9 bigger and if it's lower than one it's
10 smaller; right?

11 So it's normal -- it's
12 called normalization. So doing
13 something like that is quite normal
14 with model coefficients; it's not
15 unheard of.

16 Sometimes you have to make
17 adjustments; right? After you've done
18 the model to normalize to whatever
19 population you might want to normalize
20 to; right?

21 That's, again, not totally
22 unheard of, there's lots of techniques
23 for doing that kind of thing, you know
24 to make sure you've got your 1.0.

25 This is very important when

1 it comes to actuarial equivalence and
2 that sort of thing.

3 However, what CMS was doing
4 here essentially was saying,
5 (chuckling), "We're gonna normalize
6 everything back to the -- the costs on
7 the theory that somehow or other the,"
8 I still don't get this one honestly,
9 "On the theory that somehow or other if
10 you normalize everything back to the
11 actual cost" -- which should be the
12 same as the prediction from the model,
13 then I don't know what the heck they
14 were trying to do honestly. But that's
15 -- that's essentially what they did.

16 The problem is, the cost
17 doesn't vary whether you've corrected
18 data or uncorrected data; right?

19 So they just basically
20 normalized this corrected model back to
21 the uncorrected model. And I'm like,
22 "Okay. Well, why?" Right?

23 It's still under -- like
24 let's -- sure you can do this, but like
25 it makes no sense and all you're doing

1 is eliminating the results you just
2 found; right?

3 So you've corrected it and
4 now you've normalized it back and
5 uncorrected it again, so...

6 Q Well, let's try to break that down a
7 little bit if we can and put it into --

8 A Sure.

9 Q -- to -- to English if we can.

10 A (Laughing).

11 Q If you go to the -- it continues, or
12 you continue, you wrote in -- in the
13 next paragraph down, it starts with,
14 "CMS describes the IPARS adjustment..."
15 Do you see that paragraph?

16 A Yes.

17 Q Okay. Then you go down to the bottom
18 there you wrote, "The implementation of
19 the IPARS -- of the IPARS, amounts to a
20 complete negation of the findings of
21 the study because CMS normalized the
22 coefficient resulting from audited data
23 by using the mean expenditures of the
24 uncorrected data set."

25 A Correct.

1 Q Okay. And is that essentially a
2 summary of what you were just
3 explaining to us a moment ago?

4 A Yes, it is.

5 Q And is it fair to say, Mr. Creighton,
6 that before application of the IPARS
7 adjuster, the CMS study found that
8 about 80 percent, or at least a
9 substantial majority of the
10 coefficients, had gone up when
11 calibrating --

12 MS. MCMAHON: Object.

13

14 By Mr. Schindler:

15 Q -- a data set with the errors removed?

16 MS. MCMAHON: Objection --

17 THE WITNESS: I --

18 MS. MCMAHON: -- calls for
19 speculation.

20 THE WITNESS: And I actually
21 at this point in time, without
22 reviewing it, do not recall the
23 percentages or the results of their
24 study in that level of detail.

25 MR. SCHINDLER: Okay.

1

2 By Mr. Schindler:

3 Q But, in fact, the majority of them had
4 gone up even if you don't recall the
5 exact percentage?

6 A That --

7 MS. MCMAHON: Objection.

8 THE WITNESS: -- would not
9 surprise me. I don't recall the exact
10 percentage right now.

11 MR. SCHINDLER: Okay.

12

13 By Mr. Schindler:

14 Q So just to be clear, you were talking
15 over --

16 A Oh.

17 Q -- Ms. McMahon so, again, I just want
18 to make clear for the record that, even
19 if you don't recall the exact number
20 whether it was 80 percent or 70
21 percent, the substantial majority or a
22 majority of the coefficients had gone
23 up when calibrating on a data set with
24 the errors removed; right?

25 MS. MCMAHON: Objection.

1 THE WITNESS: I could
2 confirm that if I had the numbers in
3 front of me right now, but I do not,
4 so...

5
6 By Mr. Schindler:

7 Q If you go down to the very next
8 paragraph, it begins with, "The IPARS
9 formula produces..." Do you see that?

10 A Yeah.

11 Q All right. You say, "The IPARS formula
12 produces a factor that, when applied,
13 reduces the risk score produced from
14 the audited model on average to be
15 equal to the risk score --

16 A Yeah.

17 Q -- from the unaudited model.

18 With such an adjustment in
19 place, the revised model will never
20 show a difference from the original
21 model.

22 Indeed, as the result of the
23 IPARS adjustment, even extraordinarily
24 high Fee-for-Service error rates would
25 be effectively negated and would have

1 no impact on the model CMS used for its
2 study." Do you see that?

3 A Yes, I do.

4 Q And do you agree with what you wrote in
5 2019?

6 A I do.

7 Q And so as a practical matter, even if
8 there were 90-percent error rates in
9 the Fee-for-Service population data set
10 under -- using this IPARS formula that
11 was employed in the CMS study, there
12 would be no need for Fee-for-Service
13 Adjusters; is that correct?

14 A That is my opinion, yes.

15 Q Now on -- you indicated that you knew
16 that Mr. Smith and others within CMS
17 had undertaken the study and had
18 published the study.

19 After you published your
20 2019 critique, that we're looking at
21 here, Exhibit 1111, did anyone at CMS
22 ever reach out to you to discuss your
23 critique?

24 A No.

25 Q Did anyone associated with the study

1 ever contest your findings that the
2 study was flawed?

3 A No.

4 Q Did anyone at CMS ever present you with
5 any evidence to suggest that your
6 criticism was unwarranted?

7 A No.

8 Q Okay. Nobody at CMS called you up and
9 said, "Mr. Creighton, you just don't
10 understand the -- the underlying --

11 A (Chuckling).

12 Q -- statistical analysis"? Or, "Mr.
13 Creighton, you -- you don't understand
14 what we did; here's the explanation"?

15 MS. MCMAHON: Objection --

16 THE WITNESS: No.

17 MS. MCMAHON: -- asked and
18 answered.

19 THE WITNESS: (Laughing).

20 No -- no, they did not.

21 MR. SCHINDLER: Okay.

22

23 By Mr. Schindler:

24 Q And you stand by your critique of the
25 study to this day; do you not?

1 A Absolutely.

2 Q Are you aware of any further studies
3 being conducted by CMS on whether a
4 Fee-for-Service Adjuster is necessary
5 to account for the errors in the
6 Fee-for-Service claims data that CMS
7 uses to calibrate the risk adjustment
8 model?

9 MS. MCMAHON: Objection;
10 calls for speculation.

11 THE WITNESS: I am not aware
12 of such studies. The -- the revised
13 study and -- and data sets were
14 published.

15 I'm not aware of anything
16 from CMS since then.

17 MR. SCHINDLER: All right.

18

19 By Mr. Schindler:

20 Q Let's see if we can switch gears. All
21 right. You can put those to one side.

22 Now, do you recall
23 testifying last time, that you were
24 aware that Medicare Advantage plans
25 were performing reviews of medical

1 A Yes.

2 Q Okay. And is this the proposed medical
3 record review rule that you were just
4 talking about?

5 A Just give me one second.

6 Q Sure.

7 A (Witness reading to self). Yes, it is.

8 Q Okay. And is it fair to say you
9 reviewed this proposed rule when it
10 came out in January of 2014?

11 A That is not correct because at that
12 time I was working on the ACA.

13 And actually, yeah, given
14 this particular case, I absolutely did
15 not review this. I was aware of this
16 however.

17 Q Okay. And to be clear, prior to
18 January of 2014, CMS had no such rule
19 in place for Medicare Advantage plans
20 conducting medical record reviews;
21 correct?

22 A That is correct.

23 MS. MCMAHON: Objection;
24 vague.

25

1 By Mr. Schindler:

2 Q And ultimately the medical record
3 review ruled that was proposed in
4 January of 2014 was withdrawn by CMS;
5 correct?

6 A That is correct.

7 Q It never went in effect -- into effect;
8 did it?

9 A It was not finalized.

10 Q Okay. And as you sit here today, is it
11 fair to say that you're unaware of any
12 other regulation that CMS promulgated
13 that would've directed Medicare
14 Advantage plans to determine the
15 accuracy of diagnosis codes being
16 submitted by the MA plans?

17 MS. MCMAHON: Objection.

18 THE WITNESS: That's
19 interesting. The -- there's no direct
20 regulation that says thou shalt confirm
21 the accuracy of all codes being
22 submitted.

23 However, that being said,
24 there are multiple regulations and laws
25 covering a governing payment; right?

1 That, you know, clearly
2 indicate that a health plan has got to
3 have a, you know, a comprehensive
4 compliance rating.

5 There's the requirement that
6 the -- that what is submitted is
7 documented in the medical record.

8 However, there is certainly
9 not a requirement that MA plans
10 validate every code that is passed
11 across the CMS because literally there
12 are billions of them.

13 And it would be technically
14 unfeasible -- infeasible, not feasible.
15 You know, so... You know, so there's
16 kind of a layer of the law regulation,
17 sub-regulatory guidance, that governs
18 this.

19 But there's no specific
20 regulation that says you must look, you
21 know, validate every code.

22 It's -- it's assumed that
23 the providers -- that it's the
24 providers job.

25 It's done at hospitals; it's

1 done at provider offices and what comes
2 from those sources on the record is --
3 unless there's some reason to suspect
4 otherwise, represents the provider's
5 evaluation of the diagnosis.

6 MR. SCHINDLER: Okay.

7

8 By Mr. Schindler:

9 Q But to be clear as it relates to the
10 proposed medical record review that we
11 were looking at a moment ago, which
12 essentially says that if -- if a
13 Medicare Advantage plan undertakes a
14 medical record review, chart review --
15 A (Indicating).

16 Q -- that it must confirm the diagnosis,
17 the accuracy of the diagnosis, that had
18 been submitted; correct?

19 There was no regulation, no
20 sub-regulatory guidance, no guidance,
21 no specific provision that CMS put out
22 that specifically directed an MA plan
23 that if it was gonna conduct a chart
24 review, it was required to undertake to
25 determine the accuracy of the diagnosis

1 codes that had previously been
2 submitted?

3 MS. MCMAHON: Objection --

4 THE WITNESS: That is
5 correct.

6 MS. MCMAHON: -- asked and
7 answered. Sorry. Objection; asked and
8 answered. And compound.

9

10 By Mr. Schindler:

11 Q You can answer.

12 A That's a -- that is correct.

13 Q Okay. Now, you -- I want to switch
14 gears with you for a moment because you
15 -- you mentioned the fact that during
16 this time in 2014, for example, you
17 were working on the Affordable Care
18 Act --

19 A Correct.

20 Q -- side of CMS. So I want to talk a
21 little bit about that. I want to talk
22 about the health plans that
23 participated in the Affordable Care
24 market; okay?

25 A (Indicating).

1 Q And, again, for purpose of
2 nomenclature, if I talk about health
3 plans that participated in the ACA
4 exchange --

5 A (Indicating).

6 Q -- do you know what I'm talking about?

7 A Yes, I do. (Chuckling).

8 Q Okay.

9 MS. MCMAHON: Objection.

10

11 By Mr. Schindler:

12 Q All right. Now, in addition to
13 administering the Medicare Advantage
14 plans, CMS was also responsible for
15 overseeing the health plans that were
16 participating in the ACA exchange;
17 correct?

18 A Correct.

19 Q In fact, you were working on that;
20 right?

21 A (Indicating).

22 Q I think you told us between 2012 and
23 2015 you were working on the --

24 A -- correct.

25 Q We have to make sure, we don't talk

1 over each other --

2 A Yeah.

3 Q -- or the court reporter is gonna get
4 mad at both of us.

5 All right. Between 2012 and
6 2015 you were working on the ACA
7 exchange program; correct?

8 A That's correct.

9 Q All right. And there were a whole
10 series of requirements that health
11 plans participating in the ACA exchange
12 were required to follow; is that
13 correct?

14 A Yes, there were.

15 Q And those requirements included
16 provisions regarding data submission;
17 right?

18 A Correct.

19 Q All right. And those provisions also
20 included provisions pertaining to
21 compliance and (inaudible) maintaining
22 a compliance plan; correct?

23 A Correct.

24 Q All right. Now among other things, do
25 you recall that the ACA health plans

1 codes in the Fee-for-Service claims
2 data do not have a meaningful impact on
3 risk adjustment model estimation and,
4 further, do not bias MA plan payment."
5 Right?

6 A Correct.

7 Q Okay. Now in that last paragraph you
8 go on, you and your colleagues at
9 Avalere, go on to summarize that a,
10 "New analysis from Avalere suggests
11 that certain key assumptions embedded
12 in the CMS's analysis do not
13 appropriately capture the full
14 variation in the data and minimized the
15 impacted documentation error."
16 Correct?

17 A Correct.

18 Q And Avalere performed -- tested three
19 alternatives; correct?

20 A Yes.

21 Q And, "Avalere's analysis finds that
22 audit miscalibration bias yields under
23 payments of nearly 8 percent."

24 Correct?

25 A Correct.

1 Q All right. So at least as of 2019 the
2 work that you and your colleague had
3 done at Avalere had indicated under
4 payments of nearly 8 percent; correct?

5 A Correct.

6 Q All right. Now going back to the IPARS
7 adjustment that CMS employed in the
8 context of the study; okay? Do you
9 have that in mind?

10 A Yes.

11 Q The IPARS adjustment was a downward
12 adjustment; correct?

13 MS. MCMAHON: Objection.

14 THE WITNESS: Correct.

15 MR. SCHINDLER: Okay.

16

17 By Mr. Schindler:

18 Q And in fact CMS's own analysis had
19 determined that when using --
20 correcting for the errors in the
21 audited data, it would've resulted in a
22 higher coefficient; correct?

23 MS. MCMAHON: Objection;
24 calls for speculation.

25 THE WITNESS: So the --

1 yeah, the audited model produced
2 different coefficients than the
3 unaudited model.

4 MR. SCHINDLER: Right.

5
6 By Mr. Schindler:

7 Q And it produced higher coefficients
8 before application of that IPARS
9 adjustment; correct?

10 MS. MCMAHON: Objection.

11 THE WITNESS: Again, I have
12 no specific recollection of the exact
13 table of results, so I'm gonna take
14 your word for that.

15 MR. SCHINDLER: Okay.

16
17 By Mr. Schindler:

18 Q But going back your own Avalere
19 analysis had produced -- (inaudible)
20 the results of the own -- of your own
21 Avalere analysis had -- had indicated
22 that a correction for the errors in the
23 data used to calibrate the model
24 would've resulted in under payment --
25 A -- yes, of higher risk cores and...

1 Yes.

2 Q All right. And, in fact, the fact that
3 the IPARS adjustment was a downward
4 adjustment tells you that the results
5 CMS originally came up with would've
6 resulted in a higher coefficient;
7 correct?

8 A Correct.

9 MS. MCMAHON: Objection;
10 calls for speculation.

11 MR. SCHINDLER: All right.

12

13 By Mr. Schindler:

14 Q Let's switch gears. Do you recall
15 testifying last time about something
16 called the, "Coding intensity
17 adjustment"?

18 A I do.

19 Q Okay. You recall that the coding
20 intensity adjustment was a way to
21 account for the fact that MA plans have
22 a differential rate of increasing
23 coding relative to Fee-for-Service
24 plans -- relative to Fee-for-service;
25 correct?

1 A Correct.

2 Q And you agree that the Medicare
3 Advantage plans had a greater incentive
4 to code more completely than the
5 Fee-for-Service providers; correct?

6 A Yes.

7 Q And did you participate in attempting
8 to calculate the coding intensity
9 adjustment while you were at CMS?

10 A Yes, I did.

11 Q All right. And did the rate of the
12 coding intensity adjustment change over
13 time?

14 A (Chuckling). So there's two different
15 things there. The differential in the
16 rate of coding between Fee-for-Service
17 and MA changes over time; it fluctuates
18 slightly.

19 The coding intensity --
20 intensity adjuster, which is in the
21 payment system, is determined by law
22 and by regulation.

23 So it has been statutorily
24 -- sort of there's a statutory minimum
25 that has been in place for -- I can't

1 A Correct.

2 Q And is -- is that what you understand
3 the standard to continue to be?

4 A That is correct.

5 Q Okay. And if we can just move to one
6 other page here. If you go back to
7 Page 85 in this document -- oops.

8 Page 86; I'm sorry. Page
9 86. Which is Section 4.16, "MA
10 Organization Responsibility Regarding
11 Deletions Slide 21."

12 A Okay.

13 Q Okay. And that -- the indication Slide
14 21 next to that heading, is that what
15 you were referring to that CMS would
16 put together training slides for the MA
17 industry?

18 A Yeah; correct. So the -- so what the
19 participant guide is, if you can
20 imagine a auditorium or space, so we're
21 up there on the stage presenting the
22 slides which, you know, help present
23 the information we want the plans to
24 have.

25 There's lots of people in

1 the audience. And this is a sort of a
2 read along, if you like, with the
3 slides. So when it refers to Slide 21,
4 there's a slide deck that accompanies
5 this.

6 Q I see. Okay. And if you look at the
7 first bullet under Section 4.16 it
8 says, "MA organizations must submit
9 delete records when an erroneous
10 diagnosis cluster has been accepted by
11 RAPS and stored in the RAPS data base."
12 Correct?

13 A (Indicating). That's correct.

14 Q And it is -- it's you're understanding
15 that that's an accurate statement of
16 what CMS's rules were?

17 A It's a plan to become aware of the
18 diagnosis that was incorrect. They're
19 required to delete it using the
20 instructions provided here.

21 Q Okay. Great.

22 MS. MCMAHON: All right.
23 Let's go -- let's go to a different
24 document. We're going to pull up --
25 Martha, if you can pull up Exhibit 164,

1 previously marked 164.

2 THE WITNESS: Okay.

3 MR. SCHINDLER: You have --
4 okay.

5

6 By Ms. McMahon:

7 Q And this is a Federal Register dated
8 June 29th, 2000. Are you -- just
9 looking at these -- just looking at the
10 cover of this, are you familiar with
11 this particular Federal Register?

12 A Now that I see it in front of me I
13 can't say that I've been holding it in
14 my memory since then.

15 Q That's fine. Okay. Let's -- well, I
16 guess, if you could just turn to the
17 second page?

18 A Sure.

19 Q And if you just look -- you see that
20 it's dated June 29th, 2000; correct?

21 A Correct.

22 Q And if you just look at the -- the
23 summary the -- the very first entry on
24 the left-hand column in this document?

25 A (Indicating).

1 Q And just -- if you could like just
2 glance through it just to remind
3 yourself what this might be?

4 A (Witness reading to self). Sure. So
5 it refers to CFR 422 and -- which is
6 our favorite section, so...

7 Q Okay. Understood. And this is -- is
8 -- do you understand this to be just
9 the -- the implementing regulation of
10 the Medicare Advantage program?

11 A Sure. For that time period.

12 Q Okay. And did you -- are you aware
13 that initially the Medicare Advantage
14 program was referred to as the Medicare
15 Plus Choice program?

16 A Yes, I'm aware.

17 Q Okay. And are you also aware that CMS
18 at this time used to be referred to as
19 the Health Care Financing
20 Administration?

21 A Indeed.

22 Q Yes. And that's when you first started
23 working for CMS; correct?

24 A Yeah, it was HCFA for a number of
25 months after I joined it. And then our

1 good friend, Tom Skully, decided it
2 needed a re-branding so we became CMS.

3 Q (Laughing). All right. Okay. And
4 let's see here... If you can turn to
5 Page 100 of this document.

6 A Okay.

7 Q Okay. All right. And I think earlier
8 when Mr. Schindler was asking you some
9 questions about certifications, are you
10 -- are you aware that Medicare
11 Advantage organizations were required
12 to submit certifications or
13 attestations attesting to the
14 truthfulness, accuracy and completeness
15 of the data they're submitting?

16 A I am.

17 Q Okay. And do you understand that this
18 Point 9, it starts on the left hand
19 column, titled, "Certification of Data
20 That Determine Payment/Certification of
21 the Accuracy ACR Information."

22 That that is referring to
23 the -- the attestation that we just
24 mentioned?

25 A In fact it refers to more than that

1 STATE OF MINNESOTA)
2) ss.
3 CROW WING COUNTY)

5 I, Nathan D. ENGEN do hereby
6 certify that the foregoing transcript in
7 the matter of United States of America,
8 ex rel. Benjamin Poehling vs.
9 Unitedhealth Group, Inc., et al is true,
10 correct and accurate:

11 That said transcript was prepared
12 under my direction and control from my
13 stenographic shorthand notes.

14 That I am not related to any of
15 the parties in this matter, nor am I
16 interested in the outcome of this
17 action.

19 Witness my hand and seal this 6th day of
20 October, 2022.

Nathan D. Engen
Nathan D. Engen

EXHIBIT D-101

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

CONFIDENTIAL
Videotaped Deposition of
JOANNE DAVIS
Given Remotely
Thursday, September 8, 2022
9:02 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
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1 Q. As -- we previously saw that the cover
2 e-mail was dated September 14th, 2016; that's the
3 date on Exhibit 1315. Do you have any reason to
4 believe that this document was not accurate as of
5 September 14th, 2016?

6 A. No, I don't.

7 Q. I believe you mentioned you started
8 at the -- at the predecessor to CPI in 2008; is that
9 right?

10 A. That's correct.

11 Q. What were your job responsibilities at
12 that time?

13 A. At that time I worked in Medicaid. There
14 were -- started out on the audit resolution team. I
15 would look at audit findings conducted by people in
16 field offices. In 2010, when the Affordable Care Act
17 passed, the responsibility for writing a reg and --
18 and doing the outreach for the rollout of that reg
19 and that -- the implementation of the -- that
20 particular program.

21 Q. When you say "that particular program,"
22 are you speaking exclusively about Medicaid?

23 A. Yes.

24 Q. What was your job title when you started
25 at the predecessor to CPI in 2008?

1 A. I was a health insurance specialist.

2 Q. Did your title remain health insurance
3 specialist for the entire time that you worked at CPI
4 or its predecessor?

5 A. Yes.

6 Q. At some point while you were working in
7 CPI, did your role involve Part C Medicare Advantage?

8 A. So there was a break in between. I left
9 CPI in 2013 to go work in CM, which was Medicare
10 Advantage. Prior to 2013, I worked exclusively on
11 Medicaid issues.

12 Q. Was that October of 2013 that you moved?

13 A. Yes.

14 Q. In October of 2013, did you join the
15 Medicare Plan Payment Group?

16 A. Yes.

17 Q. Will you understand if I refer to the
18 Medicare Plan Payment Group as "MPPG"?

19 A. Yes.

20 Q. Did you join the Division of Payment
21 Validation at that time?

22 A. Yes, I did.

23 Q. Was your title health insurance specialist
24 when you joined MPPG?

25 A. Yes.

1 Q. How long did you work with MPPG?

2 A. I was there from October 2013 through
3 January 2017.

4 Q. Did your title remain health insurance
5 specialist throughout that time?

6 A. Yes, it did.

7 Q. Where did you go in January 2017, with
8 respect to your career?

9 A. I was reassigned --

10 MS. GLOVER: Go ahead.

11 THE WITNESS: I was reassigned to CPI.

12 BY MS. BLAKEMAN:

13 Q. In January 2017, when you were reassigned
14 to CPI, what was your job title?

15 A. Was health insurance specialist.

16 Q. When did you leave CPI following your
17 transition there in January of 2017?

18 MS. GLOVER: Objection. Asked and
19 answered.

20 THE WITNESS: I left CPI in October 2019.

21 BY MS. BLAKEMAN:

22 Q. Let's focus on your role at MPPG from
23 October 2013 to January of 2017 for now. Could you
24 describe your job responsibilities at that time?

25 A. I joined CM -- or I joined MPPG, or DPV,

1 to be on the RADV legal appeals team.

2 Q. What does the RADV legal appeals team do?

3 A. It was anticipated that -- that the team
4 would litigate the Medicare Advantage organization
5 appeals that would result as a -- as a -- that would
6 come as a result of the RADV audits.

7 Q. Is that what the team ultimately did?

8 A. Yes.

9 Q. What was your particular role on the RADV
10 legal appeals team?

11 A. To litigate the appeals that came in front
12 of the Office of Hearings and Inquiries.

13 Q. Were you litigating those appeals in your
14 capacity as an attorney?

15 MS. GLOVER: Objection. Form. Asked and
16 answered.

17 THE WITNESS: I was a trained attorney;
18 however, my official classification was health
19 insurance specialist.

20 BY MS. BLAKEMAN:

21 Q. So is it fair to say you were not
22 litigating in your capacity as an attorney?

23 MS. GLOVER: Objection. Asked and
24 answered.

25 THE WITNESS: I have legal training, but I

1 was classified as a health insurance specialist.

2 BY MS. BLAKEMAN:

3 Q. What did you do as a health insurance
4 specialist with respect to litigating the appeals?

5 A. I wrote briefs. I argued cases in front
6 of the administrative law judge. I did -- I held
7 prehearing conferences with the administrative law
8 judge and other parties. I sent communications to
9 the attorneys involved, and managed the case load
10 docket. And I tried the cases.

11 Q. Do you know whether or not a person must
12 have a license to practice law to appear before an
13 administrative law judge?

14 A. I don't know that.

15 Q. Did you litigate any RADV appeals with
16 respect to UnitedHealth?

17 A. Yes.

18 Q. How many times?

19 A. I don't remember.

20 Q. Could you give me a ballpark?

21 A. Under the United umbrella, there may have
22 been between four and eight contracts that had
23 numerous appeals within their contracts.

24 Q. Turning to -- turning back to your résumé,
25 I'm on the first page of Exhibit 1315-1. And I'm

1 up, you know, audio lines. So there -- there were a
2 number of activities that -- that needed to -- to be
3 completed in order to -- to put on a -- a successful
4 teleconference.

5 Q. The third bullet on the first page begins:
6 "CY 2011 Contract-Level RADV." Do you see that?

7 A. Yes.

8 Q. What did you do for CY 2011 Contract-Level
9 RADV?

10 A. So again I was a government task lead,
11 which is not the same as a contractor office
12 representative. And we met with the medical record
13 review contractors and the analytic contractors,
14 doing the same type of production activities,
15 preproduction, post production activities, to put on
16 a teleconference.

17 Q. Is the CY 2011 contract-level RADV
18 sometimes referred to as "CON11"?

19 A. Yes.

20 Q. The first sentence in that third bullet
21 reads: "Serves as GTL for the contract-level RADV
22 reconsideration/appeals process, overseeing the work
23 of medical record review contractors, coordinating
24 industry training logistics, preparing instructions,
25 slides, and other written materials."

1 Did I read that correctly?

2 A. Yes.

3 Q. What is meant by "reconsideration/appeals
4 process"?

5 A. So in the RADV regulation, there is an
6 opportunity for MAOs to dispute their medical record
7 findings, called reconsideration. And it's a
8 precursor to the appeals process.

9 Q. Did your role involve both reconsideration
10 and the appeals process?

11 A. Yes.

12 Q. Was that true just for CON11, or was that
13 true for other RADV audits as well?

14 A. CON11 was the first year that the
15 reconsideration step was -- was -- was in -- in reg.
16 Prior to CON11, would have been the 2007 audits, it
17 was a process called "medical record dispute." The
18 reconsideration became a separate step.

19 Q. And you had involvement in the medical
20 record dispute step for the 2007 RADV audits; is that
21 right?

22 A. Yes.

23 Q. While you were at MPPG, what role did you
24 have in overseeing the work of medical record review
25 contractors?

1 MS. GLOVER: Objection. Vague.

2 THE WITNESS: I was a GTL, which is
3 government task lead. So I, with others, met
4 with the medical review contractors weekly, and
5 on an ad hoc basis.

6 BY MS. BLAKEMAN:

7 Q. Did your work in overseeing the medical
8 record review contractors relate solely to
9 reconsideration appeals or medical record dispute, or
10 did it also relate to the RADV audits themselves?

11 A. So I was on the legal team, so my role
12 would have been primarily limited to medical record
13 dispute and the appeals. On a general basis, the
14 team did meet with the -- the MRRCs. But my work was
15 limited to the appeals.

16 Q. What contractors did you work with while
17 at MPPG?

18 A. All of them? Do you want me to list all
19 of them?

20 Q. Yes.

21 A. There was the -- the Signature. There was
22 Deloitte. I'm not remembering the names of the
23 medical record -- the MRRCs at the time. There were
24 two. There was Deloitte, and there was NewWave.
25 Yes.

1 C E R T I F I C A T E

2

3 I, KAREN K. KIDWELL, RMR, CRR, Notary Public
4 for the Commonwealth of Virginia, do hereby certify
5 that the witness whose deposition is hereinbefore set
6 forth, was virtually sworn under penalty of perjury
7 by me and that such deposition is a true record of
8 the testimony given by such witness.

9

10 I further certify that I am not related to any
11 of the parties to this action by blood or marriage;
12 and that I am in no way interested in the outcome of
13 this matter.

14

15

16

Karen Kidwell

17

KAREN K. KIDWELL, RMR, CRR
Registered Merit Reporter
Certified Realtime Reporter
Registration #7625774
My Commission expires:
September 30, 2023

18

19

20

21

22

23

24

25

EXHIBIT D-102

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
_____)

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
TAMMY DICKEY

(Taken virtually)

9:02 a.m. Eastern

Tuesday, May 24, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services

866-624-6221

www.MagnaLS.com

1 may be documented, but it doesn't mean that it
2 should be coded according to guidelines.

3 Q. So is the distinction that you're
4 making that it has to be documented in accordance
5 with guidelines?

6 A. In order to make the code assignment
7 for the diagnosis that is documented, it has to be
8 documented in a way that meets the guideline to
9 code that diagnosis.

10 Q. Is there a way that you can phrase
11 that that kind of going forward throughout the day
12 that you and I will both understand what you mean
13 by documented in a way that, you know, meets the
14 guidelines?

15 A. Is there -- I'm sorry, is there a way?

16 Q. Is it fair for us to say going forward
17 throughout today, based on the explanation that
18 you just gave, to say documented in the medical
19 record in accordance with guidelines?

20 A. I'm not sure because -- we're not --
21 the providers document the way they document. So
22 it's the coder's review of the record and
23 interpretation of that to make the code
24 assignment.

25 Q. So what you're saying is that in chart

1 review a coder is making code assignments based on
2 what's documented in the medical record, but those
3 coding assignments are made in accordance with
4 guidelines?

5 MS. MADDUX: Objection. Form.

6 THE WITNESS: I believe that sounds
7 correct.

8 BY MS. GLOVER:

9 Q. Okay. So is it your -- is it your
10 understanding that in chart review coders were
11 tasked or are tasked with identifying or making
12 coding assignments for a medical record in
13 accordance with guidelines?

14 MS. MADDUX: Objection. Form.

15 THE WITNESS: I would say that is
16 generally correct.

17 BY MS. GLOVER:

18 Q. Okay. Ms. Dickey, are you familiar
19 with the term "blind review" as the term was used
20 at Optum?

21 A. I am.

22 Q. What is blind review of a medical
23 record?

24 A. So at Optum a blind review means the
25 coder opens the record and assign -- you know,

1 reviews and assigns codes without any information
2 or knowledge of what that member may previously
3 have had.

4 Q. And when you say have had, do you mean
5 have had in previous date of service years?

6 A. In previous date of service years or
7 even that date of service year, I guess. They
8 just have no information. They're not informed
9 that maybe the patient had a knee amputation the
10 year before. They don't know that.

11 Q. So in that -- in a blind review, is a
12 coder -- they're looking at a medical record, but
13 they have no additional information about what the
14 beneficiary has had previously or even information
15 about diagnoses that a provider has submitted for
16 the current date of service year; is that right?

17 A. That's correct.

18 Q. And they -- and their task then is
19 to -- is to assign codes based on guidelines and
20 see what is documented in the medical record based
21 on those guidelines?

22 MS. MADDUX: Objection. Form.
23 Confusing.

24 THE WITNESS: Their -- will you repeat
25 that?

1 BY MS. GLOVER:

2 Q. Why don't we just move on. I think --
3 in Optum's blind chart review -- scratch that.

4 Does Optum -- since you've been at
5 Optum, has Optum used a blind chart review
6 approach?

7 MS. MADDOUX: Objection. Form.

8 THE WITNESS: All -- for certain time
9 frames or like -- so they're, I think,
10 during -- if something is privileged, am
11 I -- I can't --

12 MS. MADDOUX: Need to take a break?

13 MS. GLOVER: Do you need to consult
14 with your attorney?

15 THE WITNESS: I think so, yes.

16 MS. GLOVER: Okay. Why don't we go off
17 the record.

18 THE VIDEOGRAPHER: Time is now
19 10:58 a.m. We are going off the record.

20 (Recess taken from 10:58 a.m. until 11:06 a.m.)

21 THE VIDEOGRAPHER: The time is now
22 11:06 a.m. We are back on the record.

23 BY MS. GLOVER:

24 Q. And, Ms. Dickey, are you able to
25 answer my question?

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified
Court Reporter within and for the State of
Georgia, do hereby certify:

That the foregoing deposition was
taken before me on the date and at the time and
location stated on Page 1 of this transcript; that
the deponent was duly sworn to testify to the
truth, the whole truth and nothing but the truth;
that the testimony of the deponent and all
objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed; that the foregoing
deposition as typed is a true, accurate and
complete record of the testimony of the deponent
and of all objections made at the time of the
examination to the best of my ability.

I further certify that I am neither
related to nor counsel for any party to the cause
pending or interested in the events thereof.
Witness my hand, this 26th day of May, 2022.

Christine A. Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-103

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. CV 16-086FMO
BENJAMIN POEHLING,	)	FMO (SSx)
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
-----	)	

CONFIDENTIAL
Videotaped Deposition of MARK DUGGAN, Ph.D.
Given Remotely
Friday, March 29, 2024
8:31 a.m. Pacific

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 into the model using -- I forget what the function is
2 that he used in Excel to introduce the randomness.
3 But he did introduce some randomness for sure, but it
4 was thoughtfully introduced.

5 Q. Okay. You'll have no disagreement from me
6 on the thoughtfulness of Dr. Ingber's work.

7 So is your -- the point that you pointed
8 out here where Dr. Ingber said: "Essentially,
9 Lambert and Duggan's analysis is misleading because
10 it fails to recognize the different impacts
11 unsupported codes have in the TM data versus the MA
12 data." And then he explains -- the following
13 sentence he explains what he opines is the
14 difference.

15 Are -- well, I'm just going to ask you
16 straight up. Do you -- do you agree with Dr. Ingber
17 that you failed to recognize the different impact
18 unsupported codes have in the TM data versus the MA
19 data or do you disagree with Dr. Ingber on that
20 point?

21 A. I disagree with him in the sense that I --
22 as I -- I'm drawing on my many years of experience
23 studying Medicare and Medicare Advantage and so
24 forth, I recognize that in one case, the thought --
25 the quote "thought experiment" -- I don't know if

1 that's the exact phrase that he uses -- but of
2 removing a code from someone in MA or deleting an HCC
3 for someone in MA, that will mechanically lower
4 reimbursement by the government to that -- on behalf
5 of that person. Whereas, in the -- and suppose you
6 did that same deletion in the traditional Medicare
7 case, that would not influence reimbursement for that
8 person. Traditional Medicare is fee for service and
9 reimbursement is based on services, not on diagnoses.
10 So it would -- it would not influence reimbursement
11 for that person, but it would estimate -- influence
12 model coefficients.

13 And those model coefficient estimates
14 might be small, but aggregated across a big
15 population of people, it's not just affecting that
16 one person. It's not affecting that person's
17 spending actually at all. It's affecting spending
18 for this different group of people in MA and
19 that's -- that is a big -- that's a potentially big
20 effect. And so it is, I think, the -- I recognize
21 that there's those two things aren't identical by any
22 means.

23 In one case it affects reimbursement for
24 the individual with the unsupported code. And in
25 one -- and in the other case, it would not for that

1 person. It would affect it for many other people
2 potentially.

3 Q. Right. Okay. Understood. I understand
4 your point.

5 So -- so you don't have any disagreement
6 that where he states that -- that: "The effective
7 added unsupported codes in MA data when a TM
8 estimated model is being applied to determine payment
9 to the MA is quite different and increases payment.
10 There is no averaging out or redistribution of costs
11 to other HCCs or demographic factors."

12 You would agree with that statement?

13 MR. BAAK: Objection. Mischaracterizes
14 prior testimony. Form.

15 THE WITNESS: That is -- I -- I agree that
16 it is different, but not for the -- the things
17 that I would flag when I was talking about why
18 it is different would be what I just described
19 with which is in one case it affects payment for
20 one individual. In another case it affects
21 payment for many -- not that individual but many
22 other people. And aggregating that out -- it
23 tends to be the case that if you're removing
24 HCCs from the model used to estimate fee for
25 service, it tends to be the case not in every

1 CERTIFICATE

2

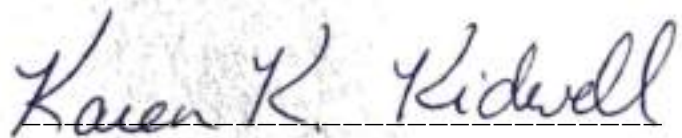
3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20



21

Karen K. Kidwell

22

Registered Merit Reporter

Certified Realtime Reporter

Notary Public

23

24

25

EXHIBIT D-104

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	No. 16-08697 FMO
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et	)	
al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL INFORMATION, SUBJECT TO PROTECTIVE ORDER

VIDEOTAPED VIDEOCONFERENCE ZOOM DEPOSITION OF
KAREN ERICKSON

August 2, 2022

9:32 a.m. Eastern Standard Time

Magna Legal Services
(866) 624-6221
www.MagnaLS.com

Prepared by:
Marcella Daughtry, RPR, RMR
CA CSR 14315
GA No. 6595-1471-3597-5424

1 to become -- just started to work with that business. I
2 talked to a lot of the experts and staff that we had in
3 that area.

4 Q Who did you talk to?

5 A I don't recall everyone's name at the time. I
6 would say -- I'm sure I talked to Jeff Dumcum, Jon Bird,
7 Katie Baker. I'm not sure -- I'm not sure who else.

8 Q Did you talk to Stephanie Will?

9 A I don't recall.

10 Q Have you ever heard the term "blind chart
11 review"?

12 A Yes, I have heard the term.

13 Q Do you have an understanding of what a blind
14 chart review is?

15 A My understanding of a blind chart review, it
16 would be a review by a coder without an understanding of
17 anything that might have been coded from that chart
18 before.

19 Q And when you say "anything that might have been
20 coded by that chart before," what do you -- what do you
21 mean by "coded from that chart before"?

22 A Well, providers -- providers send the codes in,
23 so providers provide services to the patients, and then
24 the provider's office submits the codes related to the
25 diagnosis that the provider -- and that -- that visit,

1 what codes were there. So those would be codes submitted
2 by a provider.

3 Q Okay. And so in the blind chart review, the
4 coders don't know what codes were already submitted by
5 the provider; is that right?

6 A That's my understanding.

7 Q And earlier I asked you a question about
8 whether providers submit codes, and I was unclear on your
9 answer. So it sounds like we agree that providers do
10 submit codes from their visits with beneficiaries; is
11 that right?

12 MS. SOBEL: Objection to form. Vague.

13 THE WITNESS: I don't -- I don't recall the
14 exact processes, and I'm not sure -- I'm not sure you can
15 say all providers submit all codes and to whom. I don't
16 know that I can put all of that together.

17 Q BY MS. KRIEG: Uh-huh. So some providers,
18 then, submit risk adjusting codes from their visits with
19 beneficiaries to Optum?

20 Do you agree with that?

21 MS. SOBEL: Objection to form.

22 THE WITNESS: I don't know the answer to that.

23 Q BY MS. KRIEG: Sitting here today, you don't
24 know the answer to that?

25 A Sitting here today, I don't know the answer to

1 that.

2 Q Okay. But you agree that in a blind chart
3 review at least, that coders don't have access to
4 information about diagnosis codes that providers have
5 previously submitted for a beneficiary?

6 A Yes. In my -- in my recollection in a blind
7 coding, the coders would not know what has previously
8 been submitted.

9 Q Have you ever heard the term "informed chart
10 review"?

11 A I don't know if I have heard "informed chart
12 review." I'm going to say no, I don't -- I'm not sure if
13 I understand the meaning of that term.

14 Q Okay. Have you ever heard of a chart review
15 where the providers -- strike that.

16 Have you ever heard of a chart review where the
17 coders are told to code only codes that have not already
18 been submitted by a provider?

19 MS. SOBEL: Objection to form.

20 THE WITNESS: No, I don't think so, because I'm
21 not -- I don't know how they would have known that.

22 Q BY MS. KRIEG: Okay. Are you familiar with --
23 okay, let me ask you this. When you became familiar with
24 Optum's chart review in the fall of 2012, did you gain an
25 understanding of whether the Chart Review program was a

1 blind chart review?

2 A Yeah, it was my understanding it was a blind
3 Chart Review program.

4 Q And is it correct that the charts were reviewed
5 retrospectively?

6 MS. SOBEL: Objection to form.

7 THE WITNESS: I don't understand that word,
8 when you say "retrospectively."

9 Q BY MS. KRIEG: So the charts that were reviewed
10 were not from the contemporaneously date of service; it
11 was, you know, previously, previous year's date of
12 service.

13 MS. SOBEL: Objection to form.

14 THE WITNESS: I think I would have understood
15 that at the time, but at this point I don't remember how
16 the calendar part of it worked.

17 Q BY MS. KRIEG: Okay. Because you haven't
18 worked in this area for so long?

19 A Yes.

20 Q Are you familiar with something called the
21 recode project?

22 THE COURT REPORTER: Recode?

23 MS. KRIEG: Recode. R-e-c-o-d.

24 THE WITNESS: Yes.

25 Q BY MS. KRIEG: What is the recode project?

1 MS. SOBEL: And I just want to caution the
2 witness not to reveal any aspect of the project that you
3 are familiar with that's privileged, but to the extent
4 you are able to answer and not reveal privileged
5 information, go ahead.

6 THE WITNESS: Can we -- can we consult for a
7 minute?

8 MS. SOBEL: Yeah, can we go off the record for
9 one minute?

10 MS. KRIEG: Of course. Yes. Take your time.

11 THE VIDEOGRAPHER: The time is 12:27 p.m. We
12 are off the record.

13 (The deposition was at recess from 12:27 p.m.
14 to 12:34 p.m.)

15 THE VIDEOGRAPHER: The time is 12:34 p.m., and
16 we are on the record.

17 MS. KRIEG: I don't -- I actually don't
18 remember the last question before the break. Could we
19 have it read back.

20 (The requested portion of the record was read
21 by the court reporter as follows: "What is the recode
22 project?")

23 MS. SOBEL: I will just give the same
24 cautionary language not to reveal the content of any
25 privileged conversations you had, but to the extent you

1 STATE OF GEORGIA)
2 COUNTY OF DEKALB) ss:
3

4 I HEREBY CERTIFY that the foregoing deposition
5 was taken before me; that I was then and there a
6 Registered Professional Reporter and Registered Merit
7 Reporter, License No. 6595-1471-3597-5424 for the State
8 of Georgia, and License No. 14315 in the State of
9 California; that the witness before testifying was duly
10 sworn by me to testify to the whole truth; that the
11 questions propounded by counsel and the answers of the
12 witness thereto were taken down by me in shorthand and
13 thereafter transcribed under my direction; and that the
14 foregoing pages contain a full, true, and accurate
15 transcript of all deposition testimony and proceedings
16 had, all done to the best of my skill and ability.

17 Signature requested.

18 I FURTHER CERTIFY that I am in no way related
19 to, nor employed by any of the parties hereto, nor am I
20 in any way interested in the outcome.

21 DATED at Dunwoody, Georgia, this 8th day of
22 August, 2022.

23

24

25


MARCELLA L. DAUGHTRY, RPR, RMR
GA License No. 6595-1471-3597-5424
CA CSR 14315

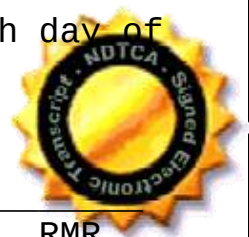


EXHIBIT D-105

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
DANIEL FARMER
Given Remotely
Friday, March 18, 2022
10:04 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 BY MS. BLAKEMAN:

2 Q. Yes. I believe you stated that you
3 worked -- well, I'll just restart.

4 Can you describe the typical work that you
5 would -- that Ms. Bella would do, for which you would
6 support her logistically?

7 A. Ms. Bella did something different every
8 day. If your question is about what work she did day
9 to day, there's not a single answer to that question.
10 I could speak broadly about some of the work of the
11 Medicare-Medicaid Coordination Office during that
12 time, but I -- I can't characterize Ms. Bella's work
13 day to day.

14 Q. Did any of the work that Ms. Bella
15 performed while you were her special assistant touch
16 upon or relate to Medicare Advantage?

17 A. Yes.

18 Q. What about risk adjustment?

19 A. Yes.

20 Q. I believe you became the special assistant
21 to Sean Cavanaugh in May of 2014; is that right?

22 A. I believe that's correct.

23 Q. Why did you change positions from being
24 the special assistant to Ms. Bella to being the
25 special assistant to Mr. Cavanaugh?

1 MS. LIKOFF: Object to form.

2 THE WITNESS: I was interested in getting
3 a different experience during my time at CMS.

4 BY MS. BLAKEMAN:

5 Q. Did you become the special assistant to
6 Mr. Cavanaugh immediately upon his taking the
7 position of deputy administrator and director?

8 MS. LIKOFF: Object to form. Vague.

9 THE WITNESS: Can you clarify?

10 BY MS. BLAKEMAN:

11 Q. Certainly. What position did
12 Mr. Cavanaugh hold at CMS when you became the special
13 assistant to Mr. Cavanaugh?

14 A. When I became Mr. Cavanaugh's special
15 assistant, he was the deputy administrator at CMS and
16 the director of the Center for Medicare.

17 Q. How long had he held those positions when
18 you became his special assistant?

19 A. I don't know.

20 Q. What were your job duties in your position
21 as special assistant to Mr. Cavanaugh?

22 A. My responsibilities for Mr. Cavanaugh as
23 his special assistant were primarily logistical. I
24 was responsible for making sure the day-to-day, his
25 calendar was up to date for meetings that he had

1 planned on the calendar, making sure that the correct
2 staff were included and were able to attend. If
3 there were external meetings, making sure that
4 Mr. Cavanaugh had received materials that the
5 external folks would have submitted. Some -- or
6 excuse me -- that wasn't specific to external
7 meetings. That would have been all meetings. Making
8 sure that Mr. Cavanaugh had materials for those
9 meetings before he attended.

10 If we were going to be using video
11 teleconferencing, I was responsible for making sure
12 the video teleconferencing was working. If we were
13 having an audio-only call, making sure that the
14 conference call was working.

15 Was also responsible for making sure that
16 Mr. Cavanaugh was notified if other parts of CMS were
17 looking to get in touch with him on an urgent or --
18 on an urgent matter, if need be.

19 So, again, helping to coordinate
20 Mr. Cavanaugh's day and his schedule.

21 Q. Were you responsible for drafting any
22 briefing materials for Mr. Cavanaugh at that time?

23 MS. LIKOFF: Object to form. Vague.

24 THE WITNESS: Could you clarify what you
25 mean by "briefing materials"?

1 BY MS. BLAKEMAN:

2 Q. Certainly. Were you responsible for
3 drafting for Mr. Cavanaugh any background materials
4 or policy summaries for Mr. Cavanaugh in advance of
5 the meetings that you helped coordinate?

6 A. No.

7 Q. Were you responsible for writing any first
8 drafts for Mr. Cavanaugh, that he would then adopt as
9 his own?

10 MS. LIKOFF: Object to form. Vague.

11 THE WITNESS: First drafts of -- of what,
12 exactly?

13 BY MS. BLAKEMAN:

14 Q. Well, I'm starting broad because I'm not
15 sure, so I'm trying to get that information from you.

16 Were you responsible for drafting any
17 documents that Mr. Cavanaugh would then edit?

18 MS. LIKOFF: Same objection.

19 THE WITNESS: So I would first say I was
20 never responsible for drafting policy documents
21 that were intended to inform Mr. Cavanaugh.
22 Those responsibilities -- that responsibility
23 for drafting that material rested with other
24 staff and policy experts within the Center for
25 Medicare, and those documents were routinely

1 provided to him in advance of internal meetings.

2 Does that answer your question?

3 BY MS. BLAKEMAN:

4 Q. I -- it answers an earlier question.

5 The next question is whether or not you
6 would draft for Mr. Cavanaugh documents that he would
7 then send out to colleagues.

8 MS. LIKOFF: Object to form.

9 THE WITNESS: So can you clarify what you
10 mean by "colleagues"?

11 BY MS. BLAKEMAN:

12 Q. Other CMS employees.

13 A. So, broadly, I had a responsibility at
14 times to draft summaries of the work of Center for
15 Medicare, either representing policy decisions or
16 policy recommendations for other parts of CMS and
17 HHS. When I would draft those materials, they had to
18 be reviewed, typically by Mr. Cavanaugh, and also
19 policy staff within the Center for Medicare, to
20 verify accuracy and narrative description.

21 Q. Did any of those summaries that you
22 drafted relate to Medicare Advantage?

23 MS. LIKOFF: Object to form.

24 THE WITNESS: I don't know.

25

1 BY MS. BLAKEMAN:

2 Q. Did any of the summaries you drafted
3 relate to risk adjustment?

4 MS. LIKOFF: Object to form.

5 THE WITNESS: I don't know.

6 BY MS. BLAKEMAN:

7 Q. Who did you report to as special assistant
8 to Mr. Cavanaugh?

9 A. I reported to Mr. Cavanaugh.

10 Q. Did you report to anyone else?

11 A. No.

12 Q. Did anyone report to you while you were in
13 that position?

14 A. No.

15 Q. Who else besides Mr. Cavanaugh at CMS
16 would you work with regularly -- I'll say weekly
17 again -- while you were in this position?

18 A. Say there were many, many people. Within
19 the Center for Medicare, I would have worked
20 regularly with other special assistants; again, for
21 coordinating materials and scheduling purposes.
22 Outside of the Center for Medicare, I would again be
23 working with representatives from other offices, when
24 Mr. Cavanaugh needed to have conversations or
25 meetings with them. I would have been in touch with

1 the press office, the legislative office, the Office
2 of Strategic and Regulatory Affairs. Those are a few
3 examples.

4 Q. Would you take notes in meetings that
5 Mr. Cavanaugh attended while you were in that
6 position?

7 A. I don't -- I don't know. No, I don't
8 know. I would say typically not.

9 Q. In April of 2016, you became the director
10 of division of payment services in the Medicare Plan
11 Payment Group at CMS. Is that right?

12 A. Yes.

13 Q. Why did you change from being the special
14 assistant to Mr. Cavanaugh to being the director of
15 division of payment services?

16 A. It was an opportunity to do different
17 work.

18 Q. And what did your work entail in that
19 position?

20 MS. LIKOFF: Objection to form. Vague.

21 THE WITNESS: Could you be more specific?

22 BY MS. BLAKEMAN:

23 Q. Sure. What does the Medicare Plan Payment
24 Group do?

25 A. The Medicare Plan Payment Group, broadly,

1 MS. LIKOFF: Object to form.

2 THE WITNESS: I didn't know that she
3 didn't attend.

4 BY MS. BLAKEMAN:

5 Q. Are you aware of any other CMS employees
6 who attended the meeting, other than yourself,
7 Mr. Cavanaugh, and Ms. Rice?

8 A. No.

9 Q. So is it fair to say there were no other
10 CMS attendees of the meeting?

11 MS. LIKOFF: Object to form.

12 Mischaracterizes the witness's testimony.

13 THE WITNESS: It's not correct. I don't
14 recall any other CMS employees attending the
15 meeting.

16 BY MS. BLAKEMAN:

17 Q. Do you remember why the meeting was held?

18 MS. LIKOFF: Object to form. Vague.

19 THE WITNESS: No.

20 BY MS. BLAKEMAN:

21 Q. What do you recall was said in the
22 meeting?

23 MS. LIKOFF: Object to form. Vague.

24 THE WITNESS: Could you be more specific?

25

1 BY MS. BLAKEMAN:

2 Q. Do you recall anything that was discussed
3 at this meeting?

4 A. I do not.

5 Q. Do you recall any questions posed to CMS
6 from United or Optum?

7 MS. LIKOFF: Object to form. Vague.

8 THE WITNESS: No.

9 BY MS. BLAKEMAN:

10 Q. Do you recall any statements from United
11 or Optum at this meeting?

12 MS. LIKOFF: Object to form. Vague.

13 THE WITNESS: No.

14 BY MS. BLAKEMAN:

15 Q. Do you recall any questions from yourself,
16 Mr. Cavanaugh, or Ms. Rice to the United/Optum folks
17 on the line at this meeting?

18 A. No.

19 Q. Do you recall any statements that
20 yourself, Mr. Cavanaugh, or Ms. Rice said at this
21 meeting?

22 MS. LIKOFF: Object to form. Vague.

23 THE WITNESS: No.

24 BY MS. BLAKEMAN:

25 Q. Do you recall any topics that were

1 discussed at this meeting?

2 MS. LIKOFF: Object to form. Vague.

3 THE WITNESS: No.

4 BY MS. BLAKEMAN:

5 Q. Do you recall whether anyone at United or
6 Optum asked yourself, Mr. Cavanaugh, or Ms. Rice for
7 clarification about whether United or Optum had a
8 proactive obligation to review diagnoses codes --
9 diagnosis codes, excuse me.

10 MS. LIKOFF: Object to form. Lacks
11 foundation. Vague.

12 THE WITNESS: Would you repeat that
13 question?

14 BY MS. BLAKEMAN:

15 Q. Do you recall at the meeting whether
16 anyone at United or Optum asked yourself, Ms. Rice,
17 or Mr. Cavanaugh for clarification about whether
18 United or Optum had a proactive obligation to review
19 diagnoses codes -- diagnosis codes -- that were
20 submitted?

21 A. No.

22 MS. LIKOFF: Object to form. Lacks
23 foundation. Vague. Compound.

24 THE WITNESS: No.

25

1 BY MS. BLAKEMAN:

2 Q. Do you recall any indication from
3 yourself, Mr. Cavanaugh, or Ms. Rice that United had
4 no proactive obligation to confirm whether diagnosis
5 codes submitted by physicians are correct?

6 MS. LIKOFF: Object to form. Lacks
7 foundation. Vague. Compound.

8 THE WITNESS: No.

9 BY MS. BLAKEMAN:

10 Q. Do you recall any indication from
11 yourself, Mr. Cavanaugh, or Ms. Rice that United did
12 have a proactive obligation to confirm diagnosis
13 codes submitted by physicians that -- excuse me --
14 that diagnosis codes submitted by physicians are
15 correct?

16 MS. LIKOFF: Object to form. Vague.
17 Compound. Lacks foundation.

18 THE WITNESS: Could you repeat that
19 question?

20 BY MS. BLAKEMAN:

21 Q. Do you recall whether yourself,
22 Mr. Cavanaugh, or Ms. Rice indicated to United at
23 this meeting that United did have a proactive
24 obligation to confirm whether diagnosis codes
25 submitted by physicians are correct?

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 DANIEL FARMER was remotely sworn to testify to the
7 truth, the whole truth and nothing but the truth.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

21

22

23

24

25



Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public
Dated: March 30, 2022

EXHIBIT D-106

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
MELISSA FERRON
Given Remotely
Wednesday, July 27, 2022
11:13 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 together into an HCC?

2 A. Yes. A subgroup of diagnostic codes are
3 grouped into HCCs, yes.

4 Q. So a single HCC, that's composed of
5 several ICD-9 or ICD-10 diagnosis codes?

6 A. Correct.

7 Q. I want to back up for a minute and talk
8 about where these codes are documenting, how they're
9 documented, and where they come from.

10 So I'm going to use an example. Let's say
11 there's a primary care doctor who has a patient who
12 comes in for her annual checkup. How does that
13 primary care doctor memorialize the medical
14 conditions that that patient has?

15 MS. CHEN: Objection.

16 BY MS. SOBEL:

17 Q. You can answer.

18 A. The provider would document in the medical
19 record, in a somewhat standardized form, for the
20 medical record, various components of the patient's
21 health and social status, and the diagnosis would be
22 documented in the medical record and then signed by
23 the provider.

24 Q. So would you agree with me that medical
25 providers record their findings about their patients

1 in their medical record?

2 A. Yes.

3 MS. CHEN: Objection. Leading.

4 BY MS. SOBEL:

5 Q. Historically, was this done by hand, by
6 the medical providers? In other words, they make the
7 medical records by writing -- you know, with a pen or
8 pencil in an actual chart?

9 A. Yes. There's a combination of handwriting
10 as well as dictation.

11 Q. And in more recent times, is this all done
12 electronically? In other words, medical records are
13 now done by doctors or medical providers with a
14 computer and in an electronic format?

15 A. Yes, that's more common now.

16 MS. CHEN: Ms. Sobel, I'm actually having
17 a really hard time hearing you. It's a little
18 bit fuzzy. Is there any way you could speak a
19 little bit closer to your microphone?

20 MS. SOBEL: Yeah. Let me figure out where
21 my microphone is. We're in a room where that's
22 not clear.

23 Yeah, let me -- let me switch places here.
24 I think I can make this better. Hold on, okay?

25 MS. CHEN: Thank you.

1 Yeah, you're -- you're sounding kind of
2 like you're on a speaker phone. I'm having a
3 hard time differentiating.

4 MS. SOBEL: No problem.

5 Is this better?

6 MS. CHEN: Can you say something else?

7 MS. SOBEL: Can you hear me?

8 MS. CHEN: I think it's a little bit
9 better. I'll let you know if I'm still having
10 the same problem.

11 MR. McNAMARA: Okay.

12 MS. CHEN: Please proceed.

13 MR. McNAMARA: Okay.

14 BY MS. SOBEL:

15 Q. We talked about this a little earlier,
16 Ms. Ferron. How does the information from a
17 patient's medical records get transformed into these
18 diagnosis codes, which we've been talking about most
19 of today?

20 MS. CHEN: Objection. Form.

21 THE WITNESS: The -- in context of what
22 we've been talking about today, a coder would
23 review the medical record and assign codes that
24 are documented in the medical record. That's
25 one way.

1 Other ways, you talked about the
2 electronic medical records. Often the physician
3 assigns the codes as they're documenting in the
4 medical record.

5 BY MS. SOBEL:

6 Q. So within a doctor's office, either the
7 physician or medical provider themselves provides the
8 actual diagnostic coding, or a coder in their office
9 does that?

10 A. Yes.

11 MS. CHEN: Object to form.

12 BY MS. SOBEL:

13 Q. I want to switch now and talk about coding
14 guidelines, which we touched upon earlier.

15 What are the various sources for coding
16 guidelines that coders like yourself use when coding
17 medical records?

18 A. Okay. They are the three that I mentioned
19 earlier: The actual ICD-10 or ICD-9 books has rules
20 for coding. And then there's the official guidelines
21 for coding and reporting that the CDC publishes. And
22 then there's Coding Clinic that the American Hospital
23 Association publishes.

24 Q. In the course of your career in coding
25 over the last 45 years, have you encountered

1 instances where these three sources, these three
2 guidelines, don't address the coding issue in medical
3 record?

4 A. All the time.

5 MS. CHEN: Object to form.

6 BY MS. SOBEL:

7 Q. Your answer was "all the time"?

8 A. All the time.

9 Q. Can you explain to me how this happens?

10 You can use examples, whatever would best explain how
11 this happens, that these three guidelines don't
12 provide a clear answer to a coding issue in the
13 medical record.

14 MS. CHEN: Object to form.

15 THE WITNESS: The -- the official -- so
16 let me just sort of describe what each of the
17 guidelines do for coding.

18 So the books themselves have conventions,
19 they're called coding conventions, that when
20 you -- gives you instruction how to look up a
21 code, and also gives you information on when an
22 additional code might be needed, when a -- a
23 code might be needing additional digits to be a
24 complete code. So that's what the ICD-10 book
25 would give you.

1 Then the official guidelines for coding
2 and reporting from the CDC -- it's only about --
3 I don't even know now, a 110-page document, so
4 it's very -- it's not very detailed. It gives
5 high-level guidelines.

6 And then Coding Clinic, which first
7 started providing guidelines in 1984, is more of
8 a question/answer type of publication, published
9 quarterly, where Coding Clinic decides what
10 questions they will answer and publish in their
11 publication.

12 But unfortunately, between all of those
13 three documents, there is not clear guidance for
14 many -- most scenarios. Only the easiest
15 scenarios can be coded.

16 Not only are they, in my opinion,
17 insufficient for the documentation in today's
18 world -- and what I mean by that, the verbiage
19 used by -- excuse me -- the verbiage used by
20 physicians aren't always in alignment with
21 the -- the coding -- the words in the coding
22 books. So they don't stay on top of changing
23 medical terminology.

24 As medical terminology evolves and
25 diseases evolve, the coding guidelines don't

1 either coded on that chart within previous years and
2 what may be a suspected condition.

3 Q. So when a coder is conducting a blind
4 coding review of a medical chart, she doesn't know
5 what codes the provider submitted on a claim to that
6 for a beneficiary?

7 A. Correct.

8 MS. CHEN: Objection. Form. Leading.

9 BY MS. SOBEL:

10 Q. I want to --

11 MS. YEVTUKHOVA: Objection. Form.

12 BY MS. SOBEL:

13 Q. I want to use another example.

14 Now, assume a provider has submitted
15 diagnosis codes for a beneficiary for diabetes and
16 heart failure. This is for a Medicare Advantage
17 beneficiary. Okay?

18 Now, in a blind review, as part of a chart
19 review program, the coder would not know that those
20 diagnosis codes were submitted, correct?

21 A. Correct.

22 MS. CHEN: Objection. Form. Leading.

23 BY MS. SOBEL:

24 Q. Assume the coder reviews the medical chart
25 and -- medical record, I should say -- and identifies

1 diabetes and hypertension as two diagnosis codes
2 documented in the medical record.

3 A. Okay.

4 Q. If the coder conducting his blind review
5 does not identify heart failure, does that mean that
6 heart failure is not documented in that patient's
7 medical record?

8 A. No.

9 MS. CHEN: Objection. Form.

10 MS. YEVTUKHOVA: Object to form.

11 BY MS. SOBEL:

12 Q. What would that coder need to do to
13 determine whether or not heart failure is in fact
14 documented in the patient's medical record?

15 A. The coder would need to know to go back to
16 the record, re-review the record, and look for the
17 diagnosis of congestive heart failure, do a more
18 thorough review of the medical record for congestive
19 heart failure.

20 Q. And have you seen instances in the course
21 of your career where a coder doesn't identify a
22 diagnosis code in a blind review, but other coders
23 subsequently find a code in a patient's medical
24 record?

25 A. It happens --

1 MS. CHEN: Object to form.

2 MS. YEVTUKHOVA: Object to form.

3 THE WITNESS: It happens all the time.

4 MS. SOBEL: Thank you, Ms. Ferron. I have
5 no more questions.

6 MS. CHEN: All right. I have a couple
7 follow-up questions, but -- can we take a quick
8 break?

9 MS. SOBEL: Sure. Yes.

10 VIDEOGRAPHER: We're now going off the
11 record. It's 6:19 p.m.

12 (A recess transpired from 6:19 p.m. until
13 6:27 p.m.)

14 VIDEOGRAPHER: We're back on the record.
15 It's 6:27 p.m.

16 FURTHER EXAMINATION

17 BY MS. CHEN:

18 Q. All right, Ms. Ferron, I just had a few
19 follow-up questions on the topics you discussed with
20 counsel for United.

21 First, you discussed your opinion that
22 there are gray areas in coding. Do you remember
23 that?

24 A. Yes.

25 Q. And so given these gray areas, how do

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

Karen Kidwell

21

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

22

23

24

25

EXHIBIT D-107

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
RICHARD SHAW FOSTER
Given Remotely
Thursday, March 31, 2022
11:01 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 to -- pardon me, to depose you in this case?

2 A. Oh, I guess it would have been last summer
3 sometime.

4 Q. And how did you learn about that?

5 A. Through a call from Martha Glover.

6 Q. When did you first learn about this
7 litigation?

8 A. I remember reading about it in the
9 newspapers some time back. I don't remember exactly
10 when.

11 Q. And have you discussed this deposition
12 with anyone other than your counsel?

13 A. My wife understands that I'm being deposed
14 in a case, but we never discussed the specifics or
15 what it's about or anything.

16 Q. All right. I should have said putting
17 aside your wife or your counsel, have you talked to
18 anyone else about the fact that you're being deposed
19 today?

20 A. No.

21 Q. Have you talked to anyone other than your
22 wife and counsel about this litigation?

23 A. No.

24 Q. Other than your wife and counsel, does
25 anybody else know that you're being deposed today, to

1 your knowledge?

2 A. No. Nobody knows.

3 Q. Mr. Foster, I'd like to go over your
4 background briefly. Could you tell us your
5 educational background?

6 A. Sure. I went to the College of Wooster in
7 Ohio and majored in mathematics. Then I went to the
8 University of Maryland at Baltimore County, to
9 graduate school in applied mathematics. Then I
10 undertook a series of national examinations to become
11 a member of the Society of Actuaries. Those exams
12 are educational in nature. They require substantial
13 studying to learn the information that you are then
14 tested on. I've studied various things on my own
15 from time to time, particularly statistics, some
16 economics.

17 I think that sums it up.

18 Q. And what was your first job after the
19 University of Maryland?

20 A. I got a job as a -- as an entry-level
21 actuary at the Social Security Administration.

22 Q. And when was that?

23 A. Either late January 1973 or early
24 February. I don't remember exactly.

25 Q. How long did you work at the Social

1 Security Administration?

2 A. Until February 1995.

3 Q. And you rose to the level of deputy chief
4 actuary there, correct?

5 A. That's correct.

6 Q. Did you leave the Social Security
7 Administration to join CMS -- or HCFA at the time?

8 A. Yes, HCFA at the time.

9 Q. And what job did you obtain at HCFA
10 in '95?

11 A. The position of chief actuary became open,
12 and I applied for that and was selected for that
13 position.

14 Q. And you served as chief actuary for
15 17 years, right?

16 A. I think it was actually 18 years.

17 Q. I didn't mean to chop off that 18.
18 Through December 2012, correct?

19 A. Through January 2013, approximately.

20 Q. Now, during your time, you prided yourself
21 on your independence, correct?

22 A. Yes. You've been doing your homework, I
23 can see. That's correct.

24 Q. In fact, you had some political pressure
25 from both sides of the aisle. Wouldn't that be

1 accurate?

2 A. Yes, that's fair.

3 Q. And in each case, you tried to do the
4 right thing?

5 A. Yes.

6 Q. Tell us how big the Office of the Actuary
7 was when you worked there.

8 A. When I first started, in 1995, the office
9 had a -- I think about 90 people in it. And
10 subsequently one -- one component of the office,
11 during a reorganization of CMS -- well, HCFA back
12 then, at large -- was broken off, and that group went
13 to the Office of Research and Demonstrations. So the
14 office size went down to maybe 70 or 75, in that
15 neighborhood. And it generally varied, while I was
16 there, between 70 and 90, over time.

17 Q. And how were those people organized within
18 the office?

19 A. Well, the office itself -- and it didn't
20 start this way immediately, but it -- before long, it
21 became the way I'll describe -- has three groups.
22 There's the Medicare and Medicaid Cost Estimates
23 Group. There is the Parts C and D Actuarial Group.
24 And there is the National Health Statistics Group.
25 And there is no further subdivision, no

1 formal subdivision within the groups.

2 Q. Approximately how large was each group
3 during your tenure there?

4 A. Well, I don't remember exactly, but each
5 group would have been in the range of 20 to
6 25 people.

7 I should add that the Parts C and D
8 Actuarial Group was not formed until after the
9 legislation that -- the Medicare Improvement Act in
10 2003.

11 Q. So Parts C and D were not in place during
12 the Balanced Budget Act of '97?

13 A. Part D was not. Part C was in place
14 already before then, or the equivalent of it; in
15 other words, a private sector managed-care operation.
16 And Part D didn't come along until the Improvement
17 Act.

18 Q. Fair enough. My question maybe wasn't
19 clear. I meant to say the Parts C and D Actuarial
20 Group within the Office of the Actuary didn't come
21 into place in '97. It first came into place in 2003.
22 Is that correct?

23 A. Technically it came into place as a result
24 of that legislation, and that happened in 2004.

25 Q. Understood. Okay.

1 There will be claims that have not yet been
2 processed or paid, and we won't know about those
3 until two or three or six months later.

4 BY MR. ABASCAL:

5 Q. But one method or one characteristic that
6 may be incomplete in fee-for-service data is the
7 diagnosis of the patient, correct?

8 A. I would say yes, there can be incomplete
9 records.

10 Q. And that's in part because in a
11 fee-for-service environment, the provider is paid
12 based on a procedure, correct?

13 A. Yes, that's right.

14 Q. And so that provider may not have the
15 incentive to code every diagnosis that that patient
16 has, when they're not being paid based on a
17 diagnosis, correct?

18 A. I would like to think that providers, as a
19 rule, follow the guidelines about what a claim has to
20 include, which includes a diagnosis.

21 And we do a pretty good job of it. Do
22 they always do a perfect job? Obviously the answer
23 is no.

24 Q. But you understood that the provider in
25 the fee-for-service environment was not obligated to

1 code every diagnosis that the patient has, correct?

2 MS. ZUPAC: Objection. Vague as to the
3 time frame you're referring to.

4 THE WITNESS: Did you want to clarify
5 that, Manny? Or should I go ahead?

6 BY MR. ABASCAL:

7 Q. Well, if you understand the question, you
8 can answer, or if you -- if you don't, I'm happy to
9 clarify it for you.

10 A. Well, would you mind just repeating the
11 question for me, please?

12 Q. Sure. You understand that a provider in
13 the fee-for-service environment is not obligated to
14 code every diagnosis that the patient has when
15 submitting a claim?

16 A. Well, that's correct. They're not only
17 not obligated to do that, but they're not supposed to
18 do that. They're supposed to include the diagnosis
19 that relates to the service that they performed on
20 that particular visit.

21 Q. Correct. So one of the pluses and
22 minuses -- a minus, if you will -- of using
23 fee-for-service data, is that it may not capture all
24 of the diagnoses that a patient has, correct?

25 MS. ZUPAC: Object to form.

1 THE WITNESS: I wouldn't call it a plus or
2 minus. It's more of a fact of life. They're
3 trying to set up a risk-adjustment model that
4 will reflect diagnoses from the prior year. And
5 you work with the data you have.

6 And then the results of that model, when
7 it's applied to calculate risk scores for
8 whatever group of beneficiaries is relevant, you
9 then also use the diagnoses you have, which
10 hopefully the completeness and the accuracy
11 would be very or fairly similar to the case, as
12 in the fee-for-service source of the data. So
13 that's the process, how it's intended to work.

14 If you end up with a more complete record
15 or a less complete record when calculating some
16 individual's risk score, that could adjust or
17 affect the calculated risk score up or down
18 accordingly. But the hope would be that on
19 average, over a sizeable group of people, those
20 kinds of differences in coding practice would
21 average out compared to fee-for-service.

22 BY MR. ABASCAL:

23 Q. But the fact of life is that the model is
24 calibrated on data that may be incomplete or
25 inaccurate with respect to the diagnoses of the

1 CERTIFICATE OF REPORTER

2 I, Karen K. Kidwell, Registered Merit Reporter
3 and Notary Public for the State of Maryland at Large,
4 do hereby certify:

5 That the foregoing deposition was taken
6 remotely before me on the date and at the time stated
7 on page 1 of this transcript; that the deponent was
8 duly sworn to testify to the truth, the whole truth
9 and nothing but the truth; that the testimony of the
10 deponent and all objections made at the time of the
11 examination were recorded stenographically by me and
12 were thereafter transcribed; that the foregoing
13 deposition as typed is a true, accurate and complete
14 record of the testimony of the deponent and of all
15 objections made at the time of the examination to the
16 best of my ability.

17 I further certify that I am neither related to
18 nor counsel for any party to the cause pending or
19 interested in the events thereof.

20 Witness my hand this 4th day of April, 2022.

21

22

23

24

25

Karen Kidwell

Karen K. Kidwell,
Registered Merit Reporter
Notary Public
State of Maryland at Large
My Commission expires:
April 14, 2025

EXHIBIT D-108

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
JANET FRY

(Taken virtually)

9:02 a.m. Eastern

Thursday, June 2, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. You are also a certified professional
2 coder, or CPC, through the AAPC; correct?

3 A. Yes.

4 Q. You've been a CPC since 2009; correct?

5 A. That's correct.

6 Q. And did you also end that when you
7 retired?

8 A. Yes.

9 Q. What is AAPC?

10 A. American Association of Professional
11 Coders.

12 Q. And what is a certified professional
13 coder?

14 A. That, again, is a certification that --
15 a test that shows you're competent in the skills of
16 coding, particularly physician records. So there's
17 not the emphasis of inpatient rules and Medicare
18 rules that there is in the clinical -- the CCS. So
19 the CPC is more physician related.

20 Q. You're also an AHIMA approved ICD-10
21 trainer; correct?

22 A. Correct.

23 Q. What does this entail?

24 A. So this was a certification and mostly
25 online classes and the ICD-10, the change to ICD-10

1 from ICD-9. So it was a complete overhaul of the
2 coding system, so I took the course to not only
3 learn the system, but be able to teach it.

4 Q. And to make sure we're on the same
5 page, ICD-10, does that refer to the International
6 Statistical Classification of Diseases?

7 A. Yes, International Classification of
8 Diseases, 10th revision.

9 Q. And what is ICD-10?

10 A. ICD-10 is the coding system that is
11 approved for use in all environments through the
12 World Health Organization and also the CMS. So
13 it's the only coding system that is approved for
14 use. 10 is the more recent reiteration of it,
15 whereas ICD-9 is mostly what has covered my
16 particular involvement in RADV. 10 didn't start
17 until after -- pretty much after I had already
18 retired. Because of the way audits are, you're
19 reviewing one, two, or three years after the fact.
20 So that was one reason I retired when I did because
21 there was this change that there was a good
22 stopping point.

23 Q. Understood. And are ICD-10 a set of
24 diagnosis codes?

25 A. Yes.

1 Q. So if you turn to page 3 of the
2 Exhibit 1212 in front of you, there -- at the
3 bottom of the page, there are sort of underlined
4 text. The second underlined line reads, "Member
5 American Health Information Management Association,
6 AHIMA."

7 Do you see that?

8 A. Yes.

9 Q. How long have you been a member of
10 AHIMA?

11 A. Since 1981.

12 Q. Are you still a member?

13 A. No.

14 Q. The next underlined line reads "Member
15 American Association for Professional Coders."

16 Do you see that?

17 A. Yes.

18 Q. How long have you been a member of
19 AAPC?

20 A. Just since -- was it 2009 that I took
21 their test? Yes.

22 Q. And are you still a member?

23 A. No.

24 Q. Okay. Do you have any degrees or
25 certificates that are not listed on your resum??

1 A. No.

2 Q. Do you have any other training in
3 medical coding?

4 A. Any other training in medical coding?

5 Q. Yes.

6 A. Just what I have mentioned. Just in
7 order to maintain your RHIA, you have to take
8 continuing education credits every two years. So
9 yes, I've kept up with the industry, but as far as
10 a formal like college course, I taught coding, but
11 I didn't take coding.

12 Q. Understood. Do you have any medical
13 training?

14 A. No.

15 Q. Are you familiar with the term
16 "Medicare Advantage"?

17 A. Yes.

18 Q. Is this term often referred to as MA?

19 A. Yes.

20 Q. What is Medicare Advantage?

21 A. Medicare Advantage is Part C of the
22 options that are available for Medicare
23 participants. A being the inpatient care, B being
24 medical, and then C is a combination of those two
25 which is a contracted organization, insurance

1 company, if you will, that contracts with Medicare
2 to cover their patients in a combined manner for
3 inpatient and outpatient services.

4 Q. How did you learn about Medicare
5 Advantage?

6 A. I was one of the original trainers for
7 Medicare Advantage back in 2000 when I worked for
8 Aspen Systems. So Medicare taught us Aspen and we
9 taught the industry. So I don't know. That's how
10 I learned from it, directly from Medicare.

11 Q. Got it. So I want to walk through your
12 different roles as a subcontractor or contractor
13 for CMS. So before you retired, were you
14 contractor for CMS?

15 A. Subcontractor, yes.

16 Q. Subcontractor, okay. If you can turn
17 back to page 1 of Exhibit 1212, there's a section
18 titled "Employment Experience." Do you see that?

19 A. Yes.

20 Q. So under employment experience on the
21 first page, it says, "Self-employed contractor,
22 Janet Fry, RHIA, LLC." Do you see that?

23 A. Yes.

24 Q. Was Janet Fry, RHIA, LLC, your company?

25 A. Yes.

1 Q. Were you the sole employee?

2 A. Yes.

3 Q. Did your company Janet Fry, RHIA, LLC,
4 contract with CMS?

5 A. I contracted with Signature Consultant
6 and different contractors for CMS, but I also had a
7 period of time where I was directly a contractor
8 with CMS.

9 Q. Did your company ever contract with any
10 other federal government agencies?

11 A. Federal government? No.

12 Q. Did you do any sort of subcontracting
13 with an entity that did contract with other federal
14 government agencies?

15 A. No, I don't think so.

16 Q. So under this, as you pointed out, it
17 says Signature Consulting Group. What is Signature
18 Consulting Group?

19 A. That is a -- how can I say this? It's
20 a group, a organization that does various work for
21 different clients. So it's like -- it's a
22 consulting group that does work for various
23 clients.

24 Q. And did you have a subcontract with
25 Signature Consulting Group?

1 A. Yes.

2 Q. Were you ever an employee of Signature
3 Consulting Group?

4 A. No.

5 Q. Under this it says "Independent
6 Statistical Consulting, ISC, contract." Do you see
7 that?

8 A. Yes.

9 Q. What is the independent statistical
10 consulting contract?

11 A. That was a portion of the total RADV
12 picture that CMS contracted with Signature to
13 provide services.

14 Q. So this contract was between CMS and
15 Signature Consulting?

16 A. Yes.

17 Q. And you were a subcontractor under this
18 contract?

19 A. Yes.

20 Q. This says next to it "August 2013 to
21 present." Do you see that?

22 A. Oh, yes.

23 Q. Do you recall this starting or starting
24 this role in August 2013?

25 A. Yes.

1 Q. Do you know when this role ended?

2 A. That would be January 2020.

3 Q. Okay. Did you have any other roles as
4 a contractor or subcontractor to CMS with Signature
5 Consulting Group?

6 A. No.

7 Q. So then the next -- or under the
8 independent statistical consulting it says,
9 "Independent coding contractor (ICC) providing
10 subject matter expertise (SME) and training in
11 medical documentation, project guidance, ICD-9-CM
12 and CMS-HCC coding for the CMS Risk Adjustment
13 Validation medical record review team and Medicare
14 Advantage, MA, organization participants."

15 Do you see that?

16 A. Yes.

17 Q. What is an independent coding
18 contractor, ICC?

19 A. That is a term that CMS came up with to
20 describe a person who is -- would help them with
21 official coding guidance, documentation. The
22 statement of work that I have, it talks about the
23 ICC will conduct training, facilitate discussions,
24 develop written communication, guidance and
25 briefing material to document and assist CMS in

1 making decisions.

2 Q. And were you the ICC?

3 A. Yes.

4 Q. What did -- in addition to what you
5 just mentioned, is there anything else that you did
6 in this role?

7 A. That pretty much covers everything.

8 Q. Okay. Who did you report to in this
9 role?

10 A. The -- let's see, I had a couple of
11 different supervisors. The last one was Cora
12 Hutchinson.

13 Q. And -- go ahead.

14 A. Project manager, yes.

15 Q. And is she at CMS?

16 A. I'm sorry. She's with Signature, yes.

17 Q. Okay. So did you report to CMS at all
18 as the ICC?

19 A. I did communicate with them directly,
20 yes.

21 Q. How long were you the ICC related to
22 this contract? It was 2013 to 2020; is that
23 correct?

24 A. Related to the Signature portion of the
25 contract, yes.

1 Q. Okay. When you say subject matter
2 expertise here, was the subject matter expertise in
3 coding?

4 A. Coding and documentation and medical
5 record guidance.

6 Q. Did you consider yourself a subject
7 matter expert in coding?

8 A. Yes.

9 Q. And then I know you've mentioned this a
10 few times, but just so it's clear, CMS Risk
11 Adjustment Data Validation here refers to RADV
12 audits?

13 A. That's correct.

14 Q. What are RADV audits?

15 A. RADV audits are the method by which CMS
16 validates that the information they receive from MA
17 organizations can be tracked back to documentation
18 that was made in a medical record at or near the
19 time of the service that was provided.

20 Q. And who is the medical record review
21 team referred to here?

22 A. Okay. So there's -- in order to
23 conduct these RADV audits, there's two -- one, two,
24 or three different teams of contractors, medical
25 record review contractors, sometimes abbreviated

1 MRRC, that are working to review medical records
2 independently, and then -- but the decisions in all
3 of that CMS needs to make and policies that are
4 need to make were filtered through the independent
5 coding contractor so that everybody was kind of
6 doing things the same way on the same page. That's
7 the team.

8 Q. Go ahead. So the medical record review
9 team, were those other contractors to CMS?

10 A. Yes. They would include other
11 contractors and CMS representation.

12 Q. And do you remember the names of any of
13 the other -- the medical record review contractors?

14 A. We've had a few over the years.
15 Strategic was one. Rely Group was one. They used
16 to be called BDS. So there's different names have
17 changed over the course of the project as the
18 contracts are released. Organizations sometimes do
19 some shifting around to get the contract to fit
20 what they're currently doing. So that makes sense.

21 Another team member would be the group
22 that does all the technical work. The -- we had a
23 tool in order to review records. So that tool had
24 to be developed by another contractor, but we
25 needed -- they needed our input as coders to

1 develop that tool. That's why we call it a team
2 because it was a lot of different contractors
3 working together to get the best result.

4 Q. Understood. If you can turn back to
5 page 1 of Exhibit 1212 on your screen, there's a
6 position midway down, it says Centers for
7 Medicaid -- Medicare and Medicaid. Do you see
8 that?

9 A. Yes.

10 Q. And underneath it reads, "Independent
11 coding contractor, ICC, providing consulting
12 services for Risk Adjustment Data Validation team
13 including SME, MA organization, and review
14 contractor project training, resource development,
15 abstraction tool development, consultation and
16 testing."

17 Do you see that?

18 A. Yes.

19 Q. This states you were in this role from
20 August of 2009 to July 2013; is that correct?

21 A. That's correct.

22 Q. Is the ICC role here the same as the
23 one we just discussed?

24 A. Yes.

25 Q. Were there any differences?

1 A. Just said I was reporting directly to
2 CMS instead of through a contractor.

3 Q. So did you contract with CMS directly
4 to be the ICC?

5 A. Yes. During that time period the
6 vehicle for the contract allowed for direct
7 contracting with CMS. And when that changed, then
8 I went and moved to Signature.

9 Q. Who did you report to at CMS related to
10 this role?

11 A. At this point of time I think it was
12 Carolyn Kapustij. Maybe Lateefah Hughes may have
13 been involved too. I had several different task
14 people over the years. So that's -- those are a
15 couple of names I recall.

16 Q. And when you say consulting services
17 for the RADV team including SME, you're referring
18 to the same RADV audits we talked about earlier?

19 A. Yes.

20 Q. And does SME also still refer to
21 subject matter expertise?

22 A. Yes.

23 Q. Was the subject matter expertise also
24 coding here?

25 A. Yes, coding and documentation.

1 Q. Okay. What does review contractor
2 project training refer to?

3 A. I was tasked with providing training to
4 the review contractors regarding each year's review
5 that we were doing, whether it was 2007 or 2008,
6 whatever the year was. So each year, each time we
7 got a new review cycle started, there would be a
8 training. So the coders from each of the MRRCs,
9 medical record review contractors, each of them
10 would come together and we would conduct a
11 training. It would be an overview of what the
12 project was about, any new coding changes that
13 occurred nationally, any lessons learned from the
14 prior audit, and then we would typically -- again,
15 it changed over the years, but typically we would
16 end with some kind of an assessment that the coders
17 understood the instructions. And then they would
18 go to their own MRRCs and continue internal
19 training from there. So it was kind of bringing
20 everybody together and then they could go and
21 adjust the information on their own. And if they
22 had any questions, then they could -- we would meet
23 fairly regularly, almost weekly or biweekly, we
24 would meet fairly regularly to discuss any
25 questions they had, any project concerns. And I

1 would, you know, help with any particular coding
2 question that came up or documentation issue that
3 came up that couldn't be answered in their own --
4 you know -- they had professional coders, so they
5 could answer their own questions. But sometimes
6 just odd things came up that they wanted another
7 opinion on, so that's where I came in.

8 Q. Got it. Okay. And the review
9 contractors were the MRRCs, as you called them, the
10 medical record review contractors?

11 A. Yes.

12 Q. And did the medical record review
13 contractors review medical records as part of the
14 RADV audits?

15 A. Yes.

16 Q. The abstraction tool that's mentioned
17 here, is that the tool you mentioned earlier that
18 would be used to review the medical records?

19 A. That's correct.

20 Q. So if you look at the very bottom of
21 the exhibit on page 1 of Exhibit 1212, it says
22 "Ascellon Corporation" and then September 2006 to
23 August 2010. Do you see that?

24 A. Yes.

25 Q. And then if you skip to page 2, it

1 Meanwhile or subsequently -- so, again,
2 different projects we did it differently -- a
3 secondary validation contractor was reviewing that
4 record and doing the same process, coding it first,
5 sending it to a senior coder if there was a
6 discrepancy. And, you know, finding the -- the
7 tool doing the work behind the scenes to do the
8 comparisons. And, yeah, so that's -- that's the
9 process -- the initial process.

10 Now, along the way there's a -- what's
11 called an escalation process in most of the review
12 years. And that would be when a coder comes across
13 a record that, for some reason, they question
14 whether that record should be coded because it
15 doesn't fit the guidelines set for the risk
16 adjustment program. It might be out of the year.
17 It might not be signed. There's no credential.
18 There's different evaluation things that happen
19 while you code.

20 So those are the type things they would
21 escalate to a senior coder and that coder could
22 then escalate it to the QA panel which I was in
23 charge of. So basically it's escalating it to me.

24 Other types of questions that could
25 come up, each of the medical record review

1 organizations had their own internal experts. So,
2 you know, they tried to handle anything they could
3 on their own based on the professional coders that
4 they had hired. But, again, there comes times when
5 there's questions. So those -- if a coding
6 question came up with how do we handle this
7 particular code in relation to this project or this
8 particular document or some kind of a discrepancy
9 of some kind, those could also get escalated to the
10 QA panel, me basically with -- you know, I would
11 look at the question and then we would talk about
12 it in the panel.

13 Q. Got it.

14 A. So that's kind of the process. Does
15 that help?

16 Again, there's different ways it was
17 done, but bottom line is at least four professional
18 coders were looking at every record. Likely more
19 than that if a supervisor is involved or myself.
20 So the run of the mill records, ones that were just
21 easy straight up coding, this is what the person
22 has, it's well documented, it's signed. Boom, it's
23 done. Those went through bought trouble.

24 But there was a percentage of records,
25 I don't know what percentage, but that for whatever

1 reason, those reasons I've mentioned, had to be
2 escalated and looked at by yet another set of eyes
3 or a physician or if the -- if it was a overarching
4 policy kind of thing, then I would need to bring
5 the whole issue up to CMS. So those were the kind
6 of things that happened during a regular medical
7 record review audit. Okay. Sorry.

8 Q. Very helpful. So one follow-up
9 question on the -- so you mentioned a percentage of
10 the records would need multiple years of review and
11 you didn't know a percentage. Do you have a sense
12 of how often that occurred?

13 MS. ZUPAC: Object to form.

14 BY MS. MADDUX:

15 Q. You can answer.

16 A. Okay. I don't have that information
17 right in front of me. I mean, just from memory,
18 the code -- the panel met in the heighth of a
19 review project. We met almost weekly reviewing
20 maybe 10 records. So we're talking 10 out of
21 thousands that were being reviewed that week. So
22 it wasn't a huge percentage.

23 Q. And I think we'll show some documents
24 in a little while. We can talk through more pieces
25 of the explanation you just provided. But do

1 but to make it the most correct review
2 possible.

3 BY MS. MADDUX:

4 Q. What is an additional HCC?

5 A. That would be a -- a HCC that was never
6 reported for that particular patient client member
7 for the whole year of review. Risk adjustment is
8 something that's not reported each time the person
9 goes to the hospital but it's more of like a
10 quarterly reporting or such. So if they've never
11 reported that particular diagnosis that triggered
12 that particular HCC, that would be -- and we found
13 it during the audit, that's an additional HCC.

14 Q. So the additional HCC is the diagnosis
15 code that the primary coder identified but had not
16 been submitted to CMS by the MA plan?

17 A. Yes. Primary or it could be the senior
18 also. It could be either one that identifies
19 something new.

20 Q. So the next paragraph in this section
21 reads, "MRRC senior level coders and/or other
22 designated coding supervisors monitor the IRR and
23 make recommendations to the project manager
24 regarding corrective action, workflow coordination,
25 and continuing education based on trends observed

1 during the review.

2 Do you see that?

3 A. Yes.

4 Q. How does the senior coder monitor the
5 IRR?

6 A. Again, this is up to each individual
7 MRRC, how they've set up their quality control
8 program. So we didn't -- I didn't give them
9 direction on how to do that. That's -- that was
10 their choice on how to monitor it.

11 Q. The next paragraph in this section
12 reads, "Senior coders have the option to reverse --
13 refer situations in which they disagree with either
14 the primary or another senior coder to the ICC for
15 another opinion. The ICC coding advice often will
16 result in clarification or addition to the coder
17 guidance document."

18 Do you see that?

19 A. Yes.

20 Q. Why would a senior coder disagree the
21 primary coder or with another senior coder?

22 MS. ZUPAC: Object to form.

23 THE WITNESS: The coders' opinions
24 could differ because of the documentation
25 that was presented. The coding is a

1 discipline that is based on multiple --
2 multiple documentation by multiple people in
3 the medical record. So one coder may have
4 seen something in a particular note that he
5 or she felt was important to pick up whereas
6 another coder might either just decided that
7 wasn't appropriate to code at that point or
8 maybe was a historical condition that the
9 person doesn't have anymore.

10 So there's these types of decisions
11 that are made every time you open up a
12 medical record to determine whether to
13 include the condition or not.

14 BY MS. MADDUX:

15 Q. So this situation is describing a
16 scenario where the senior coder may disagree about
17 whether a medical record documentation supported a
18 diagnosis code or HCC?

19 A. Yes.

20 Q. And in addition to the reasons you just
21 gave, are there any other reasons two certified
22 coders may disagree about whether a medical record
23 documentation supports a diagnosis or HCC?

24 MS. ZUPAC: Object to form.

25 THE WITNESS: Just in general. I don't

1 have any specific examples to give you, but
2 that's just a known fact. That's why we do
3 audits, because people disagree with the
4 information that's in the medical record.

5 BY MS. MADDUX:

6 Q. In your experience working with trained
7 coders, do you think it was not uncommon for two
8 certified coders to disagree on whether or not a
9 particular diagnosis code is supported in the
10 medical record?

11 MS. ZUPAC: Object to form.

12 THE WITNESS: I can't really put a
13 percentage whether to say it's common or not
14 common. I believe I mentioned before that
15 we only saw a -- we didn't see the whole --
16 100 percent of the records did not come
17 through as discrepant. So, therefore, some
18 did, but I don't have numbers as far as
19 which ones -- what the numbers were to give
20 you.

21 BY MS. MADDUX:

22 Q. While you were the ICC, do you recall
23 senior coders raising situations with you where the
24 senior coder disagreed with a primary coder or
25 senior coder?

1 A. Yes.

2 Q. Do you know how often this occurred?

3 MS. ZUPAC: Object to form.

4 THE WITNESS: Same response. I don't
5 have a percentage or a number for you.

6 BY MS. MADDUX:

7 Q. How would you resolve the disagreement?

8 A. The case would be discussed with the
9 es- -- the -- how do I say it?

10 The -- I would review the medical
11 record and look at what both -- the notes that both
12 coders gave to say what the problem was, where were
13 they having issues, you know, why did they
14 disagree, that sort of thing. And then, again,
15 since I was kind of the -- at the top as far as the
16 buck stops here, I would -- we would make a
17 decision on the guidance that we have. I'd either
18 agree with the primary or agree with the senior.
19 We may have to bring in a physician if we wanted to
20 look at it a little further, if it was a clinical
21 issue that they were disagreeing on. But primarily
22 between discussion of the -- myself plus other
23 professional coders that were on the QA panel, we
24 could typically come up with a good decision as far
25 as what the medical record documented.

1 Q. Did you ever need to reach out to the
2 Coding Clinic or another coding expert for
3 guidance?

4 A. Yes, absolutely. Yeah, the Coding
5 Clinic was in -- I'm not sure if it was in our tool
6 this early. But later on we actually could --
7 while we were reviewing records, we could look up
8 things on Coding Clinic. And so what I did before
9 that time was when these particular kind of cases
10 came up, I would see if there's any Coding Clinic
11 information on that particular condition, and I
12 kept like a spreadsheet of that information. So
13 that coders would have it for the next time that
14 particular issue came up. So it's all part of our
15 ongoing training.

16 Q. And is that the coder guidance document
17 mentioned here?

18 A. Yes. That's part of it, yes.

19 Q. So we've also been going about an
20 another hour, if we can maybe take another
21 five-minute break and go off the record.

22 THE VIDEOGRAPHER: We are going off the
23 record. The time is 11:06 a.m.

24 (Recess taken from 11:06 a.m. until 11:13 a.m.)

25 THE VIDEOGRAPHER: We are back on the

1 record. The time is 11:13 a.m.

2 BY MS. MADDUX:

3 Q. So if you can look back at Exhibit 1213
4 in AgileLaw, and we're still on page 10, but now if
5 you can sort of scroll to the right-hand side of
6 the page.

7 A. Okay.

8 Q. And the top header says "4.4.2 coder
9 guidance document"?

10 A. Correct.

11 Q. The second sentence of this section
12 reads "RADV experience has shown that provider
13 documentation varies widely in legibility, clinical
14 terminology, format, and authentication practices."

15 Do you see this?

16 A. Yes.

17 Q. Can you explain what this means?

18 A. So the documentation that is submitted
19 to support the HCCs, again it varies widely.
20 They're coming from different physician offices,
21 outpatient facilities, inpatient facilities, parts
22 of inpatient records. So there's lots of documents
23 that are coming in with -- some are electronic. At
24 this early stage, a lot of them were handwritten.
25 The formats differed. Some would have a lovely

1 summary with all of the diagnoses neatly listed.
2 Some would have no summary and you would have to
3 sort through 100 pages of progress notes to find
4 the diagnoses. Format, kind of self explanatory.
5 And then authentication practices, we want to make
6 sure that all of the medical records that came in
7 were actually from a -- they were from a provider
8 that was a Medicare supported provider, so a
9 physician or a physician extender. It couldn't
10 just be a lab report because that's not a supported
11 specialty for this -- for the RADV projects.

12 So all of this when we did the intake
13 of the medical records was -- was quite an
14 undertaking. So what we did -- well, go ahead.
15 You can go with your next question then. Does that
16 help?

17 Q. Yes. So how would legibility impact
18 medical record review?

19 A. Oh, quite a bit. Legibility and the
20 date; legibility and the diagnosis; legibility and
21 physician's signature, credential; very --
22 legibility is always an issue when you're coding
23 both currently and -- but especially
24 retrospectively since you can't go back and ask the
25 physician to interpret their handwriting.

1 Q. So the legibility of a medical record
2 may impact whether a primary or senior coder was
3 able to identify a diagnosis?

4 A. Yes.

5 Q. Could legibility be a reason that two
6 coders may review the same medical record and reach
7 different results?

8 A. Yes.

9 Q. How would variances in clinical
10 terminology impact medical record review?

11 Wendy, sorry, I think you're on mute.
12 I want to make sure --

13 A. There she is.

14 MS. ZUPAC: Thanks. Sorry.

15 BY MS. MADDUX:

16 Q. So I can repeat the question.
17 How would variance in clinical
18 terminology impact medical record review?

19 MS. ZUPAC: Object to form. Thank you.

20 THE WITNESS: The differences in
21 clinical terminology again based on the type
22 of record we received, it may be very
23 detailed or it may be not, or it could be an
24 abbreviation form or some kind of truncated
25 form. So the clinical terminology for a --

1 like a heart center teaching facility would
2 be different than the terminology used for a
3 physical done by someone who doesn't even
4 know the patient.

5 So there's different terminology that
6 could be listed. And so, again, there's
7 differences that typically these type things
8 would get escalated to a senior person to
9 sort out as would legibility actually.

10 BY MS. MADDUX:

11 Q. Would variances in clinical terminology
12 be one reason why two coders reviewing the same
13 medical record may reach different results?

14 MS. ZUPAC: Object to form.

15 THE WITNESS: Yes.

16 BY MS. MADDUX:

17 Q. So then the next section on this page
18 of Exhibit 11 -- excuse me, 1213 states in part,
19 "In addition to documentation issues, the Coder
20 Guidance summarizes selected official coding
21 guidelines for ICD-9-CM and AHA Coding Clinic for
22 ICD-9-CM sources for consistent interpretation
23 across RADV coders. These issues have been raised
24 by RADV coders as challenging coding situations
25 that impact common conditions in the Medicare

1 A. Yes.

2 Q. Why would the medical record review
3 contractor do an IRR evaluation on a test sample
4 prior to reviewing actual project records?

5 MS. ZUPAC: Object to form.

6 THE WITNESS: This would be part of the
7 hiring process. These are contractors that
8 have -- they could have several other
9 contracts going on. So in order to select
10 the coders best qualified, they do some
11 internal assessment and this is one of it.
12 They do a test sample of records to see that
13 that -- that coder is -- fully understands
14 inpatient, outpatient, physician coding
15 rules, and compare it to the -- like a gold
16 standard of records that they have set up,
17 like a test you would take for employment.

18 BY MS. MADDUX:

19 Q. Why does the primary coder need to meet
20 a 95 percent reliability score?

21 MS. ZUPAC: Object to form.

22 THE WITNESS: This would be -- the
23 number itself, I'm not sure exactly where
24 that came from. I assume it's in the
25 medical record review contractor's contract.

1 But, again, it's just showing that the
2 most -- the best coders are one that agree
3 to the gold standard of coding. So it's
4 keeping the most experienced coders that
5 understand the project the best in the --
6 for consistency purposes.

7 BY MS. MADDUX:

8 Q. Does the 95 percent threshold
9 acknowledge that coders may not agree about whether
10 a diagnosis code is supported by a medical record
11 100 percent of the time?

12 MS. ZUPAC: Object to form.

13 THE WITNESS: That's correct.

14 BY MS. MADDUX:

15 Q. Does this 95 percent threshold
16 acknowledge that coders may make mistakes and miss
17 diagnosis codes that are, in fact, supported in the
18 medical record?

19 MS. ZUPAC: Object to form.

20 THE WITNESS: True.

21 BY MS. MADDUX:

22 Q. What are some reasons why a primary
23 coder's IRR may be 95 percent or less?

24 MS. ZUPAC: Object to form.

25 THE WITNESS: All of the examples I've

1 given you previously with the documentation
2 issues, the coding, interpreting the coding
3 rules differently, experience, those are all
4 things that can contribute to the
5 95 percent.

6 BY MS. MADDUX:

7 Q. Was one reason the primary coder may
8 have missed a diagnosis code that was supported by
9 the medical record because the primary coder was
10 conducting a blind review?

11 MS. ZUPAC: Object to form.

12 THE WITNESS: I -- I don't really -- I
13 can't really answer that yes or no.

14 BY MS. MADDUX:

15 Q. If a primary coder did not identify a
16 diagnosis code in their blind review, does that
17 mean that a diagnosis code is not supported in the
18 medical record?

19 MS. ZUPAC: Object to form.

20 THE WITNESS: Well, I think we pretty
21 much already answered that with there's a
22 secondary review by a senior coder, so yes.

23 BY MS. MADDUX:

24 Q. What are coding errors?

25 A. Coding error would be one that -- in an

1 Q. Then it says two bullets later,
2 "conflicting documentation within the same record,"
3 what does that refer to?

4 A. That would be the example I gave you
5 earlier where like a specialist might say the
6 person has one thing, but the attending physician
7 doesn't feel that that's important or hasn't
8 included that in his final list of -- his or her
9 final list of diagnoses. That's where there's some
10 disagreement.

11 Q. How are coders supposed to resolve
12 conflicting documentation within the same record?

13 A. Our instructions were that the -- for
14 instance, in the inpatient record, the attending
15 physician has the final say of what the condition
16 is. So if they've included it in their final
17 progress note or summary, that would be -- that
18 would trump anything that happened earlier in the
19 process of determining the condition.

20 Q. And then why would coder education and
21 experience contribute to coder disagreement?

22 A. The coders, of course, were hired for
23 different projects and different -- they had
24 different abilities and years of experience. They
25 all met the minimum requirements. But,

1 particularly, if they had a lot of experience in
2 the hospital where the regulations are much more
3 strict, and there's a lot of use of Coding Clinic
4 whereas a physician-based coder whose -- most of
5 their career has just worked for physicians
6 wouldn't have that same level of experience with
7 coder clinic -- Coding Clinic because it's not
8 really used in physician offices, which is more of
9 a service-based coding instead of a diagnosis-based
10 coding. So theirs have levels of difference.

11 They all met the minimum requirements,
12 but through education and training, we get them all
13 up to the same speed. But there could be -- this
14 could be, as I said, this was just a subjective
15 maybe this could be a problem that the MRRCs could
16 identify and add to their quality control.

17 Q. And then the couple later it says coder
18 fatigue productivity standards. Why would coder
19 fatigue contribute to coder disagreement?

20 A. This again was just a guess on industry
21 standards and industry, you know, doing research to
22 find different reasons for coder disagreement and
23 coder fatigue is one of them.

24 Q. And why would productivity standards
25 potentially lead to coder disagreement?

1 A. Again, if it's potentially they -- and
2 I don't even know if there were productivity
3 standards at the MRRCs. But, again, if the coder
4 felt stressed to work faster, they might forget or
5 miss a particular diagnosis, which is why we have
6 the various levels so that the next person could
7 pick it up.

8 Q. And looking at this list today, are
9 there any other factors that you can think of that
10 may contribute to coder disagreement?

11 A. No. I think it's pretty -- you know,
12 can pretty much generalize because of documentation
13 and signatures and guidance. That's pretty much
14 what the -- subjectively, what we think causes
15 differences in coding.

16 MS. MADDUX: So I think if we can go
17 off the record.

18 THE VIDEOGRAPHER: We are going off the
19 record. The time is 12:09 p.m.

20 (Recess taken from 12:09 p.m. until 12:40 p.m.)

21 THE VIDEOGRAPHER: We are back on the
22 record. The time is 12:40 p.m.

23 (Exhibit 1215 marked for
24 identification.)

25 BY MS. MADDUX:

1 Q. Okay. So I'm going to direct your
2 attention back to AgileLaw. We're going to load a
3 new document. Tab 7. This will be Exhibit 1215.
4 And for the record, it is Bates stamped
5 USBP001210260. Do you see a document up on your
6 screen?

7 A. Yes.

8 Q. If you can take a minute to scroll
9 through and if you need to zoom, do that.

10 And this be appears to be an e-mail
11 chain dated April 1, 2010, between you Linda Small,
12 you, and others; is that correct?

13 A. Yes.

14 Q. Who is Linda Small?

15 A. She was a senior coder at -- or maybe
16 project manager, I'm not sure, at BDS, one of the
17 MRRCs.

18 Q. And, now, you can scroll to the bottom
19 of page 1 of Exhibit 1215, her e-mail starts there,
20 and it says, "In reviewing the 25 national CY 08
21 sample of records to be used for generating IRR
22 data on our coders, we had some difficulty with
23 three of the records," and then it continues to
24 page 2, "in establishing the final answers due to
25 gray areas, that can create inconsistency among

1 even the best coders. This coder interpretation
2 and discretion to weigh in on code assignment could
3 influence their final IRR score and ultimately
4 could result in falling below 95 percent. Since
5 coding -- code guidance instructs primary coders to
6 seek senior coder guidance in these situations.
7 The primary coder is denied their right in the IRR
8 sample test. We would like to get your input on
9 these records before they are forwarded to the rest
10 of the coders for IRR review."

11 Do you see that?

12 A. Yes.

13 Q. Is the IRR referred to here the same
14 inter reliability -- inter-rater reliability we
15 discussed earlier?

16 A. Yes. At the MRRC level, yes.

17 Q. And when Ms. Small says -- refers to
18 coding gray areas that can create inconsistency
19 even among the best coders, are those the same gray
20 areas you testified about earlier?

21 MS. ZUPAC: Object to form.

22 THE WITNESS: Yes.

23 MS. ZUPAC: Calls for speculation.

24 BY MS. MADDUX:

25 Q. Do you --

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 6th day of June, 2022.

Christine Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-109

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
STEPHANIE DAWN GARDNER
Given Remotely
Wednesday, June 30, 2021
9:04 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. Did anyone direct you to pioneer the chart
2 review program at PacifiCare?

3 MS. DO: Object to form.

4 THE WITNESS: I don't recall specifically,
5 but in my role, I -- I would have received
6 direction around that.

7 BY MS. KRIEG:

8 Q. Okay. Who did you report to during the
9 period that you worked on the chart review program at
10 PacifiCare?

11 A. I -- I believe Jim Higgins and Jeff
12 Dumcum.

13 Q. During the period that you worked at
14 PacifiCare on chart review, did you ever have a
15 conversation with anyone at CMS about the chart
16 review program?

17 A. I don't recall.

18 Q. Do you have an understanding of the term
19 "blind chart review"?

20 A. Yes.

21 Q. What do you understand a blind chart
22 review to mean?

23 A. My understanding is in a blind chart
24 review, you would have coders looking at charts
25 without any other -- any information as to what was

1 already found in those charts.

2 Q. Do you have an understanding that in a
3 blind chart review, the coders would not have any
4 information about what a provider has already
5 submitted in terms of --

6 A. Yes.

7 Q. Okay.

8 A. Sorry.

9 Q. And do you have an understanding of what
10 an informed chart review is?

11 A. Yes.

12 Q. And what is your understanding of what an
13 informed chart review is?

14 A. An informed chart review would be one
15 where the coders have information as to what was
16 previously submitted by the physician.

17 Q. Did PacifiCare's chart review program go
18 out and collect medical records from providers to
19 review?

20 A. Yes. The PacifiCare program collected
21 medical records from providers.

22 Q. Did PacifiCare's chart review program use
23 vendors to review medical records from providers?

24 A. That's my recollection, yes.

25 Q. Okay. At the time PacifiCare -- strike

1 that.

2 Did PacifiCare's chart review program
3 review medical records for completeness?

4 MS. DO: Objection. Objection to form.

5 THE WITNESS: I'm sorry, could you repeat
6 the question?

7 BY MS. KRIEG:

8 Q. Did PacifiCare's chart review program
9 review medical records for completeness?

10 A. That's my understanding.

11 Q. And using the definitions of
12 "completeness" and "accuracy," as we discussed
13 earlier, did PacifiCare's chart review program review
14 medical records for accuracy?

15 MS. DO: Objection to form.

16 THE WITNESS: My recollection is that as a
17 blind coding chart review program, it did not
18 review records for accuracy.

19 BY MS. KRIEG:

20 Q. Okay. At the time you were involved in
21 developing the PacifiCare chart review, were you
22 involved in any discussions that discussed doing a
23 chart review for completeness, but also creating a
24 process that would review medical records to review
25 whether a provider's submitted codes were correctly

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 STEPHANIE GARDNER was duly remotely sworn by me to
7 testify to the truth, the whole truth and nothing but
8 the truth.

9 I DO FURTHER CERTIFY that the foregoing is a
10 verbatim transcript of the testimony as taken
11 stenographically by me at the time, place and on the
12 date hereinbefore set forth, to the best of my
13 ability.

14 I DO FURTHER CERTIFY that I am neither a
15 relative nor employee nor attorney nor counsel of any
16 of the parties to this action, and that I am neither
17 a relative nor employee of such attorney or counsel,
18 and that I am not financially interested in this
19 action.

20

21

22 Karen K. Kidwell
23 Registered Merit Reporter
24 Certified Realtime Reporter
25 Notary Public
Dated: July 13, 2021

25

EXHIBIT D-110

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

---000---

UNITED STATES OF AMERICA, ex)
rel., BENJAMIN POEHLING,)

Plaintiff,)

vs.)

UNITEDHEALTH GROUP, INC., et)
al.,)

Defendants.)

Case No.
16-08697 FMO

---000---

TUESDAY, APRIL 2, 2024

VIDEOTAPED DEPOSITION OF CRAIG GARTHWAITE, PH.D.

CONFIDENTIAL TRANSCRIPT

---000---

REPORTER: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

1 work done searching and comparing data across large
2 datasets, from claims data, chart review data,
3 different databases over eight different years and
4 different sources and different formats.

5 Was there work that had to be done to get 09:14:58
6 that material into a form where you could, you
7 know, do your analysis on -- with that data?

8 A. Certainly there's data processing and
9 cleaning and things like that. I am not sure
10 exactly what you're asking about the work done to 09:15:18
11 get the data in the process to do the analysis. It
12 was all -- the project is done together, but
13 certainly there were steps taken to clean and
14 process the data into our servers.

15 Q. Did you have to create a comprehensive 09:15:31
16 database of your own that integrated all the
17 materials into one place?

18 A. They all exist on a server. They are not
19 all in a single database. They refer to each other
20 in query in the code. 09:15:47

21 Q. Did you have to normalize and standardize
22 the data in some fashion?

23 A. There were certainly instances where the
24 data had to be normalized to compare across.

25 Q. And did you have to write code to search 09:15:57

1 across these different datasets on the server to
2 get the information out of it that you wanted to?

3 A. I should note up front that I directed the
4 sort of writing of the code. I did not write the
5 code. But yes, there was code written to sort of 09:16:12
6 search across and compare different tables as we
7 described in the report and the type of walk-on
8 effects.

9 Q. So that sort of precisely gets at my
10 question. What role did you play in the 09:16:23
11 collection, normalization of data, standardization
12 of data, construction of consolidated databases and
13 writing of code to do the analysis that's required
14 for your report?

15 MR. MASON: Objection to form. 09:16:38

16 Q. BY MR. GALLAGHER: As opposed to Analysis
17 Group?

18 MR. MASON: Objection to form.

19 THE WITNESS: So working with a team at
20 Analysis Group, I got -- I sort of instructed what 09:16:45
21 I wanted to be done. And then not dissimilar from
22 sort of how we work with -- or how I work with and
23 other academics work with research assistants and
24 predoctoral students, sometimes postdoctoral
25 students, had that work completed by them under my 09:17:02

1 direction.

2 And then it is sort of an iterative
3 process back and forth as we look at the sort of
4 results to make sure things are operating in the
5 way we want in the model.

09:17:13

6 Q. BY MR. GALLAGHER: Did you get to see
7 interim results?

8 A. When you say "interim results," what do
9 you mean?

10 Q. Well, you said that it was an iterative
11 process and we look at the results to make sure
12 things are operating in the way we want in the
13 model. Did you get to actually look at results of
14 searches on an interim basis as you were preparing
15 your report?

09:17:19

09:17:34

16 A. So I guess that's where I was asking this
17 phrase "results" I want to be clear. As we are
18 looking through, there were times where we did a
19 number of rechecks to make sure that things were
20 happening in the way that we want.

09:17:45

21 I was very involved in that process, both
22 requesting what checks I would want to see to see
23 that things were working well. And also sort of
24 discussing how we were going to move forward with
25 that.

09:17:57

1 Q. Did you get to see interim results, for
2 example, of the final deletes list that you -- let
3 me ask that more clearly.

4 Did you see a deletes list that was the
5 result of your -- all the searching and comparing 09:18:17
6 that you did as part of your analysis before the
7 final version that was attached to your expert
8 report?

9 A. I don't know if we compiled what would be
10 sort of the final version, but throughout the 09:18:34
11 process there were steps where we were thinking
12 about the technique and thinking about ways we
13 could develop it, and I was involved in every step
14 of that process.

15 Q. So did you run searches, see the results, 09:18:45
16 and then refine the searches?

17 A. I think that the distinction where we
18 might be talking past each other a bit here is the
19 idea of seeing the results. There wasn't sort of a
20 focus on sort of what an end number was to look 09:18:59
21 like. It was more sort of interim steps. So are
22 we able to replicate the CMS risk score using sort
23 of the data we have to match the actual risk score.
24 Like that's a place where we are trying to think of
25 a validity check. 09:19:17

1 codes and ran the analysis -- and ran risk
2 adjustment with those codes deleted, right?

3 A. We identified those codes that lack
4 support in United's chart review and risk

5 adjustment data. If those were removed, we figured 10:08:19
6 out what the payment would be from them being
7 removed at the time period that we looked at it,
8 compared that to the actual payment and then
9 calculated the difference.

10 Q. So you conceptually, as well as actually, 10:08:31
11 did not calculate the effect of deleting the
12 potential deletes list, or codes that meet your
13 definition in your report of a potential delete?

14 MR. MASON: Objection to form.

15 THE WITNESS: What we did is we deleted 10:08:55
16 those codes that we believe lack support in the
17 chart review and risk adjustment data. As part of
18 that process, we identified those that were not
19 initially supported in chart review, and then set
20 at the same sort of time remove codes that had 10:09:12
21 other support in United's data it looked like, and
22 we wanted to sort of be as cautious and careful as
23 we could to remove those codes.

24 Q. BY MR. GALLAGHER: I am asking just a more
25 like just definitional question. The flow of -- 10:09:26

1 the opinion you're offering about the flow of funds
2 is not an opinion about what would happen if you
3 took a list that corresponds to what you describe
4 as the potential deletes and were to delete that?

5 A. By definition, we remove things -- we 10:09:48
6 don't -- there are some things that initially lack
7 support from chart review that we are giving United
8 credit for. We are not saying that they have
9 support. We are saying there's enough evidence
10 there in United's data that could have been relied 10:10:01
11 upon for support that we don't feel comfortable
12 saying that those are unsupported codes in United's
13 chart review and risk adjustment data.

14 Q. I think my question is simpler. You are
15 not offering an opinion about what -- how the flow 10:10:12
16 of funds would change if you took a list of codes
17 that corresponds to what you call potential deletes
18 in your report and deleted them? That's not the
19 analysis you're offering?

20 MR. MASON: Objection; asked and answered. 10:10:26

21 Q. BY MR. GALLAGHER: Right?

22 A. It is -- it's -- everything on --
23 everything that we do delete is identified in that
24 unsupported data. So it would be sort of a related
25 but not identical exercise. 10:10:37

1 Q. It's not the exercise you undertook?

2 A. No. We gave credit to United for codes

3 that they had evidence for that they also, I would

4 note, could have identified in their data or could

5 have said the reason why we're not going to delete 10:10:52

6 that code is that there's other evidence.

7 So it is not a question of them changing

8 their behavior, but a question about sort of the

9 knowledge they had at the time.

10 Q. And you also are not offering an opinion 10:11:03

11 on what would traditionally be called but-for

12 damages, right?

13 MR. MASON: Objection to form.

14 THE WITNESS: Or answering the question as

15 of what would have happened as of 2019 -- I 10:11:14

16 shouldn't say 2019. The time period I am sort of

17 looking at this question, which is given the sort

18 of COVID and the length of this from '19 to '23,

19 pick a date in there, what would happen if the

20 codes were removed. 10:11:29

21 Q. BY MR. GALLAGHER: That's not a -- you are

22 not offer -- sorry. Let me clarify.

23 You are offering an opinion about what

24 would happen if after the fact, in like 2019 or

25 2020, you removed the codes, what the flow of funds 10:11:40

1 would look like in that -- that scenario?

2 A. If it is a question about as of 2019 what
3 would happen if we removed the codes then, yes.

4 Q. You are not offering an opinion about what
5 would happen if United had done something different 10:11:58
6 in 2008 or 2009 or 2010 or 2011 at the time?

7 A. Yeah, I'm not offering an opinion about
8 how contemporaneously they would have changed their
9 other behavior.

10 Q. And you are not offering an opinion about 10:12:15
11 what would happen in a but-for world where United
12 had done the analysis you did in 2008, 2009, 2010
13 and had changed its submission of codes accordingly
14 in those years at the time?

15 MR. MASON: Objection to form. 10:12:31

16 THE WITNESS: No, I think we are very
17 clear in the report that the question we are trying
18 to answer is how would the flow of funds have
19 changed if as of the time period we're asking the
20 question, the code that lacks support in United's 10:12:41
21 chart review and risk adjustment data were removed
22 from the system.

23 Q. BY MR. GALLAGHER: Effectively giving away
24 the payments on contract years, you're effectively
25 offering an opinion about what would happen if you 10:12:54

1 were to remove the codes today or at the time you
2 testify at trial?

3 A. Yes.

4 Q. I want to step aside and ask a question
5 about just your compensation. 10:13:13

6 What is your hourly rate?

7 A. The time I worked on the report it was
8 \$900 an hour.

9 Q. And was it more than that or less than
10 that before you started working on the report? 10:13:23

11 A. I think it went up incrementally during
12 that time, a period of five years.

13 Q. What was it when you started in 2018?

14 A. I don't remember. It might have been 850
15 or something like that. 10:13:35

16 Q. Do you charge a different hourly rate for
17 testimony than you do for reading materials and
18 writing a report?

19 A. No.

20 Q. You also get 20 percent of the billings 10:13:41
21 that are submitted by Analysis Group, do you not?

22 A. Yes, I do.

23 Q. And do you get a cut of everything that
24 Analysis Group bills for their work in relation to
25 this matter, or is it some defined portion of it? 10:13:54

1 A. I believe it's for everything related.

2 Q. So if there was work done by Analysis
3 Group at the direction of the DOJ, you would get 20
4 percent of the billings for that?

5 A. I believe so, but there could be other 10:14:10
6 relationships between United and the DOJ related to
7 the case that I am not aware of.

8 Q. What we are talking about here is your
9 relationship between you and Analysis Group, right?

10 A. I don't believe that's what you were 10:14:21
11 talking about, no.

12 Q. You get 20 percent of the billings by
13 Analysis Group. Under what agreement are you
14 entitled to that 20 percent? Is it an agreement
15 with the DOJ or is it an agreement with the 10:14:31
16 Analysis Group?

17 A. So it is an agreement with Analysis Group.
18 The question I was answering was you said if
19 Analysis Group did other work for DOJ on this
20 matter, would I get 20 percent of that. I believe 10:14:41
21 so, though I don't know if there are instances
22 where AG has done work for DOJ on this that I did
23 not get 20 percent of.

24 Q. Right. Your entitlement to your 20
25 percent would be something that would be defined by 10:14:55

1 your agreement with Analysis Group, right?

2 A. Yes.

3 Q. And whether or not you get 20 percent of
4 what they are billing the DOJ or relaters' counsel,
5 you know, whether or not you get that 20 percent
6 would depend on whether it qualifies for, you know,
7 under your agreement with Analysis Group for what
8 you get 20 percent of?

10:15:08

9 MR. MASON: Objection to form.

10 THE WITNESS: Yes, I believe so.

10:15:19

11 Q. BY MR. GALLAGHER: So do you or do you not
12 get 20 percent of the work that Analysis Group has
13 done, for example, on the first interrogatory
14 response?

15 A. I believe I did.

10:15:33

16 Q. And how is that paid to you, that 20
17 percent cut of Analysis Group's billings?

18 A. I'm confused. Do you mean like how it's
19 paid?

20 Q. Do you get a check from Analysis Group?

10:15:47

21 A. I get a direct deposit from Analysis
22 Group.

23 Q. And how often do you get that payment? Is
24 it calculated monthly, quarterly, yearly?

25 A. It's, I believe, whenever payment is

10:15:59

1 Q. BY MR. GALLAGHER: Let me go back to
2 something you said. In your prior answer you said
3 it is my understanding that experts would say if
4 you have two blind reviewers that both say the code
5 doesn't exist, it would lack support. What expert 11:05:12
6 are you referring to there?

7 A. So in preparation for the deposition, I
8 read the deposition of -- I believe it is a
9 Mr. Renjilian from FTI who also wrote a rebuttal
10 report. 11:05:27

11 Q. So you're referring to Mr. Renjilian as
12 the support for your statement that experts would
13 say that if you have two blind reviewers that both
14 say that the code doesn't exist, it would lack
15 support? 11:05:39

16 A. Yes.

17 Q. And by the way, the blind reviewers,
18 again, in this process of chart review, they are
19 not being asked whether there is or is not support
20 for a particular code; they're being asked to 11:05:53
21 simply code what they think is there, right?

22 MR. MASON: Objection; form, compound,
23 asked and answered.

24 THE WITNESS: So blind reviewers are
25 supposed to create a full and accurate record -- 11:06:05

1 representation of the medical record. That is what
2 they are doing.

3 Q. BY MR. GALLAGHER: Is there an error rate
4 to that for the blind reviewers in chart review?

5 MR. MASON: Objection to form. 11:06:23

6 THE WITNESS: I would imagine that like
7 all processes in life, there are error rates. If
8 United believed there were an error made when their
9 chart review didn't find support for a diagnosis
10 code, they had the ability to go back and 11:06:39
11 investigate it further. Second-level review would
12 be an example of that.

13 The claims -- the CV program would also be
14 an example of that. So United had the ability if
15 it wanted to to investigate further the record that 11:06:51
16 was created by their trained, certified medical
17 coders.

18 Q. BY MR. GALLAGHER: So the answer is yes,
19 there is an error rate for the blind reviewers
20 doing chart review? 11:07:02

21 MR. MASON: Objection to form;
22 argumentative, asked and answered.

23 THE WITNESS: Much like our earlier
24 conversation about error rates, I would believe
25 that it is possible that a certified coder would 11:07:12

1 both add codes inappropriately if they made an
2 error and find a lack of support for codes if they
3 made an error.

4 Q. BY MR. GALLAGHER: What is the error rate
5 for the line reviewers in chart review as it 11:07:24
6 relates to, you know, missing codes that are, in
7 fact, supported?

8 A. I can't remember. I know I have seen it
9 at some point.

10 Q. Where do you think you saw an error rate 11:07:38
11 for blind reviewers missing code?

12 A. I believe it's possibly in the Renjilian
13 -- Mr. Renjilian's rebuttal report, but I read that
14 at a pretty high level. So it's possible I saw it
15 in that or in other conversations. 11:07:52

16 Q. Do you have any basis to dispute
17 Mr. Renjilian's, you know, statements in his report
18 about what the error rate would be?

19 MR. MASON: Objection to form; vague,
20 foundation. 11:08:05

21 Q. BY MR. GALLAGHER: Do you have any
22 opinions about that?

23 MR. MASON: Objection to form; vague,
24 compound, foundation.

25 THE WITNESS: I don't have a particular 11:08:12

1 databases, yes.

2 Q. And risk adjustment database, remind us if
3 that includes the claims databases or is that
4 limited to the data from which submissions were or
5 were not made?

11:43:03

6 A. So I would ask that we go from Paragraph
7 37 and then skip forward to Paragraph 40. It came
8 to our attention during deposition testimony -- I
9 will just read it. "Deposition testimony indicates
10 that a technical issue may have impacted
11 transmission of data from certain Provider-Reported
12 Claims Databases to IRADS during the at-issue
13 period. I therefore also check the

11:43:19

14 Provider-Reported Claims Databases to ensure that
15 there is just one provider associated with the date
16 of service in those databases before I match a
17 provider-reported encounter from IRADS to chart
18 review using this method."

11:43:32

19 Q. Okay. So you took steps to ensure that,
20 in fact, there was only one provider-reported --
21 there's only one provider-reported codes on that
22 day in any of the databases?

11:43:45

23 A. That was our intent, yes.

24 Q. In terms of validation other than what
25 might be inherent in your methodology for defining

11:44:19

1 a match in the first place, you mentioned looking
2 at whether there are overlapping codes in the
3 databases on that day. Is there anything else you
4 did by way of validation of a match?

5 A. I don't recall a specific example right 11:44:39
6 now. What I will say is this was a consistent
7 focus of our effort, to look at places where the
8 data were lining up correctly.

9 Q. By "our effort," you mean work done by
10 Analysis Group? 11:44:55

11 A. Work done by my team under my direction.

12 Q. So what other directions did you give in
13 terms of validation besides looking for overlapping
14 codes for your match methodology?

15 A. I guess I would turn back to my answer 11:45:05
16 from a minute ago, which I can't recall a specific
17 example, but I do remember multiple conversations
18 with the team together thinking about ways that
19 this might fail, but I don't remember the specific
20 validations. 11:45:19

21 Q. As part of the validation process, you
22 never asked to look at any sample charts to
23 determine whether there was, in fact, a
24 correspondence between what was reviewed in chart
25 review and the -- what -- that what was reviewed in 11:45:51

1 chart review was the same medical records for the
2 same encounter from which the code was submitted?

3 A. I did not look at any medical records.

4 Q. So I think we established, but I'll just
5 confirm. You agree that there would be some error 11:46:14
6 rate to United's chart review, and in particular
7 some error rate where coders doing that review
8 missed codes that were, in fact, supported by a
9 chart?

10 A. I think that there are error rates that 11:46:28
11 exist. I don't know if there's a specific estimate
12 of a United error rate with respect to their
13 coders, whether that would be the average, it would
14 be above or below average. I think of United as a
15 sophisticated organization, one of the largest 11:46:48
16 health insurers -- the largest health insurer in
17 the country.

18 So I wouldn't want to extrapolate from
19 known error rates to what they have, but the idea
20 that there could be some error in this process I 11:47:02
21 think is possible.

22 It's also, I would note, something that
23 United would also see in their data, and they had
24 the ability to go and investigate, and at times
25 did, right. So they did the claims verification 11:47:13

1 program where they did match things together. They
2 did second-level review. There were times where
3 United tried to solve these problems. With respect
4 to deletes I would know, not as much with respect
5 to adds.

11:47:30

6 Q. Now, the only way to know if there's an
7 error rate to a -- to either a provider-reported
8 code, the system of having provider-reported codes,
9 or a chart review system, the only way to know if
10 there's an error rate to that would be to go and
11 see if you could validate, by looking at the
12 charts, whether the code is or is not supported,
13 right?

11:47:51

14 MR. MASON: Objection to form.

15 THE WITNESS: When you say the only way to
16 know there's an error rate?

11:48:06

17 Q. BY MR. GALLAGHER: Right. When we are
18 talking about error rate -- I am just talking
19 conceptually here. If we are going to define an
20 error rate for -- let's start with
21 provider-reported codes. If we wanted to define --
22 or determine the rate at which providers missed
23 codes that were, in fact, supported by medical
24 records, one way to do that would be to review the
25 medical records with an eye toward validating

11:48:17

11:48:44

1 THE WITNESS: I will be offering an
2 opinion as to whether there is support in United's
3 chart review and risk adjustment data for that, and
4 that will include evidence from their second-level
5 review. It will include evidence from their claims 12:22:44
6 verification. It will include evidence from
7 unsubmitted charts, and it will be an estimate of
8 what United knew at the time when it made its claim
9 to CMS or failed to reverse its claim to CMS.

10 Q. BY MR. GALLAGHER: What percentage of 12:23:00
11 codes on your potential deletes list would be found
12 supported in the relevant medical record if you
13 were to go and look at that record?

14 MR. MASON: Objection to form; asked and
15 answered. 12:23:26

16 THE WITNESS: To be clear, and really I do
17 apologize we are having this sort of back and forth
18 again and again. When you say "relevant medical
19 record," do you mean the record from that
20 face-to-face encounter, that it went through chart 12:23:37
21 review?

22 Q. BY MR. GALLAGHER: I am trying to avoid
23 the mouthful. I am using "relevant" to what you
24 consider to be relevant medical records.

25 So what percentage of codes on your 12:23:45

1 potential deletes list would be found supported in
2 the relevant medical record, what you consider to
3 be a relevant medical record, if you were to go and
4 look at that record?

5 A. As an academic, my life is full of 12:23:55
6 mouthfuls. So I'll stick with the discussion of
7 the relevant medical record being the record from
8 that face-to-face encounter. And I think that's
9 what we're going to limit our testimony to.

10 Q. So tell me the percentage. 12:24:08

11 A. The percentage what?

12 Q. Well, what percentage of the codes on your
13 potential deletes list will be found supported in
14 the relevant medical record, as you defined it, if
15 you were to go and look at that record? 12:24:24

16 MR. MASON: Objection to form; asked and
17 answered.

18 THE WITNESS: I don't have an opinion to
19 that, but I do know that United had the ability and
20 at times undertook the ability to go and answer 12:24:32
21 that question at the time. So my opinion is
22 limited to what United knew at the time in their
23 risk adjustment and chart review data.

24 Q. BY MR. GALLAGHER: So to get to the
25 question we started this on, you don't have an 12:24:45

1 opinion and you're not going to be testifying to
2 the percentage of the codes on your potential
3 deletes list that would be found supported in the
4 relevant medical record as you defined it if you
5 were to go and look at that record, do you? 12:25:00

6 MR. MASON: Objection. Objection to form;
7 misstates the testimony.

8 THE WITNESS: I will testify to what
9 United knew through the variety of ways in which
10 they tried to find information about the level of 12:25:11
11 support for those codes.

12 Q. BY MR. GALLAGHER: Do you have an opinion
13 on that topic or not?

14 MR. MASON: Objection to form; asked and
15 answered, argumentative. 12:25:20

16 MR. GALLAGHER: We can move on. I'll
17 withdraw it.

18 Q. I want to look at Appendix D,
19 Paragraph 44, and then what I want to understand is
20 your definition of "support," okay. 12:25:52

21 This section of your appendix talks about
22 identification of supported diagnosis codes. Do
23 you see that?

24 A. Yes, I see that.

25 Q. And you say, "I consider an instance of a 12:26:02

1 beneficiary, yes.

2 Q. It was -- the encounters and the codes
3 identified in chart review, those were both by
4 beneficiary, specific to a beneficiary?

5 A. Yes.

01:52:09

6 Q. And the identification of codes that were
7 submitted to CMS, that was also specific to a
8 beneficiary, right?

9 A. Yes.

10 Q. So the deletes list is specific -- when it
11 references codes, it's specific to a beneficiary?

01:52:20

12 A. I'm not sure what you mean by "specific."
13 It is a diagnosis for a beneficiary.

14 Q. It's an instance associated with a
15 particular beneficiary?

01:52:43

16 A. It is a record of a face-to-face,
17 risk-adjustment-eligible encounter for a
18 beneficiary that lacks support in United's chart
19 review and risk adjustment data.

20 Q. And that delete on your deletes list is
21 specific to that beneficiary and does not apply to
22 other beneficiaries, does it?

01:52:54

23 A. I believe, yes.

24 Q. Deleting the code for -- that's on your
25 deletes list will only have an impact on the risk

01:53:07

1 score for that beneficiary and not anybody else,
2 right?

3 A. At the time period in which these deletes
4 are happening, it would -- those that are on the
5 list would affect that because that list does take 01:53:26
6 into account things like risk orders and things
7 like that, which then could have an effect on not
8 the diagnosis for someone else, but the payment for
9 someone else.

10 Q. Risk corridors is a concept that only 01:53:41
11 applies for the part D element of your analysis,
12 right?

13 A. In the program, yes. Because it only
14 applies in the part D program.

15 Q. And are you saying that -- let me make 01:54:09
16 sure I ask the question correctly.

17 How would deleting a code for, you know,
18 one beneficiary affect the risk score for another
19 beneficiary?

20 MR. MASON: Objection to form; misstates 01:54:41
21 testimony.

22 THE WITNESS: I did not say it would
23 affect the risk score for another beneficiary.

24 Q. BY MR. GALLAGHER: Maybe you misread my
25 question because I said deleting the code that's on 01:54:50

1 your deletes list will only have an impact on the
2 risk score for that beneficiary and not anybody
3 else, right?

4 A. Yeah, sorry. I didn't interpret you meant
5 the risk score for anybody else, just an impact on 01:55:03
6 anybody else. The risk score, yes, I believe so.

7 Q. So if your -- deleting -- at least with
8 part D, the way you've taken into account risk
9 corridors, deleting the code for one beneficiary
10 might have some impact on the payment associated 01:55:34
11 with another beneficiary?

12 A. Well, it could have a payment -- effect on
13 the payment at the plan level.

14 Q. The risk corridors is only -- that only
15 has an impact at the plan level? 01:55:48

16 A. Yeah, and then it could filter down. You
17 said any impact on anyone is how I heard it. So I
18 was trying to be complete and accurate.

19 Q. Risk corridors, that concept when it comes
20 to calculating payments, that's something that's 01:56:01
21 taken into account at the plan level, not the
22 individual level?

23 A. Yes.

24 Q. In that regard, it is like the medical
25 loss ratio for part C, which is also taken into 01:56:10

1 account at the plan level, right?

2 A. There are some important differences, but
3 the plan level point is a similarity.

4 Q. You did not take into account the medical
5 loss ratio in your calculations? 01:56:28

6 A. At the time period -- for the question I'm
7 answering, which is at the time period of the
8 report, let's say, what would be the effect of
9 removing risk codes on the flow of funds between
10 the parties, medical loss ratio would not have been 01:56:42
11 an issue.

12 Q. The reason you didn't take into account
13 medical loss ratio is that you're calculating the
14 financial impact as if though you submit deletes as
15 of the date of your report, September 29, 2023, not 01:56:56
16 a but-for world back in the day like 2008, 2009,
17 right?

18 A. I don't want to talk about -- you use the
19 term "but-for world." Because as of 2019 I am
20 accounting for those things that could change at 01:57:09
21 that point, and the medical loss ratio is not
22 revisited at that point.

23 Q. Had you looked at the impact of deleting
24 the codes as if though they had been deleted at the
25 time in during the contract year, you would have 01:57:28

1 around that.

2 Again, I don't mean to upset you. I know
3 it's late in the day, but I am trying to be as
4 complete and accurate as I can think about with the
5 data -- with the terminology we are using and don't 06:01:51
6 want to sort of give an inaccurate answer because
7 we are not being precise about the language.

8 Q. BY MR. GALLAGHER: Okay. So I will be as
9 precise as I can be. You can't tell us what
10 percentage of instances of diagnostic -- of 06:02:05
11 diagnosis codes not reported in chart review or not
12 found in chart review, what percentage of those
13 were removed in the generation of your final
14 deletes list --

15 MR. MASON: Objection. 06:02:22

16 Q. BY MR. GALLAGHER: -- because you're
17 giving credit for other instances in United's data
18 where there could be evidence around that code,
19 either submitted or unsubmitted?

20 MR. MASON: Objection to form -- 06:02:34

21 Q. BY MR. GALLAGHER: Right?

22 MR. MASON: -- vague, compound, confusing.

23 THE WITNESS: Given that the purpose of
24 what we were doing there was not to sort of have an
25 opinion about whether the codes that we don't 06:02:44

1 include on the final deletes list were supported,
2 but instead just trying to give United credit, that
3 is not a calculation that we created.

4 We also don't want to give the impression
5 that a removal of a diagnosis code instance that 06:02:56
6 showed such that it does not appear on the final
7 deletes list would be a part of my opinion that
8 that code has support in United's chart review and
9 risk adjustment data in the time period we're
10 speaking about. 06:03:12

11 Q. BY MR. GALLAGHER: At what point in your
12 analysis for any given code that ends up on your
13 final deletes list, at what point in that analysis
14 can you say that deleting the code would have an
15 impact on payment? 06:03:35

16 A. So to definitively say it has an impact on
17 payment, I think you would need to input it into
18 the CMS risk adjustment model. Though I'll note
19 that importantly I think this is the point that if
20 United were to delete the list of codes that I had, 06:04:17
21 and as we talked about, there's 1.9 million codes
22 that I identify lack support in their data, if they
23 were to remove those codes, the change of funds
24 would automatically be done -- the change in the
25 flow of funds would automatically be calculated by 06:04:34

1 CMS. And it's reasonable to assume, given the
2 number of codes that we're talking about, that
3 there would be an overpayment there.

4 And as evidence of that first, we would
5 note that given this large number of codes, it 06:04:47
6 almost certainly affects payment as determined at
7 the HCC level.

8 In United's own behavior, as we talked
9 about earlier with the CV program, was to withhold
10 revenue back with the idea that because they would 06:04:59
11 be removing codes as part of CV, then we would end
12 up having a reduction in payments from CMS.

13 Q. Do you remember what my question was?

14 A. You asked what I believe -- it would be
15 great if you just read it back, I guess. 06:05:14

16 Q. I just want to know what question do you
17 think you were answering there?

18 MR. MASON: Objection to form;
19 argumentative.

20 THE WITNESS: I don't think I want to 06:05:22
21 characterize your question. I am happy to have it
22 read back to me if you'd like.

23 Q. BY MR. GALLAGHER: You gave a long answer,
24 and I just want to know what question do you think
25 you were answering? 06:05:31

1 DEPOSITION OFFICER'S CERTIFICATE
2 (Civ.Proc. § 2025.520(e))

3 STATE OF CALIFORNIA)
4) Ss.
5 COUNTY OF SAN FRANCISCO)

6 I, Balinda Dunlap, hereby
7 certify:

8 I am the deposition officer that
9 stenographically recorded the testimony in the
10 foregoing deposition.

11 Written notice pursuant to Code of Civil
12 Procedure, Section 2025.520(a), having been sent,
13 the deponent took the following action within the
14 allotted period with respect to the transcript of
15 the deposition:

16 () In person, at the office of the
17 deposition officer, made the changes set forth on
18 the original of the transcript. (The parties
19 attending the deposition have been notified of said
20 changes.)

21 () Approved the transcript by signing
22 it.

23 () Refused to approve the transcript by
24 not signing it.

25 () By means of a signed letter, made the
 changes and approved or refused to approve the

1 transcript as set forth therein. (Said letter has
2 been attached to the original transcript and copies
3 thereof mailed to all parties attending the
4 deposition.)

5 () Failed to approve the transcript
6 within the allotted time period.

7 Dated _____.

8

9

10 *Balinda Dunlap*

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 10 OF 14
EXHIBITS D-111 THROUGH D-141
PAGES 2879 THROUGH 3589**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

**REDACTED VERSION OF DOCUMENT PROPOSED TO BE
FILED UNDER SEAL**

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EXHIBIT D-111

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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UNITED STATES OF AMERICA		
et rel. BENJAMIN POEHLING,		
Plaintiffs,		Case No.
vs.		CV 16-08697 FMO (SSx)
UNITEDHEALTH GROUP, INC.,		Hon. Fernando Olguin
et al.,		
Defendants.		
- - - - -	+	

Thursday, March 10, 2022

Remote Videotaped Deposition of RONNIE GROWER, a Witness herein, called for examination by counsel for Plaintiffs in the above-entitled matter, pursuant to notice, the witness being duly sworn by MICHELE EDDY, RPR, CRR, a Notary Public in and for the District of Columbia, taken virtually with the witness located in Nevada, at 11:31 a.m. Eastern Standard Time.

1 A That's what it says, yes.

2 Q And that means that roughly 40 percent
3 of the codes subject to this audit were not
4 validated, correct?

5 MS. MADDUX: Objection.
6 Mischaracterizes the document. Calls for
7 speculation.

8 A I can only go by what it says, that 60
9 percent were validated. I don't know about the
10 other 40 percent.

11 Q Well, do you have any reason to believe
12 that this is an inaccurate representations of the
13 results of a 2009 audit of California providers?

14 A Objection, form.

15 Q And do you recall discussing the results
16 of a 2009 audit of California providers with
17 anyone at Ingenix?

18 MS. MADDUX: Objection, form.

19 A I don't remember. I think in 2009 my
20 role had moved on to market consultation more, so
21 I don't know that I would have been involved with
22 the results of that. And California was not my --
23 was not my region that I represented.

24 Q And do you recall who at Ingenix did
25 cover the California region?

1 MS. MADDUX: Objection, form.

2 A I believe it was Pam Leal.

3 Q Okay. So going back to the chart review
4 program, was chart review a program that Ingenix
5 sold to health plan clients?

6 MS. MADDUX: Objection, form. Calls
7 for speculation.

8 A I wasn't really involved in the sales of
9 Ingenix's services to clients that I can remember.

10 Q Well, focusing less on the sale part, I
11 suppose was chart review a service that was
12 offered by Ingenix?

13 MS. MADDUX: Objection, form.
14 Ambiguous.

15 A I believe chart review was offered as a
16 service by Ingenix.

17 Q And what were the benefits of chart
18 review for Ingenix's clients?

19 MS. MADDUX: Objection, form. Vague.

20 A I think particularly in areas where
21 capitation resulted in encounter data not being
22 fully reported for every single date of service
23 and every code reported, that chart review was an
24 opportunity to go back and look in the middle
25 record and validate that there were diagnosis

1 codes that represented the patient's conditions in
2 the medical record that could be submitted to the
3 CMS.

4 Q So specifically chart review was a
5 program that looked for additional diagnosis codes
6 in the medical records that had not yet been
7 previously submitted to CMS?

8 MS. MADDUX: Objection, form.
9 Misstates prior testimony.

10 A Could you repeat the question?

11 Q Sure. I asked, so specifically chart
12 review was a program to review medical records for
13 additional diagnosis codes that had not previously
14 been submitted to CMS?

15 MS. MADDUX: Objection, form.

16 A I believe the intent was to get an
17 accurate view of the medical record for
18 particularly primary care providers and all the
19 encounters with their patients for the reporting
20 year so you would have an accurate picture of what
21 was being -- what should have been submitted from
22 the medical record.

23 Q Okay. And so was the purpose to
24 identify all diagnosis codes that could be
25 supported by a medical record?

1 MS. MADDUX: Objection, form.

2 A I was not intimately involved with the
3 chart review program at Ingenix, and I can't speak
4 to all the details associated with it.

5 Q Sorry, I'm trying to pull up a document,
6 but my -- okay, sorry.

7 I think we might have crossed wires with
8 our Q&A there for a second, so let me make sure I
9 actually understand what we're -- what we're
10 discussing.

11 Was the -- was it your understanding
12 that the intent of chart review was to identify
13 all diagnosis codes in a patient's medical record?

14 MS. MADDUX: Objection, form. Lack of
15 foundation.

16 A I think the intent of chart review, the
17 best I know, was to accurately capture codes that
18 were in the medical record.

19 Q And were you involved with advising a
20 strategy for the chart review program?

21 MS. MADDUX: Objection, form.

22 A I don't believe so, no. I think the
23 chart review program was established before I came
24 to work in Ingenix.

25 Q And did you have any understanding of

1 A I think claims verification was making
2 sure that what was reported via an encounter could
3 be documented in the medical record. And then the
4 other side of that is, if what's in the medical
5 record was not previously reported, to have that
6 reported.

7 Q So was it your understanding that chart
8 review and claims verification were two sides of
9 the same coin?

10 MS. MADDUX: Objection, form. Lack of
11 foundation. Calls for speculation.

12 A I don't know enough about how the claims
13 verification process was going to be implemented
14 or how it would work to respond to that.

15 Q So you mentioned that individuals within
16 Ingenix were discussing claims verification with
17 Ovations; is that accurate?

18 MS. MADDUX: Objection. Misstates
19 prior testimony.

20 A I believe that I remember some of that.

21 Q And do you recall who from Ovations was
22 involved in those discussions?

23 A The only people I remember involved in
24 that type of discussion would be Stephanie Will
25 and Jeff Dumcum.

1 Q And were -- okay. Thanks. Strike that.

2 MS. ZUPAC: So I'm just seeing what I
3 have left, which is a good sign that the
4 deposition is perhaps nearing to a close. Why
5 don't we go off the record briefly so I can just
6 review what I have left and we can come back on
7 and hopefully wrap up.

8 VIDEO TECHNICIAN: This ends Media Unit
9 No. 5 in the deposition of Ronnie Grower. The
10 time is 3:34 p.m. We're going off the record.

11 (A brief recess was taken.)

12 VIDEO TECHNICIAN: This begins Media
13 Unit No. 6 in the deposition of Ronnie Grower.
14 The time is 3:50 p.m. We are back on the record.

15 BY MS. ZUPAC:

16 Q Welcome back, Ms. Grower.

17 I just want to go back and make sure I
18 understand your testimony about the chart review
19 process. So was it your understanding that
20 when -- staff in chart review was to collect
21 medical records or charts from providers?

22 MS. MADDUX: Objection, form.

23 A Yes, they would collect medical records
24 from providers.

25 Q And then Ingenix would conduct a

1 thorough review of those medical records for any
2 diagnosis codes that were supported by those
3 medical records, correct?

4 MS. MADDUX: Objection, form. Lack of
5 foundation.

6 A Basically they were going in to look to
7 report the diagnoses that were in the medical
8 records.

9 Q And was it your understanding that
10 Medicare Advantage plans -- Medicare Advantage
11 organizations could only submit codes that were
12 supported by the medical records?

13 MS. MADDUX: Objection, form. Calls
14 for a legal conclusion. Lack of foundation.

15 A So Medicare Advantage plans submitted
16 codes that should be supported by the medical
17 record.

18 Q So in the chart review process when
19 Ingenix had the chart and was reviewing it for
20 codes, were there times when Ingenix -- strike
21 that.

22 So during the chart review process when
23 Ingenix had the medical records and were reviewing
24 it for codes, was it your understanding that
25 Ingenix had to delete any codes that it identified

1 CERTIFICATE OF SHORTHAND REPORTER

2

3 I, Michele E. Eddy, Registered Professional
4 Reporter and Certified Realtime Reporter, the court
5 reporter before whom the foregoing deposition was
6 taken, do hereby certify that the foregoing transcript
7 is a true and correct record of the testimony given;
8 that said testimony was taken by me stenographically
9 and thereafter reduced to typewriting under my
10 supervision; and that I am neither counsel for,
11 related to, nor employed by any of the parties to this
12 case and have no interest, financial or otherwise, in
13 its outcome.

14 IN WITNESS WHEREOF, I have hereunto set my
15 hand and affixed my notarial seal this 21st day of
16 March, 2022.

17

18 My commission expires July 20, 2022

19

20 Michele Eddy
21 MICHELE EDDY

22 NOTARY PUBLIC IN AND FOR

23 THE DISTRICT OF COLUMBIA

24

25

26

EXHIBIT D-112

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
MARY ROSE GUY
Given Remotely
Wednesday, March 30, 2022
9:01 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 MR. LEE: Objection. Vague.

2 THE WITNESS: Yeah, I -- I agree.

3 BY MS. MADDUX:

4 Q. Any certifications -- any like specific
5 certifications in a field of study?

6 A. I maintain a license within the State of
7 Maryland for clinical social work.

8 Q. And how long have you had that license?

9 A. Since about nineteen-eighty- -- well, at
10 this level, since about 1984 or '85.

11 Q. Do you have any training in medical
12 coding?

13 A. No.

14 Q. Are you a certified medical coder?

15 A. I am not.

16 Q. Do you have any specific
17 risk-adjustment-related certifications?

18 A. No.

19 Q. What is your current job title at CMS?

20 A. Health insurance specialist.

21 Q. And what is a health insurance specialist?

22 A. It's a generic label for people who are
23 working within the health insurance field at CMS.

24 Q. And what component of CMS are you
25 currently in?

1 A. I work in the Centers for -- the Center
2 for Consumer Information and Insurance Oversight.

3 Q. And is that sometimes abbreviated "CCIIO"?

4 A. That's correct.

5 Q. And what is CCIIO?

6 A. The Center for Consumer Information and
7 Insurance Oversight.

8 Q. What do they do?

9 A. We work on the marketplace --

10 MR. LEE: (Simultaneous speaking)

11 Objection. Vague.

12 THE WITNESS: -- facilitated.

13 BY MS. MADDUX:

14 Q. So is this a -- related to the Affordable
15 Care Act?

16 A. It is.

17 Q. Does your current role involve Medicare
18 Advantage?

19 A. It does not.

20 Q. How long have you been in this role?

21 A. I've been with CCIIO since 2012.

22 Q. And since 2012, have you been working on
23 the Affordable Care Act?

24 A. Predominantly.

25 Q. And has any of your work since 2012

1 related to Medicare Advantage?

2 A. No.

3 Q. Are you familiar with Medicare Advantage?

4 A. Yes.

5 MR. LEE: Object to form. Vague.

6 BY MS. MADDUX:

7 Q. What is it?

8 A. It's a -- it's Medicare Part C.

9 MR. LEE: Objection. Vague.

10 Mary -- Ms. Guy --

11 THE WITNESS: I'm sorry, John.

12 MR. LEE: -- make sure --

13 THE WITNESS: I need to pause.

14 MR. LEE: Give me a chance to insert an
15 objection.

16 THE WITNESS: Okay. Thank you.

17 MR. LEE: I'll try not to speak over you,
18 but . . .

19 Go ahead.

20 BY MS. MADDUX:

21 Q. Is Medicare Advantage often referred to
22 as "MA"?

23 A. Yes.

24 Q. So if I refer to "MA" throughout the
25 deposition, you'll understand that I'm referring to

1 Medicare Advantage?

2 A. Yes.

3 Q. Is -- sorry. Strike that.

4 If you can turn back to the exhibit on
5 your screen and look at the second page of the
6 résumé.

7 A. Uh-huh.

8 Q. Under "Health Insurance," the bolded
9 underlined text "Health Insurance Specialist/Project
10 Officer"? Do you see that?

11 A. Yes.

12 Q. This states that you were in this role
13 from December 2000 to July 2004. Is that correct?

14 A. Yes.

15 Q. Is this the first role that you had when
16 you started at CMS?

17 A. No.

18 Q. What was the first role that you had when
19 you started at CMS?

20 A. I worked in the Office of Strategic
21 Operations and Regulatory Affairs as a health
22 insurance specialist, a reg writer.

23 Q. And in this current -- excuse me. Strike
24 that.

25 In this health insurance specialist role

1 that you were in from December 2000 to July 2004, was
2 this related to Medicare Advantage?

3 A. Not that I recall.

4 Q. Was it specific to Medicaid?

5 A. Not that I recall.

6 Q. Is the "Health Insurance Specialist" here
7 the same generic title you described earlier?

8 A. Yes, with the exception of here I've
9 listed "Project Officer," so I was working on a
10 grants program.

11 Q. Now, if you can turn back to page 1 of the
12 document.

13 A. Uh-huh.

14 Q. Under "Employment," it has a bolded and
15 underlined text that says "Social Science Research
16 Analyst/Project Officer." Do you see that?

17 A. Yes.

18 Q. This states that you were in this role
19 from August 2004 to present. Do you see that?

20 A. Yes.

21 Q. Given what you testified to earlier, it
22 sounds like you moved out of this role, and you're no
23 longer -- it's not a present role; is that correct?

24 A. Correct.

25 Q. When did you leave this role?

1 A. I would have to look back, but I think it
2 was 2010.

3 Q. This also states from July 2004 to
4 February 2006, you were in the Medicare Drug Benefit
5 Group, Division of Program Analysis and Performance.
6 Do you see that?

7 A. I do.

8 Q. What is the Medicare Drug Benefit Group?

9 A. That was a label that we were given.

10 Q. What did the Medicare Drug Benefit Group
11 do?

12 A. That was the group under which I was
13 working. They had Medicare drug benefit, and we also
14 had risk adjustment under that.

15 Q. What is the Division of Program Analysis
16 and Performance?

17 A. That was a division that was managed by
18 Jeff Grant.

19 Q. And who is Jeff Grant?

20 A. It was risk adjustment data validation.

21 Q. And is that sometimes abbreviated RADV, or
22 R-A-D-V?

23 A. Yes.

24 Q. It says here that you reported to Jeff
25 Grant in this role. Is that correct?

1 A. Yes. Well, as a supervisor.

2 Q. Was -- did you have a more direct
3 supervisor?

4 A. Lateefah Hughes was our team leader.

5 Q. This also states that from February 2006
6 to present, you were in the Medicare Plan Payment
7 Group, Division of Risk Adjustment Operations. Do
8 you see that?

9 A. Yes.

10 Q. What is the Medicare Plan Payment Group?

11 A. They split the -- they took us out of the
12 Medicare Drug Benefit Group and moved us over to
13 Medicare Plan Payment Group. This was part of a
14 reorganization.

15 Q. Is it sometimes referred to as "MPPG"?

16 A. Correct.

17 Q. And what did MPPG do?

18 A. A little bit of everything. We had risk
19 adjustment under it. I don't remember all the
20 different divisions. That's been a long time ago.

21 Q. Did they have roles related to Medicare
22 Advantage?

23 MR. LEE: Objection. Vague as to time.

24 THE WITNESS: Yeah. Thank you.

25

1 BY MS. MADDUX:

2 Q. Did they oversee aspects of the Medicare
3 Advantage program?

4 MR. LEE: Objection. Vague.

5 You can answer, Ms. Guy, to the extent
6 that you think you can understand the question.

7 THE WITNESS: Thank you, John.

8 BY MS. MADDUX:

9 Q. Did MPPG oversee aspects of the Medicare
10 Advantage program?

11 A. Yes.

12 Q. Which aspects?

13 A. Risk-adjustment model. There was so
14 much -- I don't remember all the different aspects.

15 Q. And when you refer to "the model," are you
16 referring to the CMS HCC risk-adjustment model?

17 A. Yes.

18 Q. And what is your understanding of what the
19 model is?

20 MR. LEE: Objection. Lacks foundation.
21 Vague.

22 BY MS. MADDUX:

23 Q. You can answer.

24 THE WITNESS: John, are you okay with
25 that?

1 MR. LEE: Yes. To the extent that you
2 think you can understand the question, you --
3 you may answer.

4 THE WITNESS: Okay.

5 The Medicare Advantage payment model was a
6 method by which Medicare Advantage organizations
7 were paid for their patient population and the
8 diagnosis codes that were submitted.

9 BY MS. MADDUX:

10 Q. And in this role, it says you reported to
11 Sean Creighton. Is that correct?

12 A. Yes.

13 Q. I now want to direct your attention to --
14 there's a paragraph in the middle that starts with
15 the word "Developed." And this states: "Developed
16 and implemented technical aspects of risk adjustment
17 data validation (RADV) projects to ensure the
18 integrity of risk adjustment data and validate the
19 accuracy of risk adjusted payments made to Medicare
20 Advantage organizations. Activities include
21 sampling, data analysis, medical record, developing
22 medical record review methodology, and evaluation of
23 qualitative aspects of the data. Identified the
24 payment error rate for the Medicare Advantage
25 program." Do you see that?

1 A. Yes.

2 Q. Is this an accurate description of your
3 responsibilities when you were a social science
4 research analyst/project officer?

5 A. Yes.

6 Q. Does this describe your responsibilities
7 while you were in both the Medicare Drug Benefit
8 Group and MPPG?

9 A. Yes and no. Yes, but I was just learning
10 it as I started in '04.

11 Q. So would this be more what you were doing
12 while you were at MPPG?

13 A. Correct.

14 Q. Is there anything else that you remember
15 from your time at the Medicare Drug Benefit Group
16 that is not described here?

17 A. No.

18 Q. What are risk adjustment data validation
19 projects?

20 MR. LEE: Object to form. Vague. Lacks
21 foundation.

22 BY MS. MADDUX:

23 Q. Ms. Guy, you may answer.

24 MR. LEE: You may answer, Ms. Guy.

25 THE WITNESS: So the projects were

1 Q. What are discrepancies in the diagnoses?

2 MR. LEE: Objection. Lacks foundation.

3 Vague.

4 THE WITNESS: So if a payment diagnosis
5 was submitted by the MA organization, and then
6 the medical record did not support that payment
7 diagnosis, that would have resulted in the
8 discrepancy.

9 BY MS. MADDUX:

10 Q. I'm going to direct you to page 8 of
11 Exhibit 1156. And then in the middle of the page, it
12 says -- there's a bolded section header that says
13 2.1, "Staffing the Medical Record Review." Do you
14 see that?

15 A. Yes.

16 Q. Under this header, the second sentence
17 states: "BearingPoint manages the contract, prepares
18 the analysis and sampling plans, analyzes the results
19 of the medical record review, identifies the records
20 to be sent to the SVC, and prepares the final
21 report." Do you see that?

22 A. I see that sentence, yes.

23 Q. Does "SVC" stand for second-level
24 validation contractor?

25 A. I'd have to look how it's defined up

1 above, but we could look through for the acronym.

2 Q. If you look at page 6 of Exhibit 1156
3 there, in the bulleted point list above Figure 1,
4 there is -- fourth bullet from the -- the bottom of
5 the list, it says: "Identifying and sending records
6 to CMS's independent second validation contractor
7 (SVC) to confirm discrepancies." Do you see that?

8 A. I see that.

9 Q. Does "SVC" stand for second validation
10 contractor?

11 A. Yes.

12 Q. Was the SVC a different medical record
13 review contractor?

14 A. It was.

15 Q. What was their role?

16 A. So the role of the SVC was to look at the
17 record -- and code, to determine if they got an
18 answer or same code as the initial validation
19 contractor.

20 Q. The SVC would review the medical record
21 after the IVC; is that correct?

22 A. Correct.

23 Q. Why would the IVC send records to the SVC?

24 A. So the IVC would send records to the SVC
25 to -- if you had an instance where the IVC's code did

1 not match that which was submitted for payment, that
2 was one thing. So we -- we weren't -- wanted to have
3 two medical record reviewers say it didn't match.
4 It's a validation. It's a quality control.

5 Another thing that we did was we sent
6 records to the SVC to verify coding, to make sure
7 that they were coming up -- we sent a sample, medical
8 records, to verify that they both got the same codes,
9 and -- you know, if they were particularly complex
10 patients, that was another thing that we did to
11 ensure that the codes would be accurate.

12 So the idea was that we wanted to make
13 sure that we didn't have false negatives and false
14 positives. We wanted to have the diagnosis verified.
15 So if one of the contract -- my recollection is that
16 if one of the contractors found the code that was
17 submitted for payment, then there was no discrepancy.
18 If both of them found it, there was no discrepancy.
19 But if neither of them found it, there was a
20 discrepancy.

21 Q. What about if one of them found it and one
22 of them did not?

23 A. That would have not resulted in a
24 discrepancy, if I recall correctly.

25 Q. And what are false positives?

1 A. We had false positives where you had like
2 the first coder would have said one thing and the
3 other one said the other. So you had -- let me
4 think. How did that work?

5 Well, I don't -- I don't remember how we
6 did it. But we had -- we wanted to make sure that we
7 didn't code a record that otherwise would have -- and
8 given them the -- the code -- it's basically a
9 quality assurance thing, false positives, false
10 negatives, just like we have now with COVID. You
11 have some tests that give you false positives and
12 some tests that give you false negatives. That's why
13 you repeat it. You have more than one person looking
14 at it.

15 Q. So the primary coder reviews the medical
16 record first; is that right?

17 A. Correct.

18 Q. And in this scenario, your -- just to make
19 sure I understand the scenario that you're
20 discussing, a primary coder may look at the medical
21 record and not identify a diagnosis code. The
22 secondary coder may look at the record and identify
23 the diagnosis code; is that correct?

24 A. Correct.

25 MR. LEE: Object to form.

1 BY MS. MADDUX:

2 Q. And would that be considered a false
3 positive or a false negative?

4 A. I think it would -- the first instance it
5 would be a false negative, because it was found by
6 the second.

7 Q. Okay. So back to page 8 of 1156. And
8 again we're under the bolded section, 2.1, "Staffing
9 The Medical Record Review Process." The paragraph
10 provides that IPRO, or IPRO, "provides the following
11 staff."

12 Do you see that? It's at the -- it's at
13 the end of the first paragraph.

14 A. "Provides the following staff." Yes, I
15 see that.

16 Q. There's then a bulleted list. The third
17 bullet from the bottom of the list reads: "Certified
18 medical record coders (primary coders) -- abstract
19 diagnoses from each medical record."

20 Did I read this correctly?

21 A. Correct.

22 Q. What does "abstract diagnoses" mean?

23 A. That means they're basically --

24 MR. LEE: Objection. Lacks foundation.

25

1 CERTIFICATE OF REPORTER

2 I, Karen K. Kidwell, Registered Merit Reporter
3 and Notary Public for the State of Maryland at Large,
4 do hereby certify:

5 That the foregoing deposition was taken
6 remotely before me on the date and at the time stated
7 on page 1 of this transcript; that the deponent was
8 duly sworn to testify to the truth, the whole truth
9 and nothing but the truth; that the testimony of the
10 deponent and all objections made at the time of the
11 examination were recorded stenographically by me and
12 were thereafter transcribed; that the foregoing
13 deposition as typed is a true, accurate and complete
14 record of the testimony of the deponent and of all
15 objections made at the time of the examination to the
16 best of my ability.

17 I further certify that I am neither related to
18 nor counsel for any party to the cause pending or
19 interested in the events thereof.

20 Witness my hand this 7th day of April, 2022.

21

22

Karen K. Kidwell

23

Karen K. Kidwell,
Registered Merit Reporter
Notary Public
State of Maryland at Large
My Commission expires:
April 14, 2025

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EXHIBIT D-113

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. CV 16-08697 FMO
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
Defendants.	)	
_____	)	

VIDEOTAPED DEPOSITION OF JIMMY ARTHUR HIGGINS, taken on behalf of Plaintiff, UNITED STATES OF AMERICA, at 650 Town Center Drive, Costa Mesa, California 92626, beginning at 9:16 a.m., and ending at 5:42 p.m., on Tuesday, May 3, 2022, before Marceline F. Noble, RPR, CRR, Certified Shorthand Reporter No. 3024.

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Reported by:
Marceline F. Noble
CSR No. 3024
Job No. 821137

1 A. Somewhere around the due diligence
2 quotation.

3 Q. Yes.

4 So it says:

5 "We believe the Medicare -- or Medicare Plus
6 Choice organization have an obligation to undertake
7 due diligence to ensure the accuracy, completeness
8 and truthfulness of encounter data submitted to HCFA
9 or CMS, and they will be held to a best knowledge,
10 information and belief standard."

11 Do you see that?

12 A. I do. And this, sort of at a high level,
13 defines what you've got in the other document, which
14 is a little more specific.

15 Q. Understood.

16 But -- but it's your understanding it's --
17 they're using the same phrasing, "best information,
18 knowledge and belief as to the accuracy, completeness
19 and truthfulness of the data"; is that right?

20 MS. DO: Object to form and lacks
21 foundation.

22 THE WITNESS: I think so. But I, yeah, did
23 not write this so I don't -- I can't say for certain
24 what they meant.

25 ///

1 BY MS. GLOVER:

2 Q. All right. And -- so how did you ensure --
3 of your best knowledge, information and belief, how
4 did you at PacifiCare -- and this could be you or
5 your team or others at PacifiCare -- ensure that --
6 that it would -- that you submitted risk adjustment
7 data that was accurate, complete and truthful?

8 MS. DO: Object to form. Compound and lacks
9 foundation.

10 THE WITNESS: As it applied to signing the
11 EDI agreement, I knew pretty much what we were doing
12 in the process of extracting, formatting, submitting
13 data. And from that process, I would say, yes, my
14 knowledge, information and belief was that all the
15 data was true and accurate.

16 I think that from the point of view of
17 externality coming in from the provider organization,
18 I think --

19 (Reporter clarification.)

20 THE WITNESS: From the provider
21 organization, that there may be reason to believe
22 that the attestation on the claim form or the
23 encounter form would be sufficient.

24 BY MS. GLOVER:

25 Q. So the attestation that the provider signs

1 about the accuracy, completeness and --

2 A. On the HIPAA 1500, yeah.

3 Q. Okay. And because they're signing that
4 attestation, it was your understanding that that --
5 that that satisfied PacifiCare's obligations to
6 submit accurate, complete and truthful data; is that
7 right?

8 MS. DO: Objection. Mischaracterizes prior
9 testimony.

10 THE WITNESS: It identifies very specific
11 penalties, severe penalties for them not to do that.

12 BY MS. GLOVER:

13 Q. And what were those penalties --

14 A. Perjury.

15 Q. -- to your recollection?

16 Perjury. Okay.

17 A. That, you know, they could be rounded up,
18 arrested. You try them for -- for perjury.

19 Q. Okay. And, Mr. Higgins, are you familiar
20 with something called a "risk adjustment data
21 validation audit"? Sometimes called a RADV audit?

22 A. A RADV, yeah. I am familiar that they
23 occurred. I had peripheral knowledge of them going
24 on, just because, you know, a conference room was
25 commandeered and kept for weeks or months. And files

1 would pile up in there. And we would have a
2 certified coder going through them, looking at -- at
3 the medical records.

4 Q. And why was a certified coder going through
5 and looking at the medical records, in conjunction
6 with a risk adjustment data validation audit?

7 MS. DO: Objection. Lacks foundation.

8 THE WITNESS: Independent verification of
9 what was found.

10 BY MS. GLOVER:

11 Q. Independent of -- of who?

12 A. CMS.

13 Q. So in a risk adjustment data validation
14 audit, or known as a "RADV audit," is it your
15 understanding that -- that CMS was reviewing medical
16 records to assess whether diagnosis codes submitted
17 by a Medicare Advantage organization, were, in fact,
18 supported by that documentation, that medical record?

19 MS. DO: Objection. Lacks foundation.

20 THE WITNESS: I couldn't say that. I
21 wasn't -- I wasn't in the room, didn't know what they
22 were doing or what they were saying. I knew some of
23 the people that were involved, but...

24 BY MS. GLOVER:

25 Q. Who was involved?

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REPORTER'S CERTIFICATION

I, MARCELINE F. NOBLE, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 12th day of May, 2022.

Marceline F. Noble

MARCELINE F. NOBLE, CSR No. 3024

EXHIBIT D-114

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF

ANNE HORNSBY

(Taken virtually)

10:03 a.m. Eastern

Wednesday, May 18, 2022

REPORTED BY: Christine A. Taylor, RPR

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1 that.

2 Q. And approximately how long was each
3 session?

4 A. Session with John Lee?

5 Q. Yeah.

6 A. First one was about an hour. Second
7 one was a couple hours. The Agile meeting was
8 about an hour.

9 Q. I'd like to shift gears a little bit
10 to understand generally what positions and
11 responsibilities you had while you were employed
12 at CMS as well as more recently.

13 Are you currently employed anywhere?

14 A. No, I'm retired.

15 Q. Retired.

16 A. Yea.

17 Q. And -- but you previously worked at
18 the Centers for Medicare & Medicaid Services; is
19 that correct?

20 A. Yes, that's correct.

21 Q. And if I refer to that as CMS, will
22 you understand what I'm talking about, the Centers
23 for Medicare & Medicaid Services?

24 A. Yes, I will.

25 Q. Great. Over what time period did you

1 work at CMS?

2 A. From 2 -- February 2000 to March 2019.

3 Q. So you worked for CMS for a little
4 over 19 years; correct?

5 A. Correct.

6 Q. And what was your most recent position
7 at CMS?

8 A. Technically, my title was always
9 health insurance specialist for all those years.
10 You know, I was -- from 2010 onward, I worked in
11 the front office of the -- what is now the
12 Medicare Plan Payment Group assisting the managers
13 in work across the five divisions in that group.
14 I was --

15 Q. Okay.

16 A. -- technical specialist.

17 Q. So you said that was from 2010 until
18 March 2019 you worked in the front office of what
19 I will refer to as MPPG, will you understand what
20 I mean?

21 A. I will.

22 Q. That refers to Medicare -- okay.

23 And you said you worked in the front
24 office working across all five divisions. What
25 were those five divisions that you helped work

1 across?

2 A. Oh, goodness, let's see. There was --
3 they've changed so many times with
4 reorganizations. There was one that was
5 running -- that was payment policy for Part C and
6 Part D. Another that was the risk adjustment
7 division, which also did policy and model
8 calibration. There was one that was -- later on
9 was an encounter data division, but also worked on
10 Part D -- elements of the Part D program. And
11 then there was -- let's see, the fourth one -- oh,
12 my goodness, I'm kind of blanking on the other
13 two.

14 Q. Why don't we actually pull up an
15 exhibit?

16 A. Okay.

17 Q. Can we get Tab 40, please, see if that
18 maybe helps?

19 A. All I see is Document 1203. Oh, here
20 we go. There it is.

21 Q. A slight delay. You should see now
22 Exhibit 1105 previously marked.

23 A. Yes. Let me try to -- well, this is a
24 risk score development illustration.

25 Q. Yeah. So I'm going to direct your

1 attention to page 2, I'll represent -- of the PDF.
2 I'll represent to you that this was part of the
3 copy --

4 A. Oh, yes. Okay.

5 Q. Part of a hard copy collection of
6 documents that the government produced to us.
7 And, yeah, have you focus on the second page,
8 which should be Bates Number on the bottom right
9 there, USBP000507083. Do you see that?

10 A. I see the organization chart.

11 Q. Okay. And do you recognize this as an
12 organizational chart for the MPPG or Medicare plan
13 payment group within CMS?

14 A. Yes.

15 Q. You see a date there, November 1st,
16 2013. Is this consistent with your recollection
17 of how MPPG was organized at that time?

18 A. I mean --

19 MR. LEE: Objection. Vague.

20 THE WITNESS: Do I still answer?

21 BY MS. SCHEFFLER DO:

22 Q. Yeah, you can still answer.

23 A. Well, it's vague in the sense --

24 MR. LEE: If you know what she means.

25 THE WITNESS: Yeah. I don't know what

1 consistent with. I mean there were many
2 reorganizations. But the bottom line is
3 that MPPG was responsible for Part C and
4 Part D, payment policy and payment
5 operations. So that's the bottom line.
6 And the shifting combinations of divisions
7 changed over time.

8 BY MS. SCHEFFLER D0:

9 Q. Okay. Do you see where your name is
10 handwritten there on sort of the right-hand side
11 next to the top box?

12 A. I do see that.

13 Q. And this was a time when you were
14 working in the front office of MPPG; correct,
15 November 1st, 2013?

16 A. Yes.

17 Q. Did you have a supervisor at that
18 time?

19 A. Yes. Cheri Rice and Jennifer Harlow.

20 Q. And did you have any anybody that
21 reported to you at that time?

22 A. No. I was a technical 15. I was not
23 a manager.

24 Q. I can see Whitney Johnson written --
25 her name is just above yours. Was she also in the

1 front office with you at MPPG at this time?

2 A. Yes.

3 Q. So did the two of you work together on
4 projects?

5 A. Probably. I don't recall exactly.
6 She tended -- my recollection is that Whitney
7 tended to work at that time on contracting issues
8 with MPPG's contracts with various parties and
9 budget. She was really working on budget issues,
10 which I never did. And I tended to do more
11 payment policy activities.

12 Q. Okay.

13 A. Whitney's responsibilities changed
14 over time, but that's what I remember right then.

15 Q. So prior to working in the front
16 office for MPPG in 2010, what were the previous --
17 where did you fit previously as a health insurance
18 specialist for CMS?

19 A. I -- the names were changed many
20 times, but I always stayed with the same group
21 conceptually from the beginning on because I loved
22 payment policy. So I stayed in the group that did
23 Part C payment policy. And then Part D was
24 created in 2006.

25 Q. And were Cheri Rice and Jennifer

1 Harlow always your supervisors?

2 A. No.

3 Q. What other supervisors did you have
4 prior to --

5 A. Let's see.

6 MR. LEE: Objection. Vague. At what
7 point in time?

8 BY MS. SCHEFFLER DO:

9 Q. We can start with the first supervisor
10 that you remember upon starting at CMS in
11 February 2000.

12 A. Tim Love hired me. He's long gone. I
13 mean, he's retired. Then Tom Hutchinson and then
14 Bob Donnelly for a short period and then Tom
15 Hutchinson again. And I think to the best of my
16 recollection after that in 2010, Tom left and
17 Cheri took over.

18 Q. Okay. And during that entire period
19 you were in that same group conceptually working
20 on payment policy for Part C and then in --
21 starting in 2006 also Part D; is that correct?

22 MR. LEE: Objection. Vague.

23 THE WITNESS: I was not --

24 MR. LEE: Objection. Vague. When you
25 say entire period, are you talking about

1 20 -- 2000 to 2019 or some other more
2 limited period?

3 MS. SCHEFFLER D0: 2000 to 2019.

4 MR. LEE: Can you be a little more
5 clear on that? Okay.

6 THE WITNESS: So what was the question?

7 BY MS. SCHEFFLER D0:

8 Q. During that entire period while you
9 were at CMS from 2000 to 2019, you were working
10 with the same group conceptually working on Part C
11 payment policy and then eventually Part D starting
12 in 2006; is that correct?

13 A. Well, the group was working on Part D.
14 I really did not do much of anything with Part D.
15 I would just dip in and help edit or something.
16 But I really was Part C, payment policy. But the
17 group did both.

18 Q. Understood. But you personally were
19 more focused on Part C payment policy through that
20 entire time period; correct?

21 A. Yes.

22 Q. And I believe you said that you
23 started working -- or Cheri started -- was your
24 supervisor starting around 2010; is that correct?

25 A. That's my best recollection is when

1 MR. LEE: You go ahead and answer. I
2 stated my -- you can go ahead. I withdraw
3 the objection. You can go ahead and
4 answer.

5 THE WITNESS: I just think that's not
6 accurate. We require them to have an
7 effective compliance program. Who defines
8 effective as only looking for new diags?
9 You know, go figure. You could argue that
10 this amendment really does fall under the
11 general requirement for an effective
12 compliance program because, otherwise, how
13 are you going to certify that the data --
14 risk adjustment data you submit is
15 accurate, complete, and truthful.

16 Well, you know, looking both ways
17 should be conceptualized as part of an
18 effective compliance process. But if it's
19 not, then it seems like there might be a
20 need to add something in writing.

21 BY MS. SCHEFFLER D0:

22 Q. So CMS never specified this in writing
23 prior to this proposal; is that right?

24 MR. LEE: Objection. Vague.
25 Ambiguous. Argumentative.

1 THE WITNESS: I don't know the answer
2 to that question. I believe that we had a
3 lot of training, a lot of sub-regulatory
4 discussion with the industry in the annual
5 trainings and planned guidance sessions
6 about what is an effective compliance
7 process. But I was never part of those, so
8 I don't know.

9 BY MS. SCHEFFLER D0:

10 Q. CMS never specified in regulation
11 prior to this proposal that MA plans were required
12 to design their medical record review rules to
13 look for or identify overpayments?

14 A. Over and under, correct.

15 Q. Otherwise, why would you be proposing
16 this new regulation; right?

17 A. Right.

18 MR. LEE: Objection. Argumentative.

19 BY MS. SCHEFFLER D0:

20 Q. So turning to page 2, there's --
21 underneath "recommendation" there's some text for
22 adding a new paragraph to Section 422.310. Is
23 this consistent with your recollection of the new
24 requirement that CMS was considering proposing in
25 June 2013?

1 A. I don't understand. What does this
2 have to do -- this is the G2 amendment. What does
3 this have to do with the over and underpayment
4 look both ways proposal?

5 Q. Are you on page 2 of 1206-1?

6 A. Hold it. I'm trying to get to -- oh,
7 sorry. The one that has a big redacted.

8 Q. Yeah. Underneath the redacted.

9 A. Okay. Let me go full screen on that.

10 Q. For the record, this is USBP076134077.

11 A. Okay. So what's the question.

12 Q. I was asking if this is consistent
13 with your recollection of the new requirement that
14 CMS was considering proposing in June 2013?

15 A. It's consistent. I don't recall if
16 this is the actual language that actually ended up
17 in the proposed -- in the NPRM. I don't recall.
18 But this paragraph, it was something similar to
19 this. I would have to look at the reg text, the
20 NPRM.

21 Q. Let's go ahead and go to the next
22 exhibit, please. Let's go ahead and skip to
23 Tab 41.

24 And this is going to show up as
25 Exhibit Number 1115 because it's been previously

1 are you?

2 MS. SCHEFFLER DO: Page 84 of the PDF,
3 second column, last paragraph underneath
4 number 6, risk adjustment data
5 requirements.

6 THE WITNESS: Okay. I've looked at
7 that.

8 BY MS. SCHEFFLER DO:

9 Q. And do you recognize this as the rule
10 CMS first proposed in January 2014 regarding
11 medical record reviews?

12 A. I do.

13 Q. So this is the proposed rule that
14 relates to the 2A looks amendment that you
15 referenced earlier, the same thing?

16 A. Yes.

17 Q. And the proposal was to require MA
18 organizations to design medical record review
19 methodologies to "identify errors in diagnoses
20 submitted to CMS as risk adjustment data"; right?

21 A. Yes.

22 Q. Do you see --

23 A. I see that, yeah.

24 Q. So this proposed rule would have given
25 those MA organizations specific guidance and set

1 specific requirements about how to design those
2 medical record reviews, there was no existing
3 regulation on this at the time; correct?

4 MR. LEE: Objection. Vague.
5 Argumentative.

6 THE WITNESS: There was no -- again --

7 MR. LEE: You can answer.

8 THE WITNESS: I mean, again, as I said,
9 the requirement to have an effective
10 compliance process should be perceived as
11 an existing regulation on this, but to the
12 extent it was not by some MAOs, then it
13 seemed important to have further specific
14 guidance.

15 BY MS. SCHEFFLER DO:

16 Q. And at the memo we just looked at
17 previously, Exhibit 1206-1, you stated, "under
18 existing regulation there is no requirement to
19 counter the incentive for MA Organizations to
20 conduct medical record reviews, only for the
21 purpose of identifying underpayments"; right?

22 A. Right. Right.

23 Q. Do you recall receiving comments on
24 the proposed medical record review rule after this
25 was published in January of 2014?

1 A. Yes. I know we received comments and
2 there was a general uproar and the industry
3 lobbied hard against it.

4 Q. Do you recall what the arguments were
5 or what -- for lobbying hard against it, what were
6 some of the arguments for not finalizing this?

7 A. I don't remember very well. I
8 remember one argument was that there are some good
9 reasons for an MAO to conduct targeted reviews.
10 So having this requirement would be a huge burden
11 and a great expense to have to review an entire
12 medical record and --

13 Q. Okay. Anything else? I didn't mean
14 to interrupt you if you were still answering.

15 A. There were other arguments. Maybe we
16 could look at the preamble and see. I don't
17 recall other specific objections, but I knew it
18 got yanked.

19 Q. In other words, it was not finalized.
20 This proposed rule was not finalized; correct?

21 A. Correct.

22 Q. Let's go ahead and take a look at the
23 next exhibit. This is 29A and B. This is another
24 e-mail and attachment. So it's going to be
25 document -- or Exhibit Number 1207 and 1207-1.

1 (Exhibits 1207 and 1207-1 marked for
2 identification.)

3 We'll again start with the e-mail. So
4 1207. It's short.

5 A. Okay.

6 Q. This is an e-mail from you to Jennifer
7 Harlow with the subject "please review chart"
8 dated March 11, 2014. Do you recognize this
9 e-mail?

10 A. I don't have any specific memory of
11 this e-mail, but it has my name on it.

12 Q. Does this help refresh your
13 recollection of the nature of some of the comments
14 received in response to the proposed medical
15 record review rule?

16 A. Yes. The first sentence says "that
17 commenters said it was confusing and unclear.
18 This seemed to be put unfair restrictions."

19 Well, I had given an example earlier
20 of an unfair restriction that is an MAO wants to
21 conduct targeted review and only look at part of
22 the record. But confusing and unclear is an
23 additional set of comments, I guess.

24 Q. And MRR, do you take that to refer to
25 the proposed medical record review rule that we

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified
Court Reporter within and for the State of
Georgia, do hereby certify:

That the foregoing deposition was
taken before me on the date and at the time and
location stated on Page 1 of this transcript; that
the deponent was duly sworn to testify to the
truth, the whole truth and nothing but the truth;
that the testimony of the deponent and all
objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed; that the foregoing
deposition as typed is a true, accurate and
complete record of the testimony of the deponent
and of all objections made at the time of the
examination to the best of my ability.

I further certify that I am neither
related to nor counsel for any party to the cause
pending or interested in the events thereof.
Witness my hand, this 22nd day of May, 2022.

Christine Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-115

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
	)	
Defendants.	)	

CONFIDENTIAL
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videotaped Deposition of
ANNE HORNSBY
VOLUME I

Friday, May 19, 2023

Reported by: Traci M. Mertens, RDR, CRR, CSR

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1 means that the payments to MAOs under the CMS-HCC
2 model are overpayments without the coding intensity
3 adjuster to bring them -- the risk scores down, so
4 that's the impact.

5 In terms of the reliance on audited or
6 unaudited fee-for-service claims data, that cannot
7 be known until you actually run the numbers through
8 the model. I mean, it's just a fact of life. You
9 cannot predict that. You can guess that this
10 percent of HCCs will get higher dollar
11 coefficients, and that percent of HCCs will get
12 lower dollar coefficients, and -- and the age-sex
13 factors will jump up a little bit, but it's all
14 hypotheses until you actually run the numbers.

15 Q. Ma'am, respectfully, I'm not entitled --
16 I'm not asking for CMS' position. I am asking for
17 what you did to testify about facts related to how
18 errors in the fee-for-service claims data that's
19 unaudited impacts payments.

20 And other than the position that you've
21 just stated, is there anything further that you're
22 able to offer or testify about on behalf of the
23 government on topic 1D?

24 MS. KRIEG: Object to form; object to
25 government.

1 A. The last thing I'll say is I am very
2 prepared to testify in this deposition, and CMS has
3 been using 100 percent of fee-for-service claims
4 data to calibrate the model for a number of years.
5 So this distinction of audited versus unaudited,
6 it's just not that clear.

7 Q. I'm going to hand you what's been marked
8 Exhibit 1342 and Exhibit 1343-1 which is an email
9 and an attachment to that email.

10 A. Okay.

11 Q. And if you'd just take a minute to look
12 through the document.

13 MS. KRIEG: And take your time to look
14 through it.

15 THE WITNESS: Yeah.

16 Q. (By Mr. Jones) Now, Ms. Hornsby, what's
17 been marked as Exhibit 1342 is an email from
18 Jennifer Harlow to a group of folks including
19 Jonathan Smith, Cheri Rice, Carolyn Kapustij, and
20 Stacey Dieter.

21 Do you see that?

22 A. Yes, I do see that.

23 Q. And who is Ms. Harlow?

24 A. She was division director of the Division
25 of Payment Validation at this time, and then later

1 she became the deputy director of MPPG under Cheri
2 Rice.

3 Q. And you reported for periods of time to
4 Ms. Harlow, didn't you?

5 A. Well, once I was in the front office and
6 she was deputy to Cheri, yes.

7 Q. And I noticed on your list of folks that
8 you have called and consulted with that Ms. Harlow
9 isn't on the list. Is there a reason why you didn't
10 talk with her?

11 A. Oh. I thought I -- oh. Did I forget to
12 put her on? I mentioned her this morning. That's
13 -- that's my mistake. I'm sorry.

14 Q. Okay. Did you have a phone call --

15 A. Yes, I did.

16 Q. -- with Ms. Harlow?

17 A. I had a -- a brief phone call with her.

18 Q. And what did you talk to Ms. Harlow about?

19 A. Just getting her recollection on the
20 medical record review proposal and wondering if she
21 knew what MAs were doing with chart reviews which
22 she really didn't. Yeah.

23 Q. Did you talk to Ms. Harlow at all about
24 the efforts that she and others made over the course
25 of some fee-for-service adjuster discussions related

1 United's practices were in order to decide whether
2 to continue contracting with United and the Medicare
3 Advantage program?

4 A. No, because that would have been an
5 inappropriate continuation of this email
6 conversation with United.

7 Q. Why would it have been inappropriate to
8 ask for clarity if --

9 A. Because --

10 Q. -- if United is giving notices about its
11 practices?

12 A. It's because CMS requires a compliance
13 program but is not prescriptive with a
14 one-size-fits-all design for how MAOs have to go
15 about making sure their risk adjustment data is
16 accurate, complete, and truthful.

17 So to keep talking with United, bantering
18 back and forth ideas about prescribing your
19 practices, that's not what CMS would do. CMS was
20 listening in this meeting.

21 Q. Well, you -- you know that United went to
22 CMS asking for guidance, right?

23 A. That's what I'm saying.

24 MS. KRIEG: Object to form.

25 A. You go to -- for guidance in a meeting?

1 CMS is not going to do that.

2 Q. And so instead of giving guidance to
3 United about these practices that are in Exhibit 330
4 and -- and United stopping of the claims
5 verification program, CMS is suing through the
6 Department of Justice?

7 MS. KRIEG: Object to form; argumentative.

8 A. I'm sorry; what are the two sides again,
9 instead of what, then what?

10 Q. Instead of giving guidance --

11 A. Oh, okay.

12 Q. -- CMS is going through this lawsuit.

13 MS. KRIEG: Object.

14 Q. Is that your -- your view?

15 MS. KRIEG: Object to form; argumentative.

16 A. I don't understand the link between the
17 two.

18 Q. Well, United went to CMS in 2015 asking
19 for guidance, told CMS that it was stopping this
20 program, and CMS didn't give guidance or ask clarity
21 as to what United was doing, did it?

22 MS. KRIEG: Object to form; argumentative
23 and outside the scope.

24 A. Wasn't there an email from Cheri Rice that
25 stated CMS' requirements in response to Steve

1 Nelson's email?

2 Q. Did Ms. Rice say anything in that email
3 with respect to guidance about how the claims
4 verification or chart review programs needed to be
5 done?

6 MS. KRIEG: Same objections.

7 A. No, because CMS doesn't do that. CMS does
8 not prescribe to MAOs how they have to ensure or
9 certify that their data is accurate and supported in
10 the medical record. CMS does not do that because
11 MAOs differ in size. They differ in complexity.

12 There's no one-size-fits-all for a review
13 program, and CMS won't tell one MAO how to do it
14 when the conversation has not been available to all
15 of the other MAOs.

16 Q. Well, shouldn't CMS tell all of the
17 Medicare Advantage plans the rules of the road and
18 how these chart reviews should be done?

19 MS. KRIEG: Object to form; scope and
20 argumentative.

21 THE WITNESS: I'm sorry.

22 A. CMS disagrees with that statement. CMS
23 believes that the appropriate approach is to provide
24 a broad framework for what MAOs should do for
25 effective compliance actions, and that includes a

1 risk assessment. It includes monitoring and
2 internal audits.

3 There are a whole range of -- of --
4 there's seven basic elements, but CMS does not go
5 into further prescription about how to do it because
6 MAOs differ in what kinds of contracted provider
7 networks they have. They differ in the types of
8 enrollees they have. So there's just -- there is no
9 one-size-fits-all.

10 Q. So your testimony is that CMS shouldn't
11 tell Medicare Advantage plans the rules of the road
12 and how chart reviews should be done?

13 MS. KRIEG: Object to form; misstates her
14 prior testimony, object to scope, and argumentative.

15 A. I mean, there's two parts to that. CMS
16 puts out clear guidance in telling MA plans what the
17 broad framework is for having accurate data, and --
18 I'm sorry. What was the second part?

19 Q. My question was your testimony is that
20 CMS, when asked for guidance, it would have been
21 inappropriate for CMS to have told United whether
22 stopping the practice that it was doing was
23 appropriate.

24 MS. KRIEG: All the same objections.

25 A. Yeah. CMS wants all MAOs in the industry

1 to have access to the same guidance. So in a
2 meeting like this? That -- CMS would not create new
3 guidance in a meeting like this.

4 Q. Okay. Well, I think some of the topics to
5 be discussed next week have to do with some of that
6 guidance.

7 You can't -- when you talked a bit ago
8 about MAOs having different structures and different
9 sizes and different complexities, are there
10 different rules with respect to how chart reviews
11 and claims verification programs need to be done for
12 different Medicaid -- Medicare Advantage
13 organizations?

14 A. No.

15 MS. KRIEG: Object to form.

16 THE WITNESS: Oh. I'm sorry.

17 MS. KRIEG: Go ahead.

18 A. No. That's exactly the point. There are
19 no specific rules about how to do claims validation
20 because we have the seven steps of the compliance
21 program, and that gives the broad framework for how
22 MAOs should be organizing their own process for
23 validating their risk adjustment data, so that's
24 exactly the point.

25 Q. (By Mr. Jones) Should CMS be transparent

1 MR. JONES: Okay. No further questions.

2 THE WITNESS: Okay.

3 MS. KRIEG: No further questions.

4 THE VIDEOGRAPHER: This concludes today's
5 video deposition. We are officially off the record
6 at 7:06.

7 (Whereupon, the deposition was adjourned.)

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CERTIFICATE

I, TRACI M. MERTENS, Registered Diplomate Reporter and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was placed under oath to testify to the truth and nothing but the truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor counsel for any of the parties to this action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of this action.

Certified to by me on this 24th day of May, 2023.

Traci Mertens

Traci Mertens, RDR, CRR, CSR
Registered Diplomate Reporter
Certified Realtime Reporter
Certified Shorthand Reporter

EXHIBIT D-116

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
United States' 30(b)(6) Designee 1
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
At the Law Offices of Latham & Watkins
Thursday, May 25, 2023
10:24 a.m. Eastern

1 BY MR. GALLAGHER:

2 Q And -- and when -- when responding to
3 inquiries from plans, providing your expectations or
4 interpretations of the rules, you have an obligation
5 in that context, whether it's a phone call or a
6 telephonic communication or an email, you have an
7 obligation to be responsive and clear and unambiguous
8 in your instructions to them; right?

9 MS. LIKOFF: Object to form. Compound.
10 Vague.

11 THE DEPONENT: What do you mean by
12 "interpretation"?

13 BY MR. GALLAGHER:

14 Q Can you answer my question?

15 A Well, I think you had the word
16 "interpretation" in the question.

17 Q Do you not understand what the -- what
18 interpretation means?

19 A It means many different things in the
20 context.

21 Q What is the --

22 A So what's an example of interpretation in

1 the MA program rule?

2 Q Why don't you tell me the different
3 understandings of interpretation that you think might
4 apply here.

5 A If you are talking operations,
6 interpretation could be different understandings of
7 the CMS companion guide for how certain special fields
8 should be populated in order to get something
9 communicated correctly to CMS. Sometimes the -- the
10 wording of those operational instructions are hard to
11 get really precise. It could be a different
12 interpretation of how certain adjustments to the
13 benchmarks are made and then questions come in and
14 they need to be answered. So I'm not sure how to
15 answer your question.

16 Q Some- -- sometimes it's the case that --
17 that -- that CMS has general rules or rules of general
18 applicability and there might be a question in
19 interpreting that general rule about how it would
20 apply in a specific case; right?

21 MS. LIKOFF: Object to form.

22 THE DEPONENT: Okay. So that -- that will

1 make sense to me as a specific definition of
2 interpretation, how a particular rule applies in a
3 certain case. Like, the clinical trials policy for
4 Medicare Advantage Organizations, that has had to have
5 different levels of interpretation as they apply to
6 different circumstances.

7 BY MR. GALLAGHER:

8 Q It -- it's pretty widely the case that you
9 have rules of general applicability where it require
10 some active interpretation to understand how that rule
11 might apply in a particular case; fair?

12 MS. LIKOFF: Object to form.

13 THE DEPONENT: It's not fair. It's a
14 general statement. It depends on the context
15 honestly.

16 BY MR. GALLAGHER:

17 Q Well -- so -- so one way in which CMS might
18 be asked to provide an interpretation of what the
19 rules require might be a situation where a plan comes
20 to CMS and says, "Hey, we're doing something, and it's
21 not clear to us what the rules require in this
22 particular situation. Can you help us understand what

1 your interpretation is and whether the rule applies?"

2 That's one thing that might happen in these

3 communications Ms. Rice is talking about?

4 MS. LIKOFF: Objection to form.

5 BY MR. GALLAGHER:

6 Q Yes?

7 A That -- could an MAO do that? Yes. That

8 could happen. That -- it is possible that that

9 happens, that an MAO asks that.

10 Q And -- and Ms. Rice is -- has testified here

11 that -- that -- that -- that CMS would, in fact, be

12 responsive to such an inquiry, right, would provide

13 their expectations and interpretation of what the

14 rules require?

15 MS. LIKOFF: Object to form. Compound.

16 THE DEPONENT: That is not how I read her

17 statement. And I have spoken with her, and, really,

18 the goal in those situations is to restate existing

19 guidance because, depending on which rules you are

20 talking about, CMS has, on purpose, not been

21 prescriptive and has not told plans, "Oh, here you

22 have to follow the following five steps." CMS has not

1 MS. LIKOFF: Respectfully, Counsel --

2 BY MR. GALLAGHER:

3 Q Just give me a list of every document where
4 you claim that requirement you say exists is written
5 down so we can see it.

6 THE DEPONENT: Okay. I'm -- I'm going to --

7 MS. LIKOFF: Same objection. Counsel, I
8 would just respectfully state that it's the United
9 States's position that your question is beyond the
10 scope of Topic 21.

11 THE DEPONENT: The foundational requirement
12 was -- was written in 2000. And so Page 40268, we
13 believe that M+C organizations have an obligation to
14 undertake due diligence to ensure the accuracy,
15 completeness, and truthfulness of encounter data
16 submitted to HFCA. Therefore, they will be held to a
17 best knowledge, information, and belief standard.
18 Therefore, M+C organizations will be held responsible
19 for making good faith efforts to certify the accuracy,
20 completeness, and truthfulness of encounter data
21 submitted.

22

1 BY MR. GALLAGHER:

2 Q So if --

3 A We don't need a list. We've got that.

4 Q So that's the only document that you would
5 put on the list, or are there others? Because all I'm
6 asking for here -- I'm not asking you to read from the
7 documents or tell me your position about the
8 documents. I just want disclosure of the list of
9 documents that you claim support -- or that -- pardon
10 me. Let me -- let me back up and ask this
11 differently.

12 I'm not asking for you to tell me what the
13 documents say. Right now all I want is for you to
14 give us a list of every document that you claim sets
15 forth the requirement that you've testified about that
16 there exists some requirement to investigate if you
17 have any information that a set of codes is not
18 supported.

19 MS. LIKOFF: Objection. Outside the scope
20 of the notice.

21 BY MR. GALLAGHER:

22 Q So -- so you understand, the first document

1 I'll put on that list is the June -- the response to
2 the comment in June of 2000, which is in Exhibit 164
3 at, you know, Page 40286.

4 Are there any other documents that should go
5 on this list that --

6 MS. LIKOFF: Object to --

7 BY MR. GALLAGHER:

8 Q -- you say support the rule you say exists?

9 MS. LIKOFF: Object to form. Objection.

10 Outside the scope of Topic 21. Topic 21 did not ask
11 the witness to prepare to identify all instances of
12 any communications.

13 THE DEPONENT: I would say that CMS has been
14 very clear, including in Ms. Rice's deposition, that
15 CMS does not provide recipes about how MAOs should
16 conduct their chart review programs. So CMS is not
17 going to provide a threshold for what information is
18 or a threshold for what best knowledge is. That is
19 the responsibility of the MAO when designing an
20 effective compliance program that ensures that it --
21 that the -- the organization is fulfilling all program
22 requirements including the payment ones and that

1 A CMS has not put in writing a requirement to
2 conduct medical record reviews. CMS believes that is
3 the MAO's responsibility to determine how it is they
4 can truthfully certify to their risk adjustment data.

5 Q Right.

6 And you have in the proposed medical record
7 review rule a -- a prescriptive rule -- a prescriptive
8 rule to the effect that if you do a medical record
9 review, then you have to look for deletes; right?

10 MS. LIKOFF: Objection to form.

11 BY MR. GALLAGHER:

12 Q The rule is, basically, if you conduct a
13 medical record review, then it must be designed in a
14 particular way to, quote, determine the accuracy of
15 diagnosis; right?

16 A Well, if --

17 MS. LIKOFF: Objection to form.

18 THE DEPONENT: I mean, you could design a
19 medical record review in many ways that would include
20 determining the accuracy of diagnosis. But it also
21 could have other activities going on like checking
22 provider -- checking patterns of diagnosis submitted

1 by certain provider types.

2 BY MR. GALLAGHER:

3 Q Right. So my -- my point is just that the
4 medical -- the proposed medical record review rule,
5 which was never finalized, was specific and
6 prescriptive with respect to the nature of the medical
7 record review a -- an MA organization must conduct if
8 it is going to be conducting a medical record review
9 at all.

10 MS. LIKOFF: Objection to form. Vague.

11 BY MR. GALLAGHER:

12 Q Right?

13 A I don't -- CMS would not agree with the word
14 "prescriptive" but would agree that this was a more
15 specific development of a requirement that had li- --
16 existed for a long time, which is accurate data.

17 Q Right.

18 And -- and -- and in addition to not having
19 a rule that required plans to conduct a medical record
20 review before this rule --

21 A Mm-hmm.

22 Q -- you never had any rule that told plans

1 how a medical record review must be conducted or how
2 it must be designed --

3 MS. LIKOFF: Objection to form.

4 BY MR. GALLAGHER:

5 Q -- right?

6 A As I've said, CMS never told MAOs how to
7 design their medical record reviews. They -- the MAOs
8 are responsible for developing their own protocols.

9 Q And not -- not counting the protocol, you
10 had never told MAOs before this rule that medical
11 record reviews had to be, quote, designed to determine
12 the accuracy of diagnosis, had you?

13 MS. LIKOFF: Objection to form. Asked and
14 answered.

15 THE DEPONENT: Well, because CMS never had a
16 rule about requiring the con- -- the conducting of
17 medical record reviews, CMS never -- I'm sorry. I
18 lost the last half of the question.

19 Could you restate it, please?

20 BY MR. GALLAGHER:

21 Q Sure.

22 You never told MAOs before this proposed

1 medical --

2 A Mm-hmm.

3 Q -- record review how a medical record review
4 needed to be designed, what they had to do in a
5 medical record review?

6 MS. LIKOFF: Objection to form.

7 MR. GALLAGHER: I get that.

8 THE DEPONENT: That is correct. Because as
9 I've said, CMS never tells MAOs how to conduct medical
10 record reviews. That is the MAO's responsibility.

11 BY MR. GALLAGHER:

12 Q And that -- so -- so that's true to this
13 day, right, neither before nor after this proposed
14 medical record review rule has CMS, you know,
15 prescribed any requirements for MAOs as to how a
16 medical record review must be conducted?

17 A That is correct.

18 MS. LIKOFF: Objection to form.

19 THE DEPONENT: Oh, I'm sorry.

20 That is correct. CMS never set out any
21 guidance telling MAOs how to design medical record
22 reviews.

1 BY MR. GALLAGHER:

2 Q Let me hand you Exhibit 1206 and 1206-1.

3 A Thank you.

4 Oh, thanks. Okay.

5 Q Okay. So Exhibit 1206 is a -- an email that
6 you sent to Cheri Rice copying others in June of 2013.
7 And Exhibit 1206-1 is a memo that I believe you were
8 asked about at your personal deposition that is from
9 your files.

10 Do you recognize these?

11 A Let's see.

12 MS. LIKOFF: Counsel, can you clarify
13 whether the highlighting on these two documents is
14 your highlighting or if it was produced to you with
15 the highlighting?

16 MR. GALLAGHER: I don't actually know
17 because I just got a copy of the exhibit. And I -- I
18 believe, but I'm not certain, that that is language
19 that was highlighted in the original, but I don't -- I
20 can't -- I can't specify that. And the only reason
21 I -- the -- I'd say that is that it says on the first
22 paragraph of the email "in yellow on Page 1 of the

1 Honestly, I don't remember writing this
2 paper, but, you know, I certainly, at least, took part
3 in it.

4 Q All right. So let's start with the email,
5 the last paragraph. You -- of the -- of the first
6 email on the page, which actually is from June 2013
7 and carries over to the -- the second page of the
8 document.

9 So the last paragraph of that email says,
10 "We really think we should do 6B requiring any MAO
11 that conducts medical record review to look for both
12 over- and underpayments."

13 Do you see that?

14 A Yes, I do.

15 Q Okay. And that's a reference to the medical
16 record review rule that was proposed in -- in January
17 of 2014; correct?

18 A Yes, that is.

19 Q And then if you look at the memo, which is
20 1206-1, it -- it has Issue 6B. And then the bold
21 reads, "Amend Section 422.310 to require MA
22 organizations conducting medical record reviews to not

1 focus only on identifying underpayments."

2 Do you see that?

3 A Yes, I do see that.

4 Q And so you agree, at this point in time, CMS
5 understood that at least some MA organizations were
6 conducting medical record reviews that only focused on
7 identifying underpayments; right?

8 A Well, first of all, this is an internal memo
9 to MPPG. So, you know, I guess that was understood
10 within MPPG.

11 In general, CMS understood, through informal
12 networks, that looking just for additional in medical
13 records was going on, but CMS does not have that
14 information from MAOs, unless the MAOs choose to
15 volunteer it. So it was not a fact for CMS. It was
16 something that was known on informal networks.

17 Q In describing the medical record review rule
18 that was being proposed in this internal memorandum,
19 you described it as a rule that would require MA
20 organizations conducting medical record reviews to not
21 focus only on identifying underpayments because you
22 understood that at least some MA organizations were

1 doing precisely that.

2 MS. LIKOFF: Objection to form.

3 THE DEPONENT: Within MPPG, at this time, we
4 did talk about this a lot. And so that statement
5 reflects the understanding within this group.

6 BY MR. GALLAGHER:

7 Q Right.

8 The -- the -- within MPPG, which is the
9 Medicare Plan Payment Group, focus on MAO's, you know,
10 payments and the risk adjustment methodology --

11 A Yes.

12 Q -- used for that, you understood and, in
13 fact, talked about a lot the fact that plans were --
14 some plans were conducting medical record reviews to
15 look for just -- just to look for underpayments?

16 MS. LIKOFF: Objection to form.

17 THE DEPONENT: We talked a lot about -- I
18 hate to use the word "gossip," but we talked a lot
19 about what we heard on informal networks that -- that
20 the search for additionals was becoming more common.

21 BY MR. GALLAGHER:

22 Q Right.

1 And you were sufficiently concerned about
2 that, that you really wanted the medical record review
3 rule to address it --

4 MS. LIKOFF: Objection to form. Vague.

5 BY MR. GALLAGHER:

6 Q -- didn't you?

7 A Well, we wanted the medical record review
8 proposal to say that reviews should look for -- and I
9 lost the language of the proposal. Here it is -- that
10 reviews should be designed to determine the accuracy
11 of diagnosis, because in our minds, accuracy meant
12 documented in the medical records.

13 So how could you validate it without looking
14 at the medical record and checking the diagnosis
15 submitted for payment against the diagnosis in the
16 medical record? That is the discussion that was
17 happening inside MPPG. How can anybody certify
18 accuracy without actually checking the diagnosis
19 submitted for payment and -- against what was coded in
20 the medical record?

21 So it was kind of surprising that that
22 definition of accuracy wasn't widely accepted because

1 would be sent up to Cynthia.

2 Q Right. So the -- when we were looking
3 earlier at -- at Exhibit 1206-1, that was a draft of a
4 portion of this memo that you were sharing with Cheri
5 Rice. Ultimately, what would happen is, you would get
6 all of those portions pulled together in one memo.
7 And once it was cleared by her, it would go up to the
8 deputy director of the Center for Medicare?

9 MS. LIKOFF: Objection to form.

10 THE DEPONENT: Well, it -- it really would
11 depend on the rule and what Cheri decided as to
12 whether M- -- all of MPPG's provisions in a rule --
13 okay. I will wait to --

14 BY MR. GALLAGHER:

15 Q It's okay. I just forgot my mic.

16 A Okay. It may not all be rolled up into one
17 memo is what I was trying to say. Sometimes it would
18 go up in a series of separate memos depending on what
19 else was on management's plate at the time. Because
20 these are usually -- and this was -- both of these
21 provisions were part of what we call the plan year
22 rule, which would have many provisions across CM.

1 Q Right.

2 And this -- this memo, at least in the
3 heading, is talking about a particular set of those
4 that concerned the reporting and returning of
5 overpayments by Medicare Advantage organizations and
6 Part D sponsors rules; right?

7 A Yes, that's what the topic --

8 Q Yeah.

9 A -- of this memo is.

10 Q Now, there's parts of this that are
11 redacted, and I'll just represent to you that on the
12 privilege log, you are identified as the author of
13 this document.

14 A Oh, okay.

15 Q Do you recall writing it or compiling it?

16 A I do not recall what I wrote ten years ago.
17 I will say that this is the kind of thing that I --
18 that I often wrote.

19 Q All right. So let me ask you to turn to the
20 second-to-last page of Exhibit 1460, the draft options
21 memo that you wrote and the section that concerns
22 Issue 6B --

1 A Oh, okay.

2 Q -- which is the same 6B we were looking
3 at --

4 A 6B.

5 Q -- earlier, amend Section 422.310 to require
6 MA organizations conducting medical record reviews to
7 focus not only on identifying underpayments.

8 Do you see that?

9 A Yes, I do see that's Issue 6B.

10 Q All right. And -- and this Issue 6B
11 corresponds to the same discussions of the medical
12 record review rule that we had earlier in
13 Exhibit 1206-1; right? Same heading, same title?

14 A It's -- correct, but it's -- it's revised
15 text. It is definitely not the same text as in that
16 early MPPG memo.

17 Q Right. So if you look at 1460, the
18 second-to-last page --

19 A 1460.

20 Q -- in the discussion, this is the -- this is
21 the --

22 A Okay.

1 Q -- one we are looking at, the options memo.

2 A Okay.

3 Q The language here that you write is you say,
4 "Under existing regulation, there is no requirement
5 for" -- "to" -- "for plans to audit medical records
6 for overpayments."

7 Do you see that?

8 A I do see that.

9 Q And this is something that -- that's
10 something you wrote in the -- in a June 4, 2013 draft
11 of an options memo that if finalized, would go to the
12 deputy director of the Center for Medicare; right?

13 A Well --

14 MS. LIKOFF: Object to form.

15 THE DEPONENT: Yeah. I want to explain that
16 I was often the coordinator of work products like
17 this, so I would have run this by a number of people
18 within MPPG before I sent the version to Cheri for her
19 review.

20 BY MR. GALLAGHER:

21 Q Right.

22 But -- but you wouldn't have come up with

1 this on your own. It would reflect the input of the
2 entire group?

3 A Including my input, but the input of the
4 group or the people who worked on this issue, yes.

5 Q Right.

6 So this language here about how under
7 existing regulation there is no requirement for plans
8 to audit medical records for overpayments, that would
9 reflect not just your views and input but Jennifer
10 Harlow's and others within MPPG?

11 A Yes, because, as I've said today, CMS
12 doesn't have a requirement to -- for MAOs to conduct
13 medical record reviews.

14 Q So this is a true statement that as of
15 June 2013, under existing regulation, there is no
16 requirement for plans to audit medical records for
17 overpayments?

18 MS. LIKOFF: Objection to form.

19 THE DEPONENT: That's what the sentence
20 says, yes.

21 BY MR. GALLAGHER:

22 Q And that's a true statement?

1 A Yes. As I said, CMS has no requirement for
2 MAOs to audit medical records.

3 Q And then the next sentence says, "If a plan
4 is" -- "is conducting medical record reviews to
5 identify underpayments, we recommend that they be
6 required to audit as well for overpayments"; right?
7 That's the next sentence?

8 A That is what it says.

9 Q And that's a description of what you were
10 going to be recommending be made a rule through the
11 medical record review rule; right?

12 A That is correct.

13 Q At the time you wrote this with input from
14 others at MPPG -- actually, let me -- let me say this
15 differently. I apologize.

16 When you wrote with input from others at --
17 at MPPG, that group, that under existing regulation
18 there is no requirement for plans to audit medical
19 records for overpayments, all of the alleged source of
20 obligations that we talked about earlier in -- in
21 Section -- in -- in Document 1457, all of those things
22 were already in existence; right?

1 THE DEPONENT: I've already said that CMS
2 doesn't have a re- --

3 (Interruption.)

4 THE VIDEOGRAPHER: Someone is not on mute.

5 MR. BAAK: I just --

6 THE DEPONENT: As I've said, CMS doesn't
7 have a requirement that tells MAOs they must audit
8 medical records. CMS expects MAOs to develop their
9 internal procedures for validating the data on which
10 they have been paid.

11 BY MR. GALLAGHER:

12 Q All right. So you don't have a requirement
13 that requires plans to audit medical records for
14 overpayments.

15 By logic then, the requirement for accurate
16 and complete risk adjustment data does not require
17 plans to audit medical records for overpayments, does
18 it?

19 MS. LIKOFF: Objection to form. Vague.

20 THE DEPONENT: I need just a minute to
21 finish reading the rest of this memo.

22 (Deponent reviews document.)

1 THE DEPONENT: Yeah. The Medicare advantage
2 risk adjustment guidelines specify that -- as I've
3 said, that an MAO has got to be submitting accurate
4 data, accurate, complete, and truthful. So while MAOs
5 are developing their compliance plans, which is --
6 which will be a process they are putting together that
7 would include how to manage their risk adjustment data
8 submissions. While they're putting that together,
9 they are subject to the overpayment rule is -- if they
10 identify overpayments in the process of -- of managing
11 their risk adjustment programs and conducting medical
12 record review, then they do need -- then that does
13 fall under this regulation.

14 BY MR. GALLAGHER:

15 Q Was that a yes or a no?

16 MS. LIKOFF: Object to form. Asked and
17 answered.

18 BY THE DEPONENT: The overpayment
19 regulation -- it -- it's -- it's more complicated than
20 a yes or a no. I know you always want yes or no
21 answers, but it's more complicated than that.

22

1 BY MR. GALLAGHER:

2 Q Does the overpayment rule in CMS's view
3 create an obligation to investigate whether codes are
4 supported by medical records? Is that a source of the
5 obligation you say exists?

6 MS. LIKOFF: Object to form.

7 THE DEPONENT: The overpayment rule does not
8 specifically speak to risk adjustment data. I should
9 say the regulation doesn't.

10 BY MR. GALLAGHER:

11 Q Right. Because there's a difference between
12 an overpayment and an unsupported code.

13 A Yes.

14 MS. LIKOFF: Objection to form.

15 BY MR. GALLAGHER:

16 Q Just because you have an unsupported code
17 does not mean that you have an overpayment; right?

18 A That is correct.

19 Q You can have an unsupported code for lots of
20 reasons and still not have an overpayment.

21 MS. LIKOFF: Object to form. Vague.

22

1 BY MR. GALLAGHER:

2 Q Like, for example, you can have a -- an
3 unsupported code because one record doesn't support
4 it, but it's supported in another.

5 MS. LIKOFF: Object to form.

6 THE DEPONENT: No. That is not correct. If
7 you find a diagnosis code is not supported in the
8 record, it doesn't matter if it appears in another
9 medical record. It is CMS that makes the
10 determinations about overpayments. It is the MAO's
11 responsibility to delete unsupported code, so they
12 need to delete one that is not supported. And then if
13 there's another medical record that has it, that's
14 great.

15 BY MR. GALLAGHER:

16 Q MAOs don't know whether there's an
17 overpayment.

18 All they know is whether the code is or is
19 not supported; right?

20 MS. LIKOFF: Object to form. Calls for
21 speculation.

22

1 REPORTER'S CERTIFICATE

2 DISTRICT OF COLUMBIA

3

4 I, Jeaninn Y. Alexis, a Notary Public of the
5 District of Columbia, do hereby certify that the
6 with-named witness personally appeared before me at
7 the time and place herein set out, and after having
8 been duly sworn by me, according to law, was examined
9 by counsel.

10 I further certify that the examination was recorded
11 stenographically by me, and that this transcript is a true
12 record of the proceedings.

13 I further certify that I am not of counsel to any of
14 the parties, nor an employee of counsel, nor related to any of
15 the parties nor in any way interested in the outcome of the
16 action.

17 As witness my hand and seal this 5th day of June, 2023.

18

19

20

21

22



JEANINN ALEXIS

My Commission Expires: 11/30/2023

EXHIBIT D-117

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 3
DEPOSITION OF ANNE HORNSBY
As 30(b)(6) Designee 1 of
The United States

Washington, DC
November 21, 2023

Reported by: John L. Harmonson, RPR

1 Exhibit 1520: "RADV audits are intended to confirm
2 the presence of risk adjustment conditions (that
3 is, diagnoses that map to HCCs) as reported by MAOs
4 in medical record documentation."

5 Do you see that?

6 A. I do see that sentence.

7 Q. And then the next sentence begins:

8 "RADV audits confirm the presence of the diagnoses
9 related to the enrollee's HCC profile through the
10 review of certain categories of medical records
11 submitted by the MAOs for the purpose of a RADV
12 audit."

13 Do you see that, Dr. Hornsby?

14 A. Yes, I do see that sentence.

15 Q. And are those sentences consistent with
16 your understanding of how the RADV process works in
17 terms of CMS validating HCCs submitted by MAOs in
18 the medical records?

19 A. Yes, that's consistent with my
20 understanding of the CON14 and CON15 medical record
21 review methodology.

22 Q. If CMS confirms in RADV a diagnosis code
23 submitted by an MA plan, that code cannot result in
24 an overpayment to the plan; correct?

25 A. I'm sorry --

1 MS. LIKOFF: Objection to form. Vague.

2 THE WITNESS: What was that, Amy?

3 MS. LIKOFF: Oh, I just made an
4 objection. Objection to form. Vague.

5 BY MR. MARTINEZ:

6 Q. Do you need me to repeat my question?

7 A. Well, I lost the if. I looked up and
8 lost the if.

9 Q. I'm asking you a question just about
10 what CMS means when it says "confirm."

11 A. Oh, I thought you were reading. Okay,
12 sorry.

13 Q. So I'll repeat it.

14 If CMS confirms in RADV a diagnosis code
15 submitted by an MA plan, that code cannot result in
16 an overpayment to the plan; correct?

17 MS. LIKOFF: Objection to form. Vague.

18 THE WITNESS: When the medical record
19 coders code a diagnosis in a medical record that
20 matches to the HCC on which the MAO has been paid,
21 then it's steady state. No change.

22 BY MR. MARTINEZ:

23 Q. Right. And by "steady state," you mean
24 CMS is determining when it validates a diagnosis
25 code or an HCC submitted by an MA plan in RADV,

1 that that code or HCC cannot result in an
2 overpayment to the plan; correct?

3 MS. LIKOFF: Objection to form. Vague.

4 THE WITNESS: If the HCC that's being
5 audited for a beneficiary is confirmed by the
6 coder, there is no change in payment.

7 BY MR. MARTINEZ:

8 Q. Right. So if CMS confirms the HCC
9 that's being audited in RADV for a beneficiary
10 sampled from an MA plan, there is no change in
11 payment, meaning there has been no overpayment to
12 the MA plan as a result of that code or HCC;
13 correct?

14 MS. LIKOFF: Objection to form. Vague.
15 And again, I just want to make clear that the
16 witness has been designated to speak for the time
17 period post July 2021.

18 THE WITNESS: If an HCC is confirmed,
19 there is no change in the payment. So there would
20 be no overpayment.

21 BY MR. MARTINEZ:

22 Q. Let's take a look at the page ending in
23 6651 of Exhibit 1520.

24 MS. LIKOFF: Counsel, which page did you
25 say?

1 MR. MARTINEZ: 6651.

2 And for the folks on Zoom, this should
3 be the ninth page of Exhibit 1520.

4 BY MR. MARTINEZ:

5 Q. Dr. Hornsby, are you on that page?

6 A. 6651. Yes, I'm on that page.

7 Q. All right. So I would like to draw your
8 attention to a statement by CMS in the right-hand
9 column under the "Response" subheading. Do you see
10 the paragraph that begins "Response: As previously
11 explained"?

12 A. Yes, I do see that sentence.

13 Q. Okay. So I would like to direct your
14 attention a couple of sentences down to the one
15 that begins "Our initiatives."

16 Do you see that, Dr. Hornsby?

17 A. I'm reading the paragraph above. I need
18 it in context.

19 Q. Okay.

20 A. So "Our initiatives"?

21 Q. Yes. Are you there?

22 A. Yes.

23 Q. Okay. What CMS is saying here on 6651
24 of Exhibit 1520 is: "Our initiatives are designed
25 to ensure fair and accurate recovery efforts by

1 focusing on the areas at highest risk of improper
2 payments."

3 Do you see that?

4 A. I do see that sentence.

5 Q. CMS designed RADV to focus on the areas
6 of the MA program with the highest risk of improper
7 payments; correct?

8 MS. LIKOFF: Objection to form. And
9 objection. I would just like to make it clear that
10 this particular rule is not a topic in
11 UnitedHealth's 30(b)(6) notice, and so it's our
12 view that this is out of scope.

13 THE WITNESS: Yeah, so I can speak on
14 behalf of CMS for CON14 and CON15. The sampling
15 frame that was developed for those two audits does
16 take into account an estimate of risk for
17 overpayments and also takes into account health
18 conditions that previous audit experience suggests
19 could also be associated with higher overpayments.
20 And for CON14 that was diabetes. For CON15, that
21 was urinary conditions.

22 BY MR. MARTINEZ:

23 Q. Why does CMS design its RADV audits to
24 focus on variables that have a higher risk of
25 overpayments?

1 MS. LIKOFF: Objection to form. Vague.
2 And again, I'm just going to make it clear that the
3 witness' testimony is confined to the time period
4 post July 2021.

5 THE WITNESS: Speaking about CON14 and
6 CON15 on behalf of CMS, as the reg says at 422.311,
7 the point is to ensure payment accuracy. That's
8 the point of RADV audits. And to best approach
9 that with the methodology for the sampling frame
10 would be, for example, to try to come up with
11 methodologies for focusing on areas of high risk
12 for overpayment.

13 BY MR. MARTINEZ:

14 Q. Is one reason why CMS might want to
15 focus on areas of high risk for overpayment to
16 increase the payment recoveries that CMS obtains
17 through the RADV program?

18 MS. LIKOFF: Objection to form. And
19 again, I just want to object to the extent that
20 this witness is only designated to speak beyond --
21 or the time period post July 2021.

22 THE WITNESS: Speaking about CMS's view
23 for CON14 and CON15, I did ask this question; and
24 Dave said no, that's really not a focus. ROI is
25 just not a focus.

1 The point is trying to have accurate
2 payments made to MAOs. And the best way to do that
3 is to try to target enrollees who are at risk for
4 improper payments. You know, payment error.

5 BY MR. MARTINEZ:

6 Q. Would you agree with me that payment
7 accuracy requires consideration of whether an MA
8 plan has either been overpaid, underpaid, or
9 accurately paid for a given payment year?

10 MS. LIKOFF: Objection to form. Vague.
11 Again, this witness is designated to speak only to
12 the post July 2021 time period. Counsel, you've
13 had seven hours to ask another witness about
14 general questions on RADV and its purpose. Again,
15 I just want to reiterate, this witness is only here
16 to talk about the time period post July 2021.

17 MR. MARTINEZ: I understand. I'm just
18 trying to get more information about what
19 Dr. Hornsby means when she refers to payment
20 accuracy in her response.

21 BY MR. MARTINEZ:

22 Q. Do you remember my question?

23 A. Would you say it again?

24 Q. Sure.

25 Would you agree with me that payment

1 was designated to speak to that earlier time frame.
2 And again, this February 2023 rule is also outside
3 the scope of the noticed topics.

4 MR. MARTINEZ: So the problem with that
5 is --

6 THE WITNESS: Yeah.

7 MR. MARTINEZ: Let me finish.

8 I wanted to ask Carolyn Kapustij these
9 questions about the February 2023 final rule but I
10 couldn't because of her cutoff of July 2021.

11 So now I finally have a witness in front
12 of me who is designated to testify about Topic 5
13 after July 2021, and I expect that she's going to
14 do so. And this final rule is all about the RADV
15 audits for payment years at issue in Topic 5.

16 So yes, we expect that the witness is
17 going to be prepared on this issue. And I know she
18 says she hasn't reviewed the document. But that's,
19 from my perspective, an issue with her preparation
20 and not an issue with the scope of the topic as
21 noticed.

22 MS. LIKOFF: Well, counsel, we disagree.
23 I believe the witness has shown that she is
24 adequately prepared to testify on the topics that
25 are in UnitedHealth's notice. This rule is not a

1 topic in that notice. We've received no
2 correspondence following this notice to suggest
3 that UnitedHealth intended for this witness to be
4 prepared to speak about this. And so the United
5 States maintains its position that these questions
6 are out of scope.

7 MR. MARTINEZ: And we, of course,
8 disagree with that position. But I don't think we
9 need to belabor it further.

10 I do believe there is a pending
11 question, though.

12 BY MR. MARTINEZ:

13 Q. Do you remember my question,
14 Dr. Hornsby?

15 A. No.

16 Q. Would you like me to repeat it?

17 A. I don't know. I'm really not prepared
18 to testify on behalf of CMS about that 2012
19 extrapolation memo, which was a proposed policy
20 that was never finalized. So I'm not going to
21 testify on that.

22 I don't know about the audits from 2011
23 to '13 because I prepared to testify on CON14 and
24 CON15. And there is nothing -- I did ask Dave
25 Gardner that one question about whether anything

1 has been released about the '11 to '13 results and
2 he said no, and that was it. That was all the
3 preparation I needed to do.

4 Q. That was all the preparation that you
5 did with respect to payment years 2011 through
6 2013?

7 A. Right. I've done a lot of
8 preparation --

9 MS. LIKOFF: Objection.

10 THE WITNESS: Oh, sorry. I've done a
11 lot of preparation for CON14 and 15.

12 BY MR. MARTINEZ:

13 Q. Let's go back to the second page of
14 Exhibit 1520. This is the page ending in 6644.
15 And I would like to direct your attention to the
16 top left portion of the page. Actually, the
17 sentence begins on the bottom right of the first
18 page of the document. So I'll go ahead and read
19 that as well.

20 Are you there, Dr. Hornsby?

21 A. Yes, I'm there.

22 Q. So the bottom right of 6643, CMS writes:
23 "Rather than applying extrapolation beginning for
24 payment year (PY) 2011 audits as we proposed, we
25 are finalizing a policy whereby we will not

1 extrapolate RADV audit findings for PYs 2011
2 through 2017 and will begin extrapolation with the
3 PY 2018 RADV audit."

4 And then it says: "As a result, CMS
5 will only collect the non-extrapolated overpayments
6 identified in the CMS RADV audits," and then it
7 goes on to reference the HHS OIG audits as well.

8 Do you see that written here in the
9 February 2023 final rule?

10 A. Yes, I see it.

11 Q. And when CMS refers to collecting the
12 non-extrapolated overpayments for payment years
13 2011 through 2017, that's a reference to any
14 enrollee level overpayments that CMS may have
15 calculated in the RADV audits for those payment
16 years; correct?

17 MS. LIKOFF: Objection; outside the
18 scope of the noticed topics. And again, this
19 witness is only designated to testify with respect
20 to audits and activities taking place after
21 July 2021.

22 THE WITNESS: Yeah, for CON14 and CON15,
23 when they complete the results and are ready to
24 move to the stage of payment recovery for those two
25 years, they will be doing beneficiary-level

1 he said no, and that was all I asked.

2 Q. What did you understand him to mean --
3 well, strike that.

4 Did you ask him whether the results for
5 payment years prior to CON14 were final?

6 A. That's the one question I asked,
7 speaking as Anne Hornsby. Yeah.

8 Q. When you used the word "final" in your
9 question to Mr. Gardner, what did you mean?

10 A. Are all calculations done, all quality
11 assurance checks done, all review up the line with
12 CMS approval at the top.

13 Q. When you used the word "final" in your
14 question to Mr. Gardner, did you have in mind that
15 the appeals process related to those RADV findings
16 would have been concluded?

17 A. Speaking as Anne Hornsby, I was focused
18 on CON14 and CON15 where there aren't any
19 preliminary results. So I asked that one quick
20 question about the earlier years, and I did not
21 probe.

22 Q. Since July 2021, has the appeals process
23 for any of the RADV audits covered by Topic 5
24 begun?

25 A. I'm prepared to testify on CON14 and

1 CON15 on behalf of CMS. And appeals have not
2 begun.

3 Q. Are you familiar with how the appeals
4 process is supposed to work for CON14 and 15?

5 A. CMS has set forth the appeals process in
6 422.311. And I don't have it with me; otherwise I
7 would read it to you.

8 Q. So is the answer to my question yes or
9 no?

10 A. I've given you the citation where CMS
11 sets it out. And it's a detailed -- it's a very
12 long regulatory section which starts with hearing
13 officers and ends with administrative law judges.
14 So I am generally familiar, but I'm not -- I'm here
15 to testify on CON14 and 15 where it's not anywhere
16 near the appeals process.

17 Q. With respect to CON14 and 15, has CMS or
18 Deloitte prepared any documents as of today
19 summarizing the medical record review results for
20 those audits?

21 MS. LIKOFF: Objection to form. Vague.

22 THE WITNESS: Dave said that the results
23 of each contract's audits for '14 and '15 are
24 available to the contract in CDAT through the
25 continuous reporting process. So there is no need

1 at this early stage to have any other results.

2 There are no preliminary results for CON14 and 15.

3 BY MR. MARTINEZ:

4 Q. And neither CMS nor Deloitte has
5 prepared any documents summarizing the audit
6 results for CON14 and 15; is that right?

7 MS. LIKOFF: Object to form.

8 THE WITNESS: He said there are no
9 preliminary findings for CON14 or 15.

10 BY MR. MARTINEZ:

11 Q. And there's no preliminary findings code
12 for -- CMS has not created any document summarizing
13 the medical record review results for CON14 and 15?

14 MS. LIKOFF: Object to form. Asked and
15 answered.

16 THE WITNESS: Yeah. I mean CMS does not
17 have any preliminary findings on CON14 and CON15.

18 BY MR. MARTINEZ:

19 Q. So do I have it right that CMS not only
20 does not have any final audit results for CON14 and
21 15, it doesn't even have preliminary findings for
22 those two RADV audits. Is that right?

23 MS. LIKOFF: Objection to form. Asked
24 and answered.

25 THE WITNESS: Yes. CMS does not have

1 preliminary findings for CON14 nor CON15.

2 BY MR. MARTINEZ:

3 Q. When does CMS expect to have preliminary
4 findings for CON14 and CON15?

5 MS. LIKOFF: Objection; outside the
6 scope of the time frame. The witness is not here
7 to testify about what may take place in the future.

8 BY MR. MARTINEZ:

9 Q. You can answer.

10 A. Oh, okay. I asked that question, and
11 they said they just don't know. They do not have
12 dates. It's just not set.

13 Q. When did the medical record reviews for
14 CON14 begin?

15 A. Oh, my gosh. I can't remember that
16 date. But it takes at least a year to get through
17 them because each -- for each beneficiary, an MAO
18 can submit up to five records. And with 6,000
19 beneficiaries, you could have a maximum of 30,000
20 records. So it's a huge undertaking.

21 I don't know how many came in, but it
22 takes, you know, a chunk of time to finish the
23 medical record review.

24 Q. Is it your understanding that the
25 medical record review for CON14 began after

1 July 2021?

2 A. I remember when they ended. So first
3 there is the intake window opening for MAOs to
4 submit medical records, and that goes on for a
5 number of months.

6 And then the medical record intake
7 starts, which is a validity process where they're
8 checking a number of things -- I don't have to go
9 into all that detail.

10 And then finally starts the abstraction
11 process, which is where your coders -- experienced,
12 qualified coders are doing coding of the medical
13 records.

14 So I apologize. I cannot remember the
15 date it started, the actual medical record review.

16 Q. And I take it the same answer for CON15?

17 A. Yeah. I just -- I can't remember. I
18 apologize, I cannot remember those dates. There
19 are like four dates, and I remember the last one --
20 the last two.

21 Q. For CON14 or 15, has CMS calculated any
22 HCC discrepancy rates for the MA plans that it
23 audited?

24 MS. LIKOFF: Objection to form. Asked
25 and answered.

1 behalf of CMS that CMS was unaware that the
2 diagnosis data that came from providers and was
3 then submitted to CMS includes errors?

4 MS. LIKOFF: Objection; asked and
5 answered.

6 THE WITNESS: Yeah. I mean, CMS does
7 not have access to the data inside an MA0. When
8 CMS sees delete records come into the system,
9 that's when they are aware of errors. So yes, CMS
10 is aware of errors in MA data because they see the
11 deletes that come in.

12 BY MR. BAAK:

13 Q. Would you agree with Cheri Rice -- Cheri
14 Rice was your boss; right?

15 A. Yes.

16 Q. Would you agree with Cheri Rice when she
17 testified that CMS had some reason to know that
18 there was a level of diagnosis coding that was
19 unsupported in a Medicare Advantage plan's data?

20 MS. LIKOFF: Objection to form.

21 THE WITNESS: I would like to see that.
22 So let me turn to my Cheri Rice deposition copy,
23 which is Binder 3, Tab 7.

24 What page are you on, Mr. Baak?

25 BY MR. BAAK:

1 Q. Turn to page 71 of her transcript.

2 A. Okay. Where?

3 Q. Starting at line 25.

4 A. Oh, at the bottom. Okay.

5 Q. Without identifying a specific percent,
6 when you were at MPPG, you understand from the RADV
7 audit process that there was some error rate, some
8 percentage of diagnosis codes of Medicare Advantage
9 data that were unsupported?

10 A. Yes. In addition to deletes, of course,
11 the RADV audit results would tell CMS that there
12 were diagnoses that were not supported in the
13 medical record. Yeah.

14 Q. So you agree with this testimony that
15 CMS was aware that the diagnosis codes that were
16 coming from providers to MA plans and then coming
17 to CMS included some unmeasured error rate; right?

18 A. Yes.

19 MS. LIKOFF: Objection; misstates -- the
20 document and misstates the witness's testimony.

21 THE WITNESS: Keep in mind that about 30
22 MA contracts were audited a year until CON14. So
23 we're not talking about a large volume. But yes,
24 from the RADV audit process, CMS understood that
25 there was some error rate because that would be a

1 typical result of the audit process. For each
2 contract audited, there would be a payment error
3 amount.

4 And in addition, as I had been talking
5 about, CMS was aware that parent organizations were
6 deleting records that they had been paid on because
7 they found errors in the diagnosis codes.

8 BY MR. BAAK:

9 Q. You mentioned -- Dr. Hornsby, you
10 mentioned an error where a plan submits a diagnosis
11 code and then subsequently determines for some
12 reason that that code ought to be deleted. That
13 was an example you gave me a little bit earlier.

14 A. That was one example I gave, yes, that
15 CMS has seen.

16 Q. CMS is also aware that there are errors
17 where in fact a provider does document a diagnosis
18 code on a medical record but fails to submit it;
19 right? CMS knows that from the RADV process?

20 MS. LIKOFF: Objection to form. Vague.
21 Beyond the scope.

22 THE WITNESS: CMS did not have evidence
23 of that. You know, around the time of the 2014
24 rule, CMS had anecdotal evidence that MAOs were
25 conducting medical record reviews to find what

1 everybody calls additional to find diagnoses that
2 had not been submitted before that appear to be
3 supported by the medical record. CMS was not aware
4 of that as a fact, as clear knowledge. It was all
5 through professional networks and, you know, that
6 level of knowledge.

7 BY MR. BAAK:

8 Q. Just to make sure I understand,
9 Dr. Hornsby, you're testifying that over time CMS
10 became aware through professional discussions,
11 industry conferences and the like that Medicare
12 Advantage organizations were conducting medical
13 record reviews to add diagnosis codes that the
14 provider had failed to submit. Is that what you
15 just testified to?

16 A. Yes. Over time CMS became aware, around
17 2014 as a tipping point.

18 Q. It had knowledge that CMS obtained about
19 what plans were doing. That obviously predated the
20 proposed medical record review, right, since that
21 was targeted at Medicare Advantage organization's
22 chart review activities?

23 MS. LIKOFF: Object to form. Vague.
24 Misstates the witness's testimony.

25 THE WITNESS: CMS did not propose a

1 like, 80 percent? I mean, what do you mean by
2 "well known"?

3 BY MR. BAAK:

4 Q. Dr. Hornsby, you have a PhD from
5 Harvard.

6 A. That's right.

7 Q. Have you used the phrase "well known" in
8 your life before?

9 A. I'm not going to --

10 MS. LIKOFF: Objection.

11 THE WITNESS: Testifying as Anne
12 Hornsby, I'm not falling in this trap. So, you
13 know, I want to know what "well known" means to
14 you.

15 BY MR. BAAK:

16 Q. Okay. Your testimony for the jury is
17 you don't understand what the phrase "well known"
18 means without me defining it?

19 MS. LIKOFF: Objection to form.

20 THE WITNESS: My testimony is I'm asking
21 you what you mean by "knowledge" and "well known."
22 Because I have explained that that usually means
23 throughout the organization with many people and
24 all the way up the leadership chain. And CMS is
25 just not going to testify to that.

1 There was anecdotal knowledge.
2 Anecdotal knowledge. So as a social scientist, I
3 know what "anecdote" means. It's not systematic.
4 So anecdotal knowledge that MAOs were not
5 submitting diagnoses and were not deleting
6 diagnoses that needed to be deleted, and that were
7 focusing on finding additional diagnoses that had
8 not been submitted. That's what the anecdotal
9 knowledge was.

10 BY MR. BAAK:

11 Q. I'll use your phrase, then.

12 So, Dr. Hornsby, there was anecdotal
13 knowledge in CMS that the diagnosis codes that
14 providers were submitting to MA plans that was in
15 turn were getting submitted to CMS did not include
16 all diagnosis codes that were supported by the
17 patient's medical record; right?

18 MS. LIKOFF: Objection; outside the
19 scope.

20 THE WITNESS: CMS assumes that the
21 reason MAOs began to engage in identifying
22 additional was because that was your discovery --
23 MAO's discovery inside their organizations, and
24 they would be in the best position to know because
25 they're the one who have the contracts with the

1 providers. CMS does not contract with the
2 providers.

3 BY MR. BAAK:

4 Q. Dr. Hornsby, my question was: There was
5 anecdotal knowledge in CMS that the diagnosis codes
6 that providers were submitting to MA plans that in
7 turn were getting submitted to CMS did not include
8 all diagnosis codes that were supported by the
9 patient's medical records; right?

10 MS. LIKOFF: Objection; outside the
11 scope. Asked and answered.

12 THE WITNESS: I've answered that so many
13 times. I've answered that many times.

14 BY MR. BAAK:

15 Q. The answer is yes, isn't it,
16 Dr. Hornsby?

17 A. The answer is --

18 MS. LIKOFF: Objection; mischaracterizes
19 the witness's testimony.

20 THE WITNESS: The answer is CMS does not
21 contract with providers, so it doesn't know for
22 sure what providers are up to. I mean, that's just
23 reality. CMS did have anecdotal knowledge that
24 MAOs, some MAOs, were not submitting deletes they
25 should, and others were conducting medical record

1 reviews to identify additional. Well, that means
2 that the MAOs had discovered that their providers
3 were not coding completely. That's what the MAO
4 discovery is.

5 BY MR. BAAK:

6 Q. Dr. Hornsby, I want to ask about a third
7 category of potential error. So we've talked about
8 errors where the MA plan submits a diagnosis code
9 that's not reflected on a medical record. Right?
10 And I'll add to that where the patient doesn't
11 have -- does not have the diagnosis. And then we
12 just talked about another category where the
13 patient has the diagnosis but it doesn't get
14 submitted.

15 So are you with me so far, those first
16 two categories of errors?

17 MS. LIKOFF: Objection to form.

18 THE WITNESS: Yes.

19 BY MR. BAAK:

20 Q. There is also a third potential category
21 of error, isn't there, Dr. Hornsby, where the
22 patient has the medical condition and it's not
23 reflected in the medical record but it is in the
24 diagnosis data. So the medical record is in fact
25 in error; right? That's also a potential source of

1 error in the system?

2 MS. LIKOFF: Objection to form.

3 THE WITNESS: CMS does not accept that.

4 That is unacceptable because CMS, as does every

5 other healthcare transaction entity, follows the

6 guidelines of the national committee, ICD-9 and

7 ICD-10. An accurate diagnosis is defined as one

8 that is documented in the medical record. And if

9 there is no documentation in the medical record,

10 then there cannot be an accurate diagnosis.

11 BY MR. BAAK:

12 Q. I'm not asking what CMS considers the

13 basis to validate a code. I'm just asking in the

14 real world, there can be patients who have a

15 condition. It might not end up on the medical

16 record but it might be in the claims data and gets

17 submitted. You're saying, well, then that would be

18 unsupported in CMS's view. But I'm just saying

19 that there is some set of those patients that in

20 fact have the condition; right?

21 MS. LIKOFF: Objection; vague. Calls

22 for speculation.

23 THE WITNESS: CMS would not -- you know,

24 the doctor is responsible for creating the medical

25 record with complete, clear documentation. That's

1 the starting point. And that's in, you know --
2 that's what -- MAOs have the right through CMS
3 regulation to put into their contracts with their
4 providers. And so if that happens when there is no
5 note in the medical record of a diagnosis, then it
6 cannot be submitted for payment.

7 BY MR. BAAK:

8 Q. Dr. Hornsby, maybe I'm making my
9 question unclear. I'm not asking about what CMS
10 considers a valid basis for payment. I'm asking is
11 it possible that a patient has diabetes, it's
12 included as a diagnosis code in the claims data,
13 but it is not on the medical record but in the real
14 world the patient has the condition. That's
15 something that can happen; right?

16 MS. LIKOFF: Objection; outside the
17 scope of the notice. Calls for speculation.

18 THE WITNESS: CMS knows that a patient
19 can have diabetes and the doctor did not write it
20 in the medical record. But that means that that
21 can't be submitted to CMS.

22 BY MR. BAAK:

23 Q. Whether it can be submitted or not,
24 that's a mistake that could happen; right?

25 MS. LIKOFF: Object to form.

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that ANNE HORNSBY, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 27th day of November, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT D-118

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex

rel. BENJAMIN POEHLING,

Plaintiffs,

vs.

No. CV 16-08697 FMO

UNITEDHEALTH GROUP, INC., et al,

Defendants.

_____ /

REMOTE VIDEOCONFERENCE DEPOSITION OF

LATEEFAH HUGHES, DrPH

February 4, 2022

Reported by:

Anne E. Vosburgh, CSR-6804, RPR, CRR

Job No. 789846

1 L. Hughes DrPH

2 doctorate in public health from

3 Morgan State University.

4 Did you obtain that doctorate before

5 beginning your employment at CMS?

6 A. No.

7 Q. When did you obtain that doctorate?

8 A. In 2013.

9 Q. Were you working on the doctorate
10 while employed at CMS?

11 A. Yes.

12 Q. When did you begin the course of
13 study for that doctorate?

14 A. In 2003.

15 Q. Did you have a particular area of
16 focus in your doctorate work?

17 A. No. It was general.

18 Q. Did you complete a dissertation?

19 A. I did.

20 Q. What was the topic of the
21 dissertation?

22 A. Exploring the impacts of adherence
23 outcomes for HIV AIDS in Kenya and Zambia.

24 Q. What was your position at CMS when
25 you joined in 2002?

1 L. Hughes DrPH

2 A. I was a social science research
3 analyst.

4 Q. Were you assigned a particular area
5 of research analysis?

6 A. Yes.

7 Q. What was that area?

8 A. I was assigned to adjustments,
9 operations, and risk adjustment data
10 validation.

11 Q. How long did you hold the position as
12 social science research analyst?

13 A. Two years, I think, or three years.
14 Two or three years.

15 Q. What position did you take next?

16 A. Health insurance specialist.

17 Q. And what were your responsibilities
18 as a health insurance specialist while at CMS?

19 A. More of the same of what I was
20 working on, but doing -- adding more
21 coordination to the title.

22 Q. Coordination with who?

23 A. Coordination of team tasks and
24 coordination with -- on -- on industry
25 communication and activities -- outreach and

1 L. Hughes DrPH

2 communication.

3 Q. Did your responsibilities in that
4 role include risk adjustment data validation
5 audits?

6 A. Yes.

7 Q. Are you familiar with the term
8 "RADV," Dr. Hughes?

9 A. Yes.

10 Q. What do you understand it to mean?

11 A. It's a data validation that takes
12 place by CMS to validate the accuracy of risk
13 adjustment data that Medicare Advantage plans
14 submit to the agency for payment on their
15 beneficiaries, their members that are enrolled
16 in the plans.

17 Q. Okay. So if I use the shorthand
18 "RADV audit," you'll understand that I'm
19 referring to a risk adjustment data validation
20 audit?

21 A. Yes.

22 Q. What position did you take next with
23 CMS?

24 A. That was pretty much my position
25 until I left the Medicare risk adjustment work

1 L. Hughes DrPH

2 and moved to management in the Affordable
3 Care -- under the Affordable Care Act.

4 Q. And Dr. Hughes, in what year did that
5 occur?

6 A. 2012.

7 Q. At some time prior to 2012 did you
8 hold the title Team Leader for Risk Adjustment
9 Data Validation?

10 A. Yes. That was part of the broad
11 title of health insurance specialist.

12 Q. Do you recall how long you held that
13 title?

14 A. I think it was from 2006 through
15 2012, but I can confirm when I look at my
16 resume.

17 Q. Understood.

18 And when you transitioned to work on
19 Affordable Care Act issues, did you continue
20 to have responsibility for risk adjustment?

21 A. No. Not Medicare risk adjustment,
22 no.

23 Q. Did you continue to have
24 responsibility for RADV audits?

25 A. No.

1 L. Hughes DrPH

2 routine trainings to the industry, so I would
3 be responsible for coordinating information
4 for the RADV or the data collection components
5 of the training manuals that CMS put out for
6 the training.

7 Q. And during the RADV audit process,
8 what information was being evaluated?

9 A. The diagnosis data and the
10 hierarchy -- that contributed to the
11 hierarchical condition categories that are
12 used for -- assigned to beneficiaries from the
13 Medicare data. So that information was being
14 reviewed.

15 Q. When you referenced hierarchical
16 condition categories, are those sometimes
17 abbreviated HCCs?

18 A. Yes.

19 Q. So I understand you to say that the
20 information evaluated during a RADV audit
21 included diagnosis data and HCCs that were
22 assigned to beneficiaries from submitted data.

23 A. Yes.

24 Q. And how were diagnosis data
25 evaluated? Who did that?

1 L. Hughes DrPH

2 A. We had contractors that were
3 credentialed in conducting medical record
4 review in ICD-9 -- in ICD-9 coding extraction
5 for medical records.

6 Q. And did you interact with these
7 contractors?

8 A. Yes.

9 Q. Do you recall any of the
10 organizations who were credentialed in
11 conducting medical record review?

12 A. Yes.

13 Q. Okay. Would you list those for me,
14 please.

15 A. The ones I recall were Aspen -- I'm
16 just trying to go in order from when I
17 started, if I can recall that.

18 Aspen, Health Services Advisory
19 Group, HSAG, Buccaneer, IPR0. Those are ones
20 that I recall but there may have been others.

21 Q. When you reference Buccaneer, is the
22 full name Buccaneer Data Services?

23 A. Maybe. I don't know if that was
24 their name back then, but maybe.

25 Q. And the organizations that you listed

1 L. Hughes DrPH

2 performed medical record coding?

3 A. They do -- they did. And I don't
4 think that those were all, but I just can't
5 remember all, I'm sorry, the acronyms.

6 Q. And are you familiar with the process
7 as to how these organizations would evaluate
8 medical records to make determinations on
9 diagnosis data?

10 A. Yes.

11 Q. Could you please describe that
12 process.

13 A. Sure.

14 So based off my recollection, the
15 Medicare health plans would submit the
16 required medical records from their providers
17 to these organizations for beneficiaries that
18 were selected in their sample.

19 The medical record review
20 organizations would have the records reviewed
21 by a -- by what's considered a first-level
22 review or primary coder. And then that
23 record -- some records were also re-reviewed
24 by like a senior coder based off of certain
25 criteria for either quality assurance in the

1 L. Hughes DrPH

2 process.

3 And there was also a -- the process
4 was set up such that there was also a second
5 review organization that reviewed a subset of
6 some sort from the primary -- from the first
7 organization.

8 And that was used -- put in place to
9 mitigate the known issues of coder agreement
10 or levels of coder disagreement to get --
11 given that it's a pretty subjective activity
12 that -- so to be able to kind of in some way,
13 shape, or form, identify where the agency
14 could kind of err on the side of the plan when
15 there is any level of doubt that the record
16 could be accurate.

17 So there, that's kind of like an
18 interrater reliability type of activity for
19 agreement.

20 Q. Okay. The interrater reliability
21 activity that you described, would that involve
22 comparing the diagnosis codes identified by one
23 coder with the diagnosis codes identified by
24 another coder?

25 A. Yes.

1 L. Hughes DrPH

2 Q. And what was the purpose of doing
3 that?

4 A. The purpose was to, for one, in the
5 process, it's pretty known that coders
6 don't -- they may not have a high level of
7 agreement on coding.

8 So in order to -- if you look at the
9 first level of coding, it may have a pretty
10 high error rate, if you will, and then by
11 introducing maybe another layer of coding,
12 there may be something to bring that error
13 down. And to also determine their level of
14 agreement on codes.

15 So it's a measure of quality
16 assurance in the process.

17 MR. QURESHI: Okay. Dr. Hughes, if
18 I may, I'd like to take a short restroom
19 break, if that's okay with your lawyer.

20 May I propose like a five-minute
21 break?

22 MS. GLOVER: Sure. That's fine.
23 And we'll just go off the record then.

24 MR. QURESHI: Okay. Thank you.
25 We're off the record.

1 L. Hughes DrPH

2 C E R T I F I C A T E

3

4 I, ANNE E. VOSBURGH, Certified Shorthand
5 Reporter, Registered Professional Reporter,
6 Certified Realtime Reporter, and Closed
7 Captioner, hereby certify:

8 That LATEEFAH HUGHES, via remote
9 videoconference, solemnly affirmed and agreed to
10 testify to the truth, the whole truth and
11 nothing but the truth; that all counsel
12 stipulated to this process, notwithstanding the
13 location of reporter or witness at time of
14 deposition; and that this transcript is a true
15 and correct record of testimony given.

16 I further certify that I am not related
17 to any of the parties to this action and that I
18 am in no way interested in the outcome of this
19 matter.

20

21 Anne Vosburgh

22 ANNE E. VOSBURGH

23 Certified Shorthand Reporter No. 6804

24 Registered Professional Reporter

25 Certified Realtime Reporter

EXHIBIT D-119

IN THE UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

- - - - -	+	
UNITED STATES OF AMERICA		
et rel. BENJAMIN POEHLING,		
Plaintiffs,		Case No.
vs.		CV 16-08697 FMO (SSx)
UNITEDHEALTH GROUP, INC.,		Hon. Fernando Olguin
et al.,		
Defendants.		
- - - - -	+	

Wednesday, January 26, 2022

Remote Videotaped Deposition of THOMAS HUTCHINSON, a Witness herein, called for examination by counsel for Defendants in the above-entitled matter, pursuant to notice, the witness being duly sworn by MICHELE EDDY, RPR, CRR, a Notary Public in and for the District of Columbia, taken virtually with the witness located in Washington, D.C., at 10:13 a.m.

1 I would also ask that you please allow me to
2 finish my question before you answer it.
3 Oftentimes you might know what my question is
4 before I complete it, but please refrain from
5 answering it until I finish my question. I will
6 absolutely extend you the same courtesy and will
7 allow you to finish your answer before I ask my
8 next question or my follow-up question.

9 Remote depositions make this a little
10 difficult to implement, but I will certainly do my
11 best not to step on you and, if I do, I apologize
12 in advance.

13 If you need to take a break at any time,
14 sir, to -- for any reason, just let me know and we
15 can certainly go off the record. I would request,
16 however, that you not ask to take a break while a
17 question is pending unless you need to confer with
18 your counsel on an issue involving privilege. If
19 that's the case, just let me know. Is that
20 understood?

21 A It's understood.

22 Q As the deposition is occurring remotely,
23 I am unable to see what you have in front of you.
24 I would ask that you not read from any preprepared
25 notes or access any text messages or emails while

1 we're on the record. Is that clear?

2 A Yes.

3 Q Do you currently have any papers in
4 front of you, sir?

5 A I have an empty notebook or a clear
6 notebook to take notes if I need to but -- I can
7 move it if you would like.

8 Q If it's empty, you don't need to move
9 it, sir.

10 Are there any other documents in front
11 of you?

12 A No.

13 Q I would request that you not communicate
14 with anybody by computer, phone, or email, or some
15 -- some other mechanism while we are on the
16 record. Of course, if you need to confer with
17 your counsel, you can -- you can do that audibly,
18 and we can take a break as appropriate.

19 Mr. Hutchinson, are you aware of any
20 reason your deposition should not go forward
21 today?

22 A No, I -- no.

23 Q Have you taken any medication or
24 substance that might interfere with your ability
25 to testify truthfully and accurately here today?

1 A No.

2 Q Mr. Hutchinson, do you understand that
3 you are appearing here today pursuant to a
4 subpoena issued by the defendants in this
5 litigation?

6 A Yes.

7 Q When did you become aware of that
8 subpoena?

9 A I believe last fall.

10 Q The fall of 2021, sir?

11 A Correct.

12 Q Were you employed by the Centers for
13 Medicare and Medicaid Services from 1991 through
14 2010?

15 A Yes, 1991 to 2010, yes, that's correct.

16 Q And from September of 2006 through June
17 of 2010, were you the director of the Medicare
18 Plan Payment Group known by the acronym MPPG?

19 A Yes.

20 Q And did you leave CMS in June of 2010,
21 sir?

22 A Yes.

23 Q Most of my questions throughout the day,
24 Mr. Hutchinson, will focus on the time when you
25 were at CMS. If I'm interested in another time

1 period, I will specify that, but I am largely
2 interested in your tenure at CMS. Is that clear?

3 A Yes.

4 Q Mr. Hutchinson, are you familiar with
5 the term Medicare Risk Adjustment Program?

6 A Yes.

7 Q What do you understand it to mean?

8 A The risk adjustment program is the
9 payment method that CMS uses to calculate
10 individual beneficiary risk scores, which are
11 multipliers for the base bid rate that Medicare
12 Advantage plans bid to cover Medicare Part A, Part
13 B, and supplemental benefits.

14 Q In your role as director of the Medicare
15 Plan Payment Group or MPPG, did you have any
16 responsibilities for the Medicare Risk Adjustment
17 Program?

18 A Yes.

19 Q What were those responsibilities?

20 A To design and implement the payment
21 system using the risk adjustment data.

22 Q And when did you begin to design and
23 implement the payment system using the risk
24 adjustment data?

25 A And when you say -- refer to "you," is

1 that me in particular or you as a plural?

2 Q I meant you in particular, sir.

3 A I probably started designing,
4 implementing in, I guess, 2006, when MPPG was
5 created.

6 Q And, sir, are you able to describe
7 generally what process you followed to design and
8 implement the payment system using the risk
9 adjustment data?

10 A I don't understand your question.

11 Q I would like to understand generally
12 what you did in connection with your
13 responsibility to design and implement the payment
14 adjustment system. How did you go about
15 fulfilling your responsibility?

16 A Again, I guess I'm just not quite sure
17 on the question. I don't mean to be difficult,
18 but are you asking what did I in particular do or
19 what did -- what process did I lead? I -- I'm
20 just not sure of your question in the sense of how
21 to answer it.

22 Q Sure, Mr. Hutchinson. And I appreciate
23 you asking clarifying questions. I'm not assuming
24 you're being difficult. I asked you to do that
25 and you're doing exactly that and so thank you.

1 A We had a couple of processes, you know.
2 Some obviously you're more interested in than
3 others, but one thing is monthly payments -- you
4 know, the Part C and Part D program, which we were
5 responsible for, monthly payments went out to the
6 plans, and we basically had -- you know, part of
7 the responsibilities of this group was, you know,
8 in effect run a shadow payment system such that we
9 could check the accuracy of the MARx reports we
10 got regarding the amounts that the MARx, which was
11 the official payment system, calculated for each
12 plan.

13 And we could, you know -- through this
14 sort of shadow payment system, we would be able to
15 tell if there was any, you know, material
16 discrepancies in terms of what MARx calculated as
17 payments and what our shadow system did. And
18 essentially that required us to monthly, you know,
19 calculate 36 million risk scores and calculate,
20 you know -- make sure those were matched up to 36
21 million bids. You know, really it's 19 million
22 bids at that point to figure out what the MA
23 payments are, but we would kind of monthly run
24 those calculations. And that's what that group
25 did.

1 The other kind of thing they did is they
2 ran a national RADV program and process and,
3 again, as, you know, you well know, started the
4 plan level RADV process in 2007.

5 Q Anything else that comes to your mind
6 regarding the tools this group used to check the
7 accuracy of payments?

8 A Nothing in terms of tools per se, but
9 the other thing this group -- and Ann Hornsby was
10 also a part of that group -- was to work with OMB
11 to determine and publish the IPIA, the improper
12 payments annual report. Geez. But it's an annual
13 number every year that we had to put out as to how
14 accurate our payments were.

15 Q Mr. Hutchinson, would you like some
16 water?

17 A I just grabbed it.
18 Go ahead.

19 Q With respect to the calibration or
20 recalibration of the model we were discussing
21 earlier, I believe you explained that
22 fee-for-service data was used in connection with
23 those exercises. Is that correct?

24 A Correct.

25 Q During your time as head of MPPG, did

1 you have any concerns about the accuracy of the
2 fee-for-service data used for either calibration
3 or recalibration?

4 A Yes.

5 Q What were those concerns?

6 A Originally I was very concerned that the
7 fee-for-service data probably under-reported
8 diagnoses. Meaning, fee-for-service providers,
9 especially Part B providers, would see patients
10 but not necessarily document and record all the
11 diagnoses that a patient had because, again, there
12 are incentives for fee-for-service, they're a
13 little different, and it's not to provide any
14 different care, but it's -- you know, the
15 documentation you need, there -- there wasn't a
16 lot of diagnosis documentation needed in
17 fee-for-service. So originally I was concerned
18 that fee-for-service data under-reported
19 diagnoses. Originally I was not that concerned
20 about the accuracy of the fee-for-service data.

21 After we did some investigation on the
22 fee-for-service data, I, as well as others, I
23 believe, were surprised at not inaccurate -- that
24 the documentation for a lot of the fee-for-service
25 diagnoses was not as good as we had thought it

1 would be and actually rivaled kind of -- you know,
2 it was fairly similar to the documentation that we
3 had seen in MA, and I think we were surprised at
4 that.

5 Q And, sir, are you able to approximate
6 the time frame during which you had the
7 realization regarding the -- the observation you
8 just discussed?

9 A That would be in 2009 when we first
10 looked at the CERT data.

11 Q In your response you used the plural we.
12 Are you referring to MPPG or CMS or some other
13 group of individuals?

14 A MPPG. I'm sorry.

15 Q In response to one of my earlier
16 questions about the different tools used to check
17 payment accuracy, I believe you mentioned the term
18 "RADV." Do you recall that?

19 A Yes.

20 Q And when you used the term RADV,
21 R-A-D-V, do you mean risk adjustment data
22 validation?

23 A Yes.

24 Q Are you able to describe generally what
25 RADV means?

1 A Yes. So since even -- I think going
2 back to 2001, maybe 2002, CMS had always done sort
3 of a national program RADV process or audit in a
4 sense, which entailed, you know -- you know, at
5 least by the time I was running it, we had a
6 sample size of I think about 1600-odd
7 beneficiaries that we would collect medical
8 records from the approximately, you know, 350
9 different plans. And we would determine an error
10 rate of those diagnostic codes submitted through
11 RAPS based on a documentation that we would
12 receive, and we would determine the national error
13 rate.

14 Subsequently and in 2007 -- or 2009 for
15 the 2007 year was when we started looking into
16 possibly doing plan-level RADV audits, which, you
17 know, are much more specific and much more plan
18 specific, and the results could be used to
19 extrapolate a payment recovery from the plan. So
20 there had been a national one -- a national RADV
21 for years. We started, you know, a pilot project
22 doing the plan-level ones in 2009.

23 Are you still there?

24 Q Yes, I am, sir. I am working to
25 formulate my next question.

1 don't know.

2 Q That's fine, Mr. Hutchinson. Other than
3 client work and conferences, are there any other
4 contexts in which you had occasion to discuss the
5 recommendations contained in Exhibit 1024A?

6 A Again, I'm sure I've had informal
7 conversations with lots of folks about all of
8 these, you know, whether it's coding intensity or
9 whether it's the need for a fee-for-service
10 adjuster, et cetera, that would not necessarily be
11 client work or formal presentation at a
12 conference, but I don't recall any, you know,
13 exact -- what the -- who the people were, you
14 know, the exact issue, but it's not like I
15 completely forgot all this stuff as soon as I
16 walked out the building.

17 Q Understood.

18 Mr. Hutchinson, in connection with the
19 coding intensity adjuster, did you understand in
20 the spring of 2010 that MA plans would have more
21 diagnoses codes than fee-for-service for the same
22 population?

23 MR. MASON: Objection. Calls for
24 speculation. Vague and ambiguous as to would
25 have.

1 A Yeah, the Medicare Advantage program as
2 a whole had more coding and more people being
3 coded and more diseases and higher severity of
4 diseases coded than the same population in
5 fee-for-service would have had.

6 Q And did you have an understanding as to
7 why that was the case?

8 A Yeah, I think we have a pretty good
9 idea. A lot of it was severity, that Medicare
10 Advantage plans, you know, worked very hard and,
11 you know, captured oftentimes a higher level of
12 severity in a lot of diseases, whereas
13 fee-for-service a lot of times just kind of went
14 for the basic lower code and didn't really
15 determine whether they, you know, should, you
16 know, look to a more severe level of diagnoses.

17 Q Other than severity, did you have any
18 other understanding as to why MA plans would have
19 more -- would have more codes?

20 A Well, I mean, the simple fact, you know
21 -- MA plans have a much higher, you know,
22 incentive to make sure they code very completely
23 than fee-for-service providers in many cases. So,
24 you know, if you're measured on something, you're
25 going to be really good at it, and they got really

1 good at it.

2 Q Were you aware of any activities MA
3 plans engaged in to realize the incentive you just
4 described?

5 A Sure, you know, we knew about chart
6 reviews, you know. Yeah, certainly chart reviews
7 is probably the biggest factor back then. And
8 then, you know, we heard about various folks that
9 figured out how they could RADV proof things by
10 doing in-home visits, but, you know, we knew of
11 those things, yeah.

12 Q And when you say "we" --

13 A I knew those things. We knew those
14 things, so yeah.

15 Q I'm sorry, I stepped on you,
16 Mr. Hutchinson.

17 A Yeah.

18 Q When you say "we," are you referring to
19 MPPG?

20 A I am. That's what -- yes, I knew about
21 it and our whole group knew about it, you know.

22 Q And you used the phrase "chart review."
23 What did you understand the word "chart review" to
24 mean?

25 A Chart review is, you know, the process

1 -- well, when I -- when I was referring to it,
2 it's plans would target various, you know, of
3 their members with the idea that, you know,
4 either, geez, I spent a lot of money on these
5 people and there haven't been many diseases
6 reported or I know this person in the past has
7 been diagnosed with diabetes, but I don't have a
8 diabetes code for him in this year. And it's the
9 process where Medicare Advantage plans would
10 request medical records from their providers, and
11 then they would have their coders review the
12 medical record to determine if there was any codes
13 that indeed were documented in the medical record
14 but were not either part of the claim or whatever
15 or for whatever reason were not sent in to CMS
16 through the RAPS system.

17 Q As you described it, Mr. Hutchinson, did
18 you believe chart review was improper?

19 A No.

20 Q Did you believe it was fraud?

21 A No.

22 Q The coding intensity adjuster that we
23 discussed, would the calculation of that figure
24 depend on why MA plans have more codes than
25 fee-for-service?

1 A Yes.

2 Q And earlier you testified that you, when
3 you were at MPPG, you were aware that some plans
4 were doing one-way chart reviews. Is that
5 correct?

6 A Yes.

7 Q Did you know that UnitedHealth had a
8 chart review program when you were at MPPG?

9 A I don't recall if I knew any specific
10 plans that had, you know, a chart review. I mean,
11 we knew more of the chart review vendors.

12 Q So did you know any of the specifics of
13 how UnitedHealth conducted its chart review
14 program?

15 A I don't have any of the specifics for
16 how United did their program.

17 Q No, but my question wasn't just whether
18 you have those specifics now but that you didn't
19 know of those specifics when you were at MPPG; is
20 that right?

21 A That is correct, I didn't.

22 Q Did others at MPPG know the specifics of
23 the UnitedHealth Part B program, as far as you
24 know?

25 MR. QURESHI: Objection to form.

1 A I have no idea who knew or may not
2 have -- who may have known or who did know or
3 didn't know. I don't know.

4 Q You don't have any knowledge that anyone
5 at MPPG knew anything about the specifics of
6 UnitedHealth's chart review program, correct?

7 MR. QURESHI: Objection to form.

8 A That is correct.

9 Q And when you were at CMS, did CMS tell
10 MA plans that if they were reviewing charts in a
11 chart review program to look for additional codes
12 that they also had to examine whether diagnosis
13 codes submitted by providers were in fact
14 supported by a medical record?

15 MR. QURESHI: Objection to form.

16 A Not to my knowledge.

17 Q Did you ever tell -- let me rephrase
18 that.

19 When you were at CMS, did CMS ever tell
20 an MA plan that they did not have to assess
21 whether diagnosis codes submitted by providers
22 were supported by a medical record when they were
23 conducting a chart review to add diagnoses?

24 MR. QURESHI: Objection to form.

25 A I don't know if some folks may have told

1 people that or not. I don't know.

2 Q Do you have any knowledge one way or the
3 other?

4 A No.

5 Q Mr. Hutchinson, you currently work as a
6 strategic advisor at Epstein Becker Green; is that
7 correct?

8 A That's correct.

9 Q And Epstein Becker Green is a law firm?

10 A Yes.

11 Q You joined Epstein Becker Green in 2013?

12 A I think that's right.

13 Q And you've been working for Epstein
14 Becker Green since that time?

15 A Yes.

16 Q And your role as a strategic advisor
17 includes advising Medicare Advantage plans; is
18 that correct?

19 A Yes.

20 Q And Medicare Advantage organizations?

21 A Yes.

22 Q Medicare Advantage plans and
23 organizations are your clients?

24 A Oftentimes, yes.

25 MR. MASON: Can we take a short break?

1 CERTIFICATE OF SHORTHAND REPORTER

2

3 I, Michele E. Eddy, Registered Professional
4 Reporter and Certified Realtime Reporter, the court
5 reporter before whom the foregoing deposition was
6 taken, do hereby certify that the foregoing transcript
7 is a true and correct record of the testimony given;
8 that said testimony was taken by me stenographically
9 and thereafter reduced to typewriting under my
10 supervision; and that I am neither counsel for,
11 related to, nor employed by any of the parties to this
12 case and have no interest, financial or otherwise, in
13 its outcome.

14 IN WITNESS WHEREOF, I have hereunto set my
15 hand and affixed my notarial seal this 3rd day of
16 February, 2022.

17

18 My commission expires July 20, 2022

19

20 Michele Eddy
21 MICHELE EDDY

22 NOTARY PUBLIC IN AND FOR
23 THE DISTRICT OF COLUMBIA

24

25

26

EXHIBIT D-120

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
_____)

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
MELVIN INGBER
(Taken virtually)
10:02 a.m. Eastern
Tuesday, June 14, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
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1 Q. Are you aware of anyone doing so on
2 your behalf?

3 A. I'm not quite sure what you mean. Why
4 would I need any documents for a deposition, I'm
5 confused.

6 Q. Oh, not specifically for this
7 deposition, but in the context of this litigation.

8 A. I know that there was a request for us
9 to retain all e-mails and other electronic
10 documents and keep them just in case they were
11 needed, but that's the extent of it. We did not
12 participate in collection of documents per se.

13 Q. Okay. Thank you. All right. So I'd
14 like to start by going over your educational and
15 employment background and then we can talk more
16 specifically about some of your work at CMS and
17 RTI. Does that sound good?

18 A. Yes.

19 Q. Okay. Please describe any
20 undergraduate or graduate degrees you have
21 obtained including where you obtained them.

22 A. I went to Queens College in New York,
23 which is now part of City University, got a
24 Bachelor of Science in Physics. I went to Cornell
25 University and got a master's degree in physics.

1 I went to Stony Brook University and got a
2 master's degree and Ph.D. in economics.

3 Q. All right. Any other degrees or
4 certificates?

5 A. None that I can think of.

6 (Exhibit 1219 was marked for
7 identification.)

8 Q. All right. I'm going to ask my
9 colleague to introduce as Exhibit -- should be
10 1219, Tab 5.

11 A. It hasn't shown up on my screen yet.
12 Okay.

13 Q. All right.

14 A. I see it now.

15 Q. All right. Do you recognize this
16 e-mail?

17 A. I have to really read it because it
18 doesn't exactly pop out as a familiar e-mail. It
19 seems to be from 2016, so I will have to take a
20 look at it.

21 Okay. This is a chain of e-mails. Do
22 you want me to go down the whole chain here?

23 Q. Well, let's focus on the May 31, 2016,
24 e-mail, 2:35 p.m.

25 A. Okay. That's the top one that I can

1 see. It seems to be a blurb to write the
2 background of me. And I don't see anything --
3 except I see it. I don't recognize it having been
4 written, but yeah, it looks like a description of
5 my background. That's it. Yes.

6 MS. MCMAHON: Is this a document that
7 was produced in this case?

8 MS. BARNETT: Yes, this was produced by
9 RTI. Bates Number is RTI00259418.

10 MS. MCMAHON: Thank you.

11 THE WITNESS: It appears to be an
12 extraction from my resum?. It looks
13 like --

14 BY MS. BARNETT:

15 Q. Oh, no, I'm sorry.

16 A. I recognize it in that context, most
17 of it, yes.

18 MS. BARNETT: I'm sorry. I just gave
19 you the wrong Bates Number. It's
20 RTI00396783.

21 MS. MCMAHON: Thank you.

22 BY MS. BARNETT:

23 Q. All right. So does this profile
24 accurately represent your work experience?

25 A. Yes, I've done more, but -- since this

1 was written in 2016, but it's accurate as of the
2 date.

3 Q. Okay. And you currently work at
4 RTI International; is that right?

5 A. I do.

6 Q. And you're currently a principal
7 scientist at RTI?

8 A. It's a title.

9 Q. Is that right?

10 Have you held any other job titles
11 during your time at RTI?

12 A. No. That was when I walked into RTI,
13 the title, I asked somebody there who was
14 relatively senior what job title I should use.
15 Principal scientist was the title they said I
16 should use, and I've been using it ever since. I
17 was fairly senior when I came in, so it seemed
18 appropriate.

19 Q. And when did you join RTI?

20 A. 2006. Approximately June or July, I
21 don't remember which month.

22 Q. All right. And what do you do as a
23 principal scientist?

24 A. I have a range of responsibilities.
25 Some of which are to be the director of projects

1 and which is to say I lead a set of analysts for
2 working on a project, usually for the government.

3 I am also the -- a senior scientific
4 advisor to many projects that I work on without
5 being the direct leader. That's where I generally
6 fit in.

7 Q. All right. Then according to this
8 bio, you participated in projects developing and
9 maintaining risk adjustment methods for the
10 Medicare Advantage Program; is that right?

11 A. Yes.

12 Q. What were those projects?

13 A. Well, one project was the development
14 of the CMS risk adjustment project used to pay
15 managed care plans. Then -- that's the main
16 project. Then I worked on the one that -- similar
17 for ESRD beneficiaries, project to develop the
18 risk adjustment for the drug plans and the project
19 for the AHA risk adjustment projects for health
20 exchanges outside of Medicare. Those are the
21 projects -- they don't have necessarily titles
22 that make any sense, but that's the substance of
23 the work.

24 Q. All right. And for the project you
25 mentioned, CMS risk adjustment project used to pay

1 managed care plans, can you tell me more about
2 what you did for that?

3 A. At which stage are we speaking? At
4 RTI our CMS.

5 Q. Currently we're speaking about RTI.

6 A. Oh, at RTI, okay. When I came to RTI,
7 I worked on that project for -- just as a staff
8 member, then I became a project director of the
9 project for a few years. Then I reverted back to
10 being a member of the analytical staff on the
11 project, which I have been and continue to be on
12 the project in that capacity.

13 Q. All right. And specifically what were
14 you doing in that project?

15 A. Well, I -- as a basically scientific
16 advisor, I do a lot of things that are involved in
17 guiding the development of the models. It is
18 statistical models that we work with, and it
19 amounts to looking at data, understanding data,
20 analyzing data, scientifically producing reports,
21 and I work on all of these things. And my work
22 has been deep and extensive. I can't positively
23 tell you all the little things I might have done.

24 Q. All right. Did you work on a project
25 involving the calculation of a fee-for-service

1 adjuster for the risk adjustment model?

2 A. I had only a very brief acquaintance
3 with that work. That is -- I'm aware it was being
4 done. I was not a principal part of that project.
5 That piece of the main project, that is.

6 Q. And can you tell me more about what
7 that project involved?

8 A. Frankly --

9 MS. MCMAHON: Objection. Vague. You
10 can answer.

11 THE WITNESS: I don't know all the
12 parts of the project. I do know that there
13 was something involving trying to predict
14 diseases from characteristic of people to
15 see that -- whether that would fit in
16 somehow to making it clear -- making
17 adjustments to data, to actually change
18 data in some way. But I don't know the
19 details. The people who worked on it, I
20 was not working on it much, and CMS had a
21 part that I don't know in it. So I'm not
22 that deeply into that.

23 BY MS. BARNETT:

24 Q. All right. Do you know when that
25 project was implemented?

1 MS. MCMAHON: Objection. Ambiguous.
2 Go ahead.

3 THE WITNESS: I -- I don't know, I've
4 been working on this main project for so
5 many years that it's a bit of a blur. I'm
6 sorry. I don't know the dates that would
7 apply to this.

8 BY MS. BARNETT:

9 Q. Can you tell me who worked on that
10 project, the fee-for-service adjuster project?

11 MS. MCMAHON: Objection. Ambiguous.
12 Go ahead.

13 THE WITNESS: There are many people who
14 might, but the one person who I can
15 identify was named Echo Liu. I know she
16 was working on it. But as to others, I
17 don't know for sure.

18 BY MS. BARNETT:

19 Q. All right. Now before you were at
20 RTI, according to this bio, you worked for CMS for
21 16 years in several different roles. When did you
22 join CMS?

23 A. 1990.

24 Q. And what was your role at that time?

25 A. Initially I -- well, I was working in

1 the office of demonstrations, that's my initial
2 position there, and I was the government -- one of
3 government staffers on a project that was going to
4 analyze outpatient data for development of a
5 payment system.

6 Q. All right. And when did you become
7 director of the Division of Payment Research?

8 A. That would be much, much later. It
9 would be roughly -- let's see I left 2000.
10 Roughly around the year 2000, 2001. I'm not
11 positive.

12 Q. All right. And what were your
13 responsibilities in that role?

14 A. Well, as a manager I was basically
15 overseeing the work of people who are actually
16 actively being the government side of the project
17 and the project managers from the government side.
18 And so there were a number of people in the
19 Division of Payment Research that I was in. But I
20 also had to participate in management activities
21 such as budgeting, deciding what research we were
22 going to be doing the next year. And I also
23 consulted for other parts of CMS on statistical or
24 other relevant topics that they thought I could be
25 of use on.

1 Q. And can you tell me more about the
2 work that was done by the Division of Payment
3 Research?

4 A. Division of Payment Research, we did a
5 number of activities of which the risk adjustment
6 model development was one. And there were -- was
7 also work going on in development of payment
8 systems for psychiatric hospitals, for home
9 healthcare providers. I'm just trying to remember
10 how many there were. The managed care part of
11 risk adjustment was a fairly large piece of it,
12 but I don't remember all the other work that
13 everybody was doing in that particular division at
14 the time, but those are things I do remember.

15 Q. All right. And did you work on risk
16 adjustment prior to joining that department?

17 A. Before I became director of that
18 division, I was in that division, and I was
19 working on development of risk adjusters.

20 Q. Okay. When did you begin working on
21 the development of risk adjusters?

22 A. 1992 or 1993, something around that
23 time.

24 Q. All right. And what specifically was
25 your role in the development of the risk adjuster

1 for managed care?

2 A. I would be a person who managed
3 contracts and/or grants at the time. When this
4 work was being done early on, we did it through
5 those two mechanisms of funding. That was the
6 early -- the early work. I also did hands-on work
7 as well.

8 Q. And what did that hands-on work
9 entail?

10 A. After the main risk adjustment models
11 were developed, I had to work on developing the --
12 as I mentioned earlier, the model for Part D drugs
13 and for the ESRD population. Those are two that I
14 directed internally at CMS.

15 Q. So you would say the hands-on work
16 that you did was for Part D, drugs, and ESRD
17 population?

18 A. Yes.

19 Q. All right. And who did you work with
20 on the risk adjustment model for Part C?

21 A. There were many contractors and
22 grantees involved. We had Health Economics
23 Research, which was a company involved early on.
24 I think we had an earlier grant with Boston
25 University. We also contracted with 3M who had

1 their own model. We contracted with Johns Hopkins
2 University. They had a model called ACGs. We
3 worked with -- let's see Rick Kronick. He was
4 developing risk adjusters. I worked with all
5 these people who are all developing models for
6 risk adjustment for Medicare.

7 Q. And who else did you work with at CMS
8 on the risk adjustment model for Medicare Part C?

9 A. Do you mean directly or indirectly?
10 Because we in the research division did our own
11 development work for the most part and RTI became
12 a part of that work when it bought Health
13 Economics Research. So they were part of it. And
14 ultimately who else -- ultimately, when we finally
15 became part of the operations of CMS, we had to
16 communicate a lot with the -- what is now called
17 Centers for Medicare who actually implement the
18 payment system on their side. But the development
19 work is what our side mostly did, and those are
20 the people I work with. I can name some
21 individuals if you want those in the research
22 division. But not that -- they were not so much
23 involved in the Part C you're talking about. They
24 were involved in the drug and the ESRD population,
25 so they may not be relevant to your question.

1 Q. All right. Yes. Is there anyone that
2 you can remember in the Division of Payment
3 Research who worked with you on the risk
4 adjustment model for Medicare Part C?

5 A. I was the principal leader in that
6 area in the Division of Research. So, I mean,
7 obviously, I had a manager, but it was basically
8 my area in working with the contractors, of
9 course.

10 Q. All right. So you've said that you
11 were involved in the development of the risk
12 adjustment model for Medicare Part C; right?

13 A. Yes.

14 Q. Can you tell me what data was used to
15 calibrate that model?

16 MS. MCMAHON: Objection. Vague.

17 THE WITNESS: The data we used depended
18 on the stage of what we were working on,
19 but in the main it would have been
20 Medicare, fee-for-service claims data, and
21 eligibility data. That was the source.

22 BY MS. BARNETT:

23 Q. And, to your knowledge, was that data
24 audited before it was used in the model?

25 MS. MCMAHON: Objection. Vague.

1 We do an audit. We find sometimes things are not
2 supported by the medical record. That's the
3 extent of my knowledge of the differences.

4 Q. Was the RADV audit of fee-for-service
5 data?

6 A. The RADV audit was of data being
7 submitted by managed care plans and not
8 necessarily on claims per se. There were many
9 stages of the way data were submitted to CMS for
10 payment. So I -- whereas it was not the
11 fee-for-service data, the method being used was
12 not claims early on and only became claims in the
13 most recent years. So it varied as to the nature
14 of the data being audited. But it was managed
15 care data.

16 Q. Did you ever read any studies about
17 errors in fee-for-service data?

18 A. I am aware of CMS running general
19 estimates of over- and underpayments that they do.
20 I didn't -- that's a standard process that they do
21 that is not used in particular for auditing a
22 particular facility. It's to get the overall
23 error rates in Medicare.

24 I am -- I can't remember the names of
25 all these kinds of statistical studies that were

1 done. There are others that are facility specific
2 that would audit hospitals and -- I don't know the
3 error rates. I just know that these audits do go
4 on, and the statistical project I work on also was
5 to do audits of outpatient procedure codes. They
6 weren't always audits of diagnoses, by the way.
7 When I say audits, it is very general. Sometimes
8 it's diagnoses, sometimes it's procedure codes.
9 But there were many audits of one sort or another
10 on fee-for-service data for different purposes,
11 but it wasn't in my area.

12 Q. All right. And based on your
13 knowledge of those audits, it was found that there
14 were some errors in the fee-for-service data?

15 A. I would be just, you know, saying
16 something that I know from general reports that
17 they found errors in both directions missing --
18 sometimes missing data. And sometimes it wasn't
19 always missing data, it was about data that was
20 found to be false. There were all kinds of
21 reasons you would find errors in data. I can't
22 speak to the rates of data of errors or anything
23 like that.

24 Q. All right. Are you familiar with the
25 traditional Medicare fee-for-service payment

1 model?

2 A. The traditional fee-for-service model
3 is not a single model except that it pays for
4 individual services, but it pays for them in very
5 different ways. So I can't answer beyond that
6 unless you clarify the question.

7 Q. All right. Under the fee-for-service
8 payment model are providers paid based on claims
9 for medical services they provide?

10 A. Yes.

11 Q. How does that differ from the Medicare
12 Advantage model that we talked about?

13 MS. MCMAHON: Objection. Vague.

14 THE WITNESS: I'm trying to think how
15 to approach this. In one case in managed
16 care, payment is made globally since for
17 the probable cost of a particular
18 beneficiary per month and over a year
19 without regard to the individual services
20 actually rendered. In the fee-for-service
21 side depending on which provider you're
22 talking about, only specific services are
23 compensated and the picture -- the profile
24 of the patient is not what goes into the
25 payment amount so much as what services

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 16th day of June, 2022.

Christine A. Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-121

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex :
rel., BENJAMIN POEHLING, :
Plaintiffs, : Case No.:
VS. : CV-16-08697 FMO
UNITED HEALTH GROUP, INC., :
et al., :
Defendants. : Page 1-258

- - -

Thursday, March 14, 2024

- - -

Videotaped deposition of MELVIN JULES
INGBER, PH.D. taken at DLAPiper, 650 South Exeter
Street, Suite 1100, Baltimore, MD commencing at 9:42
a.m., before Sherry L. Brooks, Certified LiveNote
Reporter and Notary Public, in and for the State of
Maryland.

- - -

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1 fee-for-service Medicare data applies to Part C and
2 Medicare Advantage plans in a minute.

3 But just so that the jury understands,
4 when I say traditional Medicare or fee-for-service
5 Medicare, do you understand that I'm referring to the
6 same thing?

7 A. Yes.

8 Q. Okay. And those are both terms that
9 you've used in your work at CMS and still at RTI?

10 A. The word "traditional Medicare" is a newer
11 term for fee-for-service that's become used more, but
12 they are in effect the same thing.

13 Q. As the head of the Division of Payment
14 Research at CMS you helped make the decision about
15 what model CMS would use to calculate a risk
16 adjustment payment for Medicare Advantage plans,
17 right?

18 A. I was part of that decision-making
19 process, yes.

20 Q. And as part of that process you examined
21 potential risk adjustment models and recommended what
22 would ultimately be selected by CMS as the HCC model

1 to your superiors; is that right?

2 A. Yes.

3 Q. And the leadership at CMS accepted your
4 recommendation and implemented the CMS HCC model for
5 the purpose of calculating risk adjustment payments
6 for Medicare Advantage plans?

7 A. I made a recommendation. There were many
8 other people in the chain who had to make decisions.
9 There is one more thing I should say, is that
10 choosing the model is not the same as the
11 implementation of the model, which was made by
12 another group.

13 So as long as we understand what we're
14 talking about is model development, not
15 implementation, which was done via a different area,
16 not in the research area.

17 Q. What group worked on the implementation of
18 the CMS HCC model?

19 A. The Center for Medicare. They change
20 their names all the time. But there is the -- part
21 of CMS that makes payments to hospitals, physicians,
22 that actually does to the implementation work of all

1 of this also implemented for the risk adjustment
2 systems.

3 Q. While you were at CMS you worked with
4 folks at a company -- what became RTI to publish
5 articles and other literary papers; is that right?

6 A. The phrasing -- I'm sorry -- is not
7 correct. Those of us who worked on the development
8 of the system, including the company -- HER is the
9 initials that were used at the time, and I was
10 supervising them and made a lot of decisions.

11 And our names were all on some of the
12 publications, but I was not working in any sense for
13 HER, which is what I was hearing you say.

14 Q. I did not mean to suggest that.

15 When did you start working with or
16 supervising the individuals at HER that were doing
17 work on risk adjustment systems for CMS?

18 A. Probably 1993 or 1994 there was a sequence
19 of people working on it. It wasn't always HER, but
20 HER picked up the development after the initial work.
21 So there's a change of hands at some point, but it
22 was '93 or '94.

1 Q. What does HER stand for?

2 A. Health Economics Research.

3 Q. When did Health Economics Research end up
4 becoming RTI?

5 A. It was before I left CMS, but I just do
6 not remember.

7 Q. What does RTI stand for?

8 A. Research Triangle Institute.

9 Q. Okay. So from 1993 until the CMS HCC
10 model was adopted and implemented you had been
11 working with individuals on this project, and at some
12 point the individuals who were working -- you were
13 working with were at Health Economics Research?

14 A. Yes.

15 Q. And at least by 2000 you were publishing
16 papers with some of the individuals there at Health
17 Economics Research about the project that you were
18 supervising and working on, right?

19 A. Yes. This is not an unusual practice for
20 companies who are contractors, and CMS jointly take
21 authorship of papers. This is very common.

22 Q. Sure. And who are the folks that you were

1 of the transcript of your videotaped deposition taken
2 on June 14th, 2022?

3 A. That's what the title says it is, yes.

4 Q. And have you reviewed this deposition
5 transcript since you gave the deposition?

6 A. I did not actually.

7 Q. And you -- when you gave this deposition
8 you took the same oath you took today, right?

9 A. Yes.

10 Q. Okay. If you would turn to page 22 of
11 this deposition, page 84 of the transcript. This
12 deposition is structured -- this printout is
13 structured so it's got four pages on each page of the
14 PDF.

15 Do you see that, sir?

16 A. Yes. I'm sorry. But I'm trying to figure
17 out which ones you're referring to. 82 is the one
18 with the page number at the bottom?

19 Q. Yes. That's correct.

20 A. I'm sorry. That's page -- on top of the
21 page I'm looking at there is page 82 and a page 83.
22 Is that where I should be?

1 Q. Yes, sir. So if you look at the bottom of
2 the page 84, which is the bottom left corner page --

3 A. Yes.

4 Q. -- you were asked the question:

5 "QUESTION: But do you have a sense when
6 you talk about this (sic) fee-for-service lapses in
7 accuracy what you're referring to?"

8 And you answer:

9 "ANSWER: Coding is always potentially
10 subject to error. Sometimes people forget to write
11 something down. Sometimes people write something
12 that they shouldn't write down. We are aware of this
13 because we know how coding is done in practice in
14 offices. And it's just a question of practical
15 knowledge."

16 Do you see that?

17 A. Oh, yes. Okay.

18 Q. Okay. And do you stand by that testimony
19 today?

20 A. This is my personal belief, yes.

21 Q. Yeah. And so your personal belief that
22 you knew at the time you were developing the model is

1 that there were fee-for-service lapses in accuracy
2 because sometimes people forget to write something
3 down and sometimes people write something they
4 shouldn't write down, right?

5 A. That's not -- that is true, but it's not
6 quite the same as what you said about things not
7 being supported in the medical record.

8 I'm just opining that, yeah, probably
9 because human beings do this there's probably stuff
10 that's not right in there. That doesn't affect the
11 decision I make with respect to how to develop the
12 model, but yes.

13 Q. Sure. And I'm not impugning anything
14 about the decision to develop the model. But
15 something that you knew when you were developing the
16 model is that there are errors in data?

17 MS. MCMAHON: Objection.

18 A. When you say I knew, I knew just -- not
19 from analysis, per se. I knew because people are
20 people when they go (sic). That's all.

21 BY MR. JONES:

22 Q. Right. So your understanding when you

1 were developing the model is that there would be
2 errors in coding on the fee-for-service side and in
3 the MA side because people are people and they make
4 mistakes, right?

5 A. People make mistakes. However, that does
6 not change one's way of doing something just because
7 you know that in the background, yes.

8 Q. Did you do any work on evaluating Ms.
9 Lambert's mathematical work in terms of the
10 recalibration effort she did such that you disagree
11 with any of the math that went into her recalibration
12 as opposed to the conclusions she draws from it?

13 A. I, of course, could not see through all
14 the math. But having read the description of it, it
15 seemed that for what she wanted it was a reasonable
16 thing to do, yes, for which she was trying to get to.

17 Q. Okay. And that the -- what was described
18 was a reasonable way of potentially recalibrating the
19 model based upon what her parameters were described
20 as, right?

21 MS. MCMAHON: Objection.

22 A. Recalibrating the model could be done, but

1 it would have required -- it couldn't -- it could not
2 -- I'm sorry.

3 It could not be done practically and was
4 not what was in the law basically at the time. So it
5 could be done, yes. Mathematically, those results
6 would happen. It doesn't still mean anything about
7 the conclusion, however, of underpaid.

8 BY MR. JONES:

9 Q. Right. Leaving aside the conclusion of
10 underpayment, you don't dispute any of the math that
11 Ms. Lambert used to get to the conclusion of how
12 unsupported codes being taken out of the
13 fee-for-service model would affect the average
14 relative factors or average coefficients, right?

15 MS. MCMAHON: Objection. Form.

16 A. I don't have any objections to the
17 mathematics she did.

18 MR. JONES: Okay. Exhibit No. 1568.

19 (Exhibit Number 1568 was marked for
20 identification and was attached to the deposition.)

21 BY MR. JONES:

22 Q. Dr. Ingber, I've just handed you what's

1 been marked Exhibit 1568. Is Exhibit 1568 a copy of
2 Ms. Lambert's report to which you were responding?

3 A. It appears to be, yes.

4 Q. And if you would turn to page 23 of this
5 report. At the bottom of page 23 Ms. Lambert quotes
6 a CMS publication in 2014 that has an article written
7 by Dr. Kronick and Welch.

8 Do you see that?

9 A. On page 23 in the footnotes or someplace
10 else?

11 Q. So next to the Number 3 --

12 A. Oh, next.

13 Q. -- at the bottom.

14 A. Oh, okay. Not the reference down below,
15 but okay.

16 Q. And Ms. Lambert quotes this Kronick and
17 Welch article saying: "As noted, payment to MA plans
18 is calibrated based on coding patterns in
19 fee-for-service.

20 "If, for example, Jane Doe would have a
21 risk score of 1.0 if she were in fee-for-service, the
22 implicit assumption in the design of the MA payment

1 system is that she would have the same risk score of
2 1.0 if she were enrolled in MA."

3 Do you see that?

4 A. Yes.

5 Q. Do you agree with Dr. Kronick and Welch
6 that that is part of the implicit design of the MA
7 payment system that you developed?

8 A. I think there are some words missing from
9 that statement that would make it more correct.

10 Q. Okay. What are the words that are missing
11 from that statement that would make it more correct?

12 A. The coding would have to be -- that we're
13 talking about when we're coding people and developing
14 these risk scores, the coding that she's describing
15 and the data that's in fee-for-service -- which is
16 done without any incentives to code diagnoses at all
17 because that's the nature of coding and
18 fee-for-service. Payment is based on procedures.

19 So one of the things about this or the
20 assumption is that if the other coding were done with
21 no incentives for the coding of the diagnoses more
22 thoroughly and that the same pattern of coding people

1 right?

2 A. Yes.

3 Q. And so page -- the next page that says --
4 that has -- is titled, Costs of Unsupported Codes
5 Distributed to Demographic Factors if Removed, I
6 think part of your point is that the costs of
7 treating these patients stays in the model but then
8 is -- they are otherwise shifted around to what the
9 coefficients and relative factors are for either the
10 demographic factors or other codes that are still in
11 the model?

12 A. Yes.

13 Q. And if you go to the next page, which is
14 slide 17 of Exhibit 1571, part of your point here was
15 that --

16 A. I'm sorry. Are we skipping a page here?
17 I mean, I have a paper page 15 and a screen page 16
18 that match. But where are we on 17? Which version?

19 Q. I'm looking at -- it is the 17th page, but
20 because the first -- in the hardcopy version you've
21 got it counted page zero as the first one. The one
22 online is page 17.

1 But what I'm talking about, sir, is the
2 slide that has regression for coefficients on either
3 side, one showing your regression for one tab and the
4 other showing your regression for 2 tab.

5 Are you with me?

6 A. Yeah. I've coordinated both versions at
7 this time. There was some skipped, but you did that
8 intentionally. I wanted to make sure.

9 Q. All right. Dr. Ingber, looking at the
10 page comparing the regression coefficients for your
11 first version of the model with unsupported codes and
12 your second regression for supported codes only, your
13 -- part of your opinion was that the coefficients and
14 expected costs for treating various conditions go --
15 some go up and some can go down when you redistribute
16 the costs that the model had previously associated
17 with codes that are unsupported.

18 Is that fair?

19 A. Yes.

20 Q. And your differences tab in your Exhibit
21 1, turning to the next page, the 18th page of Exhibit
22 1571 in Agile Law, made that comparison explicit,

1 right?

2 You did the --

3 A. Yes. I did the subtraction to show the
4 differences.

5 Q. Great. And then the final slide of
6 Exhibit 1571 is designed to kind of depict the -- the
7 fact that, in your opinion and as you calculated in
8 your model, certain of the coefficients or relative
9 factors, the predicted costs for diagnoses might go
10 up, might go down, and the demographic factors might
11 go up or might go down.

12 But, ultimately, the model is distributing
13 the costs overall to that same group of factors,
14 right, the markers?

15 A. Yes.

16 Q. Dr. Ingber, I'm going to go back to
17 sharing -- and I guess I would ask that in your
18 computer you move to the spreadsheet.

19 MS. MCMAHON: Dr. Ingber's spreadsheet?

20 MR. JONES: We're going to go to the
21 share.

22 THE WITNESS: I'm sorry. So this is the

1 one that's basically in Zoom?

2 BY MR. JONES:

3 Q. This is the version that's in Zoom that
4 I'm controlling.

5 A. Yes, okay.

6 Q. And I want to add a few calculations --

7 A. Yes.

8 Q. -- to the spreadsheet with you.

9 A. Yes.

10 Q. And as a -- as an economist, Dr. Ingber,
11 you've used Excel quite a bit in your work?

12 A. I use it occasionally. It's not my main
13 tool, but I do use it.

14 Q. Okay. And you think you're fairly skilled
15 in Excel and can try to follow along?

16 A. Oh, yes, reasonably so.

17 Q. Great. And have you -- did you calculate
18 what would happen to the weighted average of the
19 relative factors in your model when you take the
20 unsupported codes out of the data on which the model
21 is calibrated?

22 MS. MCMAHON: Objection. Form.

1 A. I did not calculate the weighted average
2 given the weights of this particular population, is I
3 presume what you mean?

4 BY MR. JONES:

5 Q. Right.

6 A. Yeah.

7 Q. Okay. I'd like to go ahead and do that
8 with you. And so up on the screen can you see the
9 Exhibit 1 that I'm manipulating here?

10 A. I see it.

11 Q. Okay. And if we need to take a break for
12 you to look at any of the formulas that I've done and
13 confirm them, I'm happy to do that.

14 But first, let's do kind of a total count
15 of markers for each of the unsubmitted unsupported
16 codes, regression, supported codes regression, and
17 then your supported and unsubmitted regression.

18 Are you with me?

19 A. Yes. I thought I had done that, in fact,
20 on the last page on the differences page. The counts
21 are in there.

22 Q. I think -- you have the individual counts.

1 I'm just going to sum them up to help us with the
2 calculation. Okay?

3 A. Oh, okay.

4 Q. It's not pasting for me.

5 A. When you say you're adding them up, is
6 this just the total number of HCCs flagged, period?
7 That's what we're talking about?

8 Q. Yes. That's what we're talking about.

9 A. Okay.

10 Q. I need to save a new version of this. I'm
11 in -- what we're going to do, we're going to save a
12 new version of this Excel that we'll ultimately put
13 on as an exhibit here.

14 MS. MCMAHON: We can't see what you're
15 doing right now.

16 MR. JONES: Yeah. I've taken it down. I
17 need to get out of protected view somehow.

18 A. I'd be happy to stipulate that when you
19 take codes out the total number of codes goes down.

20 BY MR. JONES:

21 Q. Okay. Dr. Ingber, are you able to see
22 Exhibit 1 again?

1 A. I see it, yes.

2 Q. Okay. And all I've done since we were off
3 is to enable editing so that I can save the file and
4 then edit it. But this still shows last modified by
5 Mel in January of 2024. Okay. So I'm going to put
6 this on the desktop as Ingber Exhibit 1, deposition
7 version.

8 And so let's go -- you've got the count of
9 markers in each of the various regressions that you
10 run down at the bottom. I just want to have them in
11 a convenient place.

12 And what I'm going to do, Dr. Ingber, and
13 if you can help me remember I'm going to mark
14 everything that we do together today here in the
15 deposition with a different color so that it can be
16 distinguished when this is an exhibit from kind of
17 what was your original and what was in the -- what
18 we've done here in the deposition.

19 So I'm going to make it this tan color, if
20 that's okay. Okay. So to do total markers here is
21 the -- is what I'm putting in column F and I'm going
22 to sum under unsupported codes the markers that you

1 have and the count that you have in your population
2 with unsupported codes included, count of people with
3 HCC.

4 Is that -- are you with me so far?

5 A. Yes.

6 Q. And that should get the total markers that
7 were included in your population that went through
8 the regression with unsupported codes, right?

9 A. Yes.

10 Q. Okay. And then we'll do the same thing
11 for the group with unsupported codes removed and then
12 the same thing for the group with supported and
13 unsubmitted.

14 And I can slow down --

15 MS. MCMAHON: Is that a question?

16 MR. JONES: Yes.

17 MS. MCMAHON: No. I wasn't sure if you
18 were asking questions or trying to get Dr. Ingber to
19 confirm what you're doing. I'm not sure.

20 BY MR. JONES:

21 Q. All right. Are you with me, so far, Dr.
22 Ingber?

1 A. I am, but that last equation didn't
2 happen.

3 Q. That's true. Something happened with it.

4 A. But I am pleased that the number went down
5 when codes were removed, so I expect to see something
6 different.

7 Q. Okay. And, Dr. Ingber, can you agree with
8 me that what I've got in these equations would -- is
9 a count of the total markers that you have in this
10 regression or in each of your different models with
11 unsupported codes, supported codes only, and then
12 when you add back in supported but unsubmitted codes?

13 A. Yes. Indeed, the count got smaller when
14 codes are removed and then got bigger again when
15 codes were added. So it looks logical.

16 Q. Okay. And by the same token of the count
17 of markers going down when codes are removed, that
18 necessarily is a matter of math means that the cost
19 per marker that the regression is assigning to the
20 various markers is going to go up when you take out
21 unsupported codes, right?

22 A. You mean the average cost per marker or

1 something else? I'm not sure.

2 Q. Yes.

3 A. Because some went up and some went down.

4 So you're saying if we just look on average, which

5 way did they go, okay. This is a -- so far you

6 mentioned weighted. I'm not seeing any weighting

7 going on here, but that's okay.

8 Q. Sure. First I want to do a total cost per

9 marker and then we'll do a weighted average. Okay?

10 A. Okay.

11 Q. So I'm going to calculate -- your total

12 cost here for the population is the same in each of

13 the different iterations of your model, right?

14 A. I'm sorry. I'm not quite sure what you're

15 doing. b12 is the total cost in the population and

16 --

17 Q. And then if I do cost per marker in your

18 --

19 A. There's a typo there now -- okay.

20 Q. So if you divide the total cost associated

21 with treating the population, which is b12, by the

22 total markers in your regression with unsupported

1 codes, you'll get a cost per marker of essentially
2 treating the patients, right?

3 A. Yes.

4 Q. And if you are spreading the same costs
5 across fewer individuals -- or fewer markers, then
6 the cost per marker will go up from your regression
7 with -- if you've taken out unsupported codes, right?

8 A. Yes.

9 Q. And what I calculate your model as showing
10 and calculating is a cost per marker after taking
11 codes out of \$1,915 as opposed to a cost per marker
12 with unsupported codes of being \$1,812.31.

13 A. So far the math is right. The question is
14 where it goes, but we're getting there.

15 Q. Great. So then let's -- let's just go
16 ahead and do the same -- do a similar calculation but
17 with a weighted average of the individual -- of the
18 individual relative factors.

19 And so what I'm going to do is -- here
20 you've calculated the relative factors by dividing
21 the coefficient by average spending as we've talked
22 about.

1 I'm going to put here in row 51 the
2 weighted average. And, Dr. Ingber, how do you
3 calculate a weighted average?

4 A. Well, you would need the counts for each
5 one of codes, which is elsewhere in this table.

6 Q. Great. And so what I'm going to do is --
7 are you familiar with the SUMPRODUCT --

8 A. I am.

9 Q. -- formula in Excel?

10 A. Yes.

11 Q. And so if we sum the product of the
12 relative factors for the -- with unsupported codes
13 with the count of HCCs for those same factors --

14 A. Yes.

15 Q. -- and then divide by the total -- let's
16 see. You don't need to divide -- let's see. Divide
17 by the number -- by the total count of HCCs is what
18 I'm meaning to do. Then that gets at a weighted
19 average of the relative factors for the -- for your
20 regression with unsupported codes, right?

21 A. Well, it should. I'm just looking at it.
22 It seems fairly small looking at what most of the

1 factor sizes are. But it may be computed correctly.

2 Let's see -- I mean, I'd have -- if you
3 click on it, it will highlight all the data you used.
4 But I'm just saying that to me it looks a little
5 small just --

6 Q. Okay. So I've highlighted the data. So
7 I'm summing the product of b36 to 50 with c101 to 115
8 and then dividing by a count of HCCs for that version
9 of the model, right?

10 A. Okay.

11 Q. And that's a correct formula for
12 calculating a weighted average relative factor,
13 right?

14 A. Yes. It appears to be correct.

15 Q. Okay. And then let's do the same thing
16 for supported codes only and then -- so I'm summing
17 the product of c36 through 50, the count of people
18 with HCCs for the population with unsupported codes
19 removed, which is c122 through 136, and then dividing
20 by the total count of HCCs for that version of the
21 model.

22 And that would be an accurate mechanism

1 for calculating a weighted average of the diagnosis
2 codes -- or the weighted average of the relative
3 factors for the various markers in your model with
4 the -- for the version of your regression when you've
5 taken out the supported -- the unsupported codes?

6 MS. MCMAHON: Objection. Form.

7 A. It should be, yes.

8 BY MR. JONES:

9 Q. And so here you understand that the --
10 that the weighted average of the relative factors
11 goes up when you take the unsupported codes out of
12 the model on which you've calibrated the expected
13 costs, right?

14 A. Yes, it does.

15 Q. And what that means is that on average
16 each of the relative factors, each of the markers is
17 compensated less in the version where the model is
18 calibrated with unsupported codes than in the version
19 where the model is calibrated with supported codes
20 only, right?

21 A. I would agree with your remark except I
22 would take out the word "each." You would say the

1 factors on average, not each on average because that
2 implies something different.

3 Q. Sure. So the factors as a whole on
4 average are compensated or calculated as being worth
5 less in the version where unsupported codes are
6 present in the calibration of the model than when
7 they are taken out?

8 A. Yes. We're not doing the third version
9 then, I gather, or are we?

10 Q. We can go ahead and do it.

11 A. No. If this is the only point you want to
12 make about those two, fine.

13 MR. JONES: Exhibit No. 1572.

14 (Exhibit Number 1572 was marked for
15 identification and was attached to the deposition.)

16 BY MR. JONES:

17 Q. Dr. Ingber, I've just handed you what's
18 been marked Exhibit 1572. And these are
19 demonstratives that are intended to depict the
20 calculations that you and I just went through.

21 So if you look at the first page of this
22 exhibit the -- this shows the total cost of treatment

1 that your model is attributing across diagnosis codes
2 and demographic factors. It's the same in both
3 versions of your regression, right?

4 A. I'm sorry. I missed something you said.

5 Q. Sure. So in both the version of your
6 regression that include unsupported HCCs and the
7 version of your model where you're taking unsupported
8 HCCs out of the data on which the model is
9 calibrated, you're attributing the same total cost of
10 treatment across the markers in both instances,
11 right?

12 A. Yes.

13 Q. And then if you turn to the second page of
14 Exhibit 1572, this exhibit shows the weighted average
15 coefficient -- let's go back.

16 We actually haven't done the weighted
17 average coefficient yet.

18 A. We've only done the relative factors.

19 Q. Right.

20 A. I mean, I would assume for the moment that
21 you've done the math properly. The direction is
22 correct. I just -- yeah.

1 Q. And would you agree with me that
2 calculating the cost per marker overall is going to
3 be equivalent to the sum of the weighted average
4 coefficients or the -- it would be the same as the
5 weighted average of the coefficients?

6 MS. MCMAHON: Objection. Form.

7 A. Yes. That's sounds like a reasonable
8 conclusion.

9 BY MR. JONES:

10 Q. Okay. And, Dr. Ingber, you and I
11 calculated the cost per marker as \$1,812.31 with the
12 unsupported codes and then the cost per marker of
13 \$1,915.82 once the supported codes are -- unsupported
14 codes are removed.

15 So you would agree with me that what is
16 here on page 2 of Exhibit 1572 would be a calculation
17 of the weighted averages of the coefficients in those
18 two versions of your regression?

19 A. Yes. And we have to just recall for a
20 moment that the dollars are an intermediate step
21 because you calculate it in terms of relative
22 factors, where this goes, because we don't ever pay

C E R T I F I C A T E

I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this

_____ day of _____, 2024.


Notary Public



EXHIBIT D-122

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
-----)

*** CONFIDENTIAL ***

CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videoconference Videotaped Deposition OF
CAROLYN KAPUSTIJ
(Taken virtually)
9:03 a.m. Eastern
Thursday, August 25, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. Did you review any documents during
2 any of the prep sessions?

3 A. I wouldn't say we reviewed them. You
4 know, some were shown to me.

5 Q. Do you recall how many?

6 A. No.

7 Q. Did any of the documents you looked at
8 refresh your recollection about the events or
9 information displayed in the documents?

10 A. No.

11 Q. And do you typically work from home,
12 Ms. Kapustij, since the pandemic?

13 A. Yes, I have been working home -- from
14 home since the pandemic.

15 Q. And home as in Baltimore, Maryland?

16 A. Yes.

17 Q. Have you gone into the office at all
18 since the pandemic began?

19 A. I have gone in -- I think I've gone in
20 maybe twice.

21 Q. And I believe you said earlier that
22 you work for the government. Are you with the
23 Office of Inspector General for HHS?

24 A. I am.

25 Q. And prior to joining the Office of

1 Inspector General, you were with CMS?

2 A. Correct.

3 Q. And you were with CMS for about
4 12 years from 2009 through 2021?

5 A. Yes. Yes. 12 years.

6 Q. Okay. And during the period when you
7 were at CMS, you worked on a research matter
8 looking into a potential fee-for-service adjuster
9 in the context of RADV?

10 A. I was involved in that during
11 different time periods at CMS.

12 Q. And can you tell us a little bit about
13 that? What is a fee-for-service adjuster?

14 MS. YEVTUKHOVA: Objection. Form.

15 THE WITNESS: So the fee-for-service
16 adjuster was a concept that was put forward
17 by the MA industry and taken up by CMS as a
18 means to offset recoveries for risk
19 adjustment data validation audits.

20 BY MR. QURESHI:

21 Q. And when you say it was taken up by
22 CMS, what do you mean by that?

23 A. I mean the industry contacted Tom
24 Hutchinson about it and then he kind of directed
25 his staff to calculate it.

1 Q. And when you say Tom Hutchinson, is
2 that a CMS official who was with the Medicare Plan
3 Payment Group?

4 A. At the time Tom Hutchinson was the
5 group director of the Medicare Payment Plan Group.

6 Q. And during your tenure at CMS, did you
7 work with the Medicare Plan Payment Group?

8 A. I did.

9 Q. What does the Medicare Plan Payment
10 Group do?

11 A. The Medicare Plan Payment Group
12 operationally makes the plans to payments through
13 the various payment systems. It develops payment
14 policy. It develops risk adjustment policy. It
15 develops policy around Part D. It makes the Part
16 D payments. And then it also, at the time I was
17 there, did payment validation activities through
18 audits and also measured the improper payment
19 rates for Part C and Part D.

20 Q. And when you say payment validation
21 activities, are you referring to the risk
22 adjustment data validation audits?

23 A. Those and there were other activities.
24 I think there were some -- there was a monthly
25 payment validation that occurred before the

1 payments went out, and then there were also some
2 retiree drug subsidy audits going on, among
3 others. I don't know the whole scope of the
4 validation activities that were occurring
5 group-wide.

6 Q. Okay. We'll certainly return to that
7 topic later, but I want to talk a little more
8 about the fee-for-service adjuster. When did you
9 begin your involvement in that research project?

10 A. It was quite a while ago, but I
11 believe probably in the spring of 2009 shortly
12 after I started at CMS.

13 Q. And what did you understand your role
14 to be in connection with that project?

15 A. I mainly was kind of -- I was a junior
16 staffer, so I had a support role. I attended
17 meetings. I reviewed some materials. I believe I
18 worked with some of the medical review contractors
19 and the analytic contractors on some of the work.

20 Q. And if we focus us on this period of
21 time, who did you report to in the spring of 2009
22 while working on the fee-for-service project?

23 A. Jennifer Harlow. Jennifer Harlow was
24 the division director. And I believe Lateefah
25 Hughes had kind of a lead role.

1 Q. And the division you're referring to
2 is the Division of Payment Validation or DPV?

3 A. Yes.

4 Q. During the spring of 2009, did you
5 work with a gentleman named Jonathan Smith on this
6 research project into the fee-for-service
7 adjuster?

8 A. I did.

9 Q. Do you recall anyone else that you
10 worked with on this project during that time
11 frame?

12 A. I do not. I'm sure there were other
13 people involved, but I do not.

14 Q. And during this time, spring of 2009,
15 did you form any opinions about the competency of
16 the people you were working with?

17 A. No, I did not form any opinions. I
18 generally believe them to be competent.

19 Q. They didn't do anything that raised
20 doubts about the quality of the work they were
21 doing?

22 A. No.

23 Q. And prior to joining this research
24 project on the fee-for-service adjuster in the
25 spring of 2009, did you have any background on

1 Medicare risk adjustment?

2 A. I had completed the previous year in a
3 master's degree in public health, so I had general
4 knowledge of different payment systems.

5 Q. And this was a degree in public health
6 from the University of Michigan School of Health?

7 A. Yes.

8 Q. And you completed that work in 2008?

9 A. Correct.

10 Q. Other than the -- the work you did in
11 connection with your master's degree in public
12 health, did you have any other formal training or
13 background on Medicare risk adjustment?

14 A. No.

15 Q. Can you describe some of the
16 responsibilities you had in the spring of 2009
17 relating to the research into the fee-for-service
18 adjuster?

19 A. Again, as I previously stated, I -- I
20 attended meetings, I reviewed materials, and I was
21 involved with the contractors doing the analysis
22 and the medical record review work.

23 Q. The meetings you attended, were those
24 with other CMS personnel?

25 MS. YEVTUKHOVA: Objection. Form.

1 MS. YEVTUKHOVA: Objection. Form.

2 THE WITNESS: She did. She did years
3 later.

4 BY MR. QURESHI:

5 Q. Did she change her mind about the
6 appropriateness of the fee-for-service adjuster?

7 A. I don't know.

8 Q. Did you ever talk to her about it?

9 A. I recall one conversation, I don't
10 recall what year, where she said something like,
11 you know, in terms of the recoveries, you know,
12 you're paying back money that you were paid out.
13 It doesn't kind of matter what the amount was
14 paid. It could be with a random number generator.
15 If you were paid that amount and it was erroneous,
16 it should be paid back.

17 Q. And you understand her to be
18 discussing RADV payment recoveries?

19 A. Yes.

20 Q. Other than that conversation, do you
21 recall any other instance in which you and
22 Ms. Paul talked about the appropriateness of the
23 fee-for-service adjuster?

24 MS. YEVTUKHOVA: Objection.

25 THE WITNESS: I don't recall.

1 BY MR. QURESHI:

2 Q. Okay. I'd like to explore your
3 understanding of the CMS-HCC risk adjustment
4 model. What do you understand that to be?

5 MS. YEVTUKHOVA: Objection. Form.

6 THE WITNESS: So the risk adjustment
7 model is the means by which CMS makes a
8 capitated payment to the plans based on a
9 monthly basis based on the health status of
10 the beneficiaries enrolled in the plan.

11 BY MR. QURESHI:

12 Q. And do you have an understanding as to
13 the source of the data that is used to calibrate
14 the model?

15 A. Yes. Yes. It's my understanding that
16 it's fee-for-service claims data.

17 Q. Okay. Sometimes called FFS claims
18 data?

19 A. Yes.

20 Q. And do you have an understanding as to
21 whether there are diagnoses coding errors in that
22 fee-for-service claims data?

23 MS. YEVTUKHOVA: Objection. Form.

24 THE WITNESS: There potentially could
25 be.

1 BY MR. QURESHI:

2 Q. Well, are there or aren't there?

3 A. I don't know. You would have to audit
4 100 percent of the data and see if there were any
5 errors in it -- undertake that and see if there
6 were any errors in it.

7 Q. Well, while you were working on the
8 research into the fee-for-service adjuster
9 project, didn't you audit a sample of
10 fee-for-service claims data?

11 MS. YEVTUKHOVA: Objection.

12 THE WITNESS: We did audit a sample of
13 fee-for-service claims data, but I can't be
14 positive about -- positive about this
15 because different sets of data were used at
16 different times to calibrate the model. We
17 did not attempt to link the data that we --
18 that we audited, the fee-for-service data
19 to the actual data that was used to
20 calibrate the model.

21 BY MR. QURESHI:

22 Q. The audits that you did perform on
23 fee-for-service claims data, what did those audits
24 show you about the rate of diagnoses coding errors
25 in that data?

1 MS. YEVTUKHOVA: Objection. Vague.

2 THE WITNESS: To the best of my
3 recollection, it did show that there was
4 some diagnoses coding error.

5 BY MR. QURESHI:

6 Q. Okay. And so do you have any reason
7 to believe that the fee-for-service claims data
8 that's used to calibrate the risk adjustment model
9 would have no errors?

10 MS. YEVTUKHOVA: Objection. Form.

11 THE WITNESS: I don't have any reason
12 to believe that it would have no errors.
13 But I can't, you know, speak to the exact
14 amount. This is all assumptions.

15 BY MR. QURESHI:

16 Q. I'm not asking for an exact amount,
17 Ms. Kapustij. My question was does the
18 fee-for-service claims data used to calibrate the
19 risk adjustment model have diagnoses coding
20 errors?

21 MS. YEVTUKHOVA: Objection. Asked and
22 answered.

23 THE WITNESS: As I said before, I can't
24 speak to the exact amount of error that was
25 used in the data set to calibrate the

1 CMS-HCC model.

2 BY MR. QURESHI:

3 Q. Understood. And, once again, I'm
4 going to repeat my question because I think you're
5 missing part of it or I'm not explaining it well
6 enough. I'm not interested in the exact number.
7 We'll put that to one side. We'll cover that
8 later. I'm just interested in the general
9 concept.

10 Are there diagnoses coding errors in
11 the fee-for-service claims data used to calibrate
12 the risk adjustment model?

13 MS. YEVTUKHOVA: Same objection.

14 THE WITNESS: I -- I answered that
15 question to the best of my ability. I
16 can't speak to the exact data used to the
17 calibrate the CMS-HCC model. I can speak
18 to the -- I can't speak to that. I don't
19 know -- we did not look at -- make a
20 one-to-one link between the records that we
21 got to evaluate and the records that were
22 used to calibrate the model.

23 BY MR. QURESHI:

24 Q. Why were you auditing fee-for-service
25 claims data in the fee-for-service adjuster

1 project? What was the point of that?

2 A. Well, the --

3 MS. YEVTUKHOVA: Objection. Form. You
4 can answer, Ms. Kapustij.

5 THE WITNESS: Oh, sure. I'm trying
6 to -- I'm sorry, I'm just gathering my
7 thoughts.

8 Well, that was the whole assertion that
9 was being put forward by the industry is
10 that the error in claims data caused a --
11 would cause -- eventually cause an inequity
12 in -- or cause some kind of problems when
13 there were RADV recoveries.

14 BY MR. QURESHI:

15 Q. And what were the results of those
16 audits of fee-for-service claims data that you
17 worked on?

18 A. I don't recall the exact results.

19 Q. I'm not interested in the exact
20 results. Did those audits reveal the existence of
21 diagnoses coding errors in fee-for-service claims
22 data?

23 MS. YEVTUKHOVA: Objection. Asked and
24 answered.

25 THE WITNESS: Yes. The -- I'm sorry.

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified
Court Reporter within and for the State of
Georgia, do hereby certify:

That the foregoing deposition was
taken before me on the date and at the time and
location stated on Page 1 of this transcript; that
the deponent was duly sworn to testify to the
truth, the whole truth and nothing but the truth;
that the testimony of the deponent and all
objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed; that the foregoing
deposition as typed is a true, accurate and
complete record of the testimony of the deponent
and of all objections made at the time of the
examination to the best of my ability.

I further certify that I am neither
related to nor counsel for any party to the cause
pending or interested in the events thereof.
Witness my hand, this 29th day of August, 2022.

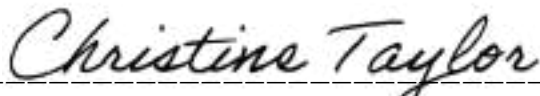

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-122A

**REDACTED VERSION OF
DOCUMENT PROPOSED TO BE
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

DEPOSITION OF CAROLYN KAPUSTIJ
As 30(b)(6) Designee 6 of
The United States

Baltimore, Maryland
August 25, 2023

Reported by: John L. Harmonson, RPR
Job No. 1011736

1 testimony yesterday besides yours?

2 A. No.

3 Q. None this week?

4 A. No.

5 Q. Was there any deposition testimony that
6 you wanted to review before testifying today?

7 A. No. I did not think about that.

8 Q. Why did you review your own deposition
9 testimony before today?

10 A. To refresh my recollection on certain
11 events.

12 Q. And did it accomplish that goal?

13 A. A bit.

14 Q. Did any of the other documents that you
15 reviewed refresh your recollection about any events
16 related to Topic 5?

17 A. To some extent, yes.

18 Q. Which ones?

19 A. Probably the partner training documents.

20 Q. Any others?

21 A. Not that I can point to offhand.

22 Q. You said you met with your counsel in
23 preparation for today. How many times did you meet
24 with them?

25 A. I don't exactly recall.

1 Q. Was it more than once?

2 A. More than -- I would say more than once,
3 to the best of my recollection, and less than five.

4 Q. Do you recall when was the last time you
5 met with your counsel before today?

6 A. Yesterday.

7 Q. What about before yesterday? When was
8 the last time you met with counsel regarding your
9 testimony today?

10 A. Earlier this week.

11 Q. Did you meet with counsel last week to
12 discuss your testimony today?

13 A. I don't recall. I may have.

14 Q. So you recall at least two meetings that
15 happened this week?

16 A. Yes.

17 Q. How long were those meetings for, the
18 ones that happened this week?

19 A. Less than an hour.

20 Q. Were they in person?

21 A. No.

22 Q. Were they by Zoom?

23 A. Yes. They were via phone.

24 Q. Via phone.

25 Did you review any documents during

1 those conversations?

2 A. Not that I recall.

3 Q. So you met with counsel yesterday; is
4 that right?

5 A. Correct.

6 Q. Do you recall yesterday if you reviewed
7 any documents with counsel?

8 A. We did -- I did not.

9 Q. And what about in the meeting earlier
10 this week?

11 A. I don't recall.

12 Q. What day was that meeting?

13 A. I believe it was Monday.

14 Q. And you don't recall whether on Monday
15 you reviewed any documents with counsel?

16 A. I don't recall.

17 Q. Did you go to work on Monday?

18 A. I did.

19 Q. Did you go to work yesterday?

20 A. I did.

21 Q. How much time in total would you say you
22 spent preparing for your testimony today?

23 A. That is a difficult number to estimate.
24 I would say maybe 40 hours.

25 Q. And the 40 hours would include any

1 documents -- any time you spent reviewing
2 documents, your conversations and communications
3 with others in preparation for today, and your
4 communications and conversations with counsel; is
5 that right?

6 A. Correct.

7 Q. Is there anything else that you did to
8 prepare for today that we haven't talked about?

9 A. No.

10 MR. MARTINEZ: We've been going for
11 about 50 minutes. Do you want to take a quick
12 break?

13 THE WITNESS: Yeah, that would be great.

14 MR. MARTINEZ: Let's go off the record.

15 THE VIDEOGRAPHER: We're going off the
16 record at 10:20.

17 (Recess taken.)

18 THE VIDEOGRAPHER: We are back on the
19 record at 10:34.

20 BY MR. MARTINEZ:

21 Q. Ms. Kapustij, you understand you're
22 still under oath?

23 A. Yes.

24 Q. RADV is the primary mechanism by which
25 CMS identifies and recovers alleged overpayments

1 made to MA plans; correct?

2 A. Yes.

3 Q. Including alleged overpayments due to
4 diagnosis codes or HCCs that are not supported by
5 medical records; correct?

6 A. Correct.

7 Q. And when I use the term "HCCs," you
8 understand I'm referring to hierarchical condition
9 categories?

10 A. Yes.

11 Q. As part of the RADV process, CMS
12 conducts medical record reviews to verify the
13 accuracy of diagnosis codes or HCCs submitted by MA
14 plans for payment; correct?

15 A. Correct.

16 Q. RADV is unique to the Medicare Advantage
17 program; correct?

18 MS. OBEREMBT: Objection; vague.

19 BY MR. MARTINEZ:

20 Q. Do you understand my question?

21 A. I understand your question. There is
22 also an exercise called HHS RADV which is performed
23 in the health insurance exchanges.

24 Q. Okay. And the HHS RADV, is that also
25 specific to the Medicare Advantage program?

1 A. No. It's to the exchange program.

2 Q. To the exchange program. Understood.

3 So the RADV -- I should clarify. RADV
4 audits that CMS performs is unique to the Medicare
5 Advantage program; correct?

6 MS. OBEREMBT: Objection; vague.

7 THE WITNESS: Technically, another area
8 of CMS does the HHS RADV audits for the exchanges
9 that are involved in that.

10 BY MR. MARTINEZ:

11 Q. And which component of CMS does that?

12 A. CCIIO.

13 Q. So I'm clear, the RADV audits
14 that -- strike that.

15 There are no RADV audits in
16 fee-for-service Medicare; correct?

17 A. Could you be more -- there are no audits
18 called risk adjustment data validation audits in
19 fee-for-service.

20 Q. CMS does not perform RADV audits on
21 fee-for-service data; correct?

22 A. It does not, because fee-for-service
23 payment is not based on risk adjustment.

24 Q. And fee-for-service Medicare has
25 different types of audits that it might conduct,

1 BY MR. MARTINEZ:

2 Q. Okay. Where did you get that
3 understanding from?

4 A. I got that from both Deloitte Consulting
5 and Hans Dutt.

6 Q. What is that one difference?

7 A. 2014, the basis for it is diabetes
8 cohort. And 2015, the basis is a renal cohort.

9 Q. Okay. I want to come back to that, but
10 I want to go back to your testimony regarding
11 payment years 2011 to 2013.

12 I believe you testified that in each of
13 those payment years, there were 30 MA plans that
14 were selected for RADV auditing. Is that correct?

15 A. Correct.

16 Q. Do you know what percentage of the total
17 MA plans that number 30 represents?

18 A. I don't know offhand.

19 Q. Is it a small percentage or a large
20 percentage?

21 A. Define large or small.

22 Q. Whether you would consider it to be a
23 large or a small percentage of the total number of
24 Medicare Advantage plans.

25 A. In the context of total plans, it's not

1 a large percentage.

2 Q. For payment years 2011 to 2013, how did
3 CMS determine which MA plans to audit through the
4 RADV program?

5 A. CMS based it on a measure of their
6 increase in coding from year to year. And the
7 plans were split into three groups -- high, medium
8 and low -- with a certain number being selected
9 from each year.

10 Q. And how was the increase -- let's start
11 with, say, payment year 2011, for example. How was
12 the increase in coding from year to year measured?

13 A. Oh, it was calculated by the growth of
14 the average enrollee risk score.

15 Q. For which time period?

16 A. I don't recall.

17 Q. And so when you refer to the high,
18 medium and low buckets, is that a reference to
19 levels of coding intensity in general, or is it a
20 reference to the size of the increase in coding
21 from year to year that CMS observed?

22 MS. OBEREMBT: Objection; compound.

23 THE WITNESS: I believe it's a measure
24 of the size of the increase.

25 BY MR. MARTINEZ:

1 Q. And why did CMS develop a methodology
2 for selecting Medicare Advantage plans for its RADV
3 audits based on an increase in -- a plan's increase
4 in coding from year to year?

5 A. I believe there was a hypothesis that an
6 increase in coding might be indicative of larger
7 probability for an error.

8 Q. So in selecting Medicare Advantage plans
9 for the 2011 to 2013 RADV audits, was it CMS's goal
10 to identify plans that were more likely to have
11 payment errors?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: I'm not sure, and none of
14 the documentation confirmed that.

15 BY MR. MARTINEZ:

16 Q. Do you have an understanding as to what
17 CMS's purpose was in designing the MA selection
18 process for the RADV audits 2011 to 2013?

19 MS. OBEREMBT: Objection; vague.

20 THE WITNESS: The objective was to get a
21 selection of contracts to audit.

22 BY MR. MARTINEZ:

23 Q. Okay. Well, you testified earlier to a
24 hypothesis that an increase in coding might be
25 indicative of a larger probability for a payment

1 error; correct?

2 A. Correct.

3 Q. So is it your understanding that CMS --
4 the reason why they were selecting plans using this
5 methodology was to try and identify plans that were
6 more likely to have higher rates of payment errors?

7 A. That was the hypothesis and that was the
8 research question. But plans were selected from
9 all three groups, high, medium and low.

10 Q. And of the 30 plans selected for each --
11 let's start with payment year 2011. How many were
12 from the high increase group?

13 A. I am going to have to look at that. I
14 do not recall offhand. I'm trying to...

15 Q. Are you searching for Tab 18 by chance?

16 A. 18 and perhaps 19. I'll start with 19.
17 And so for 2011, it was 20 from the high group,
18 five from medium, and five from low.

19 Q. So two-thirds of the plans selected for
20 payment year 2011 came from the high coding
21 increase group; is that right?

22 A. Correct.

23 Q. What about for payment year 2012? And I
24 think to help you answer that question, I've marked
25 what's in your binder as Tab 18 as Exhibit 1498.

1 (Exhibit 1498 marked for identification
2 and attached hereto.)

3 THE WITNESS: Okay.

4 BY MR. MARTINEZ:

5 Q. And I think if you look at -- you may
6 already be there. What's numbered in the bottom
7 right as page 20.

8 MS. OBEREMBT: There are no numbers.

9 MR. MARTINEZ: There is an easier way to
10 look at this.

11 BY MR. MARTINEZ:

12 Q. If you look at the third page of
13 Exhibit 1498, I think you'll see for -- you'll see
14 the breakdown for payment year 2012 in the middle
15 column.

16 A. Yes.

17 Q. And so for that year, just like with
18 payment year 2011, two-thirds of the MA plans that
19 were selected for RADV audits for payment year 2012
20 were in the high coding intensity group; correct?

21 A. Correct.

22 Q. And then for payment year 2013, that
23 number actually increases; right?

24 A. Correct.

25 Q. It goes up to 25 MA plans from the high

1 Q. Why not?

2 A. Because there was some discussions I had
3 in preparation that referenced Topic 5.

4 Q. Discussions with counsel?

5 A. Yes.

6 Q. And to be clear, I'm not asking for any
7 of the substance of those conversations. I'm just
8 asking for who is the person who is determining
9 what is within and without the scope of Topic 5 for
10 purposes of your testimony today.

11 MS. OBEREMBT: Counsel, the witness
12 already testified that she took the topics at face
13 value the way they're written. I think we've spent
14 enough time on this.

15 BY MR. MARTINEZ:

16 Q. You can answer my question.

17 A. I don't know that I considered it, you
18 know, who has primary responsibility for this.

19 Q. But in answering my question about
20 return on investment, your position is that even if
21 it was a consideration for CMS in designing its
22 RADV methodology, it's outside the scope of Topic 5
23 because the term "return on investment" was not
24 used in the notice?

25 A. Yes.

1 Q. And is that the same standard that you
2 applied in interpreting the rest of Topic 5?

3 MS. OBEREMBT: Objection; vague.

4 THE WITNESS: I cannot say. I don't
5 know.

6 BY MR. MARTINEZ:

7 Q. All right. I want to move on and talk
8 about the RADV methodology at a high level first to
9 make sure that we're on the same page. Okay?

10 A. Okay.

11 Q. So we've been talking about plan
12 selection and the sampling of enrollees. That's
13 more or less the first step in the process; right?

14 A. Correct.

15 Q. Okay. And then after the sample has
16 been ascertained, there is a medical record request
17 and submission process that takes place. Is that
18 right?

19 A. Correct.

20 Q. And then after those records have been
21 submitted, there is a medical record review process
22 that CMS oversees. Correct?

23 A. Correct.

24 Q. And that includes coding and abstracting
25 HCCs and those sorts of activities. Correct?

1 A. Yes.

2 Q. And I should clarify. By abstracting
3 HCCs, I mean reporting them or coding them into the
4 system. You understand that?

5 A. Yes.

6 Q. And then once the medical record review
7 happens, then there is a process by which payment
8 errors, if any, are calculated at the beneficiary
9 level. Correct?

10 A. Correct.

11 Q. And then there is then a calculation
12 that happens where those beneficiary-level payment
13 errors are extrapolated for the entire plan that's
14 being audited for that payment year. Correct?

15 A. Correct.

16 Q. And at the end of that process, at the
17 end of the extrapolation process, there is supposed
18 to be a preliminary audit report of findings that
19 is produced by CMS and transmitted to the plans.
20 Is that right?

21 A. Correct.

22 Q. And then once that report is
23 communicated, there is an opportunity for I believe
24 what's called medical record dispute where the
25 plans can identify specific HCCs that CMS did not

1 validate and essentially ask for reconsideration of
2 those particular HCCs. Is that right?

3 A. Correct.

4 Q. And at the end of that medical record
5 dispute process, that's when payment recovery
6 happens on the part of CMS. Is that right?

7 A. I believe so, yes.

8 Q. Okay. And then payment recovery
9 essentially would be reducing a plan's capitated
10 payments by the amount of overpayment that CMS
11 calculated for that payment year. Is that right?

12 A. Not exactly. It wouldn't reduce future
13 payments they receive. The plans would return the
14 overpayment.

15 Q. Okay. So the mechanism for payment
16 recovery is the plans returning any overpayments
17 that CMS claims to have found; right?

18 A. Correct.

19 Q. Okay. And then after that, there is a
20 mechanism for appeals that could happen that could
21 also change the results that CMS had determined in
22 the RADV process. Is that right?

23 A. Correct.

24 Q. Do I have the order generally right?

25 A. I believe so.

1 Q. Okay. All right. And as I understand
2 it, that's how the RADV audits were supposed to
3 work throughout payment years 2009 through 2017.
4 Is that right?

5 A. Yes.

6 Q. Now, we talked a little bit about that
7 first plan selection piece. But I just want to
8 confirm. So CMS does not audit every diagnosis
9 code or HCC submitted by an MA plan for payment in
10 a given payment year; correct?

11 A. It audits every HCC diagnosis for the
12 sampled beneficiaries.

13 Q. Right. It audits all of the diagnosis
14 codes or HCCs that the MA plan submits for the
15 purpose of the RADV audit; correct?

16 A. That the plan submits for the purpose of
17 payment.

18 Q. Okay. But isn't it true that CMS is
19 only taking a sample of those diagnosis codes or
20 HCCs that have been submitted for payment by the
21 plan for that year?

22 A. It's taking a sample of enrollees. So
23 it does not cover every enrollee's every diagnosis
24 code.

25 Q. Got it. So CMS is auditing every HCC

1 submitted for a particular enrollee for a
2 particular payment year; correct?

3 A. Correct.

4 Q. But it's not -- CMS is not auditing
5 every diagnosis code or HCC that the MA plan
6 submitted over the course of that payment year for
7 all of its enrollees; correct?

8 A. Correct.

9 Q. And CMS has never required MA plans to
10 do their own RADV audits; correct?

11 MS. OBEREMBT: Objection; outside the
12 scope.

13 THE WITNESS: CMS requires that plans
14 submit accurate information. It doesn't dictate
15 the method by which they determine it's accurate.
16 BY MR. MARTINEZ:

17 Q. Okay. So CMS has never required MA
18 plans to conduct their own RADV audits prior to
19 submitting data for risk adjustment payment;
20 correct?

21 MS. OBEREMBT: Objection; outside the
22 scope. And asked and answered.

23 THE WITNESS: Again, it requires
24 accurate information. It does not say you need to
25 conduct your own RADV audit.

1 BY MR. MARTINEZ:

2 Q. Okay. So I want to focus on the second
3 part of your answer because that's what's
4 responsive to my question.

5 So just so I'm clear, CMS has never
6 required MA plans to conduct their own RADV audits;
7 correct?

8 MS. OBEREMBT: Objection; outside the
9 scope. And asked and answered twice now.

10 THE WITNESS: To the best of my
11 knowledge, that is not a requirement.

12 BY MR. MARTINEZ:

13 Q. And CMS samples from an MA plan's
14 population of enrollees because there's simply too
15 many enrollees in the plans to audit all of the
16 HCCs for all of the enrollees in each given payment
17 year; correct?

18 A. Correct. With current new methods, yes.

19 Q. The volume would just be too large;
20 right?

21 A. Correct.

22 Q. Okay. So once we're past the sampling
23 portion of the RADV process, then we move to
24 medical records submission; right? Request and
25 submission?

1 A. Correct.

2 Q. And as I understand it, the MA plans
3 must submit medical records supporting all of the
4 HCCs represented in their sampled enrollees' risk
5 scores for the given payment year under audit;
6 correct?

7 A. Yes.

8 Q. Now, originally, as I understand it, CMS
9 had what it called its one best medical record
10 policy. Is that right?

11 MS. OBEREMBT: Objection; vague.

12 THE WITNESS: That's prior to the --
13 that would be prior to payment year '09.

14 BY MR. MARTINEZ:

15 Q. Okay. So was that for '07?

16 MS. OBEREMBT: Objection; outside the
17 scope.

18 MR. MARTINEZ: Fair enough.

19 BY MR. MARTINEZ:

20 Q. Prior to '09?

21 A. Yes.

22 Q. Okay. So that rule did not apply for
23 payment year 2011; right?

24 A. It did not.

25 Q. Okay. And my understanding is that

1 prior rule had been that MA plans could submit only
2 one supporting record per HCC per enrollee. Is
3 that correct?

4 MS. OBEREMBT: Objection; outside the
5 scope.

6 THE WITNESS: To the best of my
7 recollection.

8 BY MR. MARTINEZ:

9 Q. Okay. And then CMS changed that policy
10 and, for example, payment year 2011 allowed plans
11 to submit up to five medical records to support a
12 particular HCC for a particular sampled enrollee.
13 Is that right?

14 A. Yes.

15 Q. And CMS made that change because it
16 understood that even if a particular HCC is not
17 supported by one medical record, it might be
18 supported by another; correct?

19 A. Correct.

20 Q. I want to talk now about the medical
21 record review process in some more detail.

22 So we had kind of a brief exchange
23 earlier about initial validation contractors and
24 secondary validation contractors, and I think you
25 said at one point that that wasn't really the

1 nomenclature that CMS used at the time you were
2 there. Is that -- do I have your testimony
3 correct?

4 A. Yes.

5 Q. So how did CMS describe the different
6 contractors who were involved in the medical record
7 review process?

8 A. At different times, it was different
9 ways. They either called them by name or said this
10 is the contractor doing focused review. This is
11 the one doing discrepant confirmation. At one
12 point they were referred to as MRRC A and MRRC B.

13 Q. So they had different names at different
14 times over the years?

15 A. Yes.

16 Q. And when we're talking about these
17 medical record review contractors, these are all
18 folks who did not work at CMS; correct?

19 A. Correct.

20 Q. They are contracted with CMS; right?

21 A. Correct.

22 Q. And CMS oversees their work?

23 A. Correct.

24 Q. In the RADV context.

25 And CMS provided trainings to the

1 discrepant confirmation was there is another
2 medical record review contractor who would review
3 it, and there would be findings from that
4 contractor.

5 Q. Okay. So there is one medical record
6 review contractor that's doing the focused review
7 and a second medical record review contractor doing
8 the discrepant confirmation?

9 A. Correct.

10 Q. What is focused review?

11 A. So the way it evolved is focused review
12 is just a first contractor looking at the medical
13 record and doing a full coding of it.

14 Discrepant confirmation is the second
15 coder looking at it and doing a full review.

16 Q. Okay. And is the person doing the
17 focused review sometimes referred to as a primary
18 coder?

19 A. No. I believe that the person doing the
20 focused review can either be a primary or a senior
21 coder.

22 Q. Okay. And whether a primary or a senior
23 coder, in doing the focused review, they're
24 reviewing all of the medical records that an MA
25 plan has submitted to support the HCCs for a

1 particular sampled beneficiary; correct?

2 A. No. The way it worked was they -- there
3 was a system, and the coder would receive one
4 medical record and code that record. They would
5 not receive -- I do not believe they received all
6 of an enrollee's records.

7 Q. Okay. But in the focused review
8 process, was the -- was the mandate to -- for the
9 coders involved in that process to review all of
10 the medical records that an MA plan had submitted
11 in support of HCCs for sampled enrollees?

12 A. Yeah, the focused review process
13 resulted in a review of all the medical records
14 submitted.

15 Q. And the focused review was a blind
16 review; right?

17 MS. OBEREMBT: Objection; vague.

18 THE WITNESS: Define what you mean by
19 blind.

20 BY MR. MARTINEZ:

21 Q. Well, have you seen the term "blind
22 review" in preparing for your testimony today?

23 A. I have.

24 Q. What do you understand that term to
25 mean?

1 A. It's used different ways. The way I've
2 seen it used in preparing was that the medical
3 record review contractors were blind to one
4 another's findings.

5 Q. And isn't it also true that the
6 individuals doing the focused review were blind as
7 to which HCCs the MA plan had submitted for payment
8 for a given sampled enrollee?

9 A. Based on my conversations, it was my
10 understanding that the coders did have knowledge to
11 see what is called the cover sheet which indicated
12 what HCCs were submitted for payment.

13 Q. And is it your understanding that all of
14 the coders who were doing this first-level review
15 knew which HCCs were being audited?

16 A. I believe that that was the procedure
17 that was eventually adopted.

18 Q. And in preparing to testify today, you
19 didn't review any documents that referred to the
20 blind review method as meaning the coders don't
21 know which HCCs or diagnoses are being audited?

22 A. I am not sure.

23 Q. You're not sure whether you reviewed any
24 materials that defined blind review in the way that
25 I did?

1 plan in support of the sampled enrollee?

2 A. So that record will then go forward to
3 the second coder no matter what, and the second
4 coder will have a set of findings also. So at the
5 end of the review process you have a set of
6 findings from one coder and a set of findings from
7 another coder.

8 Q. And CMS understands that sometimes one
9 of those coders might miss the HCC in the medical
10 records and yet the second coder would find it to
11 be supported; correct?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: I would not necessarily
14 say that the coder misses it. Working with coders,
15 there are some gray areas and some things are open
16 to interpretation. But there are circumstances
17 where one coder would find evidence for it and the
18 other coder would feel no, that that was not
19 sufficient.

20 BY MR. MARTINEZ:

21 Q. Right. Medical record review coding
22 involves gray areas; right?

23 A. Yes.

24 Q. And lots of things in medical record
25 reviews are subject to interpretation; right?

1 MS. OBEREMBT: Objection; vague.

2 THE WITNESS: Yes.

3 BY MR. MARTINEZ:

4 Q. So I want to drill down on this a little
5 bit. Did CMS understand, then, that sometimes an
6 initial coder, as part of the RADV process, would
7 not abstract an HCC that a different coder perhaps
8 later in the process would abstract?

9 MS. OBEREMBT: Objection; vague.

10 THE WITNESS: That's why there were
11 two -- always two reviews.

12 BY MR. MARTINEZ:

13 Q. Right. And it was important to CMS to
14 have those multiple layers of review; right?

15 A. Correct.

16 Q. To make sure that they were getting the
17 most accurate results that they could in terms of
18 reviewing the medical records for supportable HCCs;
19 right?

20 A. Yes.

21 Q. Because obviously CMS would not want to
22 come out with even a preliminary finding that an
23 HCC is not supported by a medical record if it
24 hadn't done its best to make sure that that's
25 actually the case; right?

1 A. Correct.

2 Q. And so kind of in the same vein, CMS
3 understood when it was conducting its audits, RADV
4 audits for payment years 2011 through 2015, that
5 sometimes the coders that CMS oversaw would
6 disagree about whether or not an HCC was supported
7 by medical records; right?

8 A. Yes.

9 Q. And in fact, CMS I believe instructed
10 the medical record review contractors to develop
11 protocols for handling those very situations in
12 which one coder might disagree with the judgment of
13 another coder. Is that right?

14 A. I'm not sure what you're referring to.

15 Q. Have you heard of the concept of quality
16 assurance protocols in the context of the RADV
17 audits that CMS oversaw?

18 A. Medical record review contractors, it
19 was contingent on them to monitor the quality of
20 their coders.

21 Q. And that was a requirement that CMS
22 imposed on the medical record review contractors;
23 right?

24 A. Yes.

25 Q. And as one of those quality control

1 mechanisms that the medical record review
2 contractors had to have in place was a process for
3 resolving disagreements between coders about
4 whether an HCC was in fact supported by the medical
5 records?

6 A. I believe something like that did exist.
7 When I talked to Michelle Atkins to kind of
8 understand how they implemented this, when you have
9 focused review and discrepant confirmation, when
10 you have one MRRC coding it and then it goes to
11 another coder rather than a primary and senior at
12 each organization looking at it, she said that her
13 process was to -- for those HCCs that were not in
14 agreement, they would internally have someone look
15 at it and see if the coder needed additional
16 training.

17 Q. So in that instance that Michelle Atkins
18 was talking to you about, there would be a third
19 layer of review to kind of assess --

20 A. No.

21 Q. -- or remediate the disagreement?
22 No?

23 A. No, it was an internal practice by the
24 medical record review contractors. There were two
25 layers of review, and the HCC was considered

1 Q. And CMS published this -- its final
2 methodology after carefully reviewing hundreds of
3 public comments; correct?

4 A. Correct.

5 Q. And CMS had previously published what it
6 called a proposed methodology in I believe 2010.
7 Is that right?

8 A. I believe that's correct.

9 Q. And in the February 2012 publication,
10 CMS confirmed that its final methodology will be
11 applied to the payment year 2011 RADV audit;
12 correct?

13 A. Yes.

14 Q. And CMS confirmed that its RADV audit
15 findings for payment year 2011 would be
16 extrapolated using the final methodology
17 articulated in that publication; correct?

18 A. Correct.

19 Q. And by extrapolation, what we mean is
20 taking enrollee-level payment error rates and using
21 a statistical methodology to determine the payment
22 error for the entire MA plan that's being audited;
23 right?

24 A. Correct.

25 Q. So let's take those two things step by

1 step. So let's start with the beneficiary-level
2 error rate.

3 So for each sampled enrollee, CMS
4 calculates a corrected risk score and payment based
5 on the HCCs found to be supported by its medical
6 record reviewers; correct?

7 A. Correct.

8 Q. And then CMS defines enrollee-level
9 payment errors as the difference between the
10 original payment to the plan and the RADV corrected
11 payment. Is that right?

12 A. Correct.

13 Q. And so if the original payment to the
14 plan was higher than the corrected payment, CMS
15 believes the plan has been overpaid with respect to
16 that enrollee; correct?

17 A. Say that again.

18 Q. Sure.

19 If the original payment to the plan was
20 higher than the corrected payment, CMS believes the
21 plan has been overpaid for that enrollee.

22 A. Generally, that is the case.

23 Q. And conversely, if the original payment
24 is lower than the corrected payment, CMS believes
25 the MA plan has been underpaid with respect to that

1 enrollee; correct?

2 A. It does not.

3 Q. CMS does not believe that?

4 A. It says here representing a net
5 underpayment.

6 Q. Okay.

7 A. So in terms of how the RADV methodology
8 is being applied, it's considered an underpayment
9 in the calculation. As to generally whether you
10 would say something like that is an underpayment, I
11 would not say so.

12 Q. Okay. So let's break that down. And is
13 the document you're referring to, are you on the
14 first page of Tab 10 or the third page?

15 A. Third page.

16 Q. Third page of Tab 10 in Exhibit 1497.

17 And I believe your testimony was that
18 CMS considered there to be a net underpayment with
19 respect to that enrollee if the original payment is
20 lower than the corrected payment. Is that right?

21 A. For the purpose of calculating a RADV
22 payment recovery, yes.

23 Q. Okay. And then you stated that you
24 would not say it's an underpayment. Do I have that
25 right?

1 collection, CMS went with a very conservative
2 approach and offset those overpayments by what it's
3 calling underpayments for additional diagnoses.

4 BY MR. MARTINEZ:

5 Q. And that's CMS's own terminology; right?

6 A. I believe so, yes.

7 Q. And I think you said that whenever a
8 diagnosis code cannot be validated by the medical
9 records, that is an overpayment. But isn't it true
10 that not all diagnosis codes or HCCs actually
11 impact payment?

12 A. I believe all HCCs by definition impact
13 payment. All diagnosis codes do not. You can have
14 two HCCs.

15 Q. And you understand that multiple
16 diagnosis codes could support the same HCC; right?

17 A. Yes.

18 Q. And so I guess what I'm wondering is,
19 then, just because the CMS medical record review
20 contractors find that there is a certain percentage
21 of unsupported HCCs in an MA plan's submitted data
22 for a particular payment year, that does not mean
23 that the MA plan has been net overpaid as CMS
24 defines it for that payment year; correct?

25 MS. OBEREMBT: Objection; vague.

1 THE WITNESS: It's not in the terms of
2 the RADV payment recovery context.

3 BY MR. MARTINEZ:

4 Q. Is there a different context that you're
5 thinking your answer might be different?

6 A. Yes. In the payment context, plans have
7 a firm deadline for the date by which they must
8 submit diagnoses for payment.

9 Q. And so how does that deadline inform
10 your answer to my question?

11 A. Plans would not be allowed -- diagnoses
12 would not be considered that were not submitted
13 within the data submission period.

14 Q. So it's possible that a plan might just
15 submit a code or an HCC too late to be paid in a
16 certain payment year; right?

17 A. It's possible, yes.

18 Q. Is that what you're referring to?

19 A. Yeah, that's one example.

20 Q. Okay. Are there other examples?

21 A. No. Just RADV is not kind of considered
22 a forum to introduce new diagnoses into the
23 payment.

24 Q. Okay. And I want to understand that a
25 little bit. Just because in performing the medical

1 record reviews as part of the RADV program, as we
2 established, the medical record review contractors
3 also report additional HCCs that were not submitted
4 by the plans for payment; correct?

5 A. That is correct.

6 Q. And because of those additional HCCs
7 that are found by CMS's own coders, that's why you
8 get sometimes net underpayments to MA plans for a
9 particular year?

10 MS. OBEREMBT: Objection; misstates
11 prior testimony.

12 THE WITNESS: You get an enrollee net
13 underpayment.

14 BY MR. MARTINEZ:

15 Q. And then when you extrapolate to the
16 entire contract as a whole taking account of any
17 additional HCCs, that also leads to net
18 underpayments for the plan as a whole in the RADV
19 context; right?

20 A. Well, in the RADV methodology, the
21 payment recovery amount is constrained to zero. So
22 it's not a forum for plans to receive additional
23 payment.

24 Q. Right. And so what that means, it's
25 constrained to zero -- well, it means a couple of

1 things, but one thing it means is that if a
2 particular plan has a net underpayment that CMS has
3 calculated for a given payment year, there is no
4 payment recovery for CMS for that particular plan;
5 correct?

6 A. Correct. That was the methodology.

7 Q. Using the extrapolated methodology;
8 right?

9 A. Correct.

10 MS. OBEREMBT: Counsel, we've been going
11 an hour now. Can we take a break, please? We
12 started at 1:15.

13 MR. MARTINEZ: Would you like a break?

14 THE WITNESS: Uh-huh.

15 MR. MARTINEZ: Sure. We can go off the
16 record.

17 THE VIDEOGRAPHER: We are off the record
18 at 14:23.

19 (Recess taken.)

20 THE VIDEOGRAPHER: We are back on the
21 record at 14:35.

22 BY MR. MARTINEZ:

23 Q. Ms. Kapustij, I would like to dig a
24 little deeper now into the extrapolation
25 methodology that CMS published in February of 2012.

1 list is "Change methodology to recover at lower
2 bound of 95 percent confidence interval"?

3 A. I do.

4 Q. So in fact, was CMS considering as one
5 of the menu of options to change its methodology to
6 lower the confidence interval it was using to
7 extrapolate payment recovery amounts for the RADV
8 program?

9 MS. OBEREMBT: Objection; vague.

10 THE WITNESS: I did not review any
11 documents that indicated that.

12 BY MR. MARTINEZ:

13 Q. You did not review any documents
14 indicating that in preparation for your testimony
15 today?

16 A. Correct.

17 Q. So is the answer to my question that you
18 don't know?

19 A. This is an internal document you've
20 presented me with. I don't know that this went
21 beyond the Division of Payment Validation or
22 Medicare Plan Payment Group.

23 Q. And within the Division of Payment
24 Validation -- start there -- does this document
25 refresh your recollection that that division was

1 having some discussion about potentially lowering
2 the confidence interval to 95 percent as a means of
3 increasing payment recoveries through the RADV
4 program?

5 A. It does not.

6 Q. Seeing this document now, do you have
7 any reason to believe that that issue about
8 lowering the confidence interval to increase
9 payment recoveries was never discussed within the
10 Division of Payment Validation?

11 MS. OBEREMBT: Objection; vague.

12 THE WITNESS: I do not recall. I don't
13 know.

14 BY MR. MARTINEZ:

15 Q. So on the subject of payment recovery,
16 at what point in the process does -- is payment
17 recovery by CMS supposed to happen?

18 MS. OBEREMBT: Objection; vague.

19 BY MR. MARTINEZ:

20 Q. Do you understand my question?

21 A. I do. Just give me one moment.
22 Following the first level of appeal, the
23 reconsideration step.

24 Q. And I think previously you made
25 reference to the nomenclature "medical record

1 dispute" and that having changed over time. Did
2 that change into reconsideration?

3 A. Correct.

4 Q. Can you briefly describe what the
5 reconsideration process is?

6 A. The reconsideration process as designed
7 was a coder not involved in looking at the medical
8 record originally would review it based on -- plans
9 would be allowed to dispute -- if the HCC was
10 discrepant, plans would be allowed to dispute one
11 medical record and be required to point out where
12 in the medical record there was proof that the
13 patient did have that HCC.

14 Q. So I have this right -- and this was the
15 process for payment year 2011 through 2015?

16 A. This has not actually occurred for any
17 of those years.

18 Q. Okay. So the reconsideration process
19 has not occurred for even payment year 2011?

20 A. Correct.

21 Q. But how it's supposed to work is it
22 introduces a third layer of review of the medical
23 records to see if in fact a record supports a
24 particular HCC in dispute. Is that right?

25 A. Give me a moment. I want to make sure I

1 have the correct description.

2 Could you ask -- what was the question
3 again?

4 Q. The question was how reconsideration is
5 supposed to work is by introducing a third layer of
6 review of the medical records to see if in fact a
7 particular HCC is supported by the record submitted
8 by the MA plan.

9 A. Yes, it's another -- it is in effect --
10 it's supposed to be another review.

11 Q. Okay. And it's CMS's understanding that
12 through the reconsideration process, those
13 preliminary RADV findings of whether or not an HCC
14 is supported by the medical records, that those
15 could be overturned in reconsideration; right?

16 A. Correct.

17 Q. And so I just want to walk through what
18 that process would look like in practice. But
19 before I do, I want to confirm that this has not
20 happened yet; right? And by "this," I mean
21 reconsideration.

22 A. Reconsideration has not occurred for any
23 of the audits during the time period.

24 Q. Okay. And is that through July 2021, or
25 is that up until today, as far as you know?

1 A. It's through July -- I can speak to
2 July 2021. I don't think it's happened to date.

3 Q. So as I understand, the way it's
4 supposed to work is an MA plan will submit medical
5 records to support HCCs for a sampled enrollee;
6 right? Just starting at the beginning.

7 A. Correct.

8 Q. And then there's two layers of review by
9 well-trained, well-qualified RADV coders that
10 happens next. Right?

11 MS. OBEREMBT: Objection; vague.

12 THE WITNESS: There are two levels of
13 review by RADV coders.

14 BY MR. MARTINEZ:

15 Q. Okay. And then sometimes the RADV
16 coders, both of them agree that an HCC that was
17 submitted by an MA plan is not supported by the
18 medical records that have been submitted; right?

19 A. Correct.

20 Q. And then CMS presumably alerts the MA
21 plan through that preliminary audit report of that
22 finding; right?

23 A. The plan would be alerted through that
24 preliminary audit report. However, that has not
25 been issued.

1 Q. That report has not been issued for
2 payment year 2011 even?

3 A. Correct.

4 Q. So let's assume it has -- let's assume
5 that CMS alerts a plan about the HCCs that CMS
6 claims are unsupported by the medical records. Now
7 we move to the reconsideration process. And in
8 that process, an MA plan can say: No, wait a
9 minute. Take a look at this one record and that's
10 where we think it is in fact supported. Is that
11 right?

12 MS. OBEREMBT: Objection; calls for
13 speculation.

14 THE WITNESS: It would have to be a
15 record that was already submitted.

16 BY MR. MARTINEZ:

17 Q. So it's a record that's already
18 submitted; right?

19 A. Correct.

20 Q. And the plan can only point to one
21 record in the reconsideration context, not the
22 five, or up to five; right?

23 A. I believe it's one per each HCC.

24 Q. And so once the plan identifies that one
25 medical record for that one HCC, then there is a

1 third layer of review by a third coder who then
2 makes an assessment as to whether or not that
3 record supports the HCC that has been submitted for
4 payment; correct?

5 A. That was the process as designed.
6 Again, these results have not been issued, so I'm
7 being kind of speculative.

8 Q. Well, you're not being speculative, but
9 you're just explaining how the process is supposed
10 to work; right?

11 A. Based on my knowledge, yes.

12 Q. And based on your having been designated
13 as the government's representative to testify on
14 Topic 5.

15 And so if CMS's findings were in fact
16 overturned with respect to a particular HCC, that
17 would mean that this third coder would have found
18 support in the medical record submitted for that
19 HCC that two previous well-trained, well-qualified
20 coders did not report; correct?

21 MS. OBEREMBT: Objection; vague. And
22 calls for speculation.

23 THE WITNESS: That is one option.
24 Another reason a lot of records were found not to
25 support the HCC was not because of a disagreement

1 in the coding but was due to what we call invalid
2 issues such as lack of a signature, not being from
3 the correct data collection year.

4 BY MR. MARTINEZ:

5 Q. So not every discrepant finding is
6 because there is an unsupported HCC; correct?

7 A. Correct. It's unsupported in that
8 it's -- there is something that makes the medical
9 record invalid.

10 Q. Okay. And what you're saying is there
11 are multiple reasons why a medical record -- or why
12 there might be a discrepant finding. One of those
13 reasons could be that there is no support in the
14 medical record submitted for the HCC being audited;
15 right?

16 A. Correct.

17 Q. And so I'm only concerned about that
18 scenario. And so in that scenario, in the
19 reconsideration circumstance where reconsideration
20 results in overturning the previous findings, you
21 have a third coder who in that case would have
22 found the HCC to be supported by the medical record
23 when two previous well-trained, well-qualified
24 coders did not report that HCC?

25 MS. OBEREMBT: Objection; vague. Calls

1 A. I did not.

2 Q. Did you ask to review any of those
3 reports in preparation for your testimony today?

4 A. I did not.

5 Q. Why not?

6 A. I don't know.

7 Q. But you understand -- your understanding
8 is that those reports do exist and they do contain
9 information specific to plans that were audited for
10 payment years 2011, 2012 and 2013; is that right?

11 A. Yes.

12 Q. And your understanding is that -- well,
13 strike that.

14 Have you seen any of these reports
15 previously?

16 A. I have not.

17 Q. So where did you get that understanding
18 from?

19 A. I believe on the RADV public website
20 there's a presentation about it.

21 Q. Did you review that presentation in
22 preparation for your testimony today?

23 A. I do not recall. If I did, it was a
24 while ago.

25 Q. And that presentation is not in the

1 binder you have in front of you; correct?

2 A. It is not.

3 Q. All right. So let's -- I believe we
4 already established that for the payment year 2011
5 audit there were 30 MA plans that were selected for
6 auditing. Is that right?

7 A. Correct.

8 Q. And CMS audited four UnitedHealth plans
9 for payment year 2011; is that right?

10 A. That appears to be what the presentation
11 indicates.

12 Q. Okay. So if we go to page 5 of
13 Exhibit 1187-1, do you see that there are four
14 UnitedHealth Group plans listed here? The first
15 one is contract ID H0543. The second is H2226.
16 The third is H4522. And the last is H4590.

17 A. I do.

18 Q. And if I use the acronym UHG, will you
19 understand that I'm referring to the UnitedHealth
20 Group plans?

21 A. Okay.

22 Q. So looking here at the four UHG plans
23 that CMS selected for auditing for payment year
24 2011, do you see that two of those plans, H0543 and
25 H4590, are the two largest plans that were audited

1 in terms of total PY 2011 contract payment?

2 A. I'm sorry, which plans are you referring
3 to?

4 Q. I'm referring to UHG plan H0543 and
5 H4590.

6 A. Yes, those appear to be the largest in
7 terms of contract payments.

8 Q. Those are the only two plans audited for
9 PY 2011 that had contract payments for that year in
10 excess of \$2 billion; is that right?

11 A. That is what this chart indicates.

12 Q. And -- excuse me. Both of those plans
13 were in the high coding intensity bucket that we
14 talked about earlier today; right? Would you like
15 to refresh --

16 A. I don't know. I need to refresh my
17 memory on that.

18 Q. Let's go back to Exhibit 1498. And if
19 you go to, let's see, it's got 19 on the bottom
20 right of it. So let's look first for H0543. Which
21 coding intensity group is that in? It's at the
22 bottom.

23 A. High.

24 Q. Okay. And then the next one I asked
25 about was UHG plan H4590, which is the second from

1 the bottom. What coding intensity group is that
2 in?

3 A. That is also high.

4 Q. So does that refresh your recollection
5 that the two largest plans that were audited for
6 payment year 2011 were both from the high intensity
7 coding group?

8 A. That is what the document says.

9 Q. And you have no dispute the accuracy of
10 those documents?

11 A. I have no reason to dispute it.

12 Q. All right. And in fact, a third of the
13 four UHG plans was also from the high coding
14 intensity bucket. That would be H2226. Do you see
15 that in comparing Exhibits 1187-1 and 1498?

16 A. I do.

17 Q. CMS -- well, let me pause there.

18 Do you know why these four specific UHG
19 plans were selected for auditing in payment year
20 2011?

21 A. They were selected as they were part of
22 the high intensity -- coding intensity payment
23 group.

24 Q. And as far as you know, was that the
25 only criteria that was used for selecting those

1 four UHG plans for payment year 2011?

2 A. I believe so, unless it was in a,
3 quote-unquote, OIG plan, which I do not know.

4 Q. CMS's RADV results have not shown a
5 correlation between coding intensity and payment
6 error; correct?

7 A. That is correct.

8 Q. And so MA plans like these UHG plans can
9 be coding more intensely yet still be coding
10 accurately; right?

11 MS. OBEREMBT: Objection; calls for
12 speculation.

13 THE WITNESS: That is possible.

14 BY MR. MARTINEZ:

15 Q. And I think we've been over this before,
16 but the total recovery amount that CMS calculated
17 for payment year 2011 was roughly \$98 million;
18 right?

19 A. Correct.

20 Q. And the existence of -- let's take other
21 plans besides the UHG plans here. But the
22 existence of a contract-level overpayment that CMS
23 has identified, that does not mean that an MA plan
24 has engaged in fraud; correct?

25 MS. OBEREMBT: Objection; calls for

1 speculation.

2 THE WITNESS: That determination either
3 way cannot be made from the RADV audits.

4 BY MR. MARTINEZ:

5 Q. Well, just because CMS determines that
6 an MA plan, say at the contract level, has a net
7 overpayment does not by itself mean that CMS
8 believes the MA plan has committed fraud; right?

9 MS. OBEREMBT: Objection; calls for
10 speculation. And asked and answered.

11 THE WITNESS: This exercise was not
12 designed to identify fraud.

13 BY MR. MARTINEZ:

14 Q. So the answer to my question is yes?

15 MS. OBEREMBT: Objection; calls for
16 speculation. Asked and answered.

17 THE WITNESS: Please restate your
18 question.

19 BY MR. MARTINEZ:

20 Q. My question was: Just because CMS
21 determines that an MA plan at the contract level
22 has a net overpayment does not by itself mean that
23 CMS believes the MA plan has committed fraud?

24 MS. OBEREMBT: Same objection.

25 THE WITNESS: Again, this exercise was

1 speculation.

2 THE WITNESS: That determination either
3 way cannot be made from the RADV audits.

4 BY MR. MARTINEZ:

5 Q. Well, just because CMS determines that
6 an MA plan, say at the contract level, has a net
7 overpayment does not by itself mean that CMS
8 believes the MA plan has committed fraud; right?

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10 speculation. And asked and answered.

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16 speculation. Asked and answered.

17 THE WITNESS: Please restate your
18 question.

19 BY MR. MARTINEZ:

20 Q. My question was: Just because CMS
21 determines that an MA plan at the contract level
22 has a net overpayment does not by itself mean that
23 CMS believes the MA plan has committed fraud?

24 MS. OBEREMBT: Same objection.

25 THE WITNESS: Again, this exercise was

1 not designed to determine fraud. CMS can't make
2 that determination whether or not it has committed
3 fraud.

4 BY MR. MARTINEZ:

5 Q. But you understand that CMS has said in
6 the RADV context that neither payment errors nor
7 coding differences are fraud; right?

8 A. Correct. In and of themselves, no.

9 Q. Right. So in and of themselves, the
10 plans on here, not the UHG plans but the other
11 plans that have contract-level overpayments, that
12 fact alone does not mean that CMS believes they
13 have all committed fraud; right?

14 MS. OBEREMBT: Objection; calls for
15 speculation. Asked and answered.

16 THE WITNESS: Correct. But CMS is not
17 conducting this exercise to determine if there is
18 fraud.

19 BY MR. MARTINEZ:

20 Q. So staying on page 5 of Exhibit 1187-1,
21 all three -- excuse me, all four of the UHG plans
22 that were audited, CMS determined that they had no
23 recovery amounts at any of the three confidence
24 intervals listed in this chart. Is that right?

25 A. That is correct.

1 Q. In fact, CMS calculated that all four
2 UHG plans that were audited for payment year 2011
3 had net underpayments; correct?

4 A. No. H0543 had a payment error of
5 32 million, in excess of \$32 million.

6 Q. So I'm going to direct your attention to
7 page 7 of this presentation. Do you see where the
8 four UHG plans appear in this chart?

9 A. I do. But that's the confidence
10 interval calculation.

11 Q. Right. And to be clear, the confidence
12 interval calculation is the published methodology
13 that CMS disclosed that it would be using for
14 determining whether a plan at the contract level
15 had been net overpaid or underpaid; right?

16 A. Again, that was -- the confidence
17 interval was the way to determine the payment
18 recovery, whether there would be a payment recovery
19 or if it would be zero.

20 Q. Let's stay on page 7 here. But do you
21 agree with me that all four of the UHG plans, based
22 on CMS's calculations, show net underpayments at
23 the 99 percent confidence interval?

24 MS. OBEREMBT: Objection; asked and
25 answered.

1 see both exhibits report a net underpayment of
2 \$2,068,360?

3 A. Yes.

4 Q. So Exhibit 1498, which is in your
5 binder, is dated December of 2017. Is that right?

6 A. Correct. This is the same one that's
7 identical to the one in the binder except printed
8 on bigger paper?

9 Q. Yes. And so the numbers -- the point is
10 the numbers in the December 2017 version in terms
11 of net underpayments for the four UHG plans audited
12 by CMS for payment year 2011 are the same; right?

13 A. That is what it appears.

14 Q. The numbers didn't change between
15 May 2016 and December 2017; right?

16 A. They do not appear to, based on what you
17 had me look at.

18 Q. Since December 2017, has CMS amended
19 these net underpayment calculations that it made
20 for the four UHG plans audited in payment year
21 2011?

22 A. I did not review any documents that
23 showed that.

24 Q. So as far as you understand it, these
25 net underpayment amounts that CMS calculated with

1 respect to the UHG plans for payment year 2011 are
2 not going to change?

3 MS. OBEREMBT: Objection; calls for
4 speculation.

5 THE WITNESS: That calls for
6 speculation. I can't tell what will happen in the
7 future.

8 BY MR. MARTINEZ:

9 Q. Okay. So I want to turn your attention
10 to the second page of the slide deck, 1187-1. And
11 do you see in the last bullet CMS refers to the
12 recovery amounts for CON11 as preliminary?

13 A. I do see that.

14 Q. And then do you see how CMS defines
15 preliminary, which means "before a FFSA and before
16 appeals"?

17 A. That is correct.

18 Q. And FFSA refers to the fee-for-service
19 adjuster; correct?

20 A. That's my assumption.

21 Q. Okay. So if that's what preliminary
22 means according to CMS, then the recovery amounts
23 that are listed in Exhibit 1187-1, those recovery
24 amounts are only going to decrease through the
25 application of a fee-for-service adjuster or any

1 appeals process; right?

2 MS. OBEREMBT: Objection; calls for
3 speculation.

4 THE WITNESS: That would seem to be the
5 case.

6 MR. MARTINEZ: Have we been going for an
7 hour?

8 MS. OBEREMBT: No.

9 THE WITNESS: Where are we at?

10 MS. OBEREMBT: We started at 3:51.

11 (Off the record.)

12 BY MR. MARTINEZ:

13 Q. So let's go back to page 7 of
14 Exhibit 1187-1. This is the page of the CMS slide
15 deck for payment year 2011 that shows the net
16 underpayments for each of the UHG plans.

17 A. I'm sorry, what page?

18 Q. Oh, I'm sorry. Page 7.

19 A. Okay.

20 Q. Do you see there is a column on the far
21 right that says "HCC Discrepancy Rate"?

22 A. I do.

23 Q. And I think as we talked about earlier,
24 built within that discrepancy rate is some number
25 of unsupported -- strike that.

1 Built within the HCC discrepancy rate
2 reported here by CMS is some number of HCCs that
3 CMS's medical record review contractors found were
4 not supported by the medical records; correct?

5 A. Yes, according to -- yes.

6 Q. So what this chart is indicating is that
7 even though each of these four UHG plans that CMS
8 audited had HCC discrepancy rates of -- exceeding
9 10 percent in all cases, those four plans still,
10 according to CMS, had net underpayments for payment
11 year 2011; correct?

12 A. In the context of the RADV calculation.

13 Q. Right. So the answer to my question is
14 yes?

15 MS. OBEREMBT: Objection; misstates what
16 the witness just said.

17 THE WITNESS: In the case of the RADV
18 calculation and the nomenclature in the slide deck,
19 the RADV.

20 BY MR. MARTINEZ:

21 Q. Okay. So what this slide deck is
22 reporting in the RADV context for payment year 2011
23 is that all four of the UHG plans that were audited
24 and that CMS determined had net underpayments for
25 that year, each of them also had at least an

1 Q. And do you understand that parent
2 organization is essentially referring to the large
3 Medicare Advantage organizations that had plans
4 that were sampled -- that were selected for the
5 RADV audits for payment years 2011 to 2013?

6 A. The way I would phrase it is the parent
7 organization is the highest level, and under the
8 parent organizations are the contracts, and RADVs
9 were kept at the contract level.

[REDACTED]

22 Q. And then lastly, it says the
23 UnitedHealth Group plans account for 0.0 percent of
24 total recovery amount. Do you see that?

25 A. I do.

1 Q. And so according to this document that
2 was in your reliance binder, UnitedHealth Group --
3 the four UnitedHealth Group plans had the lowest
4 percentage of total recovery amount relative to the
5 other parent organizations whose plans were
6 audited?

7 A. That is what this is highlighting. But
8 it's not -- I don't believe this is inclusive of
9 all parent orgs that had plan sampled.

10 Q. Okay. And is this inclusive of parent
11 orgs that are considered peers in the Medicare
12 Advantage industry?

13 MS. OBEREMBT: Objection; vague.

14 THE WITNESS: I believe that it's of the
15 large parent orgs.

16 BY MR. MARTINEZ:

17 Q. Okay. So maybe we'll refer to the
18 information conveyed on this page as -- with
19 respect to the large parent organizations in
20 Medicare Advantage. Is that fair?

21 A. Sure.

22 Q. Okay. So among the four large parent
23 organizations that had plans that were audited by
24 CMS for payment year 2011, UnitedHealth Group
25 accounted for the lowest percentage of the total

1 recovery amount that CMS calculated for that year;
2 correct?

3 A. That's what's indicated here.

4 Q. And that's the case -- if you flip now
5 to two pages down.

6 A. What page number?

7 Q. So it's page 4. You see there are three
8 bar charts on this page?

9 A. I do.

10 Q. So let's stick with payment year 2011
11 which is in the top left. Do you see that bar
12 chart?

13 A. Yes.

14 Q. And the recovery amount is indicated by,
15 I guess, what appears to me to be an
16 orangish-reddish circle on the bar chart. Do you
17 see that?

18 A. I do see that. Give me a minute. This
19 chart has two axes. One is population and the
20 other is the recovery amount, it appears.

21 Q. And so this bar chart on the top left
22 is -- one of the things it's indicating is that,
23 again, as we know, the UnitedHealth plans audited
24 for that year, CMS calculated a zero recovery
25 amount; right?

1 A. Just give me a second to look at the
2 numbers here and put this in a little context.

3 Correct.

4 Q. And you alluded to this already, but
5 there is another axis that refers to the eligible
6 population in the thousands. Is that right?

7 A. Correct.

8 Q. And what do you understand the eligible
9 population to refer to?

10 A. I believe that refers to the population
11 to whom the sample results would be extrapolated.

12 Q. And so what this bar chart on the top
13 left for payment year 2011 is telling us is that
14 the four UnitedHealth plans that were audited that
15 year by CMS had by far the largest number of
16 eligible population members; correct?

17 A. When combined. When combined, the UHG
18 plans had the largest population.

19 Q. Okay. And looking at this chart, just
20 eyeballing it, by a significant margin it was the
21 highest population; right?

22 A. It appears so.

23 Q. And so even though the four UHG plans
24 that were audited when combined had by far the
25 largest eligible population, those UHG plans still

1 had the lowest recovery amount of any of the large
2 parent organizations that were audited for payment
3 year 2011; correct?

4 A. I do not know this. All of these seem
5 to be very close to the zero axis.

[REDACTED]

23 Could you rephrase your question?

24 Q. Sure.

25 My question is: Even though the

1 UnitedHealth Group plans had by far the largest
2 eligible populations of the large parent
3 organizations whose plans were audited for payment
4 year 2011, the UHG plans also had the lowest
5 percentage of payment recovery based on CMS's
6 calculations for that year. Correct?

7 MS. OBEREMBT: Objection; vague.

8 THE WITNESS: That is what this slide
9 deck seems to indicate, that it accounts for zero
10 percent of total recovery.

11 BY MR. MARTINEZ:

12 Q. All right. And going back to the slide
13 that you're currently on, which I believe is the
14 third page of Exhibit 1498, UHG also had the most
15 plans audited among the large parent organizations
16 for payment year 2011. Is that right?

17 A. It did.

18 Q. It had four plans audited, Aetna had
19 three, Cigna had three and Humana had one.
20 Correct?

21 A. That is what this indicates.

22 Q. And so even though UnitedHealth Group
23 had the most plans audited and the largest
24 population for payment year 2011, it had the lowest
25 percentage of total recovery amount for that year;

1 correct?

2 A. At the parent org level, that's what
3 this says.

4 Q. Let's go back to the May 2016 slide
5 deck, Exhibit 1187-1. And I would like to direct
6 your attention to page 10 of that exhibit.

7 Do you see that the title for this slide
8 is "HCC Discrepancy Rates for Major Parent Orgs"?

9 A. I do.

10 Q. And do you see that there is a column
11 for it appears to be five parent orgs, one of which
12 includes UHG?

13 A. Yes.

14 Q. And then there is another column that
15 reports the payment year 2011 HCC discrepancy rate
16 that CMS calculated for the plans that are part of
17 each of those parent organizations. Is that right?

18 A. I do see that.

19 Q. And in that column, do you see that the
20 HCC discrepancy rate for the four UnitedHealth
21 Group plans audited was 12.3 percent?

22 A. I do.

23 Q. And that figure is the lowest of any of
24 the parent organizations audited for payment year
25 2011; correct?

1 A. I cannot say that. I can say it was the
2 lowest of these five parent organizations.

3 Q. And these are the parent organizations
4 that CMS is referring to as the major parent
5 organizations?

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

10 Q. Well, CMS, in the slide deck that we're
11 looking at now, is referring to these five parent
12 organizations as the major parent organizations;
13 right?

14 A. Right.

15 Q. And among those five major parent
16 organizations that CMS has identified, UnitedHealth
17 Group has the lowest HCC discrepancy rate for
18 payment year 2011; correct?

19 A. That's what this slide shows.

20 Q. And you have no reason to dispute the
21 accuracy of this slide; correct?

22 A. I do not.

23 Q. And on the 12.3 percent number, is
24 another way of saying that that CMS validated
25 roughly 88 percent of the HCCs that the UHG plans

1 submitted as part of the RADV audit for payment
2 year 2011?

3 MS. OBEREMBT: Objection; vague.

4 THE WITNESS: Could you be more
5 specific?

6 BY MR. MARTINEZ:

7 Q. Is another way of communicating the
8 12.3 percent figure that's shown on this slide that
9 CMS, through the RADV audit, validated roughly
10 88 percent of the HCCs that the UHG plans submitted
11 as part of the RADV audit for payment year 2011?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: Yes, that's kind of
14 putting it another way. It's a little less than
15 88 percent.

16 BY MR. MARTINEZ:

17 Q. Okay. So a little less than 88 percent
18 is what we'll call the HCC validation rate for the
19 UHG plans for payment year 2011. Is that fair?

20 A. Okay.

21 Q. Is that a yes?

22 A. Yes.

23 Q. So what that nearly 88 percent number
24 means is that for 88 percent of the HCCs that the
25 four UnitedHealth plans submitted as part of the

1 2011 RADV audit, CMS was able to validate those
2 HCCs as being supported by the medical records that
3 the UHG plans submitted; correct?

4 A. Correct.

5 Q. Would you agree with me that these
6 results that we've looked at both in this exhibit
7 and the prior one demonstrate that when it comes to
8 the large or major MA parent organizations,
9 UnitedHealth Group is the industry leader when it
10 comes to submitting accurate risk adjustment data
11 as part of the RADV process?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: Could you ask that another
14 way?

15 BY MR. MARTINEZ:

16 Q. Sure.

17 Would you agree with me that
18 UnitedHealth Group is, according to CMS's own
19 calculations, performing better than its peers, all
20 of its peers, when it comes to submitting accurate
21 risk adjustment data for validation?

22 MS. OBEREMBT: Objection; vague.

23 THE WITNESS: Again, it appears on this
24 limited chart that just lists the other large
25 parent organizations, that it does have the lowest

1 discrepancy rate in that comparison.

2 BY MR. MARTINEZ:

3 Q. Okay. So we see on this chart it has
4 the lowest HCC discrepancy rate, and we saw in
5 Exhibit 1498 that it also had the lowest percentage
6 of any recovery amount for payment year 2011;
7 right?

8 A. Yes. Out of what this deck here in
9 slide 10 calls the, quote-unquote, major parent
10 orgs.

11 Q. So in that respect, would you agree that
12 UnitedHealth Group is performing better in the 2011
13 RADV audits than any of the other large or major
14 parent organizations that had plans audited for
15 that payment year?

16 MS. OBEREMBT: Objection; vague.

17 THE WITNESS: I don't know that I would
18 characterize it as performing better. [REDACTED]

[REDACTED]
20 BY MR. MARTINEZ:

21 Q. But 12 percent is lower than 15 percent;
22 right?

23 A. It is.

24 Q. And --

25 A. I don't know if it's significantly

1 THE WITNESS: I don't know if I would
2 characterize it as a good partner type of exercise.
3 And again, without getting more detailed about each
4 United contract that was audited, I can't tell.
5 Did they submit records for all of their enrollees?
6 This is a blunt number. I can't really tell.

7 BY MR. MARTINEZ:

8 Q. Did any of the UHG plans that were
9 audited refuse to participate in the process in any
10 way?

11 A. That was not indicated in any of the
12 information I reviewed.

13 Q. So as far as you know as the
14 government's designee to testify on Topic 5, you
15 have no information that any of the UHG plans that
16 were audited for payment years 2011 to 2013 refused
17 to participate in any way in any of those audits;
18 correct?

19 MS. OBEREMBT: Objection; outside the
20 scope. And vague.

21 THE WITNESS: I did not review any
22 information or receive any information that
23 indicated that.

24 BY MR. MARTINEZ:

25 Q. So I want to transition now to the

1 results for the 2012 and 2013 audits that CMS
2 conducted. To assist us in that endeavor, I'm
3 going to mark an exhibit. This will be
4 Exhibit 1500.

5 (Exhibit 1500 marked for identification
6 and attached hereto.)

7 BY MR. MARTINEZ:

8 Q. So let me give you a little bit of
9 background as to what Exhibit 1500 is. So what it
10 is is it's a printout of an Excel that took the
11 information from the last three pages of
12 Exhibit 1498 but only extracted the information in
13 that exhibit related to the UHG plans that were
14 audited by CMS for payment years 2011 to 2013.

15 Okay? Do you understand that?

16 A. Let me just double-check.

17 Okay. That's what it appears to be.

18 Q. So you've gone through and checked the
19 numbers to make sure that they tie out?

20 A. I did a spot-check, one for each year.

21 Q. Did all of the ones that you checked
22 look accurate?

23 A. Yes. Of the three I checked, yes.

24 Q. So again, what this document
25 Exhibit 1500 is showing is it's just isolating the

1 UHG plans from the spreadsheets that are included
2 at the back of Exhibit 1498. And it includes the
3 contract ID, the year in which that contract was
4 audited, the fact that these are the UHG plans, the
5 coding intensity group that CMS categorized them
6 into, and then the recovery amounts that CMS
7 calculated for each of those plans for each of
8 those years.

9 Do you see that?

10 A. I do.

11 Q. Okay. So for -- so we've already walked
12 through the net underpayments for payment year
13 2011. So I want to move now to 2012. Is that
14 okay?

15 A. Okay.

16 Q. So for payment year 2012, the first UHG
17 plan that was audited is ID number H5420.

18 A. Okay.

19 Q. And for that plan, in 2012 CMS reported
20 a recovery amount of \$15,735,769. Is that right?

21 A. That's correct.

22 Q. Okay.

23 A. That's what it indicates.

24 Q. And then for the next plan audited for
25 payment year 2012, ID R7444, for that UHG plan CMS

1 determined a net underpayment of \$3,962,831. Is
2 that correct?

3 A. That's what it indicates.

4 Q. And when you say that's what it
5 indicates, what do you mean?

6 A. That is what is on the chart, and I'm
7 assuming, based on my spot-check, that that is from
8 the slide deck produced, which I have no reason to
9 believe is incorrect.

10 Q. Okay, great.

11 And then moving on to the third UHG plan
12 audited in payment year 2012, H5652, CMS calculated
13 a net underpayment of \$4,740,216. Is that correct?

14 A. Yes, that's what it says.

15 Q. And then for contract ID H0251, a United
16 plan CMS audited in payment year 2012, CMS
17 calculated a net underpayment of \$69,295,194. Is
18 that correct?

19 A. Repeat the contract number again.

20 Q. I'm sorry. I may have messed that up.
21 I did.

22 So this is contract number R5287.

23 Strike that.

24 Let's -- strike that.

25 Going back to contract ID H0251, the net

1 underpayment that CMS reported is \$10,348,919.

2 Right?

3 A. Yes.

4 Q. My apologies for that.

5 And then for the last, the fifth and
6 final UHG contract CMS audited for payment year
7 2012, ID R5287, CMS calculated a net underpayment
8 of \$69,295,194. Is that correct?

9 A. That's what is indicated.

10 Q. Okay. So a quick summary of payment
11 year 2012, CMS audited five UHG plans for that
12 payment year; correct?

13 A. Correct.

14 Q. And all five of those plans CMS
15 classified as being in the high coding intensity
16 group?

17 A. Yes, that's what's indicated.

18 Q. And four of those five plans had net
19 underpayments according to CMS's calculations for
20 payment year 2012; correct?

21 A. For calculations in the RADV context, a
22 net underpayment was the lower bound calculation.

23 Q. Okay. And that was the case for four of
24 the five plans that CMS audited in payment year
25 2012?

1 A. Yes, that's what the information
2 indicates.

3 Q. All right. Let's transition now to
4 payment year 2013. And you can see that CMS
5 audited six UHG plans for payment year 2013. Is
6 that right?

7 A. Yes.

8 Q. And all six of those plans CMS
9 classified as being in the high coding intensity
10 group?

11 A. It appears so, yes.

12 Q. Let's go through them briefly one by
13 one. So the first plan listed for 2013 is R9896,
14 and for that plan CMS reported a recovery amount of
15 \$4,065,269. Is that right?

16 A. Yes.

17 Q. Okay. Moving on to plan H3107, a UHG
18 plan that was audited by CMS in 2013, CMS reported
19 a net underpayment of \$1,581,972. Is that correct?

20 A. Yes.

21 Q. And for UHG contract ID H0151 audited by
22 CMS in payment year 2013, CMS reported a net
23 underpayment of \$7,790,780. Is that correct?

24 A. Yes.

25 Q. For UHG contract ID H4514, CMS

1 calculated a net underpayment for that plan in
2 payment year 2013 of \$9,302,996. Correct?

3 A. Yes.

4 Q. For UHG plan H2931 which CMS audited in
5 payment year 2013, CMS calculated a net
6 underpayment of \$10,078,497. Is that correct?

7 A. Yes.

8 Q. And then finally, for UHG plan R5342
9 which CMS audited for payment year 2013, CMS
10 calculated a net underpayment of \$14,309,264. Is
11 that correct?

12 A. Correct, it indicates that information.

13 Q. So we've gone through all the recovery
14 amount information for the 15 UHG plans that CMS
15 audited during payment years 2011, 2012 and 2013;
16 right?

17 A. Yes.

18 Q. And of those 15 plans that CMS audited
19 during those payment years, 13 of them had net
20 underpayments according to CMS's calculations;
21 correct?

22 A. Correct. That's what's indicated.

23 Q. Okay. And then if you do a sum of all
24 of those overpayments and underpayments that CMS
25 calculated, that's reflected in the number on

1 Exhibit 1500 beneath the right-hand side column,
2 and that comes out to \$261 million -- sorry.
3 \$261,202,498 in total net underpayments for the 15
4 UHG plans that CMS audited in the years 2011 to
5 2013; correct?

6 A. That is what this says. I've never
7 seen -- none of the documents I reviewed had
8 information presented this way.

9 Q. And if you would like, I can show you
10 the Excel that sums this information.

11 A. Sure, that would be great.

12 MR. MARTINEZ: Okay. Let's go off the
13 record briefly so we can set that up.

14 THE VIDEOGRAPHER: Going off the record
15 at 17:37.

16 (Off the record.)

17 (Recess taken.)

18 THE VIDEOGRAPHER: We are back on the
19 record at 17:46.

20 BY MR. MARTINEZ:

21 Q. Okay. Are you able to see the Excel
22 that was used to generate Exhibit 1500 on the
23 screen?

24 A. I am.

25 Q. So I just want to draw your attention to

1 box E18. And do you see where in that box --
2 that's the box that contains the \$261 million
3 figure -- that it refers to the sum of the previous
4 entries that are listed on Exhibit 1500?

5 A. Yes.

6 Q. And if we can move up there, you can see
7 that when you sum the overpayment and underpayment
8 amounts for the 15 UHG plans that CMS audited for
9 payment years 2011 to 2013, that the results in
10 total is a net underpayment to those plans of
11 \$261,202,498?

12 A. Yes.

13 Q. So what I would like to do now is my
14 colleague is going to sort the recovery amounts by
15 size in the Excel. So he's sorting them from
16 smallest to largest. So what that means is that
17 the most negative amount is going to appear on the
18 top, and then the two plans with overpayments that
19 CMS calculated will appear at the bottom.

20 A. Okay.

21 (Exhibit 1501 marked for identification
22 and attached hereto.)

23 BY MR. MARTINEZ:

24 Q. And so what I would like to do is I'm
25 going to hand you what's been marked as

1 Exhibit 1501, which includes the same -- the exact
2 same data, it's just sorted this time for ease of
3 everyone's review.

4 A. Uh-huh.

5 Q. And then it's been color coded so that
6 the net underpayments are shown in green and the
7 net overpayments that CMS calculated are shown in
8 red.

9 Do you see that?

10 A. Yes.

11 Q. And does that match up with what you're
12 seeing on the screen?

13 A. It does.

14 Q. And so does Exhibit 1501 confirm that
15 for payment years 2011 to 2013, of the 15 plans
16 that CMS audited it calculated net underpayments
17 for 13 of those plans; correct?

18 A. In the context of RADV, yes, that is
19 what this is showing.

20 Q. Okay. Let's -- I'm going to have you
21 keep Exhibit 1501 -- I'm sorry. If you could go
22 back to Exhibit 1500. I'm just going to have you
23 keep this exhibit handy. I'm not going to ask you
24 any more questions about the numbers on the
25 exhibit, but I just want to use it as a reference

1 A. Yes, that is what the information in
2 this deck indicates.

3 Q. But you don't have the exact number that
4 CMS calculated?

5 A. I do not believe I reviewed any
6 information that has the exact number, nor do I
7 think it's in either of these two presentations
8 we've looked at.

9 Q. In preparing to testify today, did you
10 ask for the precise HCC discrepancy rates that CMS
11 calculated for the plans it audited in payment
12 years 2012 and 2013?

13 A. I did not. I do not believe I did.

14 Q. All right. So I take it, then, for the
15 remaining contract IDs listed in Exhibit 1500, for
16 purposes of today you would be able to estimate
17 what CMS calculated the HCC discrepancy rate to be
18 for those plans but you couldn't give me the exact
19 number. Is that right?

20 A. That is correct.

21 Q. And you have no reason to dispute the
22 accuracy of the information being conveyed in the
23 bar charts on what's labeled page 8 of
24 Exhibit 1498; correct?

25 A. I do not have any reason to dispute

1 that.

2 Q. Okay. So I want to direct your
3 attention to another example from payment year
4 2012. Do you see the bar corresponding to contract
5 ID H5652?

6 A. I do.

7 Q. And that was one of the UHG plans that
8 CMS audited for payment year 2012; correct?

9 A. Yes.

10 Q. And looking at this bar chart here in
11 Exhibit 1498, does it appear that the HCC
12 discrepancy rate that CMS calculated was roughly
13 10 percent?

14 A. It does.

15 Q. And so that means that for 90 percent of
16 the HCCs that were submitted by this UHG plan for
17 auditing in payment year 2012, that CMS was able to
18 validate the HCC as being supported by the medical
19 records; correct?

20 MS. OBEREMBT: Objection; vague.

21 THE WITNESS: That is an alternate way
22 of expressing a 10 percent discrepancy rate.

23 BY MR. MARTINEZ:

24 Q. So the answer to my question is yes?

25 MS. OBEREMBT: Objection; vague.

1 THE WITNESS: Yes.

2 BY MR. MARTINEZ:

3 Q. And if we were to do the same exercise
4 with the remaining contract IDs for the remaining
5 UHG plans that CMS audited for payment years 2011
6 to 2013, would your answer be the same, that when
7 these bar charts are indicating an HCC discrepancy
8 rate, another way of looking at that is a
9 percentage of the HCCs that CMS was able to
10 validate based on the submissions by the plans for
11 those payment years?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: That is another way of
14 putting it. It's typically not -- we typically
15 talk about a discrepancy rate. But that is kind of
16 the converse of the discrepancy rate.

17 BY MR. MARTINEZ:

18 Q. Okay. And that nomenclature would apply
19 to any other contract ID that we might go through
20 that's listed on these bar charts in Exhibit 1498;
21 right?

22 MS. OBEREMBT: Objection; vague.

23 THE WITNESS: Could you be more -- what
24 nomenclature?

25 BY MR. MARTINEZ:

1 Q. The sort of HCC discrepancy rate being
2 the converse of the -- what I'll call an HCC
3 validation rate?

4 MS. OBEREMBT: Objection; vague.

5 THE WITNESS: Yes. If you want to
6 phrase it that way.

7 BY MR. MARTINEZ:

8 Q. Okay. And that would apply to any other
9 contract ID that we might look at that CMS audited
10 for these payment years; right?

11 A. Yes. For the purpose of this exercise,
12 if you want to refer to it that way.

13 Q. All right. So if you go to the cover
14 page of Exhibit 1498, there is an indication that
15 it was produced in native format. Does that mean
16 that there's -- and I assume that means this was
17 produced as a native PowerPoint. Well, you may not
18 know the answer to that.

19 A. I don't know what that means.

20 Q. So I guess my question is -- and this
21 may be more a question for your counsel. Do you
22 know if there's an underlying Excel that would
23 contain the precise numbers that are represented in
24 the bar charts on what's labeled as page 8 of
25 Exhibit 1498?

1 C E R T I F I C A T E

2

3 STATE OF MARYLAND

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the State of Maryland, do hereby
6 certify that CAROLYN KAPUSTIJ, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 28th day of August, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 08/16/25

22

23

24

25

EXHIBIT D-123

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

---o0o---

UNITED STATES OF AMERICA, ex)
rel., BENJAMIN POEHLING,)

Plaintiff,)

vs.)

UNITEDHEALTH GROUP, INC., et)
al.,)

Defendants.)

Case No.
16-08697 FMO

---o0o---

MONDAY, MARCH 25, 2024

VIDEOTAPED DEPOSITION OF DANIEL KESSLER, PH.D.

CONFIDENTIAL TRANSCRIPT

---o0o---

REPORTER: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

1 Q. BY MR. THOMSON: So would that not result
2 in a higher coding intensity level for the MA
3 population in the overall pool as compared to the
4 MA population in the sample pool that was used to
5 calculate the CIA?

10:49:10

6 MR. MARTINEZ: Object to form.

7 THE WITNESS: Yes. The answer to that
8 question is yes. That's -- that's different from
9 the earlier question, but that question, yes.

10 Q. BY MR. THOMSON: And you understand that
11 one purpose of retrospective chart reviews
12 performed on behalf of MA plans is to reduce the
13 incidence of type II errors, right?

10:49:29

14 MR. MARTINEZ: Object to form.

15 Foundation. Calls for speculation.

10:49:43

16 THE WITNESS: I don't know.

17 Q. BY MR. THOMSON: You don't know one way or
18 the other whether the purpose of retrospective
19 chart review programs is to reduce the incidence of
20 absent supported codes, which you refer to as type
21 II errors?

10:49:56

22 MR. MARTINEZ: Object to form.

23 THE WITNESS: Yeah, I mean, I don't know
24 all the purposes of -- well, I mean, first of all,
25 I am not sure exactly what "retrospective chart

10:50:13

1 review programs" refer to, but I also -- I just
2 don't know what the -- why MA plans, you know, make
3 all the decisions that they make. I just don't
4 know.

5 Q. BY MR. THOMSON: What is your 10:50:31
6 understanding of why MA plans conduct chart review?

7 MR. MARTINEZ: Object to form.

8 THE WITNESS: I mean, I just don't -- I
9 just don't know the motivations of the plans. I
10 mean, I know overall. I mean, as I talked about in 10:50:56
11 my report, I understand the motivation of the plans
12 is to -- to have diagnoses that reflect the patient
13 -- better reflect the patient's true medical
14 records.

15 But I don't know in particular about any 10:51:18
16 program that plans implement, why they do what they
17 do. I don't have an opinion about that.

18 Q. BY MR. THOMSON: You're not aware of any
19 -- technically you're not aware of any MA
20 retrospective chart review programs that existed in 10:51:44
21 the 2004 to 2007 period, are you?

22 MR. MARTINEZ: Object to form.

23 THE WITNESS: I don't know one way or the
24 other.

25 Q. BY MR. THOMSON: To the extent that there 10:51:55

1 were type I or type II errors in any of the cohorts
2 studied in the '04 to '05, '05 to '06, and '06 to
3 '07 pairs of years included in the study described
4 in the GAO report, those errors were included in
5 the calculation of the CIA; is that right? 10:52:14

6 MR. MARTINEZ: Object to form. Vague as
7 to time.

8 THE WITNESS: Could you repeat the
9 question?

10 Q. BY MR. THOMSON: To the extent that there 10:52:24
11 were type I or type II errors in any of the cohorts
12 studied in the '04 to '05, '05 to '06, and '06 to
13 '07 pairs of years included in the study described
14 in the GAO reports, those errors were included in
15 the calculation of the CIA, right? 10:52:46

16 MR. MARTINEZ: Object to form.

17 THE WITNESS: Those -- those would be
18 errors in fee-for-service, right, not MA? Is that
19 what you're referring to? Because the cohorts were
20 all fee-for-service cohorts, right? 10:53:12

21 Q. BY MR. THOMSON: Do you know?

22 A. Yeah. I mean, that's my understanding.
23 I'm sorry. I'm just not -- maybe I'm just not
24 getting your question. I'm sorry.

25 Q. So your understanding is that those 10:53:38

1 calculate what the fee-for-service level of coding
2 intensity was. It is just not something United
3 couldn't conduct medical record reviews on a random
4 sample of fee-for-service claims to which it didn't
5 have the right to see.

12:10:18

6 Q. BY MR. THOMSON: But you didn't talk to
7 anybody at United to determine what United knew
8 about its level of coding intensity at any time,
9 did you?

10 A. I didn't, but just knowing -- United just
11 knowing its own coding intensity wouldn't answer
12 the question here. I mean, they'd have to either
13 know the MA industry average coding intensity plus
14 presume that the coding intensity adjuster was
15 correct. Or they would have had to have known the
16 fee-for-service coding intensity and those facts.
17 I mean, I just don't -- I have no way to believe
18 that they could have access to the information
19 necessary to do that.

12:10:38

12:10:55

20 But I haven't spoken with everyone who
21 worked at United at that time to determine that.
22 It's just -- I just don't -- I am not aware of how
23 it could possibly occur. That's all I'm trying to
24 say.

12:11:13

25 Q. Did you review any of United's documents

12:11:28

1 on this point to determine what it tracked or knew
2 about its own coding intensity adjustment at any
3 point in 2018 -- from 2008 to 2016?

4 MR. MARTINEZ: Object to form.

5 THE WITNESS: I mean, I certainly looked 12:11:41
6 at a lot of documents, but again, even if United
7 knew its own coding intensity, that wouldn't be
8 sufficient to determine whether they were overpaid
9 or underpaid. Because you'd have to know either
10 relative to the MA industry average or the 12:12:04
11 fee-for-service to get that.

12 But I don't -- I don't know what United
13 did to calculate its own coding intensity, no, I
14 don't.

15 Q. BY MR. THOMSON: Do you know whether 12:12:17
16 United had an estimate of the industry average
17 coding intensity for MA plans?

18 A. Not that I've seen.

19 Q. Did you request documents related to
20 whether United had access to that information? 12:12:37

21 MR. MARTINEZ: Object to form.

22 THE WITNESS: I mean, I -- to actually
23 calculate that, they would have had to have had
24 access to their competitors' records. It wouldn't
25 even make sense. 12:12:54

1 Q. BY MR. THOMSON: So is that a no?

2 MR. MARTINEZ: Object to form.

3 THE WITNESS: I didn't ask if they had

4 access to their competitors' records because it

5 wouldn't make sense -- it didn't make any sense to 12:13:06

6 me. So yeah, I guess I didn't ask that.

7 Q. BY MR. THOMSON: Okay. So the next

8 paragraph, Paragraph 50 --

9 A. Yes.

10 Q. -- "Second, the presence of unsupported 12:13:20

11 codes in any particular plan's data is insufficient

12 to establish that CMS has 'overpaid' or 'underpaid'

13 it. Correct calculation of the presence and extent

14 of 'overpayment' must also account for the plan's

15 level of absent supported codes and the industry 12:13:36

16 average level of present unsupported and absent

17 supported codes."

18 Can you explain the logic of this

19 paragraph to us? I am not sure I totally follow

20 it. 12:13:55

21 A. Sure, of course. I mean, the fact that

22 there are unsupported -- so the fact that there are

23 unsupported codes in Medicare Advantage doesn't

24 tell you whether Medicare Advantage plans in

25 general are overpaid or underpaid because the goal 12:14:18

1 of -- I mean, what overpaid means is paid more than
2 that needed to achieve payment neutrality. And
3 payment neutrality is this population-based concept
4 comparing aggregate payments to MA plans to what
5 the people would have cost in fee-for-service,
6 okay.

12:14:39

7 So the fact that you see an unsupported
8 code in MA in general doesn't mean MA plans in
9 general were overpaid. Because as long as the
10 relative rates of supported and unsupported codes
11 in MA mirrors that in fee-for-service, then people
12 were paid -- the plans were paid correctly.

12:14:56

13 So that same reasoning applies on a
14 plan-specific basis. And that's -- all I'm doing
15 in Paragraph 50 is carrying that reasoning down to
16 the plan level. Is that helpful?

12:15:15

17 Q. I think so. So we talked about
18 overpayment and underpayment --

19 A. Yes.

20 Q. -- that is MA plan payments in aggregate
21 as compared to fee-for-service, the estimated cost
22 for the same beneficiaries and Medicare
23 fee-for-service?

12:15:28

24 A. Yep.

25 Q. So the absent supported code -- I guess

12:15:40

1 what I am not following is why an unsupported code
2 in MA would not just be an unsupported code that
3 increases the cost beyond what that same patient
4 would have cost in fee-for-service because -- well,
5 sorry, go ahead. Go ahead.

12:16:04

6 A. No, I see what you're asking. I mean, the
7 reason that the presence of an unsupported code
8 doesn't imply overpayment is that fee-for-service
9 also has some unsupported codes in it, almost
10 surely, just as -- because both MA and
11 fee-for-service are going to have some present
12 unsupported and some absent supported codes.

12:16:20

13 And to get, you know, overpayment is
14 relative to payment neutrality, which is this
15 population-based concept.

12:16:37

16 To get payment neutrality, what you want
17 is the rates of absent -- absent supported and
18 present unsupported codes in MA to mirror that in
19 fee-for-service.

20 So if -- suppose that the rates of present
21 unsupported and absent supported codes in MA were
22 exactly the same as fee-for-service, right, then
23 you wouldn't -- you wouldn't even need a coding
24 intensity adjuster because you would have payment
25 neutrality.

12:16:58

12:17:17

1 Q. Assuming that there was the same health
2 risk among each population groups, right?

3 MR. MARTINEZ: Object to form.

4 THE WITNESS: No. I mean, you could --

5 they could have different -- they could have 12:17:36

6 different illness scores and different

7 demographics, and you would have adjusted for that.

8 And the adjustment would be exactly correct.

9 Because the rates of present support -- present

10 unsupported and absent supported codes in the two 12:17:55

11 populations were identical.

12 So if that were true, then we have no --

13 we have no problem.

14 Q. So the risk adjustment data is calculated

15 on fee-for-service -- 12:18:13

16 A. Yes.

17 Q. -- payments, right?

18 MR. MARTINEZ: Object to form.

19 THE WITNESS: Yes.

20 MR. MARTINEZ: You said data. I think you 12:18:18

21 meant model.

22 MR. THOMSON: Can you read the question

23 back? I'm sorry.

24 THE WITNESS: Go ahead.

25 (Reporter read back as requested.) 12:18:39

1 is a true record of the testimony given. (Civ.
2 Proc. § 2025.540(a))

3 I have not, and shall not, offer or
4 provide any services or products to any party's
5 attorney or third party who is financing all or
6 part of the action without first offering same to
7 all parties or their attorneys attending the
8 deposition and making same available at the same
9 time to all parties or their attorneys. (Civ.
10 Proc. § 2025.320(b))

11 I shall not provide any service or product
12 consisting of the deposition officer's notations or
13 comments regarding the demeanor of any witness,
14 attorney, or party present at the deposition to any
15 party or any party's attorney or third party who is
16 financing all or part of the action, nor shall I
17 collect any personal identifying information about
18 the witness as a service or product to be provided
19 to any party or third party who is financing all or
20 part of the action. (Civ. Proc. § 2025.320(c))

21

22 Dated: _____

23

Balinda Dunlap

24

25

EXHIBIT D-124

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	No. CV 16-08697 FMO
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et	)	
al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL TRANSCRIPT WITH REDACTED ATTORNEYS' EYES
ONLY PORTIONS. REFER TO SEPARATE TRANSCRIPT ***

VIDEOTAPED VIDEOCONFERENCE ZOOM DEPOSITION OF

THOMAS KORNFIELD

March 10, 2022
10:14 a.m.
Rockville, Maryland

Magna Legal Services
(866) 624-6221
www.MagnaLS.com

Prepared by:
Marcella Daughtry, RPR, RMR
CA CSR 14315
GA No. 6595-1471-3597-5424

1 right?

2 A Yes.

3 Q Please tell me a little bit about your roles
4 and responsibilities at AHIP as it relates to MA payments
5 and risk adjustment.

6 A I was the lead policy support person within the
7 policy group at AHIP responsible for Medicare Advantage
8 risk adjustment and payment policy.

9 Q And so in that role you would lead risk
10 adjustment policy discussions with plan members and
11 external stakeholders?

12 A Yes, in cooperation with other members of
13 the -- of the team. And by policy team, I am referring
14 to -- it may not have been explicitly called that within
15 the organization, but that's how I am referring to the
16 group that I worked in within AHIP.

17 Q And did you also -- you also oversaw research
18 and analyses about the impacts of Medicare Advantage
19 payment and risk adjustment policies; is that right?

20 A Yes.

21 Q All right. Moving back to your time at the
22 Centers for Medicare & Medicaid Services, which I will
23 refer to as CMS, you worked at CMS for over five years in
24 several different roles; is that right?

25 A I worked at CMS a total of ten years. There

1 were two five-year stints.

2 Q Thanks for correcting that.

3 So -- so focusing on your most recent five-year
4 stint, that was from around April 2010 to July 2015; is
5 that right?

6 A Yes.

7 Q And the first job in that second stint was as a
8 health insurance specialist?

9 A Yes.

10 Q What division did you work for at that time as
11 a health insurance specialist?

12 A From 2010 to 2012 I was in the Division of
13 Payment -- I'm sorry, Risk Adjustment and Payment
14 Operations, I believe is what it was called. And then
15 from 2012 to 2014 I was the division director. Before, I
16 believe it was the Division of Payment Systems. I might
17 have the name wrong, but it was -- that was the -- so
18 that was, sorry, from 2012 to 2014.

19 From 2014 to 2015 I was in CMM (sic) -- the
20 Centers for Medicare and Medicaid Innovation, where I
21 believe I was a -- their health insurance specialist, or
22 I don't remember the title.

23 Q Okay. So starting with the health specialist
24 position at the Division of Risk Adjustment and Payment
25 Policy, in that role you analyzed impacts of changes to

1 payment rates and risk scores in support of annual
2 Medicare Advantage payment notice. Is -- is that a fair
3 description from your LinkedIn profile?

4 A Yes.

5 Q So tell me a little bit about what that means,
6 particularly the Medicare Advantage payment notice.

7 A I am sorry, what is -- I don't understand the
8 question.

9 Q Sure. So part of your job was to analyze
10 impacts of changes to payment and risk scores in support
11 of this notice, and so I just wanted you to explain a
12 little bit about what this notice is. Is that -- is that
13 also something known as the final Rate Announcement? Is
14 that what you are referring to here?

15 A There is an Advance Notice and there is a final
16 Rate Announcement. Are you -- are you asking me about --
17 sorry. Can you repeat the question? I am sorry. I lost
18 track of it.

19 Q No problem. So I was just confirming that when
20 you say that you analyzed impacts of changes to payment
21 rates and risk scores in support of an annual Medicare
22 Advantage payment notice, that what you are referring to
23 is what's also sometimes referred to as the Advance
24 Notice and the final Rate Announcement; is that right?

25 A Yes.

1 Q Okay. And so there is an Advance Notice, as
2 you just mentioned, that's published, correct?

3 A Yes.

4 Q And then there is a period of time for MA Plans
5 and other stakeholders to review and provide comments; is
6 that right?

7 A Yes.

8 Q And that gives CMS some time to review the
9 comments before the final Rate Announcement is announced.

10 A Yes.

11 Q Fair?

12 A I am sorry. Can you repeat the question?

13 Q I think -- yeah, I think you said yes. That
14 just gives CMS some time to review comments before the
15 final Rate Announcement is announced?

16 A I didn't understand the question you just
17 asked.

18 Q I asked whether -- so we talked about there is
19 a period of time for MA Plans and other stakeholders to
20 review and provide comments. You said yes, and I said,
21 and that gives CMS some time to review the comments
22 before the final Rate Announcement is announced? And you
23 said yes, right?

24 A Yes.

25 Q Okay. So, for example, in early February of

1 this year, CMS released the calendar year 2023 Advance
2 Notice. Are you familiar with that?

3 A Can you be more specific on familiar? What do
4 you mean by "familiar" in this context, please?

5 Q Were you aware that in February of this year
6 CMS released the calendar year 2023 Advance Notice?

7 A Yes.

8 Q And comments were due by last Friday, I
9 believe, March 4th. Were you aware of that?

10 A Yes.

11 Q And then the final Rate Announcement is
12 scheduled to be published April 4th, 2022?

13 A The final Rate Announcement must be published
14 no -- no later than the first Monday in April.

15 Q Thank you.

16 So given the time that you were in the role of
17 a health insurance specialist working on the rate
18 announcements, is it fair to say that you were involved
19 in the calendar year 2012 and 2013 MA payment notices?

20 MS. KRIEG: Object to form. Vague.

21 THE WITNESS: Can you restate the question,
22 please?

23 Q BY MS. SCHEFFLER DO: Sure. I said, so looking
24 at the time period that you were in the role of health
25 insurance specialist working on the rate announcements,

1 is it fair to say that you were involved in the calendar
2 year 2012 and 2013 MA payment notices?

3 A What do you mean by "involved"?

4 MS. KRIEG: The same objections.

5 Q BY MS. SCHEFFLER DO: You stated earlier that
6 you analyzed impacts of changes to payment rates and risk
7 scores in support of annual rate announcements, correct?

8 A Yes.

9 Q And did you do that for the calendar year 2012
10 and 2013 MA payment notices?

11 A I know I did it for the 2012 notice. I don't
12 remember when -- quite when I -- I made the -- the
13 change. Sorry. Give me a minute, please.

14 Q Sure.

15 A I believe I worked -- yes, I believe the answer
16 is yes.

17 Q Okay. And then from there you became a
18 director within the Division of Payment Systems, Medicare
19 Plan Payment, which sits within the Medicare Plan Payment
20 Group. Did I get that right?

21 A Yes.

22 Q And you took that position in August 2012?

23 A Yes.

24 Q I may refer to the Medicare Plan Payment Group
25 as MPPG. Is that okay with you?

1 A Yes.

2 Q And you stayed in that role until
3 September 2014, correct?

4 A Yes.

5 Q And as a director within MPPG, you developed
6 payment policy for Medicare Advantage and Part D,
7 correct?

8 MS. KRIEG: Object to form. Vague.

9 THE WITNESS: Can you be more specific, please?

10 Q BY MS. SCHEFFLER DO: Sure. What did you mean
11 by developed payments policy for Medicare Advantage in
12 your LinkedIn profile?

13 A I worked on nonrisk adjustment payment policy
14 for Medicare Advantage and Part D.

15 Q Did you state nonrisk adjustment payment
16 policy?

17 A Yes. That --

18 Q What is that?

19 A That was the role of the division.

20 Q What -- what does that mean, nonrisk adjustment
21 payment policy?

22 A It means the rate book. It means Part D, bid
23 analyses. It means Part D payment. That doesn't involve
24 the risk adjustment model, and it doesn't involve the
25 risk adjustment model with Medicare Advantage or Part D.

1 Q Did you have responsibility for other payment
2 mechanisms in Medicare Advantage Plans such as the coding
3 intensity adjustment?

4 MS. KRIEG: Object to form. Vague.

5 THE WITNESS: Can you be more specific, please?

6 Q BY MS. SCHEFFLER DO: During your time at MPPG,
7 did you have any responsibilities for something known as
8 the coding intensity adjustment?

9 MS. KRIEG: The same objection.

10 THE WITNESS: I don't know what you mean by
11 responsibilities.

12 Q BY MS. SCHEFFLER DO: How would you define
13 responsibilities?

14 A I would define responsibilities as someone that
15 was accountable and -- accountable for -- for something,
16 generally speaking. So somebody who was the lead -- I
17 would say the lead person working on a -- on a topic.

18 Q Okay. Were you the lead person?

19 A Not during the time frame we're -- not during
20 the time frame we're talking, no.

21 Q At -- during any time frame.

22 A During 2005, 2006 to 2007, I worked on coding
23 intensity adjustment studies. And then following that
24 time period I -- I no longer had any -- any
25 responsibility on coding intensity. It was done else --

1 done by other members of the -- the division.

2 Q Okay. How about Risk Adjustment Data
3 Validation audits? Were you familiar with those?

4 A Yes.

5 Q Did you have any responsibilities related to
6 Risk Adjustment Data Validation audits during this time
7 period at MPPG?

8 A No.

9 Q How about at any period?

10 A Any period at CMS?

11 Q Yes.

12 A No.

13 Q But you are familiar with those audits?

14 A Yes.

15 Q And are you familiar with the RADV
16 fee-for-service adjuster?

17 A Are we -- can you define familiar, please.

18 Q I will use the same definition you gave
19 earlier.

20 A Can you remind me what that definition was?

21 Q Sure. It may be faster if you -- if you want
22 to provide your definition of familiar. Otherwise, I can
23 look on this.

24 A I just want to make sure it's consistent.

25 Q Sure. How would you define familiar?

1 A Aware of.

2 Q Okay. Are you aware of --

3 (Speaking simultaneously.)

4 THE WITNESS: Yes.

5 Q BY MS. SCHEFFLER DO: I'm sorry, go ahead.

6 A I would say -- I would define familiar as being
7 aware of something.

8 Q Are you aware of the RADV fee-for-service
9 adjuster?

10 A Yes.

11 Q Do you have -- strike that.

12 You mentioned bids, that you analyzed Medicare
13 Advantage bids and payments and changes in MA payment
14 rates. Is that something you did while at MPPG?

15 A Yes.

16 Q What does analyze Medicare Advantage bids mean?

17 A It meant that I would review the bid data after
18 it was submitted to discern any trends in payments or
19 risk scores or additional benefits in the form of rebate
20 dollars that were being offered by Medicare Advantage
21 Plans, and similarly I think for Part -- for Part D, I
22 think it was. Actually, I don't remember much of the
23 details about the Part D analyses as I think about it.
24 Most of the analyses I can think of were more on the
25 Medicare Advantage side. I may have analyzed Part D

1 data. I just don't remember details of what I did.

2 Q Okay. And you said that you would review the
3 bid data after it was submitted. Would that be before it
4 was approved --

5 A Yes.

6 Q -- with CMS?

7 And you were reviewing it, you said, to discern
8 any trends in payments or risk scores or additional
9 benefits in the form of rebate dollars that were being
10 offered to Medicare Advantage. That's a fair summary?

11 A Yes. And differences in bids by geography or
12 other variation that we might see in bids by plan type
13 perhaps.

14 (Court reporter clarification.)

15 Q BY MS. SCHEFFLER D0: Did you have any role in
16 approving the bids?

17 A No.

18 Q Okay. From MPPG you then became a health
19 insurance specialist at the Centers for Medicare and
20 Medicaid Innovation, correct?

21 A Yes.

22 Q And that's sometimes referred to as CMMI or the
23 Innovation Center; is that right?

24 A Yes.

25 Q And am I right that the Innovation Center

1 develops new payment and service delivery models with
2 CMS?

3 A Yes.

4 Q And you were there from September 2014 to
5 July 2015, correct?

6 A Yes.

7 Q In that role, did you have -- you assisted in
8 the development and implementation of alternative ACA
9 Section 2021 funded models to test value-based
10 arrangements. Can you explain what that means?

11 A I am sorry, there were a couple parts of that
12 question.

13 Q Sure. I am just reading from your LinkedIn.
14 It says you assisted in development and implementation of
15 alternative ACA Section 2021 funded models to test
16 value-based arrangements. I am just trying to understand
17 a little bit more what that means.

18 A "That" is vague to me. What -- what is the
19 "that" that you are referring to?

20 Q I am referring to the -- the line on your
21 LinkedIn profile describing what you did at CMMI that I
22 just read.

23 A The work that I did there was on supporting
24 development of models that would test other ways to pay,
25 whether it's Medicare or -- pay Medicare Advantage Plans

1 or pay other provider types within -- within the Medicare
2 program.

3 Q And did you have any responsibilities related
4 to risk adjustment in that role?

5 A Was I -- are we defining responsibil- -- how
6 are we defining responsibility?

7 Q I guess, so you -- you said that you were
8 assisting with the development in implementation of
9 different types of funded models. I am wondering if risk
10 adjustment was one of those models. Did you play any
11 role with respect to risk adjustment during your time at
12 CMMI?

13 MS. KRIEG: Object to form. Vague.

14 THE WITNESS: It's hard for me to remember how
15 risk adjustment was used in the different models. They
16 may have -- they may have had at moments a risk
17 adjustment in some of the models, but I don't recall
18 specific details around how it was -- what -- what my
19 risk adjustment work would have been at that time as --
20 as it relates to the CMMI models. I just -- I don't
21 recall.

22 Q BY MS. SCHEFFLER DO: Okay. And I -- I promise
23 we are not going to go through your entire background
24 because it's pretty lengthy. I did want to ask about one
25 more role, which was your manager -- when you were the

1 Q Were you involved in any decision-making at CMS
2 around this proposed rule?

3 A No.

4 Q Did you have any roles and responsibilities
5 related to this proposed rule?

6 A Not that I can recall.

7 Q Did you attend meetings on this topic with
8 Whitney Johnson?

9 A It's certainly possible.

10 Q Or with Anne Hornsby?

11 A Excuse me?

12 Q Anne Hornsby.

13 A Yes, it's certainly possible. If I had a role
14 it may have been in reviewing, but I wasn't a lead on any
15 of the content for that rule.

16 Q So what's your understanding of what the
17 proposed rule said?

18 A On -- on what topic? I think it may have said
19 multiple things.

20 Q Specific to medical record reviews.

21 A My recollection was that it required plans to
22 do -- if they were going to do medical record reviews,
23 that they would do two-way reviews.

24 Q And so this was being proposed for the first
25 time in January 2014, right, as part of this proposed

1 rule?

2 A That requirement?

3 Q Yes.

4 A Yes. That's my understanding.

5 Q And were you still at MPPG when CMS ultimately
6 decided not to finalize this rule?

7 A What was the date of the final rule?

8 Q May 23rd, I believe, 2014. It was in May.

9 A Yes.

10 Q And do you have an understanding of why CMS
11 decided not to finalize that rule?

12 A You mean that portion of the rule?

13 Q That portion of the rule. Thank you.

14 A I don't really remember. I feel like they had
15 gotten significant pushback from industry and that was
16 why, but that's about all I remember.

17 Q So CMS at this time, in fact, even as of 2005,
18 knew that MA Plans were conducting medical record reviews
19 to add codes, right?

20 MS. KRIEG: Object to form.

21 THE WITNESS: When you say CMS knows -- knows,
22 what does -- I don't know what that means.

23 Q BY MS. SCHEFFLER DO: That CMS was aware --
24 folks at CMS like yourself, including yourself, knew that
25 MA Plans were conducting medical record reviews to add

1 codes?

2 MS. KRIEG: Object to form. It calls for
3 speculation.

4 THE WITNESS: But you said CMS knows. I
5 don't -- I don't -- I can't speak for what CMS knew or
6 didn't know. I can just speak to what I knew and people
7 that I worked with that were involved in it. And, you
8 know, my understanding from working with Sean and Jeff
9 Grant was that plans were submitting medical records -- I
10 mean, excuse me, plans were submitting diagnoses codes
11 from medical records review and that that was permissible
12 and it was allowed. And I knew that from Tom Hutchinson
13 and Cheri Rice.

14 Q BY MS. SCHEFFLER D0: Cheri Rice. Any others
15 within CMS that you knew that from?

16 A Those are the main people I can remember that I
17 would have learned that from.

18 Q So CMS wanted to require MA Plans to look for
19 unsupported codes to read. That was the purpose of this
20 portion of the rule that we were discussing about medical
21 record reviews, right?

22 MS. KRIEG: Object to form. Calls for
23 speculation.

24 THE WITNESS: My understanding is that CMS was
25 saying if a plan conducted a medical record review, they

1 STATE OF GEORGIA)
)
2 COUNTY OF DEKALB) ss:
3

4 I HEREBY CERTIFY that the foregoing deposition
5 was taken before me; that I was then and there a
6 Registered Professional Reporter and Registered Merit
7 Reporter, License No. 6595-1471-3597-5424 for the State
8 of Georgia, and License No. 14315 in the State of
9 California; that the witness before testifying was duly
10 sworn by me to testify to the whole truth; that the
11 questions propounded by counsel and the answers of the
12 witness thereto were taken down by me in shorthand and
13 thereafter transcribed under my direction; and that the
14 foregoing pages contain a full, true, and accurate
15 transcript of all deposition testimony and proceedings
16 had, all done to the best of my skill and ability.

17 Signature requested.

18 I FURTHER CERTIFY that I am in no way related
19 to, nor employed by any of the parties hereto, nor am I
20 in any way interested in the outcome.

21 DATED at Dunwoody, Georgia, this 21st day of
22 March, 2022.

23
24
25


MARCELLA L. DAUGHTRY, RPR, RMR
GA License No. 6595-1471-3597-5424
CA CSR 14315

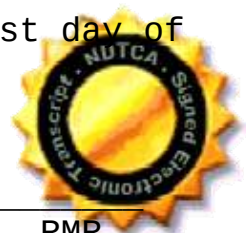


EXHIBIT D-125

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,)
ex rel., BENJAMIN POEHLING,)
)
Plaintiffs,)
) Civil Action No.
vs.)
) 16-08697 FMO
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

* * * * *

HIGHLY CONFIDENTIAL

* * OUTSIDE COUNSELS' EYES ONLY * *
* * * * *

VIDEOTAPED DEPOSITION OF
JULIA M. LAMBERT, FSS, MAAA
Friday, April 5, 2024; 9:11 a.m. CDT

Reported by: Cindy L. Sebo, RMR, CRR, CLR, RPR,
CCR, CSR, RSA, CA CSR 14409, NJ Certified CR
30XI0024460, NJ Certified RT 30XR00019500, NM CSR
589, NY Realtime Court Reporter, NY Association
Certified Reporter, OR CSR 230105, TN CSR 998, TX
CSR 12778, WA CSR 23005926, Notary Public
Job No. 1101160

1 Q. Right. Yep, yep, I agree.

2 Removal of unsupported codes
3 has an impact on the model and would cause the
4 average relative value to increase; is that
5 correct?

6 A. Yes, I can agree with that
7 statement.

8 Thank you.

9 Q. But wouldn't the addition of
10 unsubmitted codes have the opposite effect on
11 the model?

12 ATTORNEY ABASCAL: Object to form.

13 THE WITNESS: The addition of
14 unsupported codes would have the opposite
15 effect to the model, I agree.

16 BY ATTORNEY VOLDMAN:

17 Q. Unsubmitted, correct?

18 A. Unsubmitted.

19 Q. Yeah.

20 A. Yes, thank you. I --

21 Q. I -- I -- I don't know if we want
22 to think of a different phrase for those,
23 but . . .

24 Okay. So -- and -- and this

1 is where I'm a little confused, because
2 wouldn't, like, an accurate model in your
3 recalibration be based off of both removing
4 unsupported and adding unsubmitted codes?

5 ATTORNEY ABASCAL: Object to form.

6 THE WITNESS: Adding unsubmitted
7 codes would be a different study. If you
8 would do that, presumably you would be
9 creating a -- a new data set from the TM
10 data, where the new data set would have more
11 complete coding, potentially being more
12 similar to what is happening in MA. And if
13 you would do that study, you would then need
14 to consider how the CIA is already adjusting
15 for that more complete coding that's in MA.

16 BY ATTORNEY VOLDMAN:

17 Q. Okay. And if you reran this
18 calibration off of the data set you described,
19 removing unsupported and adding unsubmitted, a
20 lot of other things would change, including the
21 Coding Intensity Adjuster, probably; is that
22 right -- or it could change?

23 A. Yeah, you'd have to --

24 ATTORNEY ABASCAL: Object to form.

1 Go ahead.

2 THE WITNESS: -- you would have to
3 look at it and see. It -- it's a very
4 different payment system and calibration at
5 that point, so evaluating actuarially sound
6 payment would involve looking at the whole
7 system, yes.

8 BY ATTORNEY VOLDMAN:

9 Q. And the normalization factor could
10 change; is that right?

11 ATTORNEY ABASCAL: Same objection.

12 THE WITNESS: I just want to make
13 sure I understand what you mean by "the
14 normalization factor."

15 BY ATTORNEY VOLDMAN:

16 Q. I forget its full name. One
17 second.

18 The FSS normalization factor,
19 which you describe on 16.

20 A. And what -- what was the question
21 that I -- I'm hung up on that. So what was the
22 question, then?

23 Q. If the model was recalibrated with
24 both additions of unsubmitted codes and removals

1 codes, taken away codes, recalculated the CIA,
2 recalculated normalization factor -- for a
3 complete opinion.

4 Is there -- do you have a
5 response for why that wasn't necessary?

6 A. My analysis was evaluating how
7 relative values change, and that was important
8 for me to reestablish. It was not necessary and
9 it was not within scope of my analysis to
10 redesign the entire payment system with all of
11 those factors under this hypothetical
12 assumption. It wasn't necessary to my opinion.

13 Q. Okay. Did you work with Dr. Salve
14 on his design of what he sampled at all?

15 A. No.

16 Q. Okay. What about with Dr. Isaacs
17 on how he did the chart review in his expert
18 report?

19 A. No.

20 Q. Going back to your analysis of what
21 you summarized as how removing unsupported codes
22 would affect the relative factors.

23 Is that a fair
24 characterization?

1 A. I -- I had a moment there that I
2 didn't hear the first part of what you said.

3 Can you just say it --

4 Q. Sure.

5 A. -- what did you say?

6 Q. Like, two questions ago, you
7 testified that your analysis had to do with how
8 the removal of unsupported codes go through the
9 model and affects the relative values; is that
10 correct?

11 A. Yes.

12 Q. Okay.

13 What does that analysis or its
14 conclusions have application to this case?

15 ATTORNEY ABASCAL: Object:
16 foundation.

17 THE WITNESS: ASOP 45 indicates
18 that the application model -- the
19 application data -- sorry -- that the
20 development data and the application --
21 application data needs -- need to be
22 consistent and have consistent patterns of
23 coding.

24 If they do not, we may have a

1 problem -- or we do have a problem,
2 especially if that data impacts -- that
3 difference impacts the development of the
4 model. And my analysis shows that those
5 unsupported codes in the TM data do impact
6 those relative values in the current
7 payment system.

8 So it's important, to me, to
9 establish that there is an impact of the TM
10 unsupported codes to the model --

11 BY ATTORNEY VOLDMAN:

12 Q. Okay.

13 A. -- and because it does, you need to
14 figure out how the differences are -- are
15 impacting overall payment.

16 Q. Okay.

17 So you were hired, you know,
18 to provide an expert opinion in this lawsuit by
19 Latham & Watkins or Bartlit Beck, correct?

20 A. Yes, they were -- they engaged us,
21 correct.

22 Q. And with your expert opinion, what
23 are you trying to help the jury understand or
24 work through?

1 ATTORNEY ABASCAL: Object:
2 foundation and form.

3 THE WITNESS: From an actuarial
4 standpoint, I believe it's important to this
5 case that unsupported diagnoses do not
6 necessarily result in overpayments.

7 BY ATTORNEY VOLDMAN:

8 Q. Okay. And I'm focusing on the word
9 "necessarily."

10 Does the presence of
11 unsubmitted diagnoses in the traditional
12 Medicare data have no bearing on that?

13 ATTORNEY ABASCAL: Object to form.

14 THE WITNESS: It -- it seems to be
15 a -- a very different question, but
16 unsubmitted codes resulting -- that result
17 in MA payment having more complete coding
18 and diagnoses than TM data is, from my
19 perspective, handled as part of the CIA.

20 BY ATTORNEY VOLDMAN:

21 Q. So I understand for MA payment.
22 But, I mean, unsubmitted codes in the TM -- in
23 the calibrating data?

24 A. I'm sorry.

1 Then what -- what's the question?

2 Q. What I'm trying to understand is --
3 you're using the unsupported error rate for many
4 of your analyses, and I am trying to understand
5 why that's appropriate as opposed to using some
6 sort of net error rate that includes both
7 unsubmitted and unsupported codes.

8 A. That sort of statement would
9 require me to do an analysis of the CIA, which
10 -- which would then necessitate access to data
11 that I just don't have.

12 Q. Did you request it of your counsel?

13 A. I was -- I didn't ask -- did not
14 ask for that data from my counsel. But doing a
15 study on unsubmitted diagnoses was not necessary
16 for my opinion, so I didn't ask for it.

17 Q. Okay. Do you know how Dr. Salve
18 pulled HCC markers and what he asked for when
19 doing so?

20 A. I have a general understanding of
21 that but not a detailed understanding.

22 Q. Okay. So he identified some number
23 of HCC markers per HCC and asked the
24 United States for the -- the charts that support

1 those HCCs; is that correct?

2 A. As a general matter, yes. I agree
3 with that.

4 Q. Okay. Do you know if he asked for
5 the complete medical records of those
6 beneficiaries or just the medical records that
7 substantiate the HCC in question?

8 A. I don't know.

9 Q. Okay. If he only asked for the
10 records that substantiate the HCC in question,
11 is it possible that other medical records
12 associated with that beneficiary that have an
13 unsubmitted code mapping to that same HCC?

14 ATTORNEY ABASCAL: Object to form.

15 THE WITNESS: So, sorry, there was
16 a lot there.

17 Can you just reask that question,
18 please?

19 BY ATTORNEY VOLDMAN:

20 Q. Sure.

21 ATTORNEY ABASCAL: Do you need a
22 break soon?

23 THE WITNESS: Yeah. We can
24 probably finish this.

1 I, Cindy L. Sebo, Nationally Certified Court
2 Reporter herein, do hereby certify that the
3 foregoing deposition of JULIA M. LAMBERT, FSS, MAAA
4 was taken before me pursuant to notice at the time
5 and place indicated; that said witness duly swore to
6 tell the truth, the whole truth, and nothing but the
7 truth under penalties of perjury; that said
8 testimony of witness was correctly recorded to the
9 best of my abilities in machine shorthand,
10 thereafter transcribed under my supervision with
11 computer-aided transcription; that deposition is a
12 true and accurate record of the testimony given by
13 the witness; that I am neither counsel, nor kin to
14 any party in said action, nor interested in the
15 outcome; and that a copy of this transcript obtained
16 from a source other than the court reporting firm,
17 including an adversary or co-counsel in the matter,
18 is uncertified and may not be used at trial.

19 Cindy L. Sebo
CINDY L. SEBO, RMR, CRR, CLR, RPR, CCR, CSR, RSA,
20 CA CSR 14409, NJ Certified CR 30XI0024460,
NJ Certified RT 30XR00019500, NM CSR 589,
21 NY Realtime Court Reporter, NY Association Certified
Reporter, OR CSR 230105, TN CSR 998,
22 TX CSR 12778, WA CSR 23005926, Notary Public

23
24

EXHIBIT D-126

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *
ex rel, BENJAMIN POEHLING, *
*
Plaintiffs, *
*
VS. * CASE NO:
*
UNITEDHEALTHCARE GROUP, * CV 16-08697 FMO
et al, *
*
Defendants. *
*
* * * * *

VIDEOTAPED 30(b)(6) DEPOSITION OF:

CONNIE LYNN LEONARD,

was held on Friday, May 26, 2023, commencing
at 10:04 a.m., at Latham & Watkins, 555 11th
Street, Washington, D.C., reported by
Barbara Moore, CRR, RMR.

* * *

MAGNA LEGAL SERVICES
866-624-6221
www.MagnaLS.com

1 Q. Great. All right, Ms. Leonard.

2 You understand that you are under oath

3 today?

4 A. Yes.

5 Q. Is there any reason why you

6 cannot testify truthfully today?

7 A. No.

8 Q. Ms. Leonard, because you have not

9 had your deposition taken in this case, I'd

10 like to ask you a few questions about your

11 background so that I can get to know where

12 you fit in the whole architecture.

13 A. Okay.

14 Q. Where do you work currently?

15 A. I work at the Centers for

16 Medicare and Medicaid Services in the Center

17 for Program Integrity. I am the director of

18 the compliance group.

19 Q. Did I hear you say you're the

20 director of the Provider Compliance Group?

21 A. Yes, that's correct.

1 Q. And that is within the Center for
2 Program Integrity?

3 A. Correct.

4 Q. How long have you been the
5 director of the Provider Compliance Group?

6 A. I have been in that current
7 position since November of 2020.

8 Q. What was your job title before
9 you became director of the Provider
10 Compliance Group?

11 A. I was the deputy director of the
12 Provider Compliance Group, and I was that
13 since September of 2013 through November of
14 2020.

15 Q. And before you were deputy
16 director of the Provider Compliance Group,
17 were you with CMS?

18 A. I was, yes.

19 Q. What was your job title before
20 then?

21 A. I was the director of the

1 division of Recovery Audit Operations.

2 Q. Is the division of Recovery Audit
3 Operations part of the Provider Compliance
4 Group?

5 A. It is, yes.

6 Q. And when did you become the
7 division director for the Recovery Audit
8 Operations division?

9 A. 2008.

10 Q. Were you with CMS prior to 2008?

11 A. I was, yes.

12 Q. What was your job title before
13 then?

14 A. Yes, I've been at CMS a long
15 time. Prior to that I was a health
16 insurance specialist in the Financial
17 Services Group.

18 Q. Is the Financial Services Group a
19 different group than the Provider Compliance
20 Group?

21 A. It is, yes, it is.

1 Q. Is it also part of the Center for
2 Program Integrity?

3 A. It is not. It is part of the
4 Office of Financial Management.

5 Q. When did you start as a health
6 insurance specialist in the Office of
7 Financial Management?

8 A. In 1999, and that is when I
9 started at CMS.

10 Q. Can you briefly summarize any job
11 history you had prior to joining CMS in
12 1999?

13 A. I think you're going really far
14 back then. I joined CMS shortly right out
15 of college, so most of my relevant job
16 experience would be at CMS.

17 Q. Where did you go to college?

18 A. I have a Bachelor's from the
19 University of Baltimore and a Master's
20 degree from Loyola College in Maryland.

21 Q. What is your Bachelor's degree

1 we believe the claim is accurate.

2 BY MR. MARTINEZ:

3 Q. And when you say "accurate," even
4 though CMS hasn't reviewed that 99 percent
5 of fee for service claims, is it your
6 testimony that CMS assumes that those
7 diagnosis codes within those claims, the 99
8 percent, have support in the medical record
9 documentation?

10 A. My testimony is that CMS has paid
11 the claim on the face of the claim as passed
12 through the automated edits and the standard
13 claim processing edits, and we have paid the
14 claim with the belief that it is an accurate
15 claim. And that can either be proved true
16 or false upon medical record review, but we
17 are paying the claim on the basis of the
18 claim with the belief that it is accurate.

19 Q. Am I correct that there might be
20 reasons in which CMS pays a claim in the fee
21 for service context that has nothing to do

1 with whether the diagnosis codes are
2 accurate?

3 MS. GLOVER: Objection. Form.

4 THE WITNESS: If I'm interpreting
5 your question correctly, then yes, there
6 certainly could be some claim sites that are
7 not edits, they are algorithms in the
8 automated edits claim processing system that
9 would look at every single diagnosis that
10 would be on every single claim. And so some
11 of those claims could be paid without a
12 review of those diagnosis codes, again on
13 the face of the claim.

14 BY MR. MARTINEZ:

15 Q. Right. So just CMS pays a claim
16 in the fee for service context does not mean
17 that the diagnosis codes in that claims data
18 are accurate?

19 MS. GLOVER: Objection. Form.

20 Out of scope.

21 THE WITNESS: In the provider

1 agreement, providers sign that they are
2 going to submit accurate claims. I am
3 positive that there's more official language
4 than that in the CMS provider agreement, but
5 it boils down to they not only have to
6 submit claims, but they have to keep all
7 necessary documentation.

8 And so there is a belief that
9 providers are doing that when they are
10 submitting claims. And so CMS does take it
11 at face value that providers are, in fact,
12 submitting accurate claims, including
13 diagnosis codes when they're submitting
14 those claims and when we are making payments
15 on them on the face of the claim.

16 BY MR. MARTINEZ:

17 Q. My question was, just because CMS
18 pays a claim in the fee for service context
19 does not mean that the diagnosis codes for
20 that claim are accurate; correct?

21 MS. GLOVER: Objection. Form.

1 Asked and answered. Out of scope.

2 THE WITNESS: I do believe I have
3 answered that question. CMS and the
4 provider have entered into an agreement.
5 Part of that agreement is that they submit
6 accurate information, and CMS is taking them
7 on their word when they go through the
8 claims processing system that these are, in
9 fact, accurate claims, accurate diagnosis
10 codes when they are submitted.

11 BY MR. MARTINEZ:

12 Q. So respectfully, I don't think
13 you've answered my question, because it
14 really calls for a yes or no type of answer.
15 So I'll ask it again.

16 Just because CMS pays a claim in
17 the fee for service context does not mean
18 that the diagnosis codes for that claim are,
19 in fact, accurate; correct?

20 MS. GLOVER: Objection. Form.

21 Asked and answered. Argumentative. You

1 CERTIFICATE OF COURT REPORTER

2 I, BARBARA MOORE, do hereby
3 certify that the proceedings were recorded
4 by me stenographically and electronically at
5 the time and place mentioned on the cover
6 sheet thereof, and, thereafter, transcribed;
7 that said hearing is a true record of the
8 statements made; that I am neither counsel
9 for, related to, nor employed by any of the
10 parties to this proceeding;

11 And further, that I am not
12 financially or otherwise interested in the
13 outcome of this matter.

14 As Witnessed by my hand and
15 signature as indicated below.

16

17

18

19

Barbara Moore

BARBARA MOORE, CRR, RMR

20

21 My Commission Expires: July 31, 2023

EXHIBIT D-127

UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF)
AMERICA, ex rel.) Case No.:
BENJAMIN POEHLING,) No. 16-08697-FMO
Plaintiffs,)
V.)
UNITEDHEALTH GROUP,)
INC., et al.,)
Defendants.)
-----/

CONFIDENTIAL

CONTAINS ATTORNEYS' EYES ONLY PORTIONS

The Videotaped, In-Person, Remote deposition of KIRK LIMMER was held on Wednesday, June 21, 2023, commencing at 10:40 a.m., at the Law Offices of DLA Piper, 650 South Exeter Street, Suite 1100, Baltimore, Maryland 21202 before Susan Wootton, Notary Public.

REPORTED BY: Susan Wootton, RPR, CLR

1 A Yes, I am.

2 Q And then Topic 24, as to Finding
3 Number 1 in the OIG report, you are familiar with
4 it as well?

5 A Yes, I am.

6 Q And you're, likewise, prepared to
7 testify on behalf of CMS --

8 A Yes --

9 Q -- as to that topic?

10 A Yes. I am.

11 Q What is your current position, if any?

12 A I am the deputy director in the
13 Parts C and D Actuarial Group.

14 Q Okay. That's what I thought. For
15 some reason, pay.gov had you as former, which --

16 A I --

17 MS. ZUPAC: That might be news.

18 Q -- which confused me.

19 Okay. So you're the deputy director
20 of the Parts C and D Actuarial Group within the
21 Office of the Actuary?

22 A Correct.

23 Q And the Office of the Actuary is
24 sometimes known as OACT?

25 A Yes.

1 Q Yes. And how long -- how many years
2 have you been the deputy in charge of the Parts C
3 and D Actuarial Group?

4 A I believe I took that role on in 2012.

5 Q Okay. So about 11 years.

6 A Yes.

7 Q And what was your role before 2012?

8 A I was an actuary in the Parts C and D
9 Actuarial Group.

10 Q And how many years were you in that
11 position?

12 A From 2002 through 2012.

13 Q Your responsibilities as deputy
14 director of the Parts C and D Actuarial Group
15 involve overseeing the review of Medicare
16 Advantage Part D bids, correct?

17 A Yeah. Yes.

18 Q And was your work as an actuary,
19 between 2002 and 2012, likewise in connection with
20 the review of Parts C and D bids?

21 A From the inception in 2006, when
22 the -- after the passage of the Medicare
23 Modernization Act.

24 Q So the Medicare Modernization Act
25 introduced the Part D benefit, correct?

1 A Correct.

2 Q And it made some modifications also to
3 the Part C program and how Medicare Advantage
4 plans are paid, correct?

5 A That's correct.

6 Q So it's fair to say that in addition
7 to whatever work you did to prepare for today as a
8 designee, you're personally very familiar with the
9 Parts C and D bidding process?

10 A Yes. I'm familiar with the C and D
11 process.

12 MR. MERON: And your answers -- the
13 answers audible to you?

14 THE REPORTER: Yes.

15 (Overlapping speakers.)

16 THE REPORTER: They could be a little
17 louder.

18 THE WITNESS: Okay. I'll try to speak
19 up.

20 MR. MERON: I confess I'm a little
21 hard of hearing. So that's why I asked. I'm not
22 always the best judge, but thank you.

23 Q Prior to 2002, were you at CMS as well
24 or were you still in school? Where were you prior
25 to 2002?

1 A Prior to 2002, I -- I was working at a
2 consulting firm, working in the retirement
3 industry or retirement community industry.

4 And prior to that I worked for Blue
5 Cross-Blue Shield in Maryland as a -- both of
6 those places -- as an actuary.

7 Q As an actuary? And would your work
8 for the Blue Shield -- Blue Cross-Blue Shield as
9 an actuary have involved, you know, Medicare Plus
10 C or Choice, or whatever name it was currently
11 then known, as Medicare Advantage?

12 A I did not have any role in that -- in
13 that -- those products. My roles were on the
14 commercial products.

15 Q Commercial products. What is your --
16 could you briefly describe to me your post-high
17 school educational history.

18 A Yes. I attended four years at Loyola
19 College here in Maryland, and I have a Bachelor of
20 Science in Mathematics with a concentration in
21 actuarial science.

22 Q Do you have any post-undergraduate
23 degrees?

24 A I've sat for and taken the actuarial
25 exams, and I'm fellow of the Society of Actuaries.

1 I'm also a member of the American Academy of
2 Actuaries.

3 Q And the actuarial exams that you took,
4 were those under the offices of the society or the
5 academy?

6 A Under the society.

7 Q Under the society?

8 A Yes.

9 Q And you're familiar, obviously, with
10 the -- as a member of the American Academy -- with
11 the American Academy's code of conduct, correct?

12 A Correct.

13 Q And one of the principles I know that
14 actuaries have, and are proud of, is that they're
15 required to function with integrity, correct?

16 A That is correct.

17 Q And by that, I mean specifically have
18 some independence from the -- from the goals of
19 the organization they work for, correct?

20 A In general, I don't know if the word
21 "independent" is spelled out in that code of
22 conduct, but yes, we generally act independently
23 and without bias.

24 Q How much time, roughly, would you say
25 you've taken to prepare for the deposition today?

1 population will be, correct?

2 A Yes. A --

3 MS. ZUPAC: Objection to form.

4 A Yeah. Yes. A risk score is
5 calculated from those, from demographic and
6 diagnosis codes.

7 Q So the plan, it might not know what
8 particular conditions a particular beneficiary
9 might have in the -- in the following year, but in
10 order to project its risk score, it must be making
11 some kind of estimation about the health
12 characteristics of the population, correct?

13 MS. ZUPAC: Object to form.

14 A It is making some estimate of the risk
15 scores. I -- I wouldn't classify it as making an
16 assessment of the health conditions.

17 See, the risk score is a product and
18 it's a result of those health conditions. But I
19 wouldn't say that they're -- they're -- they're
20 trying to project the health conditions.

21 They're trying to project the risk
22 scores with the actuary's. So we're talking about
23 the risk score in the Bid Pricing Tool.

24 So the actuary would be focused on
25 what is the calculation of that risk score? So

1 what is the resulting risk score that I expect for
2 that plan, in total?

3 They -- they -- they might not get
4 into assessments of health status or -- directly.
5 I mean, there -- there are -- they do have to make
6 adjustments for population.

7 They may -- I wouldn't know exactly
8 what the particular actuaries, you know, what
9 their focus is. There's a lot of variables that
10 go into that.

11 But I don't think that would be the --
12 that wouldn't be how I would classify it, is
13 they're projecting health status, as much as
14 they're projecting a score.

15 Q Well, the ultimate projection is the
16 total risk score --

17 A Yes. Yes.

18 Q -- correct?

19 A Yes.

20 Q And, as you said, the risk score is
21 going to reflect the sum of both the demographic
22 variables and the health conditions, correct?

23 A Yes.

24 Q So in order to project a risk score,
25 don't I have to be projecting some estimate of how

1 old my population is likely to be, how sick my
2 population is likely to be, all the things that go
3 into what the ultimate risk score is?

4 MS. ZUPAC: Object to form.

5 A So I just want to -- I want to make
6 sure I'm giving the answer that -- that's
7 representative. And I think that also depends on
8 the actuary's model and their choice of model.

9 So the -- the -- I guess it all --
10 what I'm trying to point out is, it depends on the
11 level of detail that they -- they get into on
12 that.

13 They may -- they may choose another
14 population that is similar. If they're -- say,
15 for example, if they're pricing a new population,
16 they could choose another population that's
17 similar.

18 If they -- that -- that population
19 then may or may not require adjustments. And to
20 the degree it requires adjustments, they would --
21 they -- they may need -- yes, they may need to
22 reflect potentially -- you know, potential changes
23 for age and all the other demographic factors that
24 go into it.

25 They -- there -- there's adjustments

1 Q So --

2 A Okay.

3 Q Yes?

4 A So it's basically the plan is
5 representing costs which are lower than the
6 benchmark, and it's the difference between those
7 two.

8 Q And the benchmark essentially
9 represent sort of a -- a cap on how much CMS is
10 going to pay to the plan to cover traditional
11 Medicare benefits, correct?

12 A Essentially, yes.

13 Q I know we covered this before, but
14 just to make sure we're on the same page, and so
15 the plan A/B benchmark is the standardized
16 benchmark times the projected risk score for the
17 plan?

18 A Yes.

19 Q And the plan A/B bid is the
20 risk-adjusted bid?

21 A Yes.

22 Q And then on line 2, it says: Rebate
23 calculated as savings times the rebate percentage.
24 Do you see that? Instructions for line 2.

25 A Yeah. Yes.

1 Q And the rebate percentage, we said, it
2 varies somewhere in the 50 to 75 percent range
3 depending on the year and the quality ratings for
4 the plan.

5 A Yes.

6 Q And if you then turn to page 73,
7 that's Worksheet 6: MA Bid Summary.

8 A Okay.

9 Q On page 74, there's a Section B: MA
10 Rebate Allocation.

11 A Yes.

12 Q And so I think this is what you were
13 talking about before, which is the plan has to
14 take that rebate amount that it calculated and it
15 has to allocate it between these various
16 categories of what we're calling supplemental
17 benefits; namely, reducing A/B cost sharing, other
18 A/B mandatory supplemental benefits; Part B
19 premium buydown, Part B basic premium buydown, and
20 Part D supplemental premium buydown, correct?

21 A Yes. And those are the only options.

22 Q And those are the only options, you
23 said?

24 A Yes.

25 Q Right? And by that, you mean they

1 can't use it for other purposes?

2 A Correct, right.

3 Q And the rebate -- I'm sorry. Strike
4 that.

5 So what the plan needs to do is once
6 it's calculated what the rebate amount is, it then
7 has to -- I'm going to try to get this right -- it
8 has to then design a package of supplemental
9 benefits that has an actuarial value equivalent to
10 the rebate amount it calculated; is that fair?

11 A I don't know if that order or timing
12 would take place. They may design a package --
13 again, this is going to depend on the individual,
14 the plan, and what their goals are in terms of
15 offering benefits and -- and price, of course, it
16 goes out -- those are probably the two biggest
17 considerations for them.

18 But they may develop a package first,
19 then price it through and see what the premium is.
20 In -- in any case there's probably -- and again,
21 this -- I'm not working on their behalf, but
22 there's probably -- it's probably an iterative
23 process of pricing and making adjustments to
24 benefits and/or premiums.

25 Q Okay. Fair enough. So I guess my

1 But the other components of CMS do not
2 extract that information or review it to do their
3 portions of the bid review, correct?

4 A That is correct. I'll just give one
5 stipulation. One thing that I did find is there
6 was -- some of it on the demonstration side,
7 they --

8 There was, at one point, where the
9 demonstration was being implemented -- this is
10 under the Senior Savings Model of 2021 -- so it's
11 out -- I believe it's outside the scope of this
12 time period.

13 But the program was implemented late
14 or -- or close to the bid submission deadline.
15 They did not have a way to collect some
16 information, so some of that information related
17 to that program, under the demonstration, was
18 uploaded to HPMS under -- under pricing supporting
19 documentation.

20 Q I see.

21 A That's -- that's the only thing. But,
22 that was -- again, that was outside of the time
23 period.

24 Q Okay. But within the time period, the
25 material -- the Bid Pricing Tool and the

1 supporting documentation for the Bid Pricing Tool,
2 that material is -- was reviewed only by OACT and
3 not by the other components for purposes of their
4 separate review?

5 A That's correct. That -- that -- that
6 has always been my experience. Plus, in my -- my
7 talking with the other components, I was not able
8 to find anything. I did ask that specific
9 question.

10 Q Okay. Great. So all those different
11 worksheets that we looked at -- that were part of
12 the Bid Pricing Tool -- those are all
13 OACT-specific worksheets that OACT uses as part of
14 its review?

15 A Correct. They are put together by
16 OACT. Helped to -- OACT helps to develop them.
17 OACT prepares the -- the bid instructions that go
18 along with them. And then that's all used
19 strictly in our review.

20 MR. MERON: Let me have the next
21 exhibit. This has already been marked.

22 Q So I'm showing you Exhibit 1076, which
23 is entitled "Care Improvement Plus" of Texas
24 Insurance Company.

25 There's a contract number. And then

1 it says: "MA Supporting Documentation for CY2015
2 Bid, Dated June 2nd, 2014."

3 A Yes.

4 Q Is this one of the documents you
5 reviewed in preparation for today?

6 A This looks -- this looks like the one.
7 I -- I -- I do not recall the word "care
8 improvement," but --

9 I don't know if I looked at that
10 specific part of the title. But this is -- yes.
11 There was a section. Okay. Yes. It looks like
12 it was.

13 Q So before we turn to the substance of
14 it, just so I can understand again the various
15 roles. So on the top of it says: "Index MA
16 Supporting Documentation."

17 And then there's a list of sections.
18 And many of these sections have parentheses after
19 them like WS1, WS4, WS2, WS5, et cetera, right?

20 A Yes.

21 Q So I assume WS is "worksheet"?

22 A That's what I would assume, too.

23 Q Okay.

24 A That -- that is a typical notation
25 that's been -- that's used. WK is also a notation

1 that sometimes --

2 It might not be use in this document,
3 but WK is also a notation we use for -- like,
4 abbreviation for worksheet.

5 Q So looking over the document as a
6 whole -- and if I understand your testimony
7 earlier -- so this is -- this -- to your
8 knowledge, is this MA -- when it says "MA
9 Supporting Documentation," it appears to be MA
10 supporting documentation supporting the
11 information, the pricing information that's part
12 of the Bid Pricing Tool?

13 A Correct. This document here looks
14 very much like what we would see for the
15 supporting documentation of a Bid Pricing Tool.

16 Q So this document -- and, you know, we
17 can spend -- I mean, there's hundreds of MAs --

18 A Yes.

19 Q -- of United plans.

20 A Yes.

21 Q So we submit hundreds of these
22 documents. So we're not going to go through them
23 all.

24 But documents that look like this
25 index, "MA Supporting Documentation" with these

1 A Yes. It's possible. I guess it
2 depends on the circumstances for that particular
3 benefit. I'm not going to say that that's exact,
4 but, yes, that concept is correct.

5 Q Okay. So turning back to 1076. So
6 there's -- on page 6 of the supporting
7 documentation there's a section 9: "Projected
8 Risk for Development WS5." Do you see that?

9 A Section 9? Yes.

10 Q And WS5 is Worksheet 5, correct?

11 A Correct.

12 Q And as we saw, part -- one of the
13 pieces of information you have to supply in
14 worksheet 5 is your projected risk score.

15 A Correct.

16 Q And so what you're looking at are some
17 of the supporting documentation that the plan is
18 submitting to justify its projected risk score,
19 correct?

20 A Yes.

21 Q And then if you turn to page 8, the
22 last paragraph before section 10. Do you see
23 that?

24 A Yes.

25 Q It said: We also adjusted projected

1 risk scores to account for changes in our medical
2 record review processes, specifically based on
3 multiple conversations with CMS and CMS's
4 treatment of medical record review in its
5 reasonable making process.

6 The health plan has decided to cease
7 one of its prior processes that identified and
8 deleted certain diagnosis codes through the
9 medical record review process. Do you see that?

10 A Yes.

11 Q So what this paragraph is saying is
12 that the plan has adjusted its projected risk
13 score to account for cessation of a prior process
14 that identified and deleted certain diagnosis
15 codes, correct?

16 MS. ZUPAC: Object to form.

17 A It says they've decided to cease one
18 of its prior processes that identified and deleted
19 certain diagnoses codes. Yes. It does say that.

20 Q And it also says that it adjusted its
21 projected risk scores to account for that.

22 A It says: We also adjusted projected
23 risk scores to account for changes in our medical
24 review process.

25 Q And then it says: Specifically,

1 we've -- the plan has decided to cease one of its
2 prior processes and delete codes. Correct?

3 MS. ZUPAC: Object to form.

4 A Yes. It does say that.

5 Q And CMS understands, right, that an
6 adjustment to a projected risk score -- to account
7 for cessation of a process to identify and delete
8 diagnosis codes -- would be an upward adjustment
9 in the risk score, correct?

10 MS. ZUPAC: Object to form.

11 Q All else being equal?

12 A So given the -- the brief context of
13 what is provided here, I don't know if I would
14 know the -- the scope of the entire -- the entire
15 change or the magnitude.

16 I think that the -- and there --
17 there's -- there's very little information in here
18 in terms -- to make an assessment on what -- you
19 know, the -- the entirety of what's happening
20 here.

21 This doesn't really state any
22 quantitative assessment. But that's not required.
23 I mean, the Standards of Practice don't
24 necessarily require that the actuary quantify some
25 of these coding things.

1 State of Maryland

2 County of Baltimore, to wit:

3 I, Susan M. Wootton, a Notary Public of the
4 State of Maryland, County of Baltimore, do hereby
5 certify that the within-named witness personally
6 appeared before me at the time and place herein set
7 out, and after having been duly sworn by me, according
8 to law, was examined by counsel.

9 I further certify that the examination was
10 recorded stenographically by me and this is a verbatim
11 transcript of the testimony, as taken stenographically
12 by me, to the best of my ability.

13

14 As witness my hand this _____ day of
15 _____, 2023.

16

Susan M. Wootton

SUSAN WOOTTON

17

Notary Public

18

19 My Commission Expires:

20 June 12, 2027

21

22

23

24

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EXHIBIT D-128

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
 Plaintiff,)
)
 v.)Case No. 16-08697 FMO
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
 Defendants.)
-----)

VIDEOTAPED DEPOSITION OF JOHN N. MARTINEZ, taken on
behalf of Relator BEN POEHLING, at 650 Town Center Drive,
20th Floor, Costa Mesa, California 92626, beginning at
9:48 a.m., and ending at 3:55 p.m., on Tuesday,
August 30, 2022, before Marceline F. Noble, RPR, CRR,
Certified Shorthand Reporter No. 3024.

Magna Legal Services
866-624-6221
www.MagnaLS.com

Reported by:
Marceline F. Noble
CSR No. 3024
Job No. 835287

1 disagreeing.

2 BY MR. VOLDMAN:

3 Q. How was Optum paid for the chart review
4 program that it provided for its clients?

5 MR. RYDBERG: Objection. Vague and lacks
6 foundation.

7 THE WITNESS: I wasn't responsible for the
8 chart review program. So I only know that a -- for
9 each chart that's retrieved, there is a -- there is a
10 dollar amount that is paid for those charts.

11 BY MR. VOLDMAN:

12 Q. Okay. Do you know who was responsible for
13 the chart review program at Optum?

14 MR. RYDBERG: Objection. Vague.

15 THE WITNESS: My understanding at that time,
16 it was Jim Colhour.

17 BY MR. VOLDMAN:

18 Q. Okay. Anyone else?

19 A. Not to my recollection.

20 Q. Okay.

21 A. He is the main person I work with.

22 Q. Did you work closely with Jim Colhour?

23 A. No.

24 Q. Okay. Did you work with anyone at M&R
25 regarding the chart review program?

1 MR. RYDBERG: Objection to form.

2 THE WITNESS: I don't recall working with
3 anyone there --

4 MR. VOLDMAN: Okay.

5 THE WITNESS: -- no.

6 BY MR. VOLDMAN:

7 Q. So back to CV3, how did it interact with the
8 chart review program? 'Cause that's how we got
9 introduced to chart review.

10 MR. RYDBERG: Objection. Vague.

11 THE WITNESS: Are you trying to understand
12 how -- how it -- how CV functioned with it?

13 BY MR. VOLDMAN:

14 Q. Yes.

15 A. So claims verification is a completely
16 separate process, where after the chart review is --
17 is completed, those charts are then moved into the
18 claims verification queue for evaluation purposes to
19 determine if they're eligible for claim verification.

20 BY MR. VOLDMAN:

21 Q. Okay. And we'll go back to eligibility
22 criteria in a little bit.

23 But what happened to charts once they were
24 determined to be eligible for claims verification?

25 MR. RYDBERG: Objection. Vague.

1 THE WITNESS: Yes. There's multiple steps.
2 It's a complex program. But at a high level, charts
3 would be evaluated for eligibility.

4 And if they had what we called a discrepant
5 HCC, which was an HCC that was found on claims but
6 was not found during the coding review, those charts
7 would then be funneled to a human coder for review.

8 BY MR. VOLDMAN:

9 Q. Okay. What would happen if the human coder
10 then didn't find that HCC?

11 MR. RYDBERG: Objection. Vague.

12 THE WITNESS: If the coder didn't find
13 validation for that HCC, that would then be sent to a
14 separate coder under the QA process for CV.

15 BY MR. VOLDMAN:

16 Q. Okay. And what would happen if that person
17 didn't find validation for that HCC?

18 MR. RYDBERG: Same objection.

19 THE WITNESS: The HCC would be marked for
20 delete, disposition in the system, and then sent
21 downstream to a different department.

22 BY MR. VOLDMAN:

23 Q. Okay. What department was it sent
24 downstream to?

25 A. I think the team was called -- I'm going to

1 call it the deletes team. I don't remember what
2 the -- what the term -- the teams change the names a
3 lot. So I'm going to call it the "deletes team."

4 BY MR. VOLDMAN:

5 Q. Sure.

6 Do -- do you recall who worked on the
7 deletes team? Which individuals?

8 A. I do.

9 Q. Can you name some of them?

10 A. Yeah. To my recollection, I remember
11 Rebecca Martin being the main lead there.

12 Q. Okay. Anyone else?

13 A. Not to my recollection.

14 Q. Okay. Did you ever work with anyone at M&R
15 regarding the claims verification program?

16 A. Not directly.

17 Q. What about indirectly?

18 A. I attended meetings where my managers were
19 the lead in those meetings. I just -- I was just an
20 attendee.

21 Q. Okay. Who from M&R was at those meetings?

22 MR. RYDBERG: Objection. Calls for
23 speculation.

24 THE WITNESS: I don't know all of the
25 meetings, but -- actually -- I don't recall actually.

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REPORTER'S CERTIFICATION

I, Marceline F. Noble, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 5th day of September, 2022.

-----*Marceline F. Noble*

Marceline F. Noble, CSR No. 3024

EXHIBIT D-129

**REDACTED VERSION OF
DOCUMENT PROPOSED TO BE
FILED UNDER SEAL**

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

DEPOSITION OF GEORGE MILLS
As 30(b)(6) Designee 3 of
The United States

Washington, DC
September 7, 2023

Reported by: John L. Harmonson, RPR
Job No. 1018234

1 But the question is: How did CMS come
2 up with the 4 percent error rate? And you started
3 the answer by saying I'm putting on my George Mills
4 hat. So I want to get the hats straight here.

5 A. Yeah.

6 Q. Were you describing a conversation you
7 had back in 2009 about this error rate?

8 A. Yeah. They came to me because when I
9 was in PCG, I ran the error rate for Medicare and
10 Medicaid, Medicare fee-for-service and Medicaid.
11 And the error rate the prior year in 2008 was about
12 3.9. That's where they're getting the 4; they're
13 rounding up.

14 Q. So you believe this figure came from a
15 conversation with you where you're describing the
16 Medicare fee-for-service error rate --

17 A. Yeah.

18 Q. -- which you contend is different,
19 apples and oranges as you describe it?

20 MS. McMAHON: Objection.

21 THE WITNESS: It's a lot different.

22 BY MR. ABASCAL:

23 Q. Okay. Do you know who that proposal was
24 made to? "We propose using the FFS error rate."

25 A. I don't know explicitly. I can assume

1 that it was to their group director and other
2 senior leaders above them in CM.

3 Q. Do you believe CMS used the error rate
4 at that time, that 4 percent error rate at that
5 time for any purpose?

6 A. No. And in fact, there is an email from
7 Jennifer Harlow to me talking about their new
8 methodology for figuring out the error rate. I
9 don't know the exact date, but there is an email in
10 2009 from Jennifer to me about it.

11 Q. About this error rate?

12 A. No. About the new --

13 MS. McMAHON: Objection to form.

14 THE WITNESS: -- the new error rate that
15 they're doing.

16 MR. ABASCAL: We've been going about an
17 hour. I usually take breaks every hour. Is that
18 all right with you? I can keep going --

19 THE WITNESS: No, that's fine.

20 MR. ABASCAL: -- but I think everybody
21 probably wants a break.

22 THE WITNESS: Thank you. I appreciate
23 that.

24 MR. ABASCAL: So we'll take maybe a
25 ten-minute break. We'll go off the record.

1 THE VIDEOGRAPHER: Off the record. The
2 time is 10:44.

3 (Recess taken.)

4 THE VIDEOGRAPHER: On the record. The
5 time is 11:02.

6 BY MR. ABASCAL:

7 Q. All right. Mr. Mills, we're going to go
8 on to another exhibit.

9 MR. ABASCAL: This is 2010/1/28, Tab 6.

10 (Exhibit 1505 marked for identification
11 and attached hereto.)

12 BY MR. ABASCAL:

13 Q. So, Mr. Mills, I'm handing you
14 Exhibit 1505. Do you recognize this document?

15 A. I believe I've seen this in the past.
16 Yes, I'm pretty sure.

17 Q. All right. I'm going to draw your
18 attention to the first page of the document, and
19 it's titled "Calendar Year 2007 Risk Adjustment
20 Data Validation, Development of a FFS Adjuster for
21 RADV, Discussion Paper (Draft)." And it's dated
22 January 28, 2010. Do you see that?

23 A. Yes.

24 Q. It says in the top: "Issue. CMS is
25 interested in understanding the difference in

1 ICD-9-CM coding accuracy between Medicare Advantage
2 organizations and Medicare fee-for-service
3 providers. The extent of FFS diagnosis coding
4 error is not known and needs to be established in
5 order to further define payment adjustment
6 estimates."

7 Do you see that?

8 A. Yes.

9 Q. You testified that you had seen this
10 document before. Did you see it in preparation, or
11 do you believe you saw it in the course of your
12 employment?

13 A. No, I'm pretty sure this is one -- it
14 looks very familiar as one of the ones that I was
15 given previously here, not through my own work.

16 Q. Oh, so this would have been for
17 preparation?

18 A. For prep. Not as George Mills, no.
19 This is 30(b)(6).

20 Q. Okay. Looking at the third paragraph,
21 it says: "To accomplish a comparable FFS adjuster,
22 a RADV-equivalent medical record review was
23 conducted to validate risk adjustment diagnosis
24 data reported on Part B FFS claims selected under
25 the CERT audits."

1 Do you see that?

2 A. Yes.

3 Q. Do you believe that took place?

4 A. Yes. I was actually the one that
5 recommended to Jonathan and Jennifer that they use
6 the CERT data to do their study.

7 Q. Why did you recommend that?

8 A. Because the CERT data had already been
9 medically reviewed, and the other advantage is they
10 already had the records in-house and you wouldn't
11 have go out and get it. And they were in
12 electronic format which could be easily provided to
13 the coders that were looking from the RADV -- the
14 risk adjustment perspective. Not getting the
15 records -- not having to go get the records really
16 was a much easier way to do it.

17 The other thing about the CERT sample is
18 it's certified representative of fee-for-service,
19 and it's a systematic random sample and it's
20 representative of the entire fee-for-service
21 population of claims.

22 Q. Okay. Let's draw your attention to the
23 third page of this document. And at the third page
24 it says: "FFS Adjuster Summary. Table 3 below
25 provides different FFS adjusters that resulted from

1 the above-described modeling."

2 Do you see that?

3 A. Yes.

4 Q. And what's described in the chart on
5 page 3?

[REDACTED]

22 MR. ABASCAL: Let's move on to another
23 exhibit, 2010/4/15.

24 (Exhibit 1165 marked for identification
25 and attached hereto.)

1 BY MR. ABASCAL:

2 Q. Mr. Mills, the document we just had gone
3 over was January 28, 2010. I'm handing you now an
4 exhibit three months later which is dated April 15,
5 2010. This is Exhibit 1165. It's an excerpt of
6 the Federal Register.

7 Do you see that?

8 A. Yes. And this is referenced in our
9 chart.

10 Q. And by "chart," you mean it's referenced
11 in the timeline you created?

12 A. The timeline chart, yes.

13 Q. So you had a chance to review it before
14 today's testimony; correct?

15 A. Yeah. The pages referenced here, yes.
16 Yes.

17 Q. Great. We're going to go through those
18 pages, not all of them. Let me start at the
19 beginning. The document is entitled on the
20 left-hand column "Medicare Program; Policy and
21 Technical Changes to the Medicare Advantage and the
22 Medicare Prescription Drug Benefit Programs."

23 Do you see that?

24 A. Yes.

25 Q. And in the "Summary" portion in that

1 first column it says: "This final rule makes
2 revisions..."

3 Do you see that?

4 A. Yes.

5 Q. So this in fact was a final rule issued
6 by HHS; right?

7 A. Yes, that's my understanding.

8 Q. Okay. Let me draw your attention to
9 page 19749 of this final rule.

10 A. Okay.

11 Q. In the middle column, about the center
12 of the page, there is a comment, and I'm going to
13 read from it.

14 "Many commenters from the MA industry
15 recommended that before CMS audit MA organizations
16 under RADV, the agency first account for any error
17 rates inherent in Medicare FFS data that affect MA
18 error rates. These commenters stated that through
19 the proposed RADV audit appeal process, CMS is
20 imposing a set of rules regarding physician
21 recordkeeping that were not anticipated in the
22 ICD-9CM coding guidelines, is not consistent with
23 standard practices and is not enforced on original
24 Medicare claims. The result, they allege, is de
25 facto MA payment adjustments based on recordkeeping

1 discrepancies without an adjustment to original FFS
2 Medicare risk scores for the same recordkeeping
3 discrepancies."

4 Do you see that comment?

5 A. Yes, I see that comment.

6 Q. All right. And could you read for us
7 what HHS responded to that comment in the response?

8 A. Okay. Right under that comment, the
9 response says: "We recognize that there may be
10 potential merit in further refining the error rate
11 calculation. We are currently studying this
12 issue."

13 Q. So you agree that CMS stated publicly
14 that there may be potential merit in the issue
15 described in the comment; correct?

16 A. Yes. On the date that this was written,
17 yes, that was what the thought was.

18 Q. And who approved this statement?

19 A. Well, regs go through a significant
20 internal process where regs are drafted. They're
21 reviewed internally by the component creating it.
22 They go throughout the agency for review. The
23 Office of General Counsel reviews. Then the regs
24 are sent to the department, and then they -- our
25 final approval is through OMB before they're

1 published.

2 Q. So it's a thorough process; right?

3 A. Yes.

4 Q. And it reflects the belief of the agency
5 at the time; right?

6 A. Yes, at the time. Yes.

7 Q. Why did CMS believe that the issue had
8 potential merit at that time?

9 MS. McMAHON: Objection; misstates the
10 document.

11 BY MR. ABASCAL:

12 Q. I didn't mean to misstate the document.
13 So why did HHS believe that the issue
14 had potential merit?

15 MS. McMAHON: Objection; misstates the
16 document.

17 THE WITNESS: Well, it said that we
18 needed to study the issue, that we are currently
19 studying the issue and recognize that there might
20 be merit in the issue. So I don't -- I can only go
21 by what the record shows.

22 BY MR. ABASCAL:

23 Q. All right. When the response says "we,"
24 who is it referring to?

25 A. We, again, as you pointed out, means

1 CMS.

2 Q. And so why did CMS believe it had
3 potential merit?

4 MS. McMAHON: Objection; misstates the
5 document.

6 THE WITNESS: Well, to me, the way I
7 read this is that we're committing to study the
8 issue. I mean, that's exactly what Jon said.
9 That's what Cheri Rice said. That these were
10 comments that they were hearing from the community
11 of stakeholders, and that Jon specifically noted
12 that he thought we had a responsibility to
13 investigate issues that were being raised by the
14 stakeholder community.

15 BY MR. ABASCAL:

16 Q. I understand. But that's not what the
17 document says; right? The second sentence says:
18 "We are currently studying the issue." Right?

19 A. Yeah.

20 Q. But the first sentence says: "We
21 recognize that there may be potential merit in
22 further refining the error rate calculations."

23 My question is why did CMS say that?

24 MS. McMAHON: Objection; asked and
25 answered.

1 THE WITNESS: Well, again, as Jon and
2 Cheri and others had indicated, we recognized that
3 there might be potential merit there, and we were
4 going to study the issue to determine whether or
5 not it really was an issue.

6 BY MR. ABASCAL:

7 Q. So at this point in time, it's fair to
8 say that CMS had not yet decided how to calculate
9 overpayments in RADV; correct?

10 MS. McMAHON: Objection.

11 THE WITNESS: Well, RADV is not -- how
12 the process works in RADV is not something I'm
13 really talking about here today. But potentially
14 the issue was after a RADV audit was completed,
15 whether there should be some discount applied to
16 whatever overpayment is due. That's the concept of
17 the adjuster.

18 BY MR. ABASCAL:

19 Q. Correct. So the concept is when you're
20 doing a RADV audit to determine the amount of
21 overpayment CMS had to determine whether or not it
22 would apply a discount, the FFS adjuster, to
23 determine the overpayments; right?

24 MS. McMAHON: Objection; form.

25 THE WITNESS: Well, yes. That's

1 conceptually the strategy here.

2 BY MR. ABASCAL:

3 Q. And so conceptually, CMS had not yet
4 decided, as you identified, whether or not to apply
5 an FFS adjuster because they said they were
6 currently studying the issue; correct?

7 A. The date here -- yeah, there was study,
8 and we had not made any public statements about
9 whether or not we would actually do one or not.

10 Q. So at this point in time, CMS had not
11 yet settled on the final formula for calculating
12 overpayments under RADV; correct?

13 MS. McMAHON: Objection.

14 THE WITNESS: At this time, there was no
15 final, and at least in my view there wasn't a final
16 one until we did our NPRM in 2018.

17 BY MR. ABASCAL:

18 Q. Okay. So for that entire time period up
19 until 2018, there wasn't a final methodology on how
20 to calculate overpayments under RADV because the
21 FFS adjuster was still pending; correct?

22 MS. McMAHON: Objection.

23 THE WITNESS: The adjuster issue was
24 still pending, and there was a long period of time
25 until the final conclusion was reached, which was

1 in our white paper and subsequent NPRM.

2 BY MR. ABASCAL:

3 Q. And that was in 2018?

4 A. In 2018.

5 Q. So prior to that, it hadn't yet been
6 settled; correct?

7 MS. McMAHON: Objection.

8 THE WITNESS: It hadn't been settled,
9 and there were other issues going on, and even when
10 the white paper was released in 2012 there still
11 was no number or methodology provided.

12 MR. ABASCAL: Let's move on to a
13 different exhibit, 2010/6/22. This is in my Tab 9.

14 Can we go off the record for a second?

15 THE VIDEOGRAPHER: Off the record. The
16 time is 11:18.

17 (Off the record.)

18 THE VIDEOGRAPHER: On the record. The
19 time is 11:19.

20 BY MR. ABASCAL:

21 Q. Mr. Mills, I'm showing you two exhibits,
22 Exhibit 1037 and Exhibit 1348.

23 (Exhibit 1037 marked for identification
24 and attached hereto.)

25 (Exhibit 1348 marked for identification

1 and attached hereto.)

2 BY MR. ABASCAL:

3 Q. I'm going to start with 1037. Do you
4 recognize Exhibit 1037?

5 A. Yes, I'm pretty sure I've seen this
6 before.

7 Q. And would you have seen it in
8 preparation for today, or in the course of your
9 work?

10 A. I'm pretty sure -- well, I know for a
11 fact it's in the course of preparing for today.

12 Q. All right. Exhibit 1037 is a document,
13 a PowerPoint it appears, titled "FFS Adjuster" with
14 the names below that Jennifer Harlow, Lateefah
15 Hughes and Jonathan Smith, dated 6/22/2010.

16 Do you see that?

17 A. Yes.

18 Q. And it appears to be a presentation
19 regarding the fee-for-service adjuster. Do you see
20 that?

21 A. Yes. A PowerPoint presentation, yes.

22 Q. Do you know who this presentation was
23 intended for or presented to?

24 A. I don't know for sure who this was
25 intended for, but I'm assuming that it was somebody

1 above Jennifer Harlow because she's listed as one
2 of the creators.

3 Q. All right. Let's look at Exhibit 1348.
4 If you could turn to that. Do you see Exhibit 1348
5 appears to be the same PowerPoint presentation
6 titled "FFS Adjuster," 6/22/2010? Do you see that?

7 A. Yes.

8 Q. But this version has talking points
9 below that. Do you see that?

10 A. Yes.

11 MS. McMAHON: Objection.

12 THE WITNESS: I see the talking points,
13 yes. And it appears to be the same presentation
14 with PowerPoint notes at the bottom, yes.

15 BY MR. ABASCAL:

16 Q. And I refer to them as talking points.
17 I'll just say they're just words below the slides;
18 correct?

19 A. Yeah.

20 Q. All right. Let me turn your attention
21 to slide 2 on this document. Slide 2, page 2, says
22 "Purpose" at the top. If you look at the second
23 bullet point, it says: "FFS adjuster will be
24 applied to RADV contract-level payment error
25 estimates to address unsupported diagnoses in FFS

1 I stated earlier, I'm assuming that it was somebody
2 above Jennifer Harlow because she was listed as one
3 of the authors so...

4 Q. Do you know what decision -- whether the
5 person above Jennifer Harlow agreed with the
6 recommendation?

7 A. I don't -- I don't have any information
8 one way or another. I didn't see anything that
9 said yes or no. I do know that they did a second
10 study basically using the same methodology but with
11 a much larger universe of claims.

[REDACTED]

[illegible]

[REDACTED]

18 Q. Understood.

19 But this is the methodology that these
20 three individuals at least, Jennifer Harlow,
21 Jonathan Smith and Lateefah Hughes were
22 recommending; correct?

23 A. Yeah. That was the methodology at that
24 time.

25 Q. And you agree that Jennifer Harlow,

1 Lateefah Hughes and Jonathan Smith are honest
2 people; right?

3 A. They're honest people, but they can make
4 mistakes.

5 Q. But they're hardworking; right?

6 A. Yeah, they're all hardworking, very
7 competent people.

8 Q. And they're competent in their jobs;
9 right?

10 A. Yes.

11 Q. And so at the time, these honest,
12 competent people believed the rules should be
13 interpreted to calculate overpayments in the method
14 described on the recommendations page; right?

15 MS. McMAHON: Objection.

16 THE WITNESS: That was the
17 recommendation at the time.

18 MR. ABASCAL: Let's go to 2010/7/27.

19 (Exhibit 1342 and 1343-1 marked for
20 identification and attached hereto.)

21 BY MR. ABASCAL:

22 Q. It's fair to say you believe that was
23 CMS's view at the time; right?

24 MS. McMAHON: Objection.

25 THE WITNESS: That was the

1 recommendation and, from my understanding, that was
2 the belief of a number of people in CM at the time.

3 BY MR. ABASCAL:

4 Q. Not just the three people listed;
5 correct?

6 A. Yeah, I can't give you an exact number,
7 but yes, that would appear to be true.

8 Q. Let's look at another exhibit,
9 Exhibit 1342. Exhibit 1342 is an email from
10 Jennifer Harlow to Jonathan Smith, Cheri Rice,
11 Stacey Deiter and Carolyn Kapustij. Do you see
12 that?

13 A. Yeah.

14 Q. What was Stacey Deiter's role at the
15 time?

16 A. I've never met her, and I've never -- to
17 the best of my knowledge, she wasn't deposed. She
18 appeared to be just a staff member working in DPV.

19 Q. What was Cheri Rice's role at the time?

20 A. I believe at that time Cheri Rice was
21 either the director of the Medicare Plan Payment
22 Group or the deputy director of the Plan Payment
23 Group. Again, I'm not really sure when Tom
24 Hutchinson left; but when he left, Cheri Rice took
25 over that group in CM.

1 Q. If you look at the subject line of the
2 email, it says "RADV FFS Adjuster_MPPGfinal_OFM
3 Briefing." Do you see that?

4 A. Yeah.

5 Q. Was there an OFM briefing around this
6 time?

7 A. I saw documents that there was an email
8 to a gentleman by the name of Ted Doolittle as well
9 as a copy to a gentleman named John Spiegel which I
10 believe had this PowerPoint attached to it. And
11 they were talking about what was going on in the MA
12 world. Well, wait a minute. I'm screwing up.

13 That's OFM. I'm thinking CPI. Sorry.
14 To OFM. Yeah, I'm not sure. It could have been to
15 me when I was in OFM.

16 Q. Okay. Do you remember attending a
17 briefing when you were at OFM on the model
18 calibration packet?

19 A. No. I don't remember ever having a
20 meeting. I remember Jennifer, as we previously
21 discussed, came to me originally and said we're
22 just going to use a fee-for-service error rate as a
23 proxy. And I'm like, well, you're going to have
24 issues.

25 Then they came up with a methodology.

1 And then I remember that she had sent me it. I
2 don't believe I ever responded to it. But I'm not
3 sure who this was to and who they met with.

4 Q. I recall you testifying about Jennifer
5 Harlow coming to you about the fee-for-service
6 error rate as a proxy. But was there a second
7 meeting where Ms. Harlow came to you with a
8 different analysis or methodology?

9 A. It wasn't a meeting. There is an email
10 when they came up with their methodology, that they
11 sent a methodology to me. That's in there. I
12 don't believe I ever responded to it because it was
13 their methodology and I didn't really have any
14 comments on it at the time given my role.

15 Q. Understood.

16 Well, let's look at the presentation
17 that's attached to this July email. The PowerPoint
18 presentation has the same three people listed,
19 correct, Ms. Harlow, Ms. Hughes and Mr. Smith?

20 A. Correct.

21 Q. And the title of it is "Part C Payment
22 Audit: RADV Model Calibration Factor."

23 What is a model calibration factor?

24 A. I've seen this used as another
25 descriptor of the fee-for-service adjuster. To me,

1 to the next page. See "Summary of FFS Error"? Do
2 you see that?

3 A. Yeah.

4 Q. Draw your attention to the last column.
5 It says "998 coded in 2011."

6 Is it possible that the 2011 refers to
7 the same 2009 claims but they were just reviewed
8 again in 2011?

9 A. Carolyn had indicated to me that they
10 had relooked at claims that had been already coded.
11 So that is plausible.

12 Q. But you don't know as you sit here
13 today?

14 A. I didn't get into that detail with them.
15 But yes, that's potentially possible.

16 MR. ABASCAL: Okay. I'm going to turn
17 to another exhibit, Exhibit 1273. It's been
18 previously marked. It's Tab 32.

19 (Exhibit 1273 marked for identification
20 and attached hereto.)

21 BY MR. ABASCAL:

22 Q. I'm handing you now Exhibit 1273. Do
23 you recognize this exhibit?

24 A. Yeah. This is a press release.

25 Q. From February 24, 2012; correct?

1 A. Yes.

2 Q. And the press release is entitled "CMS
3 Takes Steps to Reduce Improper Payments and Save
4 Money for Medicare."

5 A. Yes.

6 Q. All right. I want to draw your
7 attention to that first paragraph. "New audits of
8 Medicare Advantage contracts will reduce the
9 payment error rate for Medicare Advantage program
10 and will recover an estimated 370 million in
11 overpayments for the first audit year."

12 Do you see that?

13 A. Yeah.

■ ■ [REDACTED]
■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]
■ ■ [REDACTED]

[REDACTED]

18 MR. ABASCAL: And then let's go to the
19 next document which is Exhibit 1005.
20 (Exhibit 1005 marked for identification
21 and attached hereto.)
22 BY MR. ABASCAL:
23 Q. I'm handing you a document from the same
24 date, February 24, 2012.
25 A. Yeah.

1 Q. This is titled "Notice of Final Payment
2 Error Calculation Methodology for Part C Medicare
3 Advantage Risk Adjustment Data Validation
4 Contract-Level Audits."

5 Do you see that document?

6 A. Yeah.

7 Q. And have you reviewed this document
8 before?

9 A. Yes. I've seen it many times.

10 Q. And is this the white paper that you
11 were referring to earlier?

12 A. That's the nomenclature that
13 everybody -- how they described it, that this is
14 our white paper, yes.

15 Q. Okay. Who wrote this document?

16 A. My understanding is this was created by
17 MPPG. And the primary author was the Division of
18 Payment Validation; so Jennifer Harlow and her
19 team.

20 Q. And who approved the document?

21 A. Well, to be released, it would have been
22 approved by Cheri and the director of CM at that
23 time. I'd have to refer back and figure out who
24 that was. And then since there is a press release,
25 the press office as well, because this document was

1 attached to the -- as a link to the press release
2 as well as the office of the administrator.

3 So yes.

4 Q. It had several levels of approval;
5 right?

6 A. Yes. At that time, I believe Jon Blum
7 was the head of CM. And I believe Marilyn Tavenner
8 was the administrator in 2012.

9 Q. And they would have approved of this
10 before it goes out?

11 A. Yeah. I mean, with a press release and
12 the rollout, yes, that would have been approved
13 through all levels of CMS.

14 Q. And this is a paper that was the subject
15 of the White House meeting you referred to earlier;
16 correct?

17 A. Yeah.

18 MS. McMAHON: Objection; calls for
19 speculation.

20 THE WITNESS: The issues discussed in
21 this white paper were part of the presentation we
22 went over earlier.

23 BY MR. ABASCAL:

24 Q. In other words, the meeting -- the
25 purpose of the meeting at the White House was to

1 let them know that this paper would be issued;
2 right?

3 A. Yeah. What the agency's plans were for
4 doing RADV audits and this issue of the adjuster.

5 Q. And to make sure the White House had no
6 objection to it; right?

7 A. Yes. Objection and to give them a
8 heads-up of what was coming down the pike. I'm
9 sure that Jeanne -- you know, it would have been
10 one of the many things that Jeanne would have seen
11 from not just CMS but other parties.

12 Q. All right. So a lot of work was put
13 into the process of issuing this document; right?

14 A. Yes.

15 Q. And the document reflects the work of
16 several qualified people in risk adjustment; right?

17 A. Yes. And as I noted, I believe it was
18 produced by MPPG, Division of Payment Validation,
19 yes.

20 Q. And it reflects a considerable amount of
21 work; right?

22 MS. McMAHON: Objection; asked and
23 answered.

24 THE WITNESS: A considerable amount of
25 work and study, and it was based on what was known

1 at the time.

2 BY MR. ABASCAL:

3 Q. In fact, it was several years of work;
4 right?

5 A. Yes. The one thing that Ilina Chaudhuri
6 wanted me to -- or told me about was that there
7 seemed to be an impression in the MA community
8 that, like, this was like the number one issue
9 going on at the agency. This was just one of
10 hundreds of issues. So it was an important issue,
11 but it wasn't, like, the entire focus of every
12 person working in MPPG working on this. This is
13 one of many issues. So there's probably dozens of
14 other issues of similar or -- impact and where
15 plans had opinions one way or another, yes.

16 Q. That's a fair point. I'm not going to
17 get into all the other work that they did there.
18 But with respect to the work reflected in this
19 document, a lot of work at CMS was put into this
20 before issuing it; right?

21 A. Yes.

22 Q. And then let's go to the last page, the
23 second-to-last page, page 4.

24 A. Okay.

25 Q. It says: "Payment Recovery Amount and

1 the Fee-For-Service Adjuster." Do you see that?

2 A. Yes.

3 Q. I'm going to draw your attention to all
4 the language. Maybe it's easier to do it that way.
5 The first paragraph: "If the CI" -- confidence
6 interval. You understand CI stands for confidence
7 interval?

8 A. Yeah.

9 Q. "If the CI for the point estimate
10 includes zero or is below zero, the contract will
11 have the payment recovery amount constrained to
12 zero."

13 Do you see that?

14 A. Yes.

15 Q. So that's explaining how an overpayment
16 would be calculated; correct?

17 A. Yeah. But it's dealing with the issue
18 of where the adjuster is more than the derived
19 error rate for a plan. And it's saying that if
20 it's below zero that it will just be set at zero.
21 So we won't make a recovery, but we won't be making
22 a payment.

23 Q. In other words, if plans are deemed
24 underpaid, they won't be paid any money from CMS
25 under the RADV process; right?

1 A. Yes.

2 MS. McMAHON: Objection.

3 BY MR. ABASCAL:

4 Q. And then the next paragraph. "If the CI
5 for the point estimate is above zero, the payment
6 recovery amount for the contract will be determined
7 as follows. First, a preliminary payment recovery
8 amount will be set at the lower bound of the
9 99 percent CI" -- confidence interval -- "for the
10 contract's point estimate. Second, to determine
11 the final payment recovery amount, CMS will apply a
12 fee-for-service adjuster (FFS adjuster) amount as
13 an offset to the preliminary recovery amount. If
14 the FFS adjuster amount is greater than the
15 preliminary recovery amount, the final recovery
16 amount is equal to zero."

17 Could you explain what that means?

18 A. It's similar to what we're talking about
19 in the first sentence. But again, if the adjuster
20 is more than the final payment or recovery amount,
21 then the amount due from the plan would be zero.

22 Q. All right. And in addition, above that,
23 it specifies that if there is an overpayment amount
24 calculated, then the fee-for-service adjuster will
25 offset or reduce that overpayment. Correct?

1 A. Yes. So -- yes. So if the error rate
2 was 10 percent and the adjuster was 8.1, then the
3 amount due would be 1.9 percent of the extrapolated
4 amount, if that's what the lower bound of the
5 confidence interval suggested.

6 Q. And it says here that CMS will apply an
7 FFS adjuster. Right?

8 A. Yes, it does indicate that.

9 Q. Now, it later says at the last part of
10 the page: "The FFS adjuster accounts for the fact
11 that the documentation standard using RADV audits
12 to determine a contract's payment error (medical
13 records) is different from the documentation
14 standard used to develop the Part C risk adjustment
15 model (FFS claims)."

16 Do you understand that's the rationale
17 behind the adjuster?

18 A. Yes. Yeah, they said that many times.
19 Yes.

20 Q. And you've seen that reflected in the
21 documents many times?

22 A. Yes. In the talking points as well.
23 Yes.

24 Q. And then it goes on to say: "The actual
25 amount of the adjuster will be calculated by CMS

1 based on RADV-like review of records submitted to
2 support FFS claims data."

3 Do you see that?

4 A. Yes.

5 Q. So that indicates that CMS would
6 calculate an FFS adjuster in the future; right?

7 A. Yes. And we had already calculated
8 several, and we talked about it. But that amount
9 was not shown in this document, nor any other
10 amount. It was that we're still going to study and
11 develop a fee-for-service adjuster.

12 Q. Why didn't CMS announce the 7.8 or the
13 4.88 figure?

14 A. Well, I talked to Cheri -- well, Carolyn
15 and Cheri and Jon Blum and I asked them. And they
16 all felt that this is a very complicated matter and
17 they wanted to be dead sure that whatever number we
18 eventually issued was rock solid and completely
19 supportable.

20 And Jon indicated to me he didn't feel
21 like at that time that it was. And that later
22 turned out to be prophetic because it was
23 completely wrong. And -- the 4.88 and 8.1. So we
24 would really be in a sticky wicket if we would have
25 announced an adjuster at that time and then had to

1 walk it back.

2 MR. ABASCAL: Okay. So let's go to a
3 different document. Tab 35.

4 (Exhibit 2002 marked for identification
5 and attached hereto.)

6 BY MR. ABASCAL:

7 Q. I just want to clarify something. I was
8 just looking at your testimony. Just going back to
9 the prior document --

10 A. Okay.

[REDACTED]

[illegible]

[REDACTED]

23 Q. Was CMS contemplating allowing plans to
24 apply their own FFS adjuster when they're doing
25 their own self-audits as reflected here?

1 A. This is something that I don't believe
2 was ever taken beyond whatever is in this document.
3 I've never seen any comments like that or any kind
4 of verbiage insinuating that. To me, I read it as
5 if the plan verifies the data is accurate, then
6 we'll apply an adjuster to the risk score, as
7 opposed to the plan creating its own risk score. I
8 don't see that here.

9 Q. Fair enough. I wasn't suggesting the
10 plan would create its own FFS adjuster. But what
11 I'm asking is did CMS contemplate the plans doing
12 their own self-audits would apply the FFS adjuster
13 as determined by CMS?

14 A. Well, I'm not exactly sure that that's
15 what this means. I don't read it necessarily that
16 way.

17 Q. Would you read CMS applying the FFS
18 adjuster, then?

19 A. Well, to me, I read this as that the
20 plans have some validation protocol that they do
21 that somehow determines that their submissions are
22 accurate. And if they met that threshold, then a
23 fee-for-service adjuster would be applied against
24 any balance due.

25 Q. Okay, fair enough. And the

1 fee-for-service adjuster would be applied by CMS?

2 A. Yeah. It's part of that.

3 What I don't know is -- I know in other
4 documents, there was discussion about, like,
5 voluntary refunds and deletions and about whether
6 there should be an adjuster applied to them or not.
7 I don't know if this is applicable to that.

8 Q. Could you explain that in more detail?
9 What do those other documents say about applying an
10 FFS adjuster to voluntary refunds and deletions?

11 A. Well, that was a question, like
12 people -- and I can't remember whose it was. There
13 was an issue about if somebody issues a voluntary
14 refund, would there be a fee-for-service adjuster
15 applied to that based on their own -- you discover
16 a problem and then you do it. It's very similar.

17 I think it was in the document that
18 talked about what do we do if the number comes up
19 under zero.

20 Q. Around what time was that concept being
21 considered within CMS?

22 MS. McMAHON: Objection; misstates the
23 witness's testimony.

24 THE WITNESS: Well, off the top of my
25 head, I can't remember the document that I saw it

1 in or where this came up. But I believe it was
2 like post 2012.

3 BY MR. ABASCAL:

4 Q. Post 2012 and before 2018?

5 A. Yes.

6 Q. And was that document in reference to
7 voluntary refunds and deletions?

8 A. I believe it was more towards voluntary
9 refunds, because it's an identified overpayment by
10 the plan being returned and whether or not an
11 adjuster should apply to that.

12 Q. And was there a similar document you saw
13 or other conversation you heard about regarding
14 deletions?

15 A. No, not related to deletions. I don't
16 recall that.

17 Q. So you testified there was an issue
18 about if somebody issues a voluntary refund, would
19 there be a fee-for-service adjuster applied to
20 that.

21 Just to expand on that, so by voluntary
22 refund you mean an overpayment; correct?

23 A. Yeah. If a plan found that they
24 submitted an HCC incorrectly and they wanted to
25 correct it, what would be the outcome and whether

1 there should be an adjuster applied.

2 Q. And so in the plan's return of an
3 overpayment, the issue was whether the adjuster
4 should be applied to that overpayment; correct?

5 A. Yeah, because it's an overpayment. An
6 overpaid in RADV, it's -- that's my understanding
7 that's where it was.

8 Q. And where did CMS come out on that?

9 A. I never saw anything related to that in
10 a final like there was on the negative number, but
11 at the end of the day where we ended up, that's all
12 a moot point anyway.

13 Q. But it was being discussed during the
14 time period between 2012 and 2016 -- 2018?

15 A. Yeah, I remember it coming up in some
16 context, either a document or a deposition.

17 Q. And CMS hadn't settled on that prior to
18 2018; right?

19 A. I didn't see much discussion of that.
20 There was more discussion of the negative number
21 after applying the adjuster when the plan error
22 rate was less.

23 Q. And the discussion of the negative
24 number meaning if there is an underpayment. Is
25 that what you mean?

1 A. Yeah. If the plan's extrapolated
2 overpayment is less than the fee-for-service
3 adjuster, should we make a payment to the plan.

□ □ □

□ □ □

[REDACTED]

■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]
■ [REDACTED]

8 Q. Okay. All right. And there was never a
9 decision published that you would not do that;
10 right?

11 MS. McMAHON: Objection; form.

12 THE WITNESS: Not until -- not until we
13 issued the white paper and the NPRM in 2018.

14 BY MR. ABASCAL:

15 Q. 2018.

16 A. We would not do any adjuster, which
17 would make that whole issue moot.

18 Q. Okay. But nothing prior to that 2018
19 NPRM; right?

20 A. No.

21 MS. McMAHON: Objection; form.

22 MR. ABASCAL: Let's move on to a
23 different document, 2017/1/10. This is Tab 46.

24 (Exhibit 1510 marked for identification
25 and attached hereto.)

1 BY MR. ABASCAL:

2 Q. I'm showing you what has been marked as
3 Exhibit 1510, Mr. Mills. This is an email from
4 Monica Reed-Asante to Phillip Steiner. Do you see
5 that?

6 A. Yes.

7 Q. Dated January 10, 2017?

8 A. Yes.

9 Q. Is this a document you reviewed in
10 preparation for today?

11 A. I've seen this, and I talked to Phil
12 Steiner.

13 Q. The attachment -- on the email, the
14 attachment is described as "Reasons for a FFS
15 adjuster." Do you see that?

16 A. Yes.

17 Q. All right. And then the attachment
18 says -- it has a one-page paper with the title
19 "Reasons for a FFS adjuster." Do you see that?

20 A. Yes.

21 Q. I'm going to read from Paragraph 1.
22 "The FFS adjuster is intended to account for
23 payment inequities that result from enforcing a
24 different documentation standard between MA and
25 FFS. While FFS does not audit diagnoses submitted

1 on claims against the medical records, the medical
2 record is enforced as the standard in MA, and total
3 payments in MA are lower than they might be if the
4 claim was used. MA plans are arguing in United
5 States v. Burwell that requiring the medical record
6 to be the standard by which MA plans should
7 identify and return overpayments violates the
8 requirements of actuarial equivalence."

9 Do you see that?

10 A. Yes, I do.

11 Q. What influence did that lawsuit cited,
12 United States v. Burwell, have on CMS's decision
13 regarding the FFS adjuster?

14 MS. McMAHON: Objection; calls for
15 speculation. And to the extent the question calls
16 for any information protected by the
17 attorney-client privilege, I would instruct you not
18 to answer.

19 THE WITNESS: Well, I don't agree with
20 sentence 2 completely, because we do look for
21 diagnoses on claims and compare it to the medical
22 records when we do medical review. Because there
23 are LCDs that require you to have certain diagnoses
24 as requirements for payment. So that's not
25 completely accurate. I mean, it's an

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that GEORGE MILLS, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 11th day of September, 2023.

19

20

21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT D-130

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

CONFIDENTIAL
Videotaped Deposition of
JONATHAN DANIEL MORSE
Given Remotely
Wednesday, August 17, 2022
10:09 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 correct?

2 A. Yes.

3 Q. And who is that?

4 A. Jenny Koh. Jenny Koh. Sorry. Last name
5 wrong.

6 Q. And -- and you did not discuss this with
7 any other counsel in connection with the deposition?

8 A. No.

9 Q. Okay. If you could start by just
10 describing what post-secondary educational degrees
11 you have.

12 A. I have a juris doctor from the University
13 of Maryland.

14 Q. And so you're -- and then -- and you are a
15 member of the bar, correct?

16 A. No, I am not. Not any longer, no.

17 Q. Were you a member of the bar at one point?

18 A. Yes. I do not -- I have not kept up with
19 my bar license, though. I do not practice at all. I
20 do consulting now.

21 Q. I see. Okay.

22 And then you have an undergraduate degree
23 as well, I assume?

24 A. I do. From Union College.

25 Q. Union College. And what -- what field is

1 that?

2 A. Political science.

3 Q. Political science. Do you have any
4 training as an actuary?

5 A. I do not.

6 Q. Do you have any training in advanced
7 statistics?

8 A. No, I do not.

9 Q. How about in advanced math?

10 A. I do -- I do not.

11 I laugh because I went to law school to
12 avoid math. So no, I do not.

13 Q. I -- I confess to have made the same
14 decision myself, so -- not surprising among our
15 profession. But I guess we'll stumble through it.

16 A. Right.

17 Q. What is your current employment?

18 A. I am the managing director and senior vice
19 president for Mathematica Policy Research, and I run
20 their health policy consulting practice.

21 Q. And how large a company is Mathematica?

22 A. About 1,600 people total.

23 Q. And how large is the health consulting
24 division?

25 A. It's about 700.

1 Q. And you said you run that 700-person
2 division?

3 A. I do.

4 Q. And you've been there since May of 2018;
5 is that correct?

6 A. That's correct.

7 MR. MERON: If we could upload Tab 36,
8 please.

9 BY MR. MERON:

10 Q. I am showing you what we're marking as
11 Exhibit 1278.

12 (Exhibit 1278 was marked for identification.)

13 BY MR. MERON:

14 Q. And this is a printout, I would say -- if
15 that's the right word, since we're looking at it
16 virtually -- of your LinkedIn profile?

17 A. That's correct.

18 Q. The -- under "Mathematica," it says
19 that -- well, the first sentence says, "Jonathan
20 leads all aspects of Mathematica's 400-plus-person
21 health care consulting practice, providing strategic
22 direction, capture priorities, and leading budget
23 development."

24 A. Mm-hmm. That's correct.

25 Q. And that correctly describes your

1 functions, correct?

2 A. That does correct -- that is correct.

3 Q. Mathematica's health consulting practice
4 provides policy expertise and program implementation
5 for federal, state, and private sector clients,
6 including Centers for Medicare and Medicaid Services,
7 and state Medicaid agencies. The division focuses on
8 Medicare and Medicaid data analytics and
9 recommendations, development and implementation of
10 payment reform models, development of quality
11 measures, and technical assistance on a variety of
12 client initiatives." Correct?

13 A. That is all correct.

14 Q. Is CMS a significant client of yours at
15 Mathematica?

16 A. Yes, they are.

17 Q. Do you have a rough sense of the dollar
18 value, of the annual dollar value of the relationship
19 with CMS?

20 A. Yes, it's about \$150 million a year,
21 total.

22 Q. And that's just CMS?

23 A. That is correct. Just CMS.

24 Q. And do you have a rough sense of, if you
25 can, of how much that relates to Medicare versus

1 Medicaid?

2 A. Yeah, we have about -- in terms of dollar
3 value, the Medicaid practice is roughly \$90 million a
4 year. And then Medicare is divided up largely
5 through the Centers for Clinical Standards and
6 Quality and the Center for Medicare and Medicaid
7 Innovations, CMMI. Those two centers at CMS
8 represent probably 40ish million a year each.

9 Q. And what proportion of the work for those
10 two centers involve issues relating to Medicare
11 Part C, or Medicare Advantage?

12 A. None for those two centers. But --

13 Q. Okay.

14 A. -- CCSQ and CMMI don't -- don't really
15 touch MA.

16 Q. Okay. Are the work -- I thought you were
17 saying that the work -- consulting work you do for
18 CMS focuses on those two centers. Do you do any
19 consulting work, does Mathematica do any consulting
20 work for CMS related to Medicare Advantage at all?

21 A. Yes. We have one project that relates to
22 doing studies of beneficiary like outcomes and
23 experience. It's a policy project where, for
24 example, we will look at impacts on, you know, the --
25 the relative impacts on COVID, as people who are

1 experienced -- who are enrolled in Medicare
2 Advantage, as per se people who are in Medicare fee
3 for service.

4 We are currently doing a study for Center
5 for Medicare on health equity issues, you know, and
6 how those relate to enrollees in the Medicare
7 Advantage programs.

8 Q. Got it. And I think you testified that
9 the -- that the dollar value of the CMS relationship,
10 annually, is about 150 million, correct?

11 A. That is correct, yes.

12 Q. And how does that compare to the total
13 value of the -- of the consulting division's overall
14 book of business?

15 A. It -- yeah, it's the vast majority of it.
16 It's about 200 million total, on an annual basis,
17 right now. The practice, I would just say, to be
18 able to get the -- my LinkedIn, just to provide -- I
19 haven't updated my LinkedIn in quite some time. So
20 the -- this is showing 400-plus people, as I'm
21 looking at it right now; we're at about 680 at the
22 moment.

23 So this is -- in the last like three to
24 four -- in the last like three years or so has
25 expanded dramatically, and that work largely has

1 expanded through Centers for Medicaid and CHIP
2 Services. So we are -- the majority of the work
3 comes out of CMCS right now, within -- within CMS,
4 but it is proximal to -- yeah, 150 out of the
5 \$200 million a year, so roughly 75 percent of the
6 work, total.

7 Q. Got it. And the -- it says here on
8 your -- the last sentence of your LinkedIn, that
9 your, you lead the division in key operations,
10 including developing client relationships. Right?

11 A. Yes. That is correct.

12 Q. And that includes what lawyers would call
13 business development?

14 A. That is -- yes, that is exactly right.

15 Q. And so it means, you know, bringing in
16 contracts, securing business. Correct?

17 A. Yes.

18 Q. And your -- is it reasonable to assume
19 that your compensation depends -- or is impacted, at
20 least in part, by your success in developing client
21 relationships?

22 A. My compensation is contingent upon the
23 division's, writ large, performance from year to
24 year. It is not contingent upon my individual client
25 interactions, relationships, work that I personally

1 bring in.

2 It is a -- I don't know, slightly
3 socialist. It is -- you know, it is --
4 proportionally we all benefit from how well the
5 division does as a whole. It is not tied to any of
6 my individual performance in terms of client
7 relationships in business and all that.

8 Q. But the -- it's fair to say the more work
9 you get from CMS, the more --

10 A. The more --

11 Q. -- better off --

12 A. The more work we get through CMS or any
13 other client, the more work we -- the more money we
14 make; kind of like any other -- you know, whether
15 you're an attorney or a consultant. Yes, that's
16 correct.

17 Q. Okay. Does Mathematica do any consulting
18 for the Department of Justice?

19 A. We do not.

20 Q. Do you do any consulting work for any law
21 firms that represent plaintiffs, or --

22 A. We do not.

23 Q. You don't do any -- no law firm clients?

24 A. We -- we do not. The entire -- just for
25 clarification, the company does both Health and Human

1 Services work, and we have a small international
2 practice. So the vast majority of the work that we
3 do -- as, again, in health out of, you know, 1,600
4 people, we've given the administrative staff that are
5 not client-facing; you know, roughly 700 them of
6 are -- are in -- in health care in some way, whether
7 that is for CMS or CDC or state Medicaid agencies.

8 And then we do work for like Department of
9 Labor, Department of Education, foundations. But
10 there is nothing within the Justice Department or --
11 or any kind of law enforcement, you know, arm, or
12 legal cases that we do.

13 Q. Or providing expert services to law firms?

14 A. Correct. That's correct.

15 Q. And according to LinkedIn, before you
16 assumed your current position at Mathematica, you
17 were the -- between December of 2016 and April of
18 2018, you were the acting deputy administrator and
19 center director for the Center for Program Integrity,
20 correct?

21 A. It is. It's a little weird the way
22 LinkedIn -- sorry, I'm just reading this -- going
23 back to do this -- it's a little weird the way
24 LinkedIn allows me to do this, because they -- yes,
25 roughly the dates are right.

1 The political appointee from the Trump
2 administration took over in March of 2018. So at
3 that point between March and May reverted back to
4 being the deputy center director, but -- yes, I mean,
5 the dates are pretty close. That's correct.

6 Q. So you -- you were the -- designated the
7 principal deputy for CPI, and under the Vacancies
8 Act, you assumed the role of acting director --

9 A. That --

10 Q. -- when there was a vacancy in the full --
11 in the full position, in the head position, correct?

12 A. That is correct, yes.

13 Q. And -- and normally the head position is a
14 political appointee?

15 A. In -- yes, although in this administration
16 it is not. In the Biden administration, it is not.
17 Prior to that, it has been, yes.

18 Q. Got it. Now, it says you were also the
19 acting deputy administrator; is the director --

20 A. Yeah, the title -- I'm sorry. The title
21 is -- technically it is acting deputy administrator
22 and center director. And that is -- with -- without
23 regard to which center.

24 So you could be acting deputy
25 administrator for Center for Medicare, Center for

1 Medicaid, Center for Program Integrity. It's
2 just sort of -- it's the full job title.

3 Q. In other words, whoever heads a given
4 center within CMS is -- by virtue of that, also holds
5 the title of a deputy administrator of CMS?

6 A. That is correct, yes.

7 Q. And it says underneath here, one of your
8 functions, reading down, is that you represented the
9 agency "to the White House, members of Congress, and
10 health care stakeholders to address inquiries on
11 program integrity and improper payments." Correct?

12 A. That is correct.

13 Q. And what does the words "program
14 integrity" mean to you?

15 A. Program integrity is -- I'm sorry. I have
16 to toggle back to the screen.

17 Program integrity, for me, is a broad
18 catch-all for sort of fraud, waste, and abuse; like
19 oversight and operations. And so it's sort of any of
20 those -- any of those three.

21 Q. I apologize. My computer has gone to
22 sleep here. Give me a second.

23 A. That's okay.

24 Q. You said it's -- it's a broad catch-all
25 for fraud, waste, and abuse, oversight and

1 operations?

2 A. That's correct. And in -- yes. In the
3 CMS setting, that is -- that is how we -- yes.

4 Q. And how is that distinguished from the
5 phrase "improper payments"?

6 A. Part of.

7 MS. KOH: Objection. Form.

8 Go ahead.

9 THE WITNESS: Sure.

10 The -- the improper payment is a part of
11 program integrity, and a part of sort of broader
12 fraud, waste, and abuse. It is -- you know,
13 part of the duty of the Center is to ensure that
14 the programs and that the federal government are
15 accurately paying, whether it is providers,
16 plans, you know, the -- the stakeholders who are
17 receiving payment from the -- you know, from the
18 Medicare and Medicaid program, or from the
19 marketplace.

20 And improper payments can sort of happen
21 in -- without regard to any -- what's the word
22 I'm looking for? Without regard to attribution.

23 You know, if the payment isn't proper, you
24 know, CMS is -- program -- the department of
25 program integrity role is to ensure that the --

1 the organization, then, is -- is making sure
2 that the payments to the different sort of plans
3 and providers are as -- are as proper as
4 possible.

5 And often those little -- the vast
6 majority of times, that comes under a fraud,
7 waste, or abuse heading, without sort of
8 ascribing one or the other necessarily.

9 BY MR. MERON:

10 Q. Would it be fair to say that a payment
11 that is a result of fraud, waste, and abuse -- or let
12 me -- let me break that down.

13 A payment that is a result of fraud would
14 necessarily be improper, correct?

15 A. Yes, it would.

16 Q. But not all improper payments are a result
17 of fraud, correct?

18 A. Absolutely right. That is the -- in many
19 ways the crux of the entire organization of the
20 Center for Program Integrity, yes. Because the very,
21 very small -- statistically speaking, a very, very
22 small proportion of payments being made by any of
23 these programs are actually attributable to fraud.

24 Q. And so when you said it's the crux of the
25 work that CPI does is to try to ferret out and

1 identify what subset of errors are fraud and what
2 are -- are simple mistakes?

3 A. Actually -- it actually is --

4 MS. KOH: Objection.

5 THE WITNESS: Sorry. Go ahead.

6 MS. KOH: Let me just -- objection. Form.
7 Go ahead.

8 THE WITNESS: Okay. Just to clarify, not
9 exactly. And I think this is -- it is important
10 to distinguish just on the -- for the purposes
11 of the role.

12 Only the Justice Department may -- can
13 make a determination as to whether or not
14 something is fraud. Because fraud involves
15 intent, and that is outside the purview of an
16 administrative agency.

17 So the Center for Program Integrity looks
18 at improper payments, to your point, writ large;
19 and then makes determinations as to like where
20 do they go for -- for their review, if they need
21 to be reviewed in any way beyond that.

22 BY MR. MERON:

23 Q. And in order to do your work of focusing
24 on improper payments, the Center has to be in a
25 position to determine what a proper payment is,

1 correct?

2 A. That is correct, yes.

3 Q. And so in your role of directing that
4 Center, you had a pretty good familiarity with the
5 basic requirements that applied to payments under the
6 various Medicare programs, correct?

7 MS. KOH: Objection. Form.

8 THE WITNESS: Yes, we do.

9 BY MR. MERON:

10 Q. So reading further on in LinkedIn, it says
11 that -- under -- under your description as the acting
12 director, it says, "Specific areas of oversight
13 include Medicare and Medicaid provider enrollment,
14 Medicare and Medicaid improper payments"; so
15 that's -- improper payments is the subject we just
16 talked about, correct?

17 A. That's correct.

18 Q. "Investigations." What was your oversight
19 role with respect to investigations?

20 A. Sure. The Center for Program Integrity
21 has -- a fairly large part of the organization is
22 called the investigations and audits group. And they
23 contract with zone program integrity contractors --
24 or ZPICs, the acronym -- to do investigations on
25 individual providers -- this is all through Medicare

1 fee for service -- where there may be a false
2 storefront. You know, essentially over like data
3 analytics for, you know, billing that is, you know,
4 for social security numbers that have been, you know,
5 made up or stolen.

6 Or schemes of, you know, potentially
7 clusters of billing that are really abnormal, and
8 that sort of show spikes of -- of billings. So
9 there's -- investigations that play out in a -- in a
10 variety of ways, using a variety of tools, whether
11 that is on the ground, and -- you know, somebody
12 knocks on the door, but you're a medical supplier
13 storefront, and it -- there's nothing there; right?
14 But yet they're billing to the Medicare program.

15 And some of it is done behind the scenes,
16 through like data analytics and sort of running
17 algorithms.

18 Q. And I think you said the investigations
19 work you do there, oversee with contractors related
20 entirely to fee for service? There was no --

21 A. That -- for -- for those programs, the
22 investigations in that way is done through Medicare
23 fee for service, because it's sort of the direct line
24 that CMS has into sort of control the program.

25 For -- for Medicaid, Medicaid is -- has

1 broad oversight at the federal level, but it's
2 actually implemented at the state level. So just
3 differentiating, to your -- to make the point, in the
4 Medicaid program, the investigations actually would
5 happen in conjunction and are driven by the states,
6 and are -- then the information is essentially fed
7 or -- or identified by CMS, eventually, through --
8 you know, again, through data.

9 But it's then operationalized or
10 investigated by, you know, the state, the -- what's
11 called the Medicaid fraud control unit. So --

12 Q. I'm sorry to stop you, but this is the --
13 the risk of when we -- when we -- don't let me
14 complete a question. I actually --

15 A. I'm sorry.

16 Q. -- was not interested in asking about
17 Medicaid. I apologize.

18 A. All right. Okay.

19 Q. I was asking -- I was -- when you said
20 "fee for service," I was distinguishing between
21 fee-for-service Medicare versus Medicare Advantage,
22 and asking whether there were any investigations-type
23 work that you oversaw relating to Medicare Part C.

24 A. Not to my knowledge -- not to my
25 recollection, no.

1 Q. And how about Medicare Part D?

2 A. No. Investigations would be -- is not the
3 correct word. I think there was some -- you know, we
4 did some -- I'm trying to think -- this is -- you
5 know, there is -- we had some interaction on Part D,
6 where the program -- you know, the -- or CPI was
7 working with the Part D drug plan to identify
8 potential sort of overpayments in, you know, in the
9 differences between -- you know, basically, we tried
10 to identify sort of overpayments in the Part D
11 program. But they were not investigations. They
12 were self-audits. So the -- "no" to the word --
13 "no," to the investigations.

14 Q. But the -- the work you oversaw relating
15 to improper payments did include Part C, but the work
16 respecting investigations, and the work done by these
17 contractors you mentioned, did not?

18 A. Correct. That's correct.

19 Q. It says here you also oversaw audit
20 strategies. What does that mean?

21 A. So similar to like what I just mentioned.
22 The program -- so CPI conducts audits of individual
23 providers. They will -- will ask either to be
24 self -- you know, release sort of self-audits, based
25 on like abnormal sort of clusters of -- of payment,

1 for example, around specific providers or specific
2 locations.

3 They will audit providers around -- for
4 overall compliance individually. Those are conducted
5 by the administrative contractors or by the ZPICs,
6 either arm of the -- of Medicare will conduct like an
7 actual -- what -- basically a compliance review of an
8 individual provider's medical records.

9 It's a manual process, and those audits
10 are done by nurse practitioners who, you know,
11 review -- they -- basically they review documentation
12 by providers to see if it matches up with what the --
13 what the basis of the payment was or what the claim
14 was being paid for.

15 Q. And what does the phrase "oversight of
16 recovery audit program oversight" mean?

17 A. So the RAC program is a post-payment
18 program where it is a large-scale auditor that
19 reviews certain types of services, writ large, as
20 prescribed by CPI; so looking at, for example, home
21 health services and Medicare.

22 The recovery audit contract program will
23 conduct data analytics, and if they find that there
24 are, you know, sort of abnormal payments, they will
25 then conduct more sort of rigorous individualized

1 audits of providers post payment, where they then
2 sort of try to collect the dollars back from the
3 providers if there is an overpayment that's found.

4 Q. Now, with respect to audit programs
5 designed to recover money, you did have some role to
6 play in audits of Medicare Advantage plans, correct?

7 A. That's correct. During --

8 MS. KOH: Object --

9 THE WITNESS: Sorry. Go ahead.

10 MS. KOH: I was going to say, objection.

11 Vague.

12 Go ahead.

13 BY MR. MERON:

14 Q. Go ahead.

15 A. Oh, sorry.

16 Yes. During my time at CPI, the RADV
17 program moved from the Center for Medicare into the
18 Center for Program Integrity, and that was really
19 the -- the first real sort of interaction I had with
20 Medicare Advantage at that time.

21 Q. And do you recall more specifically when
22 that transfer of responsibility occurred?

23 A. It would have been early 2016.

24 Q. 2016? Not 2017?

25 A. That's correct. It happened during the

1 Obama administration.

2 Q. Okay. We'll take a look at some documents
3 and see whether that refreshes your recollection on
4 that.

5 Are you -- sorry. You referred to RADV
6 previously having been under the Center for Medicare?

7 A. That's correct.

8 Q. Do you recall what unit more specifically
9 within the Center for Medicare was responsible for
10 RADV?

11 A. I honestly don't remember the acronym
12 within Center for Medicare. There's a -- there's
13 a -- there's a group that did oversight, that
14 basically was a Part C, you know, Medicare, but
15 old -- it used to be the Medicare Part C group, but I
16 honestly don't remember what their acronym is.

17 Q. Would you recall whether it was the
18 MPPG --

19 A. Yes.

20 Q. -- the Medicare Plan Payment Group?

21 A. Thank you. That is correct, yes.

22 Q. Okay. And during the time that you were
23 there, do you recall who the director or the head of
24 the MPPG was?

25 A. Offhand, I do not. I do not.

1 Q. Do you recall if it was Cheri Rice?

2 A. I -- so -- yes, I thought that -- I'm
3 sorry, I thought Cheri Rice oversaw the entire Part D
4 and Part C programs. So during my time, I thought
5 that she was actually sitting as a deputy center
6 director rather than a group director. I know these
7 are splitting the differences in this discussion,
8 but -- just -- so yes, I -- I realized that Cheri
9 Rice sits over Medicare at the time, broadly Medicare
10 Advantage, but I also thought over Part D. So -- I
11 could be getting my exact dates wrong for when she
12 moved into that position, though.

13 Q. And your -- prior to being the director,
14 according to the -- acting director, according to
15 your LinkedIn, you were the -- I think you testified
16 you were the principal deputy for the -- for CPI
17 between March '15 and December 2016, correct?

18 A. That's correct.

19 Q. And did your areas of oversight as deputy
20 differ significantly -- were they significantly
21 narrower than your areas of oversight as director?

22 A. Not necessarily. There were a -- there
23 were certain programs -- so the Center for Program
24 Integrity has two deputy center directors. My focal
25 point, as I was deputy center director, was more on

1 Medicaid, Center for Medicare and Medicaid, sort of
2 -- sorry, Center for -- the Innovation Center, CMMI,
3 and over CCIIIO.

4 And the reason for that was the other
5 deputy center director had this long tenure at CMS,
6 and had been working in the Medicare program for
7 many, many years. And the purview of Center for
8 Program Integrity had been grounded in Medicare fee
9 for service since the '90s.

10 And often my goal, when I was there, was
11 really to expand the footprint of the organization
12 and to -- making sure it had other -- that it had
13 oversight over the other programs that CMS was then
14 administering.

15 Q. Now, as part of your role in -- in
16 overseeing CPI, as you testified, was to oversee
17 various audit programs that CPI had, correct?

18 A. That is correct.

19 Q. I know you're -- you're not a
20 statistician, but I see you have some general
21 understanding of -- of the methodologies that are
22 used in audits?

23 A. Yes, I think it -- yes. I mean, in terms
24 of statistical -- statistical valid samples and
25 things like that, yes.

1 codes for every plan, or the same HCCs for each plan.

2 Q. Okay. Sorry. My question was a little
3 unclear.

4 A. I'm sorry.

5 Q. When -- when then -- when it goes then to
6 the medical record reviewer --

7 A. Okay.

8 Q. -- does the reviewer know, effectively,
9 "I'm looking to see whether diabetes is here"? Or
10 are they told, "Look at the chart; code all the
11 conditions that are in the chart, and tell me what
12 they are"?

13 MS. KOH: Objection. Form.

14 BY MR. MERON:

15 Q. Do you know?

16 A. Now I'm speculating. So -- not
17 definitively, no, I believe it is the former. I
18 believe they basically are looking at a specific HCC
19 that is set by CMS.

20 So there is some corridor, or whatever,
21 you know, parameters placed on what kind of reviews
22 are -- what -- what's being reviewed in a given time.

23 Q. Okay. But -- but not -- you're not sure,
24 as you said, about the weeds --

25 A. I'm honestly not. It's been such a long

1 time, it's -- I'm not.

2 Q. Okay. Stepping away from the details of
3 how the coding is done, there -- there is -- as part
4 of the -- the RADV, the -- the medical records were
5 reviewed to see whether the HCCs that were submitted
6 and sampled are substantiated by the medical record.
7 That's one component of the audit, correct?

8 A. Yes, correct.

9 Q. And there's also a look to see whether the
10 reviewers see other HCCs that are substantiated in
11 the medical record but were not submitted in claims,
12 correct? They look for adds?

13 A. Yes. That's right.

14 Q. And then there is a net payment error
15 determination made for each sample beneficiary, where
16 they compute what the actual payment was versus what
17 a correct payment would have been, had the coding all
18 been correct. Correct?

19 A. Yes.

20 MS. KOH: Objection.

21 THE WITNESS: Sorry.

22 Yes.

23 BY MR. MERON:

24 Q. And then the results of the sample
25 beneficiaries are then extrapolated over the whole

1 contract. Correct?

2 MS. KOH: Objection.

3 THE WITNESS: Yes, given whatever year
4 they started extrapolation, right, it talks
5 about that. So 20 -- whatever. Yes, right. At
6 a certain point, they began extrapolation,
7 right.

8 BY MR. MERON:

9 Q. And that was contract year 2011 where it
10 started, correct?

11 A. Yes, that -- right. That's what the --
12 yeah. I believe that's what the paper says.

13 Q. And by necessity, the RADV audits occur a
14 number of years after the contract year in question,
15 correct?

16 A. Yes. That's correct.

17 Q. And in particular, they occur after the
18 final deadline for submitting all the plans risk
19 adjustment data has passed, correct?

20 A. That is -- that's the trigger. That's the
21 signal of the trigger. It has to be at some point
22 after -- after that, yes.

23 Q. And it has to be that, because you've got
24 to know what the final data set is that you're
25 sending?

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

Karen K. Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-131

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
STEVEN HALE NELSON
Given Remotely
Tuesday, July 26, 2022
10:10 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 and -- and right.

2 And, you know, I'm -- and not to mention I
3 was the leader of the Medicare business group, so
4 I -- I should do that.

5 Q. Okay.

6 MS. McMAHON: All right. Let's look at
7 Tab 24, which will be Exhibit 324.

8 (Exhibit 324 was marked for identification.)

9 MS. McMAHON: And this is MAPL000497870.
10 Okay.

11 BY MS. McMAHON:

12 Q. So the first e-mail, that starts at the
13 bottom of page 1, is an e-mail from you to Cheri
14 Rice, cc'ing Thad Johnson, Dan Schumacher, Karen
15 Erickson, and yourself. And it's titled "2012
16 Attestation and follow-up from yesterday's meeting."

17 And this is the e-mail response that you
18 sent to Ms. Rice on April 30th. Correct?

19 A. Correct.

20 Q. And I won't ask you to compare this to
21 the -- to the former document; we can all do that off
22 line. But -- but do you have any memory of changing
23 the message that you sent to Ms. Rice from the one
24 that Mr. Johnson forwarded to you earlier that day?

25 MR. SUMMERS: Objection. Form.

1 THE WITNESS: No.

2 BY MS. McMAHON:

3 Q. Okay. And let's go to the paragraph that
4 starts with "Fifth." It's on the second page of this
5 document.

6 And you start that paragraph mentioning
7 the proposed rule, correct?

8 A. Correct.

9 Q. And the way you describe it was the
10 proposed rule, that if finalized would "require MA
11 plans to design any medical record reviews to
12 determine the accuracy of risk adjustment diagnoses
13 associated with those records." Correct?

14 A. Yes.

15 Q. Okay. And I'm paraphrasing, so you might
16 want to -- you can -- you can tell me if you don't
17 like my paraphrasing.

18 But you go on to indicate that you intend
19 to delete diagnosis codes that have gone through a
20 complete review. Right?

21 A. Yeah -- I'm -- just make sure.

22 "We" -- you're referring to, "We currently
23 have a process through which we review certain
24 medical records" -- accuracy -- (reading) -- and this
25 already "resulted in the identification of and, in

1 some instances, the submission of deletes."

2 Q. Yes. "Pursuant to our discussion"?

3 A. Yeah. "Pursuant to our discussion,
4 however, we will soon submit for deletion."

5 Yeah. That's a paraphrasing.

6 Q. Okay. And you did do that, correct?

7 A. That's my understanding, or that's my
8 recollection.

9 Q. Okay. And you also describe, following
10 that, that you were considering discontinuing your
11 review process for the diagnosis codes that were
12 still under review, correct?

13 A. Correct.

14 Q. Okay. Now, if you can -- and by the way,
15 this -- this e-mail communication that you sent to
16 Ms. Rice, you intended it to be -- to be clear and
17 comprehensive of the discussion you had the day
18 before, correct?

19 MR. SUMMERS: Objection. Form.

20 THE WITNESS: I think -- I mean, how I
21 would characterize the intent of this
22 communication was to confirm our understanding
23 of the conversation as we walked out, relative
24 to the proposed rule and our -- and the decision
25 that we wanted to make about continuing or

1 discontinuing the CV program, and what do we do
2 with claims that are in process, and -- and some
3 insight into, you know, the -- how do we think
4 about the proposed rule, the timing, as we think
5 about bids, and other things.

6 So I think all those things were in here,
7 we were trying to confirm what we got out of the
8 meeting. Maybe that's what you said, but that's
9 -- I just wanted to state it in my words.

10 BY MS. McMAHON:

11 Q. Okay. Good. Okay.

12 And Ms. Rice did respond sort of directly
13 to that point, didn't she? She says here, "With
14 respect to your fifth point, I would note that
15 regardless of the effective date of the proposed
16 requirement related to medical record reviews, there
17 are other laws that do impose standards, requirements
18 and responsibilities on MA plans in connection with
19 the federal payments they receive from CMS." Right?

20 MR. SUMMERS: I'm sorry, what's the
21 question, Counsel?

22 BY MS. McMAHON:

23 Q. Is that what she said in this e-mail?

24 A. I -- I read the same thing you do.

25 Q. Okay. And she also -- well, before I --

1 before I go on to that, so -- so did you understand
2 that to mean that regardless of the fate of the
3 medical record review rule, or the proposed rule,
4 that there were other laws that imposed standards,
5 requirements, and responsibilities on MA plans?

6 MR. SUMMERS: Objection. Form.

7 THE WITNESS: I understand it to be
8 exactly what she wrote, which is -- there's a
9 bunch of stuff that, you know, you need to be
10 thinking about as you make decisions, and you
11 guys came in and asked us a very specific
12 question. We gave you an answer in regards to
13 that. There's federal laws. There's all kinds
14 of things you guys should be thinking about.

15 But as far as I'm concerned, this was a
16 confirmatory communication as to our very
17 specific question about the proposed rule and
18 about our claims verification program, how we
19 handle claims that are partway through it or all
20 the way through it.

21 And so that's -- that's how -- that's how
22 we -- that's how I read this. That's how we
23 read it, that it was confirmatory to -- to the
24 impression we walked out of the meeting with,
25 that there was no proactive obligation to -- to

1 run a claims verification program.

2 And -- and pending the proposed rule,
3 finalization of which, of course, it was never
4 finalized.

5 BY MS. McMAHON:

6 Q. Right. But so let me just -- I think
7 you -- you know, you described what she says here as
8 her telling about a bunch of stuff. But let's kind
9 of try to drill down on that a little bit.

10 She tells you that there are other laws
11 that impose standards, requirements, and
12 responsibilities on MA plans. Correct?

13 A. She does state that.

14 Q. And what did you understand that to mean?

15 A. I understood exactly what I just said,
16 which is there's a lot of law -- federal laws. And
17 of course our intention is to stay compliant with
18 every federal law and every regulation, requirement
19 that CMS and, you know, the Constitution asks us to
20 do.

21 I mean, I -- it was a very far-reaching,
22 broad statement, but did not -- was not specific to
23 the topic that we covered, unless, you know -- it was
24 just -- it felt like a very broad statement, kind of
25 a catch-all statement; and we -- we read it as

1 anyone at United --

2 BY MR. HAVIAN:

3 Q. Okay.

4 A. -- specifically. Yeah.

5 Q. Okay. And was it ever your policy, you
6 personally, that United did not have to delete
7 unsupported codes if the error rate fell lower than
8 the error rate in fee-for-service data?

9 MR. SUMMERS: Objection. Form.
10 Foundation.

11 THE WITNESS: Are you asking if that was
12 my personal opinion?

13 BY MR. HAVIAN:

14 Q. No, if that was your practice, ever your
15 practice while you were at United.

16 MR. SUMMERS: Objection. Form.
17 Foundation.

18 THE WITNESS: I don't recall having
19 conversation or being aware of that discussion,
20 so I wouldn't really be able to comment on that.

21 MR. HAVIAN: Okay.

22 So that's -- you should stop the clock.
23 The videographer should stop the clock with that
24 answer. And I'll pass the witness.

25 MR. SUMMERS: Okay. Thank you.

1 We're just going to take a couple minutes
2 to get resituated here. I'm going to go sit
3 across from the witness, so that he's not
4 turning sideways.

5 So just give us a couple minutes. We can
6 go ahead and go off the record.

7 VIDEOGRAPHER: We're now going off the
8 record at 7:07 p.m.

9 (A recess transpired from 7:07 p.m. until
10 7:09 p.m.)

11 VIDEOGRAPHER: We're now back on the
12 record at 7:09 p.m.

13 FURTHER EXAMINATION

14 BY MR. SUMMERS:

15 Q. Good afternoon, Mr. Nelson. I'd like to
16 ask you just a follow-up questions, if that's okay.

17 Earlier today we discussed an April 29,
18 2014, meeting between representatives of United and
19 CMS. I'd like to ask you a few follow-up questions.

20 First, just so the record is clear, why
21 did you want to have that meeting?

22 A. As I mentioned earlier, but to be clear,
23 there's three reasons -- one is there's a proposed
24 rule out; we wanted to get clarification on that
25 as -- because we had bids coming, and so there was a

1 timing issue.

2 We also had, as I said, had a -- some
3 indication from a couple different sources that --
4 that the claims verification process was in fact not
5 needed or not required -- I should say not required.

6 And then the general opportunity to build
7 relationships and -- with CMS in a -- and to set the
8 standard for us to have, you know, transparent and --
9 and really productive dialogue around anything
10 that -- that we were fuzzy about or confused about,
11 ever. And I just wanted to set that standard.

12 And so it was in that spirit that we took
13 that very specific question to them.

14 Q. On the second issue, getting clarity with
15 regard to whether the claim verification procedure
16 was -- was necessary, did you feel that you got a
17 clear understanding or a clear answer from that
18 meeting?

19 A. On the need to continue --

20 Q. On whether you needed to continue with
21 claim verification.

22 A. We felt that we got a very clear answer.
23 And the answer was that we did not need to continue
24 it.

25 Q. Did you feel that you also got clarity on

1 the question of what to do with regard to the patient
2 files that were currently under review, but as to
3 which the review had not been completed?

4 A. Yes. We also got -- I -- you know, we
5 felt like we got clarity on -- if a claim was
6 somewhere in the middle of the process, then it did
7 not need to be deleted; but if it went all the way
8 through, it should be deleted.

9 So that's what we did.

10 Q. And you just said that that's what you
11 did. Did you, following this meeting, do what you
12 felt CMS told you you needed to do?

13 A. Yes.

14 Q. There was some questioning earlier today
15 about a comment by Ms. Rice to the effect that if you
16 knew the codes were not supported, that they should
17 be deleted. Do you recall that?

18 A. Yes.

19 Q. What was -- and I think you mentioned
20 there was a broader context to that discussion. What
21 was the context of that statement?

22 A. The context, as I remember it, was in
23 conjunction with the discussion around claims
24 verification process: How did it work. And as we
25 were trying to figure out, you know, our -- we did

1 MR. HAVIAN: That's okay. It's hard to
2 get used to.

3 THE WITNESS: Yeah. No, I -- I need to
4 wait.

5 BY MR. SUMMERS:

6 Q. Just so the record is clear, was your
7 answer "yes" or "no"?

8 A. Yes. It was "yes."

9 Q. Now, turning back to the meeting on
10 April 29, 2014, what would you have done -- to the
11 best of your knowledge, what would you have done if
12 CMS had said that under current regulation, United
13 was required to conduct claim verification?

14 A. We would have continued with it.

15 Q. Earlier today, counsel for the government
16 asked you a lot of questions about a projected budget
17 shortfall in 2014. Do you recall that questioning?

18 A. Yes.

19 Q. If CMS had told you on April 29, 2014,
20 that United was required to continue with its claims
21 verification program, or something like it, would you
22 have discontinued the program in order to meet
23 financial targets?

24 A. No. Adhering and being consistent,
25 compliant with regulations and rules, always trumps

1 hitting a budget. I mean, that's -- that's just how
2 we have to run our business. There's no way around
3 that.

4 And then you have to find -- you know,
5 continue to run the business in a proper way. But
6 the compliance and consistent with CMS regulations,
7 there's no negotiation on that.

8 Q. After your meeting with CMS on April 29 of
9 2014, after that point in time, did CMS ever come to
10 you and say that you needed to reinstate claim
11 verification or risk being sued?

12 A. Not to my knowledge.

13 MR. SUMMERS: I have no further questions.
14 Thank you for your time.

15 MS. McMAHON: All right. I just -- give
16 me five minutes to see if I have any follow-up.
17 I think we have ten minutes left on record.

18 MR. SUMMERS: I think you only had like
19 two minutes left, according to our count. And
20 the count -- the witness has a -- a flight to
21 catch, so be as fast as you can, please.

22 MS. McMAHON: Well, I will go as fast as I
23 can, but I believe I have ten minutes, and I
24 believe that was made clear at the end of
25 Mr. Havian's --

1 MR. HAVIAN: I couldn't have been --

2 MS. McMAHON: -- testimony.

3 MR. HAVIAN: Yeah, I couldn't have been
4 clearer. The clock stopped when I finished, and
5 I asked one minute worth of questions, and we
6 had ten left on the clock. But we've got -- we
7 can argue about this, and it'll take more than
8 ten minutes --

9 MR. SUMMERS: No, no, no. Let's just
10 figure out if you have any questions. Be fast,
11 please, just because the witness -- we're going
12 to stay right here, because the witness --

13 MR. HAVIAN: Okay.

14 MR. SUMMERS: -- has to catch a flight.

15 MS. McMAHON: Okay. I'm going to go off.
16 I'll be back as quick as I can. I'm going off
17 the record right now.

18 VIDEOGRAPHER: We're going off the record
19 at 7:40 p.m.

20 (A recess transpired from 7:40 p.m. until
21 7:45 p.m.)

22 VIDEOGRAPHER: We're now back on the
23 record at 7:45 p.m.

24 MS. McMAHON: Okay. 7:45.

25

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.



Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-132

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL

CONTAINS ATTORNEYS' EYES ONLY PORTIONS

(See Note on Index Page)

Videotaped Deposition of

REBECCA PAUL

Given Remotely

Wednesday, April 13, 2022

9:02 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. I had asked you when you began working for
2 CMS, and I understood you to say that in 2005, you
3 began working for the central office of CMS. Where
4 were you working prior to 2005?

5 A. I worked in a nongovernment place, non--
6 not CMS, the year before that. I worked at the
7 regional office before that. My entire time at CMS
8 is about 22 years.

9 (Reporter requested clarification.)

10 A. Regional office, for CMS.

11 Q. Prior to 2005, you worked in the regional
12 office of CMS? Is that correct, Ms. Paul?

13 A. In 2005 I began working at central office,
14 CMS's central office.

15 Q. And prior to 2005 where did you work?

16 A. Just to clarify, are you asking about my
17 CMS history or my work history? Just so I understand
18 what you're asking.

19 Q. Let's focus on CMS.

20 A. From about 1998 to 2003, I worked in the
21 San Francisco regional office of CMS.

22 Q. And where did you work between 2003 and
23 2005?

24 A. The University of California.

25 Q. What was your position at the University

1 of California?

2 A. I was a -- I don't remember my title. I
3 worked for a small program that worked at the state
4 legislature on -- reviewed specific types of
5 legislation.

6 Q. In 2012 you became the director for the
7 Division of Plan Policy in the Medicare Plan Payment
8 Group; is that correct?

9 A. The Division of Payment Policy, in the
10 Medicare Plan Payment Group, in 2012.

11 Q. And you are currently the deputy director
12 of the Medicare Plan Payment Group?

13 A. Correct.

14 Q. When did you become the deputy director of
15 the Medicare Plan Payment Group?

16 A. I believe it was made permanent in 2020.
17 I was acting for about a year before that.

18 Q. And Ms. Paul, is it fair to say that your
19 specialties include Medicare risk adjustment?

20 MR. MASON: Objection. Form.

21 THE WITNESS: Risk adjustment for Medicare
22 Advantage and Part D.

23 BY MR. QURESHI:

24 Q. My question was, Ms. Paul, is it fair to
25 say that your specialties include Medicare risk

1 adjustment?

2 MR. MASON: Same objection.

3 THE WITNESS: I have worked on risk
4 adjustment for the Medicare Advantage and Part D
5 program, which is part of Medicare.

6 BY MR. QURESHI:

7 Q. And would you consider your work for the
8 risk adjustment Part D component of the Medicare
9 program a specialty?

10 MR. MASON: Objection. Form.

11 THE WITNESS: What do you mean by
12 "specialty"?

13 BY MR. QURESHI:

14 Q. Do you -- do you understand what the word
15 "specialty" means?

16 A. I'm asking you what your -- what your
17 standard is for -- what it would mean for me.

18 Q. Yeah, and I'd like to understand what you
19 believe the word "specialty" means.

20 A. Well, I mean, there's a meaning for it,
21 but are you -- are you asking a specific level of
22 knowledge I have, or -- I have -- I'm asking you what
23 it means, what you're asking of the level of
24 knowledge.

25 Q. What level of knowledge do you ascribe to

1 the word "specialty"?

2 A. I have worked on many aspects of risk
3 adjustment.

4 Q. Okay. Ms. Paul, I'm just trying to get an
5 understanding of what your areas of focus are.
6 Perhaps it will be easy if we take a look at a
7 document.

8 MR. QURESHI: I'll ask my colleague to
9 make available a document that we will designate
10 as Exhibit 1070.

11 (Exhibit 1170 was marked for identification.)

12 MR. QURESHI: It is Tab RR for our
13 internal purposes.

14 BY MR. QURESHI:

15 Q. Let me know when it becomes available to
16 you, Ms. Paul.

17 A. Which program am I looking in? Is this
18 AgileLaw?

19 Q. Yes, it is.

20 A. I don't see anything -- Document 1? Is
21 that it?

22 Q. Yeah, we'll designate it as Exhibit 1070,
23 for the record. Let me know when it becomes
24 available for you, Ms. Paul.

25 A. Okay.

1 Q. Have you had a chance to -- to look at
2 Exhibit 1070?

3 A. Uh-huh. 11 -- it's not 1070. But it's
4 here.

5 Q. Okay. Thank you for correcting me. It's
6 Exhibit 1170?

7 A. Uh-huh.

8 Q. What is Exhibit 1170?

9 A. Looks like my LinkedIn page.

10 Q. Who created your LinkedIn page?

11 A. I did.

12 Q. And --

13 MR. MASON: Mr. Qureshi, is there a Bates
14 number associated with this document?

15 MR. QURESHI: There is not.

16 MR. MASON: Thank you.

17 BY MR. QURESHI:

18 Q. Is your LinkedIn page accurate, Ms. Paul?

19 A. Yes.

20 Q. Will you please read into the record what
21 it says under "Summary."

22 A. In the context of the LinkedIn page, under
23 "Summary," it says: "Specialties: Medicare risk
24 adjustment and plan payment."

25 Q. And when you wrote "Medicare risk

1 adjustment" in the "Specialties" section of your
2 LinkedIn page, what information were you intending to
3 convey?

4 A. That these were focuses of what I worked
5 on.

6 Q. And how long have you considered Medicare
7 risk adjustment a specialty?

8 A. I don't know. I don't know when I would
9 have.

10 Q. When did you create your LinkedIn page?

11 A. I don't know. I don't remember.

12 Q. Did you create it this year?

13 A. No.

14 Q. I think you've already addressed
15 components of my next question, but I'll -- I'll ask
16 it again: How do you define "Medicare risk
17 adjustment"?

18 A. That is quite broad. Are you asking what
19 it does, or what its purpose is?

20 Q. When you wrote that one of your
21 specialties was Medicare risk adjustment, what
22 information were you working to convey?

23 A. I don't remember what was in my head at
24 the time I wrote it. I probably just said I worked
25 on it.

1 Q. And what do you consider "Medicare risk
2 adjustment" to mean today?

3 A. And you're looking for a definition of
4 what it is?

5 Q. Correct. As you understand it, Ms. Paul.

6 A. Risk adjustment is a part of payment -- a
7 payment methodology that allows plans that enroll
8 beneficiaries for a part of groups that are expected
9 to be more costly, to be paid more money; and to
10 enroll beneficiaries for a part of groups that are
11 expected to cost less, pay less out.

12 Q. Okay. I'm having some difficulty hearing
13 you, Ms. Paul. I don't know if there's a different
14 phone line we can use, but --

15 MR. QURESHI: Might we go off the record
16 for a moment so we can address this?

17 VIDEOGRAPHER: We're now going off the
18 record. It's 9:21 a.m.

19 (A recess transpired from 9:21 a.m.
20 until 9:24 a.m.)

21 VIDEOGRAPHER: We're now back on the
22 record. It's 9:24 a.m.

23 BY MR. QURESHI:

24 Q. Ms. Paul, before we -- we took our break,
25 I had asked you what you understand the Medicare risk

1 adjustment program to mean. Would you please define
2 that for us?

3 MR. MASON: Objection. Form.

4 THE WITNESS: Risk adjustment in general
5 has the objective -- risk adjustment is one
6 aspect of a payment methodology that provides
7 the ability to calculate higher payments for
8 plans that enroll beneficiaries who are in
9 groups -- who are a part of groups that are
10 expected to have higher costs, and pay less than
11 average for -- to plans that enroll
12 beneficiaries who are part of groups that are
13 expected to have lower costs.

14 BY MR. QURESHI:

15 Q. And is the Medicare risk adjustment
16 payment methodology sometimes referred to as Medicare
17 Part C?

18 A. Medicare Part C is Medicare Advantage,
19 which . . .

20 Q. And does Medicare Advantage use a risk
21 adjustment payment methodology?

22 A. Risk adjustment is part of the payment
23 methodology.

24 Q. What are the other parts?

25 A. There is a rate book that is -- is used

1 for -- in the context of plan bidding. There is a
2 plan bid. And then there are risks, and then there
3 is the risk adjustment aspect of the payment
4 methodology, that -- at a very high level.

5 Q. Can you think of any others?

6 A. Are you looking for the payment formula?

7 Q. No, Ms. Paul. I had asked you whether
8 risk adjustment is part of the Medicare Advantage
9 payment methodology. I believe you said it's one
10 part. So I asked you to identify other parts.

11 Are there any other parts that you have
12 not yet identified?

13 A. It depends how specific you are asking.
14 At a -- there are many parts to payments. It's quite
15 complex. So those pieces are major pieces.

16 Q. The pieces you enumerated are -- are the
17 major pieces?

18 A. They are major pieces.

19 Q. Are there any other major pieces that you
20 can think of?

21 A. It's really more complex than that. Those
22 are major pieces of it. It depends on how detailed
23 you want to discuss, and what you consider major.

24 Q. And we will certainly get into the details
25 throughout the day, Ms. Paul. Right now, I just want

1 to know if there are any other major pieces that you
2 have not yet identified.

3 A. It really depends on how detailed you're
4 going to be and what you consider major. Those are
5 major pieces of how payment -- major pieces of the
6 payment.

7 Q. If we turn back to Exhibit 1170, you list
8 plan payment as among your specialties. What does
9 "plan payment" mean?

10 A. I do not know what I was thinking when I
11 wrote it, but it is a general term for payment
12 policy, payment formulas.

13 Q. Payments to who?

14 A. Plans.

15 Q. Medicare Advantage plans?

16 A. Again, I do not know what I was thinking
17 when I wrote this, but that is what I worked on, so
18 that is possibly what I had in mind when I wrote
19 that.

20 Q. What do you think it means, sitting here
21 today, Ms. Paul?

22 A. Are you asking in the context of what I
23 do, or generically?

24 Q. Exhibit 1170 is a document you created.
25 Isn't that correct, Ms. Paul? It's your LinkedIn

1 page?

2 A. Yes.

3 Q. Okay. When you wrote "plan payment," what
4 information were you trying to convey as part of your
5 specialties?

6 A. I do not know what I was thinking when I
7 wrote it. That's why I'm asking if what you're
8 asking now is what I work on.

9 Q. What do you believe it means?

10 MR. MASON: Objection. Asked and
11 answered.

12 THE WITNESS: What it means here is a
13 general category of knowledge. It is not meant
14 to be specific. But I do not remember what I
15 meant when I wrote it.

16 BY MR. QURESHI:

17 Q. Are you able to testify as to whether
18 "plan payment" refers to payments to Medicare
19 Advantage plans?

20 MR. MASON: Objection. Form.

21 THE WITNESS: That seems like a different
22 question. You're asking what I meant when I
23 wrote this. If you're asking does plan payment
24 include that -- is that the question?

25

1 BY MR. QURESHI:

2 Q. My question was, are you able to testify
3 as to whether "plan payment" refers to payments to
4 Medicare Advantage plans, Ms. Paul?

5 MR. MASON: Same objection.

6 THE WITNESS: Are you asking about the
7 generic term, or what it means here?

8 BY MR. QURESHI:

9 Q. Let's do both, Ms. Paul. What does it
10 mean here, on Exhibit 1170?

11 MR. MASON: Objection. Asked and
12 answered.

13 THE WITNESS: Again, I do not know on the
14 page what I meant when I wrote it. But it
15 was -- appears to be intended to be a general
16 term, and not specific.

17 BY MR. QURESHI:

18 Q. And what do you understand the general
19 term to mean?

20 A. The general term would mean how plans are
21 paid.

22 Q. What plans?

23 A. Given that I was working in the Medicare
24 Plan Payment Group, presumably Medicare plans.

25 Q. Medicare Advantage plans?

1 A. Those are included.

2 Q. What other plans are included?

3 A. Part D plans.

4 Q. What other plans?

5 A. Again, we're addressing the wording as
6 they exist in nature, not what's here. I don't know
7 what I meant when I wrote this.

8 Q. I understand that, Ms. Paul. My question
9 is, the concept of plan payment refers to Medicare
10 Advantage plans and Part D plans, according to you.
11 Are there any other plans that you think it refers
12 to?

13 A. And I'm just clarifying that I mean this
14 today, not what's written here.

15 Q. I'm fine with that clarification,
16 Ms. Paul. I -- I just want your best testimony.

17 When you -- you hear the word "plan
18 payment" as applied to your experience and your work,
19 what do you understand that to mean?

20 A. The vast majority of it is Medicare
21 Advantage and Part D plans. Those are the plan types
22 that the Medicare Plan Payment Group is responsible.
23 There are other plans that get paid similarly that --
24 that would come -- that would be included today;
25 again, not talking about this document -- base

1 organizations, some demonstration plans.

2 Q. Are you finished with your answer?

3 A. Yes.

4 Q. Do you use e-mail in your work at CMS?

5 A. Yes.

6 Q. What is your e-mail address?

7 A. rebecca.paul@cms.hhs.gov.

8 Q. Have you had the same e-mail address
9 throughout your tenure of work at the CMS central
10 office?

11 A. I believe so.

12 Q. Okay. Do you ever use personal e-mail to
13 conduct CMS-related business?

14 A. No.

15 Q. You've never done that?

16 MR. MASON: Objection. Form.

17 THE WITNESS: Years ago, before we had
18 work laptops, I might have sent a file home, but
19 everything would have been in my work e-mail.
20 Nothing exists outside of work e-mail.

21 BY MR. QURESHI:

22 Q. And what e-mail address would you have
23 used to send work home before you had a laptop?

24 A. I don't know which one it was, because
25 they're all . . .

1 Q. How many personal e-mail addresses do you
2 have?

3 A. I have two.

4 Q. What are those e-mail addresses?

5 A. One is rebecca_paul@yahoo.com. That's
6 probably the only one I would have used. The other
7 one is newer.

8 Q. And what is the newer one?

9 A. It's lokipaul94@gmail.com.

10 Q. Focusing on your CMS e-mail address, was
11 it your practice while working at the central office
12 to be truthful in your e-mail communications?

13 A. Yes.

14 Q. Is it your practice to review e-mails sent
15 to you at your CMS e-mail address?

16 A. Are you asking about reviewing e-mails or
17 reviewing them -- I -- the e-mail address -- what
18 you're asking.

19 Q. I'm not sure I understand your
20 clarification, Ms. Paul. I can ask my question
21 again, if that helps.

22 Is it your practice to review e-mails sent
23 to you at your CMS e-mail address?

24 A. Are you asking about the e-mail address,
25 or are you asking do I review e-mails?

1 Q. If someone sent you an e-mail at your CMS
2 e-mail address, would you review the contents of that
3 e-mail?

4 A. I do not read every e-mail I receive.

5 Q. How do you decide which e-mails to look
6 at?

7 A. It depends. Urgency, topical nature of an
8 e-mail, if I work on it, does someone else work on
9 it.

10 Q. And has that been your practice throughout
11 your tenure at the CMS central office?

12 A. I -- if I do not -- if there was -- if I
13 ever didn't read an e-mail, so general criteria are
14 likely what I was taking into account. I can't speak
15 to how I would read an e-mail, you know, a long time
16 ago.

17 Q. Are you familiar with the term "diagnosis
18 code" in the context of the Medicare risk adjustment
19 program?

20 A. Yes.

21 Q. What is a diagnosis code?

22 A. A diagnosis code is a numerical code that
23 is associated with a specific clinical diagnosis, as
24 defined by diagnosis code.

25 Q. And what role do diagnosis codes play in

1 the Medicare risk adjustment program?

2 A. Some diagnosis codes -- specified
3 diagnosis codes are used in the risk adjustment
4 models to assign a specific condition to a
5 beneficiary, and is used to calculate a risk score.

6 Q. Thank you for that, Ms. Paul. We'll talk
7 a little bit more about risk scores in a moment, but
8 first I'll direct you to another exhibit that should
9 be available soon.

10 MR. QURESHI: It's Tab H, Samantha.

11 BY MR. QURESHI:

12 Q. And Ms. Paul, we'll refer to it as
13 Exhibit 1171.

14 (Exhibit 1171 was marked for identification.)

15 BY MR. QURESHI:

16 Q. It should be up in a moment.

17 A. Okay.

18 Q. Please let me know when it is available
19 for you.

20 A. I have it.

21 Q. Might you take a moment to review it?

22 While you're reviewing Exhibit 1171,
23 Ms. Paul, we've also uploaded a document that's
24 designated Exhibit 1171-1, which is the attachment
25 to 1171. So you should have that available to you

1 now as well.

2 (Exhibit 1171-1 was marked for identification.)

3 BY MR. QURESHI:

4 Q. Ms. Paul, I'll represent for the record
5 that Exhibit 1171 is an e-mail chain, where the top
6 e-mail is from you to Ms. Cheri Rice, dated
7 September 2nd, 2014. And it bears the Bates number
8 USBP057358501. Is that correct?

9 A. Are you asking me the number on the e-mail
10 chain?

11 Q. That's right, Ms. Paul. I just want to
12 make sure we're looking at the same document.

13 A. Can you read the number again that's on
14 the e-mail chain? I -- I thought you were talking
15 about the other document.

16 Q. Sure. I'll describe the e-mail in its
17 entirety. It's an e-mail where at the top of the
18 page, you, Ms. Rebecca Paul, are sending a message to
19 Ms. Cheri Rice and others. And that e-mail is dated
20 September 2nd, 2014. The Bates number on the bottom
21 of the first page is USBP057358501. Correct?

22 A. That's what I see.

23 Q. And who is Ms. Cheri Rice?

24 A. At the time of this e-mail she was the
25 group director --

1 do you mean?

2 Q. If it's -- if it's in red text?

3 A. Yes, it's in red.

4 Q. And is there a line through the red text?

5 A. No.

6 Q. Okay. Well, that's what I have in -- in
7 the version that I'm looking at. But regardless of
8 whether it's struck out or not, would you please read
9 Item 11?

10 A. "Exclude diagnostic categories that are
11 most subject to differential coding in MA compared to
12 fee-for-service Medicare."

13 Q. And then does it say "NEW," in
14 parentheses, at the end?

15 A. Yes, yes, it says "NEW."

16 Q. And what do you understand Item 11 to
17 mean?

18 A. That -- that Medicare Advantage plans
19 would report codes -- specific categories, I guess
20 the categories differently than fee for service
21 would.

22 Q. And why would that occur?

23 MR. MASON: Objection. Form.

24 THE WITNESS: It might occur because
25 Medicare Advantage plan payments will increase

1 when they report more diagnoses, more unique
2 diagnoses, than fee for service.

3 BY MR. QURESHI:

4 Q. And why would that occur?

5 MR. MASON: Objection to form.

6 THE WITNESS: It's because there's a
7 payment incentive to report more codes, because
8 the risk score would increase.

9 BY MR. QURESHI:

10 Q. In discussing the phrase "discretionary
11 coding variation," is there a variation in how coders
12 identify diagnoses?

13 MR. MASON: Objection. Form.

14 THE WITNESS: And by "coders," you're now
15 talking about -- you're talking about
16 professionally trained coders, who review --

17 BY MR. QURESHI:

18 Q. Yes.

19 A. -- medical record.

20 Discretionary, in this sense, is a
21 clinical -- of a clinical nature, where the
22 diagnosing may vary by provider, by -- depending --
23 it's a conceptual framework for whether or not a
24 diagnosis made by a clinician may differ what -- the
25 degree to which it may differ.

1 Coding is not diagnosing. It is whether
2 or not the medical record, what is written in the
3 medical record, meets coding guidelines to assign it
4 a specific diagnosis code.

5 Your question about whether coders can
6 differ: They potentially can, but there are rules to
7 follow, which is not the "discretionary" that's
8 referred to here.

9 Q. Understood. And with respect to
10 differences between coders, how are those differences
11 resolved?

12 MR. MASON: Objection. Form. Vague.

13 THE WITNESS: I don't know. It depends on
14 the circumstances. I don't -- I wouldn't have
15 direct knowledge.

16 BY MR. QURESHI:

17 Q. I believe you said you wouldn't have
18 direct knowledge. Do you have any knowledge on this
19 issue?

20 A. I don't -- I don't work with coders. I
21 don't -- it depends on what the -- I mean, I don't --
22 is this a plan program? I don't know. I assume -- I
23 don't know how it's resolved.

24 Q. You might turn to the next page, Slide 4,
25 of Exhibit 1171-1.

1 A. Which page?

2 Q. The next slide, Slide 4.

3 A. Okay.

4 Q. The title of the slide is "NEW SLIDE?
5 Decisions Regarding the Inclusion of Individual
6 HCCs."

7 A. Uh-huh.

8 Q. Do you see that?

9 A. Yes.

10 Q. Okay. The last bullet point states:
11 "Whether diagnosis codes that are subject to
12 discretionary or differential coding should be
13 excluded." Did I read that correctly?

14 A. Yes.

15 Q. What did you understand this last bullet
16 point to mean?

17 MR. MASON: Objection. Form.

18 THE WITNESS: This slide is discussing
19 when we include specific HCCs in a risk
20 adjustment model, and we have principles and
21 decision points about when they are included or
22 not. This last bullet is discussing a decision
23 point about when to exclude an HCC from the
24 model.

25 The discretionary term here, I believe,

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

Karen K. Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-133

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF
AMERICA ex rel.
BENJAMIN POEHLING,
Plaintiffs,
vs. No. CV 16-08697 FMO
UNITEDHEALTH GROUP,
INC., et al.,

Defendants.

The videotaped deposition of
BENJAMIN POEHLING, taken pursuant to Notice
of Taking Deposition, taken before
Alexis Jensen, RPR, CRR, and a Notary Public
in and for the County of Dakota, State of
Minnesota, taken on October 18, 2022, at
Dorsey & Whitney LLP, 50 South Sixth Street,
Suite 1500, Minneapolis, Minnesota,
commencing at approximately 9:24 a.m.

1 that you wrote because you thought it or
2 something you heard others at United say?

3 A. It's -- my recollection is it's something
4 that I heard people say at United.

5 Q. And during the time you were -- you were in
6 this role, 2010/2011, did you form a view as
7 to whether it was, in fact, correct that it
8 was unreasonable to ask a Medicare advantage
9 plan to review every medical chart?

10 A. I don't know if I formed an opinion back
11 then, but when you talk about -- when you
12 say "every medical chart," that would seem
13 unreasonable.

14 Q. Well, I'll ask it again a different way.
15 Whether you recall back then,
16 sitting here today, would you agree that
17 it's not reasonable to expect Medicare
18 advantage plans to review every medical
19 chart?

20 MR. HAVIAN: Objection, form.

21 THE DEPONENT: I don't know what
22 "every medical chart," but -- refers to, but
23 literally, if you're asking review every
24 single medical chart, that does seem
25 unreasonable to me.

1 BY MR. BAAK:

2 Q. All right. We're still in the same section,
3 but I want to go over to the next page of
4 your Challenges With CMS Methodology
5 section. And there's two more bullets.

6 The first one is, Doctor -- plans
7 rely on doctors to code correctly.

8 Do you see that?

9 A. I do.

10 Q. Again, was that something you understood at
11 the time you were drafting this summary
12 document in 2011 that plans counted on the
13 doctors to code correctly?

14 A. It was something I heard at United.

15 Q. Was it something you disagreed with?

16 A. Doctors don't always code. They may have
17 coders in their office.

18 Q. "Doctors" meaning doctors' offices?

19 A. Getting -- so, we talked about IRADS
20 earlier. If they're coding things that come
21 through IRADS, we relied on those claims
22 that were coming in through IRADS that were
23 coded by someone at the doctor's office.

24 Q. You previewed the next part of this bullet,
25 which is -- it says, Many doctors do not

1 have an incentive to do so; that is, to code
2 correctly, right?

3 MR. HAVIAN: Objection to form.

4 I'm not sure if you're asking if you read
5 that correctly, or if it's correct.

6 BY MR. BAAK:

7 Q. Let me take the former. Did -- did I
8 describe your -- the bullet -- the next
9 sentence in your CMS methodology section
10 correctly, Many doctors do not have an
11 incentive to do so?

12 A. Yeah, I see those words here.

13 Q. And that's referring to doctors having an
14 incentive to code correctly, right?

15 A. I believe so.

16 Q. And the reason for that is the next
17 sentence, which is, A physician office
18 claims only require one diagnosis code to
19 justify the CPT in a Medicare claim, right?

20 MR. HAVIAN: Objection to form.

21 THE DEPONENT: Yeah.

22 BY MR. BAAK:

23 Q. What's a CPT?

24 A. I don't know what -- I can't remember what
25 it stands for. I believe it's a procedure

1 code.

2 Q. What you're trying to capture here in this
3 bullet is the reason doctors don't have an
4 incentive to completely code accurately
5 diagnosis codes?

6 MR. HAVIAN: Objection.

7 THE DEPONENT: No, this may be one
8 reason. But there may be other reasons as
9 well.

10 BY MR. BAAK:

11 Q. So, what you're capturing here, though, is
12 one reason why risk adjustment diagnosis
13 data may be incomplete?

14 MR. HAVIAN: Objection to form.

15 THE DEPONENT: Where I'm capturing
16 where, in this last sentence?

17 BY MR. BAAK:

18 Q. In this third bullet.

19 A. Can -- can you ask the question again?

20 Q. Sure. I'm just trying to understand the
21 purpose of why you put this bullet in your
22 summary you created in 2011.

23 So, are you trying to capture one
24 reason that doctors don't necessarily have
25 an incentive to code completely when they

1 submit a claim?

2 A. I -- I don't recall specifically why I put
3 it in here. I do agree that doctors' coding
4 may not be correct sometimes, but there's
5 multiple reasons why that could be true.

6 Q. And then you've got your last bullet, Plans
7 have no incentive to police overcoding.

8 And that's what you write right
9 there in the last bullet, right?

10 A. I see those words, yes.

11 Q. Is that something you thought or you heard
12 others say?

13 A. This is something I heard at the -- at the
14 company.

15 Q. And then in the last section, there's a
16 paragraph to wrap up your CMS methodology
17 challenges section. It says, Despite these
18 challenges, plans must ensure face-to-face,
19 appropriate provider type and documented in
20 medical record, right?

21 A. Yes, it says that.

22 Q. Then it says, These are the rules to
23 participate, right?

24 A. Yes, it says that.

25 Q. Did CMS ever put out -- or let me ask it a

1 STATE OF MINNESOTA)

2

COUNTY OF DAKOTA)

3

4

Be it known that I took the
videotaped deposition of BENJAMIN POEHLING
on October 18, 2022;

5

6

7

8

9

That I was then and there a notary
public in and for the County of Dakota,
State of Minnesota, and that by virtue
thereof I was duly authorized to administer
an oath;

10

11

12

13

That the witness before testifying
was by me first duly sworn to testify the
whole truth and nothing but the truth
relative to said cause;

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That the testimony of said witness
was recorded in stenotype by myself and
transcribed into typewriting under my
direction, and that the deposition is a true
record of the testimony given by the witness
to the best of my ability;

That I am not related to any of the
parties hereto nor interested in the outcome
of the action;

Witness my hand and seal this 21st
day of October, 2022.

Alexis Jensen

ALEXIS JENSEN, RPR, CRR
COURT REPORTER

EXHIBIT D-134

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex	)	
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	Case File No.
vs.	)	
	)	16-08697 FMO
UNITEDHEALTH GROUP, INC., et al.)	)	
	)	
Defendants.	)	

CONFIDENTIAL
VIDEOTAPED DEPOSITION OF
CYNTHIA POLICH
September 28, 2022
10:09 a.m.

Via Zoom Videoconferencing

Reported by: Marsi Koehl, CCR-B-2424

1 submit a diagnosis code on an encounter or a claims
2 form, that it was accurate, reflected the health
3 status or conditions of the patients they saw, that
4 it was documented in the medical record. And those
5 standards apply to both Medicare Advantage
6 organizations and Medicare fee-for-service.

7 Q. So was it your understanding that there was
8 a requirement that codes submitted had to be
9 supported by medical record documentation?

10 MR. SCHINDLER: Objection. Vague and
11 ambiguous. Asked and answered.

12 THE WITNESS: It was my understanding
13 that we were required by CMS to accurately
14 submit the codes submitted to us by
15 providers on behalf of their patients.

16 We would submit them to CMS with the
17 presumption that the provider was submitting
18 to us accurate diagnoses that reflected the
19 health status and conditions of their
20 patient and that it would be documented in
21 their medical record.

22 BY MR. LEE:

23 Q. Was there any obligation on the part of the
24 Medicare Advantage organization as to the accuracy of
25 whether or not that code was supported by medical

1 record documentation?

2 MR. SCHINDLER: Objection. Vague and
3 ambiguous.

4 THE WITNESS: As far as I understood,
5 there was no requirement for the Medicare
6 Advantage organization to verify the code
7 submitted by a provider to us on their
8 claims or encounter form, but that if we
9 were -- if the provider informed us that
10 they submitted a code in error, that we
11 would delete that code.

12 BY MR. LEE:

13 Q. Submitted in error meaning, for example, not
14 supported by the medical record? That would be a
15 valid reason to delete that code?

16 MR. SCHINDLER: Objection. Calls for
17 speculation.

18 THE WITNESS: I was referring to an
19 error of they transposed some digits or the
20 coder made a mistake, that those errors --
21 we would delete those codes and not submit
22 them to CMS.

23 BY MR. LEE:

24 Q. By codes that are unsupported by medical
25 record, codes that should be deleted?

1 MR. SCHINDLER: Objection. Calls for a
2 legal conclusion. No foundation. Calls for
3 speculation and vague and ambiguous as
4 framed.

5 THE WITNESS: There was no regulatory
6 requirement for Medicare Advantage plans to
7 verify that the diagnosis codes submitted by
8 the provider were supported.

9 BY MR. LEE:

10 Q. And Ms. Polich, I'm not asking about
11 regulatory requirements, I'm not asking about
12 verification. What I'm asking you, though, is it
13 your understanding that there was a requirement that
14 codes submitted for risk adjustment had to be
15 supported by medical records?

16 MR. SCHINDLER: Objection. Vague and
17 ambiguous. What is requirement then? She
18 just answered your question.

19 MR. LEE: Mr. Schindler, I'm going to
20 admonish you again to abide by Rule 30 --

21 MR. SCHINDLER: I am abiding by
22 Rule 30 --

23 (Simultaneous talkers.)

24 MR. LEE: -- argumentative.

25 MR. SCHINDLER: You are being

1 argumentative. That's the problem. She
2 answered your question and you turned around
3 and said she didn't answer it.

4 BY MR. LEE:

5 Q. Ms. Polich, I'm not asking you about
6 regulatory requirements. I'm not asking about
7 verifying codes. I'm asking you: Is there an
8 obligation, regulatory or not, that codes submitted
9 to CMS need to be supported by the medical records?

10 A. I don't know that.

11 Q. Isn't that what that top line in this
12 PowerPoint by Reden & Anders is trying to train you?

13 MR. SCHINDLER: Objection. Calls for
14 speculation. Asked and answered and no
15 foundation.

16 THE WITNESS: I do not know the -- what
17 they were thinking or anticipating with this
18 and this was not a presentation to us. This
19 was not a training to us. This was a
20 presentation that they would be using with
21 external clients.

22 BY MR. LEE:

23 Q. When you say a minute ago that it was
24 presumed that the codes would be accurate, do you
25 have any understanding as to whether or not there was

1 CERTIFICATE

2

3 STATE OF GEORGIA:

4 COUNTY OF FULTON:

5

6 I hereby certify that the foregoing
7 transcript was taken down, as stated in the caption,
8 and the colloquies, questions, and answers were
9 reduced to typewriting under my direction; that the
10 transcript is a true and correct record of the
11 evidence given upon said proceeding.

12 I further certify that I am not a relative
13 or employee or attorney of any party, nor am I
14 financially interested in the outcome of this action.

15 This the 3rd day of October, 2022.

16

17

18

19

Marsi Koehl

20

Marsi Koehl, CCR-B-2424

21

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25

DISCLOSURE

STATE OF GEORGIA:

COUNTY OF DEKALB:

Deposition of CYNTHIA POLICH.

Pursuant to Article 8.B. of the Rules and Regulations of the Board of Court Reporting of the Judicial Counsel of Georgia, I make the following disclosure:

I am a Georgia Certified Court Reporter acting as an agent of Magna Legal Services, who was contacted by the offices of US DOJ, to provide court reporting services for this deposition. I will not be taking this deposition under any contract that is prohibited by O.C.G.A. 15-14-37 (a) and (b).

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Marsi Koehl

Marsi Koehl, CCR-B-2424

Date: 10/4/22

EXHIBIT D-135

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.
BENJAMIN POEHLING,

Plaintiffs,

vs.

UNITEDHEALTH GROUP, INC., et al.,

No.

16-08697 FMO

Defendants.

VIDEOTAPED DEPOSITION OF TIMOTHY RENJILIAN

March 21, 2024, 9:07 a.m.

Alston & Bird

One Atlantic Center

1201 West Peachtree Street

Suite 3800

Atlanta, Georgia

Michelle R. Lowe, RPR, CCR-2748

1 beneficiary level payments?

2 MR. JONES: Objection. Form.

3 A No, not during the time period that we're
4 talking about. So I don't believe that CMS did
5 extrapolate results and -- and seek recoupment at
6 all.

7 BY MR. MASON:

8 Q Has CMS ever extrapolated RADV results?

9 A Yes.

10 Q When?

11 A In the CON11 to 13 years. There were
12 extrapolations that were done and reported out.

13 Q You mean that CMS calculated what an
14 extrapolation would look like, but they didn't
15 actually recoup payments based on extrapolated
16 results; right?

17 A That's right. But you asked me if
18 extrapolations had been done and they did calculate
19 extrapolations.

20 Q So, just to be clear, CMS, in your view,
21 has extrapolated RADV results, but they've never
22 recouped payments based on extrapolation?

23 MR. JONES: Objection. Form.

24 A Yeah, they have done extrapolation
25 calculations based on the results of their RADV

1 audits and have not sought to recoup any excess
2 payments or to make whole any underpayments.

3 BY MR. MASON:

4 Q And you mentioned that in RADV the MAOs
5 can submit up to five medical records for each
6 member-HCC that's part of the RADV sample?

7 A That's my understanding, yes.

8 Q And the MAO gets to choose those medical
9 records from the beneficiary's entire medical
10 history throughout the year?

11 A That's my understanding is that they
12 submit what they think are the -- you know, five
13 best records to support that HCC.

14 Q And they can choose any medical record
15 from throughout the year for that beneficiary?

16 MR. JONES: Objection. Form.

17 A That meets the other criteria of being a
18 face-to-face encounter from an appropriate provider.
19 I mean, so there's -- there's more to it than that,
20 but, generally speaking, yes.

21 BY MR. MASON:

22 Q And to -- to be included in a RADV
23 audit -- well, CMS selects a sample of MAO's members
24 to be included in a RADV audit; right?

25 A Yes. They have a -- their methodology was

1 fairly complicated and it's changed over time,
2 but -- but at a sort of basic level, yes, they're
3 reviewing some sort of sample of -- of MAO members.

4 Q Have you analyzed how CMS selects the
5 sample?

6 A Analyzed would probably not be the word
7 that I use. I have reviewed information about that.
8 I -- it -- as I said, it's complicated. I just
9 reviewed it to get a general understanding of -- of
10 how they do things, but I -- I couldn't give you an
11 exhaustive, you know, outline of exactly how they
12 selected their member samples in each year.

13 Q Do you have any expert opinions about the
14 statistical properties of the samples -- the RADV
15 samples?

16 MR. JONES: Objection. Form.

17 A I haven't rendered any statistical
18 opinions.

19 BY MR. MASON:

20 Q Do you -- do you have any expert opinions
21 about -- that relate to how CMS selects the RADV
22 sample?

23 MR. JONES: Objection. Form.

24 A I don't have -- I don't believe I have
25 such opinions, you know, expressed as opinions

1 you know, in particular here is as rebutting the
2 presumption that diagnosis codes not independently
3 identified by a chart reviewer were necessarily
4 unsupported.

5 Q Okay. And, likewise, you're not offering
6 an expert opinion that the 55 percent that you
7 calculated for the Garthwaite RADV overlap should be
8 applied to the entire population of the Garthwaite
9 delete list; right?

10 A Again, I'm using that principally to rebut
11 Dr. Garthwaite's presumption that the codes on his
12 delete list were necessarily unsupported.

13 Q So you agree then that you're not offering
14 an expert opinion that the 55 percent rate that you
15 calculated for the Garthwaite delete list should be
16 applied across the entire Garthwaite delete
17 population?

18 A Well, when you say should be applied, I
19 mean, I think it's -- as I've, I think, termed it in
20 my report -- it's an instructive basis on which to
21 think about that grouping, but it's not a
22 statistically valid extrapolatable [sic] rate that
23 you could say with any sort of mathematical
24 confidence reflects, you know, anything about the
25 larger population of Garthwaite deletes.

1 Q If one were to opine that the validation
2 rate of 55 percent from the Garthwaite RADV overlap
3 that you calculated should be applied to the entire
4 Garthwaite delete list, then that would also mean
5 that 45 percent of the diagnosis codes on
6 Garthwaite's list map to member-HCC combinations
7 that would not be validated in RADV; right?

8 MR. JONES: Objection. Form.

9 A Well, as I've said, I don't think the RADV
10 overlap can statistically or mathematically be
11 extrapolated to any population, which means just as
12 I wouldn't assert that that means that some certain
13 percentage of the codes are supported, it would be
14 inappropriate to conclude that that definitively
15 means that some certain percentage of the codes were
16 not supported. And that's -- I think that's
17 important.

18 Nonetheless, my view, just based on what
19 we have in the RADV overlap, that some of the HCCs
20 to which the questioned diagnoses map were found to
21 be validated definitively rebuts Dr. Garthwaite's
22 presumption that the codes on his list are
23 necessarily unsupported, but you can't do the
24 converse and say, and here's the percentage that is
25 or is not supported.

1 I think the other thing I would just throw
2 in there is that the RADV results, you know, are
3 also subject to appeal. So we don't know whether or
4 to what extent the RADV audit findings might be
5 changed by appeals that United might pursue, and I
6 haven't seen that data.

7 BY MR. MASON:

8 Q In your experience, is 45 percent of a
9 RADV audit not validating considered high?

10 MR. JONES: Objection. Form. Foundation.
11 Misstates the testimony.

12 A I don't -- I don't think there's enough
13 information here to make a judgment about that, one
14 way or the other.

15 I mean, at some level, right, if you did
16 enough work, you could find a population that had an
17 error rate of 100 percent, right, if you went all
18 the way through and did everything you needed to do.
19 That, to me, probably isn't the relevant way to
20 think about an error rate and there's not an
21 absolute standard as to what sort of error is too
22 high or not high enough. There's judgment inherent
23 in those determinations.

24 So I don't have a clear answer for you on
25 that.

1 this litigation?

2 A Well, I think the 1.9 million is this
3 artificial subset that exists only in this
4 litigation so --

5 Q Well, I'm only asking because you said
6 that you're not aware in the context of this
7 litigation and I wanted to make sure that you
8 weren't leaving something out of your answer.

9 So you're not aware of anyone inside or
10 outside of this litigation doing any analysis
11 whether the -- the remaining 1.9 million diagnosis
12 codes on Garthwaite's delete list, other than the
13 375, are supported at the diagnosis code level by
14 any charts?

15 MR. JONES: Objection. Form.

16 And you just interrupted an answer
17 midstream; so I'm going to ask you to let the
18 witness continue his answers.

19 A I am not aware of any such review.

20 BY MR. MASON:

21 Q Thank you. I'm sorry if I interrupted; I
22 thought you were done with your answer.

23 A No offense.

24 Q Great.

25 As to that remainder -- and when I say the

1 remainder, I mean the 1.9 million, approximately,
2 diagnosis codes on Garthwaite's list, less the 375
3 diagnosis codes that you say were validated in RADV.

4 So as to that remainder, can you identify
5 any specific diagnosis codes that are supported
6 either at the diagnosis code level or the member-HCC
7 level by any chart?

8 MR. JONES: Objection. Form.

9 A It's not something I've undertaken; so I
10 can't. And the reason is that it's not germane to
11 my opinion. You know, my understanding is that
12 neither Dr. Garthwaite, nor anybody else on that
13 side of -- of this matter has done that either to
14 demonstrate that these codes are, in fact,
15 unsupported.

16 BY MR. MASON:

17 Q And you don't believe it's appropriate to
18 extrapolate the 55 percent validation rate to that
19 1.9 million remainder; right?

20 MR. JONES: Objection. Form. Asked and
21 answered.

22 A That's correct. As a statistical or
23 mathematical matter, I don't think that's an
24 extrapolatable ratio.

25 BY MR. MASON:

1 Q And of the 375 that you've identified as
2 validated in RADV, how many did RADV determine the
3 same specific diagnosis code that United submitted
4 was supported by any medical chart?

5 MR. JONES: Objection. Form. Asked and
6 answered.

7 A I believe this hearkens back to our -- our
8 discussion before the break that it's -- it's not
9 possible to determine which specific diagnosis codes
10 the RADV auditors -- meaning, in terms of which
11 specific member, provider, date of service
12 combination on a particular chart were reviewed or
13 given what weight or consideration by the RADV
14 auditors. So I don't know.

15 BY MR. MASON:

16 Q And you also can't say whether any of
17 those 375 RADV found support for the specific
18 diagnosis code that United submitted; right?

19 MR. JONES: Objection. Form. Asked and
20 answered.

21 A Well, as we talked about previously, the
22 RADV auditors -- each one of those codes was either
23 found to be supported by the RADV auditors or is
24 moot.

25 BY MR. MASON:

1 A That's correct.

2 Q And so you don't have any information
3 about any specific unsubmitted but valid diagnosis
4 for any of the members on Garthwaite's deletes --

5 MR. JONES: Objection.

6 BY MR. MASON:

7 Q -- right?

8 MR. JONES: Form.

9 A The only information I have specifically
10 on valid but un -- or supported but unsubmitted
11 diagnosis codes would be what's contained within
12 United's systems, specifically those unsubmitted
13 codes with an X19 designation, as -- as one example.

14 BY MR. MASON:

15 Q The ones that Garthwaite accounted for?

16 A Yes.

17 Q In Paragraph 43, you mention -- this is
18 what you wanted to talk about earlier; right -- that
19 13 of the 15 United contracts reviewed in the
20 CON11-13 RADV audits were found to have net
21 underpayments.

22 That's -- that's your statement; right?

23 A That's correct.

24 Q Your understanding is that this was a
25 finding by CMS?

1 A This was the publicly disseminated result
2 of their audits.

3 Q Your understanding is that these results
4 were publicly disseminated?

5 A Well, I know that they were reflected
6 within a RADV audit summary that -- that I have
7 referenced in my report. I don't actually recall
8 whether that was generally publicly available,
9 available only through a FOYA request. I don't
10 recall exactly how it was obtained.

11 Q Why -- why did you refer to it as publicly
12 disseminated?

13 A Well, I apologize if that's a
14 misstatement. My understanding was that that
15 information is available and it's been incorporated
16 into my work.

17 Q Okay. So your understanding is that this
18 was a finding by CMS?

19 A Yes, that the results of their RADV audits
20 showed that 13 of those 15 contracts had negative
21 net recovery amounts or negative recovery amounts.

22 Q And do you have an understanding whether
23 that result was finalized by CMS?

24 MR. JONES: Objection. Form.

25 A I don't know what the current status is or

1 whether any appeals that United may have pursued
2 with respect to the findings of that -- of those
3 audits, you know, may also impact those results. So
4 I don't know.

5 BY MR. MASON:

6 Q You don't know that CMS considers those
7 preliminary results?

8 MR. JONES: Objection. Form.

9 A I do under -- I guess I do understand that
10 they are not final-final. My corresponding
11 understanding would be that they're not likely to
12 get worse from the MAO's perspective, but, rather,
13 that they are open to an appeal process that can be
14 initiated by the MAOs which may reverse some of the
15 adverse findings from those audits.

16 BY MR. MASON:

17 Q So let me just back up.

18 Do -- do you have an under --
19 understanding whether these results were finalized
20 by CMS?

21 MR. JONES: Objection. Form. Asked and
22 answered.

23 A I don't believe that they were
24 final-final.

25 BY MR. MASON:

1 Q You don't believe that they were
2 final-final?

3 A Correct.

4 Q Is final-final different than final?

5 MR. JONES: Objection. Form. Asked and
6 answered.

7 A I -- there are often things that are final
8 and then there's some other process that goes
9 beyond. So what I meant to say is that I don't know
10 that the ultimate adjudication of all of the
11 findings within those audits is fully and once and
12 for all complete.

13 BY MR. MASON:

14 Q And what are you basing it on that -- that
15 the result -- what is the -- what is the basis for
16 your statement that -- about the degree to which
17 these results were finalized?

18 MR. JONES: Objection. Form.

19 A I don't recall specifically and I don't
20 have the document in front of me, but I just -- my
21 recollection from my work is that they were not
22 ultimately final.

23 BY MR. MASON:

24 Q Can you -- is it in your report somewhere
25 that we can reference?

Video Deposition

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CERTIFICATE OF COURT REPORTER

STATE OF GEORGIA:

COUNTY OF COBB:

I hereby certify that the foregoing transcript was taken down, as stated in the caption, and the questions and answers were reduced to typewriting under my direction; that the foregoing 355 pages represent a true and correct transcript of the evidence given upon said proceeding.

This the 24th day of March 2024.

MICHELLE LOWE, RPR, CCR-2748

EXHIBIT D-136

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
_____)

*** CONFIDENTIAL ***

CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videoconference Videotaped Deposition OF
JEFF RENSHAW
(Taken virtually)
9:30 a.m. Eastern
Wednesday, August 24, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 A. Three.

2 Q. Was it in person or remote?

3 A. I didn't meet with all -- sorry. I
4 didn't meet with all three each time, but we met
5 three times.

6 Q. Great. Okay. And how -- for how long
7 would you say total you met?

8 A. 8 hours and 47 minutes.

9 Q. You're precise. Okay.

10 A. I got done -- we got done a little bit
11 early yesterday.

12 Q. Love it. All right. That's memorable
13 when you get to finish up early.

14 A. Yes.

15 Q. Okay. And did you -- when you were
16 preparing, did you review any documents?

17 A. Yes.

18 Q. And did any of them refresh your
19 recollection of events that we may speak about
20 today?

21 A. Certain parts of certain documents did
22 refresh my recollection.

23 Q. Great. And did you speak with anyone
24 else about this deposition?

25 A. I notified my boss and my team that I

1 was being deposed today, but beyond that, you
2 know, I didn't provide any specifics about the
3 subject matter. Just wanted them to know that I
4 wouldn't be available.

5 Q. Great. Okay. And no one else beyond
6 that?

7 A. No.

8 Q. Okay. Where are you currently
9 employed?

10 A. I work for Department of Health and
11 Human Services, Office of Inspector General in the
12 Office of Audit Services. I'm --

13 Q. And is --

14 A. Sorry.

15 Q. No, no, please. I'm sorry to cut you
16 off. Go ahead.

17 A. I was just going to say I'm currently
18 working in Region 5, which is kind of like our
19 Chicago, Midwest region.

20 Q. And is Office of the Inspector General
21 referred to as OIG?

22 A. Yes.

23 Q. So you'll understand today if I say
24 OIG, that's what I'm referring to?

25 A. Yes.

1 Q. And then same thing, is it okay if I
2 say OAS, you'll understand I mean Office of Audit
3 Services?

4 A. I will.

5 Q. Great. And how long have you worked
6 at OIG?

7 A. Since summer of 2002.

8 Q. Wow, okay. So 30 -- 30 years; is that
9 right?

10 A. No. I wish.

11 Q. 20. My math is bad.

12 MS. GLOVER: 20.

13 THE WITNESS: It's about 20 years.

14 BY MS. ZUCKERMAN:

15 Q. You can tell why I'm a lawyer.

16 20 years. Okay. Well,
17 congratulations. That's a long time.

18 A. Thank you.

19 Q. Okay. And what does OIG do, just big
20 picture?

21 A. Well, we do a number of things. I
22 mean, we do audits. We do evaluations. We've got
23 legal counsel. We have investigators. And our
24 mission is to sort of look at fraud, waste, and
25 abuse in HHS programs such as Medicare, Medicaid,

1 and others.

2 Q. Great. Okay. And which -- you said
3 you worked for -- you said you work for OAS;
4 right?

5 A. That's correct.

6 Q. How is OAS organized?

7 MS. GLOVER: Objection. Vague. You
8 can answer.

9 THE WITNESS: Okay.

10 MS. GLOVER: If you're able to, you can
11 answer.

12 THE WITNESS: Sure.

13 MS. GLOVER: Even when I object, it's
14 okay.

15 THE WITNESS: We have a headquarters
16 and we've got regions. Headquarters is --
17 is the question how is -- how is OAS
18 organized; is that correct?

19 BY MS. ZUCKERMAN:

20 Q. Yeah, let me rephrase. The question
21 is just -- is what I'm trying to do is get a sense
22 of so there's the regions and how do they fit
23 together with HQ, just sort of what are the
24 different components that make up OAS?

25 A. Yeah, so there are regions. There's a

1 established by our risk adjustment system. The
2 chart validation tested the provider's deviation
3 from that benchmark, codes found to be inaccurate
4 or incomplete through chart validations were
5 deleted."

6 Did I read that right?

7 A. I believe so, yes.

8 Q. Okay. Is your understanding that here
9 PacifiCare was explaining its chart validation
10 process?

11 A. Yes. This is -- this is a description
12 of the chart validation process.

13 Q. And what was your understanding of
14 PacifiCare's chart validation process?

15 A. So my understanding of the chart
16 validation process was that for providers that
17 PacifiCare paid on a capitated basis, so as
18 opposed to a provider that it would pay on a
19 fee-for-service basis, that -- and providers of a
20 certain size, I believe. And I don't remember
21 right now how to determine that certain size.
22 Some review of diagnosis -- the support for
23 diagnosis codes would be done.

24 So for certain diagnosis codes that a
25 capitated provider submitted to PacifiCare, it

1 would review those diagnosis codes to determine
2 whether they were supported by medical records.

3 Q. Okay. So fair to say you understood
4 that PacifiCare was only performing chart
5 validation for a subset of providers?

6 A. That's correct.

7 Q. And you understood that PacifiCare was
8 not auditing or validating every code that it
9 submitted to CMS?

10 A. Yes. That was -- that was -- that was
11 clear and made -- you know, made sense that they
12 wouldn't review everything.

13 Q. And what do you mean by it made sense?

14 A. Well, I don't think that it would be
15 reasonable to expect a Medicare Advantage
16 organization to determine whether every single
17 diagnosis submitted to CMS is supported to have a
18 good -- I mean, I don't think a good compliance
19 program would require that level of review.

20 Q. And has it ever been your
21 understanding that CMS required plans to conduct a
22 review of every code submitted?

23 MS. GLOVER: Objection. Form.

24 THE WITNESS: I've never --

25 MS. GLOVER: Go ahead.

1 THE WITNESS: I've never seen anything
2 that makes me think that CMS would expect a
3 plan to review every diagnosis that it
4 submits for -- to review medical record
5 documentation in support of every diagnosis
6 that it submits.

7 BY MS. ZUCKERMAN:

8 Q. So continuing in this very long
9 paragraph, it says, "In contrast, a chart review
10 involved review of the diagnoses reflected in a
11 selected provider's patient charts to determine if
12 any documented diagnoses had not been reported to
13 CMS. Following a chart review, we submitted to
14 CMS any new codes documented in the medical chart
15 but did not determine whether the codes previously
16 reported to CMS were documented in the medical
17 record."

18 Do you see that?

19 A. Yeah. Can I just review that real
20 quick? At first I didn't see where you started
21 reading, so I would like to just review that bit
22 myself, if that's okay.

23 Q. Of course. Take your time. Yeah,
24 just tell me when you're ready.

25 MS. GLOVER: And, Naomi, I think you

1 started with "in contrast."

2 MS. ZUCKERMAN: Yeah. Did I get that
3 wrong?

4 MS. GLOVER: No, no, no. I think I
5 also had trouble catching up to where you
6 were in the paragraph. I think maybe you
7 started with "in contrast" if you want to
8 start there, Jeff.

9 MS. ZUCKERMAN: Yeah, "in contrast."
10 It's about halfway through the big block.

11 THE WITNESS: Great. I see it. Thank
12 you.

13 Okay. Right. Thank you.

14 BY MS. ZUCKERMAN:

15 Q. What did you understand PacifiCare to
16 be explaining about its chart review program here?

17 A. I think that what PacifiCare was
18 explaining is that it's possible that there are
19 diagnoses that are relevant to the payment model
20 like I described earlier this morning, that it
21 doesn't specifically receive from the provider.
22 And so this chart review process, the purpose of
23 it would be to determine whether there's any
24 relevant diagnoses that PacifiCare could submit to
25 CMS because it's supported by the medical record

1 despite the fact that a provider had submitted
2 that diagnosis directly to PacifiCare.

3 Q. And stepping away from what PacifiCare
4 said here, did you have an understanding at this
5 time of, I think you said, there might be
6 diagnoses relevant to the payment model but that
7 the provider had not submitted. Were you aware of
8 why it would be that some providers might not
9 submit all of the diagnoses that might exist in a
10 patient's chart?

11 MS. GLOVER: Objection. Calls for
12 speculation.

13 THE WITNESS: And I don't know. I
14 mean, I can imagine there would be
15 circumstances where that would be the case,
16 but I don't really know what they would be.

17 BY MS. ZUCKERMAN:

18 Q. Were you aware of differences between
19 fee-for-service providers and providers that
20 received payment on a capitated basis in terms of
21 the completeness of coding that they would do for
22 a patient's chart?

23 MS. GLOVER: Objection. Form.

24 THE WITNESS: I don't -- I don't know.

25 BY MS. ZUCKERMAN:

1 Q. Okay. And returning to the document
2 here, did you understand PacifiCare to be saying
3 that when PacifiCare did a chart review, they were
4 only looking to add codes that had been missed by
5 the provider rather than also validating any codes
6 that had been previously submitted?

7 A. It was my understanding that this
8 would have been sort of a look for new codes,
9 meaning ones that hadn't been submitted before.

10 Q. Was it clear to you that from this
11 submission that PacifiCare was not conducting
12 validation of codes when it was doing that
13 process?

14 A. Was it clear to me that PacifiCare was
15 not doing validation of codes as part of its chart
16 review process?

17 Q. Yeah.

18 A. I don't know whether this is based on
19 my knowledge or an assumption, but I would assume
20 it was only submitting new codes that it had
21 determined were supported by medical record.

22 Q. And if you look maybe two-thirds of
23 the way down, do you see where the sentence
24 beginning follow a chart -- "following a chart
25 review"?

1 A. Yes.

2 Q. Do you see where it says, "Following a
3 chart review, we submitted to CMS any new codes
4 but did not determine whether the codes previously
5 reported to CMS were documented in the medical
6 record."

7 MS. GLOVER: Objection. Misstates the
8 document.

9 THE WITNESS: I didn't hear the
10 objection. Maybe it doesn't matter.

11 MS. GLOVER: It's okay. I think the
12 court reporter hopefully caught it, but,
13 yeah, you can go ahead and answer.

14 THE WITNESS: Okay. And what was your
15 question about this sentence?

16 BY MS. ZUCKERMAN:

17 Q. My question was whether you could see
18 that it said -- whether you could said that you --
19 PacifiCare had written here, "We did not determine
20 whether the codes previously reported to CMS were
21 documented in the medical record."

22 A. Yes, I see that.

23 Q. So is it fair to say that PacifiCare
24 explained to OIG here that as part of its chart
25 review, it was not also determining whether codes

1 previously reported to CMS were documented in the
2 medical record?

3 MS. GLOVER: Objection to form.

4 THE WITNESS: That's clear -- yeah,
5 that's clear. That's sort of -- that's
6 been my understanding of this all along.

7 BY MS. ZUCKERMAN:

8 Q. Okay. So, in other words, PacifiCare
9 was transparent about that as far as the purpose
10 of its chart review program and what it was or was
11 not doing in terms of validating diagnosis codes?

12 MS. GLOVER: Objection. Asked and
13 answered.

14 THE WITNESS: My understanding of the
15 chart review process is that it was focused
16 on identifying new supported diagnosis
17 codes that are relevant to the payment
18 model for submission to CMS.

19 BY MS. ZUCKERMAN:

20 Q. And that specifically PacifiCare did
21 not determine whether the codes previously
22 reported were documented in the medical record;
23 right?

24 MS. GLOVER: Objection. Asked and
25 answered.

1 THE WITNESS: It's clear from this
2 response to me that CMS wouldn't have been,
3 as part of its chart review process,
4 attempting to validate diagnoses that had
5 already been submitted to CMS.

6 BY MS. ZUCKERMAN:

7 Q. And when you just said "CMS wouldn't
8 have been as part of its chart review process,"
9 did you mean PacifiCare?

10 A. Thank you. Yes, that's what I meant.

11 Q. Okay. Let's -- I'm going to introduce
12 another exhibit that's been previously marked,
13 which is Exhibit 1126-1 and 1126-2. Just let me
14 know when you can see those.

15 A. Sure. I'm looking at the e-mail that
16 Juliet sent to Lisa and me and copied Cheryl on, I
17 guess after we went to Minneapolis.

18 Q. Yeah. So this is a December 8, 2009,
19 e-mail from Juliet Lo to you, Lisa Lara, and
20 Bradley Smith copying Cheryl Blackmon regarding
21 the meeting with Paul Bihm?

22 A. Yes, that's correct.

23 Q. And Ms. Lo writes, "Attached is the
24 write-up from 12/2 with Paul Bihm."

25 "It was good to meet you all last

1 week," she says, also, above.

2 Is this -- is it your understanding
3 that this is referring to the meeting in Minnesota
4 that you referenced earlier?

5 A. The -- when she talks about meeting
6 with us last week, that is what she's referring to
7 as our time in Minnesota on this audit.

8 Q. Okay. And do you recall Juliet Lo
9 taking notes at that meeting?

10 A. I don't specifically remember her
11 taking notes. I would have expected that she was,
12 and it appears that she must have.

13 Q. Do you recall if anyone else took
14 notes during the meeting?

15 A. Again, I don't have specific memories
16 of people taking notes, but I would have expected
17 Lisa and Brad to be taking notes.

18 Q. And do you remember if you would have
19 taken notes?

20 A. So I was -- I'm -- I was doing most of
21 the -- asking most of the questions, as I recall,
22 during the meetings that we had with PacifiCare
23 officials, and I don't -- I don't recall taking
24 notes. You know, I -- it would have been typical
25 for me in a situation like this to remind my team

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 28th day of August, 2022.

Christine A. Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-137

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videotaped Deposition of
CHERI RICE
Given Remotely
Wednesday, August 3, 2022
9:01 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 A. I have not.

2 Q. Let me turn to your -- your position and
3 your background. Can you -- can you tell us where
4 you currently work and what your position is?

5 A. Sure. I currently work in the Center for
6 Medicare at CMS, so I'm the deputy director in the
7 Center for Medicare, for Medicare Advantage and
8 Part D.

9 Q. To sort of place that in the hierarchy at
10 CMS, do you report to the -- to the director of CMS?

11 A. I report to the deputy administrator for
12 Medicare. So she --

13 Q. Who is that? I was going to ask, who is
14 that person?

15 A. Dr. Meena Seshamani.

16 Q. And how long have you been in the -- in
17 the position of -- of -- I think you said deputy
18 director?

19 A. Five years.

20 Q. Five years. And what did you -- what did
21 you do before that?

22 A. Before that, I was the director of the
23 Medicare Plan Payment Group, which is also in the
24 Center for Medicare.

25 Q. And what -- and what years, roughly, were

1 you the -- the director of the Medicare Payment --
2 Plan Payment Group?

3 A. Seven years. So it was approximately 2010
4 to 2017.

5 Q. And I believe you were with -- you were
6 with that group before you were director, as the
7 deputy director; is that correct?

8 A. That's correct.

9 Q. And how long were you in the role of
10 deputy director at the -- the Plan Payment Group?

11 A. Six years.

12 Q. In your current role as the deputy
13 director, do you have oversight of the -- the Plan
14 Payment Group?

15 A. Yes.

16 MS. McMAHON: Objection. Vague. Sorry.

17 BY MR. GALLAGHER:

18 Q. What is your responsibility with respect
19 to the Plan Payment Group today as the deputy
20 director?

21 A. So the -- my successor in that role, the
22 director of the Plan Payment Group reports to me. I
23 am her supervisor.

24 Q. And who -- I'm sorry. Go ahead.

25 A. So I am responsible for providing them

1 with direction, reviewing work products that they
2 develop, et cetera.

3 Q. When you were in the role of -- of
4 director of the Plan Payment Group, who -- to whom
5 did you report?

6 A. So I reported to -- there were multiple
7 folks in my current role: Tim Hill, Tim Love, and
8 Cynthia Tudor.

9 Q. In the -- like the 2010 to 2015 time
10 frame, was it Cynthia Tudor who was in your current
11 role, that you reported to?

12 A. Yeah, I can't remember exactly when --
13 when Cynthia -- it switched from Tim Love to Cynthia,
14 but certainly in the 2015, 2014 time frame, it was
15 Cynthia.

16 Q. Okay. And I'm going to refer to the Plan
17 Payment Group as "MPPG," because I think that's the
18 abbreviation that you folks use, and it's easier to
19 say.

20 A. Yes.

21 Q. So at -- at MPPG, both as the -- the
22 director and the deputy director, did you have
23 responsibility for administering the risk adjustment
24 payment plan or payment model for Medicare Advantage
25 plans?

1 A. Yes.

2 Q. And did you have responsibility for
3 defining and implementing what's sometimes referred
4 to as the coding intensity adjustment?

5 A. Yes.

6 Q. And did you run the risk adjustment data
7 validation program and -- and have some
8 responsibility for the -- what are called the RADV
9 audits?

10 MS. McMAHON: Objection. Vague.

11 BY MR. GALLAGHER:

12 Q. You can answer the question.

13 A. Yes. So RADV was part of the scope of
14 responsibilities in MPPG until the end of 2016.

15 Q. And then what happened at the end of 2016?

16 A. Then that -- the RADV audits were
17 transferred to the Center for Program Integrity in
18 CMS.

19 Q. I've heard reference to a thing called the
20 Advance Notice. Can you tell us what the Advance
21 Notice is?

22 A. So the Advance Notice is a document that
23 is actually specified in statute, where we propose
24 payment changes and payment updates to the
25 methodologies for Medicare Advantage. And we put

1 that out for public comment, and then issue a final
2 document or rate announcement in early April each
3 year. And so that lays out the payment policies,
4 including risk adjustment and capitation rates for
5 Medicare Advantage plans for the upcoming payment
6 year.

7 Q. So fair to say that the Advance Notice is
8 something that -- that CMS puts out to get comment
9 from Medicare Advantage plans before, you know,
10 setting the final rules for the bid process?

11 A. That's correct.

12 MR. BULAND: Objection.

13 BY MR. GALLAGHER:

14 Q. And as the -- in MPPG, did you have
15 responsibility for some part or all of that Advance
16 Notice?

17 A. All.

18 Q. Did you, at MPPG, have responsibility for
19 reviewing and accepting the bids that were submitted
20 by Medicare Advantage organizations?

21 A. I did not.

22 Q. Whose -- who had that responsibility?

23 A. There's two pieces to the bid, bids.
24 There are the plan benefit packages, where plans lay
25 out what their benefit offerings will be. That

1 MS. McMAHON: Go on.

2 THE WITNESS: All right.

3 No. There -- we have other longstanding
4 requirements in the program, with our compliance
5 program, with the attestations, with our managed
6 care manual, where we -- where we specify that
7 if there's an indication that the -- the
8 diagnosis is not or may not be valid, the plan
9 needs to make sure that they delete it if it's
10 not correct.

11 BY MR. GALLAGHER:

12 Q. So they -- they have to delete it once
13 they determine that it's not correct?

14 MS. McMAHON: Objection.

15 THE WITNESS: Yes. They -- they also have
16 to take steps, reasonable steps, if they have
17 information that would suggest that it's not
18 documented, to follow through on that.

19 BY MR. GALLAGHER:

20 Q. Actually, there's -- there's two things
21 there that I want to unpack.

22 The first is when you have to delete, in
23 your view. And the deletion comes when you know that
24 the code is not supported, right? That's when that
25 obligation arises?

1 MS. McMAHON: Objection.

2 THE WITNESS: Well, our attestation is
3 best information, knowledge, and belief. And if
4 the plan has information that would suggest that
5 it might not be valid, then they either need to
6 delete it or they need to take steps to
7 determine that it is valid, so that they -- it
8 can stay in the system.

9 BY MR. GALLAGHER:

10 Q. So your -- let me ask it this way: Does
11 a -- does a Medicare Advantage plan have to confirm,
12 through record review, that there is specific support
13 for every single code that it submits for risk
14 adjustment?

15 A. No.

16 Q. Okay. And do you contend that in order to
17 implement an effective compliance program, plans are
18 required to ensure that every single
19 provider-reported diagnosis code is supported?

20 A. So no, we have not said that a plan needs
21 to check every diagnosis or medical record
22 documentation. What we have said is that they have
23 to have a good faith effort, reasonable effort,
24 not -- we know that 100 percent is difficult to do.
25 But they have to have a reasonable program to

1 validate the accuracy of the data that they submit.

2 We aren't prescriptive about how they do that.

3 Q. So, but -- but the answer to my question
4 is no; you -- you don't contend that in order to
5 implement an effective compliance program, Medicare
6 Advantage organizations must ensure that every single
7 provider-reported diagnosis code is supported? You
8 don't contend that?

9 A. Unless they have knowledge that they've
10 taken steps, and they have knowledge that there might
11 be an issue and they have to follow up on it, but no,
12 we don't say, "You have to go out and get medical
13 record documentation on every code."

14 Q. But fair to say that everybody knows that
15 there's a certain error rate in provider-reported
16 diagnosis codes?

17 MS. McMAHON: Objection.

18 BY MR. GALLAGHER:

19 Q. All right. That's -- that's sort of a
20 given, in this universe, isn't it?

21 MS. McMAHON: Objection.

22 BY MR. GALLAGHER:

23 Q. You can answer.

24 A. I think -- yes, in -- no data set is going
25 to be perfect in the MA program or in the

1 we don't get into being prescriptive there.

2 Q. Earlier I asked you about the example of
3 sort of RADV audits and whether the knowledge of --
4 of the results of those might create some obligation
5 in subsequent years. If a -- if a plan, for whatever
6 reason, has done its own internal audit for one year,
7 and -- and appreciated from that that there was a
8 certain rate at which their providers had, you know,
9 coded things that were not supported by the medical
10 records, does that, in your view, create an
11 obligation in subsequent years to do something?

12 MR. BULAND: Objection.

13 MS. McMAHON: Objection.

14 THE WITNESS: I think there -- again,
15 the -- there is -- regardless of whether they --
16 what they found in the particular year, there's
17 a general requirement and expectation that
18 they're going to take a good faith effort to
19 validate the validity of the -- of the diagnoses
20 that they submit.

21 BY MR. GALLAGHER:

22 Q. I'm -- I'm sort of setting aside what
23 you've described as a general expectation that --
24 that you believe exists for plans, and I -- I want to
25 ask more specifically: Do you at CMS -- let me put

1 it this way.

2 Have you at CMS ever taken the position
3 with plans that -- that your rules require them to do
4 something in subsequent years if they learned in an
5 earlier year that some set of codes was not
6 supported?

7 MR. BULAND: Objection.

8 THE WITNESS: No, we have not specifically
9 said that.

10 BY MR. GALLAGHER:

11 Q. Do you agree that if a -- if a plan finds
12 that a code is not supported in a particular record,
13 and makes the decision to delete it, but that does
14 not actually result in a change in the amount that
15 the plan was entitled to under your model, do you
16 agree that in that scenario, there wouldn't be an
17 overpayment?

18 MS. McMAHON: Objection. Calls for legal
19 speculation.

20 THE WITNESS: So they definitely need to
21 correct it. The -- but it would not translate
22 into change in payment.

23 BY MR. GALLAGHER:

24 Q. What I'm getting at is that -- is that you
25 can have situations where a particular diagnosis code

1 is not supported for a particular enrollee. But
2 deleting that doesn't affect what the plan is
3 entitled to by way of payment. That can happen,
4 right?

5 A. That can happen if the code -- because not
6 every code feeds into our model --

7 Q. Right.

8 A. -- for payment. There are a number of
9 codes that we don't feel are predictive of future
10 costs, and so they don't -- they don't count as a
11 payment diagnosis. So . . .

12 Q. Right. That would be an example where not
13 every code -- not every diagnosis, I should say --
14 impacts a beneficiary's risk score?

15 A. That's correct. If it doesn't feed into
16 our payment model, then it wouldn't affect their risk
17 score.

18 Q. So Example 1 of a situation where you
19 might have a diagnosis code that is not supported,
20 and therefore might need to be deleted, but would not
21 affect payment, would be one where the code itself is
22 not for something that -- is for something that would
23 not affect the beneficiary's risk score?

24 MS. McMAHON: Objection. Vague.

25

1 BY MR. GALLAGHER:

2 Q. That would be one example?

3 A. Yes.

4 Q. Another example might be if you have a
5 diagnosis code that is supported by multiple records,
6 right?

7 MR. BULAND: Objection.

8 MS. McMAHON: Objection. Vague.

9 BY MR. GALLAGHER:

10 Q. Let me ask it more specifically.

11 You might -- you might have a situation
12 where a -- a diagnosis code is correctly noted in
13 Medical Record A, by Provider A, but incorrectly
14 noted in Record B, by Provider B, for whatever
15 reason. Right? So the -- the patient actually has
16 the condition, but -- you know, the medical record
17 for -- for one of these providers doesn't actually
18 provide support for the diagnosis.

19 That is a scenario I'm -- I'm giving you.
20 Do you understand it?

21 A. Yes, I understand it.

22 So under our rules, a -- a beneficiary --
23 we consider the beneficiary to have the condition for
24 risk adjustment purposes. If there's -- if it's
25 diagnosed in one -- at least one record that meets

1 our risk adjustment requirements, so in that example,
2 say they were diagnosed in a physician setting and
3 then there was a diagnosis in a hospital setting, and
4 the hospital setting didn't meet our risk adjustment
5 requirements, if it's within the right data time
6 period and meets all the other requirements, then
7 the -- we only require one per year, so that would --
8 that would count for risk adjustment purposes.

9 Q. Right. Even though you might have to
10 delete the code from the unsupported setting?

11 A. Yes.

12 Q. You would still have -- it wouldn't affect
13 payment, because even though you have to delete the
14 code because it's not supported by Provider B, you'd
15 still have the diagnosis for that enrollee, and for
16 risk adjustment purposes, from the other provider?

17 A. Yes.

18 Q. Yeah. Another -- another example might
19 be, you might have a diagnosis from like the
20 radiology record, which doesn't count, but it's
21 elsewhere supported by a physician's record or in a
22 hospital setting?

23 MS. McMAHON: Objection. Vague.

24 BY MR. GALLAGHER:

25 Q. Maybe in that situation where you might

1 have to delete it because it's not supported by the
2 radiology record, but it would still be available for
3 risk adjustment purposes?

4 A. Yes.

5 Q. And -- and therefore deleting it wouldn't
6 affect payment?

7 A. Correct.

8 Q. Do you agree that there's a difference
9 between knowing that a code is not supported by a
10 particular set of medical records and knowing that
11 that has resulted in an overpayment?

12 MS. McMAHON: Objection.

13 THE WITNESS: Yes. But our -- our
14 requirements are plans need to correct their
15 diagnosis data regardless of whether there's a
16 payment impact or not. So it's not up to them
17 to decide, "I'm not going to -- I'm not going to
18 correct this one because there's no payment
19 impact."

20 The data need to be corrected, and then it
21 will flow through our payments, and it may or
22 may not change, you know, the payment to the
23 plan. But the -- the plan needs to submit the
24 accurate diagnosis data, and then it flows
25 through our -- you know, our payment

1 methodology.

2 BY MR. GALLAGHER:

3 Q. Right. What I'm getting at is the
4 question that's kind of at issue in this lawsuit,
5 which is whether there's an overpayment. And that's
6 a different issue than whether you need to correct
7 the data, right?

8 MS. McMAHON: Objection.

9 BY MR. GALLAGHER:

10 Q. You can answer.

11 A. So -- I'm sorry, can you state your
12 question again?

13 Q. Yeah. What I'm trying to get at is that
14 there's a difference between whether there's an
15 overpayment, which is the -- which is what is alleged
16 to have happened in this lawsuit, and whether there
17 is simply a data correction that needs to be made for
18 a particular code or -- or set of data.

19 MS. McMAHON: Objection.

20 BY MR. GALLAGHER:

21 Q. Do you understand that, that distinction?

22 A. Yes. So there will be -- there could be
23 some set -- set of codes that get corrected and don't
24 have a payment impact.

25 Q. Yeah. Put another way, you can have data

1 Number 25.

2 A. Okay.

3 Q. And this concerns the -- the reasons for
4 not finalizing the proposed medical record review
5 rule.

6 A. Uh-huh. Yes, I see it.

7 Q. Did you have any personal involvement in
8 the -- first, the -- the decision to propose the
9 medical record review rule?

10 A. Yes. That was a provision that was
11 drafted by my group, the Medical Plan Payment Group.

12 Q. And did -- and you personally oversaw that
13 process, the drafting process?

14 A. Yes.

15 Q. Were you involved in -- in the policy
16 decision, I'll call it, to actually propose a rule on
17 this subject?

18 A. Yes.

19 Q. Who else was involved in that decision,
20 from a policy standpoint?

21 A. Jennifer Harlow. And then we briefed our
22 policy officials. So at the time, I think that would
23 have been Jon Blum, perhaps Sean Cavanaugh; I can't
24 remember exactly the timing. It might -- no, it was
25 Sean Cavanaugh, I believe.

1 And then the administrator's office. So I
2 believe it was -- Don Berwick was the administrator
3 at the time, I believe.

4 Q. And so was the decision to propose a
5 medical record review rule something that originated
6 from your group?

7 A. Yes.

8 Q. And what was the impetus for that? Why
9 were you proposing this?

10 A. To provide plans with some more specific
11 guidance around their -- those general obligations
12 that I described. We were concerned that we had
13 heard that, you know, many plans were doing chart
14 reviews but not -- only looking for additional, what
15 we call additional; diagnoses that hadn't been
16 submitted, but they found in the medical records, but
17 then not; while they're looking at that medical
18 record, checking the accuracy of the -- of the
19 diagnoses that had already been submitted.

20 And that was concerning to us. And so we
21 recommended proposing being more specific about
22 the -- you know, the good faith effort that a plan
23 needed to -- to undertake to live up to their
24 obligations in terms of reporting appropriate payment
25 to CMS.

1 Q. Why, if you had the general obligations
2 that you've talked about from, you know, the
3 compliance program regulation and the subregulatory
4 guidance that you've mentioned before, why propose a
5 rule if you already had that?

6 MS. McMAHON: Objection. Vague.

7 THE WITNESS: We could have left it just
8 the way it was. We felt like it would be
9 helpful to be more specific, to provide some
10 more direction to the plans.

11 But, you know, it wasn't -- like I said,
12 there was this general framework in the
13 general -- general requirement. So this was
14 just providing some more direction to the plans
15 about -- in this specific circumstance, what we
16 meant by that.

17 BY MR. GALLAGHER:

18 Q. Before you proposed the medical record
19 review rule, did you have any specific guidance, or
20 had you provided any specific guidance to plans that
21 they were somehow obligated to look both ways, or to
22 design their medical record review processes to look
23 for deletes as well as adds?

24 MR. BULAND: Objection.

25 MS. McMAHON: Objection. Vague.

1 THE WITNESS: So we -- we do not review or
2 have plans submit to us their internal
3 procedures. So no, we have not provided
4 guidance about what -- if a plan chose to do a
5 medical record chart review, what that had to
6 look like and what the steps were that needed to
7 be taken. We were not specific.

8 BY MR. GALLAGHER:

9 Q. What is the process that you have to go
10 through in order to get an approval, as a policy
11 matter, for proposing a rule like the medical record
12 review rule?

13 A. So --

14 MS. McMAHON: Objection. Vague.

15 THE WITNESS: So the -- this was a
16 provision in a much larger rule. So it was not
17 a stand-alone rule.

18 For our rule-making, the typical process
19 is we brief our -- sequentially, the officials
20 in our chain of command. So we brief the
21 Director of the Center for Medicare, then take
22 recommendations to the Office of Administrator,
23 and then the rule goes to the Department of
24 Health and Human Services, where it's reviewed
25 by the career and policy officials there, and

1 then reviewed by the Office of Management and
2 Budget.

3 BY MR. GALLAGHER:

4 Q. Was it also reviewed by somebody in the
5 Executive Office of the President?

6 A. I do not know. That doesn't always
7 happen.

8 Q. So for you at MPPG, at the time, to get a
9 rule like the medical record review rule approved,
10 you had to go through this chain of command?

11 A. Yes.

12 Q. And then once you had gotten that
13 approval, as a policy matter, to propose this rule
14 and impose these requirements, then you would go
15 through the administrative rule-making process that
16 involves notice, comment, and -- and if -- if you get
17 it, finalization of the rule, right?

18 A. That's correct.

19 Q. And then in that -- in that notice and
20 comment process, you, as the -- as the -- your group,
21 as the -- as the impetus behind the rule, you're
22 involved in reviewing the comments and -- and
23 providing your comments in response, right?

24 A. Yes. So we review public comments, and
25 then draft the final rule providing responses to

1 those comments in the preamble.

2 Q. And -- and to the extent that there is any
3 decision made about whether to finalize the rule or
4 withdraw it, do you have to then go through the same
5 chain of command of policymakers that you went
6 through to propose the rule in the first place?

7 A. So, yes. The final rule then goes through
8 the clearance process, where policy officials are
9 briefed on the comments, and any recommendations for
10 finalizing or modifying or -- however, you know,
11 whatever the scope of options for the final rule are.

12 Q. And you have the opportunity in that
13 process to make a recommendation about whether the
14 rule should be finalized, whether it should be
15 modified, or whether it should be withdrawn?

16 A. Uh-huh.

17 MS. McMAHON: Objection.

18 THE WITNESS: Yes.

19 BY MR. GALLAGHER:

20 Q. In the case of the medical record review
21 rule, what was your recommendation after the comment
22 period?

23 A. So we did not make a recommendation,
24 because a -- a decision was made that -- as I
25 mentioned, this -- this was a provision in a much

1 larger rule that had some provisions that were -- got
2 a lot of stakeholder concern and pushback. And so
3 the direction that we received was that the rule --
4 the final rule needed to include only those
5 provisions that had wide -- you know, widespread
6 stakeholder support.

7 So we did not move forward then with the
8 medical record review provision, not because we
9 didn't think it was the right thing to do or the
10 right policy, but because it had mixed reactions from
11 stakeholders. It didn't meet those criteria, and so
12 we didn't include it in the final rule.

13 Q. So you didn't withdraw -- you didn't make
14 the determination that the rule wasn't necessary?

15 MS. McMAHON: Objection.

16 BY MR. GALLAGHER:

17 Q. You made the determination that -- or
18 somebody made the determination, as a policy matter,
19 that they weren't going to go forward with it because
20 it had faced opposition?

21 MR. BULAND: Objection.

22 MS. McMAHON: Objection.

23 THE WITNESS: So we didn't make a
24 recommendation one way or the other, because of
25 the decision about what the scope of the final

1 rule was going to be.

2 BY MR. GALLAGHER:

3 Q. And -- and in this process, nobody made --
4 the rule wasn't withdrawn because somebody decided it
5 wasn't necessary?

6 MS. McMAHON: Objection.

7 BY MR. GALLAGHER:

8 Q. Right? It was withdrawn because somebody
9 decided, as a policy matter, not to go forward with
10 it?

11 MS. McMAHON: Objection.

12 THE WITNESS: The decision was not based
13 on the merits or lack thereof of the policy
14 itself. It was based on something entirely
15 separate from that provision.

16 BY MR. GALLAGHER:

17 Q. Similarly, the decision wasn't made based
18 on any determination about the need for this
19 particular rule?

20 A. Again, it was based on a decision about
21 only including provisions that were -- had widespread
22 stakeholder support, and that was the reason for not
23 finalizing it.

24 Q. You mentioned that there was some other
25 provisions that -- that had -- that were actually

1 the -- the source of that concern as a policy matter.
2 What were those other provisions?

3 A. The -- the primary one, I believe, was the
4 protected class -- proposed change to the Part D
5 protected classes.

6 Q. So that there was -- there was, in the
7 same rule-making, a provision having to do with
8 protected class under Part D that got a lot of
9 opposition from industry, or other stakeholders?

10 A. I don't know that it was industry, but
11 there was a lot of stakeholder concern about that,
12 about that proposal.

13 Q. And -- and was that the impetus for the
14 policy decision not to go forward with any provision
15 of this overall rule-making that had faced
16 opposition?

17 A. I --

18 MS. McMAHON: Objection. You can answer.

19 THE WITNESS: I do not -- I wasn't party
20 to those conversations. So I do not know.

21 BY MR. GALLAGHER:

22 Q. Were you informed at some point that --
23 I'm sorry. I didn't mean to cut you off.

24 Were you informed at some point that --
25 that a decision had been made not to go forward -- or

1 A. No.

2 Q. Do you recall if you -- if you discussed
3 that with Mr. Cavanaugh in your prep meeting
4 before --

5 A. Yeah, again, I don't remember what we
6 talked about.

7 Q. All right. So I want to -- I want to turn
8 to the actual meeting you had with folks from
9 UnitedHealth on April 29th, 2014.

10 And first, let me just ask what you recall
11 about where you were for the meeting, and who was
12 present.

13 MS. McMAHON: Objection. Compound.

14 THE WITNESS: So we -- we were meeting in
15 the Baltimore CMS headquarters, in Sean
16 Cavanaugh's office. It was myself, Sean,
17 Cynthia, and I believe Julie Uebersax was there
18 as well.

19 United was on Pictel, so they were not
20 there in person. The -- I don't remember who
21 attended from United, other than Steve Nelson.
22 I don't remember who else was there from their
23 team.

24 BY MR. GALLAGHER:

25 Q. Had you met Mr. Nelson before?

1 A. Yes.

2 Q. So that maybe explains why you remember
3 him being there, because he was a familiar face?

4 A. Yes.

5 Q. And -- and the others were not familiar
6 faces to you?

7 A. That's right.

8 Q. And I -- I guess I should ask: They were
9 faces; it was some sort of video conference, right?

10 A. Correct.

11 Q. Do you recall what the topic of
12 discussion -- topics of discussion were at the
13 meeting on the 29th?

14 MS. McMAHON: Objection. Vague.

15 THE WITNESS: So I do not remember the
16 discussion in the meeting, other than knowing
17 that it was on these topics. I don't remember
18 what was discussed.

19 BY MR. GALLAGHER:

20 Q. Did you take any notes during the meeting?

21 A. Huh-uh. I did not.

22 Q. Have you had a chance to review any notes
23 that others took of the meeting to refresh your
24 memory about what happened?

25 MS. McMAHON: Objection. I will object,

1 to the extent you're calling for information
2 discussed while she was meeting with attorneys
3 and attorney-client information that we may have
4 provided her, or she may have given us.

5 But other than that, if you can answer
6 outside of attorney-client communications . . .

7 BY MR. GALLAGHER:

8 Q. Let me ask it differently.

9 Have you reviewed anything that
10 refreshes -- that has refreshed your recollection of
11 the meeting?

12 A. No, not outside of what was provided to me
13 by the attorneys.

14 Q. Well, if it's something that was provided
15 to you by the attorneys but it refreshed your
16 recollection, I'm entitled to -- to know it. So what
17 is it you reviewed that refreshed your recollection?

18 A. I -- I really don't remember what I said
19 in the meeting or what other people said in the
20 meeting. All I see is the notes.

21 Q. So maybe another way I would ask it is:
22 You may have reviewed some things, but it has not in
23 fact refreshed your recollection of the meeting?

24 A. No.

25 Q. Sitting here today, whatever you've

1 reviewed, including notes, perhaps, of the meeting,
2 none of that provides you with a refreshed
3 recollection or independent recollection of what
4 happened at the meeting?

5 A. No.

6 Q. So if there's something in the -- in notes
7 that somebody else took, or testimony that somebody
8 else provides about what happened in that meeting,
9 sitting here today, you don't have an independent
10 recollection to confirm or deny that version of
11 events?

12 MS. McMAHON: Objection.

13 THE WITNESS: Yeah, again, I can't
14 remember specifically what was said in the
15 meeting, so . . .

16 BY MR. GALLAGHER:

17 Q. Do you recall there being, at least as a
18 matter -- as a topic, some discussion of what the
19 UnitedHealth claims verification or chart review
20 program entailed?

21 A. Again, I don't -- I don't recall.

22 Q. Do you recall being curious and asking
23 questions about what it entailed, given the subject
24 matter of the meeting and the request that United had
25 made about having this meeting?

1 MR. BULAND: Objection.

2 THE WITNESS: No, I don't recall.

3 BY MR. GALLAGHER:

4 Q. Let me show you a document and see if it
5 might refresh your memory.

6 MR. GALLAGHER: Can we have Exhibit 1061,
7 which is Tab 11.

8 (Exhibit 1061 was marked for identification.)

9 BY MR. GALLAGHER:

10 Q. So do you have that? It should be
11 Document 15 on the list there.

12 A. Yeah.

13 Q. So this was a set of notes that was
14 prepared by -- by attendees from United. So this is
15 UnitedHealth's notes, typed up.

16 A. Uh-huh.

17 Q. Have you seen this before?

18 MS. McMAHON: Objection. I'm going to
19 object, to the extent that you have -- I'm
20 sorry. I'm going to object, to the extent that
21 your response would entail privileged
22 information.

23 So if you can answer outside of
24 conversations you've had with counsel, I think
25 you've already testified that your recollection

1 was not refreshed with respect to anything
2 counsel may have showed you. So -- ask you not
3 to respond to anything that you have discussed
4 with your counsel.

5 BY MR. GALLAGHER:

6 Q. So with that instruction, can you tell me
7 whether you've seen this document before?

8 A. Yes.

9 Q. So there's a -- a reference -- if I go to
10 the meeting summary on the first page, and there's a
11 fourth bullet down, do you see where it says, "UHG
12 representatives provided a general overview of UHG's
13 claim verification process and explained that UHC had
14 already submitted a number of deletes for 2012 dates
15 of service as a result of that process."

16 Do you recall learning that during the
17 meeting in April of 2014?

18 A. No.

19 Q. Do you recall any discussion about that
20 during the meeting in April of 2014?

21 A. No.

22 Q. Are you in a position to -- to deny that
23 that was discussed?

24 A. No.

25 MS. McMAHON: Objection.

1 BY MR. GALLAGHER:

2 Q. And so it then says that -- here that
3 "Later in the meeting, UHG representatives informed
4 CMS that the number of new and unique diagnosis code
5 deletes already submitted was approximately 13,000."

6 Do you recall the discussion of that
7 during the meeting in April of 2014?

8 A. No.

9 Q. I'm going to show you another set of
10 notes.

11 MR. GALLAGHER: This is Exhibit 1062.

12 (Exhibit 1062 was marked for identification.)

13 MR. GALLAGHER: Which is Tab 23.

14 THE WITNESS: Okay.

15 BY MR. GALLAGHER:

16 Q. And we understand these to be Cynthia
17 Tudor's notes. Do you recognize her handwriting?

18 A. Yes.

19 Q. And do you recognize that as -- so this --
20 do you recognize this Exhibit 1062 as having Cynthia
21 Tudor's handwriting on it?

22 A. Yes.

23 Q. And you see it's -- the date of the -- of
24 this planner document, or calendar, is April 29th,
25 2014, which is the date of the meeting you had with

1 United, right?

2 A. Correct.

3 Q. And do you see that in these notes, in
4 Ms. Tudor's hand, there's a reference on the
5 right-hand side, under the line to something "over"
6 or something "deleted 13K."

7 Do you see that?

8 A. Uh-huh.

9 Q. So that would be 13,000?

10 MS. McMAHON: Objection. Calls for
11 speculation.

12 BY MR. GALLAGHER:

13 Q. You recognize the abbreviation "K" as a
14 common abbreviation for "thousand"?

15 A. Yes.

16 Q. And would you understand that to be a
17 reference to 13,000?

18 A. Yes.

19 Q. The same number that's in the -- the notes
20 that we were just looking at in Exhibit 1061, right?
21 That the deletes already submitted was approximately
22 13,000?

23 MS. McMAHON: Objection. Calls for
24 speculation.

25 THE WITNESS: That would --

1 BY MR. GALLAGHER:

2 Q. I'm not -- I'm not asking you to
3 speculate; I'm asking you to confirm that the number
4 13,000 in one set of notes is the same as the number
5 approximately 13,000 in the other set of notes from
6 the same meeting.

7 MR. BULAND: Object.

8 THE WITNESS: Yes.

9 BY MR. GALLAGHER:

10 Q. Does that refresh your recollection that
11 there was a discussion that included UnitedHealth
12 describing details of its process, including the
13 number of codes that had already been deleted as a
14 result of its claims verification or chart review
15 process?

16 A. No.

17 Q. Does it suggest to you that the notes we
18 just looked from -- in Cynthia Tudor's hand, are in
19 fact notes of the same meeting that is being
20 referenced in -- in the notes we have in
21 Exhibit 1061?

22 MR. BULAND: Objection.

23 MS. McMAHON: Objection. Calls for
24 speculation.

25 THE WITNESS: I believe so.

1 BY MR. GALLAGHER:

2 Q. Now, there's a reference in -- still on
3 Exhibit 1061, on that first page, there's a reference
4 in that same Bullet Number 4, under "Meeting
5 Summary," to UHG representatives indicating that "in
6 light of the proposed rule and other discussions with
7 CMS, UHC had suspended its claims verification
8 process pending a decision by the company of whether
9 it was appropriate to submit additional deletes to
10 CMS that have been identified through the company's
11 claims verification process."

12 You see that?

13 A. Yes.

14 Q. Do you recall being informed by
15 UnitedHealth that they had in fact suspended this
16 program?

17 A. Not in the meeting, no.

18 Q. Do you recall being informed that later?

19 A. So there was an e-mail the next day, that
20 Steve Nelson sent me, where I believe he said that in
21 the e-mail.

22 Q. Right. So if we could have Exhibit 1063,
23 which is Tab 12. I think that's the e-mail you're
24 referring to.

25 (Exhibit 1063 was marked for identification.)

1 BY MR. GALLAGHER:

2 Q. So Exhibit 1063 is an e-mail exchange that
3 starts at the bottom of the first page with an e-mail
4 from Steve Nelson to you, on Wednesday, April 30th,
5 at 9:55 in the morning.

6 Is this the e-mail you're referring to?

7 A. Yes.

8 Q. And if you go to the next page, in the --
9 in the paragraph that starts, "Fifth," is -- is it in
10 this paragraph that you were informed -- or that
11 UnitedHealth had in fact suspended or stopped this
12 program, the claims verification or chart review
13 program looking for deletes?

14 A. Yes. Just rereading it again here.

15 Yes, so we suspended the process, yes,
16 right.

17 Q. So you were aware of that in -- in April
18 of 2014, that whatever process UnitedHealth had, that
19 it was asking for guidance on in this meeting, it had
20 decided to suspend that process?

21 A. Yes.

22 Q. What do you recall learning about what,
23 you know -- actually, let me ask this differently.

24 Do you recall ever learning what
25 UnitedHealth's decision was with respect to claims

1 that were in -- in that process that were -- that
2 were under review at the time it was suspended?

3 MS. McMAHON: Objection. Vague.

4 BY MR. GALLAGHER:

5 Q. Let me be specific. We -- we started off,
6 we talked about the topics of the meeting, and I
7 think you said that there was -- you understood there
8 to be two things in the request for meeting. One,
9 whether they should stop -- whether they could stop
10 the program; and second, what to do with things in
11 process?

12 A. Uh-huh.

13 Q. So what do you recall, if anything,
14 learning about what UnitedHealth decided to do with
15 the code -- codes or charts that were in process of
16 being reviewed?

17 A. I don't recall learning anything after
18 this e-mail exchange with Mr. Nelson about what they
19 ultimately decided.

20 Q. And you don't -- and you don't recall
21 learning anything about that during the meeting
22 itself on the 29th?

23 A. Right.

24 Q. Do you recall any discussion during the
25 meeting on the 29th about what UnitedHealth's

1 we talked about earlier, that includes within it some
2 references to what was discussed at the meeting, does
3 it not?

4 A. Yes.

5 Q. In particular, Mr. Nelson states, "During
6 our conversation yesterday and other recent
7 conversations, CMS confirmed to us that these
8 requirements do not apply until the effective date of
9 the rule, and that MA plans are thus not currently
10 required to design their medical record reviews to
11 determine the accuracy of risk adjustment diagnoses."
12 You see that?

13 A. I do.

14 Q. And I take it from your -- from the
15 discussion we've already had that you don't recall
16 whether there was such a discussion at the meeting on
17 April 29th, because you don't recall what was
18 discussed?

19 A. Right.

20 Q. In your e-mail responding to Mr. Nelson,
21 you don't dispute that characterization of the
22 meeting, do you?

23 MS. McMAHON: Objection.

24 THE WITNESS: So I -- I was very concerned
25 with his e-mail, and that fifth point, and the

1 inference that somehow CMS was blessing this --
2 these next steps that United was suggesting.
3 And so -- I was frankly alarmed by the e-mail,
4 and wanted to make -- respond in writing that we
5 were not blessing what they were suggesting they
6 were doing in Bullet 5, and that there were
7 other laws and requirements beyond the medical
8 record review rule that they needed to be in
9 compliance with.

10 And so I, again, was very, very concerned
11 with this e-mail.

12 BY MR. GALLAGHER:

13 Q. My question was, you don't dispute, in
14 your responsive e-mail, Mr. Nelson's characterization
15 of what was said by CMS and confirmed by CMS at the
16 meeting on the 29th?

17 MR. BULAND: Objection.

18 MS. McMAHON: Objection. Asked and
19 answered.

20 THE WITNESS: I think it is making clear
21 that they should not take away from that meeting
22 that we had said that it was okay to stop the
23 claims verification program, or that it was okay
24 not to continue to review and determine whether
25 those questionable diagnoses were accurate or

1 not.

2 BY MR. GALLAGHER:

3 Q. In April of 2014, had you issued any --
4 had CMS issued any guidance, rules, requirements,
5 subregulatory or otherwise, that required plans to
6 conduct any medical record review?

7 MS. McMAHON: Objection. Asked and
8 answered.

9 THE WITNESS: Again, not specifically. We
10 had general requirements about compliance
11 programs, language in our managed care manual,
12 et cetera. But in terms of a specific procedure
13 that plans were to follow to -- to meet their
14 obligations to submit correct data, no, we did
15 not have specific procedures that we were
16 telling plans to follow.

17 BY MR. GALLAGHER:

18 Q. And in your response to Mr. Nelson, do you
19 identify any rule, regulation, subregulatory
20 guidance, you know, communication from CMS that
21 imposes an obligation to conduct medical record
22 review specifically to look for deletes?

23 A. No.

24 Q. Do you know -- do you identify any
25 requirements with specificity in your response?

1 MR. BULAND: Objection.

2 MS. McMAHON: Objection.

3 THE WITNESS: No.

4 BY MR. GALLAGHER:

5 Q. So when you refer to other laws that do
6 impose standards, requirements, and responsibilities
7 on Medicare Advantage plans, you didn't provide any
8 guidance on what those other laws might be?

9 MS. McMAHON: Objection.

10 THE WITNESS: No. Not in this e-mail. I
11 mean, United signed a contract. They're subject
12 to the regulations. They're subject to the
13 False Claims Act. I think that's all well
14 known.

15 So -- but no, we did not provide a laundry
16 list of all the different requirements here in
17 this e-mail.

18 BY MR. GALLAGHER:

19 Q. Well, you knew that United had -- had come
20 to you asking, specifically with respect to this
21 program they had in place, you know, "What are the
22 requirements? What are you -- what are you going to
23 tell us we have to do?"

24 And you had a meeting about it, and this
25 was the e-mail after the meeting, the specific

1 purpose of which was to inquire about this program
2 and -- and what the rules were, right?

3 MS. McMAHON: Objection. Misstates the
4 witness's testimony.

5 MR. BULAND: Objection.

6 THE WITNESS: And -- and we are saying we
7 are not providing advice to United about --
8 about their next steps, but that they need to be
9 in compliance with federal laws and
10 requirements, and not --

11 BY MR. GALLAGHER:

12 Q. Did you --

13 A. And not to take that meeting as some kind
14 of blessing for what plan of action they -- they
15 might have laid out.

16 Q. Did you tell them that -- that there was
17 any -- did you identify for United any rule,
18 standard, requirement, obligation imposed by you that
19 would make their proposed course of action illegal?

20 MS. McMAHON: Objection.

21 THE WITNESS: No, this was the -- this was
22 the sum total of the response.

23 BY MR. GALLAGHER:

24 Q. And this response was something that was
25 actually something you cleared with the lawyers

1 they could be applicable here.

2 BY MR. GALLAGHER:

3 Q. Let me ask -- I'm going to -- I'm going to
4 show you what was previously marked as Exhibit 330.

5 MR. GALLAGHER: This is Tab 14, Jordan.

6 (Exhibit 330 was previously marked for
7 identification.)

8 BY MR. GALLAGHER:

9 Q. Do you have -- as Document 19, I think --
10 Exhibit 330, which is a June 26, 2015, e-mail from
11 Mr. Nelson to you, with the subject matter "2013 CMS
12 RAF attestation"?

13 A. Yes. I see it.

14 Q. Do you recall receiving this e-mail in
15 connection with United's submission of their
16 certification or attestation for the 2013 service
17 dates?

18 A. I -- I don't recall this specifically, no.

19 Q. If you look at the fifth bullet down, on
20 the -- at the bottom of the e-mail, do you see it
21 says, "CMS issued a proposed rule last year that
22 would have required MA plans to design any medical
23 record reviews to determine the accuracy of risk
24 adjustment diagnoses associated with those records"?
25 You see that?

1 A. Yes.

2 Q. And then it says, "During our
3 conversations last year before the proposed rule was
4 withdrawn, CMS confirmed to us that the proposed
5 requirements would not apply until the effective date
6 of the rule, and that MA plans were thus not required
7 to design their medical record reviews to determine
8 the accuracy of risk adjustment diagnoses."

9 Do you recognize that as basically the
10 same language that was in the 2014 e-mail that you
11 responded to on May 2nd, 2014?

12 A. Yes.

13 Q. And am I right that you never responded to
14 this e-mail from Mr. Nelson disputing that
15 characterization of the advice provided by CMS?

16 A. I don't recall if I responded or not. I
17 don't believe I did, but I don't recall.

18 Q. Right. But you don't recall ever
19 disputing it one way or the other?

20 A. Right. Yeah, that's correct.

21 Q. And then there's a sentence that begins
22 later, "Based on." It says, "Based on our
23 conversations with CMS last year, CMS's withdrawal of
24 the proposed rule, and CMS's ongoing consideration of
25 a fee-for-service adjuster to address diagnoses not

1 supported by a medical record in the context of RADV,
2 we ended this process and informed you of that
3 decision." Do you see that?

4 A. Yes.

5 Q. And then it says, "That decision remains
6 operative for 2013 dates of service."

7 And do you understand that to mean that
8 United is telling you here that they are not
9 conducting the same type of medical record review for
10 the 2013 dates of service that they had started and
11 stopped for the 2012 dates of service?

12 MS. McMAHON: Objection. Calls for
13 speculation.

14 THE WITNESS: Yes.

15 BY MR. GALLAGHER:

16 Q. And they then say, "In particular, we did
17 not use our previous process to determine whether
18 diagnosis codes submitted through claims are
19 unsupported in the medical record."

20 Do you recall learning that United had
21 stopped that program in 2012, and then not done it in
22 subsequent years?

23 A. I don't recall this e-mail specifically,
24 no.

25 Q. Now, around this time, in June of 2015,

1 you were having discussions internally at CMS, and
2 with policy officials, about how you might strengthen
3 the attestation requirement, or impose additional
4 requirements on plans concerning medical record
5 review or confirmation of support for diagnosis
6 codes, were you not?

7 MS. McMAHON: Objection.

8 THE WITNESS: I don't recall.

9 BY MR. GALLAGHER:

10 Q. Let me show you Exhibit 1064, which is
11 Tab 16.

12 MR. GALLAGHER: Jordan?

13 (Exhibit 1064 was marked for identification.)

14 BY MR. GALLAGHER:

15 Q. So do you have Exhibit 1064, which is an
16 e-mail exchange from June 24th, 2015, involving you,
17 Ms. Harlow, Ms. Tudor, and Mr. Cavanaugh?

18 A. Yes.

19 Q. And so just to compare the dates,
20 Mr. Nelson's e-mail, that we were just looking at in
21 Exhibit 330, that's dated June 26th, 2015. Your
22 e-mail at the top of Exhibit 1064 is dated two days
23 prior to that, June 24th, 2015. Right?

24 A. Yes.

25 Q. So this is an exchange that is

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

21

22

23

24

25

Karen Kidwell
Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-138

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

Videotaped Deposition of
DANIEL J. SCHUMACHER
Given Remotely
Tuesday, September 20, 2022
9:04 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 to deal with a technical issue, please.

2 MR. MASON: Sure. Why don't we go off
3 the record.

4 MR. SUMMERS: This will take one
5 second.

6 We're ready to resume.

7 MR. MASON: That was -- that was really
8 quick.

9 THE VIDEOGRAPHER: I'm sorry. We're
10 going off the record. The time is 9:36.

11 THE REPORTER: Jeremy, I think we're
12 supposed to be on the record.

13 THE VIDEOGRAPHER: I apologize for the
14 miscommunication. We're on the record. The time
15 is 9:36.

16 BY MR. MASON:

17 Q. Mr. Schumacher, are you familiar with a
18 risk adjustment program that UHC undertook referred
19 to as "chart review"?

20 A. Yes.

21 Q. What is chart review?

22 MR. SUMMERS: Objection. Form.

23 THE WITNESS: Can you repeat that,
24 please?

25 BY MR. MASON:

1 Q. What is chart review?

2 A. Chart review is a program where we
3 would request medical records and evaluate those
4 medical records for conditions.

5 Q. You understood chart review is a
6 program to, you said, request medical records and
7 review those medical records for conditions?

8 A. Yes. It's a program where we request
9 medical charts, review the medical charts for
10 appropriate diagnoses for our covered members.

11 Q. Okay. And the purpose of reviewing
12 those medical records for diagnoses was to see if
13 there are additional diagnoses to submit that
14 weren't included in the original provider claims?

15 A. One -- one reason.

16 Q. What other reason?

17 A. We get to understand what conditions
18 members have and whether or not they have any, you
19 know, gaps in their medical care that need to be
20 addressed, but -- so we were evaluating diagnoses
21 and ensuring the accuracy of the diagnoses for our
22 members.

23 Q. Okay. And part of the purpose was to
24 generate revenue for UHC?

25 MR. SUMMERS: Objection. Form.

1 THE WITNESS: The purpose was to ensure
2 accuracy of the diagnoses that were submitted to
3 CMS, which informs reimbursement, potentially.

4 BY MR. MASON:

5 Q. Okay. And UHC -- after requesting the
6 medical records, UHC employed coders to review
7 those medical records to -- to ascertain what
8 conditions the beneficiary has as documented in
9 that medical record?

10 MR. SUMMERS: Objection. Form.
11 Foundation.

12 THE WITNESS: Coders would review the
13 medical chart to see what diagnoses were captured
14 in that chart.

15 BY MR. MASON:

16 Q. And those coders were instructed to
17 identify and record every diagnosis that -- that
18 they determined was supported by that chart, right?

19 MR. SUMMERS: Objection. Form.
20 Foundation.

21 THE WITNESS: I don't know the
22 specifics of exactly what they were supposed to be
23 doing. Generally speaking, they looked at medical
24 charts, and with their expertise, evaluated whether
25 or not those -- what diagnoses were -- were

1 THE WITNESS: In the beginning? In the
2 latter stages? Can you --

3 BY MR. MASON:

4 Q. Well, let's --

5 A. Can you --

6 Q. -- let's start in the beginning. You
7 said -- you said there was a high-level explanation
8 of CV and then a more detailed explanation of CV,
9 right?

10 A. Yes.

11 Q. Let's start with the high-level
12 explanation of CV. What was said about -- to CMS
13 about the CV process?

14 A. Well, we articulated that we had a
15 process underway that we had been executing that we
16 had actually suspended once the proposed rule came
17 out.

18 We said -- I don't remember the exact
19 words about the program. But it was -- the essence
20 of what we were trying to accomplish was to look at
21 where we had looked at a medical chart, confirming
22 whether or not the diagnoses reflected in -- if
23 there were any diagnoses in the claim that were not
24 reflected in that.

25 So we had a process that did that. It

1 had various steps. And looking at the proposed
2 rule, that would suggest that that's something, if
3 finalized, we would have to start doing. So our --
4 our question was, well, do we need to be doing a
5 proactive two-way look?

6 Q. Okay. And that was the high-level
7 explanation of CV?

8 A. Yes.

9 Q. And what was the more detailed
10 explanation of CV?

11 A. The more detailed conversation about it
12 went through the various steps. So, first, we do
13 this; then we do that. Then it goes out -- you
14 know, ultimately, to the earlier conversation,
15 expert reviewer is one of the steps. And so it was
16 an articulation of what happens in each of those
17 steps.

18 And then I was applying the
19 quantification around what had gone all the way
20 through all of those steps and had been submitted;
21 what had gone all the way through those steps, not
22 been submitted; and what had not completed all of
23 those steps.

24 Q. Was anything else about the CV program
25 explained to CMS at the meeting?

1 MR. SUMMERS: Objection. Form.

2 THE WITNESS: We -- we gave a
3 high-level review about what we were trying to
4 accomplish with the CV program. And then we sought
5 clarification at the beginning of the conversation
6 as to whether or not, after having heard that,
7 whether we had a proactive obligation to do a
8 two-way look prior to and until which time there
9 was actually a formal rule finalized. And the
10 answer to that was, no, you do not.

11 BY MR. MASON:

12 Q. And when you're talking about -- when
13 you said how you explained to CMS that there were
14 different codes in different stages of the CV
15 process, is that the same as the different stages
16 that were reflected in the spreadsheet we were just
17 looking at, at Exhibit 468-A?

18 A. Yes, with the exception of -- you know,
19 in there, it also had abstracts processed by XL and
20 not yet submitted -- I mean, I don't recall talking
21 about abstracts.

22 Q. Okay. But other than -- other than the
23 hospital abstracts line -- you're referring to
24 Row 22 there, right?

25 A. Yes, I am.

1 Q. Other than Row 22, when you say that
2 you explained to CMS that there was different
3 amount of work in different stages of the CV
4 process, you're referring to the stages in Rows 20
5 through 24?

6 A. 20 to 23.

7 Q. Okay. So just Rows 20, 21 and 23?

8 A. Yes. So the conversation to say,
9 here's what, you know, we -- we've already -- we've
10 already run the whole process and submitted this to
11 CMS. We've run the whole process and not submitted
12 to CMS. And then there's this universe that's at
13 various stages.

14 And then we went through what happens
15 at each stage, you know, the steps, and -- and
16 so -- you know, Karen Erickson did more of that, as
17 I recall.

18 Q. And -- and so the stages that you
19 explained to CMS were the same stages that are
20 referenced on 20, 21 and 23, but -- but instead of
21 telling CMS the dollar amounts, you told them the
22 number of codes?

23 A. We discussed the number of codes.

24 Q. Was there a different spreadsheet that
25 was prepared around this time that had the number

1 CERTIFICATE OF REPORTER

2

3 I, Cindy A. Hayden, Registered Merit
4 Reporter and Notary Public, do hereby certify that
5 the foregoing transcript is a true, accurate, and
6 complete record.

7 I further certify that I am neither
8 related to nor counsel for any party to the cause
9 pending or interested in the events thereof.

10 Witness my hand, this 23rd day of
11 September, 2022.

12

13

14

15

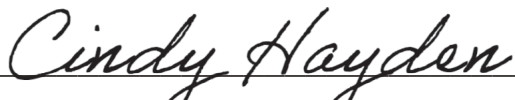
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Cindy A. Hayden, RMR, CRR

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22

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25

EXHIBIT D-139

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

_____	)	
UNITED STATES OF AMERICA	)	
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiff,	)	No. CV 16-08697 FMO
	)	
vs.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
(With Redactions)

DEPOSITION OF MELISSA SEDOR
As 30(b)(6) Designee 1 of
OptumInsight, Inc.
UnitedHealthcare, Inc.
Washington, DC
June 29, 2023

Reported by: John L. Harmonson, RPR
Job No. 988356

1 BY MS. GLOVER:

2 Q. Okay. So in this example, instead of
3 the diagnosis code coming by way of the provider
4 through the CPT that's been submitted, it's
5 identified through OptumInsight by way of a medical
6 record review of a medical record that was
7 retrieved from a physician's office or a provider's
8 office?

9 A. That is correct.

10 Q. Okay. And then once that record is
11 retrieved and Optum reviews it, Optum submits the
12 diagnosis codes to CMS that they identified as
13 being supported by the medical record; right?

14 MR. JONES: Objection; form.

15 THE WITNESS: That is correct.

16 BY MS. GLOVER:

17 Q. And in some instances, Optum deletes
18 codes that they identify as being not supported by
19 a medical record and they submit those deletes to
20 CMS; right?

21 MR. JONES: Objection; outside the
22 scope.

23 THE WITNESS: Related to the medical
24 record review, the only time that occurred was in
25 2013 when claims verification was occurring. The

1 remainder of the time in question, deletes did not
2 occur through the medical record review process.

3 BY MS. GLOVER:

4 Q. Okay. And we'll talk a little more
5 about that. I think that's one of your topics, and
6 we can talk more about that.

7 When you say claims verification, what
8 do you mean?

9 A. Claims verification was a risk
10 adjustment program we had in place in 2012 through
11 early 2014. What that program did was to, when a
12 medical record was looked at for chart review
13 purposes to identify diagnosis codes that were not
14 on the claim, it would also utilize those medical
15 records to compare against the claim submitted by
16 the provider to see if there were any codes
17 submitted on the claim that were not supported by
18 the medical records.

19 Q. Okay. So when you say compare, do you
20 mean they would compare like the results of the
21 chart review that they conducted with the claims
22 that had been submitted by the provider to identify
23 which ones -- which ones to review in claims
24 verification?

25 MR. JONES: Objection; form. Outside

1 the scope.

2 THE WITNESS: Yes, the medical
3 reviewer -- the chart review would result in the
4 identification of, let's say, three diagnosis
5 codes. The claim maybe had, for example, four
6 diagnosis codes. So that one diagnosis code that
7 was different would be looked into for claims
8 verification, assuming that the diagnosis code in
9 question was only submitted one time in that year
10 for that member that aligned to the timing of the
11 medical record review, if we had received that
12 diagnosis code for the member six times in a year,
13 it's not going to be subject to the claims
14 verification process.

15 BY MS. GLOVER:

16 Q. Understood.

17 And then if you identified diagnosis
18 codes through claims verification that had not been
19 identified in the chart review, then you would
20 delete -- you deleted those codes through the
21 process that's depicted here. You'd submit the
22 deletes to CMS; is that right?

23 MR. JONES: Objection; form. Outside
24 the scope.

25 THE WITNESS: If through the claims

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that MELISSA SEDOR, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was not requested.

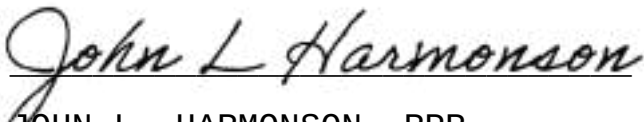
13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 3rd day of July, 2023.

19

20

21


JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT D-140

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,)
ex rel., BENJAMIN POEHLING,)
)
Plaintiffs,)
) Civil Action No.
vs.)
) 16-08697 FMO
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

* * * * *

HIGHLY CONFIDENTIAL

* * OUTSIDE COUNSEL'S EYES ONLY * *

* * * * *

VIDEOTAPED DEPOSITION OF PAUL IRA SPITALNIC
Wednesday, March 20, 2024; 9:07 a.m. EDT

Reported by: Cindy L. Sebo, RMR, CRR, CLR, RPR, CCR,
CSR, RSA, CA CSR 14409, NJ Certified CR 30XI0024460,
NJ Certified RT 30XR00019500, NM CSR 589, NY Realtime
Court Reporter, NY Association Certified Reporter, OR
CSR 230105, TN CSR 998, TX CSR 12778, WA CSR
23005926, Notary Public
Job No. 1097542

1 A. Yes.

2 Q. How long have you been Ms. Lazio's
3 direct supervisor?

4 A. I don't recall exactly when she
5 joined CMS, but I believe I -- I have been chief
6 actuary since 2013. Shortly thereafter, she was
7 selected as the director of Parts C and D Actuarial
8 Group. I've clearly been her supervisor since
9 then.

10 Prior to that, I was in -- the
11 director of the Parts C and D Actuarial Group. I
12 don't recall if she was reporting directly to me at
13 that time or another one of the managers on my
14 team.

15 Q. You also mentioned that you spoke
16 with Kirk Limmer; is that right?

17 A. Yes.

18 Q. How do you spell his last name?

19 A. I spell it L-I-M-M-E-R.

20 Q. Thank you.

21 Why did you speak with Mr. Limmer

1 THE WITNESS: Okay.

2 I am not an expert in the
3 requirements around what -- how CMS has
4 determined what the basis for diagnosis
5 submissions are. Again, my opinions are my
6 own based on my knowledge and experience of
7 the program, and I would not characterize
8 myself -- I'm certainly not providing expert
9 witness testimony to the specific
10 requirements around what MAOs are required
11 or not required to do in the supporting of
12 their codes.

13 BY ATTORNEY MARTINEZ:

14 Q. You're not providing any expert
15 opinions or testimony related to specific
16 requirements around what MAOs are obligated or not
17 obligated to do with respect to submitting
18 diagnosis codes for payment, right?

19 A. Yes.

20 Q. Can you give me a specific law,
21 regulation, piece of subregulatory guidance or

1 contractual provision that obligates MAO plans to
2 investigate whether or not a diagnosis code is
3 supported by the medical records if the plan has
4 any information that the code might not be
5 supported?

6 ATTORNEY ZUPAC: Object to form.

7 THE WITNESS: I -- I -- it sounds
8 like the same question you just asked. I --
9 I'm missing the difference, if there was one.

10 And so I -- I'm, again, not the
11 expert and don't have specific citations as
12 to whatever would lead to whatever the
13 actual requirements are. I'm just sharing
14 what my understanding is of those
15 requirements.

16 BY ATTORNEY MARTINEZ:

17 Q. So the answer to my question is you
18 cannot give me a specific law, regulation, piece of
19 subregulatory guidance or contractual provision
20 that obligates MA plans to investigate whether or
21 not a diagnosis code is supported by medical

1 records if the plan has any information that is --
2 might not be supported, right?

3 A. I cannot provide such reference.

4 Q. Can you provide me a specific law,
5 regulation, piece of subregulatory guidance or
6 contractual provision that obligates MA plans to
7 design their chart reviews to identify and delete
8 diagnosis codes that are not supported by medical
9 records?

10 A. I cannot.

11 Q. Do -- by the way, do you know what
12 "chart reviews" are?

13 A. I'm familiar with the term.

14 Q. You understand that United had a
15 chart review program in place during the period
16 relevant to this case?

17 A. I understand United takes a number of
18 actions with respect to supporting or developing or
19 -- related to the diagnoses they submit for plan
20 payment.

21 Q. And would those actions include a

1 chart review program?

2 A. That is my understanding.

3 Q. When did you first become aware that
4 United had a chart review program?

5 A. I don't think I was ever aware that
6 there was a specific program. I know that United
7 and other MAOs, Medicare Advantage organizations,
8 do various -- have various initiatives in support
9 of their diagnosis submission.

10 Q. So you have no specific information
11 about how United may have conducted its chart
12 review program during the period relevant to this
13 case?

14 A. I do not have any specific
15 information.

16 Q. I want to go back to Page 3 of your
17 report, Mr. Spitalnic. We read the first half of
18 this sentence in Paragraph Number 2. I -- I want
19 to focus now on the second half of the sentence,
20 but I'll -- I'll read the whole sentence so we've
21 got the full context.

1 are audited, right?

2 A. I am not.

3 Q. Let's go back to Page 7 of your
4 report, Mr. Spitalnic. You quote portions of Ms.
5 Lambert's report referencing statements made by
6 United in its annual bid submissions to CMS. And
7 I'm in Paragraph 8.

8 Are you with me?

9 A. I am.

10 Q. You wrote in the last sentence of
11 Paragraph 8 before the bulleted paragraphs, The
12 following assertions cited by Ms. Lambert do not
13 diminish the certifying actuary's and MA
14 organization's responsibility because CMS may, (i),
15 not have reviewed the specific information; or,
16 (ii), only reviewed this information to check
17 compliance with disclosure requirements in the
18 ASOPs.

19 Do you see that?

20 A. I do.

21 Q. As a matter of good governance, do

1 you agree with me that it's important for CMS to
2 review bid submissions by MA plans?

3 A. Yes.

4 Q. You're not suggesting here that CMS
5 should ignore portions of MA plan bid submissions,
6 right?

7 A. I'm suggesting that there may not
8 have been a reliance on certain statements that are
9 included in some aspects of the bid submission.

10 Q. Do you think it's reasonable for
11 MA plans like United to presume that CMS is
12 reviewing the bid submissions that the plans submit
13 to the Agency?

14 ATTORNEY ZUPAC: Object to form.

15 Go ahead.

16 THE WITNESS: I'm sorry. Could you
17 repeat the question?

18 BY ATTORNEY MARTINEZ:

19 Q. Do you think it's reasonable for
20 MA plans like United to presume that CMS is
21 reviewing the bid submissions that the plans submit

1 to the Agency?

2 A. I -- I certainly believe that it's
3 reasonable for a plan to expect that CMS is going
4 to do a thorough review of their bid submission.
5 And I think many of the actuaries that go through
6 the bid review procedure would agree that there is
7 a thorough review of the bid submission -- of their
8 bid submissions.

9 I would also expect that actuaries
10 would not be surprised that every word of their
11 submission is not reviewed or necessarily relied
12 upon in drawing ultimate conclusions and that, as I
13 included in this sentence before you started
14 reading, that there is a specific reliance on the
15 actuary to -- that that's -- that CMS places on the
16 actuary to ensure that there is compliance with the
17 laws, regulations and instructions and the various
18 Actuarial Standards of Practice.

19 Q. CMS does a thorough review of bid
20 submissions from MA plans, right?

21 A. Speaking on behalf of the -- on

1 behalf of the Office of the Actuary, we do as
2 thorough and comprehensive a job in reviewing those
3 bids that have been submitted as possible, given
4 the various time and other constraints placed upon
5 us.

6 Q. And you believe it's reasonable for
7 MA plans to presume that CMS is doing that thorough
8 review that you just spoke about, right?

9 A. Plans are familiar with our review
10 process.

11 Q. And how thorough it is, right?

12 A. Yes.

13 Q. Mr. Spitalnic, on the top of
14 Page 8 -- we're still in -- in Paragraph 8,
15 you -- you also wrote -- and this is in response to
16 a couple of bulleted statements -- quoting from
17 United's bid submissions. You wrote, An actuary
18 cannot disclaim that they are knowingly violating
19 the rules of the program.

20 Do you see that?

21 A. I do.

1 Q. Are you aware of any instance in
2 which CMS responded to the bulleted statements you
3 include in Paragraph 8 by saying that United's
4 decision to cease its prior process of identifying
5 and deleting certain diagnosis codes violated
6 United's obligations?

7 ATTORNEY ZUPAC: Object to form.

8 THE WITNESS: I am not aware of
9 discussions that were related to the subject
10 of those quotations.

11 BY ATTORNEY MARTINEZ:

12 Q. So let -- let's -- let's drill down
13 on one of them. Let's look at the second bullet --
14 sorry to keep flipping back.

15 We're on the bottom of Page 7 --
16 starting with the BPT submissions in 2015. And --
17 and what does "BPT" stand for?

18 A. "BPT" stands for bid pricing tool.

19 Q. All right.

20 -- starting with the bid pricing
21 tool submissions in 2015, quote, We also adjusted

1 projected risk scores to account for changes in our
2 medical record review processes. Specifically,
3 based on multiple conversations with CMS and CMS'
4 treatment of medical record review in its recent
5 rulemaking process, the health plan has decided to
6 cease one of its prior processes that identified
7 and deleted certain diagnoses codes through the
8 medical record review process.

9 Do you see that?

10 A. I do see that.

11 Q. Are you aware of any instance in
12 which CMS responded to that statement by saying
13 that United's decision to cease its prior process
14 of identifying and deleting certain diagnosis codes
15 violated United's obligations under the MA program?

16 A. I am not aware of any such
17 statements.

18 Q. Were you aware of these statements
19 from United in its BPT submissions at the time they
20 were made?

21 A. I do not believe I have -- I -- I do

1 not believe I was aware of these statements at that
2 time.

3 Q. Was anyone else in your office aware
4 of them?

5 A. I do not know of anyone in my office
6 being specifically aware of this specific
7 statement.

8 Q. And after writing your report or
9 during the process of writing your report, did you
10 ask anyone at the Office of the Actuary or at CMS
11 whether they were aware of these statements from
12 United?

13 A. I did not specifically ask anybody
14 about anything going back to 2015.

15 Q. So going -- going back to the top
16 of -- of Page 8, Mr. Spitalnic, where you wrote An
17 actuary cannot disclaim that they are knowingly
18 violating the rules of the program.

19 Are you aware of United ever
20 asserting in this case that it could knowingly
21 violate the rules of the MA program by issuing a

1 I, Cindy L. Sebo, Nationally Certified Court
2 Reporter herein, do hereby certify that the foregoing
3 deposition of PAUL IRA SPITALNIC was taken before me
4 pursuant to notice at the time and place indicated;
5 that said witness duly swore to tell the truth, the
6 whole truth, and nothing but the truth under
7 penalties of perjury; that said testimony of witness
8 was correctly recorded to the best of my abilities in
9 machine shorthand, thereafter transcribed under my
10 supervision with computer-aided transcription; that
11 deposition is a true and accurate record of the
12 testimony given by the witness; that I am neither
13 counsel, nor kin to any party in said action, nor
14 interested in the outcome; and that a copy of this
15 transcript obtained from a source other than the
16 court reporting firm, including an adversary or
17 co-counsel in the matter, is uncertified and may not
18 be used at trial. 

19 CINDY L. SEBO, RMR, CRR, CLR, RPR, CCR, CSR, RSA, CA
CSR 14409, NJ Certified CR 30XI0024460, NJ Certified
20 RT 30XR00019500, NM CSR 589, NY Realtime Court
Reporter, NY Association Certified Reporter, OR CSR
21 230105, TN CSR 998, TX CSR 12778, WA CSR 23005926,

EXHIBIT D-141

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

---o0o---

UNITED STATES OF AMERICA, ex)
rel., BENJAMIN POEHLING,)

Plaintiff,)

vs.)

UNITEDHEALTH GROUP, INC., et)
al.,)

Defendants.)

Case No.

16-08697 FMO

---o0o---

TUESDAY, MARCH 12, 2024

VIDEOTAPED DEPOSITION OF PHILIP STARK, PH.D.

CONFIDENTIAL TRANSCRIPT

---o0o---

REPORTER: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

1 evidence against the null hypothesis.

2 And a common level to use for unlikely is

3 5 percent. I believe that Dr. Salve uses that

4 level of significance in much of his report, though

5 I think he uses 10 percent in some places as well. 10:22:22

6 So in the usual scenario, the test

7 statistic has some probability distribution. If

8 the null hypothesis is true, we look at that

9 probability distribution and say this is unlikely

10 -- if the observed value is sufficiently unlikely 10:22:41

11 on the assumption that the null hypothesis is true,

12 that's evidence that the null hypothesis is not

13 true.

14 In this particular case, the observed data

15 are impossible if the null hypothesis is true. So 10:22:54

16 it's not an issue of there's a 5 percent chance

17 that I would erroneously reject the null hypothesis

18 on the assumption that the null hypothesis is true.

19 The data gets certainty that the null hypothesis is

20 false. 10:23:13

21 Q. I see. So if the null hypothesis is that

22 -- well, let's use your example here.

23 A. May I interject something else?

24 Q. Sure.

25 A. I just said -- I was a little bit sloppy 10:23:20

1 in my language in talking about whether the
2 observed value of the test statistic is
3 sufficiently unlikely. It's usually a range of
4 values for the test statistic. For example, values
5 that are as extreme or more extreme, and not a
6 single value. Because in many situations, any
7 single value of the test statistic is very
8 unlikely.

10:23:35

9 Q. Understood. Well, to summarize, if a
10 result is impossible, then you would say it's
11 certain, and the raw data provides certainty that
12 the hypothesis is wrong, correct?

10:23:48

13 A. Yes. There's another caveat here, which
14 is I'm assuming that the chart -- the reviews that
15 led to these data were -- had no error in them.
16 That's ascertaining that some particular HCC didn't
17 have support, was a complete -- was correct, and
18 that there, for example, was not support in some
19 chart that was not examined.

10:24:09

20 Q. I understand. So assuming the chart
21 review at issue is correct, if it produces a result
22 that is impossible, then you would say with
23 certainty the hypothesis is false, right?

10:24:39

24 A. Yes, I would.

25 Q. All right. Do you have any reason to

10:24:55

1 doubt whether chart reviews can provide an
2 objective answer like -- like you were describing?

3 A. Well, I understand that coders don't
4 always find the same answer. So it seems that
5 there's some variation and, therefore, some
6 uncertainty.

10:25:18

7 There's perhaps a platonic ideal notion of
8 whether a perfect inspection of, you know, every
9 chart associated with a particular member in a
10 particular year would show support versus whether a
11 perfect inspection of the subset of charts that
12 were examined by the coders behind the data that
13 Dr. Salve relied upon would have found support
14 versus actual human beings doing the work.

10:25:35

15 Q. Fair enough. But based on the work you
16 performed in this case, you saw some variation in
17 the coding, correct?

10:25:57

18 A. I did not look at -- no, I did not.

19 Q. I mean variation in the results, I should
20 say, of people who had reviewed the coding,
21 correct?

10:26:11

22 A. Well, I understand that the -- one of the
23 basic issues in this litigation is that the United
24 chart review coders didn't find some of the
25 submitted codes. And so if the submitted codes

10:26:31

1 were based on reading the charts, then it seems
2 that those charts were read in more than one way.

3 Q. All right. So let's go back to the
4 Paragraph 81 in your report. And here you were
5 discussing whether there was support for HCCs in 10:27:03
6 the study that Dr. Salve had done.

7 And I'll ask you, if a hypothesis were the
8 rate of unsupported HCCs in the population is zero,
9 then a finding of nonzero would prove with
10 certainty that the hypothesis is false, right? 10:27:27

11 A. Yes, sir. Again, subject to uncertainty
12 -- on the assumption that the reading is perfect.

13 Q. On the assumption that -- right, that that
14 particular reading of the coding is correct?

15 A. Yes, sir. Of the charts underneath. 10:27:45

16 Q. Yes, the reading of the charts and the
17 identification of the codes is correct?

18 A. Yes, sir.

19 Q. Okay. Great. Let's go over your opinion
20 on Page 7. Dr. Stark, you analyze whether 10:28:03
21 member-HCC -- actually, let me go to that. Let me
22 go to footnote 6 first. You used the term
23 "member-HCC-year" as a unit of measure in footnote
24 6?

25 A. Yes, sir. 10:28:33

1 Q. Okay. I am going to try to use the same
2 term today, "member-HCC-year," so that we're
3 consistent.

4 A. Thank you.

5 Q. All right. Now, in your -- I am going to 10:28:41
6 call this Opinion II on Page 7 because it's got the
7 Roman II. Your Opinion II found support in RADV
8 for diagnosis instances with no payment impact was
9 higher than those with payment impact, correct?

10 A. I'm sorry. I didn't hear the last part of 10:29:07
11 the question.

12 Q. That you -- in your Opinion II, you found
13 that the RADV validation rate of diagnosis
14 instances with no payment impact was higher than
15 those with payment impact, correct? 10:29:24

16 A. No, sir. I didn't independently examine
17 whether any diagnosis instance had financial
18 impact. I'm relying on Mr. Renjilian's Opinions 2
19 and 3 for that determination. I'm doing
20 calculations based on his labeling of diagnosis 10:29:40
21 instances as potentially having financial impact or
22 not.

23 Q. Fair enough. Let's go into what you did
24 here. Let's look at your Paragraph 24.

25 In Paragraph 24 you write "To evaluate the 10:29:59

1 rates at which RADV audits found support for
2 member-HCC-years that Mr. Renjilian identified as
3 having financial impact if deleted, I replicated
4 and extended portions of Mr. Renjilian's analysis,"
5 right?

10:30:17

6 A. Yes, sir.

7 Q. So you did not verify Mr. Renjilian's work
8 on whether a diagnosis instance had payment impact
9 or not; you just accepted his Opinions 2 and 3,
10 correct?

10:30:32

11 A. I used his determination. I -- "accepted"
12 is a little stronger. I used his determination.

13 Q. Fair enough. You used his determination.
14 And you did the work identified in your Paragraphs
15 25 through 29, correct?

10:30:47

16 A. Yes, sir.

17 Q. All right. After doing that work -- well,
18 I should say in Paragraph 24 you say "I replicated
19 and extended portions of Mr. Renjilian's analysis."
20 And you did that by doing the work in Paragraphs 25
21 through 29, correct?

10:31:28

22 A. Yes, sir.

23 Q. And in Paragraph 30 --

24 A. Some of the extension is not just

25 described there. That's -- Paragraphs 25 through

10:31:41

1 29 are for preparing the database for -- creating a
2 database that I used then for subsequent
3 calculations that are described later in the
4 report.

5 Q. Okay. 10:31:55

6 A. That's not the full extent of the work.

7 Q. Fair enough. You feel confident in the
8 methods you used, correct?

9 A. Yes, yes.

10 Q. And you feel confident in the results you 10:32:07
11 achieved, right?

12 A. Yes.

13 Q. All right. In Paragraph 30 you state the
14 following: "My results match the 2011-2013 counts
15 in the left panel of Figure 15 of the Renjilian 10:32:20
16 report." Do you see that?

17 A. Yes, sir.

18 Q. Is that accurate?

19 A. That's to the best of my recollection,
20 yes. 10:32:32

21 Q. So the independent analysis that you
22 performed matched the same results as Mr. Renjilian
23 on Figure 15 of his report, right?

24 A. The left panel?

25 Q. Yes. 10:32:45

1 A. For 2013 -- from 2011 through 2013, yes,
2 sir.

3 Q. And let's go ahead and look at that left
4 panel in Mr. Renjilian's report. And that's on
5 Page 87 of his report. 10:33:01

6 You're referring, Dr. Stark, to the panel
7 that says at the top "Member-HCCs, 2011-2013"?

8 A. I think it says CON13 -- "CON11-13."

9 Q. Yeah, I think you have a different
10 pagination than I do. So go to Page 86. 10:33:38
11 Member-HCC-years -- member-HCCs 2011-2015. Do you
12 see that?

13 A. I see something that says "CON11-13." Is
14 that --

15 Q. CON11-13? 10:33:57

16 A. Not 2011 through '15. Yes, sir.

17 Q. Great. Okay. And Dr. Stark, you
18 replicated and reached the same result as in that
19 upper left panel, right?

20 A. Our arithmetic agrees, yes. 10:34:12

21 Q. Your arithmetic agrees.

22 A. Yes.

23 Q. All right. So you found, Dr. Stark, that

24 -- I want to go through these numbers in some more

25 detail. You found that for 2011 through 2013, your 10:34:24

1 arithmetic found that there was 1,119

2 member-HCC-years with a diagnosis instance that was

3 on the first interrogatory response, right?

4 A. As I sit here, I can't remember whether

5 this is counting diagnosis instances or HCCs rolled 10:35:05

6 up to the member-year level.

7 Q. Well, you stated in your report you

8 replicated and found the same results, correct?

9 A. Yes.

10 Q. And Mr. Renjilian writes "Member-HCCs" at 10:35:25

11 the top of that chart, correct?

12 A. Yes, sir.

13 Q. So that would suggest these are

14 member-HCC-years, correct?

15 A. It would, although Mr. Renjilian's 10:35:36

16 terminology isn't -- I think he sometimes uses the

17 same phrase to talk about diagnosis instances and

18 sometimes to talk about HCC-years.

19 Q. Okay. Well, assuming this is

20 member-HCC-years for now, and if you discover later 10:35:54

21 it was diagnosis instance, you'll let us know.

22 A. Yes.

23 Q. Okay. So to state it plainly, there were

24 1,119 instances where a provider submitted a code

25 after an encounter, a United chart review coder 10:36:09

1 reviewed the chart and did not identify that
2 submitted code, and then the member-HCC-year was
3 reviewed in RADV, correct?

4 A. That's my understanding, yes.

5 Q. And out of those 1,119 instances, the RADV 10:36:31
6 auditors found 980 of them to be supported, right?

7 A. Not of the diagnosis instances, but of the
8 resulting HCC for that beneficiary for that year.

9 Q. Thank you for correcting that.

10 So in -- let me restate. So in 980 of 10:36:50
11 those instances, the RADV auditors validated the
12 member-HCC-year associated with that diagnosis
13 instance, right?

14 A. That's my understanding. My understanding
15 is that RADV does not look at the diagnosis 10:37:06
16 instances to see whether the diagnosis instances
17 are supported. RADV looks at members and the HCCs
18 that those members were assigned for the year and
19 asks United or whoever the MAO is to provide
20 documentation to support that HCC for that 10:37:29
21 beneficiary for that year.

22 Q. All right. Let me just establish some
23 foundation about RADV. What do you understand RADV
24 to be?

25 A. I understand it to be a review that's done 10:37:40

1 by CMS of some contracts and some years, that it
2 involves sampling beneficiaries and then looking
3 for -- or asking the MAO for support for the HCCs
4 that were assigned to that beneficiary that year,
5 that the MAO is allowed to provide up to five
6 pieces of information -- I think their chart
7 specifically, but five pieces of information to
8 support each HCC, and that support might or might
9 not be from the diagnosis instance that was
10 originally submitted.

10:38:06

10:38:26

11 Q. And you understand that the CMS auditors
12 will then review the charts to determine if the
13 member-HCC-year is supported, correct?

14 A. That's my understanding, yes, sir.

15 Q. All right.

10:38:45

16 A. I have a little bit more detail in the
17 understanding of RADV. I understand that at least
18 in some years the sample -- first of all, I
19 understand that the samples are drawn from contract
20 years.

10:38:59

21 Second, I understand that at least in some
22 years, the sample was a stratified random sample,
23 that it was stratified by a tercile of payment for
24 the beneficiary in question.

25 I have also seen language somewhere that

10:39:14

1 said it was somehow risk -- risk aware, that
2 somehow it was attempting to focus on things that
3 were perceived to have more risk, but I don't
4 understand the detail of that.

5 Q. Okay. Thank you for clarifying that. 10:39:29

6 We are going to assume today, Dr. Stark,
7 that the RADV auditors always get it right.

8 A. I don't know whether the RADV auditors
9 always get it right.

10 Q. Do you have any doubts whether they always 10:39:41
11 get it right?

12 A. I mean, any process involving humans
13 reading printed materials, some error rate. I just
14 don't know -- I haven't seen attempts to quantify
15 it. I don't have an independent basis for knowing 10:39:59
16 what the accuracy would be.

17 Q. Fair enough. Well, let's assume for the
18 purposes of today, I'll give you an assumption,
19 that the RADV auditors are always correct.

20 A. Okay. 10:40:16

21 Q. And I'll -- I'll restate that assumption
22 when I ask you various questions.

23 A. Okay.

24 Q. But if you have any doubts, you can say,
25 "Are you assuming RADV is correct?" 10:40:25

1 A. I'll do my best here.

2 Q. Okay. Great. All right. Going back to

3 Mr. Renjilian's chart that you verified the

4 arithmetic, you agree that there were 980 instances

5 where a provider submitted a code after an 10:40:42

6 encounter, United chart review coders reviewed the

7 chart and failed to find the diagnosis code

8 submitted by the provider, and RADV auditors

9 reviewed the member-HCC-year associated with that

10 diagnosis instance and found it to be supported, 10:41:06

11 right?

12 A. My understanding is that one of -- at

13 least one of the up to five pieces of information

14 provided by United, possibly from different

15 diagnosis instances or even diagnosis instances 10:41:20

16 that were not submitted, provided support for that

17 HCC, or possibly something in the -- higher in the

18 hierarchy for that beneficiary for that year.

19 Q. Okay. Thank you for those caveats. But

20 in summary, in those 980 instances, ultimately the 10:41:41

21 RADV auditors found the member-HCC-year to be

22 supported, correct?

23 A. They found the member-HCC-year to be

24 supported, yes, sir.

25 Q. All right. And then the next line in 10:41:54

1 Figure 15 says "No Overlap." And you understand
2 that to be the member-HCC-years in which the
3 diagnosis instance was not missed by United chart
4 review coders, correct? I can rephrase if this --

5 A. I understand that to be member-HCC-years 10:42:29
6 that didn't intersect those diagnosis instances
7 identified in FIR.

8 Q. Right. So the FIR is the first
9 interrogatory response, right?

10 A. Yes, sir. 10:42:50

11 Q. And that involves diagnosis instances that
12 were submitted by a provider but not found in the
13 United chart review, right?

14 A. That's my understanding, yes, sir.

15 Q. All right. So the second line of 10:43:00
16 Mr. Renjilian's Figure 15 are the member -- the
17 validation rates in RADV of member-HCC-years in
18 which the diagnosis instances were not on the first
19 interrogatory response, correct?

20 A. That's my understanding, yes. 10:43:16

21 Q. All right. And so Mr. Renjilian found,
22 and you confirmed, that the RADV validation rate
23 for codes on the first interrogatory response for
24 member-HCC-years associated with diagnosis
25 instances on the first interrogatory response was 10:43:37

1 higher, 87.6, than the validation rate for
2 member-HCC-years that did not overlap with the
3 first interrogatory response, right?

4 A. Yes. By about 1.1 percent, yes, sir.

5 Q. And you confirmed that with your own 10:44:08
6 arithmetic, right?

7 A. Yes, sir, but again, based on
8 Mr. Renjilian's determination -- sorry. In this
9 instance it doesn't involve Mr. Renjilian's
10 determination. I apologize. Yes. 10:44:20

11 Q. What do you mean it doesn't involve
12 Mr. Renjilian's --

13 A. I was thinking of his Opinions 2 and 3,
14 but this doesn't rely on his Opinions 2 and 3.

15 Q. Right. You confirmed these numbers based 10:44:30
16 on your own work?

17 A. Yes, sir.

18 Q. All right. And by "these numbers," I mean
19 the numbers in Figure 15 of Mr. Renjilian's report,
20 upper left-hand corner, 2011 through 2013? 10:44:39

21 A. Yes. CON11-13, yes, sir.

22 Q. Dr. Stark, tell me whenever you want to
23 take a break. I am happy to keep going. I am
24 going to rely on you and your counsel to tell me
25 when you need a break. 10:45:02

1 A. Thank you.

2 Q. I want to now go to your Opinion II on
3 Page 7. So Dr. Stark, you performed the work you
4 described in this section, and that led you to
5 create a table on Page 11. Can you go to that
6 table, please?

10:45:38

7 A. Yes, sir.

8 Q. And that's called -- you called it "Table
9 2," right?

10 A. Yes, sir.

10:45:54

11 Q. I want to walk through your results here.
12 You have a model -- a column called "Model," V12
13 and V22. Can you explain what those terms mean,
14 "V12" and "V22"?

15 A. My understanding is the CMS model that's
16 used to determine payments to MAOs, it's a
17 regression model calibrated to fee-for-service
18 data. And V12, I believe, is the version of the
19 model that was in use exclusively for a portion of
20 the time at issue in this matter.

10:46:08

10:46:28

21 At some point V22 started to be used as
22 well. I think during some years payments were
23 based on some combination of V12 and V22.

24 Q. And the next column is "Years," which is
25 self-explanatory. The next column says, "RADV

10:46:47

1 supported op 3=1." Can you describe what that
2 column means?

3 A. Yes. So that's looking again at diagnosis
4 instances in FIR. I received a database that was,
5 I think, FIR with additional annotations, 10:47:12
6 additional columns that were added by Mr. Renjilian
7 or his team which included flags, so values that
8 were true or false, zero or one. I don't recall
9 the original coding.

10 Op 3=1 means that according to 10:47:32
11 Mr. Renjilian's Opinion 3, deleting that diagnosis
12 instance would not result in money flowing from --
13 it wouldn't affect the payments.

14 Q. All right. Let me try to restate that
15 last part. 10:47:57

16 So this chart shows that there were 3,082
17 member-HCC-years in which --

18 A. No, sir. That's diagnosis instances.

19 Q. Okay. Fair enough. There were 3,082
20 diagnosis instances in which a provider met with a 10:48:20
21 patient and diagnosed the patient, or had an
22 encounter and diagnosed the patient. And then a
23 United chart review coder reviewed the charts and
24 did not find the diagnosis. And then RADV found
25 the diagnosis instance to be supported, and in all 10:48:46

1 circumstances this is a diagnosis instances that
2 did not have payment, right?

3 A. I'm sorry. My understanding is RADV does
4 not diagnose individual diagnosis instances to
5 determine if they were reported. They examine 10:49:02
6 whether HCC corresponding to that diagnosis or a
7 different HCC higher in the hierarchy in the same
8 branch is supported by at least one of the pieces
9 of the information that the MAO provides RADV.

10 Q. Fair enough. So let me restate it then. 10:49:17
11 So there were 3,082 diagnostic instances in which a
12 provider, after an encounter with a patient,
13 submitted a diagnosis, the United chart review
14 coders reviewed the chart and did not find the
15 diagnosis, and then that encounter was reviewed -- 10:49:36
16 or that member-HCC-year was reviewed in RADV, and
17 then the RADV auditors found it to be supported,
18 correct?

19 A. Again, approximately. My understanding is
20 that the review -- the RADV review might or might 10:49:58
21 not include review of the particular diagnosis
22 instances that were submitted. It's a review of
23 whatever materials the MAO provides RADV to support
24 that HCC for that year.

25 So it is not a quality control check on 10:50:20

1 individual diagnosis instances and the supporting
2 materials provided to RADV that gave support for
3 those HCCs might or might not be the original
4 diagnosis instances that was submitted.

5 Q. I understand. But with that caveat, you 10:50:37
6 agree that there were 3,082 instances in which a
7 provider submitted a diagnosis code after an
8 encounter, United chart review coders did not find
9 that diagnosis, the member-HCC-year associated with
10 that diagnosis was then reviewed in RADV and the 10:50:57
11 RADV auditors found support for it, and the
12 universe being diagnosis codes that had no payment?

13 A. No, sir. The word "it" in your question
14 suggests that it was the diagnosis instance that
15 was reviewed, and it might or might not be the 10:51:16
16 diagnosis instance that was reviewed. The
17 diagnosis instance might, in fact, not support that
18 particular HCC, or that diagnosis -- sorry. The
19 chart might not support that particular diagnosis
20 instance, but there was at least one chart that 10:51:34
21 year that supported the HCC that that diagnosis
22 instance maps to or an HCC that's higher in the
23 hierarchy.

24 Q. Thank you for clarifying. I wasn't trying
25 to be cute or mislead with the word "it." I meant 10:51:51

1 -- by "it" I meant member-HCC-year.

2 A. Yes, sir.

3 Q. But I can restate it so that we are
4 absolutely clear. And thank you for being so
5 careful.

10:52:02

6 You agree there were 3,082 instances in
7 which a provider submitted a diagnosis code after
8 an encounter, United chart review coders did not
9 find that diagnosis, the member-HCC-year associated
10 with that diagnosis was reviewed by RADV auditors, 10:52:18
11 and RADV auditors found support for that
12 member-HCC-year?

13 A. Yes, sir, I agree with that.

14 Q. All right. Now, let's go to the second
15 half of your chart, and you have a column "RADV 10:52:39
16 supported op 3=0." Do you see that?

17 A. Yes, sir.

18 Q. Okay. What does that mean?

19 A. It means that according to
20 Mr. Renjilian -- I don't want to mischaracterizes 10:52:51
21 what he said. I think op 3=1 means that he
22 determined that it would not have -- that that
23 diagnosis code would not have financial impact if
24 it were deleted. Op 3=0 -- I don't know whether he
25 means would have financial impact if deleted or he 10:53:16

1 that diagnosis instance, but that might or might
2 not be on the basis of that diagnosis instance.

3 Q. That's right. And I wasn't asking whether
4 -- I am not trying to suggest it was based on the
5 same diagnostic instance, but I'm saying that RADV 11:20:38
6 auditors found support at the member-HCC-year level
7 3,619 times for member-HCCs associated with
8 diagnosis instances that were missed in chart
9 review, right?

10 A. Well, again, missed in chart review, or 11:20:54
11 chart review didn't find them. Yes, that's
12 correct, I believe, assuming that your arithmetic
13 is correct, yes.

14 Q. All right. So Dr. Stark, I want to
15 present you with a hypothesis. Every time a United 11:21:11
16 chart review coder fails to find a diagnosis code
17 submitted by a provider, a member-HCC-year
18 associated with that code is unsupported.

19 Now, you agree, based on the work you
20 performed, that that hypothesis is false, correct? 11:21:33

21 A. Yes, I -- well, yes. RADV finds support
22 at the HCC level for the HCCs associated with some
23 of the diagnosis instances where chart review did
24 not find the diagnosis, but the diagnosis had been
25 submitted previously. 11:22:07

1 So somewhere in some chart that was
2 presented by United to RADV, there was support for
3 that HCC for that member for that year.

4 Q. I understand that caveat, and you've
5 mentioned it a few times. In understanding that 11:22:24
6 caveat, which I am going to cover in a minute, I
7 just want to restate the hypothesis and make sure I
8 understand your opinion.

9 The hypothesis is every time a United
10 chart review coder fails to find a diagnosis code 11:22:37
11 submitted by a provider, the member-HCC-year
12 associated with that diagnosis code is not
13 supported, that hypothesis is false, correct?

14 A. I agree.

15 Q. Okay. And you agree that that's false to 11:22:56
16 a certainty, right?

17 A. Yes, sir. Well, yes, my -- if by
18 "supported," we mean RADV found support, yes.

19 Q. Fair enough. We talked about that
20 assumption earlier, but you had said that human 11:23:12
21 beings are fallible and so RADV auditors may be
22 fallible, right?

23 A. Yes, I am just worried about the
24 definition of "supported," but yes, I -- yes, RADV
25 finds support for some nonzero fraction of 11:23:27

1 member-HCC-years for which corresponding to some of
2 the diagnoses that were originally submitted but
3 not found in chart review.

4 Q. All right. Fair enough.

5 I want to cover this caveat that you've 11:23:48
6 raised a number of times about a member-HCC-year
7 potentially being supported from another chart.

8 And so if I understand what you're saying,
9 Dr. Stark, is that a diagnosis instance in the
10 first interrogatory response would have involved a 11:24:14
11 provider meeting with a patient in an encounter,
12 having an encounter with a patient, submitting a
13 diagnosis and that mapping to a member-HCC-year;
14 but then another provider, meaning -- or having an
15 encounter with a patient and also submitting a 11:24:35
16 diagnosis.

17 And you're saying that the member-HCC-year
18 in RADV could have been supported by that second
19 encounter, not the first encounter on the first
20 interrogatory response; is that correct? 11:24:50

21 A. That's my understanding, or it could have
22 been a different encounter with the same provider,
23 or it could have been an encounter with the same
24 provider or a different provider with a different
25 diagnosis that mapped to either the same HCC or an 11:25:02

1 HCC higher in the hierarchy.

2 Q. That's correct. So just to put it in

3 plain terms, a provider may meet with a patient and

4 diagnosis a patient as having diabetes and that may

5 not be found in chart review, the diabetes 11:25:19

6 diagnosis; but then a different provider may meet

7 with the same patient, diagnosis diabetes, and then

8 that would be the chart that the RADV auditors

9 would find as supporting the member-HCC-year,

10 right? 11:25:37

11 A. I think it's a little more complicated

12 than that, in that my understanding is that RADV

13 doesn't do its own selection of materials to

14 review, that it's the MAO that provides RADV with

15 materials that they purport support the HCC for 11:25:53

16 that member for that year.

17 So my understanding is that the materials

18 presented to RADV in support of a particular

19 HCC-member-year could be one of the diagnosis codes

20 that chart review -- diagnosis instances that chart 11:26:15

21 review did not find.

22 It could be based on an encounter with the

23 same or a different provider, a different

24 encounter, and it could be support for, for

25 example, a more severe form of diabetes than the 11:26:35

1 particular HCC corresponding to the diagnosis event
2 that was originally submitted but not found in
3 chart review.

4 Q. Fair enough. Okay. Dr. Stark, I want to
5 change the hypothesis a little bit and focus just 11:26:53
6 on payment impact codes.

7 So the -- I want to present to you this
8 hypothesis. Every time a United chart review coder
9 fails to find a diagnosis code with payment impact
10 that had been submitted by a provider, the 11:27:13
11 member-HCC-year associated with that diagnosis
12 instance was unsupported.

13 You agree, based on the work you
14 performed, that that hypothesis is false, right?

15 A. Not quite. I have made no independent 11:27:31
16 determination of whether a diagnosis instance has
17 financial impact. My analysis relies either on --
18 in some cases on Mr. Renjilian's determination of
19 whether it has financial impact, and in some case
20 on Mr. Garthwaite -- Dr. Garthwaite's determination 11:27:51
21 on whether that diagnosis instance has financial
22 impact.

23 But I agree with what I think the gist is
24 of your assertion, which is that there are examples
25 of HCCs that were identified by one or the other or 11:28:04

1 both of Mr. Renjilian and Dr. Garthwaite as having
2 financial impact where RADV found support for that
3 HCC for that member for that year.

4 That determination might or might not have
5 been based on a review of the chart corresponding 11:28:25
6 to that, to the diagnosis event that was explicitly
7 stated.

8 Q. Okay. Dr. Stark, thank you for that
9 clarification. I will make my hypothesis even more
10 precise. 11:28:42

11 A. Okay.

12 Q. Because I am not trying to play gotcha,
13 and I'm glad you're being careful about the
14 wording.

15 So let me present you this hypothesis: 11:28:49
16 Every time a United chart review coder fails to
17 find a diagnosis code that either Mr. Renjilian or
18 Dr. Garthwaite identified as having payment impact
19 that have been submitted by a provider, the
20 member-HCC-year associated with that diagnosis 11:29:10
21 instance was unsupported?

22 A. Again, the word "supported" bothers me.
23 RADV found support for some of them.

24 Q. That RADV found support?

25 A. Yeah. So if you change that to "RADV 11:29:22

1 determined that it was unsupported," then -- then I
2 would agree.

3 Q. Okay. And the reason you have trouble
4 with "found support" is it requires an assumption
5 that the RADV auditors were correct, right?

11:29:41

6 A. Well, I -- RADV reviews -- my
7 understanding is that RADV reviews up to five
8 pieces of information provided by United. There
9 might be other charts that were not presented to
10 RADV -- even though I understand those to be
11 United's best attempt to demonstrate support for
12 that member-HCC-year combination. It's possible
13 that there would be support somewhere else. It's
14 possible that -- it's possible that RADV made a
15 mistake. There's a lot of things that are
16 possible.

11:30:11

11:30:28

17 And I just want to be clear that we are
18 talking about whether RADV found support rather
19 than some more abstract notion --

20 (Clarification by the reporter.)

11:30:46

21 THE WITNESS: Abstract notion of
22 supported. And I want to be also clear about the
23 distinction between whether a particular diagnosis
24 instance is supported by the chart corresponding to
25 that diagnosis instance or the HCC that that

11:31:03

1 diagnosis instance maps to has support somewhere in
2 some chart for that subscriber for that year.

3 Q. BY MR. ABASCAL: Thank you.

4 A. Or something higher in the hierarchy.

5 Q. But assuming the RADV auditors were 11:31:22
6 correct, you would agree that that hypothesis is
7 false, right?

8 A. I have now -- I am no longer holding your
9 statement in memory. Let me try to say it myself.

10 I agree that the hypothesis that when RADV reviewed 11:31:42
11 a member-HCC-year instance that -- for which a
12 diagnosis code had been submitted but not found by
13 the chart reviewers, and that -- and that diagnosis
14 instance had been identified by either

15 Mr. Renjilian and/or Mr. Garthwaite as having 11:32:29
16 financial impact, some fraction of the time that
17 they never found -- with a hypothesis that they
18 never -- that RADV never found support for that
19 HCC. And I agree that that hypothesis is false.

20 Q. All right. Let me try to state this in a 11:32:53
21 little plain terms, which is pretty dangerous.

22 So just because a United chart review
23 coder did not find a provider-submitted code, that
24 does not mean that the associated member-HCC-year
25 is unsupported, assuming RADV is correct? You 11:33:27

1 agree with that, right?

2 A. Yes, the -- just because chart review did
3 not find support for a diagnosis code submitted for
4 a particular diagnosis instance, there might be
5 somewhere -- there still might be somewhere support
6 for the HCC that that diagnosis code maps to or an
7 HCC higher in the hierarchy, possibly in the chart
8 that was reviewed by the United chart reviewers and
9 possibly in some other chart for that member for
10 that year.

11:33:56

11:34:17

11 Q. And you verified that through your own
12 analysis as reflected in Table 2?

13 A. I couldn't hear the last part of your
14 sentence. My analysis of?

15 Q. As reflected in your Table 2?

11:34:32

16 A. Yes, sir.

17 Q. All right. Dr. Stark, you understand that
18 payment to United is based on a member-HCC-year,
19 correct?

20 A. That's my understanding, yes, sir.

11:34:46

21 Q. All right.

22 A. And other characteristics of the members,
23 including demographic information.

24 Q. Fair enough. And you understand that if
25 the RADV auditors find support for the

11:34:58

1 member-HCC-year, then the payment is appropriate,
2 right, that portion of the --

3 MS. GLOVER: Objection; calls for legal
4 conclusion.

5 THE WITNESS: Yeah, I don't know what 11:35:14
6 "appropriate" means in this context. I don't know
7 the terms of the contract between the MAOs and CMS.

8 I understand that as a matter of practice
9 that RADV does not ask to be reimbursed when they
10 find -- if support is found for that HCC, but I 11:35:33
11 don't know the connection between the common
12 practice and RADV and the legal terms of the
13 contract between the MAO and the government.

14 Q. BY MR. ABASCAL: That's fair, Dr. Stark.

15 Do you understand that if a 11:35:54
16 member-HCC-year is unsupported, that would be
17 considered an overpayment?

18 MS. GLOVER: Objection; calls for a legal
19 conclusion.

20 THE WITNESS: I don't know -- I don't know 11:36:08
21 how that word is used in this context. I mean, in
22 lay terms, my understanding is that the practice of
23 RADV is to count that payment against -- against
24 the MAO, but I don't know -- again, I don't know
25 how the term is used. I don't know whether it is a 11:36:30

1 legal term of art. I don't know whether it is a
2 term that appears in the contract.

3 Q. BY MR. ABASCAL: That's fair. I am not
4 trying to play gotcha or suggest a term or trick
5 you with a term of art. So let me rephrase it. 11:36:42

6 Do you understand that if a
7 member-HCC-year is unsupported, then the payment
8 would be inappropriate?

9 A. Again, I don't really know what
10 "inappropriate" means here. And "unsupported," I 11:37:10
11 think you mean if RADV determines that none of the
12 pieces of information provided by the MAO support
13 that HCC for that member for that year. I
14 understand that that's considered some kind of
15 error and that there's some kind of accounting. 11:37:27
16 But I don't know -- I don't know details.

17 I understand informally that RADV allows
18 offsets as well, but, again, this is -- I don't
19 know the rules under which RADV operates. And I
20 don't understand in detail how a RADV audit results 11:37:48
21 in any kind of reconciliation of money between the
22 MAO and the government.

23 Q. I understand you're not an expert in RADV,
24 and I am not trying to suggest that anything you
25 say would bind the government on its interpretation 11:38:04

1 of RADV.

2 I am trying to find the word that would
3 make you more comfortable. And you said the word
4 "improper," so let me try that.

5 A. I'm sorry. I need to answer verbally 11:38:20
6 here. I don't -- I mean, I understand that there's
7 some kind of accounting for HCCs that RADV
8 determines were unsupported, HCC-member-year
9 combinations that RADV determines were unsupported,
10 but I don't know the details of that. 11:38:40

11 Q. Fair enough. Do you understand that
12 payment would be improper to United if the
13 member-HCC-year were unsupported?

14 A. Again, I'm a little hung up on the word
15 "improper." I think that I -- I think that -- 11:38:55
16 yeah, I don't know what to say.

17 Q. That's fair enough. If you're
18 uncomfortable, I don't want to make you
19 uncomfortable.

20 You do not know whether payment would be 11:39:07
21 proper or improper if a United member-HCC were
22 unsupported, correct?

23 A. Again, I don't know the sense of the word
24 "improper." I understand that -- I understand
25 informally that the MAOs don't submit HCCs. They 11:39:35

1 submit diagnosis instances to a government system.

2 And I understand that payments are based on the
3 member demographics and the HCCs that the diagnoses
4 for that member map to for the year that only a

5 single instance of each HCC matters. Multiple 11:40:05

6 instances don't change anything. And that there
7 are hierarchies for some HCCs and only, in some
8 sense, the riskiest of HCC in that hierarchy

9 matters if more than one has been assigned to a
10 given subscriber for the year. 11:40:25

11 I understand that there is some obligation
12 to submit only genuine diagnosis instances and some
13 obligation to correct errors that the MAO is aware
14 of or should be aware of. But beyond that, I don't
15 really know. 11:40:50

16 Q. All right. Fair enough. Well, Dr. Stark,
17 let's move on to a different part of your report.
18 I am going to focus on Section III of your report,
19 and this is where you analyze the member-HCC-year
20 combinations associated with the Garthwaite final 11:41:16
21 delete list, right?

22 I am going to draw your attention to
23 Paragraph 39, Dr. Stark. In Paragraph 39 you state
24 "For the V12 model, overall, RADV found support for
25 41,681 of 49,978 audited member-HCC-year 11:41:45

1 combinations, a rate of 83.4 percent."

2 Then you go on to say, "In contrast, RADV

3 found support for 264 of the 464 member-HCC-year

4 V12 combinations it checked that are among the

5 Garthwaite Final Deletes List, a rate of 56.9 11:42:10

6 percent."

7 Dr. Stark, those are your conclusions,

8 right, based on the work you performed for this

9 report, correct?

10 A. Yes, sir. 11:42:24

11 Q. And do you remain confident in those

12 conclusions?

13 A. Yes.

14 Q. Nothing's changed since you wrote the

15 report? 11:42:34

16 A. I understand that Dr. Garthwaite is

17 submitting another erratum, and it's possible that

18 the numbers in that new version could change this

19 conclusion, but I have not seen that report yet.

20 Q. Other than that caveat, your analysis you 11:42:59

21 still stand by, correct?

22 A. I believe that it's correct, yes.

23 Q. All right. So looking at Paragraph 39,

24 you found 264 circumstances in which a provider

25 submitted a diagnosis code that was not found by 11:43:19

1 United chart review coders, and Dr. Garthwaite
2 added that diagnosis instance to his final delete
3 list, and RADV auditors found support at the
4 member-HCC-year associated with that diagnosis
5 instance, right? 11:43:49

6 A. I am stumbling slightly over the word
7 "added." That diagnosis instance is -- there are
8 -- to the best of my knowledge, 400 -- and at the
9 time that I wrote this report -- 464
10 member-HCC-year V12 combinations that, according to 11:44:21
11 Dr. Garthwaite -- sorry. Let me try again.

12 Among the diagnosis instances that
13 Dr. Garthwaite says should be deleted because the
14 -- the chart review did not support that diagnosis
15 instance, those correspond to 464 member-HCC-year 11:44:58
16 V12 combinations and RADV found possibly based on
17 other diagnosis instances, support for 264 of those
18 member HC year -- HCC-year combinations for the V12
19 model.

20 Q. Understood. And you say RADV found 11:45:27
21 possibly based on other diagnosis instances, but
22 you would agree they may have found, possibly based
23 on the same diagnosis, instances too, correct?

24 A. It could have been based on the chart from
25 the encounter that led to the diagnosis instance 11:45:42

1 that chart review -- sorry. The diagnosis instance
2 that was originally submitted and which chart
3 review did not confirm, did not find, it could have
4 been based on a different chart.

5 Q. So however the member-HCC-year was 11:46:06
6 supported, it remains true that there were 264
7 member-HCC-years that RADV auditors found support
8 for where the diagnosis instance is included in the
9 Garthwaite deletes list, right?

10 A. Yes. 11:46:26

11 Q. All right. So Dr. Stark, I want to
12 present another hypothesis to you. All of the
13 diagnosis instances on the Garthwaite final deletes
14 list are associated with member-HCC-years that are
15 unsupported? 11:46:42

16 MS. GLOVER: Objection; calls for legal --

17 Q. BY MR. ABASCAL: You agree that that is
18 false, right?

19 A. Unsupported by what?

20 Q. Unsupported by RADV auditors. 11:46:51

21 A. Yes.

22 Q. I'll restate it.

23 All of the codes on -- all of the
24 diagnosis instances on the Garthwaite final deletes
25 list are associated with member-HCC-years that are 11:47:02

1 unsupported according to RADV auditors; you agree
2 that hypothesis is false, correct?

3 A. Let me restate it just slightly. RADV
4 found support for the HCC that some of those
5 diagnosis instances map to or an HCC higher in that 11:47:33
6 HCC hierarchy some fraction of the time.

7 Q. I appreciate you restating it, but I'd
8 like to get an answer to the way I've stated it,
9 Dr. Stark. So let me state the hypothesis.

10 All of the diagnosis instances on the 11:47:58
11 Garthwaite final deletes list are associated with
12 member-HCC-years that RADV auditors found to be
13 unsupported. You agree that that hypothesis is
14 false, right?

15 A. Are associated with -- I'd like to change 11:48:18
16 your language to that they map to rather than --

17 Q. Okay.

18 A. -- than associated with. And I'd like to
19 change whether those HCCs were supported to those
20 HCCs were something higher in the hierarchy. 11:48:36

21 Q. Let's try it again.

22 A. And then I agree.

23 Q. All right. All right. Assuming the RADV
24 auditors are correct, with that assumption, all --
25 let me restate. Hold on a second. 11:49:02

1 So here's the hypothesis, Dr. Stark, that
2 I'd like to ask you to opine on. All of the
3 diagnosis instances on the Garthwaite final deletes
4 list map to a member-HCC-year, or one higher in the
5 hierarchy, that RADV auditors found to be
6 unsupported; you agree that that is false, correct?

11:49:45

7 A. I agree that that's false.

8 Q. Let me try to state it in plain language.

9 Just because a diagnosis code is on the Garthwaite
10 final delete list, that does not mean that the
11 member-HCC-year that maps to that code is
12 unsupported; do you agree with that?

11:50:22

13 A. Again, we're talking about support by
14 RADV, and we're talking about that HCC or one
15 higher in the hierarchy. So which way -- shall we
16 try again?

11:50:50

17 Q. Let me try again.

18 Just assuming the RADV auditors are
19 correct, just because a diagnosis code is on the
20 Garthwaite final deletes list, that does not mean
21 that the member-HCC-year mapping to that code or
22 another member-HCC-year higher in the hierarchy is
23 unsupported, right?

11:51:05

24 A. Can we link "support" to "RADV" a little
25 bit more tightly in this statement?

11:51:33

1 Q. You don't like my assumptions. So I will
2 add that to my statement. Fair enough.

3 A. RADV found support for the HCC that -- or
4 a higher HCC in the hierarchy corresponding to some
5 of the diagnosis events on Dr. Garthwaite's list. 11:51:57

6 Q. Thank you for that clarification. I'm
7 going to try my question again and incorporate how
8 you said it --

9 A. Okay.

10 Q. -- so that we're aligned and comfortable. 11:52:23
11 I understand, I think, where you're coming out.

12 So let me phrase it this way. Just
13 because a diagnosis code is on the Garthwaite final
14 deletes list, that does not mean that the RADV
15 auditors failed to find support for that 11:52:48
16 member-HCC-year or another one in the hierarchy,
17 correct?

18 A. Corresponding to that diagnosis.

19 Q. Right.

20 A. Yes, I think that that's correct. I am 11:53:02
21 trying to hold it all in my mind at the moment, but
22 if you could repeat it once more, please, I will
23 try.

24 Q. Sure. Just because the diagnosis code is
25 on the Garthwaite final deletes list, that does not 11:53:19

1 mean that the RADV auditors failed to find support
2 for the member-HCC-year or another one higher in
3 the hierarchy that maps to that diagnosis code?

4 A. Yes. It doesn't necessarily mean that,
5 yes. 11:53:40

6 Q. Because you found 264 instances in which a
7 diagnosis instance was on the Garthwaite final
8 deletes list, yet the member-HCC that mapped to
9 that diagnosis instance was found by RADV auditors
10 to be supported, correct? 11:54:01

11 A. Yes. That one or one higher in the
12 hierarchy, yes.

13 Q. And that conclusion, Dr. Stark, I want to
14 clarify, is based on your own work that you
15 performed in this case on behalf of the plaintiffs, 11:54:29
16 right?

17 A. Yes, sir.

18 Q. Okay. Dr. Stark, you would agree that
19 neither Unitedhealth Care nor the plaintiffs in
20 this case could determine whether a member-HCC-year 11:54:45
21 would be supported simply by knowing if the
22 diagnosis code submitted by the provider was not
23 found by United chart review coders, right?

24 MS. GLOVER: Objection; calls for a legal
25 conclusion. 11:55:07

1 THE WITNESS: So I don't know what you
2 mean by "supported." Again, we had several
3 different notions of support. And it feels like
4 that's, to my ear, a little bit inside out because
5 the diagnosis codes are -- the diagnosis instances 11:55:27
6 are individual events which in some sense are
7 aggregated to an annual level, indicating whether a
8 particular -- whether a particular member has a
9 particular HCC in a particular year.

10 So I would agree that by reviewing the 11:55:46
11 chart behind a single diagnosis event, it is not
12 possible to tell whether the HCC that that -- that
13 the diagnosis maps to is -- if a -- I agree if a
14 particular diagnosis event is not supported by the
15 chart corresponding to that encounter, that is not 11:56:16
16 enough information to know whether there is some
17 other diagnosis event or some other chart that
18 would support the same -- that HCC that that
19 diagnosis event maps to or an HCC higher in the
20 hierarchy. 11:56:37

21 Q. Thanks for that clarification. Let me
22 follow up on that.

23 If the only piece of information you had,
24 Dr. Stark, was that a United chart review coder
25 failed to find a provider-submitted code, you agree 11:56:55

1 that you would not have enough information to know
2 whether a member-HCC-year associated with that code
3 was supported or not supported, right?

4 MS. GLOVER: Objection; calls for a legal
5 conclusion.

11:57:12

6 THE WITNESS: Again, I am worried about
7 the use of the word "supported." But I agree that
8 even if the chart doesn't provide evidence for a
9 particular diagnosis and that diagnosis maps to
10 some particular HCC, that looking at that single
11 chart is not enough -- I can't tell you whether
12 there is some other chart from some other encounter
13 from some other diagnosis event that would support
14 that HCC -- that provides evidence that that member
15 is appropriately labeled with that HCC for that
16 year.

11:57:31

11:57:48

17 Q. BY MR. ABASCAL: You would need more
18 evidence to determine whether or not the chart --
19 the member-HCC-year was supported in that
20 circumstance, right?

11:58:06

21 A. Yes, sir.

22 Q. All right. And the same is true for those
23 codes that were not found by United chart review
24 coders, right? In other words -- let me rephrase
25 that.

11:58:17

1 Again, the fact that a provider submitted
2 code was not found by a United chart review coder,
3 that does not provide you enough information to
4 know whether the associated member-HCC-year would
5 be found to be supported or not in a RADV audit, 11:58:32
6 correct?

7 A. It would not -- it would not be enough
8 information to know whether the materials that
9 United might provide to RADV auditors would show
10 support for that HCC for that member for that year. 11:58:53

11 Q. You would need more information, right,
12 than just knowing whether or not the code is on the
13 first interrogatory response, right?

14 A. Right. So the fact that the coders are
15 unaware of any support for a diagnosis code for a 11:59:08
16 particular encounter does not mean that nowhere in
17 the record is there support for the HCC that that
18 diagnosis code maps to or something higher in the
19 hierarchy.

20 Q. I am going to try to simplify that, which 11:59:44
21 is probably a mistake.

22 Let me say it this way: Simply because a
23 United chart review coder did not find a code
24 submitted by a provider, that does not mean an
25 associated member-HCC-year is going to be found to 12:00:00

1 be unsupported by a RADV auditor, correct?

2 A. So in -- so it is -- there are examples

3 which I have counted here where RADV did find

4 support for the HCC or something higher in the

5 hierarchy that corresponds to a diagnosis event 12:00:24

6 that the chart review did not confirm.

7 Q. And the same is true for the Garthwaite

8 deletes and -- final deletes? In other words, that

9 you found that RADV auditors found support at the

10 member-HCC-year level for several diagnostic 12:00:50

11 instances that were on Dr. Garthwaite's final

12 delete list, correct?

13 A. Not for the diagnostic codes, no, sir.

14 Q. Thank you for being so precise.

15 You found -- you found that RADV auditors 12:01:06

16 found support at the member-HCC-year level for

17 several diagnosis codes that were on

18 Dr. Garthwaite's final delete list, correct?

19 A. No, sir.

20 Q. Well, how would you describe the 264 12:01:23

21 instances that you identified in Paragraph 39?

22 A. Those are not confirmations of diagnosis

23 codes. They are finding support for an HCC, not a

24 diagnosis code.

25 Q. So I thought my question said it supported 12:01:38

1 at the member-HCC-year level. Maybe that was what
2 was confusing. So I can rephrase.

3 You found that RADV auditors found support
4 for member-HCC-years that map to diagnosis
5 instances that were on the Garthwaite final deletes 12:02:04
6 list, right?

7 A. Again, I put the mapping the other way
8 around. The diagnosis instances map to HCC codes,
9 and it's -- I know that you have a background in
10 mathematics. It is sort of a many-to-one mapping. 12:02:20

11 Q. I get it.

12 You found -- let me rephrase.

13 You found diagnosis instances on the
14 Garthwaite final deletes list that mapped to
15 member-HCC-years that RADV auditors found support 12:02:36
16 for, correct?

17 MS. GLOVER: Objection; misstates prior
18 testimony.

19 THE WITNESS: Yes. I found examples of
20 diagnosis instances in Dr. Garthwaite's final 12:02:51
21 deletes list that map to HCCs for which RADV found
22 support or found support for something higher in
23 the hierarchy.

24 Q. BY MR. ABASCAL: Right. So just because a
25 diagnosis instance is on the Garthwaite final 12:03:16

1 deletes list, that does not mean that the
2 member-HCC-year that is associated with that
3 diagnosis instance was found to be unsupported by
4 RADV, correct?

5 A. I'm not sure what "associated with" means 12:03:31
6 here, but there may be -- the materials that United
7 provided to RADV showed support for the HCC or an
8 HCC higher in the hierarchy for that member for
9 that year in some instances that were -- the
10 diagnosis instance -- corresponding to diagnosis 12:04:02
11 codes that were on Dr. Garthwaite's final deletes
12 list.

13 Q. Okay. Dr. Stark, I want to go to FTI's
14 report.

15 A. Sorry. Which report? 12:04:26

16 Q. Mr. Renjilian. I called him FTI. He
17 works for FTI. The Renjilian report, Figure 15,
18 I'd like to clarify some of his analysis and how it
19 compares to your analysis.

20 If you look at the bottom of 12:04:53
21 Mr. Renjilian's report, he quantifies a
22 member-HCC-years for all years CON11-15, and you
23 see the total, 55,730?

24 A. I'm sorry. I'm looking at -- you said
25 Figure 16? 12:05:11

1 Q. 15.

2 A. 15.

3 Q. One five.

4 MS. GLOVER: It is on Page 87.

5 THE WITNESS: Okay. Sorry. Okay. Please 12:05:17
6 start the question again.

7 Q. BY MR. ABASCAL: I am drawing your
8 attention to the bottom chart on Figure 15,
9 CON11-15, member-HCC-years.

10 A. Yes, sir. 12:05:27

11 Q. And do you see that Mr. Renjilian counted
12 55,730?

13 A. Yes, sir.

14 Q. All right. Drawing your attention,
15 Dr. Stark, to Paragraphs 39 and 40 of your report, 12:05:37
16 you also calculated the overall RADV support rate
17 under the V12 model and the V22 model. And in
18 Paragraph 39 you calculated 49,978 audited
19 member-HCC-year combinations under V12. And then
20 48,044 member-HCC-year combinations under V22. Do 12:06:07
21 you see that?

22 A. Sorry, 41,681. I'm sorry. Could you -- I
23 was finding my place in the document. I apologize.
24 Could you repeat?

25 Q. No problem. To give you a high-level 12:06:30

1 summary of my question, you'll see that
2 Mr. Renjilian counted 55- -- approximately 55,000
3 member-HCC-years as the total amount of
4 member-HCC-years that were audited in RADV, yet you
5 have different figures in Paragraphs 39 and 40, and 12:06:54
6 I am trying to reconcile those two.

7 A. Mr. Renjilian's determination of support
8 was some combination of V12 and V22, and I have
9 separated them out.

10 If I understand his code correctly, he 12:07:15
11 considered a diagnosis instance to have been
12 supported by RADV if all of the HCCs corresponding
13 to that diagnosis instance that were reviewed by
14 RADV were found to be supported whether those HCCs
15 were V12 or HCC V22. 12:07:37

16 Q. And how is your analysis different?

17 A. I looked separately at whether HCC V12
18 were supported and HCC V22 were supported. He
19 combined the two in some way on a
20 diagnosis-instance-by-diagnosis-instance level. 12:08:00

21 Q. All right. Dr. Stark, I am presenting you
22 now with another exhibit. What number are we at?

23 MS. RAETHER: We are up to 1552.

24 (Discussion off the record.)

25 (Reporter marked Exhibit No. 1552 12:08:46

1 for identification.)

2 Q. BY MR. ABASCAL: Dr. Stark, I put
3 Mr. Renjilian's Figure 15 totals at the top of this
4 chart, and I put your totals for Paragraphs 39 and
5 40 on the bottom of the chart. 12:08:58

6 And I also took the percentage of RADV
7 support as reflected in your Paragraphs 39 and 40
8 and added the percentages there in the final
9 column, "Percent Supported."

10 I want to give you a minute to look at the 12:09:15
11 exhibit that I presented to you to make sure you're
12 comfortable that I put the figures down correctly
13 from your Paragraphs 39 and 40.

14 A. Okay. I think I see where the numbers
15 come from, yes. 12:10:05

16 Q. All right. Dr. Stark, as you can see,
17 Mr. Renjilian has a different total count than you
18 have. And I think you just provided an explanation
19 of why that difference is. And my question is:
20 Are you still confident that your calculations are 12:10:21
21 correct?

22 A. I believe my calculations are correct,
23 yes, calculated slightly differently.

24 Q. And so the difference is driven by the
25 methodology used for the count and doesn't reflect 12:10:36

1 any error, correct?

2 A. I can't vouch for Mr. Renjilian's work. I
3 am -- an error is always possible, but I believe
4 that my numbers are accurate, yes.

5 MR. ABASCAL: I am going to present you 12:10:58
6 another exhibit.

7 (Reporter marked Exhibit No. 1553
8 for identification.)

9 MS. RAETHER: This will be 1553.

10 Q. BY MR. ABASCAL: Dr. Stark, I am handing 12:11:28
11 you Exhibit 1553, which is a chart that I prepared
12 based on the data in your report.

13 Dr. Stark, what I did here in this chart
14 is I took the data from Table 2 and the data from
15 Table 39 -- sorry. Paragraph 39 of your report, 12:11:49
16 and I combined them into one chart.

17 Take a moment to look at Exhibit 1553 and
18 be comfortable that I put the numbers down
19 correctly.

20 A. Okay. I don't entirely understand. I see 12:14:44
21 where the numbers come from. I haven't verified
22 the combined percentage, but I think that's
23 approximately right.

24 What does -- I don't know what -- oh, one
25 plus zero. Okay. You are saying it is both. 12:15:07

1 Okay. I think I understand what you're
2 representing here for V12.

3 Q. All right. Dr. Stark, I can walk through
4 those last few columns.

5 What I did here is I took the data from 12:15:17
6 Table 2 and the data from your Paragraph 39, and I
7 put them on the chart, and I added two columns at
8 the end of the chart.

9 The first column is "Is the code on the
10 first interrogatory response (1=yes)." And then 12:15:32
11 the last column is "Does the code have payment
12 impact." And I put one for yes and zero for no,
13 which I realize may be confusing because you had op
14 3=1. So you had no payment impact being one in
15 your Table 2. So I switched that a bit to try to 12:15:59
16 be clear.

17 A. Can we agree that that means Mr. Renjilian
18 determined it didn't have payment impact?

19 Q. Correct. Yes. This is -- zero means
20 Mr. Renjilian determined it was no payment impact. 12:16:13
21 So that zero would mean it is actually on Opinion
22 39.

23 A. Understood.

24 Q. I apologize for the confusion. And one is
25 that the code does have payment impact, according 12:16:31

1 to Mr. Renjilian.

2 A. Okay.

3 Q. So Dr. Stark, you found that the overall

4 validation rate for diagnosis instances that had

5 their member-HCC-years reviewed in RADV for V12 to 12:16:48

6 be 88.8 percent, that is 3,619 out of 4,077,

7 correct?

8 A. I'm sorry. I'm trying to understand why

9 -- could you please repeat the question?

10 Q. Sure. Let's -- let me walk you through 12:17:26

11 it.

12 If you look at my third row, "Total from

13 Table 2," there were 4,077 diagnostic instances

14 that you had counted in Table 2 associated with

15 V12, right? 12:17:47

16 A. Yes, sir.

17 Q. And of those diagnostic instances, you

18 found 3,619 of them to be supported at the

19 member-HCC-year level, right?

20 A. Yes, sir. 12:18:00

21 Q. For a total support rate of 88.8 percent,

22 correct?

23 A. Yes, sir.

24 Q. All right. And you found for V12 in

25 Paragraph 39 that there were a total of 49,978 12:18:10

1 audited member-HCC-year combinations, of which 83.4
2 percent were supported, correct?

3 A. I'm sorry. I wasn't paying attention when
4 you read the numbers, but yes, the conclusion I
5 agree with. I believe that's what I state in that 12:18:35
6 Paragraph 39.

7 Q. Right. So Dr. Stark, you found that the
8 RADV validation rate percentage for diagnosis
9 instances that were on the first interrogatory
10 response to be actually higher than the overall 12:18:52
11 validation rate for member-HCC-years of all codes
12 for V12, correct?

13 A. Yes. Without regard to whether they have
14 financial impact or not, yes, sir.

15 Q. That's right. And I prepared the same 12:19:12
16 chart for the V22 --

17 A. I am ready for a break soon. I was
18 wondering --

19 Q. Let's do one now.

20 A. Should we take lunch now instead? 12:19:26

21 Q. Yeah, let's take lunch now.

22 A. Does that make sense?

23 Q. Yeah, whatever you want. I want to make
24 sure you're comfortable.

25 THE VIDEOGRAPHER: This marks the end of 12:19:33

1 media file labeled No. 2. We are off the record at
2 12:19 p.m.

3 (Whereupon the noon recess was
4 taken.)

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1 And those are which of the codes in the Garthwaite
2 final delete list are included in Opinion 2 or 3,
3 right?

4 A. Yes, sir. It's, in essence, the overlap
5 -- among other things that one can get from that 01:32:55
6 table is the overlap of diagnosis instances enter
7 -- diagnosis instances reflected that -- listed in
8 Dr. Garthwaite's final deletes list with those
9 diagnosis instances in FIR that Mr. Renjilian --
10 and again, I don't know whether the right way to 01:33:22
11 say it is didn't find, couldn't have financial
12 impact, or found it had financial impact.

13 Q. Right. But the point is you didn't do
14 work either for Mr. Renjilian or Dr. Garthwaite
15 that would allow you to be in a position to say one 01:33:37
16 way or another whether each of them -- either of
17 them -- okay. I am going to start that all over
18 because I put too much in there. I know you want
19 to be precise, so let's start with Renjilian.

20 You cannot, as you sit here today, opine 01:33:53
21 one way or the other whether Mr. Renjilian's
22 Opinion 3 is correct?

23 A. Well, again, I did not check the
24 underlying coding. I did check some of the
25 arithmetic, and I did check the underlying coding 01:34:07

1 against Dr. Garthwaite's opinion.

2 But I did no independent work to determine
3 whether either of them was correct in their
4 flagging of a particular diagnosis instance as
5 having financial impact or not. I just looked at 01:34:26
6 the concordance of the two.

7 Q. Perfect. And when you said "either of
8 them," you meant Mr. Renjilian and Dr. Garthwaite?

9 A. Yes, sir.

10 Q. All right. Great. 01:34:39

11 Let's go through your Table 1, then. I'd
12 like to go through the results on your Table 1,
13 Dr. Stark, and draw your attention to the number
14 that's approximately 28 million.

15 Dr. Stark, you found that there were -- or 01:34:59
16 you confirmed the count of the number of diagnostic
17 instances in the first interrogatory response to be
18 27,937,651, correct?

19 A. Yes, sir.

20 Q. Okay. In plain terms, there were 01:35:26
21 approximately 28 million diagnosis instances in
22 which a provider submitted a code and the United
23 chart review coder did not find that code, correct?

24 A. If by "code," we mean diagnosis code
25 associated with a particular date of service, yes, 01:35:46

1 sir.

2 Q. All right. And then you also counted
3 1,977,921 diagnostic instances in the Garthwaite
4 final delete list, right?

5 A. Yes, sir. 01:36:06

6 Q. And you verified these numbers, correct?

7 A. Yes, sir.

8 Q. In your Opinion II, which is right below
9 your Table 1, you state the following, "RADV found
10 support for those (inconsequential) diagnosis 01:36:26
11 instances at a much higher rate (approximately 96
12 percent) than the instances that have financial
13 impact if deleted."

14 What did you mean by "inconsequential
15 diagnosis instances"? 01:36:48

16 A. I meant according to that -- Mr. Renjilian
17 flagged them in his Opinion 3 as having no
18 financial impact if deleted.

19 Q. And they are inconsequential because they
20 could not have affected payment, correct? 01:37:00

21 A. They are inconsequential only in the sense
22 that Mr. Renjilian claimed that deleting them would
23 not -- would not have any financial consequences.

24 Q. Fair enough. I don't want to suggest that
25 you verified that work. So I like your caveat. 01:37:14

1 Let me restate it.

2 So they're inconsequential because,
3 according to Mr. Renjilian, they did not affect
4 payment, right?

5 A. Deleting them would not have changed the 01:37:27
6 payment, according to Mr. Renjilian.

7 MR. ABASCAL: Okay. Let's show you
8 another exhibit.

9 MS. RAETHER: I think this is 1555.
10 (Reporter marked Exhibit No. 1555 01:37:57
11 for identification.)

12 Q. BY MR. ABASCAL: Dr. Stark, I am showing
13 you Exhibit 1555, which are excerpts of your Table
14 1 with some additional arithmetic.

15 A. You subtracted the 65 -- 63,506 from 1.9 01:38:15
16 million-ish; is that correct?

17 Q. Yes, that is correct, Dr. Stark. I took
18 -- let me go through that in some detail.

19 You found in Table 1 that there were
20 certain diagnosis instances that were not on the 01:38:33
21 first interrogatory response but were on
22 Dr. Garthwaite's final delete list, right?

23 A. Yes, sir.

24 Q. You found 63,506 diagnosis instances that
25 were on the Garthwaite final delete list but not in 01:38:46

1 HCCs that RADV gives very little information about
2 regardless of how the RADV sample is drawn.

3 Q. Well, you raise a good point, Dr. Stark.

4 Why don't I take a step back. Let's go to the

5 first sentence of your opinion. You say "The RADV 02:53:13

6 samples of individual HCCs are very small." Do you

7 see that?

8 A. Yes, sir.

9 Q. All right. And then you then describe in

10 several pages how that small sample size affects 02:53:25

11 whether or not the RADV results can be extrapolated

12 to a larger population, right?

13 A. It -- no. It -- if the sample had been --

14 even if the sample had been drawn in a way that

15 would permit statistical extrapolation, the 02:53:48

16 uncertainty in that extrapolation would be very

17 large because the sample sizes are small.

18 Q. That's right. What I'd asked is you

19 described in several pages how that small sample

20 size makes it difficult to extrapolate without 02:54:08

21 considerable statistic bias?

22 A. No, sir. The bias issue is different.

23 This is about statistical uncertainty under a

24 hypothetical counterfactual assumption that the

25 sample had been drawn in a way that I understand it 02:54:26

1 was not drawn, but in a way that is easier to
2 analyze and that would lead to smaller
3 uncertainties.

4 So this is a -- even in sort of the most
5 optimistic view, the uncertainty in extrapolation 02:54:40
6 due to sampling variability would be large, which
7 is a separate issue from bias, which has to do with
8 the population from which the sample was drawn, the
9 particular design of the sample, the fact that this
10 was a stratified cluster sample of HCCs, not a 02:55:02
11 uniform sample of HCCs and so on. Other sources,
12 for example, that RADV is potentially, if not
13 actually, looking at different underlying charts.

14 Q. I am going to try something different.

15 A. Okay. 02:55:28

16 Q. Let's go to your Paragraph 54.

17 A. Paragraph 56?

18 Q. 54.

19 A. 54.

20 Q. Yeah. I want to draw your attention to 02:55:37

21 the middle of that paragraph. It says, "The raw
22 RADV support rate should not be extrapolated to the
23 Garthwaite Final Deletes List." Do you see that?

24 A. Yes.

25 Q. All right. Could you explain why? 02:55:55

1 A. There's a very long list of reasons. One
2 of them is that in sampling and extrapolation, we
3 draw -- meaning statistics draws a distinction
4 between the sampling frame and the population.

5 The sampling frame is the collection of 02:56:27
6 units from which the sample is drawn, and that
7 might or might not be identical to the population
8 to which one would like to extrapolate.

9 My understanding is that the sampling
10 frame for RADV was a particular collection of 02:56:43
11 contract years that did not comprise every contract
12 year that's relevant to the present matter.

13 So there's a mismatch between the sampling
14 frame and the population that already makes
15 extrapolation impossible without bias of unknown 02:57:09
16 magnitude.

17 Second issue is within each contract year
18 that RADV did examine, the way the sample was drawn
19 was not a simple random sample of HCCs, which is
20 what would be required for -- in order to 02:57:39

21 extrapolate from a sample of HCCs to the contract
22 year from which those HCCs were selected, those
23 member-HCC-years were selected, for the raw rate to
24 be an unbiased estimate, that sample needs to have
25 been drawn in such a way that every HCC-member-year 02:58:06

1 in that contract was equally likely to be selected.

2 That is not how the sample was drawn. The

3 sample was drawn -- I understand the way that RADV

4 works in general -- although I understand there's

5 been some variation from year to year. But I

02:58:25

6 understand in general the way RADV works is by

7 sampling members, not sampling HCCs. Because it is

8 sampling members and then looking at all of the

9 HCCs that go with a given member. Instead of being

10 an equal probability sample, it is a cluster

02:58:40

11 sample. It doesn't sample all the subsets with

12 equal probability.

13 And secondly, even the members are not

14 drawn with equal probabilities -- sorry. The

15 design of the sample, even at the member level --

02:58:56

16 at the level of members is a stratified sample, I

17 understand that it involves first dividing payments

18 -- dividing members into three groups based on the

19 amount that was paid for that member in that year.

20 So terciles of payment.

02:59:20

21 So all of those differences need to be

22 taken into account in extrapolating the sample rate

23 for the RADV sample from a single contract year to

24 that entire contract year. But then the number of

25 the sampling rates, meaning the fraction of the

02:59:52

1 population that each sample represents, I
2 understand may vary from contract to contract that
3 RADV audits. So weights need to be used to adjust
4 for those differences in sampling rates.

5 And beyond that, there's no statistical 03:00:13
6 justification for extrapolating beyond the
7 particular contract years that RADV looked at.

8 So there are a large list of reasons that
9 the raw rate of support has unknown bias in
10 addition to statistical variability if it's being 03:00:38
11 used as an estimate of the overall rate of support
12 for HCCs corresponding to diagnosis instances
13 identified on the Garthwaite final deletes list.

14 Q. Have you completed your answer, Doctor?

15 A. Yes, I think so. 03:01:02

16 Q. All right. Great. I may have to ask you
17 to repeat it again because I am going to change --
18 I am going to change -- it's torture, isn't it --
19 the question slightly.

20 You said in Paragraph 54 "the raw RADV 03:01:17
21 support rate should not be extrapolated to the
22 Garthwaite Final Deletes List."

23 Now I want to be a little bit more
24 specific. In Paragraph 39 you concluded, or you
25 found -- you counted, you counted that RADV found 03:01:33

1 support for 264 of the 464 member-HCC-year V12

2 combinations. By inference, they did not find

3 support for 200 of them, correct?

4 A. Yes, sir.

5 Q. Okay. Would it be appropriate for any of 03:01:55

6 the parties in this case to extrapolate those RADV

7 findings, the support or lack of support rate, to

8 the full Garthwaite final deletes list?

9 A. No, it would not. This is a statement

10 about the RADV sample itself. It's not a statement 03:02:12

11 about the populations from which the RADV sample

12 was drawn.

13 Q. All right. In your Table 2 you found that

14 codes/diagnosis instance with payment impact were

15 supported at 61.3 percent for all years for V12, 03:02:44

16 right?

17 A. In the intersection of the RADV sample --

18 sorry. The 61.3 percent you're pointing out the

19 V12 --

20 Q. Yes. 03:03:05

21 A. -- row?

22 Q. Yes.

23 A. And we're looking at those diagnosis

24 instances that were not flagged by Mr. Renjilian as

25 having -- 03:03:17

1 Q. Right.

2 A. -- financial impact if deleted. Yes, that
3 61.3 percent applies to sort of the intersection of
4 FIR Renjilian's opinion 3=0 and RADV. It doesn't
5 apply more broadly than that. I have no basis for
6 extrapolating that to any larger group.

03:03:37

7 Q. That was going to be my question. It
8 would be inappropriate to extrapolate the findings
9 in Table 2 to any broader population, correct?

10 A. There's no statistical basis for
11 extrapolating it any further.

03:03:53

12 I might need to think about it more. But
13 given that if I knew in detail the design of the
14 RADV sample, it might be possible to take a
15 weighted combination of the underlying data and
16 come up with some percentage that could be
17 extrapolated to the particular contract years that
18 RADV sampled, but it would not be the raw rate, and
19 it would not apply beyond the frame from which RADV
20 drew its sample, meaning contract years that were
21 not audited by RADV.

03:04:25

03:04:50

22 Q. I understand, but you haven't done that
23 work?

24 A. No, I have not. I don't know the RADV
25 design in detail, and it would require -- yes, it

03:05:02

1 would -- that's work I have not done.

2 Q. And Dr. Garthwaite did not do that work in
3 creating his report?

4 A. I don't believe so, no.

5 Q. And neither did Mr. Renjilian? 03:05:12

6 A. No, sir.

7 Q. So to your knowledge, no one's done that
8 work, correct?

9 A. To my knowledge, nobody's done that work.

10 Q. To -- well, let's go to -- let's switch 03:05:24
11 gears a little bit.

12 A. Time for another five-minute break?

13 MR. ABASCAL: Yeah, sure.

14 (Discussion off the record.)

15 THE VIDEOGRAPHER: This marks -- 03:05:37

16 (Discussion off the record.)

17 MS. GLOVER: Real quick before we go off

18 the record, I didn't state an objection earlier

19 that I'd like to state. For Exhibit 1557, I object

20 to the use of this exhibit and questions about it 03:05:51
21 for lack of foundation.

22 MR. ABASCAL: Okay. Fair. Fair enough.

23 THE VIDEOGRAPHER: Off the record?

24 MR. ABASCAL: Yes.

25 THE VIDEOGRAPHER: Okay. This marks the 03:06:01

1 final deletes that would be supported based on the
2 data available here in this case, correct?

3 MS. GLOVER: Objection; form.

4 THE WITNESS: When you say "supported," do
5 you mean had RADV examined every member-HCC-year in 03:53:29
6 every contract?

7 Q. BY MR. ABASCAL: Yes.

8 A. Yes. We did -- there is not appropriate
9 data for doing that. Because there's only data on
10 a subset of contracts and a subset of years and -- 03:53:46
11 there's no way to extrapolate that without sampling
12 from the whole universe.

13 And then in doing that, the design of the
14 sample would need to be taken into account. So in
15 detail I would need to understand how RADV draws 03:54:08
16 its sample and take that into account in doing the
17 extrapolations of each contract year separately and
18 then amalgamating those to get an overall estimate
19 of the rate.

20 Sorry. I'm answering a different 03:54:27
21 question. I apologize. Your question was
22 specifically about the final deletes list. It was
23 not about all contract years or...

24 I agree that there is not -- I'm not aware
25 of any data that speaks to that that would allow 03:54:45

1 one to estimate what fraction of the diagnosis --
2 sorry. What fraction of the diagnosis events in
3 the final deletes list map to an HCC-member-year
4 that RADV would have found support for had it
5 examined every member-HCC-year that intersects
6 Garthwaite's final deletes list.

03:55:05

7 Q. I am going to try to restate that.

8 A. You want me to say it again?

9 Q. No, I am going to try to restate it.

10 A. Okay.

03:55:46

11 Q. Based on the data that you have available
12 and that you have reviewed in your work on this
13 case, there is not a way to reliably estimate the
14 fraction of diagnosis instances in the final
15 deletes -- the Garthwaite final deletes list that
16 map to an HCC-member-year that would be supported
17 by RADV auditors, right?

03:56:03

18 A. I agree with that.

19 Q. And similarly, there's not a way to
20 estimate the fraction that would not be supported,
21 correct?

03:56:32

22 A. I agree with that, too.

23 Q. All right.

24 A. If there were, there would be a way to do
25 it the first time.

03:56:44

1 Q. One minus.

2 In Paragraph 84 of your report, Dr. Stark,
3 you say at the bottom, "However, it is impossible
4 to know how many additional HCC instances would
5 have been supported by the unretrieved charts." 03:57:11
6 What do you mean by that?

7 A. Without retrieving the charts, one doesn't
8 know whether they would have shown support for that
9 member for that HCC for that year.

10 And without retrieving at least a random 03:57:39
11 sample of those charts, there's no reliable way to
12 estimate statistically how many additional
13 instances would have found support.

14 Q. Dr. Stark, you mentioned "response
15 schedule" in your report. Can you explain what is 03:58:04
16 a response schedule?

17 A. "Response schedule" is a term of art,
18 describes a mathematical relationship that, in
19 essence, is how nature generated the data in
20 question. 03:58:26

21 So in order to use a fitted function to
22 make causal inference as a function fitted to data
23 to make a causal inference about what would have
24 happened had there been an intervention and
25 something changed, the relationship needs to be a 03:58:49

1 DEPOSITION OFFICER'S CERTIFICATE
(Civ.Proc. § 2025.520(e))

2 STATE OF CALIFORNIA)
3) ss.
COUNTY OF SAN FRANCISCO)

5 I, Balinda Dunlap, hereby
6 certify:

7 I am the deposition officer that
8 stenographically recorded the testimony in the
9 foregoing deposition.

10 Written notice pursuant to Code of Civil
11 Procedure, Section 2025.520(a), having been sent,
12 the deponent took the following action within the
13 allotted period with respect to the transcript of
14 the deposition:

15 () In person, at the office of the
16 deposition officer, made the changes set forth on
17 the original of the transcript. (The parties
18 attending the deposition have been notified of said
19 changes.)

20 () Approved the transcript by signing
21 it.

22 () Refused to approve the transcript by
23 not signing it.

24 () By means of a signed letter, made the
25 changes and approved or refused to approve the

1 transcript as set forth therein. (Said letter has
2 been attached to the original transcript and copies
3 thereof mailed to all parties attending the
4 deposition.)

5 () Failed to approve the transcript
6 within the allotted time period.

7 Dated _____.

8

9

10 *Balinda Dunlap* _

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1 -----
 E R R A T A
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4	PAGE	LINE	CHANGE FROM	CHANGE TO	REASON
5	12	16		and Constantine Cannon	Incomplete Answer
6	22	08	Nothing I can think of.	Not that I can think of.	Transcript Error
7	23	18	adjusted.	adjusting.	Accuracy
8	30	07	probability distribution. If	probability distribution if	Accuracy
9	30	08	is true, we	is true. We	Accuracy
10	30	19	gets	gives	Accuracy
11	37	11	member-HCCs 2011-2015.	member-HCCs 2011-2013.	Transcript Error
12	38	10	writes "Member-HCCs" at	writes "Members plus-HCCs	Transcript Error
13	38	20	member-HCC-years	member plus-HCC-plus years	Transcript Error
14	40	06	I think their chart	I think they're charts	Accuracy
15	41	13	materials, some error rate.	materials has some error rate.	Accuracy
16	46	05	additional annotations,	additional annotations--	Clarity
17	46	07	or his team which included flags, so values	or his team-- which included flags: values	Clarity
18	46	08	were true or false	were either true or false	Transcript Error
19	47	04	not diagnose	not examine	Clarity
20	47	05	determine if they were reported.	determine whether they were reported.	Transcript Error
21	48	04	instances that was	instances that were	Clarity
22	55	13	that were multiplies	that were multiples	Transcript Error
23	56	10-11	Well, again, missed in chart review, or chart review didn't find them.	Well, again, "missed in chart review," versus "chart review didn't find them."	Clarity
24	62	19	than some more abstract notion	than some more abstract or platonic notion of what support might be --	Transcript Error

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1 -----
 E R R A T A
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3

4	PAGE	LINE	CHANGE FROM	CHANGE TO	REASON
5	62	22	supported.	"supported."	Clarity
6	68	04	for the year that only a	for the year and that only a	Clarity
7	70	16	found possibly	found--possibly	Clarity
8	70	17	instances, support	instances--support	Clarity
9	71	03	did not find, it	did not find. It	Clarity
10	81	10	diagnosis instance--corresponding	diagnosis--corresponding	Transcript Error
11	84	03	Mr. Renjilian's Figure 15 totals	Mr. Renjilian's totals from Figure 15	Transcript Error
12	86	22	39	3	Transcript Error
13	97	10	The map	That map	Transcript Error
14	103	11	it is didn't	it is, "didn't	Clarity
15	103	11	find, couldn't have financial	find couldn't have financial	Clarity
16	103	12	impact, or found it had financial impact.	impact," or "found it had financial impact."	Clarity
17	108	18	percent if FIR would have been	percent if your arithmetic is correct.	Transcript Error
18	110	02	If you go to Paragraph 21.	If you go to your Paragraph 21.	Transcript Error
19	110	09	report?	report, not Dr. Garthwaite's report	Transcript Error
20	110	11	I thought you were talking about	I was looking at	Transcript Error
21	117	03	"missed in chart review."	words "missed in chart review,"	Clarity
22	117	04	When chart review didn't find them,	but "when chart review didn't find them"	Clarity
23	121	02	HCCs annual HCCs for members --	HCCs-- annual HCCs for members --	Clarity
24	121	15	HCC validation rates.	HCC-year validation rates.	Transcript Error

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4	PAGE	LINE	CHANGE FROM	CHANGE TO	REASON
5	123	11	hierarchy.	in the hierarchy.	Transcript Error
6	130	19	then maps to were not.	then maps to or not.	Transcript Error
7	131	07	supported or not, if	supported or not... if	Clarity
8	131	08	pulling opinions, things that	pulling opinions... things that	Clarity
9	131	10	member-HCC-year combination -- that	member-HCC-year combination that	Clarity
10	131	11	examined by RADV, we	was examined by RADV. We	Clarity
11	131	15	to Opinion 1	to Opinion 3	Transcript Error
12	133	9	Fisher's exact test, which imagines	Fisher's exact test, which asks,	Clarity
13	133	10	if the labeling as	"if the labeling as	Clarity
14	133	12	were as if a random label	were a random labelling	Clarity
15	133	13-14	see this difference.	to see this difference?"	Clarity
16	135	8	saying, is that	saying, "is that	Clarity
17	135	14	support or not.	support or not?"	Clarity
18	141	11	Other sources,	There are other sources of bias,	Clarity
19	143	9	given member. Instead	given member, instead	Transcript Error
20	143	16	stratified sample, I	stratified sample. I	Transcript Error
21					
22					
23					
24					



1 -----
 E R R A T A
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3

4	PAGE	LINE	CHANGE FROM	CHANGE TO	REASON
5	<u>149</u>	<u>19</u>	<u>Yes. Without considerable bias, yes.</u>	<u>Yes. Without unknown bias, yes.</u>	<u>Transcript Error</u>
6	<u>150</u>	<u>20</u>	<u>Tab l</u>	<u>Tab i</u>	<u>Correction</u>
7	<u>158</u>	<u>21</u>	<u>as I know that these estimates are basically</u>	<u>as I know. These estimates are basically</u>	<u>Clarity</u>
8	<u>163</u>	<u>15</u>	<u>today, I understand</u>	<u>today. I understand</u>	<u>Transcript Error</u>
9	<u>167</u>	<u>03</u>	<u>you say at the bottom, "However, it is impossible</u>	<u>you say at the bottom, "it is impossible</u>	<u>Transcript Error</u>
10	<u>167</u>	<u>22</u>	<u>make causal inference as a function fitted to data</u>	<u>make causal inference -- use a function fitted to data</u>	<u>Transcript Error</u>
11	<u>168</u>	<u>14</u>	<u>So it has some resting weight. If I now,</u>	<u>So it has some resting length. If I now,</u>	<u>Transcript Error</u>
12	<u>171</u>	<u>08</u>	<u>random number generator in STATA, the Mersenne</u>	<u>random number generator, the Mersenne</u>	<u>Transcript Error</u>
13	<u>175</u>	<u>17</u>	<u>But we did have examples where it broke</u>	<u>But we didn't have examples where it broke</u>	<u>Transcript Error</u>
14	<u>176</u>	<u>13</u>	<u>generator that you did, correct?</u>	<u>generator that you developed, correct?</u>	<u>Transcript Error</u>
15	<u>179</u>	<u>24</u>	<u>Jupiter notebook</u>	<u>Jupyter notebook</u>	<u>Wrong Spelling</u>
16	<u>180</u>	<u>11</u>	<u>to correct. You said 1597. You mean 1557?</u>	<u>to correct. You said Exhibit 1597. You mean 1557?</u>	<u>Transcript Error</u>
17	<u>181</u>	<u>25</u>	<u>and Human Services (HSS)</u>	<u>and Human Services (HHS),</u>	<u>Transcript Error</u>
18	<u>182</u>	<u>09</u>	<u>Before I jump into this particular</u>	<u>Before I jump into this thick</u>	<u>Transcript Error</u>
19	<u>183</u>	<u>02</u>	<u>particular abandon</u>	<u>particular abandoned</u>	<u>Transcript Error</u>
20	<u>183</u>	<u>05</u>	<u>is in [0.1].</u>	<u>is in [0,1].</u>	<u>Transcript Error</u>
21	<u>188</u>	<u>14</u>	<u>other things, SAS, at least Version 9.2,</u>	<u>other things, the algorithm SAS, at least Version 9.2,</u>	<u>Clarity</u>
22	<u>189</u>	<u>06</u>	<u>specific paragraph you drew my attention to.</u>	<u>paragraph you drew my attention to.</u>	<u>Transcript Error</u>
23	<u>191</u>	<u>11</u>	<u>and this comes up in several cases,</u>	<u>and this comes up in several places,</u>	<u>Transcript Error</u>
24	_____	_____	_____	_____	_____

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 11 OF 14
EXHIBITS D-142 THROUGH D-160
PAGES 3590 THROUGH 3973**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT D-142

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE CENTRAL DISTRICT OF CALIFORNIA

3 - - - - -
4 UNITED STATES OF AMERICA,

5 Plaintiff,

6 vs.

7 UNITEDHEALTH GROUP, INC.,
8 et al,

9 Defendants.
10 - - - - -

Civil Action No.

2:16-cv-08697-

MWF-SS

11 Videotaped Deposition of Marilyn B. Tavenner

12 Washington, D.C.

13 Wednesday, February 28, 2018

14 9:06 a.m.

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21
22
23
24 Reported by: Laurie Donovan, RPR, CRR, CSR

25 Job No: 137792

Page 27

1 A I don't know what it's titled, so I 9:19AM
2 can't go there. 9:19AM

3 Q Based on the review of those articles, 9:19AM
4 did you form any opinions about whether this 9:19AM
5 lawsuit has merit? 9:19AM

6 A I did not. 9:19AM

7 Q So let's switch gears a little bit. 9:19AM
8 Can you give me a general background, 9:19AM
9 your education? 9:19AM

10 A Sure. I started -- my first career was 9:19AM
11 in nursing. I went to a three-year diploma school 9:19AM
12 of nursing in Roanoke, Virginia and worked as a 9:19AM
13 nurse for several years while I went back and 9:20AM
14 continued my education, getting a degree in 9:20AM
15 nursing by 1983. 9:20AM

16 Q Okay. 9:20AM

17 A And continued working in nursing and 9:20AM
18 nursing management until the early '90s, by which 9:20AM
19 time I had finished graduate school and moved into 9:20AM
20 administration, hospital administration. 9:20AM

21 Most of my career was with the Hospital 9:20AM
22 Corporation of America, about 25 years' worth, and 9:20AM
23 then I went into public service, working for 9:20AM
24 Governor Tim Kaine. I then moved into federal 9:20AM
25 service, working for President Obama. 9:20AM

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1 Q And can you tell us, when did you go 9:20AM
2 into federal service? 9:20AM

3 A February of 2010. 9:20AM

4 Q And was that, was that at CMS? 9:20AM

5 A It was. 9:20AM

6 Q Okay, and what was your title at CMS at 9:20AM
7 that point? 9:20AM

8 A At that point it was chief deputy 9:20AM
9 administrator. 9:20AM

10 Q And how long were you the chief deputy 9:21AM
11 administrator? 9:21AM

12 A On and off from February of 2010 until 9:21AM
13 May of 2013. 9:21AM

14 Q Okay. 9:21AM

15 A I had several titles during that time. 9:21AM

16 Q What titles did you have? 9:21AM

17 A I had that title, chief deputy 9:21AM
18 administrator and chief operating officer, and 9:21AM
19 then I also was acting administrator at different 9:21AM
20 points, prior to Don Berwick coming on board and 9:21AM
21 after Don Berwick left -- 9:21AM

22 Q Okay. 9:21AM

23 A -- until I was confirmed in May of 2013. 9:21AM

24 Q And you were confirmed as administrator 9:21AM
25 in May of 2013, and how long did you serve as the 9:21AM

1 administrator?

9:21AM

2 A Until February of 2015.

9:21AM

3 Q Okay, and can you describe your

9:21AM

4 responsibilities as the administrator of CMS?

9:21AM

5 A Well, CMS is a large organization that

9:21AM

6 is located both in -- well, has regions throughout

9:21AM

7 the country, but chief headquarters are in

9:21AM

8 Baltimore, and there's also an office in

9:21AM

9 Washington, D.C.

9:22AM

10 So your first responsibility is to run

9:22AM

11 the organization, so everything from hiring,

9:22AM

12 firing, staffing sort of thing, and second would

9:22AM

13 be you obviously worked -- it was a political

9:22AM

14 position, so you worked at the pleasure of the

9:22AM

15 President and for the Secretary of Health, so a

9:22AM

16 big part of your job was working with the White

9:22AM

17 House and HHS and also with members of Congress.

9:22AM

18 Q Okay.

9:22AM

19 A And then probably the third part was

9:22AM

20 taking the laws that were enacted by Congress and

9:22AM

21 converting those into regulation, policy, kind of

9:22AM

22 taking what was a statute and making it workable

9:22AM

23 for those in the health field.

9:22AM

24 Q Okay. So is it fair to say that you

9:22AM

25 oversaw the development of policies that were

9:22AM

Page 30

1 adopted by CMS while you were the administrator? 9:22AM

2 MR. FREEBORNE: Objection to form. 9:22AM

3 You can answer. 9:22AM

4 THE WITNESS: I think it's fair to 9:23AM

5 say that I oversaw policy development, but I 9:23AM

6 was not involved in the day-to-day policy 9:23AM

7 development. The agency is much too large to 9:23AM

8 have a hands-on CEO, if you will. 9:23AM

9 BY MR. SCHINDLER: 9:23AM

10 Q Understood, but to the extent that a 9:23AM

11 policy was developed within the agency before it 9:23AM

12 was ultimately adopted, is it something that you 9:23AM

13 would have to review and approve before it became 9:23AM

14 agency policy? 9:23AM

15 A If it was a formal policy, that would be 9:23AM

16 yes, and then it would go to the Secretary. There 9:23AM

17 was quite an elaborate approval process. 9:23AM

18 Q And what about regulations that were 9:23AM

19 issued by CMS? 9:23AM

20 A For regulations, again if it was a 9:23AM

21 formal regulation, usually that would go to the -- 9:23AM

22 come to me ultimately after it was developed and 9:23AM

23 went through several departments inside CMS, and 9:23AM

24 then I would sign it, and ultimately the Secretary 9:23AM

25 would sign it before it became a regulation, 9:24AM

Page 31

1 proposed regulation that would then go into the 9:24AM
2 Federal Register for consumers to read and give 9:24AM
3 input. 9:24AM

4 Q Got it, and what about rules? To the 9:24AM
5 extent that CMS would issue proposed rules or 9:24AM
6 actual rules, again understanding that you had 9:24AM
7 people below you who developed them, would they 9:24AM
8 come by you before they would actually be 9:24AM
9 published or issued? 9:24AM

10 A Not always. Not for rules and 9:24AM
11 sub-regulatory guidance. It would be wrong for me 9:24AM
12 to say that I saw all of those. That would not -- 9:24AM
13 it didn't have quite the formal process. 9:24AM

14 Q Could rules then be issued without your 9:24AM
15 approval or without your knowledge? 9:24AM

16 MR. FREEBORNE: Objection to form. 9:24AM
17 You can answer. 9:24AM

18 THE WITNESS: Again, it would 9:24AM
19 probably be more guidance, not rules. 9:24AM

20 BY MR. SCHINDLER: 9:24AM

21 Q Okay. 9:24AM

22 A I'm really talking some pretty technical 9:24AM
23 terms. 9:24AM

24 Q Understood, and you're going to have to 9:24AM
25 help me with some of those, because you know it 9:24AM

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1 better than I do, but guidance is separate from 9:24AM
2 rules; is that a fair -- 9:25AM

3 MR. FREEBORNE: Objection to form. 9:25AM
4 You can answer. 9:25AM

5 THE WITNESS: So you would propose 9:25AM
6 regulations and they would go through a 9:25AM
7 public process, and then those regulations 9:25AM
8 would be modified, adopted or not adopted. 9:25AM
9 Once the regulations were out and in the 9:25AM
10 public domain, there were usually guidance -- 9:25AM
11 probably "guidance" is a better word than 9:25AM
12 rules -- that went out to help people with 9:25AM
13 their interpretation. 9:25AM

14 BY MR. SCHINDLER: 9:25AM

15 Q But there was something called "rules" 9:25AM
16 as well, right, in the course of your time as 9:25AM
17 administrator of CMS -- 9:25AM

18 A So it's been four years since I was at 9:25AM
19 CMS. If we're going to start to define rules and 9:25AM
20 guidance and policy, I'll probably have to say I 9:25AM
21 can't remember all of that. 9:25AM

22 Q Let me just ask you this: Were there 9:25AM
23 instances as you sit here where you recall rules 9:25AM
24 being issued by CMS during the time that you were 9:25AM
25 administrator? 9:25AM

1 A If by "rules" you mean "regulations"? 9:25AM
2 If you're calling rules and regulations the same 9:25AM
3 thing? 9:25AM

4 Q Well, I'm, I'm asking if you draw any 9:25AM
5 distinction in your mind whether there were 9:26AM
6 instances where there were rules as opposed to 9:26AM
7 regulations. 9:26AM

8 MR. FREEBORNE: Objection to form. 9:26AM
9 You can answer. 9:26AM

10 THE WITNESS: I don't, I don't 9:26AM
11 remember enough detail to talk about the 9:26AM
12 difference. I would say that I was 9:26AM
13 responsible for signing and approving 9:26AM
14 regulations. 9:26AM

15 BY MR. SCHINDLER: 9:26AM

16 Q Okay. 9:26AM

17 A And I'd have to leave it at that level. 9:26AM

18 Q Let me switch gears with you for a 9:26AM
19 moment. 9:26AM

20 Are you familiar with the concept of a 9:26AM
21 "litigation hold"? Have you heard that expression 9:26AM
22 before? Do you know what that means? 9:26AM

23 A I've heard the term "litigation hold" in 9:26AM
24 various -- you'd have to give me the definition 9:26AM
25 you're talking about. 9:26AM

strengthen existing regulations related to the accuracy of risk adjustment data by amending section 422.310 on risk adjustment data validation."

Do you see that?

A I do.

Q Okay, and if you continue reading and go up to the third column on that page, at the top of that third column you'll get to the first sentence that begins, "Under our proposal, medical record reviews conducted by an MA organization cannot be designed only to identify diagnoses that would trigger additional payments by CMS to the MA organization; and medical record review methodologies must be designed to identify errors in diagnoses submitted to CMS as risk adjustment data, regardless of whether the data errors would result in positive or negative payment adjustments."

Do you see that?

A I do.

Q Okay, and this was a proposed rule that you signed off on, correct?

A Correct.

Q And do you recall that, in fact, this

Page 110

1 rule was never finalized? 11:15AM

2 A I do. 11:15AM

3 Q Now, do you recall that in April of 11:15AM

4 2014, you were approached by Larry Renfro of 11:15AM

5 United to discuss whether or not MA plans were 11:15AM

6 required to conduct reviews that would look not 11:15AM

7 only for diagnosis codes to add but for diagnosis 11:15AM

8 codes to be deleted? 11:16AM

9 MR. FREEBORNE: Objection to form. 11:16AM

10 THE WITNESS: I remember being 11:16AM

11 approached by Larry to discuss a concern he 11:16AM

12 had about the process that involved review of 11:16AM

13 charts. 11:16AM

14 BY MR. SCHINDLER: 11:16AM

15 Q And tell me what you recall about that. 11:16AM

16 A That he was asking me about something 11:16AM

17 that was in the proposed rule that related to 11:16AM

18 chart review, and giving me his ideas on what he 11:16AM

19 thought it meant, and I listened to him, and then 11:16AM

20 I referred him to our staff. 11:16AM

21 Q Do you recall telling Mr. Renfro that 11:16AM

22 because this proposed rule was not yet in effect, 11:16AM

23 that there was no requirement for United to go 11:17AM

24 back to look at charts in order to look for codes 11:17AM

25 to delete? 11:17AM

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1 A No. 11:17AM

2 Q Okay. Do you recall telling him that 11:17AM

3 two-way looks were not required because this 11:17AM

4 proposed rule was not yet in effect? 11:17AM

5 A No. I recall sending him to the staff 11:17AM

6 to ask that question. 11:17AM

7 Q Okay. Well, as you sit here, do you 11:17AM

8 recall whether he, in fact, went to the staff or 11:17AM

9 whether the staff met with Mr. Renfro or anybody 11:17AM

10 at United to discuss this question? 11:17AM

11 MR. FREEBORNE: Objection to form. 11:17AM

12 You can answer. 11:17AM

13 THE WITNESS: So I recall that I 11:18AM

14 recommended that he meet with the staff and 11:18AM

15 ask the staff to make that happen. 11:18AM

16 BY MR. SCHINDLER: 11:18AM

17 Q That you asked the staff to meet with 11:18AM

18 him, okay, and when you asked the staff to make 11:18AM

19 that happen, did they follow your instructions? 11:18AM

20 A I don't know the answer to that, because 11:18AM

21 I handed it off to them to manage, which is the 11:18AM

22 way I handled everything in the agency. 11:18AM

23 Q Okay. 11:18AM

24 (Exhibit 1007 was marked for 11:18AM

25 identification.) 11:18AM

CERTIFICATE OF SHORTHAND REPORTER -- NOTARY PUBLIC

I, Laurie Donovan, Registered Professional Reporter, Certified Realtime Reporter, the officer before whom the foregoing deposition was taken, do hereby certify that the foregoing transcript is a true and correct record of the testimony given; that said testimony was taken by me stenographically and thereafter reduced to typewriting under my supervision; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 1st day of March, 2018.

My commission expires: March 14th, 2021

DATED: MARCH 2, 2018

LAURIE DONOVAN
NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA

EXHIBIT D-143

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

Videotaped Deposition of
GIFT TEE
Given Remotely
Wednesday, November 30, 2022

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com
REMOTELY APPEARING

1 whether anyone collected any handwritten notes from
2 you; is that right?

3 A. Correct.

4 Q. Okay. Do you maintain like a file of
5 these hard copy notes that you keep, or is there a
6 central sort of repository where you store them?

7 A. I wish I were that organized. I just go
8 through notebooks, and then over time, I lose the
9 notebooks.

10 Q. Okay. Great.

11 So we can shift gears a little bit, and I
12 just sort of want to start with a little bit of
13 background on your job history and your roles that
14 you've held at CMS.

15 I understand you currently work for the
16 Centers for Medicare and Medicaid Services; is that
17 correct?

18 A. Yes.

19 Q. Okay. If I call it "CMS," will you
20 understand that I mean the Centers for Medicare and
21 Medicaid Services?

22 A. Yes.

23 Q. Great. Is CMS within -- is CMS a part of
24 the Department of Health and Human Services?

25 A. Yes.

1 Q. Okay. And if I call that "HHS," you'll
2 understand I mean the Department of Health and Human
3 Services?

4 A. Yes.

5 Q. So let's turn back to AgileLaw, please.

6 MR. RYDBERG: I'm going to mark the next
7 document, which I believe should be
8 Exhibit 1426.

9 Nayan, that's Tab 1.

10 (Exhibit 1426 was marked for identification.)

11 MR. RYDBERG: For the record, this
12 document is Bates-stamped USBP006995062.

13 BY MR. RYDBERG:

14 Q. So you know, the Bates stamp is -- is that
15 number in the bottom right-hand corner. It's just a
16 sort of consecutive pagination that lawyers use in
17 litigation.

18 Do you see Exhibit 1426 up on your screen?

19 A. Yes.

20 Q. Okay. Great. Do you recognize this
21 document?

22 A. Yes.

23 Q. It's a copy of your résumé, right?

24 A. From days gone by, yes.

25 Q. That was my next question. The metadata

1 for this document suggests it was created in or
2 around 2014. Does that seem correct to you?

3 A. Yes.

4 Q. Okay. So obviously it's been a few years.
5 But sitting here today, is it an accurate summation
6 of your professional education -- excuse me, of your
7 education and professional history through 2014?

8 A. From 2014, you said?

9 Q. Yeah. So as of 2014, is this sort of an
10 accurate summation of your educational background and
11 your professional experience?

12 A. Yes.

13 Q. And you actually drafted this document; is
14 that right?

15 A. Yes.

16 Q. Let's start with your education. If you
17 turn to page 4 of the résumé, which is the last page,
18 there's a section called "Education." Do you see
19 that?

20 A. Yes.

21 Q. So it looks like you earned a bachelor of
22 science degree in biology from SUNY Albany in May --
23 May 2000; is that right?

24 A. Yes.

25 Q. And then you also earned an MPH, with a

1 concentration in health policy and management.

2 That's again from SUNY Albany, in December 2002; is
3 that right?

4 A. Yes.

5 Q. Okay. Are there any other degrees or
6 certificates that you've earned that aren't listed on
7 this?

8 A. No.

9 Q. Okay. Let's turn, then, to your
10 professional history.

11 You currently work at CMS. What is your
12 current job title at CMS?

13 A. I am currently the director of the
14 division of practitioner services in the Center for
15 Medicare.

16 Q. The division of practitioner services,
17 okay. And what is the division of practitioner
18 services responsible for?

19 A. We are responsible for the development of
20 policy, implementation of what is known as the
21 physician fee schedule, how Medicare pays physicians
22 and nonphysician practitioners.

23 Q. And so that would relate, then, to Part A
24 of the Medicare program; is that correct?

25 A. No. That would relate to Part B,

1 professional services.

2 Q. Part B. Okay. Thank you. That's a good
3 correction.

4 It does not, however, relate to Part C,
5 Medicare Advantage; is that correct?

6 A. Correct.

7 Q. Okay. And how long have you held that
8 role?

9 A. Four years and 55 days, just about.

10 Q. Extremely precise. I appreciate that.

11 So that would be, if my math is correct,
12 October 1st, 2018?

13 A. You know what? Maybe I'm not as precise.
14 Whatever today's date is, back up to September or
15 August, end of August, and -- just say four years.

16 Q. Okay, okay. Sounds good. So late summer,
17 early fall 2018, you take on this role?

18 A. Uh-huh.

19 Q. Okay. And so as the division director,
20 what exactly are your responsibilities?

21 A. Fall guy, leader, cheerleader, analyst,
22 all of those things. But to boil it down, just
23 responsible for managing the work of approximately
24 17 analysts to develop, implement all the different
25 policies that fall into the professional Part B

1 policy space for -- for physicians and nonphysician
2 practitioners.

3 Q. So you have 17 direct reports in that
4 role?

5 A. If I'm counting correctly, yes.

6 Q. Okay. I won't hold you to it.

7 So before that role, were you the director
8 of the department of -- were you the director of the
9 division of encounter data and risk adjustment
10 operations?

11 A. Yes.

12 Q. Okay. And if we turn back to page 1 of
13 your résumé, it lists you as -- January 2013, says
14 "to present," but we'll understand that means to
15 2018 -- as a supervisory health insurance specialist.
16 And then underneath it, it has your I guess
17 functional titles. Is that a fair description?

18 A. Yes.

19 Q. Okay. So you were first the deputy
20 director of the division of encounter data and risk
21 adjustment operations from January 2013 to
22 April 2014; is that right?

23 A. Yes.

24 Q. Okay. And then you assumed the director
25 position, first as acting director, and then I assume

1 no longer acting, in April 2014; is that right?

2 A. Yes.

3 Q. Okay. When you were the deputy director,
4 who did you report to at that time?

5 A. Greg McGuigan.

6 Q. And is that spelled -- how do you spell
7 that?

8 A. M-c-G-u-i-g-a-n, McGuigan. Yes.

9 Q. McGuigan. Okay. I would not have gotten
10 that right. So thank you.

11 So in this role, your position was the
12 director -- first the deputy director and then the
13 director -- of -- how many people did you oversee in
14 the director position? Do you recall?

15 A. I'm going to say eight. Approximately
16 eight.

17 Q. Eight, okay. And were those analysts as
18 well?

19 A. Yes.

20 Q. Okay. And when you were in the director
21 position, who did you report to?

22 A. I reported to the director of the Medicare
23 Plan Payment Group, Cheri Rice.

24 Q. And was that Cheri Rice the entire time
25 that you were the director?

1 A. No. For the last -- for the last year, I
2 reported to Jennifer Harlow, who was the acting
3 director at the time, because Cheri Rice was now the
4 acting deputy center director.

5 Q. Okay, okay. And am I correct that during
6 the time that Cheri Rice was the director of the
7 Medicare Plan Payment Group, Jennifer Harlow was the
8 deputy director?

9 A. Yes. Correct.

10 Q. And is it okay with you if I call the
11 Medicare Plan Payment Group "MPPG"?

12 A. Yes.

13 Q. Okay. So this role that you held within
14 the division of encounter data and risk adjustment
15 operations, that was related to the Medicare
16 Advantage program; is that right?

17 A. Yes.

18 Q. Okay. So you are familiar with the
19 Medicare Advantage program, then?

20 A. "The Medicare Advantage program" is pretty
21 broad. I'm familiar with what I was responsible for
22 in MPPG.

23 Q. Okay. How would you describe Medicare
24 Advantage?

25 A. Medicare Advantage is a program

1 administered by Medicare that involves relationships
2 with private health plans, to enroll Medicare
3 beneficiaries and provide services under the MA
4 program.

5 Q. And it's an alternative to the traditional
6 Medicare program; is that right?

7 A. Yes.

8 Q. Okay. I think you just referred to it
9 as "MA." So I assume that -- it's okay if I refer to
10 it as "MA," you'll understand I mean Medicare
11 Advantage?

12 A. Yes.

13 Q. Okay. And the division of encounter data
14 and risk adjustment operations: That's a long name.
15 Is it okay if I refer to that as "DEDRA0"? Is that
16 what you typically call it, D-E-D-R-A-0?

17 A. No, that's not okay. It's DEDRA0.

18 Q. DEDRA0. Oh, my gosh. I've been
19 pronouncing it wrong this whole time. Okay, DEDRA0.

20 What is DEDRA0 responsible for?

21 A. DEDRA0 is responsible for -- or was
22 responsible for, if I'm to pin it to my specific role
23 there, the capture of encounter data, and also risk
24 adjustment data -- which encounter data is risk
25 adjustment data -- but risk adjustment, RAPS data,

1 processing data, to support the calculation of risk
2 scores that factor into MA payment.

3 Q. So let's drill down a little bit there, if
4 that's okay.

5 You said one of the things that -- that
6 DEDRA0 was responsible for was the capture of
7 encounter data. What is encounter data?

8 A. One can think of encounter data as Part C
9 claims, right? Essentially, what services were
10 furnished to enrollees, plan enrollees, and also the
11 diagnostic information that came along with those
12 services. So the equivalent of Part A, Part B
13 claims.

14 Q. Okay. And you also mentioned something
15 called "RAPS data." What is RAPS data?

16 A. Risk adjustment processing system data is
17 really the capture of diagnostic information for
18 enrollees in -- in the health plan that was used to
19 capture -- that is used to capture that information
20 and calculate risk scores for MA payment.

21 Q. Okay. And how does RAPS data differ from
22 encounter data?

23 A. RAPS data is really just a diagnostic
24 information for those enrollees, versus encounter
25 data being a more robust capture of the services and

1 the diagnostic information related to the services
2 furnished.

3 Q. So is it fair to say that encounter data
4 is similar to RAPS data, but it just includes more;
5 it's got more information than RAPS data does?

6 A. Yes.

7 Q. Okay. You also mentioned that the RAPS
8 data -- and I think encounter data as well -- is used
9 to capture information that's used to calculate risk
10 scores for MA payment. What is a risk score?

11 A. A risk score is a -- a calculated variable
12 that suggests just how healthy or unhealthy an
13 enrollee is relative to -- relative -- that is used
14 to adjust payments to the plans.

15 I can go into more detail if you want, but
16 at a high level, think of it that way.

17 Q. Okay. And how exactly is it used to
18 adjust payment to the plans?

19 A. So payment under the MA program is
20 capitated. In other words, some acknowledgment of a
21 cost per bene per month. The risk scores are really
22 an acknowledgment that not every enrollee is of the
23 same health profile, and so diagnostic information is
24 used to adjust those payments, recognizing where
25 benes are healthier or less healthy relative to the

1 plan's enrollees and -- and what their costs are.

2 Q. All right. And we've used the phrase
3 "diagnostic information" a few times. What exactly
4 does that mean?

5 A. Just diagnoses that are captured in an
6 encounter, or in an interaction between provider
7 and -- and enrollee.

8 Q. Okay. And how does that diagnosis
9 information get to CMS, in the Medicare Advantage
10 program?

11 A. That information is submitted to CMS
12 through the RAPS system, and then processed in -- in
13 subsequent systems.

14 Q. And is it submitted by the provider, or by
15 the MA plan, or -- who is the one doing that
16 submitting?

17 A. Good question. It's submitted by the
18 MA plan.

19 Q. Okay. And presumably the MA plan gets it,
20 then, from the providers?

21 A. Presumably.

22 Q. Okay. Let's turn back to your résumé, if
23 possible. We can talk in a little bit more detail
24 about what you did in the -- the deputy director
25 and -- and director roles at DEDRA0.

1 So if you turn back to page 1 of your
2 résumé, do you see there's a section that says -- and
3 it's in italics -- "Roles and Responsibilities
4 (Summary)"?

5 A. Yes.

6 Q. Okay. Underneath that, it says:
7 "Developed and implemented operational payment policy
8 on highly complex and politically sensitive health
9 care financing issues for Medicare Advantage
10 organizations (MAOs) under the Medicare Advantage
11 program, including risk adjustment of plan payments
12 and the collection and analysis of encounter data."

13 Did I read that correctly?

14 A. Yes.

15 Q. Okay. And that's a little bit about what
16 we were just talking about now, right, that payment
17 under the MA plan is capitated based on the risk
18 scores that are calculated from diagnostic
19 information, in part; is that right?

20 A. Let me say that slightly differently.
21 Payment under the MA plan is capitated, but that
22 payment is adjusted by diagnostic information that
23 are used to calculate risk scores suggesting the
24 health profile of the enrollees.

25 Q. Okay. So you wrote here that the health

1 care financing issues that you developed and
2 implemented were "highly complex and politically
3 sensitive." What does that mean?

4 A. It's -- it's résumé jargon, suggesting
5 that of course we are making payments under the
6 Medicare program, and deliberations that go into
7 those payments are complex and -- and sensitive;
8 i.e., we work through a process to develop those
9 payments and -- and policies, and all of that can
10 have impact.

11 Q. We talked a little bit about the risk
12 adjustment plan payments already. But were you
13 actually, yourself, involved in calculating plan
14 payments?

15 A. Help me understand your question a bit
16 more.

17 Q. Sure. So your résumé says that you
18 "developed and implemented payment policy ...
19 including risk adjustment of plan payments."

20 So what was your involvement in developing
21 and implementing policy for the risk adjustment plan
22 payments?

23 A. So my role was specifically on the
24 operational side of the house. But. Right? If one
25 is to think about plan payment as a continuum,

1 there's certainly role -- there's a role that I
2 played in -- in getting to the end, right? In other
3 words, there's development of payment policies, and
4 then the implementation of those payment policies,
5 which, to a certain extent, means you understand
6 parts of what you are doing versus just blindly doing
7 things, and then ultimately handing off to another
8 component that actually makes those payments.

9 So think of, you know, policy
10 developments, policy operationalizing and then actual
11 implementation, i.e., payment through our systems.
12 The next bullet point -- no, it's not a bullet point,
13 excuse me. The next sentence in that same paragraph
14 says you "Provided oversight and technical direction
15 to division staff responsible for the development,
16 deployment, and maintenance of the encounter data
17 processing system (EDPS) and the risk adjustment
18 suite of systems (RASS)."

19 Did I read that correctly?

20 A. Yes.

21 Q. Okay. What is the encounter data
22 processing system?

23 A. The encounter data processing system,
24 which I actually miss, was CMS's attempt to capture
25 what I described earlier as Part C claims. Right?

1 Really capturing more information than what we had
2 had before, to help inform future policy development,
3 or just frankly have more information on -- on what
4 we were paying.

5 Q. Okay. And -- and the EDPS system, or I
6 guess just EDPS, was implemented sometime in the
7 2014, 2015 time frame; is that right? Or was it
8 earlier than that?

9 A. A little earlier than that. When I came
10 on, it had just been implemented and -- and was just
11 starting to get going.

12 Q. Okay. And so that would have been the
13 2013 time frame?

14 A. Around then. Around then. Maybe earlier.

15 Q. Okay. Risk adjustment suite of systems,
16 RASS, what is that?

17 A. It's a collection of systems -- we talked
18 about RAPS before, the risk adjustment processing
19 system, which falls into RASS, which really captures
20 information and then processes the information to --
21 to get to the risk scores.

22 Q. Okay. So RAPS is one of, but not the only
23 system, within the risk adjustment suite of systems?

24 A. Correct.

25 Q. What are the names of some of the other

1 systems in the -- the suite? Do you remember?

2 A. Well, RASS is really the system, but it
3 has -- let's just call it a front end and a back end,
4 with RAPS being the front end and then RASS just
5 being the collection of processes within a back end.

6 In other words, a plan submits information
7 to RAPS, and then the information goes through a
8 whole bunch of processes that at the end are turned
9 into risk scores.

10 Q. Okay. Have you heard of something called
11 the front end risk adjustment system, FERAS?

12 A. Yes, FERAS.

13 Q. FERAS, okay. Is that also part of the
14 suite, the risk adjustment suite of systems?

15 A. Yes. Yes. So forgive me, my -- my -- the
16 way I normally tell this story is really dated. But
17 FERAS is truly the front end to RAPS, and then RAPS
18 sort of feeds into, right, the processes I described.
19 But it's just a front end for capturing that, the
20 RAPS information.

21 Q. And so we talked a little bit about plans
22 submitting data to RAPS. Do they actually submit to
23 RAPS, or do they submit to FERAS?

24 A. They submit to FERAS. FERAS feeds into
25 RAPS. And then there's a whole bunch of processes

1 after that.

2 Q. Okay. That makes sense.

3 The next sentence in your résumé, the last
4 sentence in that sort of full paragraph there, it
5 then says, "Managing all activities related to the
6 calculation of Medicare Part C and Part D risk
7 adjustment factors that are used to adjust capitated
8 payments to MAOs, including the deployment of
9 resources relevant to this effort."

10 Do you see that?

11 A. Yes.

12 Q. Okay. So we talked a little bit about
13 the -- the ways that risk scores are used to adjust
14 capitated payments to MAOs. Is a -- is a risk
15 adjustment factor the same as a risk score? Or is
16 there a difference there?

17 A. There's a difference.

18 How weedy do you want me to get?

19 Q. As weedy as you think you need to be to
20 help me understand.

21 A. All right. I'll try to stay surface
22 level.

23 Again, remember, my -- my information may
24 be dated. I'm going off of memory, you know, days
25 gone by, but think of information flowing into RAPS,

1 right, diagnostic information, that are then used as
2 inputs to various risk scoring models, right? The
3 idea that you take such information and acknowledge
4 that there are different characteristics that are in
5 play for different sections of a population.

6 Think about folks that have ESRD, folks
7 that don't have ESRD, and other considerations as
8 well, too.

9 Those models are designed to use that
10 information to generate what are called risk factors,
11 right, that are then also processed into risk scores.

12 And now that's a very high generalization
13 of -- of the process, but think of factors as the
14 things that come before the scores.

15 Q. Okay. So the score is sort of the end
16 result of -- of calculations that are done using risk
17 factors; is that right?

18 A. Correct.

19 Q. Okay.

20 A. At a high level, yes.

21 Q. Okay. If I'm ever oversimplifying to the
22 point that you think it's wrong, please jump in and
23 let me know. I'm sure you have much more
24 in-the-weeds knowledge than I do about this.

25 So, you also said here that you manage

1 activities and resources related to the collection
2 and analysis of encounter data. What sort of
3 analyses were you running on encounter data?

4 A. Really working to determine the -- the
5 quantity, the appropriate quantity and quality of the
6 data. CMS did not have Medicare Part C claims in
7 that form or fashion prior to encounter data really
8 getting rolling. So really understanding what we
9 were capturing and -- and what it looked like and
10 felt like was -- was really the basis for the
11 analysis. Or analyses.

12 Q. And let's go back to the -- the risk
13 adjustment factors and the risk scores for a second.
14 Because we've talked about the adjustment of -- of
15 payments to plans, but the -- the way that -- well,
16 let me ask it this: What is your understanding of
17 how the risk scores were used to adjust payments to
18 MA plans?

19 A. At a high level, once you had calculated a
20 risk score for a beneficiary, right? Again, applying
21 that risk score to the capitated payment amount --
22 think per bene per month -- was how -- how it was
23 implemented through our payment systems.

24 Q. Okay. And at a high level, the idea is
25 that MA plans are paid based on sort of historical

1 diagnostic information in a way that's used to
2 predict their future risk score expenses for that
3 particular beneficiary; is that right?

4 A. Let me say it slightly differently. I
5 think you nailed it, but let me just say it slightly
6 differently.

7 MA plans were capturing information on
8 their enrollees that they submitted to CMS, which was
9 used to calculate risk scores that would be used to
10 adjust payment.

11 Q. And the idea behind sort of risk adjusting
12 payments to plans was that if you didn't do this, a
13 plan might not want to enroll sicker beneficiaries,
14 because they may not be paid sufficient -- paid
15 sufficiently to cover their future risks?

16 A. Well, that's a -- that's -- that's a
17 packed statement.

18 That's a tough one. Ask your question
19 again a different way.

20 Q. Okay. Why -- why would CMS risk -- why
21 implement the risk adjustment system for the payment
22 to Medicare Advantage plans? What's the rationale
23 behind that?

24 MR. DYAL: Objection. Form.

25

1 BY MR. RYDBERG:

2 Q. And you can still answer.

3 A. So I would say -- and this is just me
4 riffing -- that CMS was recognizing that, you know,
5 there may be characteristics of the enrollees that
6 should be taken into account, factored into payment,
7 given that, you know, again, the idea of the healthy
8 versus the less healthy enrollee being a true thing.

9 Q. And the characteristics that we're talking
10 about, that includes both demographic characteristics
11 and then also diagnostic coding; is that right?

12 A. That is right.

13 Q. Okay. Let's turn back to your résumé.
14 And we can skip down to -- two bullets -- there's a
15 bullet -- I believe it's the fourth from the top. It
16 says: "Providing oversight of the research,
17 analysis, and plan communication related to the
18 operational aspects of risk adjustment and encounter
19 data." Do you see that?

20 A. Yes.

21 Q. Okay. What sort of plan communication
22 were you responsible for?

23 A. "Related to the operational aspects of
24 risk adjustment and encounter data." So consider
25 submission, communications, announcements of when

1 plans should submit, if plans were having issues,
2 communicating with the plans globally, right, through
3 memos -- communications like that.

4 Q. Okay. And that would be sort of -- that
5 would be both formal communications, like memos that
6 go out to the whole industry, but also if a
7 particular plan was having a problem, you might deal
8 with them one on one and help them with that issue;
9 is that right?

10 A. Yes, that is right.

11 Q. Okay. And then if we turn to the next
12 page of your résumé, the last bullet point above
13 "Health Insurance Specialist," it says: "Maintaining
14 relationships with, and providing technical
15 assistance to internal and external stakeholders
16 including other state and federal government
17 agencies, professional associations, and MAOs on MA
18 risk adjustment and encounter data operational/policy
19 issues."

20 Is that sort of the same thing that we
21 were just talking about, that you would communicate
22 with MA plans on operational and policy issues? Or
23 is this different?

24 A. This -- this goes a little broader. It's
25 the same -- same thought, but the idea that we were,

1 quote/unquote, the operational experts for MA
2 encounter data, and really having to work internally
3 and externally with folks that had questions or, you
4 know, needed -- needed help with -- with technical
5 aspects of what we were doing.

6 Q. And so that obviously, I think it says
7 here, includes other state and federal government
8 agencies, and also professional associations.
9 What -- what professional associations did you -- do
10 you have any specific professional associations in
11 mind when you drafted this?

12 A. There are a couple of professional
13 associations out there. AHIP comes to mind. Again,
14 you know, within the realm of MA, you know, the idea
15 that this is -- an association like AHIP was really
16 representing a collection of MA plans wanting more
17 information on, I don't know, submission timelines,
18 or, you know, if there were an issue with our
19 systems, being able to broadly communicate were
20 really I guess typical conversations that we would
21 have.

22 Q. Okay. That makes sense.

23 And then if we turn down on that same sort
24 of same page of your résumé, you then have another
25 role, that's health insurance specialist CM -- I

1 assume that's "Center for Medicare"; is that right?

2 A. Yes.

3 Q. Okay. And that's November 2004 to
4 January 2013.

5 What did you do in this role? And was it
6 multiple roles within the same -- within that overall
7 time period, or was it just a single role?

8 A. Multiple roles within that time period.

9 Q. Okay. Were any of those roles related to
10 Medicare Advantage?

11 A. These were fun times, and a lot less
12 responsibility.

13 I would say that -- no, there was some
14 overlap in risk adjustment. Let's say, for example,
15 the physician value program. But that was more as an
16 input into how we were thinking about patient
17 profile, but it was really just leveraging risk
18 adjustment scores.

19 Q. Okay. So when you came into the DEDRAO
20 position in 2013, did you have any background with
21 risk adjustment? Did you understand what risk
22 adjustment was?

23 A. At a high level, yes. You know, just the
24 accounting of diagnostic information to suggest a
25 healthy versus a less healthy beneficiary. But that

1 was it.

2 Q. Okay. So how did you go about learning
3 about risk adjustment once you took on that role at
4 DEDRA0?

5 A. Like anyone learns something new, you
6 start from the beginning and try to work your way to
7 the end.

8 Q. And what's the beginning? Is it -- are
9 there documents that you read? Statutes? Did you
10 talk to people?

11 A. Yeah, yeah. You know, you sort of start
12 with, what is a risk score? And, you know, how is it
13 calculated? And what information feeds into it?

14 And, you know, I -- I wasn't the first
15 person to step into that role, so thankfully I -- I
16 had a whole group around that was invested in -- in
17 getting me up to speed.

18 Q. So you -- you relied on your colleagues at
19 DEDRA0 to sort of teach you informally about risk
20 adjustment?

21 A. That's what -- yes. Yes.

22 Q. Okay. Were there any colleagues outside
23 of DEDRA0 that you relied on?

24 A. Well, outside of the DEDRA0, to be -- yes,
25 MPPG, as a whole. Right?

1 VIDEOPHOTOGRAPHER: The time is 9:58 a.m.

2 We're off the record.

3 (A recess transpired from 9:58 a.m. until
4 10:08 a.m.)

5 VIDEOPHOTOGRAPHER: The time is now 10:08 a.m.

6 We're on record.

7 BY MR. RYDBERG:

8 Q. Welcome back, Mr. Tee.

9 I want to shift gears a little bit and
10 just ask you a series of background questions about
11 Medicare Advantage. It's going to be high level but
12 designed to figure out sort of your -- your knowledge
13 and involvement in a variety of different topics.

14 So you talked about this sort of
15 indirectly, I think, but have you heard of something
16 called the "CMS-HCC risk adjustment model"?

17 A. Yes.

18 Q. Okay. CMS, Centers for Medicare and
19 Medicaid Services. What does the "HCC" stand for,
20 though?

21 A. Hierarchical condition categories.

22 Q. Okay. And what is that?

23 A. That's an imposed hierarchy on -- on --
24 how do I -- how do I say this at a high level?

25 You know what? I -- I don't know.

1 Q. Okay. Let me ask it this way: If --
2 let's say you have two diseases, diabetes without
3 complications and diabetes with complications. Would
4 those two diseases fall in the same hierarchical
5 condition category?

6 A. No. There would be a hierarchy imposed.
7 And I -- I didn't want to get into that level of
8 detail, which is why I defaulted to -- you know, my
9 knowledge is stale at this point, so being nuanced
10 and -- and precise are probably not within my
11 capability.

12 Q. And that's okay. It has been a long time,
13 and this isn't a memory test. So -- really just
14 looking for your best recollection as you recall. So
15 no worries there.

16 We talked a little bit about this already,
17 but traditional Medicare is Parts A and B of the
18 Medicare program; is that right?

19 A. Correct.

20 Q. And is that sometimes called
21 fee-for-service Medicare?

22 A. Yes.

23 Q. And is that because the providers, the
24 rendering providers, are paid on a per-service basis
25 by the Medicare program?

1 A. Generally, yes.

2 Q. Okay. Fee for service, is that sometimes
3 called "FFS," as an abbreviation?

4 A. Yes.

5 Q. Okay. Have you heard of -- have you heard
6 the phrase "chart review" before?

7 A. Yes.

8 Q. What does it mean?

9 A. Different concepts for different
10 scenarios, but if we're asking about under the MA
11 program, it's consideration of diagnostic information
12 in an enrollee's chart.

13 Q. Okay. Have you heard the phrase "one-way
14 look" before?

15 A. "One-way look." "One-way look." No.

16 Q. Okay. Did your position at DEDRAO involve
17 chart review in any way?

18 A. Yes.

19 Q. How so?

20 A. Well, we were responsible for capturing
21 information. So there was the idea that the plans
22 were submitting information that they either gathered
23 through their systems for capturing such information,
24 or through some subsequent or concurrent chart review
25 process by which they were also capturing that

1 information to submit to us.

2 Q. Okay. So sometimes plans would submit
3 diagnostic data that flowed directly from a provider,
4 and other times they would submit data that was the
5 result of these chart reviews; is that fair?

6 A. They were submitting data all the time,
7 but it was clear to us in some instances that there
8 was information that was captured as a direct flow,
9 right, of the services being furnished into a system,
10 versus some additional work to capture additional
11 information, or different information.

12 Q. And you said it was clear to you. What --
13 was it a timing thing? Why was it clear to you?

14 A. Maybe that was being overoptimistic, but
15 there was just a cadence to -- well, that's not even
16 true. Because, you know, all the plans did things
17 differently. There were certainly plans that looked
18 the same and others that just looked different, so --
19 who knows exactly when they were capturing
20 information.

21 But there was a lot of work to try to
22 understand the flow and cadence. I don't know if we
23 ever truly got there, and it's been a while, so -- I
24 don't know where those -- that crew got to. But the
25 capture of information was nuanced, and we tried to

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 GIFT TEE was remotely sworn and/or affirmed by me to
7 testify to the truth, the whole truth and nothing but
8 the truth.

9 I DO FURTHER CERTIFY that the foregoing is a
10 verbatim transcript of the testimony as taken
11 stenographically by me at the time, place and on the
12 date hereinbefore set forth, to the best of my
13 ability.

14 I DO FURTHER CERTIFY that I am neither a
15 relative nor employee nor attorney nor counsel of any
16 of the parties to this action, and that I am neither
17 a relative nor employee of such attorney or counsel,
18 and that I am not financially interested in this
19 action.

20

21

Karen K. Kidwell

22

Karen K. Kidwell

Registered Merit Reporter

23

Certified Realtime Reporter

Notary Public

24

Dated: November 30, 2022

25

EXHIBIT D-144

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

CONFIDENTIAL

Videotaped Rule 30(b)(6) Deposition of
UnitedHealthcare, Inc. and OptumInsight, Inc.,
Designee 4, by SCOTT THEISEN
Given Remotely
Tuesday, June 6, 2023
10:08 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

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1 did was in complete good faith, and designed to
2 work in a transparent, collaborative way with
3 CMS. So anything and everything we did from a
4 control, and compliance, as well as just our
5 internal controls, our operating controls, the
6 integrity and expectations of our employees, the
7 way in which we behaved, our culture, was all
8 centered around doing the right thing. So we
9 would never intentionally disregard or
10 purposefully, you know, not take sufficient
11 actions to identify errors.

12 BY MS. McMAHON:

13 Q. So if you had some information or belief
14 that some of the diagnosis codes that you had
15 submitted might not be accurate, did you check to see
16 if they were?

17 MR. BAAK: Objection. Form. Way beyond
18 the scope. Incomplete hypothetical.

19 THE WITNESS: Yeah, I think there's -- you
20 know, I think I'd probably want you to define
21 for me what you mean by "knowledge of
22 information," because one could take the
23 position that knowing that there's a material
24 error rate in fee-for-service claims data, as
25 documented by CMS, that depending upon your view

1 of things, one could argue that that is
2 knowledge. Does that -- would that knowledge
3 then imply a requirement to audit every claim
4 and diagnoses back to the medical record? No.
5 So I just want to be careful about the scope of
6 what that question relates to.

7 BY MS. McMAHON:

8 Q. So if you had some information or concern
9 that there were diagnoses codes -- let's say after
10 you had done a chart review, and you had some -- some
11 reason to believe that there were diagnoses codes
12 that -- in those charts that had been reviewed, that
13 you -- that might not be supported by medical
14 records, did you take it upon yourself to check to
15 see if any of those -- to see if those diagnosis
16 codes were, in fact, supported before you submitted
17 these attestations?

18 MR. BAAK: Objection. Form. Beyond the
19 scope of today's topics. We're really far
20 afield here.

21 THE WITNESS: Yeah, I would describe that
22 as the company's practices. For a period of
23 time, we were performing what we call claims
24 verification, and then as part of the
25 discussions with CMS, and the proposed rule and

1 when that rule was rescinded, and the clarity
2 they provided around us, the decision to not
3 perform claims verification, which I think is
4 what you're describing in your question, is a
5 decision that was based on our understanding of
6 CMS's guidance, which was that it was no longer
7 required because the rule itself was not
8 published.

9 And the fact that the rule was published
10 in the first place, proposed rule, you know,
11 from a deductive reasoning standpoint, also
12 would indicate that those specific practices
13 with regard to medical record review would not
14 have been required by CMS prior to that date.
15 Otherwise, there would have been no need to
16 propose a rule.

17 BY MS. McMAHON:

18 Q. Prior to -- prior to May of 2014, did you
19 rely on your claims verification program to -- as
20 part of your knowledge, information, and belief, that
21 your data was accurate, complete, and truthful when
22 you submitted these attestations?

23 MR. BAAK: Objection. Form. Beyond the
24 scope.

25 THE WITNESS: I would say that, no, I did

1 not rely on claims verification as a basis for
2 being able to certify and attest. My view, and
3 the company's view, that claims verification was
4 a business practice we deployed as a result of
5 some ambiguity with regard to what the view of
6 CMS and rules and regulations are, and we
7 deployed it in the interest of being
8 conservative.

9 Did I feel it was necessary and required
10 for me to be able to attest to the accuracy of
11 the information we submitted? No, it was not.
12 And I would say that's because, essentially, we
13 were auditing fee-for-service claims data,
14 which -- back to medical records, which was not
15 a requirement or an expectation of CMS. So, no,
16 I don't believe it was necessary for me to
17 certify, nor do I -- nor does the company
18 believe that.

19 BY MS. McMAHON:

20 Q. That claims verification process did
21 identify a lot of unsupported codes that had been
22 submitted, did it not?

23 MR. BAAK: Objection. Beyond the scope.

24 Linda, I've given you a lot of rope, but we
25 have witnesses on claims verification, and

1 Mr. Theisen is not it, so...

2 MS. McMAHON: But we're talking about the
3 certification of accuracy, which is exactly
4 what's in here. I am sure you will not let the
5 CV witness talk about that because it would be
6 beyond the scope of that topic.

7 MR. BAAK: The last question you asked had
8 nothing to do with certification. It was just
9 claims verification. So I'll give you a little
10 more rope, but we're not -- we're not taking
11 another deposition today.

12 THE WITNESS: We did process some deletes
13 of diagnosis codes as a result of the claims
14 verification process when it was -- when it was
15 being deployed.

16 BY MS. McMAHON:

17 Q. And as part of submitting an attestation
18 to CMS, certifying that the data it submitted was
19 accurate, complete, and truthful, the data that it
20 had submitted was accurate, complete, and truthful,
21 did you consider it important to seek to identify or
22 confirm any potential inaccuracies that might be in
23 the data that you knew about?

24 MR. BAAK: Objection. Form. Beyond the
25 scope. Asked and answered.

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.





Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-145

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

Videotaped Deposition of
CYNTHIA G. TUDOR, Ph.D.
Given Remotely
Tuesday, August 23, 2022
9:59 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

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866-624-6221
www.MagnaLS.com

1 am not at will to tell you that.

2 Q. Did you --

3 A. I was just complaining about it.

4 Q. Understood.

5 Let's talk a little bit about what
6 you're doing today. You are the -- currently, the
7 president of The Tudor Group; is that correct?

8 A. Yes.

9 Q. What is The Tudor Group?

10 A. It's me, myself and I. And I am a
11 consultant for Medicare Advantage Part D plans,
12 some consulting firms, some law firms, some trade
13 associations.

14 Q. Does The Tudor Group have any employees
15 other than yourself?

16 A. No.

17 Q. And do you work at The Tudor Group
18 full-time?

19 A. Not now. I used to.

20 Q. About how many hours a week are you
21 presently consulting through The Tudor Group?

22 A. Somewhere around five.

23 Q. You've been at The Tudor Group since
24 you left the Center for Medicare in 2017; is that
25 correct?

1 A. Yes.

2 Q. Have you done any consulting for the
3 government since you left the Center for Medicare
4 in 2 -- in 2017?

5 A. I believe that I did some consulting
6 for a contract that someone had with the
7 government, yes.

8 Q. Did that contract relate to risk
9 adjustment?

10 A. I -- not that I recall.

11 Q. Have your clients, either current or
12 former, at The Tudor Group included Medicare
13 Advantage plans?

14 A. Yes.

15 Q. What is the nature of the consulting
16 advice, your -- your work you've done for Medicare
17 Advantage plans?

18 A. It's -- can be things related to
19 compliance actions that the government is taking,
20 quality ratings. It can be around risk adjustment,
21 risk adjustment data. But I don't remember any
22 specifics that I've done that. But it could be
23 anything related to Part C and Part D.

24 Q. Do you have any current Medicare
25 Advantage plans that you're advising related to

1 risk adjustment or compliance?

2 A. Yes.

3 Q. Who are those Medicare Advantage plans?

4 A. I have nondisclosure agreements, and I
5 would have to clear that I'm revealing their name
6 to you with each of the clients before I do so.

7 Q. Without revealing the particulars, are
8 these major Medicare Advantage plans that I would
9 have heard of?

10 A. Yes.

11 Q. Are these Medicare Advantage plans that
12 are currently dealing with actions by CMS related
13 to compliance issues?

14 A. Well, these things come up all the
15 time. So I'm not really sure what you're getting
16 at. Over time, there have been issues around
17 compliance. The issues that I talked with these
18 clients about in the last couple of weeks have not
19 been about risk adjustment, encounter data or any
20 of that.

21 Q. Have you provided advice through
22 The Tudor Group to Medicare Advantage plans on what
23 their requirements are related to the submission of
24 risk adjustment data?

25 A. Not that I recall.

1 Q. Have you provided advice through
2 The Tudor Group to Medicare Advantage plans related
3 to the design of their compliance programs?

4 A. Not that I recall.

5 Q. Have you provided advice through
6 The Tudor Group to Medicare Advantage plans related
7 to the design of their medical record review
8 programs?

9 A. I provide -- no. I did provide
10 assistance to a law firm that was being -- that was
11 the -- I forget the relationship of the different
12 parties. But there was a whistleblower that
13 accused a plan of -- of false claims because of
14 their medical record review process in terms of
15 appeals.

16 Q. You were retained by the law firm that
17 represented the whistleblower or the defendant?

18 A. The defendant.

19 Q. What's the name of the law firm?

20 A. Again, I'm under nondisclosure. This
21 was about appeals. This was for services. This
22 was not about encounter data.

23 Q. When you say "appeals," can you explain
24 what you mean?

25 A. Yeah, the -- the patient got denied a

1 service. It went to the plan. The plan used an
2 automated sort of criteria review, denied the claim
3 again, and it went to second-level review.

4 So it was about whether those -- and
5 this was on the Part C side -- whether those
6 denials at that first level were consistent with
7 what Medicare said or not. And, again, these were
8 Part C.

9 Q. Did you provide an expert report in
10 connection with that case?

11 A. I -- I -- no. I was on -- just sort of
12 on the side. I refuse to do expert testimony.

13 Q. Have you ever done expert testimony,
14 Dr. Tudor?

15 A. No.

16 Q. Other than that example you just gave
17 me where you were retained by the defendant's
18 counsel in a whistleblower case, have you done any
19 other litigation consulting?

20 A. Yes. Early on, I did some around
21 Part D, in a whistleblower on the Part D side.

22 Q. Other than that case, are there any
23 other instances where The Tudor Group and you have
24 provided litigation support?

25 A. Not that I recall.

1 Q. In the example you just mentioned on
2 the Part D side, were you retained by the
3 defendant's counsel in that whistleblower case?

4 A. No.

5 Q. In the Part D example you gave, you
6 were retained by the whistleblower's counsel?

7 A. Yes, sir.

8 Q. Do you know what the ultimate
9 disposition of that case was?

10 A. I got an email about it, but I pretty
11 much ignored it. I -- I think that they won at an
12 early stage. I'm not sure that the whole thing is
13 over with yet.

14 Q. And what about --

15 A. But I'm not involved in it.

16 Q. Sorry for interrupting you.

17 What about the other case where you
18 were retained by the defendant's counsel? Do you
19 know what the ultimate disposition of that case
20 was?

21 A. I believe they won that. I, again --
22 you could read it -- read something about it and
23 say it's not still over, but in my opinion, they
24 won.

25 Q. Your work for The Tudor Group, have you

1 provided any consulting to Medicare Advantage plans
2 related to the submission of their bids?

3 A. You know, it's -- I think there might
4 have been questions that related to bids. I don't
5 remember what the specifics are, though.

6 Q. In your work for The Tudor Group, have
7 you ever advised any of your Medicare Advantage
8 plan clients that a compliance program required
9 them to design their medical record review to look
10 for codes to delete in addition to add?

11 A. Not that I recall.

12 Q. And stepping more broadly, not just
13 your Tudor work, but at any point during your work
14 for the Center for Medicare or The Tudor Group, do
15 you ever recall telling a Medicare Advantage plan
16 that as part of their compliance program they were
17 required to design their medical review -- medical
18 reviews to look for codes -- diagnosis codes to
19 delete in addition to add?

20 MS. CHEN: Object to form.

21 THE REPORTER: I'm sorry. Who was
22 that?

23 MS. CHEN: This is Geng Chen, counsel
24 for relator.

25 BY MR. BAAK:

1 Q. You can answer, Dr. Tudor.

2 A. The answer is: Probably.

3 Q. Can you --

4 A. In general -- in general, I would say
5 that you have to design medical record review to
6 look for both adds and deletes.

7 Q. Dr. Tudor, sitting here today, can you
8 identify any Medicare Advantage plan that you
9 advised that they had to design their chart-review
10 programs to look to delete diagnosis codes in
11 addition to add?

12 A. I don't remember which specific
13 plans --

14 MS. CHEN: Object to form.

15 BY MR. BAAK:

16 Q. The answer to my question, Dr. Tudor,
17 is: Sitting here today, you can't identify any
18 Medicare Advantage plan that you recall telling
19 that they needed to design their chart review to
20 look to delete diagnosis codes in addition to add,
21 correct?

22 A. That's correct.

23 Q. I want to back up in time. When did
24 you first join CMS?

25 A. 1992.

1 Q. And when did you leave CMS?

2 A. 2017.

3 Q. What was your last position at CMS?

4 A. Deputy director for the Center for
5 Medicare.

6 Q. During what period were you the deputy
7 director at the Center for Medicare?

8 A. I was acting from, I think, early 2013
9 to some point in 2014, and I couldn't really tell
10 you when. And then I was the director from that
11 point in 2014 through when I left in July of 2017.

12 Q. Before you were the deputy director at
13 the Center of Medicare, what position did you hold
14 at CMS?

15 A. The one prior to that would have been
16 the director of the Medicare Drug Benefit Group.

17 Q. Is that also the Data -- referred to as
18 the Data Group?

19 A. No. I don't know what the Data Group
20 is.

21 Q. Was the -- your position director
22 Medicare Drug Benefit and C & D Data Group?

23 A. Yes. That probably was -- I think
24 the -- the C & D Data Group probably got dropped
25 later, and it was the Medicare Drug Benefit Group.

1 Q. And how long did you hold that
2 position?

3 A. Well, I don't have my r?sum? in front
4 of me, so I can't really tell you whether these
5 dates are exactly right. But that would have been
6 somewhere from about 2005 in an acting position to
7 when I -- to 2013. So I would have been acting for
8 a while and then permanent director.

9 Q. During your time as the director of the
10 Drug -- Medicare Drug Benefit and C & D Data Group,
11 did you have responsibility for Medicare Advantage
12 plans?

13 A. I would say that the answer to that
14 question is no, that the Medicare Advantage plans
15 were under the Medicare Contract Administration
16 Group, also called MCAG, which had the policy --
17 the policy for Part C. And then there was a
18 Payment Group that had control over the encounter
19 data and ultimately the PDE data for Part D.

20 Q. So just so the jury understands, so
21 when you say "Part C," you're referring to Medicare
22 Advantage, right?

23 A. That's correct.

24 Q. And so during the time you were the
25 director of the Medicare Drug Benefit and C & D

1 Data Group, what responsibilities, if any, did you
2 have related to Medicare Advantage?

3 A. I really -- I couldn't tell you the
4 specifics. I mean, that -- I don't remember the
5 difference between the Medicare Drug Benefit and
6 C & D Data Group and the Medicare Drug Benefit
7 Group.

8 But basically, the division of labor
9 was around policy, which for Part C would have been
10 through the MCAG Group, which I referenced earlier.
11 I would have had control over Part D policy. I
12 also had the Health Plan Management System, HPMS,
13 and -- and the star ratings in my group.

14 Some other groups -- the Plan Payment
15 Group had the encounter data and the PDE data.
16 Another group had compliance, and the other group
17 had sort of enrollment and different policies
18 around that.

19 Q. So during the time that you were the
20 director of the Medicare Drug Benefit and C & D
21 Data Group, it sounds like you had some
22 responsibilities related to Medicare Advantage,
23 including the HPMS and star ratings, but not sole
24 responsibility or overall oversight for Medicare
25 Advantage; is that correct?

1 A. That's correct.

2 Q. Before you became the director of the
3 Medicare Drug Benefit Group, what role did you hold
4 at CMS?

5 A. So I'm not -- I may not get the
6 sequence right, but I was a division director in
7 part there where we were collecting encounter data
8 for risk adjustment.

9 And that -- and then prior to that, I
10 was in something called the Office of Research and
11 Demonstrations. Maybe we just start there. I was
12 hired into the Office of Research and
13 Demonstrations. Worked first on Medicaid
14 financing. And then worked on the demo side where
15 I was special assistant in other things. And then
16 got moved to a position where I was the chief
17 technical in charge of making risk adjustment,
18 getting it into legislation and then get it
19 implemented for Medicare.

20 Q. I want to focus on that last piece.
21 When were you -- when did you first start working
22 on risk adjustment for Medicare?

23 A. You know, it's really hard to remember.
24 But I think it was some point around 1992 or -- I'm
25 sorry -- 1994, something like that.

1 And it was in the Office of Research,
2 which was in the Office of Research and
3 Demonstrations. And it essentially was helping the
4 research group decide which of many risk adjustment
5 methodologies should be -- become the method for
6 payment for managed care plans.

7 Q. Were you involved in the design of the
8 risk adjustment system that's used today by -- by
9 CMS?

10 A. Yes.

11 Q. I meant to cover this earlier, but I
12 want to just briefly discuss your educational
13 background, and then I'm going to come back to your
14 CMS experience.

15 Where is your undergraduate degree
16 from?

17 A. Georgia State University.

18 Q. You have a Ph.D. in sociology from
19 Johns Hopkins University?

20 A. Yes.

21 Q. Do you have any legal training?

22 A. No.

23 Q. Any other degrees beyond the --

24 A. I did a postdoc at University of
25 Maryland Medical School. I have a master's degree

1 from Georgia State as well.

2 Q. What was your master's from Georgia
3 State?

4 A. Also in sociology.

5 MR. BAAK: Let's go ahead and mark our
6 first exhibit today, which, Jordan, let's go to
7 Tab 27 -- 67, rather.

8 MS. MCMAHON: Can I interrupt for one
9 second? Dr. Tudor, are you signed on to AgileLaw
10 yet?

11 THE WITNESS: I don't think so. Let me
12 see if I can find it. Let's see. There's
13 AgileLaw. Let's try to join now.

14 MS. MCMAHON: I did email the PIN to
15 you, but if you need me --

16 THE WITNESS: Yeah. This says "Waiting
17 to be authenticated."

18 MS. MCMAHON: Okay. Perfect.

19 MR. GOLDS: You should be in now,
20 Dr. Tudor.

21 THE WITNESS: It still hasn't given me
22 anything to click on yet. It says on -- it says
23 "Tudor, Cynthia" on it, but it doesn't -- I don't
24 have anything showing up.

25 MS. MCMAHON: Oh, yes, I think they

1 to go through the formal rulemaking procedure as
2 opposed to more informal subregulatory guidance?

3 MS. MCMAHON: Objection. Form.

4 THE WITNESS: I -- I'm -- I'm not
5 really familiar with that. I'm -- and I'm talking
6 about putting out on a website something. I'm not
7 really familiar with what they put out on websites
8 on that issue.

9 BY MR. BAAK:

10 Q. Fair.

11 More generally, during your time at
12 CMS, do you remember any sort of written policy
13 that was administered by CMS that told you we need
14 to go through the formal Administrative Procedure
15 Act route versus something more informal?

16 A. I don't really remember that. I -- I
17 can remember conversations where someone -- and I
18 can't remember the name of the office -- might say
19 you need to put out a rule. And our answer was, we
20 have -- under this statute, we have the right to
21 publish an Advance Notice and then a Final Rates
22 Notice, and then it will go in that.

23 Q. I think you indicated you had some
24 familiarity with the Allina Health case the supreme
25 court issued several years ago. Is it your

1 understanding that that has influenced when CMS
2 thinks it needs to pursue formal regulation as
3 opposed to subregulatory guidance?

4 A. I think that --

5 MS. MCMAHON: Objection. Calls for
6 speculation.

7 THE WITNESS: I -- I don't think I
8 could answer that. That happened, really, when I
9 was leaving -- either after I had left or when I
10 was leaving. So I didn't pay a lot of attention to
11 it.

12 BY MR. BAAK:

13 Q. Understood.

14 I mentioned, Dr. Tudor, earlier -- I
15 asked earlier who you recalled meeting with from
16 UnitedHealth. And you mentioned Steve Nelson as
17 somebody you remember. What do you remember just
18 in general about your interactions with Mr. Nelson?

19 A. He was a pleasant man.

20 MS. MCMAHON: Objection. Vague.

21 BY MR. BAAK:

22 Q. Did you have a good working
23 relationship with Steve Nelson?

24 A. Yes.

25 Q. Do you recall meeting with Steve Nelson

1 and other executives from United in April of 2014?

2 A. No.

3 Q. Can you recall just -- I know it
4 sounded like you met with Mr. Nelson somewhat
5 regularly; is that correct?

6 A. Yes.

7 Q. Do you recall the specifics about what
8 was discussed at any of those meetings with
9 Mr. Nelson?

10 A. No.

11 Q. Do you recall the specifics of any
12 meeting you had with anyone from UnitedHealth,
13 Mr. Nelson or otherwise?

14 A. The specifics, I would say no.

15 Q. Do you recall the subject matters of
16 any of the meetings you had with Mr. Nelson or
17 anyone else from United?

18 A. Well, a lot of times, United would come
19 in and talk to us about clinical programs they had
20 for one purpose or another. Sometimes they would
21 talk about their marketing. Those are -- those are
22 the ones that sort of -- in general, that's what
23 plans talked to us about.

24 Q. I asked about the -- an April 2014
25 meeting with Mr. Nelson, and I think you just said

1 you don't recall the specifics. Do you recall in
2 general the April 2014 meeting you had with Steve
3 Nelson?

4 A. Well, only because people had asked for
5 what was in my Day-Timer at the time. And I looked
6 at my Day-Timer, and it told me that there had been
7 a meeting.

8 Q. You're referring to your Day-Timer.
9 Dr. Tudor, did you take notes at the meeting you
10 had with Steve Nelson and others from United in
11 April of 2014?

12 MS. CHEN: Object to form.

13 THE WITNESS: I don't know about the
14 date, but I know that there was a piece of paper
15 that had something on it.

16 BY MR. BAAK:

17 Q. Was it your practice to take notes of
18 meetings with -- your meetings with Steve Nelson?

19 A. No. Not necessarily. It'd depend upon
20 what the subject of the meeting was. It'd depend
21 upon who else was there, what role I was serving.
22 It's all sort of situational.

23 Q. Did reviewing the notes you took of the
24 April 2014 meeting in your Day-Timer, the meeting
25 with Steve Nelson and others from United, did it

1 refresh your recollection at all about what the
2 subject matter of that meeting was?

3 A. Well, my -- the way I remember that
4 piece of paper, it was pretty vague. And it -- you
5 know, there were other people there who knew more
6 than I did about these subjects. So I -- as my
7 general practice was, those people should take the
8 lead.

9 Q. And the subjects you just referenced,
10 what were the subjects of that April 2014 meeting,
11 as you recall?

12 A. I don't -- I don't --

13 MS. CHEN: Object to form.

14 THE WITNESS: I don't really remember
15 this April '14 meeting, so I don't think I can
16 answer that.

17 BY MR. BAAK:

18 Q. Do you recall how it was determined
19 that you would attend the April 2014 meeting with
20 Mr. Nelson and others from United?

21 A. Well, I was the deputy director, so I
22 was there. Because I'm sure that whoever was the
23 director -- I think it was Sean Cavanaugh at that
24 point -- told me to come, so I came.

25 Q. Do you recall what you said, if

1 anything, at the April 2014 meeting?

2 A. No.

3 Q. Do you recall what Mr. Cavanaugh said
4 at the April 2014 meeting with UnitedHealth?

5 A. No.

6 Q. Do you recall what Cheri Rice said at
7 the April 2014 meeting with UnitedHealth --

8 A. No.

9 Q. -- executives?

10 A. No.

11 Q. Do you remember saying anything at the
12 April 2014 meeting with Steve Nelson and the other
13 United executives?

14 A. No.

15 Q. In your experience, who would have been
16 the person who would normally take a lead in a
17 meeting like that --

18 MS. MCMAHON: Objection. Vague.

19 BY MR. BAAK:

20 Q. -- from the CMS side?

21 A. Well, if Sean Cavanaugh was there, it
22 would have been the -- the director would have
23 started, unless the director said somebody take the
24 lead, and they would have done that.

25 Q. Do you recall anything that Steve

1 Nelson said at the April 2014 meeting that you had
2 with him?

3 A. No.

4 Q. Do you recall anything that anyone from
5 the UnitedHealth -- do you remember any of the
6 other -- let me withdraw that.

7 Do you remember any of the other
8 attendees, beyond Mr. Nelson, at the April 2014
9 meeting you had?

10 A. I don't.

11 Q. Do you recall anything that anyone from
12 the -- the group that came from UnitedHealth said
13 at the April 2014 meeting you had?

14 A. I don't remember the meeting. Again, I
15 remember the piece of paper, but I don't really
16 remember the meeting.

17 Q. Let me show you the meeting invite,
18 which is Tab 26, and it's previously been marked as
19 Exhibit 1059.

20 (EXHIBIT 1059, Appointment dated
21 4/29/14, Subject: Meet with Optum, Bates
22 USBP051354814, was previously marked for
23 identification.)

24 BY MR. BAAK:

25 Q. Tell me when that is in front of you.

1 A. I have it.

2 Q. Great.

3 Exhibit 1059 is Bates-stamped ending in
4 4814. And it is an appointment from Outlook, it
5 appears. And it's to you. It's sent from
6 Alyssa [sic] Simpkins. Do you see that?

7 A. Yes.

8 Q. Who is Alyssa [sic] Simpkins?

9 A. I don't remember. My guess is that she
10 was the -- the administrative assistant for Sean,
11 but I could be wrong.

12 Q. And the recipients include you, Cheri
13 Rice, Jennifer Harlow, Julia [sic] Uebersax and
14 Robert Ahern, correct?

15 A. Ahern, yes.

16 Q. Ahern.

17 Do you recall which of the recipients,
18 other than yourself and Cheri Rice, attended the
19 meeting?

20 A. No. I don't know whether the special
21 assistants were there. That's -- Julie Uebersax at
22 that point and Rob Ahern were both special
23 assistants. I -- I don't know who was there,
24 though.

25 Q. Do you see down below it says meeting

1 That's what it says. I don't know what
2 it means.

3 Q. Do you recall who provided the
4 information that you wrote down in the bottom
5 left-hand corner of your notes about the obligation
6 to stop review or tell us what they found?

7 A. No.

8 Q. Do you recall who -- do you surmise
9 that this is also information that came from
10 United, at least in part?

11 MS. MCMAHON: Objection. Calls for
12 speculation.

13 BY MR. BAAK:

14 Q. Actually, let me withdraw that.

15 Do you recall who at the meeting,
16 whether it was someone from CMS or United, said
17 stop work at the -- at the end?

18 A. I don't -- I don't know who said it.

19 Q. The date 2012 -- so this meeting is
20 taking place in 2014. Did you understand that 2012
21 date to refer to the dates of service for which the
22 attestation was -- was coming up?

23 MS. MCMAHON: Objection. Calls for
24 speculation.

25 THE WITNESS: I don't -- I don't really

1 remember.

2 BY MR. BAAK:

3 Q. And what does -- in your experience,
4 what does "chart review" refer to?

5 MS. MCMAHON: Objection. Vague.

6 THE WITNESS: Well, in general, chart
7 review is looking at a chart to see what's in it,
8 what's documented.

9 BY MR. BAAK:

10 Q. During your time at CMS, did you come
11 to understand that Medicare Advantage plans
12 conducted chart reviews to look for diagnosis
13 codes -- to look for diagnoses that maybe the
14 provider failed to include?

15 MS. MCMAHON: Objection. Vague.

16 THE WITNESS: Well, that's one reason
17 for chart review.

18 BY MR. BAAK:

19 Q. And if I use the -- in part, to keep
20 things simple, if I -- if I use the term "chart
21 review" to that process by which a chart is
22 reviewed to potentially add diagnosis codes, do you
23 understand what I'm referring to?

24 A. Yes.

25 Q. Do you recall who -- who said -- the

1 section on the obligation to stop review or tell us
2 what they found, do you recall whether someone from
3 CMS said that to United?

4 A. No, I don't remember.

5 Q. Based on the context, does that look
6 like something that came from CMS?

7 A. I don't remember.

8 Q. Just stepping back from the notes a
9 little bit, there's a reference to "attestation."
10 What do you understand "attestation" to refer to?

11 A. Well, the attestation is a requirement
12 that either the CEO or the CFO attests to the
13 reliability of the risk adjustment data being
14 submitted to CMS.

15 Q. Is that an annual process?

16 MS. MCMAHON: Objection.

17 THE WITNESS: I believe it's more than
18 an annual process. I believe that monthly they're
19 supposed to do this. But I'd have to go look at
20 what the requirements are.

21 BY MR. BAAK:

22 Q. You can set the notes aside or -- or --
23 electronically or otherwise. I want to just ask
24 the follow-up on your answer on chart review a
25 second ago.

1 Q. Just take a second to review this.

2 A. Okay.

3 (Witness peruses document.)

4 Q. And I'm going to focus just on the top
5 section.

6 A. Okay.

7 Q. And this is under the category of
8 improving payment accuracy, and it says: To
9 strengthen existing regulations on Medicare
10 Advantage organizations' accountability for valid
11 risk adjustment data validation prior to
12 submission, we recommend proposing that -- and then
13 there's a colon. Do you see that?

14 A. Yes.

15 Q. Let's go through. There's two bullets
16 after -- just so we're clear on the context, these
17 are proposals that CMS was thinking about offering;
18 is that accurate?

19 MS. MCMAHON: Objection. Vague.

20 THE WITNESS: I -- I don't know. I --
21 given the time, the date of this presentation, my
22 guess is it was some sort of briefing document for
23 internal CMS use.

24 BY MR. BAAK:

25 Q. Right. I can show you an email later

1 if it'd help refresh your recollection. But, yes,
2 this is an internal -- you understood this is an
3 internal CMS document that's talking about various
4 policy proposals that CMS might adopt, correct?

5 A. Yes.

6 Q. So these are not -- this is
7 forward-looking. These are new rules that CMS is
8 thinking about implementing, correct?

9 A. Yes.

10 MS. MCMAHON: Object.

11 BY MR. BAAK:

12 Q. And one of the new rules -- let's just
13 start with the bullet -- the first bullet here
14 that -- this is what CMS is thinking about
15 proposing.

16 And CMS is thinking about proposing
17 here in 2013 that MA organizations -- that's
18 Medicare Advantage, right?

19 A. Yes.

20 Q. -- Medicare Advantage organizations
21 that conduct internal medical record review for the
22 purposes of submitting risk adjustment data to CMS
23 would have to identify overpayments as well as
24 underpayments, correct?

25 A. Yes.

1 Q. So this is something that CMS is
2 contemplating proposing through regulation in 2013,
3 correct?

4 A. I don't know whether they proposed it
5 in 2013, but yes. They were propose -- they were
6 thinking about proposing.

7 Q. I think it was actually proposed in
8 2014, but we'll get to the rule in a little bit.

9 A. Okay.

10 Q. But as of 2013, CMS is deliberating
11 internally about whether to impose this new
12 requirement on Medicare Advantage plans, correct?

13 A. Yes. Yes.

14 MS. MCMAHON: Objection. Form.

15 BY MR. BAAK:

16 Q. And then the second bullet says -- this
17 is another change that's being contemplated --
18 Medicare Advantage organizations would not be able
19 to submit additional diagnoses for the payment year
20 after payment reconciliation. And then it says, in
21 parentheses, (codifies current practice). Correct?

22 A. Yes.

23 Q. The "codifies current practice"
24 language, that's not in the prior bullet on the --
25 the new proposal for medical record reviews,

1 correct?

2 A. Yes.

3 Q. Does this situate you back in time that
4 in 2013 CMS was contemplating a new proposal -- a
5 new obligation for Medicare Advantage plans on how
6 they conduct chart review?

7 MS. MCMAHON: Objection. Form.

8 THE WITNESS: Well, it doesn't require
9 them to do it, at least the way this is written.
10 It only requires that they do it both ways if they
11 do it.

12 BY MR. BAAK:

13 Q. Thank you for that clarification.

14 So the first bullet I'm just focusing
15 on is just a recognition that Medicare Advantage
16 plans, you know, may conduct chart review, not --

17 A. Right.

18 Q. -- that they have to, correct?

19 A. Right.

20 Q. And the rule -- the new rule in 2013
21 that CMS was thinking about is telling plans that
22 if you do that kind of chart review for risk
23 adjustment, you have to look for overpayments as
24 well as underpayments. That's what was being
25 contemplated, correct?

1 they're unlikely to affect your year two cost
2 because the flu or in a broken arm is gone.

3 BY MR. BAAK:

4 Q. And so if I'm a Medicare Advantage
5 plan, and I learn that a particular code was just
6 submitted in error, I might delete that code, but
7 it might not have any impact on the ultimate risk
8 adjustment payment, correct?

9 A. That's correct.

10 MS. CHEN: Objection.

11 BY MR. BAAK:

12 Q. And another reason that might be true
13 is, let's say I do a chart review and I don't find
14 a particular diagnosis code that was submitted in
15 one record, and so I delete it. But, in fact, it's
16 supported by another record. That's another
17 example, right, where a deletion of a code doesn't
18 impact the risk adjustment payment, right?

19 MS. MCMAHON: Objection. Calls for
20 speculation.

21 THE WITNESS: Yes, generally.

22 BY MR. BAAK:

23 Q. If a Medicare Advantage plan then finds
24 a diagnosis code and deletes it -- actually, let me
25 step back and rephrase that.

1 Another reason that if you delete a
2 particular unsupported code, it might not be --
3 have an impact on risk adjustment payment is that
4 it rolls up into -- that you have another diagnosis
5 that rolls up into the same hierarchical condition
6 code, correct?

7 A. That's -- that's true.

8 MS. CHEN: Objection.

9 BY MR. BAAK:

10 Q. So if I'm a Medicare Advantage plan,
11 and I'm looking at charts and I -- or I get wind
12 from the provider who tells me, "Hey, we made a
13 mistake. This code was wrong," that doesn't
14 necessarily tell me, if I'm the plan, that I've
15 been overpaid, correct?

16 MS. MCMAHON: Objection to form.

17 THE WITNESS: You have enough
18 information to determine whether you've been
19 overpaid, but you have to run that person through a
20 risk adjustment methodology to find out if you
21 have.

22 BY MR. BAAK:

23 Q. Right. The plan might go delete the
24 code, but just knowing that there was a single code
25 that was unsupported, that alone wouldn't tell you

1 you've been overpaid if you're the plan, right?

2 MS. MCMAHON: Objection.

3 THE WITNESS: Probably.

4 BY MR. BAAK:

5 Q. You would need to know, for example, if
6 another record supported the code, correct?

7 A. Yes. Yes.

8 MS. CHEN: Objection.

9 BY MR. BAAK:

10 Q. A few minutes ago, you were talking
11 about, sort of in general, your view of how plans
12 ought to run down areas where they thought they had
13 some indication that the code might be wrong.

14 Do you ever articulate -- do you recall
15 ever articulating kind of what -- what percentage
16 or what degree of suspicion a plan had to have to
17 go investigate a code?

18 A. No.

19 MS. MCMAHON: Objection.

20 MS. CHEN: Objection.

21 BY MR. BAAK:

22 Q. And as someone who continues to consult
23 in the industry, sitting here today, do you have a
24 view as to how much information a plan would have
25 to have that a code might be unsupported to go do

1 further investigation?

2 MS. MCMAHON: Objection.

3 THE WITNESS: You know, if you asked me
4 as -- as somebody who knows how to research topics,
5 I could ponder it. But I haven't really
6 articulated that.

7 BY MR. BAAK:

8 Q. What I'm trying to get at is, given
9 that we know there's a certain number of codes in
10 the data that just are going to be wrong, right, a
11 certain number of diagnosis codes that are going to
12 be unsupported, correct?

13 A. Yes, some number.

14 Q. And CMS has never said you've got to go
15 check every code, correct?

16 A. Correct.

17 Q. In your view, would a plan need to know
18 that it's sort of -- that any given code is more or
19 less -- more likely than not to have resulted in an
20 overpayment to go investigate?

21 MS. MCMAHON: Objection.

22 THE WITNESS: Say again.

23 BY MR. BAAK:

24 Q. Yeah, it was -- it was confusing. Let
25 me try that again.

1 investigate a code or not, would it be appropriate
2 to take into account whether a given code is more
3 likely than any random code to have resulted in an
4 overpayment?

5 A. Well --

6 MS. MCMAHON: Objection.

7 THE WITNESS: -- I think my -- my
8 answer stands. I still think there's other issues
9 they have to look at.

10 BY MR. BAAK:

11 Q. During your time at CMS, did you ever
12 supervise folks that -- for CMS who were doing
13 reviews of medical records to look for diagnosis
14 codes?

15 A. Well, part of the Medicare Plan Payment
16 Group was the national error rate, which was, what
17 is the percentage of payments made incorrectly to
18 Medicare Advantage plans under -- under that
19 system.

20 So they were doing some medical record
21 reviews there, and I supervise -- I -- people who
22 did that reported to people who reported to me.

23 Q. Understood.

24 So, Dr. Tudor, it sounds like you were
25 not reviewing medical records, but --

1 A. Correct.

2 Q. -- somewhere down in the CMS
3 organization, there were folks that were
4 reviewing --

5 A. Yes.

6 Q. -- medical records --

7 A. Yes.

8 Q. -- that reported up to you, correct?

9 A. Yes. And there were studies
10 occasionally of -- of things like Part D
11 prescribing where we got medical records to look at
12 what was going on and various things. But I'm not
13 a physician, so I generally don't review medical
14 records.

15 Q. There was one point I wanted to circle
16 back on. We talked about situations where a
17 Medicare Advantage plan might delete a code that
18 does risk adjust, but there's no overpayment
19 because that code was supported by another provider
20 record. Do you recall those questions?

21 A. Yes.

22 Q. In that scenario, if the plan did not
23 delete the code, there still would be no
24 overpayment, right, because even the deletion of
25 the code did not impact payment?

1 MS. MCMAHON: Objection. Form.

2 THE WITNESS: Yes.

3 BY MR. BAAK:

4 Q. And similarly -- so the plan deletes --
5 if the plan finds a code that if it deleted would
6 not impact payment, it's also the case that the --
7 the identification of that particular unsupported
8 code, the inclusion of that in the risk adjustment
9 data in the first place did not cause an
10 overpayment, right?

11 MS. MCMAHON: Objection. Vague.

12 THE WITNESS: I don't know how to
13 answer that question.

14 BY MR. BAAK:

15 Q. Well, let me just see if I can be a
16 little more precise with the hypothetical.

17 If -- if a plan determines that a
18 particular diagnosis code is not supported --
19 right?

20 A. Right.

21 Q. -- but if they -- but that code is
22 supported, for example, by another record in my
23 hypothetical --

24 A. Right.

25 Q. Do you have me -- with me so far?

1 A. Yes. Yes.

2 Q. -- on those facts, the plan might go
3 ahead and delete the code that they found that was
4 unsupported, but the initial submission of that
5 code did not result in any overpayment because
6 there was no impact on risk adjustment, right?

7 A. Right.

8 MS. MCMAHON: Objection.

9 BY MR. BAAK:

10 Q. I have questions -- a couple questions
11 on chart review, and we won't spend a lot of time
12 on them.

13 But, you know, in your experience,
14 like -- particularly today, if you're advising a
15 plan, if it goes and looks -- it's doing chart
16 review, and it doesn't find a code that was
17 submitted, but it doesn't have the complete medical
18 record, in your view, should the plan delete that
19 code?

20 MS. MCMAHON: Objection.

21 THE WITNESS: Well, I think from a
22 business standpoint, the plan needs to try to get
23 the medical record, whatever part of it they think
24 they're missing.

25 And if they can't, then they need to --

1 I mean, again, I'm protecting the business in the
2 answer to this question -- they should be doing
3 other things to see whether clinically -- it could
4 have disappeared, whether or not there are drugs
5 that indicate the person does have that problem,
6 just other things they could do to validate
7 whether -- in the absence of the right medical
8 record, this could be sustained.

9 BY MR. BAAK:

10 Q. So I guess the way you would approach
11 this, it would depend on the context, right?

12 A. Absolutely.

13 Q. If you can't get the complete medical
14 record, and you know you don't have the complete
15 medical record, the mere fact the diagnosis code
16 isn't there doesn't tell you the diagnosis code is
17 wrong and needs to be deleted. You'd have to look
18 at sort of other information, correct?

19 MS. MCMAHON: Objection.

20 THE WITNESS: Right. But, you know, if
21 you're looking -- if you're missing the -- the
22 dermatologist's record and you're looking for
23 congestive heart failure, my belief is that
24 dermatologist records are not going to help you,
25 and truly, you have the records that are important

CERTIFICATE OF REPORTER

I, Cindy A. Hayden, Registered Merit Reporter and Notary Public for the State of Maryland at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 26th day of August, 2022.

Cindy A. Hayden

Cindy A. Hayden, RMR, CRR

My Commission expires

April 26, 2025

EXHIBIT D-146

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
JULIE UEBERSAX
Given Remotely
Wednesday, June 29, 2022
10:05 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 the -- like I said, over the years at CMS, and -- and
2 differing -- conversations with differing Department
3 of Justice attorneys over the years.

4 Q. So other than the conversations with
5 Department of Justice attorneys, did those
6 conversations involve discussing the merits of this
7 case?

8 A. Not that I can recall.

9 Q. Is it your testimony that the
10 conversations were more, where does this case stand,
11 for example?

12 A. Correct. Right. It's an ongoing matter.

13 Q. Okay. I'd like to turn to your
14 educational background briefly. Did you graduate
15 from an undergraduate institution?

16 A. I did.

17 Q. Which one?

18 A. Towson. Towson State University.

19 Q. What was your major there?

20 A. Psychology.

21 Q. And when did you graduate?

22 A. 1998.

23 Q. Did you attend graduate school?

24 A. I did.

25 Q. Where?

1 A. University of Baltimore.

2 Q. And what did you study there?

3 A. Law.

4 Q. Did you receive your JD?

5 A. I did.

6 Q. What year?

7 A. 2002.

8 Q. I missed that. Was it 2002? Is that what
9 you said?

10 A. Correct. 2002.

11 Q. Are you currently admitted to any bars?

12 A. I am.

13 Q. Which?

14 A. At the State of Maryland.

15 Q. When were you first admitted to the
16 Maryland bar?

17 A. In 2002.

18 Q. And have you maintained active membership
19 in the Maryland bar since 2002?

20 A. I have.

21 Q. Have you practiced as an attorney at any
22 point in your career after graduating?

23 A. I did.

24 Q. And when was that?

25 A. Immediately following my being sworn in, I

1 was an attorney practicing law until I joined the
2 government in October of 2010.

3 Q. What type of law did you practice?

4 A. I worked at a law firm that I refer to as
5 sort of a boutique firm, where we represented general
6 business clientele, for which we performed services
7 in that nature. So it was kind of a -- I'd say a
8 broad base of contract law, employment law, you know,
9 some real estate, leases, transactions of those
10 nature -- of that nature.

11 Q. And how long were you a practicing
12 attorney?

13 A. From the time I was sworn in, in 2002,
14 until I -- until I left that job and became employed
15 by the government in October of 2010.

16 Q. Have you ever been employed in a legal
17 capacity during your time at the government?

18 A. No.

19 Q. So you don't provide legal advice as part
20 of your job?

21 A. No. Not on the government's behalf. I'm
22 sorry.

23 Q. My apologies.

24 And is it -- is it accurate that you never
25 have, since joining the government?

1 A. That's correct. I do not represent the
2 government.

3 Q. When you first joined the government, did
4 you join CMS?

5 A. I did.

6 Q. And you said that was October 2010, right?

7 A. That's correct.

8 Q. What was your first job at CMS, starting
9 in October of 2010?

10 A. As a health insurance specialist in one of
11 the divisions of the Medicare Plan Payment Group.

12 Q. Is that abbreviated MPPG?

13 A. Correct.

14 Q. Was there a specific division that you
15 were working when you first joined?

16 A. Yes. The acronym was DRAPP. I believe it
17 stood for Division of Risk Adjustment and Payment
18 Policy. It was something like that. DRAPP was the
19 acronym.

20 Q. And how long did you work as a health
21 insurance specialist in DRAPP for?

22 A. For approximately a year and a half to
23 two years.

24 Q. Who did you directly report to, as a
25 health insurance specialist at DRAPP --

1 A. Sean --

2 Q. -- when you first started?

3 A. I'm sorry.

4 Sean Creighton was my immediate supervisor
5 at that time.

6 Q. And what were your job responsibilities at
7 that time?

8 A. So it was -- I was brought on board to
9 facilitate payment -- the development of payment
10 policy. The ACA, the Affordable Care Act, had
11 recently passed, and there were a number of statutory
12 changes being made at that time, so my responsibility
13 was to engage in those activities and the policy
14 development underlying those changes.

15 Q. So your focus was ACA-related work?

16 A. Primarily, yes.

17 Q. What other areas -- you said "primarily,"
18 so what other areas were there that you worked on?

19 A. There was ad hoc -- you know, other
20 related areas of -- being new to the government and
21 new to the work, I was given, you know, broad
22 training and responsibility to sort of learn all
23 the -- the foundational elements of Medicare
24 Advantage, the historical payment policies and such,
25 so . . .

1 Q. Did any of your work involve risk
2 adjustment?

3 A. Some of it.

4 Q. What types of work did you do related to
5 risk adjustment?

6 A. So when I was first coming to the
7 government, one of the areas I was learning was, what
8 is risk adjustment? How does it function generally
9 within the Medicare Advantage program? What is a
10 risk adjustment model? What are the principles of
11 risk adjustment? Some -- you know, some of those
12 basic elements, and how it relates to payment.

13 Q. Do you have any -- can you think of any
14 examples of projects you worked on related to risk
15 adjustment at that time?

16 A. I don't know that I could recall very a
17 specific project. I can say generally that there
18 were pieces of risk adjustment. As I said, sort of
19 learning how the model functions and what -- how it
20 impacts payment. But off the top of my head, I can't
21 remember a specific project, no.

22 Q. What was your next job, after health
23 insurance specialist at DRAPP?

24 A. So after that, there was a brief time that
25 I was on detail as special assistant. That

1 ultimately became a permanent position. Special
2 assistant to Cheri Rice, who was the group director
3 for the Medicare Plan Payment Group.

4 Q. How long did you serve as a special
5 assistant to Cheri Rice?

6 A. From approximately two thousand --
7 sometime in 2012 to sometime -- I want to say in
8 2015, roughly.

9 Q. Had you worked with Cheri Rice before
10 becoming her special assistant?

11 A. She had -- she was the group director at
12 the time that I reported to Sean Creighton, so she
13 has been -- she was in my management chain. So I did
14 not work for her directly, but indirectly, yeah.

15 Q. Had you interacted with her before
16 becoming her special assistant?

17 A. Yes.

18 Q. You said that was approximately 2012 to
19 sometime in 2015, right?

20 A. Right, approximately. I don't remember
21 the specific dates, but that's about right.

22 Q. And why did you -- why did you leave the
23 special assistant role in roughly 2015?

24 A. To take a different position in the
25 Medicare Plan Payment Group, in a different division.

1 And it was a promotion.

2 Q. And what was that new role?

3 A. The title of the job was also health
4 insurance specialist, but it was in, I -- I believe,
5 division of -- I don't remember the name of the
6 division. I apologize. But it was in a different
7 division. One of the divisions in the Medicare Plan
8 Payment Group.

9 Q. Was it Division of Payment Systems?

10 A. Yes, that's correct.

11 Q. And you said that was a promotion from the
12 special assistant role; is that right?

13 A. Correct. Correct.

14 Q. And how long did you work as a health
15 insurance specialist at DPS?

16 A. Until I left the Medicare Plan Payment
17 Group to take a job as Cheri's senior advisor in her
18 current role. I want to say that was approximately
19 sometime in the summer of 2019, I believe.

20 Q. And what did your job responsibilities
21 entail while serving as a health insurance specialist
22 at DPS?

23 A. Sure. I was a senior advisor in -- or a
24 senior technical advisor in that division, where that
25 division has primary responsibility for developing

1 policies, payment policies related to Part C and D
2 payment that are unrelated to risk adjustment.

3 So that's the easiest way I can define it.
4 So it was everything but risk adjustment under Part C
5 in the payment policy.

6 Q. And what types of policies, specifically,
7 were you helping develop?

8 A. So there are a lot of underlying payment
9 mechanisms in the Medicare Advantage in Part D
10 programs. And so in Medicare Advantage, for example,
11 there are the benchmarks that need to be calculated
12 in conjunction with the Office of the Actuary. There
13 are various other payment policies that need to be,
14 you know, considered; how to pay employer group
15 waiver plans, and developing Part D policies, like
16 for the Advance Notice rate announcement process,
17 like the benefit parameters and such.

18 Q. And then you said approximately summer
19 2019, you left that role and became a senior advisor
20 working with Cheri Rice again?

21 A. Correct.

22 Q. Is that your current role as well?

23 A. That's true, yes. That's accurate.

24 Q. What's your official title?

25 A. Health insurance specialist.

1 Q. And what does your current role involve?

2 A. So it's -- it's hard to describe, but I
3 describe it as a lot of strategic planning, which is
4 anything from facilitating policy development to
5 perhaps researching, you know, independent projects,
6 communicating with the office of legislation on
7 technical assistance, things of that nature.

8 Q. So one thing you mentioned was
9 facilitating policy development.

10 A. Yes.

11 Q. What does that entail?

12 A. It's also pretty broad. Some of that is
13 coordinating efforts between our leadership, Cheri,
14 each of the underlying groups, understanding when a
15 question comes down who to ask, how to ask it, how to
16 make sure that we're being responsive. Also things
17 like how to put forward policies in a way that makes
18 sense in, you know, a strategic way, you know, when
19 to talk about certain things and in a -- in a
20 rule-making cycle or an Advance Notice rate
21 announcement-type cycle of our, you know, processes,
22 and how those things operate within the agency.

23 Q. Are you responsible for drafting
24 substantive policies?

25 A. No, not in my current role.

1 Q. Have you previously been responsible for
2 drafting substantive policies?

3 A. In the past I have participated in the
4 development of substantive policies, yes.

5 Q. Which substantive policies have you
6 participated in the development of?

7 MS. ZUPAC: Objection. Vague.

8 You can answer.

9 THE WITNESS: One example would be when I
10 was a health insurance specialist in the
11 Medicare Plan Payment Group in the DPS position.
12 One thing that I worked on was the development
13 of a Part C employer group waiver plan payment
14 policy. That was something that I worked
15 closely with -- with the Office of the Actuary
16 to develop, propose, and finalize.

17 BY MR. ROWE:

18 Q. What other examples can you think of?

19 A. At one point in time I was involved in
20 helping develop the policy with regard to Part D
21 payment, with DIR and pharmacy price concessions, and
22 how that should or could be reported to the
23 government.

24 Q. Any other examples you can think of?

25 A. I mean, there's been a wide range over the

1 years of different policies. I've been involved
2 in -- either ancillary or -- you know, I don't know
3 that I could specifically articulate some -- those --
4 those two that I mentioned are -- are some that are
5 reasonably recent and where I had some significant
6 involvement.

7 Q. Have any of the policies related to risk
8 adjustment?

9 A. Not that I can recall, in having a
10 significant role.

11 Q. Going back to your time as special
12 assistant to Cheri Rice, which you said was
13 approximately 2012 to approximately 2015, right?

14 A. In that range, correct.

15 Q. What did your job as a special assistant
16 entail?

17 A. Again, it's -- it's kind of a hard job to
18 describe; but again, as a sort of a facilitator
19 between Cheri and the divisions, and also as a
20 liaison to our business office staff, and to
21 coordinate, you know, requests that we would get from
22 other areas of the agency or other, you know,
23 higher-ups, if you will, about requests and -- and
24 how to answer requests, and that nature.

25 So it was a role where a lot of -- a lot

1 of items would come through me in order to get
2 coordinated and responded to.

3 Q. Did your responsibilities change over
4 time? Or were they roughly the same during your
5 tenure as special assistant to Cheri Rice?

6 A. I would say roughly the same.

7 Q. Did you attend meetings with Ms. Rice?

8 A. I did.

9 Q. Did you regularly attend meetings with
10 Mrs. Rice -- Ms. Rice?

11 A. Yes. Not every meeting, but regularly.

12 Q. Did you ever attend meetings on behalf of
13 Ms. Rice?

14 A. Occasionally, in -- as special assistant.
15 Not often.

16 Q. When you attended meetings with Ms. Rice,
17 what would your role be in those meetings?

18 A. It would vary. Sometimes it's just to be
19 present and listen. Sometimes it would be to take on
20 follow-up actions as -- as needed.

21 Q. Would you typically take notes during
22 meetings?

23 A. It would depend on the nature or type of
24 the meeting. Sometimes I would, and -- and sometimes
25 it would not be my practice to do so, depending on

1 Q. Did you discuss this meeting with anyone
2 beforehand?

3 A. Not that I recall.

4 Q. Do you recall preparing for this meeting
5 in any way?

6 A. Not that I can recall.

7 Q. Do you recall discussing the meeting with
8 Cheri Rice in advance?

9 A. Not that I can recall.

10 Q. Do you recall preparing Cheri Rice in any
11 way before this meeting?

12 A. No, not that I can remember. No.

13 Q. Do you recall how you first found out
14 about this meeting?

15 A. No. I don't remember.

16 Q. Do you recall whether you knew, heading
17 into the meeting, that the proposed rule was not
18 going to be finalized?

19 A. I don't remember anything about that, no.

20 Q. You said the meeting took place in Sean
21 Cavanaugh's office, correct?

22 A. That's my recollection.

23 Q. Do you recall whether everybody was there
24 in person?

25 A. To the best of my recollection, the CMS

1 people were in person. The United folks were on VTC
2 or television screen at a different location.

3 Q. Do you know why they were in a different
4 location?

5 A. No, I don't know.

6 Q. Do you recall how long the meeting lasted?

7 A. No. I don't remember.

8 Q. During the meeting, United raised various
9 issues, correct?

10 A. As I said, I don't recall specifically
11 much about the contents of the meeting. I generally
12 remember that it was for them to talk about a risk
13 adjustment program that they had.

14 Q. Do you recall them talking about claims
15 verification program?

16 A. I don't remember those specific words, no.

17 Q. Did you understand that United at that
18 time was doing two-way looks?

19 A. I don't --

20 MS. ZUPAC: Objection to form.

21 THE WITNESS: I don't remember anything
22 about that.

23 BY MR. ROWE:

24 Q. Do you recall that United during the
25 meeting was trying to understand whether the "look

1 both ways" rule would be finalized?

2 MS. ZUPAC: Object to form.

3 THE WITNESS: I don't -- I don't remember
4 that level of specificity about the discussion.

5 BY MR. ROWE:

6 Q. Do you recall that they were seeking to
7 understand their current obligations in light of that
8 proposed rule?

9 A. Again, I don't remember that level of
10 detail.

11 Q. Do you recall United describing the risk
12 adjustment program that they had in place?

13 A. Again, I have a general recollection that
14 they were discussing their risk adjustment program.
15 I don't remember any details about their description,
16 the discussion.

17 Q. You don't recall that they told you they
18 were currently doing two-way looks as part of that
19 program?

20 A. I don't recall that level of detail, no.

21 Q. Do you recall United discussing deletes
22 that it had already submitted for 2012 dates of
23 service?

24 A. I don't remember that level of detail.

25 Q. Do you recall that United told CMS that it

1 had suspended its two-way look program?

2 A. I don't remember.

3 Q. Do you recall that Cheri Rice told United
4 that until the proposed rule was finalized, MA plans
5 did not have a proactive obligation to confirm
6 whether diagnoses submitted by providers were
7 correct?

8 A. I don't remember that level of detail of
9 the meeting, no.

10 Q. Do you recall Cheri Rice saying that if a
11 plan had actual knowledge that a specific code
12 submitted by a provider was unsupported, that a plan
13 should delete the code?

14 A. I don't remember that level of detail.

15 Q. Do you recall anyone from CMS telling
16 United that existing rules did not require MA plans
17 to design their chart review programs to identify
18 unsupported codes submitted by providers?

19 A. I don't remember that level of detail.

20 Q. Do you recall anything that anyone from
21 CMS said at that meeting?

22 A. I don't recall any specific phrases,
23 conversations, no.

24 Q. Do you recall generally?

25 A. No.

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

21 Karen K. Kidwell
22 Registered Merit Reporter
23 Certified Realtime Reporter
24 Notary Public
25

EXHIBIT D-147

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

Videotaped Deposition of
MARYBETH MEYER
Given Remotely
Tuesday, June 7, 2022

Reported by: Karen K. Kidwell, RMR, CRR

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1 and accurate diagnoses, or do you think they can do
2 less than that?

3 A. I think physicians need to comply with
4 what CMS is asking.

5 Q. Okay. That's all I'm asking.

6 Right below, it says, "Physicians must
7 report the ICD-9-CM diagnosis codes to the highest
8 level of specificity and report these codes
9 accurately." Do you see that?

10 A. Yes.

11 Q. Do you agree that physicians must report
12 the diagnosis codes with the highest level of
13 specificity and report these codes accurately?

14 A. Again, this -- CMS is making this
15 requirement. I don't have an opinion on how they
16 define their requirements.

17 Q. Well, as -- as an experienced executive of
18 United, you have some involvement in dealing with CMS
19 requirements, correct?

20 A. In my role, I didn't have direct
21 responsibility for regulatory or CMS requirements.

22 Q. But you did have responsibilities relating
23 to the accurate reporting of diagnosis codes with
24 CMS, correct?

25 A. I had responsibility to ensure that we

1 submitted the codes that we received from the
2 providers.

3 Q. Did you have any responsibility at all
4 with respect to the accuracy of the codes that were
5 submitted to CMS?

6 A. No. I would say my responsibility was to
7 submit the codes as we received them from the
8 provider.

9 Q. If you were to learn that a code that was
10 submitted was inaccurate, you had no responsibilities
11 at all with respect to inaccurate codes?

12 A. If a provider told us that a code was
13 inaccurate, we would delete those codes.

14 Q. Okay. And that was because there was an
15 obligation to delete inaccurate codes, correct?

16 A. Again, I am not the one who defined the
17 obligations or the requirements.

18 Q. Well, you understood that that's what CMS
19 expected?

20 A. Well, I understand that that's what CMS
21 has specified in this technical guide, that providers
22 need to submit accurate diagnosis codes.

23 Q. And it was the responsibility of MAOs and
24 providers to submit accurate codes, right?

25 A. It was the provider's responsibility to

1 submit accurate codes. I think the Medicare
2 Advantage organization's responsibility was to submit
3 the data as they received it from the provider.

4 Q. Did the Medicare Advantage organization
5 have any responsibility at all to check the accuracy
6 of provider-submitted codes?

7 A. That would not have been something within
8 my scope to define.

9 Q. Is it your understanding that MAOs could
10 submit any and all codes that were given by providers
11 without any regard to the accuracy of the codes?

12 A. It's my understanding that MAOs were
13 responsible to submit the codes that we received from
14 the providers.

15 Q. Did MAOs have any obligation to ensure
16 that the codes provided by the providers were
17 accurate?

18 A. Again --

19 MR. MERON: Objection. Asked and
20 answered.

21 THE WITNESS: -- defining that obligation
22 was not something within my scope of
23 responsibility.

24 BY MR. LEE:

25 Q. Right. I'm not asking you to define it,

1 but I'm asking you if you understood it to be an
2 obligation of MAOs.

3 MR. MERON: Asked and answered.

4 THE WITNESS: Have an opinion on that. It
5 was not something that was within my scope of
6 responsibilities.

7 BY MR. LEE:

8 Q. Did -- did United delete inaccurate codes
9 out of the goodness of its heart or because it felt
10 that it was an obligation owed to CMS?

11 A. Again, the process for deleting codes
12 was -- other than -- if a provider came to us and
13 told us they submitted the data inaccurately, we
14 would delete the codes. Other reasons for deleting
15 the codes were outside of my scope of responsibility.

16 Q. Why did United delete inaccurate codes?

17 A. If the provider told us they made a
18 submission error, we would delete those codes.

19 Q. But why? Because it was an obligation,
20 correct?

21 MR. MERON: Objection.

22 THE WITNESS: Again, I am not the one who
23 defined the obligations. I can't answer that
24 question.

25

1 For claim verification --

2 Q. And how -- I'm sorry. Go ahead.

3 A. So for -- and for claim verification --

4 say it was really a lot of the same input factors.

5 We would have received information from Optum on HCCs

6 that they were suggesting be deleted, information on

7 whether or not that was the only instance of that HCC

8 for the member. Those -- those types of inputs would

9 have been provided to -- primarily Mark -- Mark

10 Beckmann was the actuary on my team that would have

11 calculated those analytics.

12 Q. And how often would United obtain those

13 estimates?

14 A. We refreshed our estimates at least, for

15 chart review, monthly. I don't know how often the

16 claim verification estimates were refreshed.

17 Q. Was it -- do you think it was monthly or

18 something less frequent than that?

19 A. I just -- I don't -- I don't recall.

20 Q. Was it every quarterly at least?

21 A. I don't recall.

22 MR. LEE: I'm still not seeing 196 up. Is

23 anybody else seeing 196 up yet?

24 THE WITNESS: No, it's not displayed.

25 MR. LEE: Yeah, let's -- I think we may be

1 having some technical issues. Let's take a
2 quick break and see if we can get this resolved.

3 Go off the record.

4 MR. MERON: Okay.

5 VIDEOGRAPHER: The time is 2:44. We're
6 going off the record.

7 (A recess transpired from 2:44 p.m. until
8 2:47 p.m.)

9 VIDEOGRAPHER: The time is 2:47 p.m. We
10 are on the video report.

11 BY MR. LEE:

12 Q. Okay. Exhibit 196 is an e-mail chain from
13 you to Tim Trujillo, dated August 8, 2014. Do you
14 have that up, Ms. Meyer?

15 A. Yes, I do.

16 Q. Okay. Take a look at that. I'm going to
17 ask you about this e-mail.

18 Have you had a chance to look at the
19 e-mail?

20 A. I'm just about done. I need another
21 minute.

22 Q. Okay.

23 A. Okay.

24 Q. All right. About the middle of the page,
25 it says, under "Chart Review," "The chart review

1 program targets members' charts based on member and
2 provider information. We plan to conduct chart
3 review for over half of M&R's membership during this
4 program year. The selection of the charts is
5 dependent upon chart review selection criteria and is
6 not designed to ensure that a member's chart is
7 reviewed every year." Did I read that correctly?

8 A. Yes.

9 Q. Is that an accurate description of the
10 chart review program?

11 MR. MERON: Objection. Lack of
12 foundation.

13 THE WITNESS: To the best of my
14 recollection, that's accurate for the program.

15 BY MR. LEE:

16 Q. And up at the top, you responded to
17 Mr. Trujillo, who wrote this, and said, "It looks
18 accurate to me; thanks," did you not?

19 A. Yes, I did.

20 Q. Okay. And that was because you felt that
21 it was accurate at that time?

22 A. I don't recall this memo, but that's
23 certainly how I responded.

24 Q. Do you have any reason to believe that
25 it's inaccurate today?

1 A. Today? I -- since I'm no longer an
2 employee, I couldn't comment on what the chart review
3 program is today.

4 Q. No, not -- not what the program is today,
5 but do you today have any reason to believe that that
6 statement was inaccurate when it was written in 2014?

7 A. No.

8 Q. All right. What's the -- what's meant by
9 the selection criteria that's referenced in the
10 second sentence of that paragraph? In other words,
11 what I'm asking, what is the chart review selection
12 criteria that's referenced there?

13 A. Well, the member had to have a clinical
14 encounter during the calendar year in order to be
15 targeted for the chart program.

16 Q. Okay. Anything else involved in the
17 selection criteria for the chart review program?

18 A. Not that I recall.

19 Q. Are you familiar with the phrase "suspect
20 logic"?

21 A. Yes.

22 Q. What does that mean?

23 A. Well, suspect logic is the first -- the
24 first thing in suspect logic is does the member have
25 a clinical encounter during that calendar year. And

1 THE WITNESS: This is saying that \$245
2 would be the incremental risk adjustment revenue
3 that we were forecasting to receive per chart.

4 BY MR. LEE:

5 Q. How is that different from the average
6 yield per chart of \$221?

7 A. I -- I don't know.

8 Q. Does that mean that for every chart that
9 United would review, it was estimating revenues of
10 \$245?

11 MR. MERON: Objection. Lack of
12 foundation. Calls for speculation.

13 THE WITNESS: That's -- that's what this
14 is saying, yes, that we would expect \$245 in a
15 yield per chart.

16 BY MR. LEE:

17 Q. Okay. For every chart on average that
18 United would review, United would generate revenues
19 of \$245, correct?

20 A. Yes. That's what this is saying.

21 Q. Do you know how the yield per chart was
22 calculated?

23 A. Well, when a diagnosis or a HCC was
24 identified in the chart that was new and unique, it
25 had not been received from a claim, that HCC would be

1 worth a certain risk adjustment value. HCCs -- they
2 all have a different value, so this is just saying --
3 and not all charts found new HCCs, so this is
4 saying --

5 Q. Let me direct your attention -- I'm sorry.

6 A. -- take your total number of charts that
7 are reviewed and the total value of the HCCs that
8 you're finding on those charts to arrive at an
9 average value.

10 Q. Okay. Let me direct your attention to the
11 second page toward the bottom under the heading
12 "Deletes." Let me know when you're on that page.

13 A. Yes.

14 Q. Under the fourth bullet point, it says,
15 "Action Item: Provide MBM with proposed 2012 deletes
16 per review (done 12-4)." Is MBM you?

17 A. Yes, it is.

18 Q. Okay. Were you provided with the proposed
19 2012 CV deletes for review?

20 A. I don't remember.

21 Q. Was that customary for you to be provided
22 with deletes for review?

23 MR. MERON: Objection. Asked and
24 answered.

25 THE WITNESS: Yes. I think I testified

1 earlier that towards the end of 2013, Scott
2 Theisen, who was my boss, asked me to review the
3 proposed CV deletes.

4 BY MR. LEE:

5 Q. And in accordance with that instruction
6 from Scott Theisen, you would review deletes and
7 instruct Optum to submit them after you reviewed
8 them?

9 A. We reviewed the -- the CV deletes. Yes.

10 Q. And was that for the purpose of
11 instructing Optum to delete them when appropriate?

12 A. We were asked to review the CV deletes
13 because we were receiving complaints from providers
14 that transactions were being deleted inappropriately.
15 We received those complaints through the RACCR
16 program specifically.

17 So when Scott asked me to start reviewing
18 and approving CV deletes, we were finding the same --
19 we were finding similar logic errors in Optum's
20 proposed deletes. So I don't recall how many deletes
21 were approved for Optum to process.

22 MR. LEE: Okay. Let me ask my colleague
23 to put up Tab 14, which will be Exhibit 198.

24 (Exhibit 198 was marked for identification.)

25

1 BY MR. LEE:

2 Q. I'll ask you to take a look at that. You
3 see 197, Ms. Meyer?

4 A. Yes, I do. Yes, I do.

5 Q. 198, I mean. Do you have 198 up yet?

6 A. Yes, I do.

7 Q. Okay. 198 is an e-mail chain.

8 MR. LEE: For the record it's
9 MAPL001453589.

10 BY MR. LEE:

11 Q. It's series of e-mails. Up at the top, it
12 says Kimberly Fadden, addressed to you, March 24,
13 2014. The subject is "Chart Meeting." Toward the
14 bottom of that first page, there's an e-mail from you
15 to Scott Theisen, dated March 24, 2014. Do you see
16 the e-mail I'm referring to?

17 A. Yes, I do.

18 Q. The second paragraph there says, "We know
19 that we need 2013 DOS chart review to deliver same
20 revenue as we are estimating for 2012 DOS charts."
21 "DOS" refers to date of service?

22 A. Yes, it does.

23 Q. How did you know that you needed the 2013
24 DOS chart review to deliver the same revenues as
25 2012?

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

Karen K. Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT D-148

2023 WL 2241806 (U.S.) (Appellate Brief)
Supreme Court of the United States.

UNITED STATES, ex rel. Tracy Schutte, et al., Petitioners,
v.
SUPERVALU INC., et al.;
United States, ex rel. Thomas Proctor, Petitioner,
v.
Safeway, Inc.

Nos. 21-1326, 22-111.
February 24, 2023.

On Writs of Certiorari to the United States Court of Appeals for the Seventh Circuit

Brief for the United States as amicus curiae supporting petitioners

Elizabeth B. Prelogar, Solicitor General Counsel of Record, [Brian M. Boynton](#), Principal Deputy Assistant Attorney General, [Malcolm L. Stewart](#), Deputy Solicitor General, Benjamin W. Snyder, Assistant to the Solicitor General, [Michael S. Raab](#), [Charles W. Scarborough](#), Joshua Dos Santos, Attorneys, Department of Justice, Washington, D.C. 20530-0001, SupremeCtBriefs@usdoj.gov, (202) 514-2217.

***i QUESTION PRESENTED**

The False Claims Act (FCA), [31 U.S.C. 3729 et seq.](#), imposes civil liability on persons who “knowingly” submit false claims for payment to government programs or “knowingly” make false statements in support of such claims. [31 U.S.C. 3729\(a\)\(1\)\(A\) and \(B\)](#). The FCA defines “knowingly” to mean that a person (i) has “actual knowledge” of the falsity of information in the claim or statement; (ii) “acts in deliberate ignorance of the truth or falsity of” such information; or (iii) “acts in reckless disregard of the truth or falsity of” such information. [31 U.S.C. 3729\(b\)\(1\)\(A\)](#). The question presented is as follows:

Whether a person who submitted a claim or statement that falsely asserted compliance with applicable legal requirements, and who subjectively believed or had strong reason to believe that the claim or statement was false, can establish that he did not act “knowingly” by showing during the FCA litigation that the claim or statement was consistent with an incorrect but objectively reasonable interpretation of those legal requirements.

[Note: Page ii missing in original document]

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*1 INTEREST OF THE UNITED STATES

These cases present important questions concerning the scienter requirements of the False Claims Act (FCA or Act), 31 U.S.C. 3729 *et seq.* The FCA is the primary tool by which the federal government combats fraud in federal contracts and programs. The United States therefore has a substantial interest in proper *2 interpretation of the Act. At the Court's invitation, the United States filed a brief at the petition stage in No. 21-1326.

STATEMENT

A. Legal Background

1. The FCA imposes liability on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment” to a government spending program (whether directly to a federal official or through a third-party contractor or grantee), or who “knowingly makes, uses, or causes to be made or used” a “false * * * statement” material to such a claim. 31 U.S.C. 3729(a)(1)(A) and (B); see 31 U.S.C. 3729(b)(2)(A)(i) and (ii). The Act defines “knowingly” to “mean that a person, with respect to information,” (i) “has actual knowledge of the information”; (ii) “acts in deliberate ignorance of the truth or falsity of the information”; or (iii) “acts in reckless disregard of the truth or falsity of the information.” 31 U.S.C. 3729(b)(1)(A).

Either the Attorney General or a private party (known as a relator) may sue under the FCA. 31 U.S.C. 3730(a) and (b). When a relator files a “qui tam” suit, the government may “elect to intervene.” 31 U.S.C. 3730(b)(2) and (3). If the government declines to intervene, the relator may proceed with the litigation and share in any judgment. 31 U.S.C. 3730(b)(4)(B) and (d).

2. These cases concern claims for payment submitted to government healthcare programs including Medicaid and Medicare Part D.

a. The Medicaid Act, 42 U.S.C. 1396 *et seq.*, establishes a cooperative federal-state program that provides medical assistance to certain low-income individuals. States may offer outpatient prescription-drug coverage as part of their Medicaid plans. *3 42 U.S.C. 1396d(a)(12). Regulations promulgated by the Centers for Medicare and Medicaid Services (CMS) limit reimbursement for many drugs to the lower of (1) a pharmacy's “usual and customary charges to the general public” or (2) the drug's actual acquisition cost plus a reasonable dispensing fee. 42 C.F.R. 447.512(b)(2).

Consistent with those federal regulations, state Medicaid agencies typically calculate reimbursement amounts to be paid to pharmacies as the lesser of various payment amounts, one of which is often the pharmacy's “usual and customary charge” to the general public. See Medicaid.gov, CMS, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State, Quarter Ending September 2022* (last updated Nov. 16, 2022), <https://www.medicaid.gov/medicaid/prescription-drugs/state->

prescription-drugresources/medicaid-covered-outpatient-prescription-drugreimbursement-information-state/index.html. State Medicaid agencies may issue program guidance to further define “usual and customary charges.” See 11-cv-3290 D. Ct. Doc. 172-1, at 12 (May 21, 2018).

b. The Medicare Act, 42 U.S.C. 1395 *et seq.*, provides federally funded health-insurance coverage to individuals who are age 65 or older or are disabled. Through Medicare Part D, 42 U.S.C. 1395w-101 *et seq.*, beneficiaries can obtain prescription-drug coverage through private plan sponsors. See 42 C.F.R. 423.30, 423.32. CMS makes ongoing payments to a plan sponsor and at the end of the year reconciles those payments with the sponsor's actual costs to determine whether the sponsor is owed additional funds or instead must return excess payments. See 42 C.F.R. 423.315, 423.329, 423.343.

Part D beneficiaries typically obtain prescription drugs from retail or mail-order pharmacies, which then *4 seek reimbursement from the plan sponsors (or from intermediary organizations known as pharmacy benefit managers). Plan sponsors and pharmacies negotiate the price to be paid for each drug. See 42 U.S.C. 1395w-111(i); 42 C.F.R. 423.100. Plan sponsors often contract to pay the lesser of a negotiated price or the amount that the pharmacy reports as its “usual and customary” price for cash (*i.e.*, non-insurance) sales to the general public, with that term sometimes further defined in the contract. See 21-1326 Pet. App. 8a; 22-111 Pet. App. 4a, 10a-11a.

B. Facts And Procedural History

In these consolidated cases, petitioners filed FCA qui tam suits against respondents, which operate hundreds of retail drug pharmacies nationwide. Petitioners alleged that respondents had submitted to government healthcare programs claims that knowingly overstated respondents' “usual and customary” prices, leading to reimbursements substantially greater than what respondents were lawfully entitled to receive. The cases were assigned to the same district court, which granted summary judgment to respondents in separate decisions. 21-1326 Pet. App. 59a-87a; 22-111 Pet. App. 42a-105a. The court of appeals affirmed both judgments. 21-1326 Pet. App. 1a-58a; 22-111 Pet. App. 1a-41a.

1. Petitioners' allegations pertain to pricing programs that respondents adopted to compete with steep discounts announced in 2006 by other pharmacies such as Walmart, which began offering 30-day supplies of many drugs for just \$4. 21-1326 Pet. App. 6a-7a; 22-111 Pet. App. 5a. Respondents in No. 21-1326 (collectively, SuperValu) adopted a price-match program in which SuperValu's pharmacies would match a competitor's lower price at a customer's request, and would then *5 automatically apply that price to future refills. 21-1326 Pet. App. 7a. Respondent in No. 22-111 (Safeway) adopted a similar price-match program, and also adopted a “membership” discount program that operated during most of the same period. 22-111 Pet. App. 5a-7a. Under Safeway's membership program, customers could receive steeply discounted generic drug prices (typically \$4 for a 30-day supply) by filling out a form with basic information (*e.g.*, name, address, date of birth) that petitioner asserts Safeway usually already had. *Id.* at 6a-7a.

Respondents' discount programs were sufficiently popular that the discounted prices comprised a majority of non-insurance sales for many drugs during the period when respondents offered the discounts. In 2012, a majority of SuperValu's cash sales for 44 of its 50 topselling drugs were made at discounted price-matched prices. 21-1326 Pet. App. 8a & n.3, 35a (Hamilton, J., dissenting). For 30 of those drugs, more than 80% of cash sales were at the lower price-matched prices. *Id.* at 35a. Discounted prices accounted for 75%-88% of cash sales for Safeway's top 20 drugs during the last five years of the program, and 56%-66% of all such sales. 22-111 Pet. App. 35a (Hamilton, J., dissenting). The discounts were substantial, with customers sometimes paying six to 16 times less than respondents' retail prices. 21-1326 Pet. App. 35a; 22-111 Pet. App. 39a.

Despite the widespread use of respondents' discount programs, respondents disregarded sales under those programs when reporting their “usual and customary” cash prices to state Medicaid agencies, Medicare Part D sponsors, and other third-party payors. Respondents instead reported only their higher retail prices, even for drugs for which a majority of sales occurred at

*6 substantially discounted prices. 21-1326 Pet. App. 35a (Hamilton, J., dissenting); 22-111 Pet. App. 38a-39a (Hamilton, J., dissenting). Between 2008 and 2012, for example, Safeway charged just \$10 in 94% of its cash sales for a 90-day supply of lovastatin, a “high-volume drug” used to reduce cholesterol. 22-111 Pet. App. 38a-39a. But rather than reporting \$10 as its “usual and customary” price for a 90-day supply of lovastatin, Safeway instead reported prices ranging from \$81.42 to \$108.99 during that period. *Id.* at 39a (citation omitted).

2. Discovery in both cases revealed evidence that respondents hid their discounted prices from third-party payors (including Medicaid programs and Medicare Part D sponsors) despite respondents' awareness that they were expected to report their discounted prices as their “usual and customary” prices.

a. Petitioner in No. 22-111 identified multiple instances in which third-party payors, including Medicare Part D sponsors and state Medicaid agencies, told Safeway that its “usual and customary” price reporting was required to reflect its discounted prices. In 2006, Safeway received a reminder from Medco Health Solutions, a pharmacy benefit manager working with many Medicare Part D plans, stating that “by contract,” the “usual and customary” price is “the lowest net price a cash patient would have paid on the day that the prescription was dispensed inclusive of all applicable discounts. These discounts include ... a competitor's matched price, or other discounts offered to customers.” 22-111 Pet. App. 10a-11a (brackets omitted).¹ Notices from *7 other pharmacy benefit managers in January and February 2007 conveyed similar messages. *Id.* at 11a; see *id.* at 69a (quoting notice from pharmacy benefit manager stating that “usual and customary” prices included “Promotional Pricing program[s]” such as “membership[s]”); see also *id.* at 32a-33a (Hamilton, J., dissenting), 50a-51a, 72a, 82a. Forwarding one such notice, a Safeway director wrote: “Another Example of how plans are reacting, ie, any modified price needs to be offered to the 3rd party if meets U&C definition. Received a similar [notice] from Medco.” *Id.* at 33a (Hamilton, J., dissenting).

Several state Medicaid agencies communicated the same message. In 2008, one Safeway pharmacy manager told corporate headquarters that Nebraska's Medicaid program had informed him that “by matching a price, it becomes our usual & customary.” 22-111 Pet. App. 33a (Hamilton, J., dissenting) (citation omitted); see *id.* at 52a, 57a (describing similar instructions from other state Medicaid agencies). A few days later, a Safeway executive e-mailed a senior vice president to advise that “[w]e may have some issues with U&C and state medicaid with price matching.” *Id.* at 33a (Hamilton, J., dissenting) (citation omitted). That executive explained that “if you [match a] price offer, that becomes your usual and customary for that day and that pricing needs to be extended to medicaid”—something he acknowledged Safeway was not doing. *Ibid.* (citation omitted; brackets in original).

The evidence suggests that Safeway sought to conceal its discount practices from third-party payors rather than change its price reporting. The executive who *8 expressed concern about “issues with U&C and state medicaid,” for example, indicated that Safeway “need[ed] to keep a low profile” with its discounts, because “[i]f we advertise this price match-it is going to Alert the medicaid programs to start looking.” 22-111 Pet. App. 33a-34a (Hamilton, J., dissenting) (citations and emphasis omitted). Another executive responded to the information about the Nebraska Medicaid program's understanding of “usual and customary price” by asking “how the state of Nebraska will know that we offered to match any price out there.” *Id.* at 33a (citation and emphasis omitted). And consistent with a desire to maintain “stealth” around its discount pricing, *id.* at 29a (citation omitted), Safeway instructed employees not to “put any of this in writing” and not to admit to price-matching “if an unidentified customer calls in,” so that Safeway could “avoid trouble with the media or competitors.” *Id.* at 31a (citation and emphases omitted).

A final example captures Safeway's apparent thinking. In 2009, a Safeway executive inquired about the reason for adopting a membership program rather than simply offering a \$4 price, noting that “it seems like * * * this whole thing revolves @ the insurance angle to get the \$10 per item from them vs the \$4 cash price.” 22-111 Pet. App. 36a (Hamilton, J., dissenting) (citation omitted). A director responded that “[o]ff the record that is exactly the angle,” “getting the maximum we can from the insurance.” *Ibid.* (citation and emphasis omitted).

b. Petitioners in No. 21-1326 presented similar evidence about SuperValu. SuperValu received the same 2006 notice from Medco about SuperValu's contractual obligation to report “all applicable discounts,” including *9 a “competitor's matched price.”

21-1326 Pet. App. 66a. A SuperValu executive forwarded the notice and stated: “Note the comment about price matching. Theoretically, they could audit.” 11-cv-3290 D. Ct. Doc. 169, at 9-10 (May 21, 2018) (citation omitted).

Later, when a different pharmacy benefit manager asked about SuperValu's price-match practices, one of SuperValu's managers stated that she was “concerned about any response where we acknowledge doing it.” 11-cv-3290 D. Ct. Doc. 327, at 7 (Dec. 10, 2019) (citation omitted). An executive replied that “[w]e should not respond unless we know what they are going to do with this information,” and directed the manager to “[m]ake sure [one of SuperValu's attorneys] can defend our price match policy as not being our U and C if they are pressing for a response.” *Ibid.* (citation omitted). And in another exchange, SuperValu executives weighed the risks of running advertisements for its price-match program, noting that “damage control” would be necessary if pharmacy benefit managers saw the ads but determining that it was “[u]nlikely anyone [at a third-party payor] will really see” them. 11-cv-3290 D. Ct. Doc. 191-1, at 39 (June 11, 2018) (citation omitted).

3. The district court granted summary judgment to respondents in both cases.

a. In an initial decision, the district court found that SuperValu's price-matched “prices * * * are the usual and customary prices for their drugs,” and therefore should have been reported with SuperValu's claims for payment from Medicare Part D and Medicaid. 2019 WL 3558483, at *8. But in a subsequent ruling, the court held that SuperValu was still entitled to summary judgment on the ground that it had not acted “knowingly.” 21-1326 Pet. App. 59a-87a. Relying on this Court's *10 decision in  *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007), which had interpreted the term “willfully” in the Fair Credit Reporting Act,  15 U.S.C. 1681n(a), the district court construed the FCA to require a showing that SuperValu's submissions were inconsistent with any “objectively reasonable” interpretation of “usual and customary” price. 21-1326 Pet. App. 75a. Because petitioners could not meet that standard, the court held that SuperValu was entitled to summary judgment “regardless of [SuperValu's] subjective beliefs” about the accuracy of its submissions. *Id.* at 83a.

b. The district court applied the same analysis in granting summary judgment to Safeway. 22-111 Pet. App. 42a-105a. The court concluded that, “if a defendant adopts one of multiple reasonable interpretations, its ‘subjective intent’ is legally irrelevant.” *Id.* at 81a (quoting  *Safeco*, 551 U.S. at 71 n.20). Despite the evidence of Safeway's subjective understanding that it should report its discounted prices, the court held that “Safeway is entitled to summary judgment under *Safeco*.” *Id.* at 103a.

4. The court of appeals affirmed in separate divided decisions.

a. The court of appeals decided SuperValu's case first. 21-1326 Pet. App. 1a-58a. The court held that *Safeco* controlled the interpretation of the FCA term “knowingly.” *Id.* at 11a-20a. On that understanding, the court held that an FCA “defendant who acted under an incorrect interpretation” of governing legal requirements will avoid liability “if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it.” *Id.* at 12a.

The court of appeals explained that, under its reading of *Safeco*, “a defendant's subjective intent does not *11 matter.” 21-1326 Pet. App. 27a. The court stated that “it is not enough that a defendant suspect or believe that its claim was false” because the standard is “objective” and turns on whether the defendant “*know[s]*” that its claims are false. *Id.* at 26a-27a. The court found it “irrelevant” to that inquiry whether the defendant had actually “held [an objectively reasonable exculpatory interpretation] at the time that it submitted its false claim” or instead was “concocting ‘post-hoc arguments.’” *Id.* at 26a.

Applying its two-step analysis, the court of appeals affirmed the grant of summary judgment. 21-1326 Pet. App. 22a-31a. It first held that SuperValu's conduct was consistent with an objectively reasonable understanding of “usual and customary” price because no statute or regulation squarely foreclosed SuperValu's approach. *Id.* at 22a-26a. It then determined that no authoritative guidance had warned SuperValu away from that understanding. *Id.* at 27a-31a. The court held that, for these purposes, only “circuit court precedent or guidance from the relevant agency” can qualify as “authoritative guidance,” so that the contractual guidance provided by pharmacy benefit managers was “automatically exclude[d].” *Id.* at 28a.

Judge Hamilton dissented. 21-1326 Pet. App. 31a-58a. In his view, the majority's reliance on *Safeco* ignored the FCA's text, history, and common-law background, which he viewed as indicating that "subjective bad faith" can establish the necessary scienter. *Id.* at 42a. Judge Hamilton concluded that the district court's grant of summary judgment should be reversed because the evidence would allow "[a] reasonable jury [to] find that SuperValu either actually knew or deliberately *12 chose to keep itself in ignorance that it was submitting false, hugely inflated claims." *Id.* at 37a-38a.

b. The court of appeals subsequently affirmed the district court's grant of summary judgment to Safeway "[f]or the same reasons" it had identified in SuperValu's case. 22-111 Pet. App. 17a; see *id.* at 1a-41a. The court recognized that "Safeway effectively used its [membership program] as a fig leaf to disguise a Wal-Mart-style generics program without reporting those prices as U&C." *Id.* at 17a. It concluded, however, that no authoritative guidance had rendered that practice "objectively unreasonable at the time." *Id.* at 18a. The court held that the notices from pharmacy benefit managers, as well as definitions in specific contracts, were "irrelevant" to the scienter analysis "because they did not come from the agency." *Ibid.* And because Safeway's actions were consistent with an objectively reasonable understanding of "usual and customary" price, the court refused to consider "evidence of the defendant's subjective awareness that its interpretation might be wrong." *Id.* at 14a-15a (citation omitted).

Judge Hamilton again dissented. 22-111 Pet. App. 25a-41a. In his view, the court of appeals' analysis erroneously disregarded "egregious" facts demonstrating "Safeway's fraudulent intent at the time it was submitting false claims to the government." *Id.* at 26a, 28a (Hamilton, J., dissenting).

SUMMARY OF ARGUMENT

A. The FCA includes a three-pronged definition of "knowingly," which covers a person who (i) has "actual knowledge" of the falsity of information in a claim or statement that the person submits to a government program; (ii) "acts in deliberate ignorance of the truth or falsity of" such information; or (iii) "acts in reckless *13 disregard of the truth or falsity of" such information.  31 U.S.C. 3729(b)(1)(A). The ordinary meaning of those words, along with their statutory context and the historical background of common-law fraud, makes clear that the FCA's scienter standard encompasses circumstances in which persons subjectively believe they are submitting false claims or statements to the government; are subjectively aware of a substantial risk that their claims or statements are false but deliberately avoid taking readily available steps to obtain clarification; or act in reckless disregard of known or objectively obvious facts indicating a high likelihood of falsity.

The court of appeals erred in adopting a narrower scienter standard, under which a defendant's subjective bad faith at the time the defendant acted becomes irrelevant if the defendant (or the defendant's lawyers) can later identify an exculpatory theory that is wrong but objectively reasonable. That approach disregards Congress's three-pronged statutory definition, which focuses on a defendant's subjective state of mind when submitting the false claims or statement. See  31 U.S.C. 3729(b)(1)(A) (referring to "actual knowledge" and "deliberate ignorance"). It likewise ignores common-law principles of fraudulent misrepresentation that Congress drew on in enacting the FCA, which focus on a defendant's subjective bad faith. And it would allow defendants who *intentionally* submit false claims for payment to the government to escape FCA liability based on concededly incorrect post hoc justifications, flouting the principle that "those who seek public funds" must "act with scrupulous regard for the requirements of law."  *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 63 (1984).

*14 B. This Court's decision in  *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007), does not support the court of appeals' result. *Safeco* involved a provision of the Fair Credit Reporting Act that imposed penalties for "willfully" violating that statute's requirements.  15 U.S.C. 1681n(a). In interpreting the "willfully" requirement there to establish an objective-reasonableness defense, *ibid.*, the Court did not address a three-pronged statutory definition, like the one in the FCA, that expressly focuses on a defendant's subjective state of mind. Moreover, the Court relied on common-law standards relating to physical safety, not

the common law of fraud that is relevant here. And *Safeco* concerned a general regulatory requirement, rather than conditions specifically imposed on those who choose to do business with the government. Just as this Court has declined to extend *Safeco* to the patent context, see  *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93 (2016), so too should the Court decline to extend it here to protect those who intentionally submit false claims for payment to the government.

The other arguments put forward by the court of appeals or respondents likewise lack merit. The fact that a defendant who believes she is submitting false claims might not be *certain* about the claims' falsity does not absolve her of culpability under the FCA's statutory standard. Similarly, defendants who intend to submit false claims, or who deliberately avoid inquiries that would confirm whether their claims are false, cannot complain about a lack of fair notice.

C. The court of appeals further erred in holding that only circuit-court precedents or guidance from the relevant agency is sufficiently authoritative to give notice of a claim's falsity. That standard, which the court *15 purported to derive from *Safeco*, would be particularly inappropriate under the FCA. The FCA applies to claims submitted under contracts with non-federal intermediaries who help to administer federal spending programs like Medicare Part D and Medicaid. No sound basis exists for allowing participants in those programs to disregard guidance from, or contracts with, the very entities that Congress has designated to administer their claims.

D. Under the appropriate scienter standard, respondents are not entitled to summary judgment in either case. The evidence petitioners presented would allow a reasonable factfinder to conclude that respondents “knowingly” submitted false claims or statements to government healthcare programs.  31 U.S.C. 3729(a)(1)(A) and (B). The Court therefore should reverse the court of appeals' judgments and remand for further proceedings.

ARGUMENT

THE SEVENTH CIRCUIT ADOPTED AN OVERLY DEMANDING STANDARD FOR PROVING SCIENTER UNDER THE FCA

The FCA imposes liability on those who “knowingly” present false claims for payment to government programs, or who “knowingly” submit false statements in support of such claims.  31 U.S.C. 3729(a)(1)(A) and (B); see  31 U.S.C. 3729(b) (4). Under the Act's definition, construed in light of common-law background principles, that standard is satisfied when a person (1) is subjectively aware that a claim or statement is false; (2) subjectively recognizes a substantial risk that the claim or statement is false but deliberately avoids taking readily available steps to obtain clarification; or (3) acts with reckless disregard of known or objectively obvious *16 facts indicating a high likelihood that the claim or statement is false. See  31 U.S.C. 3729(b)(1)(A).

The court of appeals adopted a substantially narrower view of the Act's scienter requirement, under which a person who submits false claims or statements can categorically escape liability by identifying a post hoc rationale for its prior representations that, while legally wrong, is “objectively reasonable.” *E.g.*, 21-1326 Pet. App. 22a. That standard, which respondents liken to “qualified immunity” for FCA defendants, 21-1326 Resp. Supp. Br. 4, is untethered to the statute's text, context, or history. Under the proper standard, the relators in both cases here presented sufficient evidence that respondents knowingly submitted false claims and statements. The court of appeals' judgments should be reversed.

A. The FCA's Text, History, And Common-Law Background Demonstrate That Scienter Under The Act Turns On The Defendant's State Of Mind At The Time Of Its False Claims Or Statements

1. This Court has “taken [care] to construe” words like “‘knowing,’ ‘intentional,’ or ‘willful’ * * * in their particular statutory context.”  *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L. P. A.*, 559 U.S. 573, 585 (2010). Until 1986, the FCA imposed liability for “knowingly” presenting “a false or fraudulent claim for payment or approval,” without defining the term “knowingly.”  31 U.S.C. 3729(1) (1982 & Supp. III 1985). Some courts interpreted that provision to require proof of a specific “purpose on the part of [the defendant] to cheat the Government.”  *United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007 (5th Cir. 1972) (citation omitted; brackets in original). As part of wide-ranging FCA amendments, Congress rejected that interpretation as *17 unduly narrow. See False Claims Amendments Act of 1986 (1986 Amendments), Pub. L. No. 99-562, § 2(7), 100 Stat. 3153-3154. The 1986 Amendments stated that “no proof of specific intent to defraud is required,” and added a new three-pronged definition of “knowingly.” § 2(7), 100 Stat. 3154; see  31 U.S.C. 3729(b)(1)(B). Under that definition, a person acts “knowingly” if she (i) has “actual knowledge” of the falsity of information in a claim or statement the person submits to the government or a designated intermediary; (ii) “acts in deliberate ignorance of the truth or falsity of” such information; or (iii) “acts in reckless disregard of the truth or falsity of” such information.  31 U.S.C. 3729(b)(1)(A).

The first two terms within that statutory definition cover distinct species of subjective bad faith. The first, “actual knowledge,”  31 U.S.C. 3729(b)(1)(A)(i), refers to a “state of mind that one considers that he knows.” *Black’s Law Dictionary* 784 (5th ed. 1979) (defining “knowledge”). That generally means that the defendant was subjectively “aware of” a violation.  *Intel Corp. Investment Policy Committee v. Sulyma*, 140 S. Ct. 768, 776 (2020). The second, “deliberate ignorance,”  31 U.S.C. 3729(b)(1)(A)(ii), covers a defendant who is “subjective[ly] aware[ly]” of a substantial risk that his statement may be false, and intentionally avoids taking steps to confirm the statement’s truth or falsity.  *United States v. Ricard*, 922 F.3d 639, 656 (5th Cir. 2019); see  *Global-Tech Appliances, Inc. v. SEB S. A.*, 563 U.S. 754, 769 (2011) (same definition for “willful blindness”); *Black’s Law Dictionary* 672 (5th ed. 1979) (“Voluntary ignorance exists when a party might, by taking reasonable efforts, have acquired the necessary knowledge.”) (emphasis omitted). The third term, “reckless disregard,”  31 U.S.C. 3729(b)(1)(A)(iii), *18 describes circumstances in which a defendant disregards a “high risk” of falsity “that is either known or so obvious that it should be known,”  *Farmer v. Brennan*, 511 U.S. 825, 836 (1994). Unlike the first two clauses, the third clause does not require proof of the defendant’s subjective awareness, but can be satisfied through evidence that the risk of falsity was objectively apparent.

By covering all three states of mind, Congress cast a net broad enough to reach those who act in subjective bad faith with respect to claims that implicate ambiguous legal conditions, as well as those who act with a grossly substandard degree of care. If a defendant believes (correctly) that it is violating a legal requirement that makes its claims false and ineligible for payment, the defendant acts with “actual knowledge” if it submits the false claims—even if its lawyers later identify an objectively reasonable (but incorrect) exculpatory interpretation. See  *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154-1156 (11th Cir. 2017) (considering evidence of defendant’s belief in illegality). If a defendant is subjectively aware of a substantial risk that its submissions are false, but chooses not to make readily available inquiries that could clarify their accuracy, that defendant acts with “deliberate ignorance” even if the underlying law is ambiguous. *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1212 (9th Cir. 2019). And if a defendant disregards warnings about likely falsity from knowledgeable sources such as attorneys, internal compliance officers, or government contractors, or fails to consult objectively obvious sources that would have provided such warnings, that defendant acts with “reckless disregard” of the truthfulness of its claims. See  *19 *United States ex rel. Polukoff v. St. Mark’s Hospital*, 895 F.3d 730, 744 (10th Cir. 2018), cert. dismissed, 138 S. Ct. 2690 (2019).

2. Each of the three prongs of the FCA’s definition of “knowingly” addresses the “culpability” of the person’s state of mind “at the time of the challenged conduct.”  *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 105 (2016). Each prong uses the present tense, with the first prong looking to what knowledge the person “has,” while the second and third

look to whether the person “acts in” the specified mental states.  31 U.S.C. 3729(b)(1)(A)(i)-(iii). Within the Act's operative prohibitions, the adverb “knowingly” modifies such verbs as “presents,” “makes,” and “uses.”  31 U.S.C. 3729(a)(1)(A) and (B). That phrasing makes clear that the state of mind that matters is the person's state of mind when she “presents,” “makes,” or “uses” the false claim or statement. The ability of that person (or her lawyer) to identify wrong-but-reasonable exculpatory theories or interpretations after those events occur cannot retroactively alter the state of mind with which the person engaged in the specified conduct.²

The Act's focus on the defendant's state of mind at the time of the challenged conduct is essential to protect potential defendants from unwarranted FCA liability. After a person submits claims for payment that it reasonably believes are legitimate, new agency guidance or *20 intervening judicial decisions may make clear that the claims rested on an incorrect view of the law. New information likewise may make clear that previously submitted claims rested on factual misunderstandings. If the defendant's knowledge at the time of the FCA litigation were decisive, the government or qui tam relators could seek treble damages and civil penalties in those circumstances. The pertinent FCA provisions are carefully worded to preclude that untoward result. But just as such intervening developments cannot support the imposition of FCA liability on persons who acted without the requisite knowledge, post hoc identification of wrong-but-reasonable exculpatory legal theories cannot negate scienter.³

3. The FCA's primary focus on a defendant's subjective bad faith at the time of the relevant act is consistent with the Act's common-law background. Cf., e.g.,  *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 187 (2016) (construing the FCA term “false or fraudulent claims” to incorporate the common-law rule that “fraud” includes some “misrepresentations by omission”). As Judge Hamilton observed below, “the most authoritative summary of the common law's treatment of fraudulent scienter,” found in Section 526 of the Restatement (Second) of Torts, “makes subjective bad faith central.” 21-1326 Pet. App. 41a-42a *21 (Hamilton, J., dissenting). That summary explains that, for purposes of the common-law tort of fraudulent misrepresentation, a speaker acts with a culpable state of mind if he “(a) knows or believes that the matter is not as he represents it to be, (b) does not have the confidence in the accuracy of his representation that he states or implies, or (c) knows that he does not have the basis for his representation that he states or implies.” *Restatement (Second) of Torts* § 526 (1977) (emphasis omitted); accord, e.g., 1 Joseph Story, *Commentaries on Equity Jurisprudence* § 193 (6th ed. 1853). Each of those categories focuses unmistakably on the speaker's subjective bad faith.

Given the subjective criteria that historically were used to identify “common-law fraud,”  *Escobar*, 579 U.S. at 187, Congress could be expected to speak clearly if it wished to make the defendant's subjective intent irrelevant to scienter under the FCA. See Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 318 (2012) (“[S]tatutes will not be interpreted as changing the common law unless they effect the change with clarity.”). By enacting the third (“reckless disregard”) prong of the FCA's definition of “knowingly,” Congress made clear that an extreme lack of due care can provide an *additional* basis for liability, even when subjective bad faith is absent. But nothing in the FCA's text, context, history, or structure suggests that Congress intended to displace the common-law approach altogether.

B. The Court Of Appeals Erred In Treating Respondents' Post Hoc Rationales For Their Conduct As Negating Scienter Under The FCA

The contrary arguments adopted by the court of appeals or advanced by respondents lack merit.

***22 1. This Court's decision in *Safeco* provides no sound basis for the court of appeals' construction of the FCA's scienter requirement**

The court of appeals viewed this Court's decision in  *Safeco Insurance Co. v. Burr*, 551 U.S. 47 (2007), as dictating that a defendant's subjective state of mind is “irrelevant” under the FCA. 21-1326 Pet. App. 26a. Based on its reading of *Safeco*, the

court held that an FCA defendant cannot be found to have acted “knowingly” if its conduct was consistent with an objectively reasonable interpretation that had not previously been rejected by an appellate court or agency guidance—whether or not “the defendant * * * held that view at the time that it submitted its false claim.” *Ibid*. That approach is erroneous.

a. In *Safeco*, several insurers failed to notify consumers that the insurers had taken “adverse action[s]” based on the consumers’ credit reports. 551 U.S. at 52 (quoting 15 U.S.C. 1681m(a)). A provision of the Fair Credit Reporting Act (FCRA), 15 U.S.C. 1681 *et seq.*, imposed penalties for “willfully” failing to provide such notifications. 15 U.S.C. 1681n(a). This Court granted review to decide whether that provision “reache[d] reckless disregard of” FCRA’s requirements and, if so, whether the insurers’ violations had been “reckless.” *Safeco*, 551 U.S. at 52, 56.

Based on “clue[s] in the text” and statutory context, the Court held that FCRA violations committed “willfully” included both knowing and reckless violations. *Safeco*, 551 U.S. at 59. The Court further held that Safeco had not acted recklessly because its interpretation of the notice provisions was “not objectively unreasonable.” *Id.* at 69. The Court stated that Safeco had not had “the benefit of guidance from the courts of *23 appeals or the Federal Trade Commission (FTC) that might have warned it away from the view it took,” and observed that an “informal staff opinion” suggesting that Safeco’s practice was incorrect had explicitly stated it was not “binding.” *Id.* at 70 & n.19 (citation omitted). Under those circumstances, the Court concluded that Safeco had not run an “unjustifiably high risk of violating the statute.” *Id.* at 70 (internal quotation marks omitted).

In a closing footnote, the Court addressed an argument that, “for purposes of [Section] 1681n(a),” “evidence of subjective bad faith must be taken into account.” *Safeco*, 551 U.S. at 70 n.20. The Court stated that “[w]here, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.” *Ibid*. The Court concluded that “Congress could not have intended such a result for those who followed an interpretation that could reasonably have found support in the courts, whatever their subjective intent may have been.” *Id.* at 71 n.20.

b. As discussed, p. 16, *supra*, terms like “knowing” and “willful” must be “construe[d] * * * in their particular statutory context.” *Jerman*, 559 U.S. at 585; see *Safeco*, 551 U.S. at 68 (emphasizing that a recklessness standard is “not self-defining” and depends on the context in which it appears) (quoting *Farmer*, 511 U.S. at 836). For four reasons, *Safeco*’s analysis of willfulness under FCRA does not support the Seventh Circuit’s holding that a wrong-but-reasonable post hoc exculpatory theory precludes a finding of scienter under the FCA.

*24 First, it is far from clear that such post hoc rationales are sufficient to defeat willfulness even under FCRA. The *Safeco* Court stated that “Safeco did not give [the plaintiffs] any notice because it thought [the notice requirement] did not apply to initial applications.” 551 U.S. at 68. That description indicates that the Court understood Safeco to have actually based its decision not to send notices on the specific legal rationale that the Court described as “not objectively unreasonable.” *Id.* at 69.

Second, and in any event, the FCRA and FCA scienter provisions contain significantly different language. FCRA imposes penalties on anyone who “willfully fails to comply” with the statute’s requirements, without defining the term “willfully.” 15 U.S.C. 1681n(a). The FCA, in contrast, imposes liability on persons who “knowingly” submit false claims or statements, and it defines that term to include mental states that turn on the defendant’s subjective knowledge or intent at the time of those submissions. 31 U.S.C. 3729(b)(1)(A)(i) (“actual knowledge”); 31 U.S.C. 3729(b)(1)(A)(ii) (“deliberate ignorance”); see pp. 17, 19, *supra*. Mechanically importing into the FCA’s scienter provision an approach that incorporates new legal theories

developed after the claims were submitted would disregard that statutory language. Indeed, the *Safeco* Court emphasized the need to give distinct meaning to different terms like “knowing” and “willfully,” and it noted that “knowing” action does “not simultaneously fall within * * * reckless[ness].”  551 U.S. at 59-60.

Third, *Safeco* involved a consumer-protection statute unrelated to the FCA's common-law antecedents. Lacking a common-law tradition directly analogous to FCRA's consumer-protection objectives, this Court *25 looked to the section of the Restatement (Second) of Torts that “define[d] reckless disregard of a person's physical safety.”  *Safeco*, 551 U.S. at 69. The Court concluded that, in that context, “the essence of recklessness at common law” was a “high risk of harm, *objectively* assessed.” *Ibid.* (emphasis added). But as discussed, pp. 20-21, *supra*, common-law decisions addressing fraudulent misrepresentation—the foundation for the FCA—have long recognized the sufficiency of *subjective* intent in the context of that distinct tort. See 21-1326 Pet. App. 41a-42a & n.1 (Hamilton, J., dissenting). The court of appeals' approach does not account for those materially different background legal standards.

Fourth, the FCA applies specifically to claims for government money or property, and accordingly implicates the principle that “those who seek public funds” have a heightened duty to “act with scrupulous regard for the requirements of law.”  *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 63 (1984). Holding contractors liable when they submit claims in subjective bad faith is thus consistent with “history and current thinking” about the obligations of those who do business with the government,  *Safeco*, 551 U.S. at 71 n.20, in a way that imposing liability for the credit-report-related violations in *Safeco* was not.⁴

*26 c. This Court's decision in *Halo Electronics*, *supra*, confirms that a claimant's wrong-but-reasonable post hoc rationale for its billing practices cannot negate scienter under the FCA.

In *Halo Electronics*, the defendant in a patentinfringement suit had “all-but instructed its design team to copy” existing patented technology, “opting to worry about the potential legal consequences later.”  579 U.S. at 102 (brackets and citations omitted). This Court ultimately considered whether the defendant could be held liable for enhanced damages for “willful” patent infringement.  *Id.* at 103; see  *id.* at 97. Relying on *Safeco*, the Federal Circuit had required plaintiffs seeking enhanced patent-infringement damages to make two distinct showings. The first, which the Federal Circuit had described as a showing of “[o]bjective recklessness,” required “clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.”  *Id.* at 100 (citations omitted). The Federal Circuit had made clear that a finding of “objective recklessness” was precluded if the defendant offered a wrong-but-reasonable defense at trial, “even if the defendant was unaware of the arguable defense when he acted.” *Ibid.* “Second, after establishing objective recklessness,” the plaintiff was required to “showagain by clear and convincing evidence—that the risk of infringement ‘was either known or so obvious that it should have been known to the accused infringer.’”  *Id.* at 101 (citation omitted).

Applying that standard in *Halo Electronics*, the Federal Circuit held that enhanced damages were *27 unavailable because the defendant could identify, after the fact, an objectively reasonable argument that the patent-in-suit was invalid.  579 U.S. at 100; see  *id.* at 100-102. This Court reversed, explaining that “culpability is generally measured against the knowledge of the actor at the time of the challenged conduct.”  *Id.* at 105 (citing, *inter alia*, Restatement (Second) of Torts § 8A (1965)). The Court explained that the Federal Circuit had strayed from that principle by allowing “someone who plunders a patent * * * without any reason to suppose his conduct is arguably defensible” to “nevertheless escape any comeuppance * * * solely on the strength of his attorney's ingenuity.” *Ibid.* The Court clarified that, in determining whether a particular defendant's conduct was sufficiently egregious to justify enhanced damages, “[n]othing in *Safeco* suggests that we should look to facts that the defendant neither knew nor had reason to know at the time he acted.”  *Id.* at 106. The Court also rejected an expansive reading of

Safeco's footnote 20, explaining that while “a showing of bad faith” is not relevant under FCRA, courts in patent infringement suits had long recognized that subjective bad faith could warrant “enhancing patent damages.”  *Id.* at 106 n.*.

Respondents attempt to distinguish *Halo Electronics* by arguing that it arose “[i]n the historical context of patent law,” where proof of “bad-faith infringement” was sufficient to establish the necessary scienter. 21-1326 Resp. Supp. Br. 7 (citation omitted). But that argument simply reinforces the oddity of transplanting FCRA's scienter standard into the current statutory setting. As discussed above, pp. 17, 20-21, *supra*, the FCA's text and the traditional contours of common-law fraud strongly indicate that proof of “subjective bad *28 faith” is sufficient to establish scienter under the Act, just as it is in patent cases.  *Halo Electronics*, 579 U.S. at 105.

2. Additional arguments advanced by the court of appeals and respondents do not support adoption of an “objective reasonableness” standard here

a. The court of appeals concluded that, even if a defendant “suspect[s], believe[s], or intend[s]” that its claim is false, the defendant “cannot *know* that its claim is false” unless the position it adopts is objectively unreasonable in light of statutory or regulatory text and “authoritative guidance.” 21-1326 Pet. App. 21a-22a.

That sort of “radical epistemological doubt” provides no defense in “any other areas of law,” and it would be particularly inappropriate in construing a fraud statute. 21-1326 Pet. App. 39a (Hamilton, J., dissenting). A courier who correctly believes he is transporting drugs cannot disprove his knowledge of that fact by showing that he never opened the package (or performed a field test) to be sure. See *ibid.* A chief financial officer who intends to cook the books does not escape liability by insisting that she never double-checked the math herself and therefore “did not ‘know’-not *really-that* the earnings reports were inflated.” *Ibid.*; cf. pp. 20-21, *supra* (discussing common-law fraud). The same principle applies here.

b. At the certiorari stage, SuperValu stated that, under the third prong of the FCA's definition of “knowingly,” a defendant can defeat a showing of recklessness—“the most capacious form of scienter” by establishing that its conduct was “objectively reasonable.” See 21-1326 Resp. Supp. Br. 4. SuperValu argued that a showing of objective reasonableness should likewise be sufficient to disprove the additional forms of *29 scienter (actual knowledge and deliberate ignorance) set out separately in the FCA. *Id.* at 4-5; see 21-1326 Pet. App. 16a (similar). SuperValu described that approach to the FCA's “knowingly” standard as creating a defense “analogous to qualified immunity.” 21-1326 Resp. Supp. Br. 4.

Even under the third prong of the FCA's definition, SuperValu is mistaken in suggesting that a wrong-but-reasonable post hoc rationale can defeat a finding of scienter. That third prong encompasses a claimant who “acts in reckless disregard of the truth or falsity of the information” contained in a claim or statement.  31 U.S.C. 3729(b)(1)(A)(iii). The “reckless disregard” prong is partly objective, since it encompasses circumstances where a reasonable person would perceive a high risk of falsity, even if the actual claimant does not. But the present-tense phrase “acts in,” and the definition's relationship to the Act's operative prohibitions, make clear that “reckless disregard” depends on the information available to the defendant at the time false claims or statements are submitted, not later-acquired information. See p. 19, *supra*; cf. *Black's Law Dictionary* 594 (11th ed. 2019) (definitions of “reckless disregard” that focus on the defendant's actual or constructive knowledge at the time of the relevant act).

The *Halo Electronics* Court drew the term “objective recklessness” from the Federal Circuit's own opinions, see  579 U.S. at 100, and the Court used the term as shorthand to distinguish that requirement from the second prong of the Federal Circuit's two-part test for enhanced patent damages, see  *id.* at 101; p. 26, *supra*. But this Court's reference to (and rejection of) the particular conception of “objective recklessness” that the Federal Circuit had adopted does not suggest that a *30 post hoc rationale for challenged conduct can *generally* preclude a finding of recklessness. To the contrary, the *Halo Electronics* Court observed that “culpability is generally measured against the knowledge of the actor at the time of the challenged conduct.”  579 U.S. at 105.

In any event, extending SuperValu's proposed "qualified immunity" defense to the first two prongs of the FCA's scienter definition would be particularly unsound. In *Halo Electronics*, the Court held that the Federal Circuit was wrong to "require[] a finding of objective recklessness in every case" because "intentional or knowing" conduct can exist "without regard to whether [the] infringement was objectively reckless." 579 U.S. at 104-105. The Court found that subjective bad faith could be a sufficient predicate for enhanced damages even though "such damages are generally reserved for egregious cases of culpable behavior." *Id.* at 104. Where defendants subjectively intend to submit false claims for payment, their conduct is highly culpable even if a later-identified ambiguity in the governing requirements could plausibly be resolved in their favor. The same is true of defendants who submit claims that they strongly (and correctly) suspect are false, rather than invoking readily available avenues for obtaining clarification.

c. Respondents also defend the court of appeals' approach as necessary to force "agencies to speak clearly," contending that "considerations of due process and fair notice" preclude liability for conduct that is consistent with an objectively reasonable reading of the applicable statute, regulation, or contract. 22-111 Br. in Opp. 27-28; see 21-1326 Resp. Supp. Br. 8-9 (similar). That contention fails for two reasons.

*31 First, those who affirmatively believe that they are submitting false claims, or who deliberately avoid inquiries that would either confirm or dispel that suspicion, cannot justifiably complain about a lack of fair notice. Such a state of mind has always been sufficient to establish scienter under the common law of fraudulent misrepresentation, even in circumstances where the falsity of the defendant's representation was not objectively clear at the time of the challenged conduct. And those who act based on a subjective, good-faith belief in a "reasonable interpretation of an uncertain legal obligation later determined to be erroneous," 21-1326 Br. in Opp. 30, will not be liable under any prong of the FCA's "knowingly" definition. Adoption of respondents' proposed defense is thus unnecessary to protect the dueprocess values they invoke.

Second, respondents' argument ignores the specific context in which all FCA claims arise. Respondents object to any standard that would require companies to "affirmatively seek 'clarification' * * * from the government when the law is ambiguous," insisting that dueprocess principles make the government responsible for "proactively clarif[y]ing] regulatory ambiguities." 21-1326 Resp. Supp. Br. 8-9 (citation omitted). But whatever force that objection might have in the context of general regulatory laws, it does not apply to those who request federal funds. "[W]hen a private party seeks to spend the Government's money," it can "expect no less than to be held to the most demanding standards." *Heckler*, 467 U.S. at 63.

Given its limited resources and the administrative complexity of many federal funding programs, the government cannot feasibly address in advance every potential ambiguity that motivated attorneys might later *32 identify. The government therefore relies on its contracting partners to approach the inevitable ambiguities in good faith, following what they understand to be the best interpretation and seeking clarification when necessary. By allowing claimants for government funds to escape FCA liability simply by identifying wrongbut-reasonable post hoc justifications for their conduct if and when litigation occurs, the decisions below substantially reduce contractors' incentives to seek clarification before claims are submitted. That approach cannot be reconciled with this Court's longstanding recognition that "[m]en must turn square corners when they deal with the Government." *Rock Island, Arkansas & Louisiana Railroad Co. v. United States*, 254 U.S. 141, 143 (1920).

C. The Court Of Appeals Erred In Treating Contractual Language And Warnings From Non-Governmental Actors As Irrelevant To The Scienter Analysis

The court of appeals further erred in holding that only "circuit court precedent or guidance from the relevant agency" is sufficiently "authoritative" to give notice of a claim's falsity. 21-1326 Pet. App. 28a; see 22-111 Pet. App. 18a ("[W]e may only consider binding precedent from the courts of appeals or appropriate guidance from the relevant agency."). On the court's view, even "contract definitions" in the very contract under which a defendant seeks payment are apparently irrelevant to the

reasonableness of the defendant's interpretation if they originate from a source other than the agency itself. 21-1326 Pet. App. 28a. The Court should reject that unwarranted limitation on the types of evidence that may bear on whether an FCA defendant acted with a culpable state of mind.

*33 The court of appeals derived its “authoritative guidance” limitation from a single paragraph in *Safeco*. See 21-1326 Pet. App. 27a-28a. There, this Court observed that “no court of appeals had spoken” on the disputed legal question when the defendant insurance companies acted, and “no authoritative guidance ha[d] yet come from the” relevant agency.  *Safeco*, 551 U.S. at 70. “Given this dearth of guidance and the less-than-pellucid statutory text,” the Court held that “Safeco's reading was not objectively unreasonable.” *Ibid*.

That short discussion of the specific circumstances present in *Safeco* provides no basis for categorically foreclosing courts and juries from considering additional materials in assessing scienter under the FCA. The *Safeco* Court did not expressly adopt such limits even with respect to FCRA. And in any event, the FCA differs from FCRA in ways that would make the extension of such a rule particularly inappropriate.

The FCA applies not just to claims submitted directly to federal officials, but also to claims submitted “under a contract or otherwise” to a government “contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest.”  31 U.S.C. 3729(b)(2)(A)(ii). The Act thus contemplates that deceptive conduct vis-à-vis non-federal intermediaries can give rise to FCA liability. Such non-federal actors play an integral role in the implementation of many federal funding programs, including Medicare Part D and Medicaid, in a way that has no usual analogue under ordinary regulatory laws. It would flout the congressional design to grant claimants in such programs *carte blanche* to ignore guidance from, or *34 contracts with, the very entities that Congress has designated to administer their claims.⁵

D. Petitioners' Evidence Demonstrates Material Disputes Of Fact Regarding Knowledge

Under the appropriate standard, the district court should not have granted summary judgment to respondents in either case. As discussed above, petitioners identified evidence indicating that respondents were subjectively aware of a high risk that they were misleading government-funded healthcare programs by submitting false “usual and customary” prices, but chose to hide their conduct for as long as possible rather than make inquiries to ensure compliance. See pp. 6-9, *supra*. Petitioners pointed to emails from executives and managers demonstrating awareness of likely illegality and a desire to keep government-funded programs from learning of their practices. *Ibid*. Petitioners also offered notices from pharmacy benefit managers and contract language strongly suggesting that respondents were reporting false “usual and customary” prices to at least some of those programs. *Ibid*. Finally, petitioners identified a stark disconnect between the amounts that respondents claimed were “usual and customary” prices for cash sales of particular prescription drugs and the amounts that respondents actually charged for most such cash sales. *Ibid*. That evidence would allow reasonable factfinders to conclude that respondents “knowingly” submitted false claims or

*35 statements to government healthcare programs.  31 U.S.C. 3729(a)(1)(A) and (B).

The Court therefore should reverse the court of appeals' decisions affirming the grants of summary judgment as to knowledge, and remand for further proceedings. At a minimum, the Court should vacate and remand for the court of appeals to evaluate petitioners' evidence of scienter under the appropriate legal standard.

CONCLUSION

The judgments of the court of appeals should be reversed.

Respectfully submitted.

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FEBRUARY 2023

Footnotes

- 1 Much of the evidence concerning Safeway's knowledge of its usual-and-customary price obligations was filed under seal at Safeway's request. See 11-cv-3406 D. Ct. Doc. 189 (Dec. 23, 2019). This brief accordingly relies on descriptions of that evidence in the lower courts' opinions.
- 2 The Dictionary Act, 1 U.S.C. 1, provides that “unless the context indicates otherwise * * * words used in the present tense include the future as well.” *Ibid.* Here, however, “context indicates otherwise.” *Ibid.* A defendant who submits a false claim that she reasonably believes to be true, for example, is not subject to FCA liability merely because she later acquires “actual knowledge” that the claim was false, though that defendant may become liable if she then “knowingly conceals” an obligation to return funds.  31 U.S.C. 3729(a)(1)(G) and  (b)(1)(A)(i); see pp. 19-20, *infra*.
- 3 A claimant who intends to cheat the government *can* escape FCA liability if his trial attorney identifies a post hoc legal rationale for the claims that is not only reasonable but correct. Such a showing would mean that the defendant did not submit “false or fraudulent claims” in the first place.  31 U.S.C. 3729(a)(1)(A) (emphasis added). That would preclude FCA liability, even if the defendant in submitting his claims had acted with one of the forms of scienter identified in  31 U.S.C. 3729(b)(1)(A).

- 4 As these cases illustrate, moreover, companies that seek funds from the government (particularly on a recurring basis) often have ready avenues for resolving ambiguity about payment rules—for example, by consulting their contacts in state Medicaid agencies, or contractual intermediaries like pharmacy benefit managers. See, *e.g.*, 21-1326 Br. in Opp. 8-9 (arguing that SuperValu asked for clarification from certain state Medicaid agencies and pharmacy benefit managers). When such avenues for clarification are readily available, a contractor's failure to invoke those mechanisms while seeking public funds may be evidence of deliberate ignorance or recklessness under the FCA.
- 5 More generally, no textual or logical reason exists why the FCA's scienter provisions would preclude a factfinder from considering warnings that a defendant received from other knowledgeable non-governmental sources, such as attorneys, compliance officers, or government-contracting experts.

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EXHIBIT D-149

March 28, 2003

NOTE TO: Medicare+Choice Organizations and Other Interested Parties

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2004
Medicare+Choice (M+C) Payment Rates

In accordance with Section 1853(b)(2) of the Social Security Act (the Act), we are notifying you of proposed changes in the M+C capitation rate methodology and risk adjustment methodology for CY 2004. Preliminary estimates of the various national per capita M+C growth percentages and the methodology changes for CY 2004 are also attached. For 2004 and 2005, CMS will announce the M+C rates on the second Monday in May before the calendar year concerned, in accordance with Section 532 of P.L. 107-188, the Public Health Security and Bioterrorism Response Act of 2002. This Advance Notice is published 45 days before that date.

Attachment I shows the preliminary estimates of the national per capita growth percentage for both the blend rates and the floor amount. Attachment II of this Notice includes a detailed discussion of the new CMS-HCC risk adjustment model that will be in effect for CY 2004, the new ESRD payment approach, and various implementation issues affecting CY 2004 payments.

We will continue paying M+C organizations in 2004 on a fee-for-service basis for covered clinical trial items and services provided to their members.

Comments or questions may be addressed to:

Ms. Anne Hornsby
Centers for Medicare & Medicaid Services
7500 Security Boulevard
C4-01-22
Baltimore, Maryland 21244

In order to receive consideration prior to the May 12, 2003 announcement of M+C capitation rates, comments must be received by April 14, 2003.

/ s /

Gail Pardue McGrath
Director
Center for Beneficiary Choices

/ s /

Solomon Mussey, A.S.A.
Director
Medicare and Medicaid Cost Estimates Group
Office of the Actuary
Attachments

Attachment 1

Preliminary Estimate of the National Per Capita Growth Percentage for Calendar Year (CY) 2004

Payments to Medicare+Choice (M+C) organizations are based on the highest of three amounts specified in statute for each payment area (generally a county): (1) a “blended rate” based on both national and local data; (2) a “floor” amount specified in statute; and (3) an amount representing 102 percent of the prior year's rate. Both the blended rate and the floor amount are annually adjusted based on the national per capita M+C growth percentage defined in Section 1853(c)(6) of the Social Security Act (the Act), while the blend amount is subject to a separate adjustment under section 1853(c)(5) intended to make aggregate payments the same as they would be if area-specific rates were used. In this notice, we provide preliminary estimates of the national per capita M+C growth percentages in CY 2004, and the increase in the floor payment rates in CY 2004. Each of these estimates reflects the components required by the BBA: an underlying trend change for CY 2004; and an adjustment for changes in the estimates of prior years' growth percentages. The underlying trend change for CY 2004 and the revision to the CY 2003 estimate reflect changes made by the Consolidated Appropriations Resolution, 2003, (Public Law 108-7) enacted on February 20, 2003.

The current estimate of the change in the national per capita M+C growth percentage for aged enrollees in CY 2004 is 9.5 percent. This estimate reflects an underlying trend change for CY 2004 in per capita costs of 3.7 percent and an adjustment for the fact that the current estimate of prior years' cumulative aged M+C growth percentages (for CYs 1998 through 2003) is 5.6 percent higher than the estimates actually used in calculating the CY 2003 capitation rate book that was published March 1, 2002 (as required by Section 1853(c)(6)(C) of the Act).

The table below shows the increases in the national per capita growth percentages for the aged, disabled, ESRD, and the combined aged + disabled.

The preliminary estimate of the floor for aged beneficiaries in CY 2004 is \$592.29 for any area in an MSA within the 50 States and the District of Columbia with a population of more than 250,000, and \$535.88 for all other areas within the 50 States. In both cases this represents a 8.2 percent increase over the respective CY 2003 floors of \$547.54 and \$495.39. As with the estimate of the national per capita M+C growth percentage, this estimate reflects an underlying trend change for CY 2004 in per capita costs of 3.7 percent. The total change for the floors includes an adjustment of 4.3 percent for revised estimates of prior years' aged M+C growth percentages only for 2002 and 2003, since legislation reestablished the base floor amounts in 2001.

The following tables summarize the estimates for the change in the national per capita M+C growth percentage and the floor increase.

National Per Capita Growth Percentage (for Blend)

	Aged	Disabled	ESRD	Aged+Disabled
2004 Trend Change	3.7%	3.8%	2.9%	3.7%
Revision to CY 1998 Estimate	0.1%	-0.4%	-1.8%	0.0%
Revision to CY 1999 Estimate	0.4%	0.8%	-0.9%	0.5%
Revision to CY 2000 Estimate	-0.3%	0.0%	3.7%	-0.3%
Revision to CY 2001 Estimate	1.1%	3.1%	-4.7%	1.3%
Revision to CY 2002 Estimate	2.1%	1.4%	6.2%	1.9%
Revision to CY 2003 Estimate	2.2%	3.4%	1.2%	2.4%
Total Change	9.5%	12.7%	6.3%	9.8%

National Per Capita Growth Percentage (for Floor)

	Aged	Disabled	ESRD	Aged+Disabled
2004 Trend Change	3.7%	3.8%	2.9%	3.7%
Revision to CY 2002 Estimate	2.1%	1.4%	6.2%	1.9%
Revision to CY 2003 Estimate	2.2%	3.4%	1.2%	2.4%
Total Change	8.2%	8.8%	10.6%	8.2%

Note: The above percentages are multiplicative not additive.

These estimates are preliminary and could change before the final rates are announced on May 12, 2003. Further details on the derivation of the national per capita M+C growth percentage will also be presented in the May 12 announcement.

Attachment 2

Changes in Methodology Since Calendar Year (CY) 2003 Rates

There are a number of changes in M+C payment methodology for CY 2004. Section A discusses the new risk adjustment model to be implemented in 2004, Section B describes refinements to this model for the ESRD population, and Section C discusses the frailty adjuster to be introduced in the PACE program and certain other demonstrations. Section D reviews a range of implementation issues. Section E discusses Medicare as Secondary Payer, and Section F describes the new method for estimating costs of National Coverage Determinations and other legislative changes in benefits. Section G provides an overview of public comments on the February 3, 2003 public meeting on risk adjustment.

A. The new CMS-HCC risk adjustment model.

Background. The Balanced Budget Act of 1997 (BBA) mandated that a risk adjustment payment methodology, incorporating information on beneficiaries' health status, be implemented in the Medicare+Choice (M+C) program no later than January 2000. The BBA timelines for data collection indicated that initially risk adjustment of M+C payments should be based only on data from enrollees' inpatient hospital stays, with later implementation of risk adjustment based on data from additional sites of care. CMS (formerly the Health Care Financing Administration) selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to be implemented in 2000. This model recognizes diagnoses for which inpatient care is most frequently appropriate and which are predictive of higher future costs. Until October 2002 M+C organizations submitted to CMS encounter data on enrollees' inpatient hospitalizations only (analogous to claims), which CMS processed through the PIP-DCG model to calculate payments to M+C organizations.

To assist managed care organizations, CMS provided for a gradual phase-in of the effects of risk-adjustment, initially adjusting only a portion of the total payment based on the new PIP-DCG methodology, with the remainder still adjusted under the pre-BBA method based only on demographic information. This element of the risk adjustment methodology provided a safeguard against abrupt changes in payments to M+C organizations. For 2000, the transition schedule called for basing 90 percent of the prospective monthly payment per enrollee on the demographic-only method and 10 percent on the PIP-DCG risk adjustment method. The demographic-only portion of the payment was adjusted for age, gender, Medicaid eligibility, institutional status, and working aged status. The risk adjusted portion of the payment, under the PIP-DCG model, was adjusted for age, gender, Medicaid eligibility, whether originally entitled to Medicare due to disability, and working aged status, as well as health status.

The Balanced Budget Refinement Act of 1999 adopted CMS's "phase in" concept in statutory language, but altered CMS's proposed timing by mandating that the 90/10 blend would continue through 2001. Most recently, the Benefits Improvement and Protection Act of 2000 (BIPA) again modified the phase-in schedule to further soften the financial impact of risk adjustment on M+C organizations. Under BIPA, the 90/10 blend continues through 2003. In 2004 the risk

adjusted portion of the M+C payment increases to 30 percent, in 2005 to 50 percent, in 2006 to 75 percent, and in 2007 to 100 percent.

Although the PIP-DCG model was an improvement over the previous demographic payment model, CMS recognized that its utility was limited by only using inpatient hospital data and providing additional payment for only a small number of high cost seriously ill beneficiaries. Subsequently, BIPA required the implementation of a model using not only diagnoses from inpatient hospital stays, but also from ambulatory settings beginning in 2004. To prepare for implementation in 2004 of a risk adjustment model based on multiple sites of care, in 2001 CMS required M+C organizations to begin submitting data on enrollees' hospital outpatient and physician office encounters. Although these encounters would have provided additional data for quality measures and re-estimation of payment weights for future risk adjustment models, CMS was concerned about the administrative data burden on M+C organizations.

Physician encounter data collection began in October 2000 and hospital outpatient encounter data collection began in April 2001. In response to concerns of M+C organizations, in May 2001 Secretary Thompson suspended the requirement for submission of hospital outpatient and physician office encounter data in order to allow CMS the opportunity to "explore and implement a risk adjustment process for M+C payments that balances accuracy and administrative burden."

As a result, we have selected a new risk adjustment model for 2004 (described below) as well as significantly reducing the administrative burden on M+C organizations. By redesigning our data collection and processing systems, we now require that only a few data elements besides diagnoses be submitted for payment purposes. Fewer diseases will be used by the new model (compared to other comprehensive risk adjustment models) and the requirement to report each encounter has been removed. In addition, CMS requires that relevant diagnoses be submitted for each beneficiary only once during a data collection period. Also, M+C organizations may choose to submit diagnoses on a quarterly basis.

Selection of the new CMS-HCC risk adjustment model . Our goal was to select a clinically sound risk adjustment model that improved payment accuracy while minimizing the administrative data burden on M+C organizations. CMS worked with a number of outside researchers to develop a more comprehensive risk adjustment model using inpatient and ambulatory data. We also sought public input on model selection via consultations with industry trade groups and staff from different M+C organizations, a public meeting (conducted on January 16, 2002), publication of a Federal Register notice, and solicitation of public comments on the meeting and Notice. (For information CMS published during 2002 on the development of the more comprehensive risk adjustment model, see the Risk Adjustment web page at <http://www.cms.hhs.gov/healthplans/riskadj/>.)

The payment models CMS considered used only demographic and diagnosis data to avoid incentives related to tying payment to treatment modalities. CMS chose one of the comprehensive models that would lend itself most easily to necessary modifications that would be clear to analysts and physicians. The resulting model is a CMS modification of the comprehensive model created by Health Economics Research (now a division of RTI), which

also developed the PIP-DCG model currently being used for M+C payment. We will refer to this model as the CMS-HCC model.

CMS-HCC Model Characteristics

The CMS-HCC model is a selected significant disease type of model because it incorporates a selected subset of ICD-9-CM diagnosis codes and places them into approximately 64 disease groups called Hierarchical Condition Categories (HCCs). Each disease group includes conditions that are related clinically and have similar cost implications. (See **Exhibit 1** for a draft list of coefficients for each disease group. A final list of disease groups, their coefficients, and a crosswalk to the required ICD-9 codes will be available in the May 12 Announcement of M+C Payment Rates and on the CMS website. These annual coefficients will be used to calculate per person per month payments to M+C organizations. At that time, CMS will also make available for public use risk adjustment payment software that will appropriately assign diagnoses to CMS-HCC groups to identify relevant disease hierarchies and calculate risk scores for each enrollee.)

The model is prospective in the sense that it uses diagnosis information from a base year to predict costs and adjust payments for the next year. Models of this type are largely driven by the costs associated with chronic diseases, and they capture the systematic risk (costs) associated with Medicare populations. CMS will make available a full report on the CMS-HCC model. For a description of the underlying principles and development methods for the selected model, see the report on earlier versions of the HCC model, “Diagnostic Cost Group Hierarchical Condition Category Models for Medicare Risk Adjustment (Final Report); December 2000”, available from the CMS website at <http://www.cms.hhs.gov/researchers/projects/>.

As in the PIP-DCG model, there are demographic variables for age and sex, Medicaid eligibility, and originally disabled status. There is also an adjustment for working-aged status. The recognition of the additional costliness to the Medicare program of people characterized by Medicaid eligibility is maintained as it was in the PIP-DCG model. Note, however, that this variable has less importance (less incremental cost) in models that recognize health status using disease groups because more of the dollars in the model are associated with specific diseases rather than demographic categories. As in PIP-DCG, the Medicaid payment adjustment is triggered by a beneficiary having Medicaid status any one month in the data collection year.

We also continue to recognize that those eligible for Medicare due to disability continue to be more expensive for their age after 65. There are variables in the model capturing that the original reason for Medicare entitlement was disability.

Unlike the PIP-DCG model, which does not have an institutional status adjuster, the CMS-HCC model has a modification that distinguishes the community-dwelling Medicare population from the long-term institutionalized populations. This long-term institutional adjuster differs from the institutional factor used in the demographic-only payment model. The new institutional adjuster is explained at the end of this section.

Clinical Features of the CMS-HCC Model

HCCs are disease groups broadly organized into body systems, somewhat analogous to the ICD-9-CM major diagnostic categories. Unlike the ICD-9-CM categories, however, the diagnoses within each disease group are related clinically and in terms of cost to the Medicare program.

Whereas the PIP-DCG model places a person in only a single cost group based on his/her principal inpatient diagnosis with the greatest cost implications, the CMS-HCC model is structured so that each disease group contributes its incremental predicted cost to payment amounts. Conceptually, disease groups are not mutually exclusive because unrelated disease processes each contribute to the predicted costs of care. The CMS-HCC model uses diagnoses from physician visits and hospital inpatient and outpatient stays to assign each beneficiary to none, one, or more than one disease group. For example, an M+C enrollee with heart disease, cerebrovascular disease, and cancer would be assigned to three separate disease groups, and CMS's payment for this enrollee will reflect increments for each of these conditions. We refer to this as an additive model because, in general, each additional diagnosis results in an increased payment.

In some cases, however, an additional diagnosis does not trigger an additional payment increment because a more severe diagnosis supercedes a less serious one. That is, the CMS-HCC model also can characterize a beneficiary's illness level within a disease process. In some disease groups the diagnoses are clinically related and ranked by (cost) severity in a hierarchy, since the more severe manifestations of a disease process principally define the impact of that disease group on cost.

An example is the diabetes hierarchy. Diabetes diagnoses are organized into four severity groups, ranked from uncomplicated diabetes to diabetes with renal manifestations (highest cost implications). A person may be coded with diagnoses in any or all of the four severity groups, but only the highest code in the hierarchy is used to increment payment for diabetes. There are similar hierarchies among cancers and cardiac diseases. In short, costs are additive across hierarchies and disease groups, but not within hierarchies. (See **Exhibit 2** for a draft list of the disease groups that have hierarchies.)

CMS-HCC Model Refinement.

In the original HCC model developed by Health Economics Research, there were approximately 5,000 ICD-9 codes grouped into about 100 disease clusters used for payment, which is about a third of the approximately 15,000 possible codes in ICD-9-CM. The developers isolated and excluded codes that were vaguely defined, only represented signs or symptoms, and did not contribute significantly to the predictive power of the model. They made decisions about how to cluster codes and which to exclude in consultation with a panel of physicians using statistical information and clinical input.

CMS was able to reduce further the size of the original HCC model, with only a modest effect on the power of the model to predict costs, by taking into account the clinical and cost significance of various disease groups relative to the model's overall performance and clinical coherence. The CMS-HCC model categorizes a reduced set of ICD-9-CM diagnosis codes (approximately 3,300 codes grouped into a reduced set of about 800 codes) into approximately 64 disease groups

(HCCs). (The draft list of the reduced code set that triggers payment in the CMS-HCC model was published in April 2002 on the CMS website at <http://www.cms.hhs.gov/healthplans/riskadj/>. The final list of codes for 2004 will be published May 12, 2003 in the Announcement of M+C Payment Rates. Each year we will issue a list of required diagnoses to take into account new ICD-9 codes.) CMS analysts used both statistical information and clinical input from physicians to trim the original HCC model. The general principles for trimming the model included: retaining disease categories from each body system; not disrupting hierarchies; removing the categories with the smallest cost and predictive power implications; removing categories with very few people unless very costly; removing marginal categories that require a large number of codes; and including categories based on clinical judgment.

The clear structure of the original HCC model allowed us to associate diseases categories with incremental costs and construct tables to show how often certain disease groups occur in the Medicare population (based on a 5 percent fee-for-service sample of Medicare beneficiaries). We used stepwise regression, a technique that ranks the variables by their predictive power, to identify the disease groups that were weakest from a statistical point of view, i.e., the groups with the least predictive power.¹ Based on the results of this analysis, we produced a range of possible models from one with very few disease groups to a full comprehensive model, and discussed the advantages and disadvantages of each with a panel of physicians from within and outside CMS. Most of the panelists preferred the more comprehensive models because they were more clinically defensible and less subject to gaming. However, they found that a model such as the CMS-HCC version presented here was a reasonable compromise, given the need to balance improved payment accuracy with minimizing administrative data burden.

Since the initial selection of the CMS-HCC model, CMS has continued to refine the model, addressing concerns about coding practices and model performance. CMS contracted with an independent group to study issues of coding practice and its effect on how the model would perform when applied. Based on the findings, CMS modified the cancer and diabetes hierarchies. For example, metastatic (secondary site) cancer codes are not reported as frequently as they should be in fee-for-service claims data, so the distinction between multiple primary sites and metastases is poor in the Medicare data. Reflecting this, the secondary site codes have been merged with other costly primary cancers. For diabetes, further study of the costs and coding resulted in a reordering of the codes within the diabetes hierarchy. We will continue to assess the need for improvements in the model in 2004 and beyond.

CMS also incorporated some interactive terms in the model to capture the combined effects on cost of certain diseases. In most instances, simply adding the incremental costs of multiple diseases captures the combined effect that individual diseases have on costs. However, research

¹ Regression analysis is a technique used to predict outcomes, measure the strength of the association between independent variables (predictors, e.g., demographic variables) and the dependent variable (outcome, i.e. Medicare expenditures), and, to identify the subset of independent variables that are most effective for estimating the outcome. Stepwise regression is a form of this technique that is used to identify the subset of variables that is most effective for estimating the outcome. It works by eliminating those independent variables from the regression that contribute least to explaining the outcome.

has shown that some combinations of diseases are more or less costly to treat than the sum of the costs of individual diseases. Thus, interactive terms representing combined effects are in the model. The diseases involved are diabetes, congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, renal failure, and coronary artery disease. There are also terms in the model that distinguish the costs of the disabled (under 65) from the aged for specific diseases. These are disorders that typically have more expensive treatment patterns in the younger population, e.g., drug and alcohol psychosis and dependence, opportunistic infections, and cystic fibrosis.

See the end of this section for information on another CMS refinement of the HCC model – the addition of an adjuster for long-term institutional status.

Estimation methods. The fee-for-service data used to calibrate the models are from 1999 and 2000. The diagnoses and Medicaid status are from 1999, and the total costs for each beneficiary are from 2000. ESRD patients were excluded from calibration of the CMS-HCC model. They will be paid under an alternative payment methodology to reflect their unique costs, described in Section B.

Decedents in 2000 are included and treated as they were in the previous payment models. First, their costs were annualized, i.e., inflated to correspond to a full 12-month period. Then, when the model was estimated, the decedents were assigned a weight according to the proportion of the year they were alive. M+C enrollees and hospice patients are treated similarly: their costs are included until they enter hospice or enroll in an M+C organization. All claim types were used to compute costs. Hospital inpatient, outpatient and clinical practitioner claims were used to collect diagnoses. Principal and secondary diagnoses were used from institutional bills and the diagnoses from claim headers were used from the practitioner bills. Fully denied claims were not used. However, diagnoses were accepted from claims that had Medicare Secondary Payer as the reason for denial.

The estimation was done using the weighted least squares method. The cost variable was annualized and weights were set to the fraction of the year in months that each person was alive and not in a hospice or M+C organization. Annualization and weighting was also done to reflect a beneficiary's time and expenditures in the community or institutionalized status category. The expenditures in each status were summed separately. Statistical formulations more elaborate than weighted linear regression have been researched but did not improve the performance of risk adjustment models significantly or consistently.

When models are estimated using the regression method, each characteristic (demographic or diagnostic) is estimated to determine its marginal costliness to the Medicare program. Use of the regression method produces a coefficient for each variable (characteristic), which represents the marginal (additional) effect of each variable in predicting program costs. These coefficients are then converted to relative cost factors, because in order to use the model as an adjuster to a base rate, costs must be converted to relative costs – i.e., risk adjustment factors. This is done by dividing the marginal costs by the average per capita costs in fee-for-service Medicare. For example, if the average per capita cost in Medicare is \$5000, a marginal cost of \$1000 for some characteristic becomes a relative risk factor of 0.2. To arrive at a beneficiary's total risk

adjustment factor, add the factors associated with each applicable demographic characteristic and each applicable disease group.

Adjustment for coding intensity and population changes. We believe that there have been sufficient changes in the national average predicted expenditures from 1997 to 2004 that it may not be appropriate to use the 1997 national average predicted expenditures to calculate the relative risk factors for the 2004 CMS-HCC model. These changes are related to changes in fee-for-service-population data attributable to changing demographics, average disease burdens, and coding patterns (i.e., later data tends to reflect more precise coding).

The CMS-HCC risk adjustment model is calibrated on expenditures and disease patterns for 1999 and 2000. When the coefficients from that calibration are used to predict expenditures from earlier or later periods, the model would predict the same mean were it not for the factors above. However, the predicted means from earlier years tend to be lower than those from later years. Fee-for-service coding intensity and specificity, particularly in physician claims, has increased over time. In other words, if we created relative risk factors for our 2004 CMS-HCC model using 2000 claims data on a sample of fee-for-service beneficiaries and then used these risk factors to calculate the risk scores for a 2004 sample fee-for-service beneficiaries with exactly the same demographic and actual disease profile as the 2000 sample, the 2004 group would still have higher risk scores than the 2000 group.

When calculating the ratebook for 1997, we are exploring using the national means from each of three years to compute the relative risk scores for the counties. This method would make the mean relative risk factor for fee-for-service equal to 1.0 for that period. It is desirable that the mean relative score stay at this value, so CMS will consider an actuarial adjustment to the national mean predicted expenditures used to calculate relative risk factors so that the mean relative risk factor in fee-for-service remains close to 1.0 for the payment period. Note that any changes in population demographics and rising coding intensity are happening in the fee-for-service population, which is the basis for the risk adjustment model.

Adjustment for long-term institutionalization. In the course of our research addressing other characteristics distinguishing cost among beneficiaries, we found further evidence for differences in cost between the community population and the long-term institutionalized (defined as those in institutions more than 90 days) within the same disease groups. The direct recognition of health status in the model results in a large overprediction for the long-term institutionalized if not controlled for in the model. We also found that the costs for the short-term institutionalized resemble the costs for beneficiaries with similar health status residing in the community.² These findings do not show that the long-term institutionalized are not expensive to Medicare. What we are recognizing is that people in the community are even more expensive to the program than equally ill people (in the same disease groups) who are long-term institutionalized.

Institutional status is recognized in the payment year, not the prior year. To implement an adjuster without creating burden for the M+C organizations, CMS is using the Minimum Data Set (MDS) collected routinely from nursing homes to identify the population of long-term

² Hereafter, the term “community” will be used to refer to community-based and short-term institutionalized populations.

institutionalized. MDS assessments are sent to the States and CMS on at least a quarterly basis. CMS is using the presence of a 90-day assessment in the payment year to identify the long-term residents for payment purposes. Payment at the long-term rate would start in the month following the assessment. Once persons are so identified, they remain in long-term status until discharged home for more than fourteen days. Note that this marker is different from the institutionalized marker used in the demographic system. That marker largely captured the higher costs of older and sicker people who go into skilled or unskilled levels of care. In the risk adjustment model, the health status markers capture most of these characteristics. We are concentrating on long-term residents and their cost patterns, after controlling for disease.

The CMS-HCC model has been calibrated separately for the community and long-term institutionalized populations. Disease-related incremental payments for the community population are generally higher than those for the institutionalized. The age/sex payments are higher for the institutionalized than the community population. The costs associated with high mortality rates in the long-term institutionalized group are all captured in this calibration, which included only the institutional months for this population. The CMS-HCC model for the institutionalized has been simplified even further than the community model. The same diseases are captured, but many disease groups have been merged to assure stable coefficients. The resulting model is similar to some of the reduced models that were researched for the whole population.

B. New payment methodology for M+C ESRD enrollees.

Simultaneous with the implementation of the CMS-HCC model for risk adjustment, we are implementing a new approach to improve payments on behalf of enrollees with End Stage Renal Disease (ESRD). Section 605 of BIPA required CMS to adjust our approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration then in place. We interpret this to mean that ESRD payments to M+C organizations should employ the same basic approach as under the ESRD demonstration referenced in section 605. To implement the BIPA provision for 2002, CMS increased the base rates by three percent and began adjusting payments with age and sex factors, while continuing to review other options. Effective January 2004, M+C enrollees with ESRD will be incorporated into diagnosis-based risk adjustment using a different version of the CMS-HCC model. (See **Exhibit 3** for a draft list of coefficients for each disease group.) The new ESRD payment model will align us further with the method used in the ESRD S/HMO demonstration by allowing us to capture co-morbidity information in addition to demographic information and basic disease markers for ESRD beneficiaries. ESRD status is recognized in the payment year. The data for 100 percent of ESRD beneficiaries were used to develop the model. The three parts of the ESRD CMS-HCC model are:

1. A full risk adjustment model for people on dialysis that is calibrated only on this population, so the payment weights are unique to these beneficiaries. A rescaled state-level ratebook will be created to reflect this population's program costs.
2. A series of lump-sum payments to reflect costs associated with transplant procedures. Transplant costs associated with the month of transplant and two following months are carved out of expenditures for the ESRD population to allow CMS to make larger

transplant-specific payments (outside of the risk adjustment model) over a three-month window.

3. A modified version of the regular CMS-HCC model for people who have successful kidney transplants. The model has an additional term to recognize the extra costs of immunosuppressive drugs and higher intensity of care for this group.

We developed this three-part model in response to our findings on expenditures patterns for ESRD beneficiaries. Dialysis patients have high ongoing costs, while transplant patients incur a very high one-time cost. Functioning graft patients are much more similar to the general population than they are to dialysis patients. Using the same payment weights for all three groups would lead to over- or underpayments to M+C organizations that do not have enough ESRD enrollees to have an average mix. To address this problem, CMS developed separate payment approaches for these three populations.

Risk adjustment model for dialysis patients. The dialysis model has the same HCC categories as the CMS-HCC model for the non-ESRD population, except that HCCs with kidney disease diagnoses are excluded (HCC128 to HCC132). The model is calibrated only on dialysis patients, so the disease weights used for payment recognize disease and expenditure patterns unique to this population.

The data used for calibrating the ESRD models were 1999 (diagnostic) and 2000 (cost) data on fee-for-service ESRD beneficiaries. For example, expenditures for a fee-for-service beneficiary on dialysis from January through August 2000 who received a transplant in September 2000 are included in the dialysis group for eight months, but then are excluded. From September through November 2000, this beneficiary's costs are included in the transplant data to determine estimated average transplant costs. As of December 2000, this beneficiary is included in the functioning graft model.

Transplant patients. To pay more accurately for the high costs of kidney transplants, CMS will make transplant-specific payments to M+C organizations for three months for each member who received a transplant, beginning in the month of transplant. CMS calculated a national average cost for three months (the transplant month and two subsequent months) and divided the average for the three months by three to get the average monthly cost. CMS converted the average monthly cost to a relative factor. The ratio of this monthly cost to the national average monthly cost for dialysis patients is the factor. This factor multiplies the rates in the dialysis ratebook to determine payment. No additional ratebook is needed, as this method produces a payment that is the national rate, geographically adjusted.

For example, assuming that the national average three-month program cost for a transplant is \$40,000 and that the national average monthly cost for a dialysis patient is \$3,500, the relative factor would be 3.81 (i.e., $[40,000/3]/3500$). Payments for a transplant for a resident of a nationally average county would be $3.81 \times 3,500 = \$13,335$ for each of three months. Payments in higher or lower cost counties would vary.

See Section D.6 for information on a new option M+C organizations may choose to adopt for reporting dialysis and transplant status of members.

Functioning graft beneficiaries. The model for functioning graft enrollees is based on the model for the general population, except that HCCs for kidney transplant status, dialysis status and renal failure are excluded. This means that for their members with functioning grafts, M+C organizations will be paid in 2004 based on the diseases reported for functioning graft members recorded in 2003 (the reporting year for 2004). However, CMS also will make an add-on payment for each functioning graft enrollee to recognize the extra costs associated with immunosuppressive drugs and additional intensity of services for this population. The payment model is a slight modification of the regular model; all the coefficients are the same (with the exclusions above) but a term with a factor for the average additional costs of these beneficiaries is included.

The functioning graft payment automatically begins the month after the third transplant payment unless CMS hears from the M+C organization or the CMS data system that the member has returned to dialysis. Anytime a functioning graft patient returns to dialysis, payment is made using that model.

Since Section 605 of BIPA required CMS to adjust our approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration then in place, we interpret this to mean that the new three-part model will be implemented at 100 percent of payments for 2004, just as the 2002 changes to the ESRD methodology per BIPA were implemented at 100 percent. See Section E for a discussion of Medicare Secondary Payer status.

C. Changes in Methodology for PACE and certain Demonstrations

Background.

Overview: CMS has developed a Medicare payment approach that adjusts the payment to an organization according to the frailty of an organization's enrollees. The frailty adjustment approach will be applied to the PACE program in 2004. The current PACE demonstrations are expected to transition to PACE program status during 2003. New PACE demonstrations will be paid under the same approach as the PACE program in 2004.

The current social HMO (S/HMO) demonstration is scheduled to end by December 31, 2003. In the absence of a legislative extension, we plan to continue the S/HMO demonstration with the risk adjusted payment methodology incorporating the frailty adjustment approach. The current waiver for the Wisconsin Partnership Program (WPP) demonstration expires on December 31, 2003. Pending a decision on the extension of the waivers, we intend to apply the frailty adjustment approach to the WPP demonstration in 2004. The adjustment approach will also apply to the Minnesota Senior Health Options (MSHO) and the Minnesota Disability Health Options (MnDHO) demonstrations in 2004.

The Balanced Budget Act of 1997 (BBA) mandated that Medicare capitated payments to PACE organizations be based on M+C payment rates, adjusted to account for the comparative frailty of PACE enrollees. The payment approach described herein is a further refinement to risk

adjustment to ensure that capitated payments to organizations that serve frail community-based populations are accurate.

The frailty adjustment approach is to be applied in conjunction with the CMS-HCC risk adjustment model. As mentioned above, the CMS-HCC model has been designed to pay appropriately for the long-term institutionalized population. Therefore, the frailty adjustment approach will apply only to community-based and short-term institutionalized enrollees³ (i.e., the frailty adjustment for long-term institutionalized enrollees is zero). Risk adjustment predicts (or explains) the future Medicare expenditures of individuals based on diagnoses and demographics. But risk adjustment may not explain all of the variation in expenditures for frail community populations. The purpose of frailty adjustment is to predict the Medicare expenditures of community populations with functionally impairments that are unexplained by risk adjustment.

Basic Approach: The first step in the estimation of an adjuster was determining the measures that were candidates for frailty adjustment. Certain measures of functional impairment (such as activities of daily living (ADLs)) were considered to be the most meaningful for purposes of payment. Beneficiary characteristics (such as age and gender) were also considered. In order to develop the frailty adjustor, CMS needed a database that linked measures of functional impairment to Medicare expenditures at the individual level. The Medicare Current Beneficiary Survey (MCBS) included the necessary linked information. Therefore, the candidate functional impairment measures were selected from among those collected by MCBS.

The next step was finding the relationship between the above measures or characteristics and the Medicare expenditures that were unexplained by risk adjustment. For example, the actual Medicare expenditures for each group of people with similar functional impairments were compared to the expenditures predicted by the CMS-HCC model for that group. As described below, the frailty adjustor was designed to explain (or adjust for) the average difference between the predicted and actual expenditures for each group.

The final step in the estimation was to select the appropriate measures from among the candidates. The selection process considered a number of criteria such as face validity, reliability, appropriate incentives, fairness, simplicity, and gameability. The measure(s) that best met the criteria were to be included in the frailty approach. The frailty model was to consist of a set of factors (one factor for each group) for the measure(s) that were selected.

Consistent with the way diagnosis data are used in risk adjustment, the frailty adjuster was designed to be prospective. That is, prior-year functional impairment data were used to predict the next-year's payment adjustment.

Estimating the Frailty Model

Calibration of Frailty Factors: The draft frailty factors were developed using the MCBS cost and use files for 1994 through 1997. Since the model was prospective, information from the "base year" was used to predict payment in the following year. Prior-year diagnosis and functional impairment information were linked to next-year Medicare expenditures to create

³ Hereafter, the term "community" will be used to refer to community-based and short-term institutionalized populations.

three data sets with person-year observations: 1994-95, 1995-96, and 1996-97. These data sets were pooled, and Medicare payments were predicted for these person-years using the CMS-HCC model. The difference of actual payments and predicted payments for each person-year (residual expenditures) was then related to beneficiary functional and institutional status using regression modeling. The frailty factors were derived from these regression coefficients and reflect the mean Medicare payments related to functional status that are not explained by the CMS-HCC model.

The residual expenditures for the MCBS institutionalized population were virtually zero. That is, the CMS-HCC model accurately predicted the average expenditures for this population. Therefore, the frailty adjuster applies only to the community population.

The frailty model was based on Activities of Daily Living (ADLs) as the core measure of functional impairment. Individuals were grouped according to their difficulty with 0 ADLs, 1 to 2 ADLs, 3 to 4 ADLs, and 5 to 6 ADLs. CMS considered whether the frailty model could be improved by including other measures and characteristics interacting with ADLs. Among other things, these included demographics, self-reported health status, chronic conditions, needing help or special equipment with ADLs, and physical measures of impairment (such as walking 2-3 blocks). In general, adding other measures did not appear to improve the frailty model. Some interaction terms were not statistically significant. That is, they did not improve the explanatory power of the model once ADLs were taken into account. Some measures lacked face validity, i.e., greater functional impairment failed to be associated with greater expenditures. Others were not considered reliable in that they could potentially suffer from a large degree of random variation due to small sample sizes. And still others were potentially gameable or provided incentives for inappropriate utilization. Therefore, CMS decided to base the frailty model on ADL groupings only.

Frailty Factor for the Under-55 Disabled: CMS analyzed the residual expenditures for the Medicare disabled population in MCBS. For the 55-and-over population, the residuals were significantly different from zero for all ADL groups. But for the under-55 population, the residuals were not significantly different from zero regardless of the degree of functional impairment. That is, the CMS-HCC model appears to adequately predict the expenditures of the under-55 population without the need for an additional frailty adjuster. Therefore, the frailty factor for this population is zero.

Mortality: The MCBS observations included persons who died in the payment year. The higher expenditures of these persons were included in the frailty model, using the same approach for treating the deceased as was used for the CMS-HCC model. Each ADL group in MCBS has an inherent mortality rate. To test whether the inherent mortality rates were reasonable, CMS investigated whether these mortality rates were representative of the mortality rates for the PACE program. The MCBS mortality rates for each ADL group were applied to the distribution of PACE enrollees by ADL group. This yielded a predicted mortality rate for PACE (i.e., the mortality rate that PACE would have experienced if it had the same rate of mortality as the MCBS population). The predicted mortality was similar to the actual mortality rate across all PACE organizations. That is, once ADLs were accounted for, the PACE mortality rate was

similar to the MCBS mortality rate. Frailty adjustment appears to adequately account for the rate of mortality for frail populations.

Draft Frailty Factors: The draft frailty factors for the 55-and-over community populations are as follows:

<u>Difficulty in ADLs</u>	<u>Frailty Factors</u>
0	-0.14
1-2	0.17
3-4	0.34
5-6	1.09

The final factors will be published in the May 12, 2003 Announcement of M+C Payment Rates.

D. CMS-HCC Model Implementation Issues

CMS will implement the CMS-HCC risk adjustment model following the approach used to estimate the model (as described above). The model will apply to M+C organizations and PACE organizations. The Evercare Demonstration is currently scheduled to end December 31, 2003. Pending a decision on the extension of the waivers, we intend to implement the CMS-HCC model for Evercare in 2004. The CMS-HCC model will also apply to the S/HMOs, WPP, MSHO, and MnDHO demonstrations, as mentioned in Section C. In determining a risk score for a beneficiary, we will determine the status of each variable included in the model based on the same definitions used to estimate the model. For example, in determining a beneficiary's Medicaid status, we will determine whether the beneficiary was eligible for Medicaid for at least one month during the data collection period. Then, the beneficiary's status on each variable in the model (i.e., age, sex, original reason for entitlement, Medicaid eligibility, institutional status (long-term versus community and short-term), and diagnoses) will be used to determine his/her risk factor. The risk factor (and frailty factor, if applicable) is then multiplied by the correct rate book amount to determine the risk adjusted payment. The demographic portion of the payment will continue to incorporate demographic variables such as age, sex, Medicaid eligibility, and institutional status. The final step is to implement the correct transition blend (see section D.7).

1. New Enrollee Factor.

If a beneficiary has less than 12 months of enrollment in Part A and Part B during the data collection period, then he/she will be assigned a new enrollee factor. During the payment year, a new enrollee factor will also be assigned to any beneficiary whose risk score is not available. In this case, the beneficiary's correct risk score will be determined during the next reconciliation. For ESRD payments, the dialysis and functioning graft models will have new enrollee factors for enrollees whose risk scores are not available.

2. Addressing Age Weights

In the past, CMS has recognized that people have birthdays that put them into age groups during a given year by either switching the payment group during the year in the demographic payment model or by paying a weighted average of the 2 groups each month to avoid having to switch age

groups during the year (as the PIP-DCG model does). In response to industry feedback, CMS will now base payments on the age an enrollee attains as of February 1st of each year. This change will help simplify the M+C payment system.

3. Reporting Institutional Status.

As described above, CMS is incorporating institutional status into the CMS-HCC risk adjustment model. Under risk adjustment, institutional status will be determined from information included in the Minimum Data Set (MDS) that is reported by Medicare certified nursing homes. As described in the previous section, presence in the MDS of the 90-day assessment for an individual will be used to determine his/her long-term institutional status.

Under risk adjustment, M+C organizations will not have to report the institutional status of their enrollees monthly as they do for the institutional adjustment under the demographic-only method. Thus, under risk adjustment the reporting burden on M+C organizations will not be increased. Note that M+C organizations may continue to track the institutional status of their enrollees to ensure that CMS correctly identifies institutional status.

Currently, most M+C organizations have a small proportion of long-term institutionalized enrollees. In fact, less than 20 organizations currently have more than 5 percent long-term institutionalized. In order to minimize the number of adjustments to monthly payments, CMS will assume that all enrollees in most M+C organizations are community-based. Payments will be based during the payment year on the community version of the risk adjustment model. The final reconciliation for 2004 will determine the correct institutional status for each enrollee for each month.

For the small number of M+C organizations who have a larger proportion of long term institutionalized enrollees (e.g., between 5 and 75 percent), we will determine the enrollees who are long-term institutionalized as of a point in time in the prior year (e.g. June 30, 2003 for the 2004 payment year). We are still determining the appropriate approach for applying the institutional adjuster for this group of enrollees. We would appreciate comments on this issue.

Finally, for M+C organizations or demonstrations where a majority of enrollees are long-term institutionalized persons, we will assume that all of their enrollees are institutionalized during the payment year. Again, in reconciliation, these M+C organizations will receive an adjustment reflecting the correct monthly institutional status for each person for each month for 2004 as reported through the MDS.

4. Elimination of the Data Lag.

The CMS-HCC risk adjustment model was calibrated using diagnostic data from the prior calendar year to predict resource use for the subsequent calendar year. While CMS's initial PIP-DCG risk adjustment model was calibrated on a calendar year basis, it was implemented with a six month "lag" between the data collection year and the payment year. This implementation approach was preferred (at that time) by M+C organizations. However, risk adjustment models estimated with no lag are more accurate in predicting payments than those models that incorporate a lag because the prediction period is closer to the data collection period. Therefore,

beginning in 2004 CMS will eliminate the lag to improve the accuracy of payments under the CMS-HCC model.

CMS will initially implement payments in 2004 based on diagnoses occurring between July 1, 2002 and June 30, 2003. Beneficiaries' statuses on all variables will also be determined based on that data collection period. Initially in 2004, M+C organizations will be paid based on this lagged data collection period. Then, in order to eliminate the data lag, CMS will recalculate risk factors for all enrollees, moving the data collection period to the immediate preceding calendar year (i.e., for 2004, the immediately preceding calendar year is January 1, 2003 to December 31, 2003). This process will eliminate the lag. During 2004, CMS also expects to reconcile payments back to January 2004 based on these new factors.

5. Reconciliation of Late Risk Adjustment Data.

Because M+C organizations have only three months after the end of a data collection year to submit the diagnostic data that is used to develop risk factors, the final reconciliation for a year allows all the late diagnostic data to be incorporated into the enrollee's risk score. For example, M+C organizations must submit risk adjustment data from the January 1, 2003 through December 31, 2003 data collection period by March 5, 2004 in order for the data to be included in the preliminary risk factor based on non-lagged data for 2004. Diagnostic data submitted after this date will not be incorporated into initial payments based on this data collection period. However, CMS will accept late data for the 2003 calendar year through March 31, 2005. After this date, CMS will no longer accept data for risk adjustment for CY 2004.

The reconciliation incorporates all the diagnoses from the correct data collection period in addition to other changes in enrollee's status (e.g., age, gender, Medicaid eligibility) to be factored into each enrollee's risk factor. Then, adjustments are made to ensure that M+C organizations' final payments for a year are correct. There is a single final reconciliation for each payment year. The final reconciliation for 2004 payments will be conducted in the spring of 2005, with final reconciled payments for 2004 provided to M+C organizations in the August 2005 payments.

6. Reporting Timely End-Stage Renal Disease (ESRD) Status.

In moving to the implementation of the new ESRD risk adjustment method, CMS will utilize the existing systems for identification of enrollees receiving dialysis services. Currently, M+C enrollees are assigned ESRD status as a result of a physician certifying their ESRD status on CMS Form 2728, the End Stage Renal Disease Medical Evidence Report. The ESRD facility sends Form 2728 to the Renal Network, which then transmits the status to CMS systems where various databases are updated to record the ESRD status. Payments for dialysis are triggered by this system.

The ESRD information system would also remain the standard for identifying enrollees who received a transplant. However, M+C organizations would be given the opportunity to notify CMS directly of a transplant in order to receive more timely payments for a transplant. We are examining different ways of implementing more timely reporting of transplant status and will provide information on this process soon. Ultimately, M+C organization-reported ESRD status

will be reconciled against CMS's existing ESRD information reporting system to determine final ESRD status for payment.

7. Transition Payment Blends.

For M+C organizations, in 2004 the CMS-HCC model will be implemented at a 30 percent risk adjusted payment, with the remaining 70 percent being a demographic payment. The portion of risk adjusted payment will increase to 50 percent in 2005, to 75 percent in 2006 and finally to 100 percent in 2007. However, the ESRD models for dialysis, transplant, and functioning graft payments will be implemented at a 100 percent level. See Section B for further information.

The same 30 percent risk adjusted and 70 percent demographic payment schedule will apply to EverCare and S/HMOs, but the non-risk adjusted portion of the payment will be based upon their current payment methodology rather than the demographic payment. For S/HMOs a frailty adjuster will also be applied.

For PACE organizations and certain demonstrations, i.e. WPP, MSHO and MnDHO, an alternative transition payment blend will be used, so that full implementation of risk/frailty adjustment for PACE and these demonstrations will occur in 2008 instead of 2007. In 2004, the CMS-HCC model with a supplemental frailty adjuster will be implemented at a 10 percent risk adjusted payment, with the remaining 90 percent being based on the plan's current payment methodology. The transition blends for PACE and certain demonstrations are discussed in more detail in Section D.9 below. See **Exhibit 4** for a chart summarizing the transition payment blends being used for various plans.

8. Budget Neutrality.

In 2004, risk adjustment will be implemented in a budget neutral manner in an effort to further stabilize the M+C program. The implementation of risk adjustment budget neutral to the M+C program will ensure that risk adjustment does not reduce the aggregate amount of payments to M+C organizations. The Office of the Actuary (OACT) will estimate the amount of adjustment to be incorporated into the rescaling factor, which for 2004 redistributes estimated payment reductions that would result from risk adjustment without this adjustment. The estimate is the difference between the aggregate M+C payments that would be made using the demographic-only method for 100 percent of payments versus the aggregate payments that would be made using 100 percent of risk adjusted payments. The budget neutrality estimate is a multiplier applied to the rescaling factor.

M+C organizations will be required to reflect budget neutrality payments for 2004 in their 2004 Adjusted Community Rate Proposals (ACRPs). The ACRPs for 2004 are due by statute in September 2003. M+C organizations will see payments that reflect this budget neutral approach in the beneficiary-level amounts that are shown on the Monthly Membership Reports (MMR.), beginning in January 2004. The reports for January 2004 will be available for downloading in late December 2003.

9. Application of Frailty Model

To apply the frailty adjuster, it was necessary to develop an approach for collecting functional impairment data for an organization's enrollees. Initially, the Health Outcomes Survey (HOS)

was considered as a potential source of the data for PACE. However, the historical HOS response rates for PACE (generally under 50 percent) have been considered too low to be useful for payment adjustment. Therefore, CMS developed an alternative survey instrument that was much shorter than the HOS. This instrument was pilot tested on a sample of the PACE population in 2002, resulting in substantially higher response rates (68 percent). The PACE Health Survey (PHS) will be administered in 2003 to support PACE payment adjustment in 2004.

9a. PACE

The PHS will be administered in 2003 to support PACE payment adjustment in 2004. The PHS will be administered to PACE organizations that were active as of January 1, 2002. Responses from participants residing in the community will be used to determine the organization-level frailty scores. Once the data are collected, they will be applied to the frailty model to determine a frailty "score" for each organization. The organization-level frailty score will be calculated as the weighted average frailty factor across all community survey respondents for that organization, as follows. The number of community respondents with difficulty in 0 ADLs, 1 to 2 ADLs, 3 to 4 ADLs, and 5 to 6 ADLs will be counted. These counts will be multiplied by the corresponding frailty factor. The resulting products will be summed for each organization. This sum will be divided by the number of community respondents, yielding a weighted average factor (or frailty score) for each PACE organization. The same frailty score will be used for all respondents and nonrespondents who reside in the community. This frailty score will be added to the risk score of each community enrollee in the organization (including only those ESRD beneficiaries in post-transplant status), resulting in a risk+frailty score for each individual. Payments to these plans will be the product of this score and the risk adjusted county rate.

For new PACE organizations not active as of January 1, 2002, the frailty score will be the weighted average factor across all community respondents of all PACE organizations.

Exhibit 5 illustrates how the payment for each PACE organization will be calculated. Each enrollee's risk score will be determined based on demographics, diagnoses and residence (community or institutional). The organization-level frailty score (calculated as above) will be added to each 55-and-over community enrollee's risk score, while zero will be added to the risk score of each institutional enrollee. This "risk+frailty" score will be multiplied by the restandardized county rate to produce the frailty-adjusted payment for each enrollee. This approach will be similarly applied to the demonstrations below.

To lessen the initial negative impact of frailty adjustment on some organizations, the phase-in schedule for frailty adjustment will lag the phase-in of M+C risk adjustment by one year. In 2004, the PACE Medicare capitation payment will be a blended payment consisting of 90 percent of the current payment (i.e., 2.39 times the demographic ratebook amount) plus 10 percent of the frailty adjusted payment. In 2005, the blend will be 70 percent current payment and 30 percent frailty adjustment. The blend will be 50/50 in 2006 and 25/75 in 2007. In 2008, frailty adjustment will be fully phased in for PACE.

Pace Health Survey (PHS) Nonresponse Bias: During the pilot test there was no evidence of significant survey nonresponse bias. Based on assessment data from the medical records, the

functional status of survey respondents was similar to that of nonrespondents. After the 2003 PHS has been administered, CMS will again examine nonresponse bias for PACE. If significant nonresponse bias is detected, PACE payments in 2004 could be adjusted as part of reconciliation.

9b. Other Demonstrations.

S/HMO Demonstrations: CMS intends to collect HOS data in 2003 to support frailty adjustment for Social HMO organizations (S/HMOs) in 2004. The project's 2001 Report to Congress indicated that S/HMO members were not significantly different than beneficiaries enrolled in M+C organizations. Therefore, the phase-in schedule for S/HMOs will be consistent with the M+C program. The blend in 2004 will be 70 percent current payment and 30 percent frailty adjustment. The blend will be 50/50 in 2005 and 25/75 in 2006. In 2007, frailty adjustment will be fully phased in for S/HMOs.

WPP Demonstrations: CMS intends to collect PHS data in 2003 to support frailty adjustment for WPP organizations in 2004. The WPP demonstration has a health care delivery model that is similar to PACE and serves a population that is identical to the PACE population. Therefore, the phase-in schedule for WPP will be consistent with the PACE phase-in schedule. That is, the blend will be 90/10 in 2004 and will continue to lag the M+C phase-in schedule by one year through 2008.

MSHO and MnDHO Demonstrations: CMS intends to collect PHS data in 2003 to support frailty adjustment for MSHO and MnDHO in 2004. These are dual eligible demonstrations that have community-frail populations that are similar to PACE but also serve community-well and institutionalized beneficiaries. We are considering approaches for determining the frailty score for new demonstrations. The phase-in schedule will be consistent with the PACE phase-in schedule. The blend will be 90/10 in 2004, and will lag the M+C phase-in schedule by one year through 2008.

9c. Biases in Survey Responses

The frailty factors were estimated using MCBS. They will be applied to payment using the PHS or the HOS. Differences in survey questions of mode of administration between MCBS and PHS or HOS could result in biased payments. Preliminary research indicates that HOS respondents may report a significantly greater degree of functional impairment than MCBS respondents. This disparity suggests that the organization-level frailty scores should be adjusted downward for HOS respondents to account for this effect. CMS intends to study this issue further, as well as HOS nonresponse bias. We welcome any comments on this issue.

E. Medicare Secondary Payer status in M+C payments.

CMS currently makes beneficiary-level adjustments to M+C payments based on whether members are working aged or not. We will continue to work with the industry on approaches to adjusting for working aged status. For example, we are considering whether to replace the monthly beneficiary level adjustment with an annual, plan-specific prospective factor representing the proportion of working aged in the plan.

We are still determining the appropriate approach for handling Medicare as Secondary Payer (MSP) status for M+C ESRD beneficiaries when calibrating the new ESRD payment models. To date, we have conducted a separate analysis to ensure we did not underestimate average transplant costs. When identifying the population used to calculate average transplant costs, we excluded any beneficiaries with MSP during their transplant period and any beneficiaries with transplant costs that were too low even if they were not identified as MSP in our system.

We would appreciate comments on this issue. After reviewing public comments, we may announce working aged/MSP policies in the May 12 Announcement of M+C rates

F. New approach to accounting for costs of National Coverage Determinations.

When “the Secretary makes a determination with respect to [Medicare] coverage or there is a [statutory] change in benefits required to be provided [by M+C organizations] that the Secretary projects will result in a significant increase in . . . costs,” section 1853(c)(7) of the Act requires the Secretary to “adjust appropriately” M+C payments to reflect these new significant costs. CMS has interpreted what constitutes “significant” costs for these purposes in regulations at 42 C.F.R. §422.109. Under these provisions, the costs of a coverage change are considered significant if the average cost of providing the service exceeds as specified threshold, or if the total cost exceeds an aggregate cost threshold. Currently, the costs of newly covered services are taken into account annually when OACT estimates the M+C growth rate. The costs of new benefits thus are built into the M+C growth rate. However, the growth rate is only used to update the floor rates and blended rates. Changes in the growth rate do not affect payment in counties where the payment amount is based on the minimum two percent update to the prior year’s rate.

CMS has determined that payments in counties in which payment is based on the minimum two percent update rate is not appropriately adjusted to reflect new coverage costs as required by section 1853(c)(7). Historically, most M+C enrollees have lived in counties receiving the two percent rate, and in 2003 all counties in the country but six received the two percent rate.

Beginning in 2004, CMS will apply a “bundled NCD factor” to the two percent minimum update rates each year. OACT would calculate a factor representing the percent of total Medicare costs attributed to the aggregate costs of all significant NCDs and legislative changes in benefits in a given year. For example, for those counties that will be minimum update counties in 2004, we would apply the 2002 bundled NCD factor to the 2003 minimum update rates, and then update the rates by two percent. We expect to provide details on the calculation and application of the NCD factor in the May 12 Announcement of M+C rates. Also, we are considering changing the definition of “significant cost” in the regulation to include all NCDs in the prior year. Should CMS’s definition of significant cost change in 2003, the new policy would automatically apply to M+C payments for CY 2004.

G. Responses to Public Comments

We solicited comments to the proposed approach for 2004 from interested parties via a Federal Register notice (67 FR 79122), posted on December 27 and at our public meeting conducted on February 3. We received 21 comments by the end of the two-week comment period, which ended on February 19. The comments included six from PACE plans, two from SHMO plans, two from WPP plans, one from MSHO, one from EverCare, three from M+C organizations and six from other interested parties.

Most of the comments related to the implementation of a frailty adjustor for PACE, SHMO, and certain other specialty demonstration sites and the proposed payment blend schedule. Many of these comments appeared to indicate the need for more discussions with the affected plans. CMS intends to conduct additional outreach with these plans to provide more information. Three commenters were concerned about the elimination of the lag between the data collection period and the payment year and were concerned about the increased administrative burden of this approach, as well as the possible impacts on plan revenues as the data collection period on which the risk factor was based is moved. CMS will address issues related to the lag at the time of the final notice. Other commenters requested additional information regarding the proposed ESRD payment methodology. We have provided draft coefficients for that model in this notice. Other general issues raised by these commenters (e.g., inclusion of the institutional factor, measurement of Medicaid status) will be addressed in the final notice.

EXHIBIT 1. Draft Community And Institutional Annual Coefficients for the CMS-HCC Model with Constraints And Demographic/Disease Interactions, used in Calculation of Monthly M+C Payments¹

Variable	Disease Group	Community Estimate	Institutional Estimate
Age/Sex Coefficients			
Female0-34		\$600	\$5,500
Female35-44		1,000	5,500
Female45-54		1,100	5,500
Female55-59		1,400	5,500
Female60-64		1,900	5,500
Female65-69		1,600	6,000
Female70-74		2,000	6,000
Female75-79		2,500	5,100
Female80-84		2,900	4,800
Female85-89		3,400	4,500
Female90-94		4,100	4,000
Female95+		4,100	3,000
Male0-34		300	5,700
Male35-44		600	5,700
Male45-54		1,000	5,700
Male55-59		1,400	5,700
Male60-64		1,800	5,700
Male65-69		1,800	7,400
Male70-74		2,300	6,400
Male75-79		3,000	6,200
Male80-84		3,400	6,200
Male85-89		4,100	6,400
Male90-94		4,600	5,400
Male95+		5,300	4,300
Medicaid & Originally Disabled Interactions with Age & Sex			
Medicaid Female, Disabled		1,100	0
Medicaid Female, Aged		900	0
Medicaid Male, Disabled		600	0
Medicaid Male, Aged		900	0

Variable	Disease Group	Community Estimate	Institutional Estimate
Originally-Disabled Female		1,200	0
Originally-Disabled Male		800	0
Disease Group Coefficients²			
HCC1	HIV/AIDS	3,500	6,900
HCC2	Septicemia/Shock	4,600	4,900
HCC5	Opportunistic Infections	3,300	6,900
HCC7 or 8	Metastatic Cancer, Acute Leukemia, and Other Severe Cancers	7,500	2,800
HCC9	Lymphatic, Head and Neck, Brain, and Other Major Cancers	3,500	2,300
HCC10	Breast, Prostate, Colorectal and Other Cancers and Tumors	1,200	1,300
HCC15	Diabetes with Renal or Peripheral Circulatory Manifestation	3,900	3,100
HCC16	Diabetes with Neurologic or Other Specified Manifestation	2,800	3,100
HCC17	Diabetes with Acute Complications	2,000	3,100
HCC18	Diabetes with Ophthalmologic or Unspecified Manifestation	1,800	3,100
HCC19	Diabetes without Complication	1,000	1,300
HCC21	Protein-Calorie Malnutrition	4,700	2,200
HCC25	End-Stage Liver Disease	4,600	1,400
HCC26	Cirrhosis of Liver	2,600	1,400
HCC27	Chronic Hepatitis	1,800	1,400
HCC31	Intestinal Obstruction/Perforation	2,100	1,400
HCC32	Pancreatic Disease	2,300	1,400
HCC33	Inflammatory Bowel Disease	1,600	1,400
HCC37	Bone/Joint/Muscle Infections/Necrosis	2,500	2,500
HCC38	Rheumatoid Arthritis and Inflammatory Connective Disease Tissue	1,700	1,500
HCC44	Severe Hematological Disorders	5,200	2,300
HCC45	Disorders of Immunity	4,300	2,300

Variable	Disease Group	Community Estimate	Institutional Estimate
HCC51	Drug/Alcohol Psychosis	1,800	1,100
HCC52	Drug/Alcohol Dependence	1,400	1,100
HCC54	Schizophrenia	2,800	1,100
HCC55	Major Depressive, Bipolar, and Paranoid Disorders	2,200	1,100
HCC67 or 68	Quadriplegia/Paraplegia/Extensive Paralysis	6,100	500
HCC69	Spinal Cord Disorders/Injuries	2,500	500
HCC70	Muscular Dystrophy	2,000	500
HCC71	Polyneuropathy	1,400	500
HCC72	Multiple Sclerosis	2,700	500
HCC73	Parkinsons and Huntingtons Diseases	2,400	500
HCC74	Seizure Disorders and Convulsions	1,400	500
HCC75 (applies only to institutional)	Coma, Brain Compression/Anoxic Damage	NA	500
HCC75 or 154 (applies only to community)	Severe Head Injury, Coma, Brain Compression/ orAnoxic Damage	2,900	NA
HCC77	Respirator Dependence/Tracheostomy Status	10,800	7,300
HCC78	Respiratory Arrest	7,300	7,300
HCC79	Cardio-Respiratory Failure and Shock	3,500	1,500
HCC80	Congestive Heart Failure	2,100	900
HCC81 or 82	Acute Myocardial Infarction/ or Unstable Angina and Other Acute Ischemic Heart Disease	1,800	1,500
HCC83	Angina Pectoris/Old Myocardial Infarction	1,200	1,500
HCC92	Specified Heart Arrhythmias	1,400	1,000
HCC95	Cerebral Hemorrhage	2,000	800
HCC96	Ischemic or Unspecified Stroke	1,600	800
HCC100	Hemiplegia/Hemiparesis	2,200	500
HCC101	Cerebral Palsy and Other Paralytic Syndromes	800	500
HCC104	Vascular Disease with Complications	3,500	2,600
HCC105	Vascular Disease	1,800	600

Variable	Disease Group	Community Estimate	Institutional Estimate
HCC107 or 108	Chronic Obstructive Pulmonary Disease/ or Cystic Fibrosis	1,900	1,200
HCC111	Aspiration and Specified Bacterial Pneumonias	3,600	2,400
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	1,000	2,400
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	1,800	5,100
HCC130	Dialysis Status	15,800	16,000
HCC131	Renal Failure	3,000	2,200
HCC132	Nephritis	1,400	2,200
HCC148	Decubitus Ulcer of Skin	5,300	1,600
HCC149	Chronic Ulcer of Skin, Except Decubitus	2,500	1,300
HCC150	Extensive Third-Degree Burns	4,900	1,300
HCC154 (institutional only)	Severe Head Injury	NA	1,300
HCC155	Major Head Injury	1,200	1,300
HCC157	Vertebral Fractures without Spinal Cord Injury	2,500	500
HCC158	Hip Fracture/Dislocation	2,000	0
HCC161 or 177	Traumatic Amputation/ or Amputation Status, Lower Limb/Amputation Complications	4,300	1,300
HCC164	Major Complications of Medical Care and Trauma	1,300	1,300
HCC174	Major Organ Transplant Status	3,700	4,500
HCC176	Artificial Openings for Feeding or Elimination	4,100	4,500
Disabled/Disease Interactions			
D-HCC5	Disabled*Opportunistic Infections	4,000	0
D-HCC44	Disabled*Severe Hematological Disorders	4,600	0
D-HCC51	Disabled*Drug/Alcohol Psychosis	2,600	0
D-HCC52	Disabled*Drug/Alcohol Dependence	2,100	0
D-HCC107	Disabled*Cystic Fibrosis	9,500	0

Variable	Disease Group	Community Estimate	Institutional Estimate
Disease Interactions			
INT1	DM*CHF ⁴	1,300	1,100
INT2	DM*CVD	600	0
INT3	CHF*COPD	1,200	1,900
INT4	COPD*CVD*CAD	400	0
INT5	RF*CHF ⁴	1,200	0
INT6	RF*CHF*DM ⁴	4,400	

NOTES

¹ The dollar amounts in this table will be converted to relative risk scores for the May 12 Announcement of M+C Rates. That is, these dollar amounts will be divided by the national average predicted expenditures to get relative risk scores we will report May 12.

² All estimates are rounded to the nearest hundred dollars.

³ Beneficiaries with HCC128 Kidney Transplant Status were excluded from the sample because they will be included in the ESRD model sample.

⁴ Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms DM*CHF and RF*CHF. Rather, it is hierarchical to, and excludes these interaction terms. A beneficiary with all three conditions is not “credited” with the two-way interactions. All other interaction terms are additive.

DM= diabetes mellitus (HCCs 15-19)

CHF= congestive heart failure (HCC 80)

COPD= chronic obstructive pulmonary disease (HCC 108)

CVD= cerebrovascular disease (HCCs 95-96, 100-101)

CAD= coronary artery disease (HCCs 81-83)

RF= renal failure (HCC 131)

Source: RTI Analysis of 1999/2000 Medicare 5% Sample

EXHIBIT 2. Draft List Of Disease Groups (HCCs) with Hierarchies

DRAFT DISEASE HIERARCHIES		
If the Disease Group is Listed in This Column...		...Then Drop the Associated Disease Group(s) Listed in This Column
Disease Group (HCC)	Disease Group Label	
5	Opportunistic Infections	112
7/8	Metastatic Cancer, Acute Leukemia, and Other Severe Cancers	9,10
9	Lymphatic, Head and Neck, Brain and Other Major Cancers	10
15	Diabetes with Renal Manifestations	16,17,18,19
16	Diabetes with Neurologic or Other Specified Manifestation	17,18,19
17	Diabetes with Acute Complications	18,19
18	Diabetes with Ophthalmologic Manifestations	19
25	End-Stage Liver Disease	26,27
26	Cirrhosis of Liver	27
51	Drug/Alcohol Psychosis	52
54	Schizophrenia	55
67/68	Quadriplegia/Paraplegia/Extensive Paralysis	69,100,101,157
69	Spinal Cord Disorders/Injuries	157
77	Respirator Dependence/ Tracheostomy Status	78,79
78	Respiratory Arrest	79
81	Acute Myocardial Infarction	82,83
82	Unstable Angina and Other Acute Ischemic Heart Disease	83
95	Cerebral Hemorrhage	96
100	Hemiplegia/Hemiparesis	101
104	Vascular Disease with Complications	105,149
111	Aspiration and Specified Bacterial Pneumonias	112
130	Dialysis Status	131,132
131	Renal Failure	132
148	Decubitus Ulcer of the Skin	149
154	Severe Head Injury, Coma, Brain Compression/Anoxic Damage	75,155
How Payments are Made with a Disease Hierarchy EXAMPLE: If a beneficiary triggers Disease Groups 148 (Decubitus Ulcer of the Skin) and 149 (Chronic Ulcer of Skin, Except Decubitus), then DG 149 will be dropped. In other words, payment will always be associated with the DG in column 1, if a DG in column 3 also occurs during the same collection period. Therefore, the M+C organization's payment will be based on DG 148 rather than DG 149.		

EXHIBIT 3. Draft Annual Coefficients for CMS-HCC End Stage Renal Disease Model for Dialysis Patients

Variable	Disease Group	Estimates
Age/Sex Coefficients		
Male, 0 to 34		28,600
Male, 35 to 44		28,300
Male, 45 to 54		29,600
Male, 55 to 59		30,200
Male, 60 to 64		31,100
Male, 65 to 69		31,000
Male, 70 to 74		31,300
Male, 75 to 79		32,000
Male, 80 to 84		33,400
Male, 85 to 89		34,800
Male, 90 to 94		33,400
Male, 95 and older		35,900
Female, 0 to 34		30,200
Female, 35 to 44		30,600
Female, 45 to 54		31,400
Female, 55 to 59		32,100
Female, 60 to 64		33,100
Female, 65 to 69		32,500
Female, 70 to 74		33,300
Female, 75 to 79		34,500
Female, 80 to 84		34,400
Female, 85 to 89		34,900
Female, 90 to 94		37,800
Female, 95 and older		33,000
Medicaid & Originally Disabled		
Medicaid status in 1996		3,200
Originally entitled due to disability		1,800
Disease Coefficients		
HCC1	HIV/AIDS	8200
HCC2	Septicemia/Shock	5400
HCC5	Opportunistic Infections	2800
HCC7 or 8	High Cancer	6600
HCC9	Medium Cancer	3300
HCC10	Low Cancer	1600
HCCDIAB1	Diabetes: Renal and Circulatory Complications	5900
HCCDIAB2	Diabetes: Neurological and Other And Specified Complications	3800

Variable	Disease Group	Estimates
HCCDIAB3	Diabetes:Ketoacidosis and Other Ophthalmologic Complications	2300
HCCDIAB4	Diabetes: Uncomplicated	1900
HCC21	Protein-Calorie Malnutrition	5300
HCC25	End-Stage Liver Disease	7600
HCC26 or 27	Cirrhosis Liver/Chronic Hepatitis	3900
HCC31	Intestinal Obstruction/Perforation	4400
HCC32	Pancreatic Disease	3800
HCC33	Inflammatory Bowel Disease	4200
HCC37	Bone/Joint/Muscle Infections/Necrosis	5600
HCC38	Rheumatoid Arthritis and Inflammatory Connective Tissue Disease	2500
HCC44	Severe Hematological Disorders	1400
HCC45	Disorders of Immunity	200
HCC51 or 52	Drug/Alcohol/Psychosis/Dependence	4200
HCC54 or 55	Schizo.& Major Depressive Disorders	5000
HCC67 or 68	Quad & Paraplegia	8500
HCC69	Spinal Cord Disorders/Injuries	4900
HCC70	Muscular Dystrophy	2700
HCC71	Polyneuropathy	3000
HCC72	Multiple Sclerosis	6700
HCC73	Parkinson's and Huntington's Diseases	4100
HCC74	Seizure Disorders and Convulsions	3800
HCC75	Coma, Brain Compression/Anoxic Damage	8300
HCC77 or 78	Resp. Depend / Resp. Arrest	10600
HCC79	Cardio-Respiratory Failure and Shock	5700
HCC80	Congestive Heart Failure	3500
HCC81 or 82 or 83	AMI Angina Isch Heart Disease Ang Pect	3500
HCC92	Specified Heart Arrhythmias	3400
HCC95 or 96	Cerebral Hemorrhage/Ischemic or Uns. Stroke	2800
HCC100	Hemiplegia/Hemiparesis	5300
HCC101	Diplegia (Upper), Monoplegia, and Other Paralytic Syndromes	1600
HCC104	Vascular Disease with Complications	8100
HCC105	Vascular Disease	4200
HCC107 or 108	CF/COPD	1000
HCC111	Aspiration and Specified Bacterial Pneumonias	4000
HCC112	Pneumococcal Pneumonia, Empyema, Lung Abscess	3000
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	1300
HCC128	Kidney Transplant Status	NA ¹
HCC130	Dialysis Status	NA ¹

Variable	Disease Group	Estimates
HCC131	Renal Failure	NA ¹
HCC132	Nephritis	NA ¹
HCC148	Decubitus Ulcer of Skin	9800
HCC149	Chronic Ulcer of Skin, Except Decubitus	5700
HCC150	Extensive Third-Degree Burns	6800
HCC154	Severe Head Injury	6000
HCC155	Major Head Injury	3600
HCC157	Vertebral Fractures	5300
HCC158	Hip Fracture/Dislocation	5100
HCC161 or 177	Traumatic/Lower Limb Amputation	5500
HCC164	Major Complications of Medical Care and Trauma	3800
HCC174	Major Organ Transplant Status	1100
HCC176	Artificial Openings for Feeding or Elimination	3600
Disabled & Disease Interactions²		
D-HCC107	Disabled with Cystic Fibrosis	10200
DM * CHF	Diabetes and Congestive Heart Failure	1500
DM * CVD	Diabetes and Cardiovascular Disease	1800
CHF * COPD	CHF and chronic obstructive pulmonary disease	1900
COPD*CVD *CAD	COPD, CVD, and Coronary Artery Disease	500

Notes

¹ The dialysis model has the same HCC categories as the CMS-HCC model for the non-ESRD population, except that HCCs with kidney disease diagnoses are excluded (HCC128 to HCC132). The model is calibrated only on dialysis patients, so the disease weights used for payment recognize disease and expenditure patterns unique to this population.

² DM= diabetes mellitus (HCCs 15-19)
 CHF= congestive heart failure (HCC 80)
 COPD= chronic obstructive pulmonary disease (HCC 108)
 CVD= cerebrovascular disease (HCCs 95-96, 100-101)
 CAD= coronary artery disease (HCCs 81-83)

**Exhibit 4. Summary Chart of Transition Payment Blends
For Risk/Frailty Adjustment in 2004**

	Risk adjustment with a frailty adjuster?	Is there a need to further adjust aggregate risk adjusted payments?	Transition Blend-representing the percentage of current versus risk adjusted payment to be used in 2004
Medicare+Choice organizations	No, risk adjustment only	No	70/30%
Program of All-inclusive Care For the Elderly (PACE)	Yes	No, but CMS will evaluate on an annual basis.	90/10%
Wisconsin Partnership Program (WPP)	Yes	No	90/10%
Minnesota Senior Care Options (MSHO) and Disability Health Options (MnDHO)	Yes	No	90/10%
Massachusetts Senior Care Options	Yes	No	90/10%
Social Health Maintenance Organizations (S/HMOs)	Yes	No	70/30%
Evercare	No, risk adjustment only	No	70/30%

**Includes only those ESRD members in post-transplant status

Exhibit 5. Payment Methodology under Frailty Adjustment

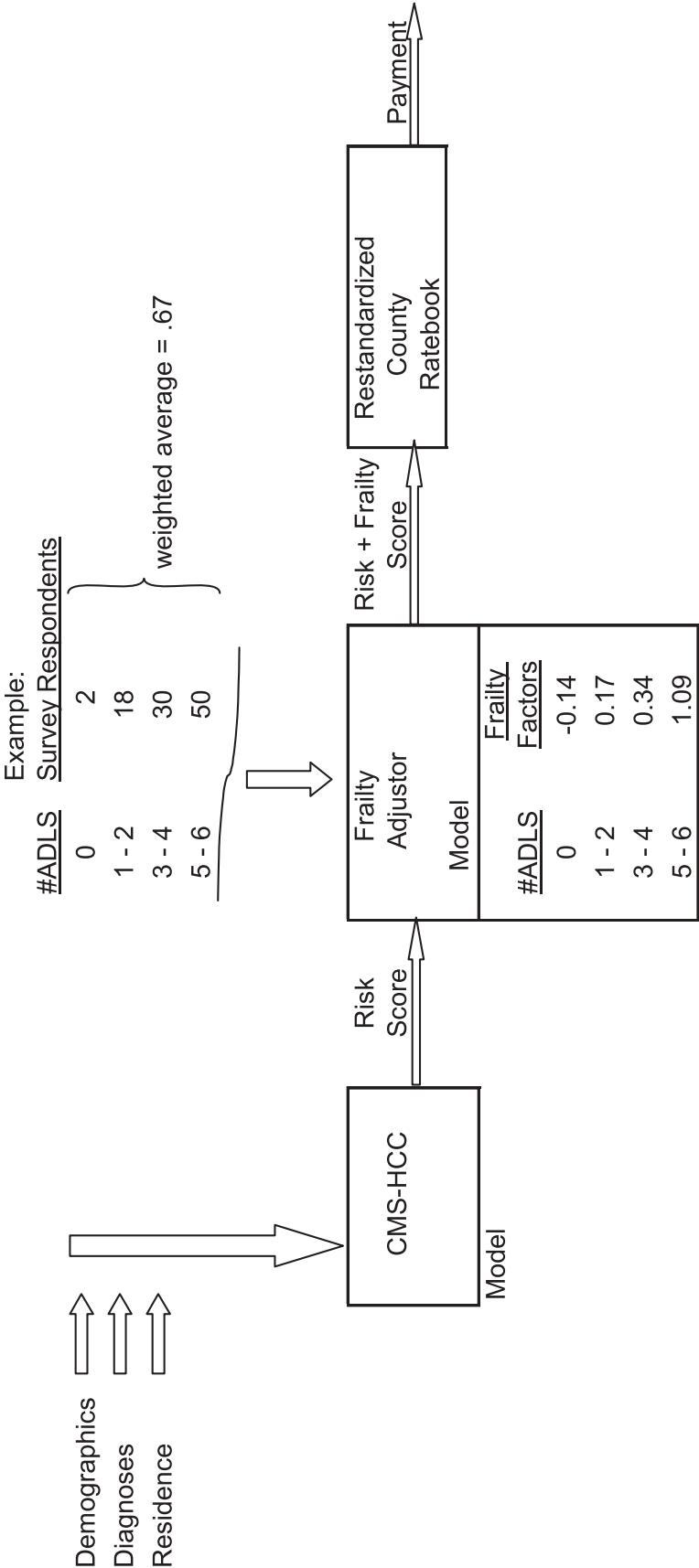


EXHIBIT D-150
FILED UNDER SEAL IN ITS
ENTIRETY

EXHIBIT D-151

1. Please provide copies of all policies and procedures (P&P) relevant to obtaining, processing, and submitting risk adjustment data for the CY 2006 data collection period (i.e., the CY 2007 payment period).

Historically, our encounter operations process has been largely automated. We did not have a formal, written P&P for that process during data collection period for 2006 dates of service. Please refer to our response to Question 1 of the second set of questions for a more detailed explanation of our 2006 practices related to obtaining, processing, and submitting risk adjustment data.

2. Please provide any quality assurance policies and procedures relevant to H4590 and H0543's risk adjustment processes.

Please see our response to Question 1.

3. For contracts H4590 and H0543, please provide the names, titles, and locations of personnel responsible for obtaining risk adjustment data from providers, processing data at the plan level, and submitting the data to CMS.

Numerous employees had responsibility in this area over the past four years. Some of the key employees with responsibility in this area include:

Jeff Dumcira
Senior Vice-President and General Manager
Clinical Assessment Solutions
Eden Prairie, MN

Stephanie Will
Vice-President, Program Delivery
Clinical Assessment Solutions
Eden Prairie, MN

Pam Leal
Vice-President, Market Consultation
Clinical Assessment Solutions
Santa Ana, CA

Randy Myers
Associate Director of Encounter Collection, Submission & Controls
Clinical Assessment Solutions
Phoenix, AZ

EXHIBIT

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4. What systems are used to generate and/or store encounter data at the plan level?

For 2006 dates of service, we used several systems to generate and/or store claims and encounter data, including (i) our core claims transaction system for medical claims, called NICE, (ii) our core claims transaction systems for behavioral health claims, called FACETS, and (iii) our professional encounter system or "PES," which processed encounter data received from capitated providers. We also received encounter data through our provider portal that was subsequently loaded to our risk adjustment processing system.

5. For the current and the CY 2006 data collection periods, please provide your instructions to providers for coding and submitting risk adjustment data.

For the 2006 plan year, we used a provider manual that was implemented in 2005. Attached as Attachment A are the portions related to RAI data submission. Attached as Attachment B are the portions of the current provider manual related to RAF data submission.

6. How do providers submit risk adjustment data to the plan?

For 2006 dates of service, providers submitted risk adjustment data to the plan through (i) claims and/or encounter data sent electronically through a claims clearinghouse, (ii) encounter data sent electronically through a "direct connection" that allowed some capitated providers to submit encounters directly, bypassing a clearinghouse, (iii) claims and/or encounter data sent through paper claims and/or encounter forms submitted by providers not yet able to submit claims electronically, and (iv) risk adjustment data sent electronically via our provider portal.

7. Does the plan participate in the Healthcare Effectiveness Data and Information Set (HEDIS)?

Yes.

8. Do providers submit claims to the plan indicating diagnoses (whether for risk adjustment, HEDIS, or other purposes)?

Yes.

9. Who is responsible for reviewing provider-coded diagnoses for accuracy? What is the process for reviewing these diagnoses?

Providers are responsible for the accuracy of the diagnosis codes they send to the health plan. The plan is not in a position to review such codes for accuracy because it does not have the medical chart for each claim. The plan's automated systems do, however, review provider-submitted codes to ensure such codes correspond to a valid ICD-9 code. Upon this review, any codes that our systems determine do not correspond to a valid ICD-9 code are flagged within our risk adjustment processing system for review and logged in a work queue with an "invalid diagnosis" error.

Codes logged in the "invalid diagnosis" work queue are reviewed by a team of error correction analysts. Error correction analysts determine whether the code can be corrected by either reviewing the original claim image (in case of a keying error in the initial entry of the claim in our system) or by contacting the rendering provider directly. If an error correction analyst is able to identify a valid code through one of the two processes identified above, the analyst corrects the code in the system and removes the error flag, which then clears the code to be sent to CMS. If no valid code can be identified, the error flag is retained and the invalid code is not submitted to CMS. As described more fully below, the plan also reviews codes for accuracy through chart validations.

10. Please describe or provide any documentation you may have in support of provider training or outreach performed with respect to coding diagnoses for risk adjustment.

Please see the information provided by Brian Lund on June 10, 2009, relating to provider training and outreach during the data collection period for 2006 dates of service.

11. Please provide a copy of the standards you have established with providers for maintaining enrollee health records.

Our provider contracts require the retention of medical records. We have numerous agreements with provider groups. Our template California capitated provider agreement contains the following language:

2.7 Medical Records: Medical Group and its Participating Providers shall maintain all patient medical records relating to Covered Services provided to Members, in such form and containing such information as required by the QI Program, Accreditation Organizations and State and Federal Law. Medical records shall be maintained in a manner that is current, detailed, organized and permits effective patient care and quality review by Medical Group and PacifiCare pursuant to the QI Program. Medical records shall be maintained in a form and physical location which is accessible to Medical Group's Participating Providers, PacifiCare, Government Agencies and Accreditation Organizations. Upon request and within the time frame requested, Medical Group and its Participating Providers shall provide to PacifiCare, at Medical Group's or Participating Provider's expense, copies of Member medical records for purposes of conducting quality assurance, case management and utilization reviews, credentialing and peer review, claims processing, verification and payment, resolving Member grievances and appeals and other activities reasonably necessary for the proper administration of the Managed Care Plans consistent with State and Federal Law. If Medical Group or its Participating Providers do not provide copies of Member medical records to PacifiCare within the time frame requested, Medical Group and its Participating Providers shall allow PacifiCare immediate access to such medical records for onsite copying and shall reimburse PacifiCare for the actual copying expense. Medical Group and its Participating Providers shall maintain the confidentiality of all Member medical records and treatment information in accordance with State and Federal Law and maintain

procedures that specify the purpose for which the information will be used within Medical Group's organization and to whom and for what purposes Medical Group may disclose the information outside of Medical Group. Medical records shall be retained by Medical Group and its Participating Providers for at least six (6) years following the provision of Covered Services and as required by State and Federal Law. The provisions of this Section shall survive termination of this Agreement for the period of time required by State and Federal Law.

Our template PCP contract in Texas is largely the same, containing the following language:

2.6 Medical Records. Physician shall maintain all patient medical records relating to Primary Care Services provided to Members, in such form and containing such information as required by the QI Program, Accreditation Organizations and State and Federal Law. Medical records shall be maintained in a manner that is current, detailed, organized and permits effective patient care and quality review by Physician and PacifiCare pursuant to the QI Program. Medical records shall be maintained in a form and physical location which is accessible to Physician, PacifiCare, Government Agencies, and Accreditation Organizations. Upon request and within the time frame requested, Physician shall provide to PacifiCare, at Physician's expense, copies of Member medical records for purposes of conducting quality assurance, case management and medical management, credentialing and peer review, claims processing, verification and payment, resolving Member grievances and appeals, and other activities reasonably necessary for the proper administration of the Managed Care Plans consistent with State and Federal Law. If Physician does not provide copies of Member medical records to PacifiCare within the time frame requested, Physician shall allow PacifiCare immediate access to such medical records for onsite copying and shall reimburse PacifiCare for the actual copying expense. Physician shall maintain the confidentiality of all Member medical records and treatment information in accordance with State and Federal Law and have procedures in place that specify the purpose for which the information will be used within Physician's organization and to whom and for what purposes Physician may disclose the information outside of Physician's organization. The provisions of this Section shall survive termination of this Agreement for the period of time required by State and Federal Law.

"INGENIX Clinical Assessments Solutions Encounter Operations" Follow-up Questions

Please answer the following questions with respect to H4590 and H0543.

1. Please explain the role, responsibilities, and relationship to PacifiCare of INGENIX?

Ingenix is a wholly-owned subsidiary of UnitedHealth Group ("UHG"). PacifiCare of Texas and PacifiCare of California are indirect, wholly-owned subsidiaries of UHG.

Among other things, Ingenix provides an assortment of healthcare related information and technology services to health plans operated by Ovation, one of four business families that constitute UHC. H4590 and H0543 are operated by Ovation and were acquired by UHC in December 2008 as part of UHC's acquisition of Pacificare Health Systems.

Clinical Assessment Solutions ("CAS") is a business unit of Ingenix that provides clinical quality and risk scoring analytic services to Ovation. The services that CAS provides Ovation include:

- a. Provider engagement and education around accurate and complete diagnostic coding
- b. Oversight of encounter collection, submission and reconciliation
- c. Clinical support programs to encourage early assessment and on-going evaluation of chronic disease
- d. Monitoring the appropriateness and accuracy of provider coding
- e. Revenue reconciliation & analysis of payments received from CMS
- f. Annual working aged survey
- g. Financial and risk score projections
- h. Ad hoc reporting and analyses relating to Medicare Advantage revenue and risk scores
- i. Data mining and tool development to support these services

2. Was INGENIX involved in the operations of H4590 and H0543 during the CY 2006 data collection period?

Yes. The personnel group that comprises CAS today was part of Ovation in the beginning of the data collection period for 2006 dates of service. In June or July of 2007, personnel who performed clinical quality and risk scoring analytic services transitioned from Ovation to Ingenix to form the initial CAS team.

3. Where is INGENIX located?

Ingenix is headquartered in Eden Prairie, Minnesota.

4. May we obtain copies of the P&P that were in effect during CY 2006? If these P&P are not available, please explain any differences between the 1/1/2009 revision (version 1.0) and what was in effect during 2006.

As mentioned above, we did not have a formal, written P&P for obtaining, processing, and submitting risk adjustment data to CMS during the data collection period for 2006 dates of service. This process is and has been largely automated and has changed since

2006 because we moved to a new risk adjustment processing system. The system we used for 2006 dates of service was called BLS1. We have since changed to a system called IRADS. The main difference between BLS1 and IRADS is the point in time at which each filters data for bill type, revenue code, CPT code and provider specialties. The Encounter Operations P&P that we provided to you on May 5, 2009 focuses on the process embedded in IRADS.

In other respects, our processes for 2006 dates of service are similar to our current processes. At that time, our encounter operations group submitted risk adjustment data to CMS based on, among other things, (1) chart validations, (2) chart reviews, and (3) other reporting mechanisms. A chart validation involved the review of a provider's patient charts to determine whether they supported certain codes that the provider had reported. We selected a provider for chart validation based principally on whether the provider's coding was unusually high compared to a national benchmark established by our risk adjustment system. The chart validation tested the provider's deviation from that benchmark. Codes found to be inaccurate or incomplete through chart validations were deleted. During a chart validation, we did not seek to verify other codes reported to CMS or to capture other diagnoses that were documented in the chart but not reported to CMS. In contrast, a chart review involved review of the diagnoses reflected in a selected provider's patient charts to determine if any documented diagnoses had not been reported to CMS. Following a chart review, we submitted to CMS any new codes documented in the medical chart but did not determine whether the codes previously reported to CMS were documented in the medical record. Our encounter operations group also received other reports of inaccurate codes from providers and deleted any such code found to be inaccurate. With respect to our current practices, we have begun conducting chart validations for 2008 dates of service on the IRADS system using criteria similar to that used for 2006 dates of service and are conducting chart reviews in substantially the same manner as we did for 2006 dates of service. The P&P we provided to you should not be read to suggest that we follow or have followed a different process.

Finally, we would like to make clear that although the P&P we provided to you reflects current practice as described above, that policy is a working draft. We plan to formally adopt and implement a final policy later this year.

5. The P&P were approved by Randall Myers. Who is Randall Myers? Who would have approved the P&P that were in place during CY 2006?

Randy Myers is the Associate Director of Encounter Collection, Submission, and Controls within CAS. Randy has been in this role since September 2007. As discussed above, there were no written P&Ps regarding encounter collection and submission during the data collection period for 2006 dates of service.

6. Please describe the “core transaction systems” (i.e., the claims and encounter systems; see p. 2). What data are included in each system and how does that data get there?

As discussed above, for 2006 dates of service, our “core transaction systems” included NICT, FACTS, PFS and a provider portal. As mentioned above, during the data collection period for 2006 dates of service, providers submitted risk adjustment data to the plan through (i) claims and/or encounter data sent electronically through a claims clearinghouse, (ii) encounter data sent electronically through a “direct connection” that allowed some capitated providers to submit encounters directly, bypassing a clearinghouse, (iii) claims and/or encounter data sent through paper claims and/or encounter forms submitted by providers not yet able to submit claims electronically, and (iv) risk adjustment data sent electronically via our provider portal.

7. What filter/extract logic is applied to extract data from the core transactions systems before they are submitted to RAPS (see 4.2)?

As discussed above, during the data collection period for 2006 dates of service, the core transaction systems performed filtering on bill types, revenue codes, CPT codes, and provider specialties.

8. Can the systems generate reports showing invalid diagnoses identified during data extraction?

During the data collection period for 2006 dates of service, the BEST system could generate reports showing codes that the BEST system identified as not corresponding to a valid ICD-9 code.

9. Please clarify the data processing described in 4.14: “Diagnosis codes that are determined to be invalid before being submitted to CMS are flagged in our risk adjustment system and are worked through that application. If the code is later found to be valid, it is submitted via the CMS RAPS submission process. If the code is later found to be invalid, the code is never submitted to CMS.”

a. Why would a code be flagged as invalid?

A code would be flagged as invalid if our systems determine that the code does not correspond to a valid ICD-9 code. For example, 250.43 would not be flagged as invalid because it is a valid ICD-9 code, but 250.48 would be flagged as invalid because it does not correspond to a valid ICD-9 code.

b. What does “worked through that application” mean?

As discussed above, codes that our systems determine do not correspond to a valid ICD-9 code are flagged within our risk adjustment processing system for review and logged in a work queue with an “invalid diagnosis” error. Such codes are reviewed by a team of error correction analysts. Error correction analysts determine whether the code can be corrected by either reviewing the original claim image (in case of a keying error in the

initial entry of the claim in our system) or by contacting the rendering provider directly. If an error correction analyst is able to identify a valid code through one of the two processes identified above, the analyst corrects the code in the system and removes the error flag, which then clears the code to be sent to CMS. If no valid code can be identified, the error flag is retained and the invalid code is not submitted to CMS. As described more fully below, the plan also reviews codes for accuracy through chart validations.

10. Do you have a database that includes the diagnosis codes that were changed as a result of chart review? (See 4.15.)

We do not have such a database. As discussed above, for 2006 dates of service, risk adjustment data submitted to CMS was managed and stored on several databases. In order to answer your question, we would have to (i) access those databases, which have been archived, (ii) build custom queries and (iii) manually trace and research the reason underlying each changed diagnosis codes. Because this process is so labor-intensive, we would like to explore with you potentially less-burdensome avenues for us to assist you in this area.

EXHIBIT D-152

Chapter 4: Diagnosis Documentation & Coding

Documentation is the key influence on proper diagnosis code selection. For years we have seen diagnosis codes misused across many levels of care and in various settings. Healthcare professionals have in general become lazy with regard to documentation of diagnoses. In fact, one of the largest drivers of diagnosis code selection in real-world scenarios continues to be those diagnoses that support the procedure codes being billed to show medical necessity.

Diagnosis coding guidelines state that providers should document all diagnoses that are a part of the medical decision making (MDM) for each visit.

Example

A patient comes in for a possible strep pharyngitis and has known diabetic neuropathy; it would be appropriate to choose the pharyngitis as the primary diagnosis code (or main reason for the visit) and include codes for the diabetic neuropathy. Those diagnoses are taken into consideration when treating the presenting problem.

Coding professionals consistently have seen a decline in the accuracy of diagnosis coding. Often the quickest code found on the superbill/encounter form is reported even though it may not accurately describe the patient's condition. Another common error is to only report the primary diagnosis without reporting all the applicable diagnosis codes for the encounter. Providers and coders are equally guilty of choosing generic, non-specific codes because they are memorized and easier to code than stopping to look up a more specific diagnosis code supported by documentation.

Documenting complications and comorbidities is important for risk adjustment purposes. Many providers still do not realize the coding guidelines largely prohibit medical coders from assuming any cause and effect relationships and if these are not clearly documented in the medical record, they are lost in translation.

Diabetes is one of the biggest challenges. Many providers have memorized the basic diabetes code, yet that primary unspecified diabetic code should only be used for diabetics who have no complications from their diabetes. Overall, this is often not the case for many diabetics, and complications of diabetes, which are rated higher in risk adjustment

models, are left undocumented. This not only skews the reality of the state of health of each patient, but it also skews data being collected and how the United States compares by reported diagnosis codes to the health of other nations.

Another example of diagnosis coding challenges is hypertension, which similar to diabetes has potential cause and effect conditions that might lead to a different diagnosis code selection. An example is hypertensive heart disease.

Many providers still are not aware there are coding guidelines for coding a stroke. Once a patient has been discharged from an inpatient treatment for a stroke, it is no longer appropriate to use the stroke diagnosis code. Instead, a history of stroke code and any residual late effect diagnosis should be documented and coded. These examples help support the value of having certified medical coders.

Certified coders are not automatically knowledgeable on every topic, and most coders have particular strengths in certain specialties. There is a slightly different mindset for the risk adjustment coder.

Coders are accustomed to submitting diagnosis codes on claims for the purposes of reimbursement validation for services already rendered. In the risk adjustment models, coders are not submitting codes for services rendered, but instead submitting codes to properly calculate each patient's risk score, which affects the financial and disease management resources that will go toward future treatments necessary to treat the existing diagnoses.

Collecting these diagnoses is not for the purpose of submitting a claim, but rather to send the diagnoses in a supplemental file to account for all the conditions the patient has documented as a current condition each year. These diagnosis codes are converted to a risk adjustment factor (eg, HCC value or CDPS value) and the patient's risk score is steadily and yearly adjusted according to those risk adjustment-associated diagnosis codes. The end result is not the storage of a group of diagnosis codes, but instead, their affiliated diagnosis values, such as HCC value or CDPS value as documented and reported.

As discussed earlier, these values establish the budgeting for the care of each patient for each following year. Some argue that risk adjustment is inflating previously unreported diagnoses; however, the truth is that risk adjustment is finally requiring providers and health plans to pay close

attention to the diagnoses being documented and this has, in turn, caused a surge in more specific diagnosis codes being captured correctly. While coders must use caution to avoid over-coding or up-coding of any diagnoses, they also must ensure diagnosis code selection is as specific as possible. This attention to detail in recent years has created what might appear to be a surge in diagnosis reporting, but in reality diagnosis code selection is becoming more accurate than ever before.

Note that the acronym “ICD” is used here to reference diagnosis codes in general to include ICD-9-CM, as well as the ICD-10-CM codes implemented October 1, 2014. The general coding guidelines that instruct the reporting of all coexisting diagnosis codes for each encounter do not change from ICD-9-CM to ICD-10-CM.

Coding For All Diagnoses Noted in a Date Of Service (DOS)

Medicare defaults much of its risk adjustment diagnosis coding guidance to the official coding guidelines and American Hospital Association (AHA) *Coding Clinic*® determinations. In risk adjustment coding in accordance with the Official Coding and Reporting Guidelines, it is appropriate to document and code for all coexisting conditions in all dates of service for each calendar year.

In DRG coding, which is familiar with many hospital-based coders, diagnosis codes are only selected when they are identified as part of the reason for the visit, treatment, or procedure. Diagnoses not currently being treated are avoided. The focus here is choosing those codes directly related to services rendered to help explain the why of the encounter(s). This rule does not apply to risk adjustment diagnosis coding, where the goal is to correctly capture all diagnosis codes for all current conditions without regard to current treatment, as risk adjustment values will largely apply to future needed treatment related to those diagnoses.

Risk adjustment models tend to shy away from using diagnosis codes for diagnostic testing, and with good reason. Often providers might choose to list a diagnosis he or she is ruling out as the reason for the test instead of the correct selection of the signs and symptoms as the reason for the test. In risk adjustment models, providers are expected to update any diagnostic findings such as a newly confirmed diagnosis from laboratory or X-ray findings in an addendum to the DOS when the test was ordered, or in the next face-to-face encounter with the patient. It is appropriate for coders to capture such diagnostic findings when they

have been updated in the addendum or the next follow-up encounter documentation, not directly from reports.

When reviewing 1995 and 1997 documentation guidelines for E/M services, diagnoses must be documented to include how they have been evaluated or addressed. The focus here is solely on choosing the appropriate level of E/M service. These guidelines are in relation to the procedure code assignment and are not diagnosis coding guidelines or rules, but rather rules to be followed when using diagnoses to support a level of service. A coder should not give credit for the time and attention of a diagnosis not listed on the DOS and certainly not use its existence to bump up the level of service when choosing the E/M procedure code.

When coding diagnoses for risk adjustment purposes, the goal is to honestly report all current diagnoses a patient has in face-to-face encounters by approved provider types during each calendar year (January–December). There is not a justification in only reporting those diagnoses that were treated or addressed or explain a level or service. Following ICD guidelines, it is appropriate to code for all coexisting diagnoses and this should not be curbed by only those addressed or treated in the visit, but all which were a part of the medical decision making of the visit or encounter. Any diagnoses previously treated, no longer existing, or are truly only historical in nature are not coded.

Coders and providers have developed improper diagnosis coding and billing habits derived from the Fee-For-Service (FFS) model and insurance carrier denials. If one were to ask any coder, biller, or provider how a diagnosis code is chosen for a particular visit, the answer will likely be the diagnosis code that will get the procedure code paid, or the diagnosis that exists and is supported in an Local Coverage Determination (LCD). While this has evolved from various payment methodologies across the country, this is not what is instructed in the Official Guidelines for Coding and Reporting. The coding guidelines instruct to select a primary code (main reason for the visit/encounter) and additional codes for other coexisting conditions.

Coders rely on coding guidelines to support coding decisions. Excerpts from the ICD-9-CM and ICD-10-CM Official Coding Guidelines for Coding and Reporting are provided as support for the coding advice covered in this chapter.

Guideline Excerpt

Selection of primary diagnosis and first-listed diagnosis

ICD-9-CM:

Section II. Selection of a Principal Diagnosis

These circumstances of inpatient admission always govern the selection of principal diagnosis. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."

The UHDDS definitions are used by hospitals to report inpatient data elements in a standardized manner. These data elements and their definitions can be found in the July 31, 1985, Federal Register (Vol. 50, No. 147), pp. 31038-40.

Since that time the application of the UHDDS definitions has been expanded to include all non-outpatient settings (acute care, short term, long term care, and psychiatric hospitals; home health agencies; rehab facilities; nursing homes, etc).

In determining principal diagnosis the coding conventions in the ICD-9-CM, Volumes 1 & 2 take precedence over these official coding guidelines.

(See Section I.A., Conventions for the ICD-9-CM)

The importance of consistent, complete documentation in the medical record cannot be over emphasized. Without such documentation the application of all coding guidelines is a difficult, if not impossible task. (ICD-9-CM, 2014)

ICD-10-CM:

Section II. Selection of a Principal Diagnosis

These circumstances of inpatient admission always govern the selection of principal diagnosis. The principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."

The UHDDS definitions are used by hospitals to report inpatient data elements in a standardized manner.

These data elements and their definitions can be found in the July 31, 1985, Federal Register (Vol. 50, No. 147), pp. 31038-40.

Since that time the application of the UHDDS definitions has been expanded to include all non-outpatient settings (acute care, short term, long term care, and psychiatric hospitals; home health agencies; rehab facilities; nursing homes, etc).

In determining principal diagnosis the coding conventions in the ICD-10-CM, the Tabular List and the Alphabetic Index take precedence over these official coding guidelines.

(See Section I.A., Conventions for the ICD-10-CM)

The importance of consistent, complete documentation in the medical record cannot be over emphasized. Without such documentation the application of all coding guidelines is a difficult, if not impossible task. (ICD-10-CM, 2014 Draft)

ICD-9-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

A. Selection of first-listed condition

In the outpatient setting, the term first-listed diagnosis is used in lieu of principal diagnosis.

In determining the first-listed diagnosis the coding conventions of ICD-9-CM, as well as the general and disease specific guidelines take precedence over the outpatient guidelines.

Diagnoses often are not established at the time of the initial encounter/visit. It may take two or more visits before the diagnosis is confirmed.

The most critical rule involves beginning the search for the correct code assignment through the Alphabetic Index. Never begin searching initially in the Tabular List as this will lead to coding errors. (ICD-9-CM, 2014)

ICD-10-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

A. Selection of first-listed condition

In the outpatient setting, the term first-listed diagnosis is used in lieu of principal diagnosis.

In determining the first-listed diagnosis the coding conventions of ICD-10-CM, as well as the general and disease specific guidelines take precedence over the outpatient guidelines.

Diagnoses often are not established at the time of the initial encounter/visit. It may take two or more visits before the diagnosis is confirmed.

The most critical rule involves beginning the search for the correct code assignment through the Alphabetic Index. Never begin searching initially in the Tabular List as this will lead to coding errors. (ICD-10-CM, 2014 Draft)

Guideline Excerpt

Selecting codes for coexisting conditions

ICD-9-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

H. ICD-9-CM code for the diagnosis, condition, problem, or other reason for encounter/visit

List first the ICD-9-CM code for the diagnosis, condition, problem, or other reason for encounter/visit shown in the medical record to be chiefly responsible for the services provided. List additional codes that describe any coexisting conditions. In some cases the first-listed diagnosis may be a symptom when a diagnosis has not been established (confirmed) by the physician. (ICD-9-CM, 2014)

K. Code all documented conditions that coexist

Code all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment. (ICD-9-CM, 2014)

ICD-10-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

G. ICD-10-CM code for the diagnosis, condition, problem, or other reason for encounter/visit

List first the ICD-10-CM code for the diagnosis, condition, problem, or other reason for encounter/visit shown in the medical record to be chiefly responsible for the services provided. List additional codes that describe any coexisting conditions. In some cases the first-listed diagnosis may be a symptom when a diagnosis has not been established (confirmed) by the physician. (ICD-10-CM, 2014 Draft)

J. Code all documented conditions that coexist

Code all documented conditions that coexist at the time of the encounter/ visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (categories Z80-Z87) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment. (ICD-10-CM, 2014 Draft)

The CMS Risk Adjustment Participant Guide specifically directs us to follow the Official Guidelines for Coding and Reporting and determinations provided in the AHA Coding Clinic®.

Excerpt from the Medicare/

CMS Risk Adjustment Participant Guide:

6.4.1 Co-Existing and Related Conditions

The instructions for risk adjustment implementation refer to the official coding guidelines for ICD-9-CM, published at www.cdc.gov/nchs/icd9.htm and in the Coding Clinic®. Physicians should code all documented conditions that co-exist at the time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19 not in HCC model) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment.

Co-existing conditions include chronic, ongoing conditions such as diabetes (250.XX, HCCs 15-19),

congestive heart failure (428.0, HCC 80), atrial fibrillation (427.31, HCC 92), chronic obstructive and pulmonary disease (496, HCC 108). These diseases are generally managed by ongoing medication and have the potential for acute exacerbations if not treated properly, particularly if the patient is experiencing other acute conditions. It is likely that these diagnoses would be part of a general overview of the patient's health when treating co-existing conditions for all but the most minor of medical encounters.

Co-existing conditions also include ongoing conditions such as multiple sclerosis (340, HCC 72), hemiplegia (342.9X, HCC 100), rheumatoid arthritis (714.0, HCC 38) and Parkinson's disease (332.0, HCC 73). Although they may not impact every minor health-care episode, it is likely that patients having these conditions would have their general health status evaluated within a data reporting period, and these diagnoses would be documented and reportable at that time.

MA organizations must submit each required diagnosis at least once during a risk adjustment reporting period. Therefore, these co-existing conditions should be documented by one of the allowable provider types at least once within the data reporting period. (CMS Participant Guide, 2008)

Use of "history of." In ICD-9-CM, "history of" means the patient no longer has the condition and the diagnosis often indexes to a V code not in the HCC models. A physician can make errors in one of two ways with respect to these codes. One error is to code a past condition as active. The opposite error is to code as "history of" a condition when that condition is still active. Both of these errors can impact risk adjustment. (CMS Participant Guide, 2008)

Because the purpose is to code for all known diagnoses for each patient in risk adjustment models, diagnoses from any portion of the record should be reported, provided that they are accurately documented as current diagnoses.

Coding Diagnoses from Chief Complaint (CC) or History of Present Illness (HPI)

Entries from the CC and HPI portion of any record should be carefully evaluated for the wording used by the treating provider. All documented diagnoses should be coded and any that are only noted as historical should be left as Past Medical History (PMH) or questionable, which is covered later in this chapter.

In the two examples below, diagnoses highlighted in green would be appropriate to code as current diagnoses and those in yellow would be PMH or questionable.

Example

Example 1: CC: Ms. Jones is a 70-year-old female who comes in today for follow up of her diabetes and COPD. She has a history of DVT and peripheral vascular disease. She has had no issues or complaints since her last visit to the office.

Rationale: The CC clearly states the patient is here for the diabetes and COPD. The DVT and PVD are mentioned as historical in nature and are not clear to be current conditions. Additionally, these two conditions are not known to be permanent and life-long and therefore should not be coded as current.

Example 2: CC: Ms. Jones is a 70-year-old female with a history of diabetes and COPD and she is here today for a follow up on her blood sugar control and to evaluate her inhaler effectiveness.

Rationale: This CC lists both conditions as "historical" yet it also affirms that they are current conditions being treated and therefore are appropriate to code as current. Cardiovascular: Patient reports she had an MI at age 50

Coding Diagnoses from PMH and other Historical Lists

PMH is one of the biggest areas of contention when reviewing medical records. As stated in the Medicare/CMS Risk Adjustment Participant Guide, CMS recognizes that providers may sometimes incorrectly list a current diagnosis as PMH or vice versa. “One error is to code a past condition as active. The opposite error is to code “history of” a condition when that condition is still active” (CMS Participant Guide, 2008).

Coders see a plethora of documentation variations that can be challenging to even the most skilled. While it is evident that one should report all current diagnoses (regardless of treatment), there are some diagnoses, which may only be listed as historical in nature. According to the coding guidelines, as well as CMS guidance, coders cannot code for conditions previously treated and that no longer exist.

PMH is loosely used in clinical documentation, sometimes as a stand-alone listing of diagnoses and sometimes as a separately identifiable true listing of past conditions. Because of varying methods of documentation used by providers across the country, there must be a standardized way to interpret these lists. This is also true when the words *history of* are included in other portions of the documentation.

Coders cannot make assumptions. Even if a diagnosis may be commonly known as a condition that once diagnosed, is life-long and does not go away. If such a condition is not listed as current and only as historical, there must be a way to identify those diagnoses that are still valid separate from those that are truly historical. In an ideal situation, it would be appropriate to query the treating provider for clarification; however, risk adjustment coding work may be done remotely by coders representing the health plan who do not have interactions with the provider. Sometimes risk adjustment coding work is done by trusted vendors who hire coders with no communication with the documenting provider(s).

The Official Coding and Reporting guidelines instruct coders on the appropriate coding of previous or historical conditions for inpatient as well as outpatient settings.

Guidelines Excerpt

Selecting codes for previously treated or historical diagnoses:

ICD-9-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

K. Code all documented conditions that coexist

Code all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment. (ICD-9-CM, 2014)

ICD-10-CM:

Section IV. Diagnostic Coding and Reporting Guidelines for Outpatient Services

J. Code all documented conditions that coexist

Code all documented conditions that coexist at the time of the encounter/visit and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (categories Z80-Z87) may be used as secondary codes if the historical condition or family history has an impact on current care or influences treatment. (ICD-10-CM, 2014 Draft)

Many in the coding profession are familiar with the acronym MEAT, which stands for Monitor, Evaluate, Assess, or Treat as a reminder of scenarios where diagnoses can be coded in normal fee-for-service models or when choosing supporting diagnosis codes for procedures or other services already rendered. This acronym does not address all diagnoses that can be reported in risk adjustment coding because there are more scenarios that would qualify a diagnosis code as current or active for risk adjustment purposes. The MEAT acronym supports diagnosis code selection to support E/M services.

IonHealthcare, LLC, has created a new trademarked acronym specifically to address those diagnoses in question. If a coder believes any diagnosis is current, but it is only listed as PMH or historical, coders should ask themselves: “Did the provider TAMPER™ (Treatment, Assessment, Monitor/Medicate, Plan, Evaluate, or Referral) with the

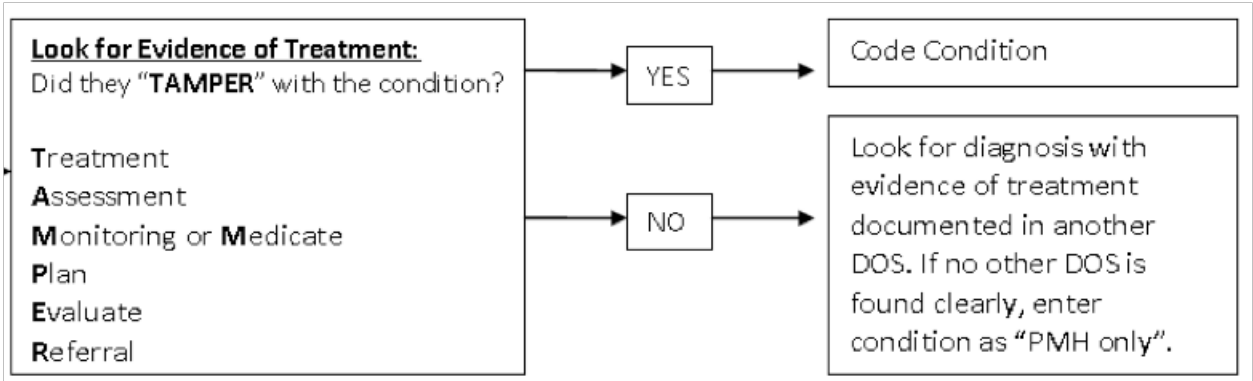
diagnosis on the DOS? If the answer is yes, then the diagnosis can be considered current, and if the answer is no, then do not report the code as current and consider the diagnosis as a PMH (historical) diagnosis which is not normally submitted or shared for risk adjustment purposes.

Some health plans record historical diagnoses that lack ongoing evidence of treatment or medical decision making in an effort to identify additional suspect conditions that may be present elsewhere. These are usually stored for evaluation purposes, but not captured or reported officially for risk adjustment purposes. Some health plans feel uncomfortable reporting any diagnosis not currently being treated or addressed and may choose to only include those diag-

noses that are in the assessment portions of the encounter documentation. This is a very conservative approach, and may become difficult to manage because of the many diagnoses which may never be documented in those areas but are pertinent to risk adjustment such as old MI, amputations, ostomy status, etc.

Because many of these diagnoses are permanent and life-long, many carriers have identified a select listing of diagnoses, which when even if only listed as historical, may be overridden and submitted for risk adjustment purposes. This is at the discretion of the client/carrier and is not recommended as proper coding guidelines for risk adjustment.

Figure 2—TAMPER™ Decision Flow



Source: IonHealthcare, LLC

There are many diagnoses in risk adjustment models that have medication therapy, where those medications are only used for those diagnoses alone, and these are often utilized to establish a diagnosis as current or valid to submit. In such cases, it is important to be sure that the medication is current, and prescribed for the diagnosis to make it a current diagnosis. Medications documented that can be used for several different diagnoses or conditions do not help support an active diagnosis if they are not linked in some manner to the diagnosis itself. Query of the treating provider is the best method to validate the codes; however, coders may justify the codes if self-evident.

Special caution is advised for those records where diagnoses appear to be continually repeated or “cut and pasted” into each subsequent DOS and caution should be taken to only include those diagnoses which meet the TAMPER™ criteria above when diagnoses are listed as historical.

The following diagnoses are examples that are often improperly coded as current. Some organizations utilize a system of code harvesting that allows for a historical or PMH only flagging to identify codes which seem to be unclear as to whether they are current or prior history items. Such practice should be used very carefully as many of these codes should not be reported as historical, or they may have a more specific “history of” code such as a V code that might be more accurate.

- **Fractures**—Fractures are not coded once they are repaired. However, compression fractures of the vertebrae are often not treated in the elderly, and if a vertebral fracture appears to be a current diagnosis, it may be coded.
- **Cancers**—There are ‘history of’ diagnosis codes to express this, and these may or may not risk adjust (they do for some commercial plans, but do not for CMS HCC purposes.).
- **CVA**—Coding guidelines state a CVA may not be coded once a patient is discharged for this problem, instead a history of code should be used.
- **Myocardial Infarction**—There is a specific code for old MI (412) which does risk adjust in most models.
- **HIV**—This diagnosis has no cure and could never be merely historical.
- **Amputations**—Amputated body parts are permanent.
- Anything that is listed as: repaired, resolved, fixed, or managed through prophylaxis.

When PMH is listed as a separately identifiable list of true historical conditions, coders are required to find evidence within that same date of service (DOS) to substantiate that particular PMH diagnosis as actually current unless it is a condition that never goes away, such as HIV infection. This would include medication, which is irrefutable for the condition or shows other evidence of “TAMPER™”, including notation of the condition being current, stable, active, reviewed, unchanged, etc.

When coders are presented with documentation where there are PMH listings separated from another listing noted as active, current, ongoing, etc., they are instructed to treat all those listed as current, active, ongoing, etc. as current, within reason, and to follow the above rule for those listed in the separate PMH only listing. Providers need to be reminded of the importance of list headers and to categorize diagnoses appropriately.

Coding from Lists

Use caution when given diagnosis lists. While it is appropriate to code for all known current diagnoses, exercise caution to avoid improperly coding any diagnosis in a list which could not be current, is not believed to be current, or appears to be mistakenly brought forward from a past visit documentation. Some of these lists have columns designating diagnoses as current or resolved, but even with this level of detail, use caution to avoid coding any old diagnoses no longer present or those which the coder knows could not possibly still be true.

In general, if diagnoses are listed as current, ongoing, active, chronic, etc., they may be coded, especially if there is another specific separate listing of PMH diagnoses. Conditions that resolve and have no additional mention in the record should not be coded unless TAMPER™ guidance is met.

Example: Chronic Problems:

- A-Fib (on Coumadin)
- Acute Pancreatitis (admitted 2002)
- Old MI
- CVA (2000)
- CKD (Followed by Dr. Jones, nephrology)
- Prostate CA

RATIONALE: The above list may be titled as “chronic conditions, but not all of the conditions listed are current. This is a common problem for coders. The A-fib is clearly current as there is medical treatment. The acute pancreatitis appears to be historical only. The old MI may be coded as factual, and the CVA is not only historical (one could code a history of code and any related residual conditions if noted), but an active CVA code cannot be coded once a patient has been discharged for the CVA. CKD is clearly still under treatment, and prostate CA lacks any current ongoing treatment that would be necessary to code a cancer as current.

Coding Diagnoses from Review of Systems (ROS)

Some coders have voiced concerns about coding diagnoses from the ROS portion of the record and this hesitation can be related back to the E/M coding guidelines. When choosing a level of service for E/M purposes, coders are instructed that the ROS area is used in meeting the history taking element toward the E/M selection. This portion of the medical record documentation is intended to document the provider's questioning of the patient for feedback regarding how they are doing by systems. Many providers will document accurate diagnoses in this section of the record. The main warning in this area is to avoid coding for any patient-stated conditions. Conditions or diagnoses that are only reported by the patient as recounting to the current provider are not acceptable without provider validation.

In the two examples below, those diagnoses highlighted in green would be appropriate to code and those in yellow would be PMH or questionable.

Example

Example 1: ROS: Respiratory: COPD, Hypoxia, on inhaler and home oxygen Cardiovascular: no complaints of SOB, no palpitations, MI 1992

Rationale: The above ROS annotates that the patient is on current treatment for the COPD and there is a valid Old MI noted during the ROS as well that is valid.

Example 2: ROS: Respiratory: patient states her PCP told her she has COPD

Rationale: The above ROS merely annotates a patient stated condition that is not confirmed by the current treating provider. It is 'diagnosis hearsay' and should not be coded.

Example

Example 1: Exam: Extremities: Good Lt. pedal pulses; Rt. above knee amputation (2006).

Rationale: In the above exam, the provider merely uses the exam portion to annotate that there is an above the knee amputation. The code for amputation status would be appropriate to code.

Example 2: Exam: Appearance: Appears cachectic.

Rationale: In the above exam, the provider is merely annotating an appearance and not making a diagnosis of cachexia. "Appears" is the same as "likely" which is not a diagnosis.

Coding from Assessment and Plan

The assessment and plan portions of any record are the final portions of documentation for each encounter. The diagnoses documented in the assessment and plan should generally always be coded, with one word of caution-many providers will list items in the assessment, which have resolved or are no longer current.

Examples of assessment documentations that should not be coded:

- **Stroke**—When the patient is not having or being treated for a stroke it is improper to code this diagnosis.
- **Cancers**—Cancers may only be coded when they are current and not current by the above definitions, as they have their own rule. Cancers must only be coded as current when there is evidence of current treatment toward the cancer (or the patient has refused treatment, or "watchful waiting" is being followed). Special caution must be taken by the coder when reviewing records for follow up of old cancers which have resolved, been eradicated, or are no longer being actively treated and avoid coding those incorrectly as current.

Coding Diagnoses from the Exam Portion of a Record

The exam portion of the medical record is where the provider documents the objective findings from the actual physical exam portion of the encounter with the patient. Many providers may list valid diagnoses in this section of the record and any diagnoses documented, as current should be coded appropriately.

EXHIBIT D-153

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422, 423, 438, and 498

[CMS-4185-P]

RIN 0938-AT59

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Bipartisan Budget Act of 2018; improve quality and accessibility; clarify certain program integrity policies; reduce burden on providers, MA plans, and Part D sponsors through providing additional policy clarification; and implement other technical changes regarding quality improvement. This proposed rule would also revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals to implement certain provisions of the Bipartisan Budget Act of 2018.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 31, 2018.

ADDRESSES: In commenting, please refer to file code CMS-4185-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4185-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4185-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Theresa Wachter, (410) 786-1157, or Cali Diehl, (410) 786-4053, MA/Part C Issues.

Elizabeth Goldstein, (410) 786-6665, Parts C and D Quality Ratings Issues. Mark Smith, (410) 786-8015,

Prescription Drug Plan Access to Parts A and B Data Issues.

Vanessa Duran, (410) 786-8697, D-SNP Issues.

Frank Whelan, (410) 786-1302, Preclusion List Issues.

Jonathan Smith (410) 786-4671, or Joanne Davis, (410) 786-5127, MA RADV Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Executive Summary

A. Purpose

The primary purposes of this proposed rule are to: make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain

provisions of the Bipartisan Budget Act of 2018. The proposed changes are necessary to—

- Implement the Bipartisan Budget Act of 2018 provisions;
- Improve program quality and accessibility;
- Clarify program integrity policies; and
- Implement other changes.

This proposed rule would meet the Administration’s priorities to reduce burden across the Medicare program by reducing unnecessary regulatory complexity, and improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary’s healthcare needs. Because the Bipartisan Budget Act of 2018 requires the Secretary to establish procedures, to the extent feasible, for integration and unification of the appeals and grievance processes for dually eligible beneficiaries who are enrolled in Medicaid and in MA special needs plans for dually eligible individuals, this proposed rule also includes proposals to revise the appeals and grievances requirements for Medicaid managed care and MA special needs plans for dually eligible individuals. We note CMS plans to release a proposed Medicare rule in the near future to further the President’s agenda of reducing drug costs.

B. Summary of the Major Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

Section 50323 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123) created a new section 1852(m) of the Social Security Act (the Act), which allows MA plans to provide “additional telehealth benefits” to enrollees starting in plan year 2020 and treat them as basic benefits for purposes of bid submission and payment by CMS. The statute limits these authorized additional telehealth benefits to services for which benefits are available under Medicare Part B, but that are not payable under section 1834(m) of the Act and have been identified for the applicable year as clinically appropriate to furnish through electronic information and telecommunications technology (section 1852(m)(2)(A)(i) of the Act). Under this proposal, MA plans would be permitted to offer—as part of the basic benefit package—additional telehealth benefits beyond what is currently allowable under the original Medicare telehealth benefit. In addition, we propose to continue authority for

MA plans to offer supplemental benefits (that is, benefits not covered by original Medicare) via remote access technologies and/or telemonitoring for those services that do not meet the requirements for additional telehealth benefits.

Section 1852(m)(4) of the Act mandates that enrollee choice is a priority. If an MA plan covers a Part B service as an additional telehealth benefit, then the MA plan must also provide access to such service through an in-person visit and not only as an additional telehealth benefit. The enrollee must have the option whether to receive such service through an in-person visit or as an additional telehealth benefit. In addition, section 1852(m)(2)(A)(ii) of the Act excludes from additional telehealth benefits any capital and infrastructure costs and investments relating to such benefits. These statutory provisions have guided our proposal.

We propose to establish regulatory requirements that would allow MA plans to cover Part B benefits furnished through electronic exchange as “additional telehealth benefits”—and as part of the basic benefits defined in § 422.101—instead of separate supplemental benefits. We believe additional telehealth benefits would increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We are soliciting comments from stakeholders on various aspects of our proposal, which would help inform CMS’s next steps related to implementing the additional telehealth benefits.

2. Dual Eligible Special Needs Plans Provisions (§§ 422.2, 422.60, 422.102, 422.107, 422.111, 422.560 Through 422.562, 422.566, 422.629 Through 422.634, 422.752, 438.210, 438.400, and 438.402)

Section 50311(b) of the Bipartisan Budget Act of 2018 amends section 1859 of the Act to require integration of the Medicare and Medicaid benefits provided to enrollees in Dual Eligible Special Needs Plans (D–SNPs). In particular, the statute requires: (1) Development of unified grievance and appeals processes for D–SNPs; and (2) establishment of new standards for integration of Medicare and Medicaid benefits for D–SNPs.

The statute specifies a number of key elements for unified D–SNP grievance and appeals processes and grants the Secretary discretion to determine the extent to which unification of these processes is feasible. In particular, the unified processes must adopt the

provisions from section 1852(f) and (g) of the Act (MA grievances and appeals) and sections 1902(a)(3) and (5), and 1932(b)(4) of the Act (Medicaid grievances and appeals, including managed care) that are most protective to the enrollee, take into account differences in state Medicaid plans to the extent necessary, be easily navigable by an enrollee, include a single written notification of all applicable grievance and appeal rights, provide a single pathway for resolution of a grievance or appeal, provide clear notices, employ unified timeframes for grievances and appeals, establish requirements for how the plan must process, track, and resolve grievances and appeals, and with respect to benefits covered under Medicare Parts A and B and Medicaid, incorporate existing law that provides continuation of benefits pending appeal for items and services covered under Medicare and Medicaid. The statute requires the Secretary to establish unified grievance and appeals procedures by April 1, 2020 and requires D–SNP contracts with state Medicaid agencies to use the unified procedures for 2021 and subsequent years.

With respect to the establishment of new standards for integration of Medicare and Medicaid benefits, the statute requires that all D–SNPs meet certain new minimum criteria for such integration for 2021 and subsequent years, either by covering Medicaid benefits through a capitated payment from a state Medicaid agency or meeting a minimum set of requirements as determined by the Secretary. The law also stipulates that for the years 2021 through 2025, if the Secretary determines that a D–SNP failed to meet one of these integration standards, the Secretary may impose an enrollment sanction, which would prevent the D–SNP from enrolling new members. In describing the “additional minimum set of requirements” established by the Secretary, the statute directs the Federally Coordinated Health Care Office in CMS to base such standards on “input from stakeholders.” We intend to use this rulemaking to solicit input from stakeholders on the implementation of these new statutory provisions as well as to clarify definitions and operating requirements for D–SNPs.

3. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

In the Medicare Program; Contract Year 2019 Policy and Technical

Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (hereafter referred to as the April 2018 final rule), CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration’s effort to increase transparency and advance notice regarding enhancements to the Part C and D Star Ratings program. That final rule included mechanisms for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the specifications of measures change such that the specifications are no longer believed to align with positive health outcomes) but, generally, removal of a measure for other reasons would also occur through rulemaking.

At this time, we are proposing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. We are also proposing substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2020 measurement period and the 2022 Star Ratings.

4. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6))

In the April 2018 final rule, CMS removed several requirements pertaining to MA and Part D provider and prescriber enrollment that were to become effective on January 1, 2019. We stated in that final rule our belief that the best means of reducing the burden of the MA and Part D provider and prescriber enrollment requirements without compromising our payment safeguard objectives would be to focus on providers and prescribers that pose an elevated risk to Medicare beneficiaries and the Trust Funds. That is, rather than require the enrollment of MA providers and Part D prescribers regardless of the level of risk they might pose, we would prevent payment for MA items or services and Part D drugs that are, as applicable, furnished or prescribed by demonstrably problematic

process. Risk adjustment discrepancies can be aggregated to determine an overall level of payment error. In turn, payment error for a sample of contract enrollees can be extrapolated to calculate a contract-level payment error estimate. Although we have the authority to extrapolate from a statistically valid sample to calculate a contract-level audit recovery, we have not yet done so.

From 1999 until 2003, our payment validation activity for the MA program had both an educational and audit focus and was intended to improve the accuracy of the risk adjustment data that was being submitted to CMS for payment. Payment adjustments were limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. At the time, only 10 percent of the MA payment amount was risk adjusted. As a result, payment recovery amounts for the small number of plans audited was very small. Since payment year 2004 was the first year for which MA payments were based on the current HCC risk adjustment model, we considered payment years 2004 through 2006 as pilot years for the purpose of RADV and no payment recovery activity occurred.

Payment recovery resumed for payment year 2007, when we audited 37 MA contracts and recouped \$13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the payment validation audit. (Although we suggested that we would make contract-level payment adjustments for the payment year 2007 audits, we did not ultimately do so.) In the course of that audit process, as in previous years, we reviewed medical record documentation provided by each audited MA organization to substantiate conditions reported by the organization for beneficiaries in each audit sample. After CMS' findings were reported to each MA organization, any organization that disagreed with CMS' determinations could challenge them through a three-stage administrative process established by regulation in 2010. (See 42 CFR 422.311). This dispute and appeals process is currently ongoing.

No payment validation audits were conducted for payment years 2008, 2009, or 2010. In those years, we were considering the development of a methodology for calculating payment adjustments based on statistical RADV MA contract-level payment error audit findings. The development of contract-level RADV audits would enable us to make contract-level payment adjustments rather than simply

adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we proposed a methodology on the CMS website for selecting a statistically-valid sample of enrollees from each audited MA contract and extrapolating from the results of that sample audit to calculate a contract-level payment adjustment. We invited public comment on this proposed methodology, and received more than 500 comments, which we carefully reviewed. On February 24, 2012, we published what we described as the final methodology for RADV contract-level payment error calculation.²⁴ That methodology described sampling techniques and the statistical calculation to be used to extrapolate from the sample selected. In brief, up to 201 enrollees from each audited MA contract would be selected according to certain criteria, including their continuous enrollment in the contract for the entire data collection year and January of the payment year; their lack of end-stage renal disease (ESRD) status and hospice status for that entire period; their enrollment in Medicare Part B coverage for the entire data collection year; and their submission of at least one diagnosis during the data collection year leading to at least one CMS-HCC assignment in the payment year. The RADV-eligible enrollees would be ranked by risk score and then divided into three equal strata. An equal number of enrollees would then be randomly selected from each stratum (67 enrollees per stratum in the case of an audit of 201 enrollees). After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year. A payment error rate for each stratum would be calculated, and then an overall payment error rate for the audited contract, computed at a ninety-nine percent confidence interval. We stated that this methodology would be applied to the next round of RADV audits, which would be conducted on payment year 2011. Audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, at a total cost of approximately \$150 million to

the agency, but have not yet been finalized. These audits are in addition to RADV and related MA audits conducted by the Office of Inspector General, which are conducted pursuant to OIG's independent authorities at sections 2(1) and 4(a)(1) of the Inspector General Act.

We also stated in 2012 that, after using this methodology to calculate a preliminary payment recovery amount, we would apply a FFS Adjuster as an offset before finalizing the audit recovery. The FFS Adjuster was intended to account for any effect of erroneous diagnosis codes in the data from Medicare Parts A and B (often referred to as "Fee-For-Service" Medicare) that are used to calibrate the MA risk adjustment model. We stated that the FFS Adjuster would calculate a permissible level of payment error (for example, a percentage of the total payments made on an MA contract in a given year) and limit RADV audit recovery to payment errors above that level. The FFS Adjuster was never intended to set a permissible rate for the submission of erroneous diagnosis codes. We stated that the FFS Adjuster would be calculated based on a RADV-like review of records submitted to support the Medicare Part A and B diagnosis codes. That review is now complete, and will be discussed later.

c. Discussion of Proposals

(1) Extrapolation

The Secretary intends to recover overpayments based on extrapolated audit findings through the use of statistically valid random sampling techniques. Although we described our February 2012 publication as the final methodology to be used to calculate contract-level RADV audit recoveries for payment year 2011, it has never been implemented. As we stated earlier, audits for payment years 2011, 2012, and 2013 have been conducted according to this methodology, but contract-level recoveries have not yet been sought. We are now providing additional notice and again welcoming public input on the agency's methodology for calculating a contract-level payment error in RADV audits, including the sample sizes used in these contract-level audits. CMS is not required to set forth the methodology for calculating an extrapolated payment error through regulatory provisions (it does not do so in Parts A and B, where Medicare Administrative Contractors (MACs) may use any statistically valid sampling and extrapolation methodology they determine to be appropriate), however, in the interest of transparency, we are updating

²⁴ Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf>.

stakeholders on our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate.²⁵ All audits will be based on statistically valid sampling and extrapolation methodologies.

In addition to the contract-level methodology described earlier, we have identified other potential methodologies for sampling and extrapolation, which would calculate improper payments made on the audited MA contract for a particular sub-cohort or sub-cohorts in a given payment year, and the agency may also use such a methodology to calculate improper payments made to the audited MA contract. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as the three diabetes HCCs) was reported. After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees for the sub-cohort or sub-cohorts. After reviewing the medical records of those enrollees, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for covering enrollees for the sub-cohort or sub-cohorts in that payment year. We would use the same statistical calculation for this sub-cohort-level extrapolation as we do for the contract-level extrapolation (although we welcome comment as to whether to stratify the sample population for the sub-cohort audits, as we currently anticipate doing for the contract-level audits).

We believe that, because any sub-cohort is necessarily a subset of the enrollees covered through a particular MA contract, we could often use a much smaller sample size to calculate a statistically significant extrapolated recovery for a sub-cohort than would be required to calculate a contract-level recovery (up to 201 enrollees, according to our anticipated contract-level methodology). This smaller sample size would allow us to spread our audit resources across a wider range of MA contracts, while still generating statistically significant recoveries. This sub-cohort-based audit methodology would allow us to focus on cohorts of enrollees that appear to raise programmatic concerns.

We invite comment on both the contract-level audit methodology published in February 2012, and our

proposal for an extrapolated audit methodology based on sub-cohorts of enrollees. We also seek comment on whether there are particular situations in which one methodology may be preferable to the other, and whether the agency should revise the contract-level audits that have been conducted but not finalized for payment years 2011, 2012, and 2013. Neither proposed methodology is meant to displace our longstanding authority to audit the medical records of particular enrollees who we believe may be associated with improper payments or to use any statistically valid audit methodology.²⁶

If we finalize one or more sampling and extrapolation methodologies through this rulemaking, we would make any future changes to that methodology (or those methodologies) through the Health Plan Management System.

We are also considering whether to explicitly expand the MA organizations' RADV appeal rights, particularly in light of the upcoming auditing and recoveries in the MA program. One option would be to permit appeal of the RADV payment error calculation methodology used in a RADV audit similar to practices in the Part A and Part B space of Medicare FFS. We invite comments on this matter.

(2) Application to Payment Year 2011 and Subsequent Years

We intend to apply the finalized RADV payment error methodology or methodologies to payment year 2011, and all subsequent years. (However, we do not expect to use a sub-cohort-based methodology, if finalized, for any payment year before 2014). Section 1871(e)(1)(A) of the Act authorizes retroactive application of rules where “(i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change would be contrary to the public interest.” We are considering whether application of the finalized methodology or methodologies to payment year 2011, and all subsequent years, would require the exercise of this statutory authority to engage in retroactive rulemaking. We invite comment on the subject.

²⁶ We may begin to conduct RADV audits for payment years 2014 and 2015 before this proposal is finalized, pursuant to our longstanding authority to review the medical records of any MA enrollee and recoup any improper payments identified. Although we would design these audits so that the individuals selected would form a statistically significant sample that would support an extrapolated recovery, we would not seek to recover on an extrapolated basis until the rule is final. At the very least, these audits would support enrollee-level recoveries.

In any case, we believe that failure to apply the finalized RADV payment error methodology or methodologies to those payment years would be contrary to the public interest. The public has a substantial interest in the recoupment of millions of dollars of public money improperly paid to private insurers. The public also has a significant interest in providing incentives for those insurers to claim only proper payments in the future, which would be promoted by the recoupment of funds improperly paid in the past. Given the amount of improper payments identified under the MA program (estimated to be \$14.35 billion in FY 2017,²⁷ the \$650 million in recovered improper payments represents, if this policy was finalized, 3 years improper payment for 30 plans), the interest in determining an accurate recovery amount for each audited MA plan, and the importance of protecting the overall integrity of the program, we believe that it is in the public interest for CMS to apply the RADV payment error methodology or methodologies adopted through this rulemaking to payment year 2011 and all subsequent years. In applying this methodology (or these methodologies) to those payment years, CMS would be acting in compliance with the IPERIA statute²⁸ as

²⁷ CMS has historically reported high levels of payment error in the Part C program. The Part C error rate has ranged between 11 percent and 9 percent between fiscal years (FY) 2011 and 2014, respectively. In FY 2017, the reported Part C error rate was 8.31 percent or \$14.35 billion.

²⁸ Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA, Pub. L. 112–248). The RADV program is a corrective audit activity developed by CMS to address provisions included in the IPIA of 2002, as amended by the IPERA of 2010, and further amended by IPERIA. These statutes require that government agencies annually estimate and report improper payments. RADV audits were initiated because Part C payment error was out of compliance with IPIA. The IPERIA requires the Office of Management and Budget (OMB) to annually identify agencies for greater levels of oversight and review, and with that agency “establish annual targets and semi-annual or quarterly actions for reducing improper payments associated with each high-priority program.” In November 2009, Executive Order (E.O.) 13520 was signed in an effort to reduce improper payments by increasing transparency in government and holding agencies accountable for reducing improper payments. In March 2010, OMB issued guidance for agencies regarding the implementation of E.O. 13520 entitled Part III to OMB Circular A–123, Appendix C (Appendix C). Appendix C outlines the responsibilities of agencies, determines the programs subject to E.O. 13520, defines supplemental measures and targets for high priority programs, and establishes reporting requirements under E.O. 13520 and procedures to identify entities with outstanding payments. One of those remedies is payment recapture audits, a requirement that any program that expends at least \$1 million must implement payment recapture audits. A recovery audit, or payment recapture audit, is a review process designed to identify erroneous payments. Additionally, it is a corrective

Continued

²⁵ The Office of the Inspector General, which is required by law to conduct audits and follow generally accepted government auditing standards, does not seek comment on its methodology for risk adjustment audit work that may lead to overpayment recoveries from MA organizations.

well as its own fiduciary responsibility to recover funds due and owing to the Medicare Trust Funds. We note also that our February 2012 publication put MA organizations on notice that CMS expected to calculate a contract-level payment error for payment year 2011 and beyond by extrapolating from its review of a statistically valid sample of enrollees, and that (as explained earlier) MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records.

Application of the finalized RADV payment error methodology or methodologies to payment year 2011 and all subsequent years therefore would not upset any settled interest.

If the finalized contract-level audit methodology differs from the one we published in February 2012, we will also consider whether to apply the new contract-level payment error methodology to payment years 2011, 2012, and 2013, or to only apply it to payment year 2014 and subsequent years, and to finalize the audits for those earlier payment years according to the methodology published in February 2012. We invite comment on this subject, as well. In any event, and however audits for prior years are ultimately handled, we believe that it is vitally important for the health of the MA program to have extrapolated recoveries available for future audit years.

(3) Implementation

This proposal would announce CMS' intention to recover improper payments based on extrapolation of payment error from RADV audit samples to MA organization specified populations. CMS would calculate and recover improper payments based on extrapolation methodologies. MA organizations would be required to remit extrapolated recovery amounts from audit findings as calculated by CMS through its payment system, Medicare Advantage and Prescription Drug system (MARx). MARx is the CMS system that makes monthly payments and payment adjustments to the MA organizations and Part D sponsors. Overpayment recoveries of all types are considered payment adjustments which are done as offsets to the plans' monthly payments. RADV recovery amounts are included in this category. In the month the plan has been notified that the recovery amount will be offset, the MARx system makes an offset to the

plans monthly payment equal to the amount of the recovery amount. In the event the recovery amount exceeds the payment in 1 month, the recovery will be spread across adjustments for multiple months until the full amount is recovered. CMS may likewise require MA organizations to remit such recovery amounts based upon audit findings by OIG.

(4) Recoupment of Improper Payments in Part C

Improper payments identified by CMS outside of the RADV audit process or self-identified by the MA organization that are not returned in accordance with §§ 422.330, and are identified and/or estimated through extrapolation or other estimation methodologies as a result of CMS audits will be recovered following CMS audit processes including payment offset. We propose that MA organizations be required to remit funds that CMS calculates as improper payments through the extrapolated RADV audit findings in accordance with §§ 422.310(e). RADV audit results can be appealed by MA organizations using the regulatory administrative appeals process outlined in § 422.311.

(5) FFS Adjuster

After our 2012 RADV publication, we conducted an extensive study regarding the presence and impact of diagnosis error in FFS claims data. Our study suggests that errors in FFS claims data do not have any systematic effect on the risk scores calculated by the CMS-HCC risk adjustment model, and therefore do not have any systematic effect on the payments made to MA organizations.²⁹

The study began by auditing 8,630 outpatient claims paid through Medicare Part B in a given year. We reviewed the medical records associated with each claim (a small subset of the medical records associated with each beneficiary) to determine whether the diagnosis associated with the claim was supported by medical record documentation. A discrepancy rate for each CMS-HCC was then calculated. For example, the data set contained 484 claims submitted with a diagnosis of chronic obstructive pulmonary disease, which is CMS-HCC 108. Of those diagnoses, 388 were supported by medical record documentation, and 96 were not, for a discrepancy rate of 19.8

percent. To account for the fact that the data set contained extremely small samples of many CMS-HCCs—for example, one diagnosis of extensive third degree burns and two diagnoses of severe head injury—we calculated a high, low, and baseline discrepancy rate. Each CMS-HCC was assigned one of these three mean discrepancy rates depending on its relationship to the baseline discrepancy rate: CMS-HCCs with a discrepancy rate significantly higher than the baseline were assigned to the high category, and those with a discrepancy rate significantly lower than the baseline were assigned to the low category. All other CMS-HCCs were assigned the baseline discrepancy rate. These rates were 46.2 percent, 33.8 percent, and 20.9 percent.

In a given year, multiple claims are submitted for Medicare Part B services received by a given beneficiary and associated with a given diagnosis. For example, an average beneficiary with metastatic cancer or acute leukemia, which is CMS-HCC 7, has seven claims associated with that diagnosis. Because we were interested in determining whether a given beneficiary had a documented diagnosis in a given year, and not whether any particular claim was associated with medical record documentation, we used the claim-level discrepancy rates described above to calculate beneficiary-level discrepancy rates.³⁰

After calculating this beneficiary-level discrepancy rate for each HCC, we ran fifty simulations in which we removed diagnoses from a data set of more than 1.4 million Medicare Part A and B beneficiaries at the beneficiary-level discrepancy rate.³¹ After removing diagnoses at the indicated rates, we used each simulated "corrected" data set to recalibrate the CMS-HCC risk adjustment model, applied the recalibrated risk coefficients to a data set of MA beneficiaries, and compared their original risk scores to the risk

²⁹ For example, metastatic cancer or acute leukemia was assigned the baseline discrepancy rate of 33.8%. We therefore reasoned that each of the seven claims associated with the average beneficiary for whom such a diagnosis was reported had a 66.2% chance of being supported by medical record documentation, and only one instance of medical record support was necessary to make the diagnosis valid for that year. If each beneficiary with such a reported diagnosis has 7 claims associated with that diagnosis, and each claim has a 66.2% chance of being supported by medical record documentation, then 99.95% of all beneficiaries will have at least one instance of medical record support, and only 0.05% of beneficiaries will lack any medical record documentation of their reported diagnosis.

³¹ For metastatic cancer and acute leukemia, 1 in 2,000 diagnoses was removed (corresponding to an error rate of 0.05%).

control activity designed to identify and recapture erroneous payments, and, as such, is a management function and responsibility.

²⁹ We are aware of the district court's recent ruling in *United HealthCare Insurance Co. v. Azar*, No. 16-cv-157 (D.D.C. September 7, 2018), and the government is reviewing that decision and considering its response. In any event, that ruling was made on the basis of the administrative record before the court, which did not include the results of our study.

scores calculated with the recalibrated model. We found that the difference between the risk scores was very small, and that the recalibrated risk scores tended to be slightly lower than the original risk scores. Therefore, we concluded that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program.

An executive summary of the findings and a technical appendix describing the data and methodology can be found at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html>. Because it appears that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program, we propose not to include an FFS Adjuster in any final RADV payment error methodology.

Moreover, even if we had found that diagnosis error in FFS claims data led to systematic payment error in the MA program, we no longer believe that a RADV-specific payment adjustment would be appropriate. RADV audits are used to recover payments based on diagnoses that are not supported by medical record documentation, which thus should not have been reported to CMS. If a payment has been made to an MA organization based on a diagnosis code that is not supported by medical record documentation, that entire payment is in error and should be recovered in full, because the payment standard has not been met, and the MA organization is not entitled to any payment for that diagnosis. RADV audits do not address issues with the accuracy of payments based on diagnosis codes that are supported by medical record documentation. Consequently, an adjustment to RADV recoveries to remedy payment accuracy concerns is inappropriate. For this reason, we believe that it would not be appropriate to correct any systematic payment error in the MA program through a payment adjustment that was only applied to audited contracts. Doing so would introduce inequities between audited and unaudited plans, by only correcting the payments made to audited plans.

Because our study suggests that diagnosis error in FFS claims data does not lead to systematic payment error in the MA program and because we believe it would be inequitable to correct any systematic errors in the payments made to audited plans only, we would not include an FFS Adjuster in any RADV extrapolated audit methodology. We welcome public comments on this study.

d. Proposed Changes

In this section, we discuss the proposed changes to the regulation in Parts 422 and 423 governing the MA Program. We are proposing to apply extrapolation to plan year audits for payment year 2011 forward.

The following is a summary of the proposed changes included in this proposed revision:

We propose to revise § 422.300 to include “collection of improper payments.”

We propose to amend § 422.310(e) Validation of risk adjustment data, to apply extrapolation to plan year audits for payment year 2011 forward.

We propose to amend § 422.310(e) Validation of risk adjustment data, by adding a requirement to set forth the provision for MA organizations to remit improper payments based on RADV audits and established in accordance with stated methodology, in a manner specified by CMS.

We propose to amend § 422.311, the RADV audit dispute and appeal process section, by adding language to clarify that recovery of improper payments from MA organizations will be conducted according to the Secretary’s payment error extrapolation and recovery methodologies and that CMS will apply extrapolation to plan year audits for payment year 2011 forward.

D. Implementing Other Changes

1. Clarification Regarding Accreditation for Quality Improvement Programs

Section 1852(e) of the Act requires each MA organization to have an ongoing quality improvement program to improve the quality of care provided to its enrollees and establishes the requirements for the quality improvement programs. Section 1852(e)(4) of the Act requires the Secretary to deem that an MA Organization has met all of the requirements for any one out of the six program areas listed in section 1852(e)(4)(B) of the Act if the MA Organization is accredited in that area by an accrediting organization that has been approved by CMS and that uses the same (or stricter) standards than CMS uses to evaluate compliance with the applicable requirements. Section 1852(e)(4)(B)(i) of the Act references the quality improvement programs in section 1852(e) of the Act. Thus, an MA Organization could be deemed to meet CMS’ requirements related to quality improvement programs by a CMS-approved accrediting organization.

Section 722(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) revised the quality improvement

program requirements in the Act. Section 1852(e) of the Act was revised by adding a new clause “(2) Chronic Care Improvement Programs” and renumbering the existing clauses accordingly (that is, existing clause “(2) Data” became “(3) Data”). Section 722(a) of the MMA also revised section 1852(e)(4)(B)(i) of the Act. Prior to the MMA, section 1852(e)(4)(B)(i) of the Act indicated that the requirements in clauses (e)(1) (general requirements for quality improvement programs) and (e)(2) (the collection, analysis, and reporting of data related to quality improvement programs) could be deemed. Consistent with the changes made to section 1852(e) of the Act described earlier, section 722(a) of the MMA amended section 1852(e)(4)(B)(i) of the Act to provide, “(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).” However, the printed and online versions of section 1852(e)(4)(B)(i) of the Act continue to cross-reference clauses (e)(1) and (e)(2) erroneously. Therefore, we are clarifying in this proposed rule that the requirements in section 1852(e)(3) of the Act and the subsections of § 422.152 related to section 1852(e)(3) of the Act may be deemed.

2. Delete the Reference to Quality Improvement Projects in § 422.156(b)(1)

Section 1852(e) of the Act requires each MAO to have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to its enrollees. Our regulations at § 422.152 outline the QI Program requirements MA Organizations. Section 422.152(a)(3) requires each MA Organization to conduct quality improvement projects (QIPs) for its enrollees, and § 422.152(d) establishes the requirements for the QIPs. Effective January 1, 2019, CMS eliminated the requirements for QIPs in §§ 422.152(a)(3) and 422.152(d) in the April 2018 final rule (83 FR 16440). However, the reference to QIPs was not deleted in § 422.156(b)(1), which says QIPs are exempt from the process for deeming compliance based on accreditation. Therefore, we are proposing a technical correction in this rule that would delete the phrase “the quality improvement projects (QIPs) and” from § 422.156(b)(1).

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of

section, a prescriber who is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the prescriber's reenrollment bar.

(B) Except as provided in paragraphs (c)(6)(vii)(C) and (D) of this section, a prescriber who is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the prescriber had the prescriber been enrolled and then revoked.

(C) Except as provided in paragraph (c)(6)(vii)(D) of this section, a prescriber, regardless of whether the prescriber is or was enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are—

- (1) The severity of the offense;
- (2) When the offense occurred; and
- (3) Any other information that CMS deems relevant to its determination.

(D) In cases where a prescriber is excluded by the OIG, the prescriber must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(viii) Payment denials under paragraph (c)(6) of this section that are based upon the prescriber's inclusion on the preclusion list are not appealable by beneficiaries.

* * * * *

■ 30. Section 423.153 is amended by revising the section heading and adding paragraph (g) to read as follows:

§ 423.153 Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts.

* * * * *

(g) *Parts A and B claims data extracts*—(1) *General rule.* (i) Beginning in plan year 2020, a PDP sponsor may submit a request to CMS for the data described in paragraph (g)(2) of this section about enrollees in its prescription drug plans.

(ii) CMS will make the data requested in paragraph (g)(1)(i) of this section available to eligible PDP sponsors, in accordance with all applicable laws. The data will be provided at least quarterly on a specified release date, and in an electronic format to be determined by CMS.

(iii) If CMS determines or has a reasonable belief that the PDP sponsor has violated the requirements of this paragraph (g) or that unauthorized uses,

reuses, or disclosures of the Medicare claims data have taken place, at CMS' sole discretion, the PDP sponsor may be denied further access to the data described in paragraph (g)(2) of this section.

(2) *Data described.* The data that may be requested under paragraph (g)(1) of this section are standardized extracts of claims data under Medicare parts A and B for items and services furnished under such parts to beneficiaries who are enrolled in a plan offered by the PDP sponsor at the time of the disclosure.

(3) *Purposes.* A PDP sponsor must comply with all laws that may be applicable to data received under this provision, including state and federal privacy and security laws, and, furthermore subject to the limitations in paragraph (g)(4) of this section may only use or disclose the data provided by CMS under paragraph (g)(1) of this section for the following purposes:

(i) To optimize therapeutic outcomes through improved medication use, as such phrase is used in paragraph (d)(1)(i) of this section.

(ii) To improve care coordination so as to prevent adverse health outcomes, such as preventable emergency department visits and hospital readmissions.

(iii) For activities falling under paragraph (1) of the definition of "health care operations" under 45 CFR 164.501.

(iv) For activities falling under paragraph (2) of the definition of "health care operations" under 45 CFR 164.501.

(v) For "fraud and abuse detection or compliance activities" under 45 CFR 164.506(c)(4)(ii).

(vi) For disclosures that qualify as "required by law" disclosures at 45 CFR 164.103.

(4) *Limitations.* A PDP sponsor must comply with the following requirements regarding the data provided by CMS under this paragraph (g):

(i) The PDP sponsor will not use the data to inform coverage determinations under Part D;

(ii) The PDP sponsor will not use the data to conduct retroactive reviews of medically accepted indications determinations;

(iii) The PDP sponsor will not use the data to facilitate enrollment changes to a different prescription drug plan or an MA-PD plan offered by the same parent organization;

(iv) The PDP sponsor will not use the data to inform marketing of benefits.

(v) The PDP sponsor will contractually bind its contractors that have access to the Medicare claims data, and any other potential downstream

data recipients, to the terms and conditions imposed on the PDP Sponsor under this paragraph (g).

(5) *Ensuring the privacy and security of data.* As a condition of receiving the requested data, the PDP sponsor must attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data listed in paragraphs (g)(3) and (4) of this section. ■ 31. Section 423.182 is amended in paragraph (a) by adding the definitions of "Absolute percentage cap", "Cut point cap", "Guardrail", "Mean resampling", "Restricted range", and "Restricted range cap" in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outlier fence outliers (first quartile - 3 * Interquartile Range (IQR) and third quartile + 3 * IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's

EXHIBIT D-154

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex
rel. BENJAMIN POEHLING,
Plaintiffs,

vs.

No. CV 16-08697 FMO

UNITEDHEALTH GROUP, INC., et al,
Defendants.

_____ /

REMOTE VIDEOCONFERENCE DEPOSITION OF
BRIAN THOMPSON
March 1, 2022

Reported by:

Anne E. Vosburgh, CSR-6804, RPR, CRR

Job No. 792085

1 B. THOMPSON

2 MR. LEE: How long of a lunch break
3 would you like?

4 MR. QURESHI: 30 minutes, please.

5 MR. PRESTES: At a minimum.

6 MR. LEE: Let's come back at
7 11:15 Pacific, which would be 1:15
8 Central, I think.

9 MR. QURESHI: Okay. We'll work on
10 the math over the break, but we'll see
11 you in 30.

12 THE VIDEOGRAPHER: The time is 1:45
13 p.m. and we are off the record.

14 (Lunch recess taken.)

15 -----

16 AFTERNOON SESSION

17 -----

18 THE VIDEOGRAPHER: The time
19 is 2:35 p.m. and we are back on the
20 record.

21 BY MR. LEE:

22 Q. Good afternoon, Mr. Thompson.

23 Earlier today you testified about
24 certain contradictions and discussions that
25 you had within United I believe starting in

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2 January 2014 with the medical record rule.

3 Do you remember that testimony?

4 A. Yes.

5 Q. What in particular were the
6 contradictions that you were referring to?

7 A. Yes. Thank you.

8 In January of 2014 a proposed rule
9 came out that to my recollection had a
10 requirement that was similar to that of claims
11 verification as a process, that had a proposed
12 implementation date that was forward-looking,
13 meaning it had not yet been implemented.

14 That led to a lot of confusion on
15 our part inside UnitedHealthcare. As you
16 know, we had a claims verification process in
17 place at the time, and we sought clarity with
18 respect to the proposed rule and whether or
19 not it was required prior to implementation.
20 It seemed contradictory, and we sought clarity
21 from CMS on that in that regard.

22 Q. What in particular was contradictory,
23 the obligation that the proposed rule would
24 impose?

25 A. Yes. In particular, what the

1 B. THOMPSON

2 requirements were prior to the implementation
3 of the rule.

4 Q. And what was your understanding of
5 what the requirements were prior to the
6 implementation of the rule?

7 A. Well, that is specifically the
8 questions by which we sought counsel from CMS.
9 And we specifically said that given this rule
10 is a proposal, it seems to us that it is not
11 yet a requirement.

12 And is it clear to you, like it
13 appears to us, that it is not yet a
14 requirement until implemented.

15 And then we went further to explain
16 our existing process, meaning claims
17 verification, and also got clarity in the
18 affirmative from CMS by the four executives I
19 mentioned that until the implementation date
20 of the proposed rule, the processes associated
21 with claims verification were not required.

22 And that was a clarity that I was
23 seeking as CFO prior to the attestation at the
24 end of April of 2014.

25 Q. So as I understand it, your

1 B. THOMPSON

2 understanding of the contradiction is that
3 there was some belief that the medical record
4 rule as implemented would impose some
5 obligation to look back that was contradictory
6 to United's practice before then?

7 MR. QURESHI: Objection to form.
8 Mischaracterizes testimony.

9 A. Yeah. I'll just summarize it again
10 to try to clarify.

11 We were seeking clarity about the
12 timing of the proposed rule and the
13 requirements to which it promulgated, if you
14 will, prior to implementation of proposed
15 rule.

16 And that was the question that we
17 asked of CMS on several occasions, what are
18 our requirements prior to implementation,
19 specifically informing them of our claims
20 verification process.

21 And it came back in the affirmative
22 from that conversation that until
23 implementation of rule, claims verification
24 was not a requirement.

25 And that was the clarity that I

1 B. THOMPSON

2 sought and we sought as a company prior to
3 attestation.

4 BY MR. LEE:

5 Q. Were there any other areas of
6 inconsistency or contradictions that you saw?

7 MR. QURESHI: Objection to form.

8 A. In that specific meeting, that was
9 the primary focus. There have been many other
10 inconsistencies around the need for an error
11 rate as a comparison to determine overpayment,
12 but the specific contradiction to which I'm
13 referencing related, to my recollection,
14 particularly around this concept of claims
15 verification, as I remember it.

16 BY MR. LEE:

17 Q. Okay. You mentioned a need for an
18 error rate.

19 What exactly do you mean by that?

20 A. Yes. Medicare Advantage is paid on
21 a basis of consistency, actuarial equivalence,
22 with fee-for-service Medicare.

23 The rate structure upon which
24 Medicare Advantage is reimbursed is based on
25 the same processes and protocols of

1 B. THOMPSON

2 fee-for-service. And it's been important that
3 the alignment of processes be consistent with
4 fee-for-service.

5 When a process is introduced to one
6 or the other, fee-for-service or
7 Medicare Advantage, without accommodation in
8 the rate structure, there's no longer
9 consistency and the payment structure upon
10 which it's founded is no longer consistent.

11 Q. And what is that contradictory to?

12 A. To the fee-for-service baseline upon
13 which reimbursement for Medicare Advantage is
14 based and founded.

15 Q. And tell me what your understanding
16 is of contradiction and why it exists.

17 MR. QURESHI: Objection to form.

18 Asked and answered.

19 A. Yes. I just explained error rate
20 and why, if there's a new process introduced,
21 it would create a contradiction. And I just
22 explained the contradiction in the proposed
23 rule with its implementation date being
24 prospective.

25 Those are the two contradictions

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2 that I'm talking about, sir.

3 BY MR. LEE:

4 Q. All right. Let's take those one at a
5 time.

6 The contradictions relating to the
7 proposed medical records rule, was the
8 contradiction that you didn't know when and if
9 the rule would go into effect or something
10 else?

11 MR. QURESHI: Objection to form.
12 Mischaracterizes testimony.

13 A. I think there were several --

14 BY MR. LEE:

15 Q. Tell me what --

16 A. I'm sorry. I spoke over you, sir.

17 Q. I'm sorry. I spoke over you.

18 Tell me what the contradictions were
19 specifically.

20 A. Yes. I apologize that my
21 recollection might not be as strong, but I
22 will do my best.

23 I remember being confused on at
24 least one topic, and I will explain that
25 first. The topic being, we had a process in

1 B. THOMPSON

2 place called claims verification, to which we
3 spoke earlier.

4 There was a proposed rule that came
5 out in January that suggested the potential
6 for the implementation of a rule that would
7 include requirements very consistent with the
8 processes and procedures that we were
9 deploying at that time in claims verification.

10 So our confusion was around whether
11 or not, before implementation of proposed
12 rule, there was a requirement on behalf of
13 Medicare Advantage plans to do what was in the
14 proposal. That was -- that was where we
15 lacked clarity and sought clarity directly
16 from CMS.

17 Because it was very important to me
18 and to our organization that that confusion
19 not be satisfied only with our own
20 interpretation, but be directly handled
21 through communication with CMS, given our
22 confusion.

23 Q. Was there any discussion of any
24 contradictions before the proposed medical
25 records rule was discussed?

1 B. THOMPSON

2 So, yeah, I would assume that they
3 are potentially linked but, again, I don't
4 recall this document.

5 Q. All right. Let's take a look at the
6 second page. Under 9, it says "Policy Review,
7 necessity of CV, attestations, and chart
8 selection logic."

9 Do you see that?

10 A. I do see that.

11 Q. Okay. What's your understanding of
12 what that means, "necessity of CV"?

13 MR. QURESHI: Objection to form.

14 A. I have no idea, sir. I didn't write
15 this document. I don't recall this document.
16 I can tell you, again, my broad framing of CV
17 and what we talked about, but I didn't write
18 this document.

19 BY MR. LEE:

20 Q. Well, is it your recollection that
21 around April 29th of 2014, some policy review
22 concerning whether CV was necessary was being
23 discussed by management?

24 MR. QURESHI: Objection to form.

25 A. We certainly were seeking clarity

1 B. THOMPSON

2 from CMS around April 29th, as we had
3 discussed, with the four senior leaders who
4 had visited with CMS directly.

5 BY MR. LEE:

6 Q. And this is on the date of the CMS
7 meeting, correct?

8 A. This meeting here or this document?

9 Q. This document.

10 A. I don't know. We'll have to look
11 back to the date that it was sent.

12 Yeah. It appears that it was.

13 Q. Do you agree that the necessity of CV
14 as a policy matter was being considered on
15 April 29th -- at least on April 29, 2014?

16 MR. QURESHI: Objection to form.

17 A. I'm not sure what your question is.
18 I have told you now several times that there
19 were conversations had with CMS around this
20 time. So, yes, of course, these conversations
21 were being had with CMS.

22 Haven't I been clear on that point?

23 BY MR. LEE:

24 Q. Yes, you have been very clear on that
25 point. My point is -- my question is somewhat

1 B. THOMPSON

2 different.

3 And my question specifically is:
4 Would you agree that the prospect of whether
5 CV was necessary was being considered by
6 management as a policy matter, at the latest,
7 by April 29, 2014?

8 MR. QURESHI: Objection to form.

9 Mr. Lee, I think you said that the
10 email was sent on April 29th, but 85A is
11 dated May 2nd. So I'm not sure if you
12 misspoke or if I'm missing something.

13 MR. LEE: Abid, you can just say
14 objection to form.

15 MR. QURESHI: I'm just trying to
16 clarify the date, Mr. Lee.

17 MR. LEE: I'm talking about the date
18 on 85C, which shows April 29th.

19 MR. QURESHI: Okay. I thought you
20 used the word "the date sent" and that's
21 why I looked at the email. I'm sorry.

22 A. What's your question, Mr. Lee?

23 BY MR. LEE:

24 Q. Would you agree that as of
25 April 29th, the necessity of CV was being

1 B. THOMPSON

2 considered by United as a policy matter?

3 MR. QURESHI: Objection to form.

4 A. I can't get specific to the dates.
5 What I can assure you is that as we approached
6 CMS, yes, UnitedHealthcare was assessing the
7 necessity of claims verification. And I've
8 been very clear about that throughout this
9 dialogue today.

10 BY MR. LEE:

11 Q. And it was considered as part of the
12 M&R \$200 million challenge. It was part of the
13 brainstorming ideas that were being thrown
14 around at that time, correct?

15 MR. QURESHI: Objection, asked and
16 answered.

17 A. I would not put claims verification
18 in a category of brainstorming and being
19 thrown around at that time. I would say that
20 our concerted effort to contact CMS was much
21 more formal than that at this time.

22 BY MR. LEE:

23 Q. Well, you may not do it, but this
24 document does, doesn't it? It says
25 "Brainstorming Ideas, M&R

1 B. THOMPSON

2 \$200 Million Challenge." And then number 9 of
3 those ideas is "necessity of CV."

4 Isn't that consistent with your read
5 of this document?

6 MR. QURESHI: Objection to form.

7 A. I didn't put this document together.
8 I can't speak on behalf of why it's on this
9 document. But certainly, if we are talking
10 about our business at this time, clearly we
11 were trying to get clarity on the CV policy.
12 I don't find that out of the ordinary or
13 unusual, sir.

14 MR. LEE: Okay. I'm going to ask my
15 colleague to put up Document 22 --
16 actually, strike that. I think we did
17 look at 22.

18 Okay. I'm going to ask my colleague
19 to put up Document 23, which is going to
20 be Exhibit 119.

21 (05/05/2014 Email chain, beginning
22 Bates MARA1920588, marked as
23 Exhibit 119.)

24 MR. QURESHI: Mr. Lee, if we're
25 going to leave Exhibit 85, I'll just note

1 B. THOMPSON

2 that I think it's incomplete.

3 We have an 85A and C. I don't know
4 if there is a B, but it seems to be
5 lacking from introduction in this
6 deposition.

7 MR. LEE: I think 85B is one of the
8 other attachments that's indicated in the
9 cover memo.

10 MR. QURESHI: And will we be -- do
11 you intend to introduce it?

12 MR. LEE: It's part of Mr. Theisen's
13 transcript, I believe. I think it's a
14 spreadsheet.

15 BY MR. LEE:

16 Q. Mr. Thompson, do you see Exhibit 119
17 in front of you?

18 A. Is it this claw-back button?

19 MR. QURESHI: No. I don't think
20 it's the claw-back button. If you scroll
21 further --

22 THE WITNESS: One moment, sir. I
23 just opened it up.

24 BY MR. LEE:

25 Q. Okay. 119 is an email from you to

1 B. THOMPSON

2 Jay Matushak.

3 Who is Jay Matushak?

4 A. At this time Jay would have been in
5 charge of financial planning and analysis on
6 my team and finance for Medicare and
7 Retirement.

8 Q. Okay. And it says in the body:

9 "Just for clarity, we have not
10 made a final determination to our
11 CV policy. Our RAF counsel" --

12 Is that Risk Adjustment Factor
13 counsel?

14 A. I assume so. I don't recall writing
15 this, sir.

16 Q. Do you know what the RAF counsel is?

17 A. It's been eight years. I don't
18 recall specifics.

19 Q. Do you know who was on that counsel?

20 A. I don't, eight years later.

21 Q. It goes on to say:

22 "Our RAF counsel will make that
23 determination and it will be
24 predicated on several items, one
25 key item of which is our stage of

1 B. THOMPSON

2 progress to date."

3 Do you see that?

4 A. I do.

5 Q. And what were the several items upon
6 which that final determination would be made?

7 A. Sir, I don't remember writing this
8 email. Would you rather I contextualize my
9 memory of the situation? I think I can be
10 more helpful.

11 Q. Yes.

12 A. I do remember that after the
13 affirmative from CMS that we can stop claims
14 verification, that we needed to decide
15 formally how to complete that program and
16 sunset it, and also had discussions with CMS
17 about the program as it was in flight --
18 meaning when we talked to CMS, claims
19 verification was an ongoing program.

20 And we sought clarity from CMS after
21 they were affirmative that we could stop, how
22 we stopped mid-process on those in review.
23 That's my recollection.

24 I can only assume this is related to
25 that, sir.

1 B. THOMPSON

2 Q. When it says "One key item of which
3 is our stage of progress to date," what does
4 that mean?

5 A. I don't know, sir. Again, I just
6 gave you my general recollection. I don't
7 remember writing this email. I thought that
8 would be helpful.

9 Q. Is it your understanding that CV had
10 various stages to it?

11 A. Yes. I think that's a fair
12 representation, sir.

13 Q. And what's your understanding of what
14 the stages were?

15 A. Yes. As I said earlier, I'm not a
16 claims expert. I just know it is a process.

17 Q. And it was a process by which a chart
18 would be looked at multiple times by different
19 coders with different levels of expertise?

20 MR. QURESHI: Objection to form.

21 Asked and answered.

22 A. Yeah. I can't talk to the different
23 levels of expertise. I just know that it was
24 a process that was not just a one-time review
25 that is very black and white. I know it

1 B. THOMPSON

2 included elements of a process. And our
3 questions related to those that had not yet
4 completed the process.

5 If you want specifics on the process
6 itself, sir, I would point to either John Bird
7 or Marybeth Meyer. I certainly don't
8 recollect and believe I probably never knew
9 the specifics of that process.

10 BY MR. LEE:

11 Q. Did your understanding of the
12 generalities of that process include the
13 understanding that there were multiple reviews
14 of the same medical chart by different people?

15 MR. QURESHI: Objection, asked and
16 answered.

17 A. Again, I don't know the elements of
18 the process so I don't want to speak as if I
19 do.

20 What I do know is that there was a
21 process, and my general recollection is that
22 until the process is complete, the claims
23 verification is incomplete.

24 The elements of the process, again,
25 I will state I don't recall or know if I ever

1 B. THOMPSON

2 knew.

3 BY MR. LEE:

4 Q. Okay. But you did have the
5 understanding that claims verification was not
6 complete until all of the stages of the process
7 was completed, correct?

8 A. That is correct, sir.

9 Q. Further down in that email is an
10 email from Jay Matushak to Jeffrey Putnam and
11 others, including yourself.

12 And it says, under "Full Year
13 Implications":

14 "M&R CV delete good guy is around
15 \$250 million for the year."

16 Do you see that?

17 A. I do, sir.

18 Q. And then it says:

19 "Note this is just the M&R piece
20 and there is an incremental
21 component at C&S."

22 Did I read that correctly?

23 A. You did, sir.

24 Q. What does that indicate to you about
25 the \$250 million for the year? What does that

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B. THOMPSON

C E R T I F I C A T E

I, ANNE E. VOSBURGH, Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, and Closed Captioner, hereby certify:

That BRIAN THOMPSON, via remote videoconference, solemnly affirmed and agreed to testify to the truth, the whole truth and nothing but the truth; that all counsel stipulated to this process, notwithstanding the location of reporter or witness at time of deposition; and that this transcript is a true and correct record of testimony given.

I further certify that I am not related to any of the parties to this action and that I am in no way interested in the outcome of this matter.



ANNE E. VOSBURGH

Certified Shorthand Reporter No. 6804
Registered Professional Reporter
Certified Realtime Reporter

EXHIBIT D-155

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex
rel. BENJAMIN POEHLING,
Plaintiffs,

vs.

No. CV 16-08697 FMO

UNITEDHEALTH GROUP, INC., et al,
Defendants.

_____ /

** CONTAINS CONFIDENTIAL PORTIONS **

REMOTE VIDEOCONFERENCE DEPOSITION OF
JONATHAN BLUM
March 4, 2022

Reported by:

Anne E. Vosburgh, CSR-6804, RPR, CRR

Job No. 789903

1 J. BLUM

2 MS. LIKOFF: Object to form. Vague.

3 A. The purpose of the audit was to
4 review the individual plan submissions for the
5 risk-adjustment codes.

6 BY MR. SUMMERS:

7 Q. Right. And was the objective to
8 determine the extent to which reported
9 diagnostic codes could not be validated based
10 on the medical record that was submitted?

11 MS. LIKOFF: Object to form.

12 A. The purpose was to review a sample
13 of submitted diagnoses and determine the
14 accuracy based upon that sample.

15 BY MR. SUMMERS:

16 Q. And then through the RADV program,
17 did you seek to make adjustments on a
18 plan-specific basis to adjust the payments
19 provided to each plan?

20 MS. LIKOFF: Objection to form.

21 Vague.

22 A. I thought of it as to collect
23 payments that were made in error to plans.

24 BY MR. SUMMERS:

25 Q. To recover payments that were made in

1 J. BLUM

2 error?

3 A. "Recover" is a better word. Thank
4 you.

5 MR. SUMMERS: Heather, let's go
6 ahead and -- let me ask, Heather, if you
7 can go ahead and start pulling up Tab 7,
8 I'm going to go ahead and ask another
9 question or two while you're doing that.

10 BY MR. SUMMERS:

11 Q. Mr. Blum, by 2010, you were well
12 aware that the data submitted provided by MA
13 plans often contained diagnostic codes reported
14 by the healthcare providers that were not
15 always supported by the underlying medical
16 records, were you not?

17 MS. LIKOFF: Objection to form.

18 Lacks foundation. Vague.

19 A. I was aware that the Agency faced
20 vulnerabilities in its program, part of which
21 being diagnosis codes that were submitted that
22 weren't documented by medical record.

23 BY MR. SUMMERS:

24 Q. And when you say "faced
25 vulnerabilities," you knew that it was an

1 J. BLUM

2 issue, correct?

3 MS. LIKOFF: Objection to form.

4 A. Yes.

5 BY MR. SUMMERS:

6 Q. Okay. Let's go ahead and pull up
7 what Heather has marked as Exhibit 1094.

8 (12/07/2010 Memorandum, Bates
9 USBP000543752, marked as
10 Exhibit 1094.)

11 BY MR. SUMMERS:

12 Q. Mr. Blum, do you have Exhibit 1094 in
13 front of you?

14 A. Not yet. Just pulling up.

15 Yes.

16 Q. Great. Feel free to take a look at
17 it. It's only a two-page exhibit.

18 Can you please tell us what
19 Exhibit 1094 is.

20 A. It's a memo written to me from the
21 OIG documenting their findings of their own
22 audits with the plans' risk-adjustment
23 submissions.

24 Q. Okay. If we look at the top of the
25 memorandum, do you see it's dated December 7,

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J. BLUM

C E R T I F I C A T E

I, ANNE E. VOSBURGH, Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, and Closed Captioner, hereby certify:

That JONATHAN BLUM, via remote videoconference, solemnly affirmed and agreed to testify to the truth, the whole truth and nothing but the truth; that all counsel stipulated to this process, notwithstanding the location of reporter or witness at time of deposition; and that this transcript is a true and correct record of testimony given.

I further certify that I am not related to any of the parties to this action and that I am in no way interested in the outcome of this matter.



ANNE E. VOSBURGH

Certified Shorthand Reporter No. 6804
Registered Professional Reporter
Certified Realtime Reporter

EXHIBIT D-156

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel., BENJAMIN POEHLING, NO. CV 16-08697 FMO

Plaintiffs,

UNITED HEALTHGROUP, INC.,
et al.,
Defendants.

*** CONTAINS ATTORNEYS' EYES ONLY PORTIONS
BOUND SEPARATELY ***

* * * * *

TRANSCRIPT OF THE VIDEOTAPED DEPOSITION

BY VIDEOCONFERENCE OF:

JENNIFER HARLOW,

TAKEN ON BEHALF OF DEFENDANTS, REPORTED IN THE ABOVE
ENTITLED AND NUMBERED CAUSE BY YOLANDA J. PENA,
CERTIFIED COURT REPORTER FOR THE STATE OF LOUISIANA.

* * * * *

COMMENCING AT 10:03 A.M. EST, ON AUGUST 5, 2022

1 Q. And according to Exhibit 1253, around February
2 of 2007, you became a division director within MPPG.
3 Is that consistent with your recollection?

4 A. So I -- I would caveat that with I did become
5 the division director in the Medicare Plan Policy
6 Group. I don't remember the exact dates, so, you know,
7 I couldn't speak to February 2007. And when we say
8 "MPPG," that would be the Medicare Plan Policy Group.
9 So I became a division director in the Medicare Plan
10 Policy Group to start with.

11 Q. Okay. And at some point in time, did the
12 Medicare Plan Policy Group change its name to the
13 Medicare Plan Payment Group?

14 A. Yes, that's correct.

15 Q. Do -- do you know when that happened?

16 A. I don't remember.

17 Q. Okay. Do you know who -- why it happened?

18 A. I -- I don't -- I don't remember.

19 Q. And what, generally, were the functions of the
20 Medicare Plan Policy Group?

21 A. I -- I would go back to my original answer,
22 which was generally to address policy and Medicare
23 Advantage. I -- I don't remember beyond that, at this
24 point, what the, you know, more specific functions of
25 the group were.

1 Q. And the reference to division director, do you
2 recall what division you were directing in or around
3 February of 2007?

4 A. So I don't remember the exact name. I think
5 it was division of payment validation. So that was it.

6 Q. And sometimes abbreviated as DPV?

7 A. Correct, yes.

8 Q. And at some point, subsequently, you became
9 the deputy director for the Medicare Plan Payment
10 Group?

11 A. Correct, yes. Yeah.

12 Q. Ms. Harlow, you -- you refer to the Medicare
13 Advantage or Medicare Part C program. What's your
14 understanding of what that program does?

15 A. The -- the -- the Medicare Advantage program
16 provides managed care to Medicare beneficiaries.

17 Q. And what's your understanding of the phrase
18 "risk adjustment"?

19 MR. MASON: Objection; vague.

20 A. Could -- could you please provide more framing
21 around "risk adjustment" and what -- where that
22 question is directed?

23 BY MR. QURESHI:

24 Q. Sure. I'm trying to understand what you
25 believe "risk adjustment" refers to in connection with

1 the Medicare Advantage program.

2 A. Risk -- I'm sorry. Are you asking me what the
3 definition of "risk adjustment" is -- or can -- can you
4 just frame it a little bit more?

5 Q. Sure. I'm just trying to ascertain how best
6 you understand that phrase, "risk adjustment," as it
7 applies to the Medicare Advantage program.

8 A. Risk adjustment is a policy that we apply to
9 payments in the Medicare Advantage program.

10 Q. And when you say "payments," you're referring
11 to payments that are made by Medicare to Medicare
12 Advantage plans?

13 A. Correct, yes.

14 Q. How did you familiarize yourself with the
15 Medicare Advantage program during your time with either
16 the Medicare Plan Policy Group or the Medicare Plan
17 Payment Group?

18 MR. MASON: Objection.

19 A. So I'd just like to clarify. Is this question
20 directing -- directed at sort of starting with no
21 understanding of Medicare Advantage when I started
22 working with the Medicare Plan Policy Group?

23 BY MR. QURESHI:

24 Q. I'm trying to understand what your base of
25 knowledge was about the Medicare Advantage program,

1 REPORTER'S CERTIFICATE

2 I, YOLANDA J. PENA, Certified Court Reporter in
3 and for the State of Louisiana, Registered
4 Professional Reporter, and as the officer before whom
5 this testimony was taken, do hereby certify that
6 JENNIFER HARLOW, after having been duly sworn by me
7 upon authority of R.S. 37:2554, did testify as set
8 forth in the foregoing 187 pages.

9 I further certify that said testimony was reported
10 by me in the Stenotype reporting method, was prepared
11 and transcribed by me or under my direction and
12 supervision, and is a true and correct transcript to
13 the best of my ability and understanding.

14 I further certify that the transcript has been
15 prepared in compliance with transcript format
16 guidelines required by statute or by rules of the
17 board and that I have been informed about the complete
18 arrangement, financial or otherwise, with the person
19 or entity making arrangements for deposition services.

20 I further certify that I have acted in compliance
21 with the prohibition on contractual relationships, as
22 defined by Louisiana Code of Civil Procedure Article
23 1434, and in rules and advisory opinions of the board.

24 I further certify that I am not an attorney or
25 counsel for any of the parties, that I am neither
related to nor employed by any attorney or counsel
connected with this action, and that I have no
financial interest in the outcome of this matter.

This certificate is valid only for this
transcript, accompanied by my original signature and
original raised seal on this page.

Baton Rouge, Louisiana, this 10th day of August,
2022.

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Yolanda J. Pena

YOLANDA J. PENA, CCR, RPR
CCR NO. 2017002, RPR NO. 907346

EXHIBIT D-157

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
MARICRUZ BONFANTE
(Taken virtually)
10:33 a.m.
Monday, March 21, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 from occurring.

2 Q. I'm sorry, that last part of your
3 sentence cut out. You said prevent fraud, waste,
4 and abuse in our --

5 A. Oh, from occurring.

6 Q. From occurring, okay.

7 What are your responsibilities?

8 MS. YEVTUKHOVA: Object to form.

9 BY MS. KOPPEL:

10 Q. You may answer.

11 A. My responsibilities, I guess I have
12 several. We have a process in which the different
13 groups within our center for program integrity may
14 bring forward certain areas where they've seen an
15 uptick in fraud, waste, or abuse. And my division
16 basically processes those instances and we triage
17 them. So we basically try to find out more
18 information about each incident, find out, like,
19 what the common denominators are and then try to
20 find out which programs may assist in trying to
21 mitigate or address the different types of
22 vulnerabilities.

23 Q. Okay. And this was for the Medicare
24 Part C program?

25 A. I'm sorry, I couldn't hear you.

1 Q. I'm sorry. This relates to the
2 Medicare Part C program?

3 MS. YEVTUKHOVA: Object to form.

4 THE WITNESS: No. It relates to all
5 programs.

6 BY MS. KOPPEL:

7 Q. All programs including Medicare
8 Part C?

9 A. Yes and no. We haven't really touched
10 on any Medicare Part C issues. We've been most
11 focused on fee for service and Medicare Part D.

12 Q. Ms. Bonfante, who do you currently
13 report to directly?

14 A. Directly, Dennis Sendros and Laura
15 Minassian-Kiefel.

16 Q. How long have you reported directly to
17 those individuals?

18 A. For the last two years.

19 Q. Is there anybody else, since you've
20 held this position, that you've reported directly
21 to?

22 A. They're my direct supervisors. But at
23 one point I was on a detail with -- as a special
24 assistant for Jennifer Dupee and Steven Ferraina,
25 and they're in the front office of the audits and

1 vulnerabilities group.

2 Q. And you said prior to the
3 reorganization you worked in a similar capacity
4 for three years. Who did you report directly to
5 during those three years?

6 A. Reported to Samantha Richardson.

7 Q. Have you held any other positions
8 within CMS?

9 A. Well, the one I held previously when I
10 was working for the Center for Medicare.

11 Q. When was that?

12 A. Well, it would have been between 2010
13 and 2016, I think.

14 Q. Do you recall what your position was
15 at that time?

16 A. It was a health insurance specialist.

17 Q. So it was just for a different
18 division?

19 A. Yes.

20 MS. YEVTUKHOVA: Object to form.

21 BY MS. KOPPEL:

22 Q. And what were your responsibilities as
23 a health insurance specialist while you were
24 working for center for -- you said --

25 A. Well, it depended on the position I

1 was in. I was in two different divisions when I
2 worked for the Center for Medicare. But within my
3 position with the Medicare plan payment group
4 under the Division of Payment Validation, my
5 responsibilities were primarily to help develop an
6 appeals process that would be used when and if we
7 were able to start auditing and issue findings
8 against plans based on any kind of -- of erroneous
9 coding or -- erroneous payment. And then I had
10 several other roles as well. I helped -- I was
11 the contracting officer's representative for two
12 or three different coding contracts during the
13 time that I was with the division of payment
14 validation. And then I left the Division of
15 Payment Validation and started working for the
16 division of -- and the acronym is what sticks out
17 in my head, I don't know if I'm going to get this
18 right, but it's the Division of Encounter Data and
19 Risk Adjustment Operations, yes. And for them, I
20 worked primarily on advising on contracts that
21 they were going to enter into for the front end
22 encounter data system, and I don't remember what
23 that system was called, but -- and then I also
24 handled other things such as systems of record
25 notices, preparing those notifications, and I

1 Q. Yes.

2 A. I may have, but I don't recall.

3 Q. You understood when you e-mailed
4 Ms. Davis and Ms. Kapustij that these were the
5 final slides used for the White House briefing?

6 MS. YEVTUKHOVA: Object to form.

7 THE WITNESS: Well, the e-mail I sent
8 in 2018, I mean, I don't know how I would
9 know personally that these were final. I
10 probably just looked -- I mean, I don't
11 know. I don't remember the circumstances
12 behind that, but I definitely wasn't
13 working in RADV at that time and I may have
14 just, you know, looked for something that
15 said final on it and saw John Scott's
16 e-mail.

17 BY MS. KOPPEL:

18 Q. I'm sorry, I didn't mean to jump on
19 you there. But you used the word "finalized"
20 there?

21 A. That may have been my understanding
22 when I sent the e-mail, but I don't recall the
23 specifics of this.

24 Q. So are you saying that sitting here
25 today you don't know whether these were final, but

1 you believed them to be final when you sent this
2 e-mail in 2018?

3 A. I don't know whether they were final.
4 I can presume that because John Scott sent me an
5 e-mail that had an attachment that said final on
6 it that it was a final document. But I -- I don't
7 recall ever reviewing this.

8 Q. Is it your practice to send along
9 things without reviewing them?

10 A. Well, again, I don't know the context
11 of the discussion or why it was being sent, but --
12 and the circumstances around it being sent, but if
13 I was no longer working in the RADV program and
14 I -- if I had perhaps -- again, this is a
15 hypothetical, this may not explain the
16 circumstances. But if I had to reached out to
17 John Scott who used to be the special assistant
18 for the group director, I would trust that
19 whatever he sent me, if it said final on it, it
20 was probably final. And if all I was doing was
21 taking the document and sending it to the people
22 who are actually working on that program, then I
23 would not reviewed it. I would have just
24 forwarded it to them because it would not have
25 been my -- as someone that works in CPI, that's

1 not part of my role.

2 Q. And trusting that the documents were,
3 in fact, final because you trusted John Scott's
4 work?

5 A. Yes. Absolutely.

6 Q. Okay. So sitting here today, is it
7 your understanding that the slide deck in
8 Exhibit 1147-3 were the final slides that were
9 used for the White House briefing in January of
10 2012?

11 MS. YEVTUKHOVA: Object to form.

12 THE WITNESS: Again, my understanding
13 today based on the e-mail chain that's
14 provided seems to show that this was a
15 final document.

16 BY MS. KOPPEL:

17 Q. And it includes a discussion -- or,
18 rather, a recommendation that CMS apply the
19 fee-for-service adjuster to offset any amounts
20 owed to account for the underlying error in the
21 traditional FFS program; correct?

22 MS. YEVTUKHOVA: Object to form.

23 THE WITNESS: I'm sorry, which slide
24 was that again? I just want to --

25 BY MS. KOPPEL:

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 1st day of April, 2022.

Christine Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT D-158

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: Medicare Advantage Organizations
Medicare Advantage-Prescription Drug Organizations
Cost-Based Contractors
Prescription Drug Plan Sponsors
Employer/Union-Sponsored Group Health Plans
Programs of All-Inclusive Care for the Elderly Organizations

FROM: Jonathan Blum, Acting Director, Center for Drug and Health Plan Choice

RE: Issuance of the 2010 Call Letter

DATE: March 30, 2009

I am pleased to provide you with the 2010 Call Letter for Medicare Advantage (MA) organizations (MAOs); section 1876 cost-based contractors; prescription drug plan (PDP) sponsors; demonstrations; Programs of All-Inclusive Care for the Elderly (PACE) organizations; and employer and union-sponsored group plans, including employer-union-only group waiver plans (EGWPs). The Call Letter contains information these organizations will find useful as they prepare their bids for the upcoming contract year.

We received approximately 190 comments from plan sponsors and plan sponsor associations; advocacy organizations and consumer groups; pharmaceutical manufacturers and their associations; members of Congress; States and State associations; pharmacists and pharmacy associations; providers and provider associations; and other individuals on the draft Call Letter we issued for public comment on February 23, 2009. We carefully considered all comments we received and have made revisions and clarifications in response to these comments in this final 2010 Call Letter.

In some areas, we received a number of constructive comments which we will consider addressing for future contract years. For example, we requested comments regarding whether, and if so, how we should calculate and disseminate information about plans' medical loss ratios. Given this issue's complexity, we will continue evaluating methodologies for possible future implementation. We will also continue to study the issue of our reassignment processes for low-income subsidy (LIS) eligible individuals for potential future improvements that are consistent with our statutory authority. We will also continue to work with plans that are losing members to identify appropriate ways to reach out to these members to explain how they can remain in their current plan and what their premium liability will be if they choose to do so.

As we indicated in the draft document, the 2010 Call Letter focuses on new guidance necessary for preparing for contract year 2010. Sponsoring organizations continue to remain responsible for familiarizing themselves with statutory requirements, regulations, and guidance governing the MA and Part D programs, including the Medicare Managed Care and Prescription Drug Benefit Manuals. CMS will separately issue technical and procedural clarifications regarding bid and formulary submissions, benefits, HPMS data, CMS marketing models, and other operational issues of interest to sponsoring organizations.

We hope this information helps you implement and comply with CMS policies and procedures as you prepare either to offer a plan for the first time or continue offering plans under the MA and/or Part D programs.

2010 Call Letter

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How to Use this Document

The 2016 Call Letter contains information on the Part C, cost-based, and Part D programs combined into one document. Also, we indicate when sections apply to PACF and employer and union-sponsored group health plans. Section A provides MA, MA-PD, and cost plan guidance; Section B provides information for Part D sponsors; Section C contains marketing related information that applies to all plan types; and Section D contains attachments to the material contained in Sections A-C.

If you have questions concerning this Call Letter, please contact Vanessa Duran at Vanessa.Duran@cms.hhs.gov or Rosetta Hicks at Rosetta.Hicks@cms.hhs.gov.

Section A – 2010 MA, MA-PD, and COST PLAN SECTIONS

Note on 2010 MA, MA-PD, and Cost Plan portion of the Call Letter6

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APPENDIX II – Risk Adjustment Implementation**1. Risk Adjustment Data Submission Schedule**

Table 1. Risk Adjustment Implementation Calendar (below) provides the updated submission schedule for all diagnosis data submitted for all risk adjustment models. This includes data for both the Part C CMS-HCC and FSRD models and the Part D Drug risk adjustment model.

Table 1. Risk Adjustment Implementation Calendar

CY	Dates of Service	Initial Submission Deadline*	First Payment Date	Final Submission Deadline
2008	July 1, 2006 through June 30, 2007	September 7, 2007	January 1, 2008	N/A**
2008	January 1, 2007 through December 31, 2007	March 7, 2008	July 1, 2008	January 31, 2009
2009	July 1, 2007 through June 30, 2008	September 5, 2008	January 1, 2009	N/A**
2009	January 1, 2008 through December 31, 2008	March 6, 2009	July 1, 2009	January 31, 2010
2010	July 1, 2008 through June 30, 2009	September 4, 2009	January 1, 2010	N/A**

2010	January 1, 2009 through December 31, 2009	March 5, 2010	July 1, 2010	January 31, 2011
2011	July 1, 2009 through June 30, 2010	September 3, 2010	January 1, 2011	N/A**
2011	January 1, 2010 through December 31, 2010	March 4, 2011	July 1, 2011	January 31, 2012

*March and September dates reflect the first Friday of the respective month.

**All risk adjustment data for a given payment year (CY) must be submitted by January 31st of the subsequent year.

Changes in payment methodology for 2010, including Part C and Part D payment and risk adjustment, are described in the February 20, 2009, *Advance Notice of Methodological Changes for Calendar Year (CY) 2010 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* and the April 6, 2009, *Announcement of CY 2010 MA Capitation Rates and MA and Part D Payment Policies* (which will be available at <http://www.cms.hhs.gov/MedicareAdvSpecRateStats/>).

2. Part A Risk Adjustment Factor Options

Determinations of Risk Status

As stated in the April 3, 2006 Announcement of Calendar Year (CY) 2007 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies (available at <http://www.cms.hhs.gov/MedicareAdvSpecRateStats/>), plans subject to risk adjusted payments have the option of treating beneficiaries with 12 months of Part A data but less than 12 months of Part B enrollment in a data collection year.

Table 2. Which Risk Adjustment Factors to Apply to Payment*

Time Period Beneficiary Has Been Enrolled in Part B Medicare**	Time Period Beneficiary Has Been Entitled to Benefits under Part A Medicare**	
	0 – 11 months	≥ 12 months
0 – 11 months	New enrollee factors	Plan's option: New enrollee or full risk adjustment factors
≥ 12 months	Full risk adjustment factors	Full risk adjustment factors

*Applies to Part C and D payments for MA plans, demonstrations, and PACE organizations. Note that MA enrollees must be entitled to benefits under Part A and enrolled in Part B.

**During data collection period (previous calendar year).

Table 2. Which Risk Adjustment Factors to Apply to Payment (above) illustrates that beneficiaries with 12 or more months of Medicare Part B enrollment during the data collection period (previous calendar year) are considered full risk enrollees. The new enrollee factors do not apply.

Beneficiaries with less than 12 months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period will be treated as new enrollees, as they are now.

Currently beneficiaries with 12 or more months of entitlement to benefits under Part A and less than 12 months of Part B enrollment during the data collection period (referred to as "Part A only" enrollees) are considered new enrollees for the purpose of risk adjusted payments. Because of concerns expressed by some sponsors of demonstration plans that "Part A only" enrollees are always considered to be new enrollees, CMS has created an option for how the risk adjustment payments for this category of enrollees are determined. Effective as of 2006 payments, organizations may elect to have CMS determine payments for all "Part A only" enrollees using either new enrollee factors or full risk adjustment factors. The organization's decision will be applied to all "Part A-only" enrollees in the plan. Plans may not elect to move some eligible "Part A-only" enrollees into risk adjustment, while retaining others as new enrollees.

Option to Elect Full Risk Option for "Part A-only" Enrollees

EXHIBIT D-159

**Attestations
Internal Approval Form**
Version date: 12.29.09

The management of Qvotons and AmeriChoice is responsible for establishing and maintaining adequate internal controls over completion of attestations. Please refer to the XXX Policy & Procedure for the details of this internal control process.

This form is used to confirm that the appropriate legal, regulatory, and business owners have reviewed the attestation. This completed form and any additional attached documentation provides the needed confirmation that it is appropriate for the designated Executive to sign the attestation (or this form). The final signed document, including the signature sheet below with appropriate signatures from approvers, should be scanned and retained by PSMG Regulatory Affairs.

Attestation Information	
Name of Attestation	Calendar Year 2009 Risk Adjustment Attestation
Brief Description of Attestation	Annually, CMS requires Medicare Advantage Organizations to attest to the previous submitted risk adjustment data for it's complete and accuracy.
Attestation to be Submitted to: (CMS, State, etc.)	CMS
Designated Executive for Signature:	Jack Larson, CEO of PSMG
Segment or Product Line (Qvotons, SecureHorizons, Evercare, AmeriChoice, etc.)	Qvotons, AmeriChoice, Uniserv and Sierra
Due Date for Designated Executive Signature:	March 26, 2010
Due Date for Submissions to Regulating Body:	March 25, 2010
Approver Signoff(s)	
Business Owner(s) – The following business owners have reviewed the content of the attestation and confirmed that the attestation is factually accurate and that the business segment is meeting the stated requirements in the attestation. The attached internal attestations (or emails) serve as approval in place of signature on this form. Name & Title: Sharon Thout, Michigan RPO	Date: 3/26/2010
Signature: See Attached signature	
Notes: Great Lakes Health Plan Business Owner(s) – The following business owners have reviewed the content of the attestation and confirmed that the attestation is factually accurate and that the business segment is meeting the stated requirements in the attestation. The attached internal attestations (or emails) serve as approval in place of signature on this form. Name & Title: Jeff Durnham, General Manager, Clinic Assessment Solutions	Date: 3/26/2010
Signature: See attached electronic signature	
Notes: Ingenix	
Business Owner(s) – The following business owners have reviewed the content of the attestation and confirmed that the attestation is factually accurate and that the business segment is meeting the stated requirements in the attestation. The attached internal attestations (or emails) serve as approval in place of signature on this form. Name & Title: Michael Gifford, Vice President, Operations	Date: 3/26/2010

Signature: See attached electronic signature

Notes: Sierra Health Plans

Legal (Confidential Attorney-Client Communication) Lead- Based on the acknowledgement above from the business owner that we are meeting the stated requirements, the individual signing below acknowledges that he/she has reviewed the content of the attestation to confirm that it complies with applicable legal requirements and determined that it is appropriate for the designated executive to proceed with signature. Please insert any notes.

Name & Title: Keith Dobbs, Sr. General Counsel

Date: 8/2/10

Signature:

Notes:

Corporate Responsibility & Compliance Lead- Based on the acknowledgement above from the business owner that we are meeting the stated requirements, the individual signing below acknowledges that he/she has reviewed the content of the attestation to confirm that it complies with applicable regulatory requirements and determined that it is appropriate for the designated executive to proceed with signature. Please insert any notes.

Name & Title: Rebecca Feyrer, Manager Regulatory Affairs

Date: 8/2/10

Signature:

Notes:

INSTRUCTIONS TO DESIGNATED EXECUTIVE

Paper Copy Signatures: Please review this form, the attached internal attestations (if applicable) and the attached attestation itself.

And

Electronic Submissions: Please review this form, the attached internal attestations (if applicable) and the attached attestation itself [or description of the attestation, if too long to attach]. If this attestation is submitted electronically to the regulating body (and therefore a "wet signature" is not required), the responsible executive should sign below, acknowledging approval of the attestation statement and agreeing that the attestation may be submitted to the regulating body electronically.

If you have any questions, please contact Emily Yue, 952-931-4677, or emily_e_yue@uhc.com.

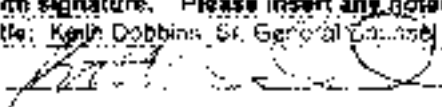
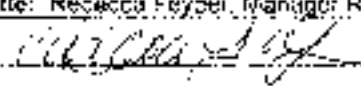
Please sign below and this form to Emily Yue by 08/26/2010.

RESPONSIBLE EXECUTIVE: By signing below, I give the authority to submit this attestation to the regulating body on my behalf.

Name & Title: John Liden, Chief Financial Officer of Public & Senior Market Group

Date: 8/26/10

Signature:

Signature: See attached electronic signature	
Notes: Sierra Health Plans	
Legal (Confidential Attorney Client Communication) Lead- Based on the acknowledgement above from the business owner that we are meeting the stated requirements, the individual signing below acknowledges that he/she has reviewed the content of the attestation to confirm that it complies with applicable legal requirements and determined that it is appropriate for the designated executive to proceed with signature. Please insert any notes.	
Name & Title: Keith Dobbins, Sr. General Counsel	Date: 3/26/10
Signature: 	
Notes:	
Corporate Responsibility & Compliance Lead- Based on the acknowledgement above from the business owner that we are meeting the stated requirements, the individual signing below acknowledges that he/she has reviewed the content of the attestation to confirm that it complies with applicable regulatory requirements and determined that it is appropriate for the designated executive to proceed with signature. Please insert any notes.	
Name & Title: Rebecca Foyder, Manager Regulatory Affairs	Date: 3/26/10
Signature: 	
Notes:	

INSTRUCTIONS TO DESIGNATED EXECUTIVE

Paper Copy Signatures: Please review this form, the attached internal attestations (if applicable) and the attached attestation itself.

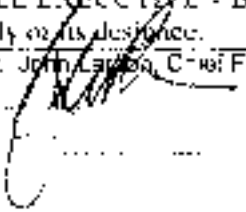
And

Electronic Submissions: Please review this form, the attached internal attestations (if applicable) and the attached attestation itself [or description of the attestation, if too long to attach]. If this attestation is submitted electronically to the regulating body (and therefore a "wet signature" is not required), the responsible executive should sign below, acknowledging approval of the attestation statement and agreeing that the attestation may be submitted to the regulating body electronically.

If you have any questions, please contact Emily Vue, 952-931-4677 or emily_e_vue@ahc.com

Please sign below and this form to Emily Vue by 03/26/2010

RESPONSIBLE EXECUTIVE - By signing below, I give the authority to submit this attestation to the regulating body on its behalf.

Name & Title: John Carlson, Chief Financial Officer of Public & Senior	Date: 3/26/10
Market Group	
Signature: 	

For use with 09-10 All documents with Group 2406329192

2/4

Attestations
Internal Approval Form
 Version date: 12.29.09

The management of Ovalons and AmenChoice are responsible for establishing and maintaining adequate internal controls over administration of attestations. Please refer to the XXX Policy 5 Procedure for the details of this internal control process.

This form is used to confirm that the appropriate legal, regulatory, and business owners have reviewed the attestation (the completed form and any additional attached documentation) provides the needed confirmation that it is appropriate for the designated Executive to sign the attestation (on this form). The final signed document, including this signature sheet below with appropriate signatures from approvers, should be scanned and retained by PSMO Regulatory Affairs.

Attestation Information	
Name of Attestation	Calendar Year 2009 Risk Adjustment Attestation
Brief Description of Attestation	Annually PSMO requires Medicare Advantage Organizations to attest to the previous submitted risk adjustment data for its complete and accuracy.
Attestation to be Submitted to: (CMS, State, etc.)	CMS
Designated Executive for Signature:	Jack Larson, CEO of PSMO
Segment or Product Line (Ovalons, SecureHorizons, Evercare, AmenChoice, etc.)	Ovalons, AmenChoice, Unisen, and State
Due Date for Designated Executive Signature:	March 23, 2010
Due Date for Submissions to Regulatory	March 25, 2010
Body:	
Approver Signoff(s)	
Business Owner(s) of the following business owner(s) have reviewed the content of this attestation and confirmed that the attestation is factually accurate and that the business owner(s) is meeting the stated requirements of the attestation. The attached internal attestations for each business owner are attached to this form.	
Name & Title:	Date:
Signature: <i>Sharon Thayer, President</i>	<i>3/20/10</i>
Notes: Great Lakes Health Plan	
Business Owner(s) of the following business owner(s) have reviewed the content of this attestation and confirmed that the attestation is factually accurate and that the business owner(s) is meeting the stated requirements of the attestation. The attached internal attestations for each business owner are attached to this form.	
Name & Title: <i>Jeff Dornier, General Manager, Ohio, West Virginia</i>	Date:
Signature:	
Notes: Ingenix	
Business Owner(s) of the following business owner(s) have reviewed the content of this attestation and confirmed that the attestation is factually accurate and that the business owner(s) is meeting the stated requirements of the attestation. The attached internal attestations for each business owner are attached to this form.	

US6P060624238

Vue, Emily E

From: Vue, Emily E
Sent: Friday, March 26, 2010 11:23 AM
To: Vue, Emily E
Subject: FW: Risk Adjustment attestation
Importance: High
Attachments: 2009 attestation (risk adjusters) final w/o contracts.doc; CY 2009 Internal Attestation.doc

From: Duncum, Jeff S
Sent: Friday, March 26, 2010 10:03 AM
To: Vue, Emily E
Subject: FW: Risk Adjustment attestation
Importance: High

Please accept this as my electronic signature for the internal attestation.

From: Vue, Emily E
Sent: Friday, March 26, 2010 8:14 AM
To: Threlt, Sharon; Duncum, Jeff S; Goffner, Michael
Cc: Dobbins, Keith E
Subject: Risk Adjustment attestation
Importance: High

Good morning,

Attached are two documents.

1. the adjusted language for the CMS Risk Adjustment attestation that ultimately Jack Larsen will be attesting to for your review and
2. the internal attestation that you are attesting to the language in #1 to Jack for the accuracy of the Risk Adjustment data

Please review the language and if you have a sub-attestation prepared please provide that to me to present to Jack as well. I would prefer that we all sign the same internal executive attestation so please wait until I forward you the Attestation with the appropriate order of signers. **We must have this completed before 2pm today because Jack Larsen will be leaving at 3pm.**

-Sharon Threlt please sign first (also please add your title) to get this process rolling

Thank you

Emily Vue

Sr. Regulatory Affairs Analyst
Ovation - PSMG
UnitedHealth Group, Inc
952-931-4677
emily_e_vue@unh.com

3/26/2010

Vue, Emily E

From: Gaffinet, Michael
Sent: Friday, March 26, 2010 10:53 AM
To: Vue, Emily E
Cc: Campbell, Michelle
Subject: CY 2009 Internal Attestation doc
Attachments: CY 2009 Internal Attestation.doc

Here is my electronically signed attestation

3/26/2010

Emily Vuoc
Regulatory Affairs
UnitedHealth Group
MN00842500
9701 Data Park Drive
Minnetonka, MN 55343

March 19, 2009

Ms. Marilyn Hunter
Centers for Medicare & Medicaid Services
7500 Security Blvd
Mailstop C4-22-04
Baltimore, MD 21244

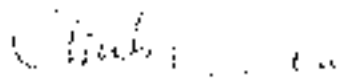
Re: 2008 Risk Adjustment Attestation

Dear Ms. Hunter:

Please find attached the signed 2008 Risk Adjustment Attestations for Securix Longevity
Evantam and Agency Choice on behalf of the UnitedHealth Group.

If you have any questions, I may be reached via email at emily.vuoc@uhc.com or by
telephone at 952/931-4677.

Sincerely,


Emily Vuoc
Regulatory Affairs Analyst
PSMG Regulatory Affairs



11933 Foundation Pl. D
Rancho Cordova, CA 95670

March 22, 2010

Ms. Marilyn Hunter
The Centers for Medicare and Medicaid Services
Mailstop 04-21-25
7500 Security Blvd.
Baltimore, MD 21244

Subject: Risk Adjustment Attestation form for Health Net

Dear Ms. Hunter:

Attached, please find the completed attestation from Health Net.

If you have any questions about this document, please feel free to contact me at
916-935-1459

Sincerely,

A handwritten signature in cursive script that reads 'Janet L. Lima'.

Janet L. Lima
Medicare Director
Health Net, Inc.

www.healthnet.com
(916) 794-1600

ATTACHMENT B

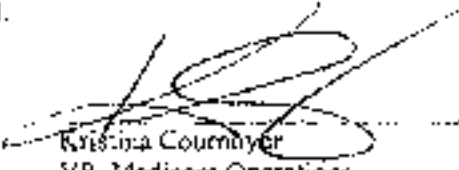
**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING
TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and Health Net, Inc., hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage- Prescription Drug plans including:

H0351 - Health Net of Arizona, Inc.
H0562 - Health Net of California, Inc.
H0755 - Health Net of Connecticut, Inc.
H5439 - Health Net Life Insurance Company
H5520 - Health Net Life Insurance Company
H5721 - Health Net Insurance of New York, Inc.
H5996 - Health Net Life Insurance Company
H5863 - Health Net Life Insurance Company

the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2009, to December 31, 2009, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of December 31, 2009, with respect to the above-stated MA and MA-IPD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

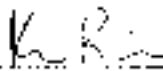

Kristina Courmyer
VP, Medicare Operations
Health Net, Inc.

March 15, 2010
DATE

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contracts between the Centers for Medicare & Medicaid Services (CMS) and the UnitedHealth Group affiliate listed in Attachment 1, hereafter referred to as the MA Organization, governing the operation of the Medicare Advantage and Medicare Advantage- Prescription Drug plans listed in Attachment 1, the MA Organization hereby requests payment under the contract and, in doing so, makes the following attestation concerning CMS payments to the MA Organization.* The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2008 to December 31, 2008 all risk adjustment data available to the MA Organization as of December 31, 2008, with respect to the MA and MA-PD plans listed in Attachment 1. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.



Kara Reis, Chief Financial Officer, AmeriChoice
On behalf of the UnitedHealth Group
entities listed in Attachment 1

3/15/09

DATE

* This Certification is based on facts reasonably available or made available to the MA Organization as of the date of this Certification and is not to be construed as a representation by the entities listed in Attachment 1, their affiliates, officers, representatives, or agents that the data in which the Certification relate may not require subsequent modification should additional information become available. Best knowledge, information, and belief means based on normal business practices. In addition, the scope of this Certification does not include risk adjustment data related to "long-term institutionalized" or "community," which the MA Organization is not required to report to or otherwise verify for CMS. Such designations are made by CMS based on a CMS data source and are subject to reconsideration by CMS in accordance with Section 91.4.2 of Chapter 7 of the Medicare Managed Care Manual. As previously communicated to CMS, we believe these designations are materially inaccurate. However, we acknowledge CMS' position that such designations are generally accurate.

UnitedHealth Group Affiliates and its subsidiaries

Attachment I

<u>Contract</u>	<u>Contracting Party</u>
H332*	Arizona Physicians IPA, Inc.
H3164	AmeriChoice of New Jersey, Inc.
H3387	UnitedHealth Care of New York, Inc.
H4837	UnitedHealth Care of Wisconsin
H5281	UnitedHealth Care Plan of the River Valley, Inc.

3. United States Department of Health and Human Services



March 2, 2009

VIA UPS EXPRESS OVERNIGHT MAIL

Ms. Marilyn Hunter
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C4-22-07
Baltimore, Maryland 21244

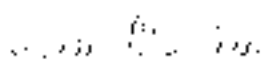
REFERENCE: *Sierra Health and Life Insurance Company, Inc.*
H2905, H4449, R5674
2008 Risk Adjustment Attestation

Dear Ms. Hunter:

Enclosed please find the annual Risk Adjustment Attestation for the period January 1, 2008 – December 31, 2008, signed by Jonathon W. Bunker, President of Sierra Health and Life Insurance Company, Inc.

If you have any questions regarding this submission, or if you need any additional information, please feel free to contact me. I can be reached at (702) 242-7173 or by email at shelley.cranley@unc.com.

Sincerely,


Shelley Cranley
Director, Regulatory Affairs

Enclosure



SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

ATTACHMENT B

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and Sierra Health and Life Insurance Company, Inc., hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans H2905, H4449, and R5674, the MA Organization hereby requests payment under the contract, and in doing so makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2008, to December 31, 2008, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of December 31, 2008, with respect to the above-stated MA and MA-IPD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

Jonathan W. Bunker, President

On behalf
of Sierra Health and Life Insurance Company, Inc.

3/2/09

Date



UnitedHealthcare Insurance Company

March 2, 2009

VIA UPS EXPRESS OVERNIGHT MAIL

Ms. Marilyn Hunter
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C4-22-07
Baltimore, Maryland 21244

REFERENCE: *Health Plan of Nevada, Inc.
H2931 and H2961
2008 Risk Adjustment Attestation*

Dear Ms. Hunter:

Enclosed please find the annual Risk Adjustment Attestation for the period January 1, 2008 – December 31, 2008, signed by Jonathan W. Sunker, President of Health Plan of Nevada, Inc.

If you have any questions regarding this submission, or if you need any additional information, please feel free to contact me. I can be reached at (702) 242-7173 or by email at shelley.cranley@uhc.com.

Sincerely,


Shelley Cranley
Director, Regulatory Affairs

Enclosure



HEALTH PLAN OF NEVADA
A UnitedHealthcare Company

ATTACHMENT B

**ATTTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and Health Plan of Nevada, Inc., hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans H2931 and H2961, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2008, to December 31, 2008, all risk adjustment data (INPATIENT HOSPITAL, OUTPATIENT HOSPITAL, AND PHYSICIAN) available to the MA Organization as of December 31, 2008, with respect to the above-stated MA and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

Jonathan W. Bunker, President

On behalf
of Health Plan of Nevada, Inc.

3/2/09

Date

Print name (last, first, middle initial)

P.O. Box 16848 • Las Vegas, Nevada 89114 • (702) 262-7200

ATTACHMENT B

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION PROVIDED BY A
MEDICARE SECTION 1876 COST ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF MEDICARE SECTION 1876 COST ORGANIZATION), hereafter referred to as the Cost Organization, governing the operation of the following Medicare Cost plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), the Cost Organization makes the following attestation concerning risk adjustment data provided to CMS by the Cost Organization.

The Cost Organization has reported to CMS for the period of January 1, 2008, to December 31, 2008, all risk adjustment data (INPATIENT, OUTPATIENT, if applicable, OUTPATIENT HOSPITAL if applicable, AND PHYSICIAN) available to the Cost Organization as of December 31, 2008, with respect to the above stated Cost plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful. The Cost Organization acknowledges that misrepresentations to CMS regarding the accuracy of such information may result in Federal civil action and/or criminal prosecution.

(INDICATE THE FIELD OFFICE or
delegation) on behalf of

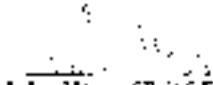
(INDICATE COST ORGANIZATION)

DATE: _____

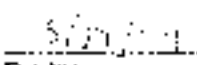
**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contracts between the Centers for Medicare & Medicaid Services (CMS) and the UnitedHealth Group affiliate listed in Attachment I, hereafter referred to as the MA Organization, governing the operation of the Medicare Advantage and Medicare Advantage- Prescription Drug plans listed in Attachment I, the MA Organization hereby requests payment under the contract and, in doing so, makes the following attestation concerning CMS payments to the MA Organization.* The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2008 to December 31, 2008 all risk adjustment data available to the MA Organization as of December 31, 2008, with respect to the MA and MA-PD plans listed in Attachment I. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.



John Way, Chief Financial Officer, Securus Horizons
On behalf of the UnitedHealth Group
entities listed in Attachment I



DATE

* This Certification is based on facts reasonably available or made available to the MA Organization as of the date of this Certification and is not to be construed as a representation by the entities listed in Attachment I, their affiliates, officers, representatives, or agents that the data to which the Certification relates may not require subsequent modification should additional information become available. Best knowledge, information, and belief means based on normal business practices. In addition, the scope of this Certification does not include risk adjustment data related to "long-term institutionalized" or "community," which the MA Organization is not required to report to or otherwise verify for CMS. Such designations are made by CMS based on a CMS data source and are subject to reconciliation by CMS in accordance with Section 91.12 of Chapter 7 of the Medicare Managed Care Manual. As previously communicated to CMS, we believe these designations are materially inaccurate. However, we acknowledge CMS' position that such designations are generally accurate.

Annual Risk Adjustment Attestation/ Certification form

Attachment 1

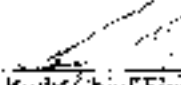
<u>Contract</u>	<u>Contracting Party</u>
H0151	United HealthCare of Alabama, Inc.
H0303	PacificCare of Arizona, Inc.
H0316	United HealthCare of Arizona, Inc.
H0401	United HealthCare of Arkansas, Inc.
H0543	PacificCare of California
H0609	PacificCare of Colorado, Inc.
H0752	Oxford Health Plans (CT), Inc.
H1080	United HealthCare of Florida, Inc.
H1111	United HealthCare of Georgia, Inc.
H1303	United HealthCare Insurance Company
H1509	United HealthCare Insurance Company
H1717	United HealthCare Insurance Company
H2001	United HealthCare Insurance Company
H2406	United HealthCare Insurance Company
H2654	United HealthCare of the Midwest, Inc.
H2802	United HealthCare of the Midlands, Inc.
H2803	United HealthCare Insurance Company
H2949	PacificCare of Nevada, Inc.
H3107	Oxford Health Plans (NJ), Inc.
H3207	Oxford Health Plans (NY), Inc.
H3378	United HealthCare of New York, Inc.
H3456	United HealthCare of North Carolina, Inc.
H3659	United HealthCare of Ohio, Inc.
H3749	PacificCare of Oklahoma, Inc.
H3805	PacificCare of Oregon, Inc.
H3912	United HealthCare Insurance Company
H3921	United HealthCare Insurance Company
H4102	United HealthCare of New England, Inc.
H4406	United HealthCare of Tennessee, Inc.
H4456	United HealthCare Plan of the River Valley, Inc.
H4522	United HealthCare Insurance Company
H4590	PacificCare of Texas, Inc.
H4604	United HealthCare of Utah
H4720	United HealthCare Insurance Company of New York
H5005	PacificCare of Washington, Inc.
H5256	United HealthCare of Wisconsin, Inc.
H5417	United HealthCare Insurance Company
H5424	United HealthCare Insurance Company
H5435	PacificCare Life & Health Insurance Company
H5507	United HealthCare Insurance Company
H5516	United HealthCare Insurance Company
H5532	United HealthCare Insurance Company
H9011	United HealthCare of Florida, Inc.
R3175	United HealthCare Insurance Company
R5257	United HealthCare Insurance Company
R5342	United HealthCare Insurance Company of New York

Source: Public Access to Court Records System, PACER

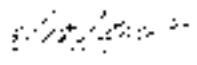
**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contracts between the Centers for Medicare & Medicaid Services (CMS) and the UnitedHealth Group affiliate listed in Attachment 1, hereafter referred to as the MA Organization, governing the operation of the Medicare Advantage and Medicare Advantage-Prescription Drug plans listed in Attachment 1, the MA Organization hereby requests payment under the contract and, in doing so, makes the following attestation concerning CMS payments to the MA Organization.* The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2008 to December 31, 2008 all risk adjustment data available to the MA Organization as of December 31, 2008, with respect to the MA and MA-PD plans listed in Attachment 1. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.



Justin Kerk, Chief Financial Officer, Evercare
On Behalf of the UnitedHealth Group
entities listed in Attachment 1

DATE 

* This Certification is based on facts reasonably available or made available to the MA Organization as of the date of this Certification and is not to be construed as a representation by the entities listed in Attachment 1, their affiliates, officers, representatives, or agents that the data on which the Certification rests may not require subsequent modification should additional information become available. Best knowledge, information, and belief means based on normal business practices. In addition, the scope of this Certification does not include risk adjustment data related to "long-term institutional and" or "nursing facility," which the MA Organization is not required to report to or otherwise verify for CMS. Such designations are made by CMS based on a CMS data source and are subject to record correction by CMS in accordance with Section 91.4.2 of Chapter 7 of the Medicare Managed Care Manual. As previously communicated to CMS, we believe these designations are materially inaccurate. However, we acknowledge CMS' position that such designations are generally accurate.

Attest: N/A. Attachment 1 is attached hereto.

Attachment I

<u>Contract</u>	<u>Contracting Party</u>
H0319	UNITED HEALTHCARE INSURANCE COMPANY
H0408	UNITED HEALTHCARE INSURANCE COMPANY
H0470	UNITED HEALTHCARE INSURANCE COMPANY
H0620	UNITED HEALTHCARE INSURANCE COMPANY
H0624	UNITED HEALTHCARE INSURANCE COMPANY
H0710	UNITED HEALTHCARE INSURANCE COMPANY
H1108	UNITED HEALTHCARE INSURANCE COMPANY
H1286	UNITED HEALTHCARE INSURANCE COMPANY
H2003	UNITED HEALTHCARE INSURANCE COMPANY
H2111	UNITED HEALTHCARE INSURANCE COMPANY
H2228	UNITED HEALTHCARE INSURANCE COMPANY
H2228	UNITED HEALTHCARE INSURANCE COMPANY
H2406	UNITED HEALTHCARE INSURANCE COMPANY
H3113	OXFORD HEALTH PLANS OF NEW JERSEY, INC
H3209	UNITED HEALTHCARE INSURANCE COMPANY
H3435	UNITED HEALTHCARE INSURANCE COMPANY
H3887	UNITED HEALTHCARE INSURANCE COMPANY
H3912	UNITED HEALTHCARE INSURANCE COMPANY
H4105	UNITED HEALTHCARE INSURANCE COMPANY
H4514	EVERCARE OF TEXAS, LLC
H4779	UNITED HEALTHCARE INSURANCE COMPANY
H5009	UNITED HEALTHCARE INSURANCE COMPANY
H5440	UNITED HEALTHCARE INSURANCE COMPANY
H5598	UNITED HEALTHCARE INSURANCE COMPANY
H5652	UNITED HEALTHCARE INSURANCE COMPANY
H5676	UNITED HEALTHCARE INSURANCE COMPANY
H5697	UNITED HEALTHCARE INSURANCE COMPANY
H5754	UNITED HEALTHCARE INSURANCE COMPANY
H5816	UNITED HEALTHCARE INSURANCE COMPANY
H7187	UNITED HEALTHCARE INSURANCE COMPANY
H7274	UNITED HEALTHCARE INSURANCE COMPANY

Contract Data Management System, Inc.

EXHIBIT D-160

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United States Attorney
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18 Email: david.corielli@usdoj.gov
19 Attorneys for the United States of America

20
21 UNITED STATES DISTRICT COURT
22 FOR THE CENTRAL DISTRICT OF CALIFORNIA
23 WESTERN DIVISION
24
25
26
27
28

1 UNITED STATES OF AMERICA *ex*
2 *rel.* BENJAMIN POEHLING,

3 Plaintiffs,

4 v.

5 UNITEDHEALTH GROUP, INC., *et al.*,

6 Defendants.

No. CV 16-08697 FMO-PVCx

JOINT STIPULATION RE EDI
AGREEMENTS, MA CONTRACTS, MA-
PD ADDENDA, AND ATTESTATIONS
AND RELATED ENTITIES

1 For the purposes of the above captioned case only, the parties hereby agree and stipulate
2 to the following:

3 1. The Medicare Advantage Organizations named as Defendants in this case are
4 identified on Exhibit A to this Stipulation and are referred to as the “UnitedHealth
5 MAOs.”

6 2. Each of the UnitedHealth MAOs executed a Medicare Advantage (“MA”)
7 Contract, Medicare Advantage – Prescription Drug (“MA-PD”) Addendum, and an
8 Attestation, and had an Electronic Data Interchange (“EDI”) Agreement in place with
9 Centers for Medicare and Medicaid Services (“CMS”), for each year in which that
10 UnitedHealth MAO had submitted a diagnosis code to CMS that is listed as a delete on
11 Attachment 1 to Dr. Garthwaite’s expert report, and Optum, Inc. executed an EDI
12 Agreement applicable to that MA or MA-PD plan with respect to each such year.

13 3. Each of the diagnosis codes listed on Attachment 1 to Dr. Garthwaite’s expert
14 report is associated with a UnitedHealth MAO that executed an applicable MA Contract,
15 MA-PD Addendum, EDI Agreement and an Attestation, and for which Optum executed
16 an EDI Agreement.

17 4. Each of the Contract Numbers listed on Attachment 2 to Dr. Garthwaite’s expert
18 report refer to MA Contracts entered into by a UnitedHealth MAO.

19 5. MAPL008081457 is an exemplar of an EDI Agreement executed by the
20 UnitedHealth MAOs. All other EDI Agreements executed by the UnitedHealth MAOs
21 contained identical terms.

22 6. MAPL007637301 is an exemplar of an EDI Agreement executed by Optum, Inc.
23 All other EDI Agreements executed by Optum, Inc. applicable to the other UnitedHealth
24 MAOs contained identical terms.

25 7. Exemplars of the MA Contracts, MA-PD Addenda, and Attestations are included,
26 by year, in the table below. All of the MA-PD Addenda and Attestations executed by
27 the UnitedHealth MAOs contained identical terms to the exemplar from the same year.

With the exception of the specific UnitedHealth MAOs identified in paragraphs 8-10 below, all of the MA Contracts executed by the UnitedHealth MAOs contained identical terms to the exemplar MA Contract from the same year.

Year	MA Contract	MA-PD Addendum	Attestation
2009	MAPL003539599	USBP008083344	USBP060624234 at USBP060624253- USBP060624254
2010	MARA263031	USBP009865279	USBP008083511
2011	USBP009428514	USBP009428508	USBP060623193 at USBP060623193- USBP060623195
2012	USBP009426552	USBP009426546	USBP060623193 at USBP060623223 - USBP060623225
2013	USBP009424556	USBP009424550	USBP009417769
2014	USBP009422773	USBP009422767	USBP009417676
2015	USBP009421065	USBP009421059	USBP009417590
2016	USBP009419597	USBP009419590	USBP009417505
2017	USBP009418488	USBP009418481	USBP009417433

8. For CY 2009-2017, H5435 CARE IMPROVEMENT PLUS SOUTH CENTRAL INSURANCE COMPANY entered into Private Fee-for-Service (“PFFS”) contracts. The PFFS contracts had the terms included in the documents in the table below:

Year	Bates Number
2009	USBP009866901
2010	USBP009866901
2011	USBP009427636
2012	USBP009425668

2013	USBP009423731
2014	USBP009422007
2015	USBP009420324
2016	USBP009419115
2017	USBP009418065

9. For CY 2014-2017, H2531 UNITEDHEALTHCARE COMMUNITY PLAN OF OHIO, INC. entered into Medicare-Medicaid Plan (“MMP”) contracts. The MMP contracts had the terms included in the documents in the table below:

Year	Bates Number
2014	USBP009865290
2015	USBP009865290
2016	USBP009865495
2017	USBP009866017

10. For CY 2015-2017, H7833 UNITEDHEALTHCARE COMMUNITY PLAN OF TEXAS, LLC entered into MMP contracts. The MMP contracts had the terms included in the documents in the table below:

Year	Bates Number
2015	USBP009866581
2016	USBP009866233
2017	USBP009865709

11. For 2013-2017 Contract Years (“CY”), UnitedHealth sent emails to Cheri Rice in conjunction with the execution of its Attestations. CMS employees responded to each of those emails.

- MARA1296257 is an accurate record of the email sent by Steve Nelson in conjunction with UnitedHealth’s 2013 CY Attestation and Cheri Rice’s response to that email from Steve Nelson.

- USBP001354165 is an accurate record of the email sent by Steve Nelson in conjunction with UnitedHealth's 2014 CY Attestation and Cheri Rice's response to that email from Steve Nelson.
- USBP001354107 is an accurate record of the email sent by Steve Nelson in conjunction with UnitedHealth's 2015 CY Attestation and Cheri Rice's response to that email from Steve Nelson.
- USBP058101090 is an accurate record of the email sent by Brian Thompson in conjunction with UnitedHealth's 2016 and 2017 CY Attestations.
- USBP009866579 is an accurate record of the letter sent from Jennifer Shapiro to Brian Thompson in response to Mr. Thompson's email found at USBP058101090.

Related Entities

12. The UnitedHealth MAOs are all owned by UnitedHealth Group, Inc., either directly or through one or more subsidiaries.

13. United HealthCare Services, Inc. is also owned by UnitedHealth Group, Inc., either directly or through one or more subsidiaries.

14. United HealthCare Services, Inc. performed management functions for the UnitedHealth MAOs pursuant to management services agreements with those MAOs.

15. United HealthCare Services, Inc. is a "Related Entity" to the each of the UnitedHealth MAOs, as defined by 42 C.F.R. §§ 422.2 & 422.500.

16. United Healthcare Services, Inc., in turn delegated some management functions for the UnitedHealth MAOs to its subsidiary Optum, Inc., either directly or through OptumInsight, Inc.

17. Optum, Inc. is owned by UnitedHealth Group, Inc., either directly or through one or more subsidiaries.

18. Optum, Inc. is a "Related Entity" to the each of the UnitedHealth MAOs, as defined by 42 C.F.R. §§ 422.2 & 422.500.

19. OptumInsight, Inc. is owned by UnitedHealth Group, Inc., either directly or through one or more subsidiaries.

20. OptumInsight, Inc. is a “Related Entity” to the each of the UnitedHealth MAOs, as defined by 42 C.F.R. §§ 422.2 & 422.500.

Dated: May 28, 2024

MICHAEL D. GRANSTON
Deputy Assistant Attorney General, Civil
Division
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United States Attorney
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ROSS M. CUFF
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AMY L. LIKOFF
GREGORY A. MASON
MARTHA N. GLOVER
WENDY ZUPAC
Civil Division, Department of Justice

TRINI E. ROSS
United States Attorney
DAVID CORIELL
Assistant United States Attorney



Martha N. Glover

Attorneys for the United States of America

1 Dated: May 29, 2024

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Denver, Colorado 80202-6318
Telephone: +1.303.592.3100
Facsimile: +1.303.592.3140

24 

25 By _____
26 Daniel Meron

27 Attorneys for UnitedHealth Defendants
28

UnitedHealth MAOs
AmeriChoice of New Jersey, Inc.
AmeriChoice of New York, Inc. ¹
Arizona Physicians IPA, Inc.
Care Improvement Plus of Maryland, Inc. ²
Care Improvement Plus of Texas Insurance Company
Care Improvement Plus South Central Insurance Company
Care Improvement Plus Wisconsin Insurance Company
Citrus Health Care, Inc. ³
Health Plan of Nevada, Inc.
Preferred Care Network, Inc. f/k/a Medica HealthCare Plans, Inc.
Oxford Health Plans (CT), Inc.
Oxford Health Plans (NJ), Inc.
Oxford Health Plans (NY), Inc.
PacifiCare Life and Health Insurance Company
PacifiCare of Arizona, Inc.
UnitedHealthcare of the Rockies f/k/a PacifiCare of Nevada, Inc.
PacifiCare of Colorado, Inc.
Physicians Health Choice of Texas, LLC
Preferred Care Partners, Inc.
Sierra Health and Life Insurance Company
UnitedHealthcare Insurance Company of American f/k/a Symphonix Health Insurance Inc.
UHC of California
Unison Health Plan of Tennessee ⁴
UnitedHealthcare Benefits of Texas, Inc.
UnitedHealthcare Community Plan, Inc.
UnitedHealthcare Community Plan of Ohio, Inc.
UnitedHealthcare Community Plan of Texas, LLC
UnitedHealthcare Insurance Company
UnitedHealthcare Insurance Company of New York
UnitedHealthcare of Alabama, Inc.
UnitedHealthcare of Arizona, Inc.
UnitedHealthcare of Arkansas, Inc.
UnitedHealthcare of Florida, Inc.
UnitedHealthcare of Georgia, Inc.
UnitedHealthcare of New England, Inc.

¹ AmeriChoice of New York, Inc. merged with and into Defendant UnitedHealthcare of New York, Inc. on December 31, 2007.

² Care Improvement Plus of Maryland, Inc. merged with and into UnitedHealthcare of the Mid-Atlantic, Inc. on December 29, 2015.

³ Citrus Health Care, Inc. merged with and into UnitedHealthcare of Florida, Inc. on December 31, 2014.

⁴ Unison Health Plan of Tennessee merged with and into Three Rivers Holdings, Inc. on August 10, 2012.

UnitedHealth MAOs
UnitedHealthcare of New York, Inc.
UnitedHealthcare of North Carolina, Inc.
UnitedHealthcare of Ohio, Inc.
UnitedHealthcare of Oklahoma, Inc.
UnitedHealthcare of Oregon, Inc.
UnitedHealthcare of Pennsylvania, Inc.
UnitedHealthcare of Tennessee, Inc. ⁵
UnitedHealthcare Plan of the River Valley, Inc.
UnitedHealthcare of the Mid-Atlantic, Inc.
UnitedHealthcare of the Midlands, Inc.
UnitedHealthcare of the Midwest, Inc.
UnitedHealthcare of Utah, Inc.
UnitedHealthcare of Washington, Inc.
UnitedHealthcare of Wisconsin, Inc.

⁵ UnitedHealthcare of Tennessee, Inc. merged with and into UnitedHealthcare Plan of the River Valley, Inc. on June 30, 2011.

LATHAM & WATKINS LLP
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Email: *hunter.thomson@usdoj.gov*

Attorneys for the United States of America

[Additional Counsel Listed on Next Page]

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 12 OF 14
EXHIBITS P-1 THROUGH P-34
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Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT P-1

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1 UNITED STATES OF AMERICA *ex*
2 *rel.* BENJAMIN POEHLING,

3 Plaintiffs,

4 v.

5 UNITEDHEALTH GROUP, INC., *et al.*,

6 Defendants.

No. CV 16-08697 FMO-PVCx

JOINT STIPULATION RE EDI
AGREEMENTS, MA CONTRACTS, MA-
PD ADDENDA, AND ATTESTATIONS
AND RELATED ENTITIES

1 For the purposes of the above captioned case only, the parties hereby agree and stipulate
2 to the following:

3 1. The Medicare Advantage Organizations named as Defendants in this case are
4 identified on Exhibit A to this Stipulation and are referred to as the “UnitedHealth
5 MAOs.”

6 2. Each of the UnitedHealth MAOs executed a Medicare Advantage (“MA”)
7 Contract, Medicare Advantage – Prescription Drug (“MA-PD”) Addendum, and an
8 Attestation, and had an Electronic Data Interchange (“EDI”) Agreement in place with
9 Centers for Medicare and Medicaid Services (“CMS”), for each year in which that
10 UnitedHealth MAO had submitted a diagnosis code to CMS that is listed as a delete on
11 Attachment 1 to Dr. Garthwaite’s expert report, and Optum, Inc. executed an EDI
12 Agreement applicable to that MA or MA-PD plan with respect to each such year.

13 3. Each of the diagnosis codes listed on Attachment 1 to Dr. Garthwaite’s expert
14 report is associated with a UnitedHealth MAO that executed an applicable MA Contract,
15 MA-PD Addendum, EDI Agreement and an Attestation, and for which Optum executed
16 an EDI Agreement.

17 4. Each of the Contract Numbers listed on Attachment 2 to Dr. Garthwaite’s expert
18 report refer to MA Contracts entered into by a UnitedHealth MAO.

19 5. MAPL008081457 is an exemplar of an EDI Agreement executed by the
20 UnitedHealth MAOs. All other EDI Agreements executed by the UnitedHealth MAOs
21 contained identical terms.

22 6. MAPL007637301 is an exemplar of an EDI Agreement executed by Optum, Inc.
23 All other EDI Agreements executed by Optum, Inc. applicable to the other UnitedHealth
24 MAOs contained identical terms.

25 7. Exemplars of the MA Contracts, MA-PD Addenda, and Attestations are included,
26 by year, in the table below. All of the MA-PD Addenda and Attestations executed by
27 the UnitedHealth MAOs contained identical terms to the exemplar from the same year.

With the exception of the specific UnitedHealth MAOs identified in paragraphs 8-10 below, all of the MA Contracts executed by the UnitedHealth MAOs contained identical terms to the exemplar MA Contract from the same year.

Year	MA Contract	MA-PD Addendum	Attestation
2009	MAPL003539599	USBP008083344	USBP060624234 at USBP060624253- USBP060624254
2010	MARA263031	USBP009865279	USBP008083511
2011	USBP009428514	USBP009428508	USBP060623193 at USBP060623193- USBP060623195
2012	USBP009426552	USBP009426546	USBP060623193 at USBP060623223 - USBP060623225
2013	USBP009424556	USBP009424550	USBP009417769
2014	USBP009422773	USBP009422767	USBP009417676
2015	USBP009421065	USBP009421059	USBP009417590
2016	USBP009419597	USBP009419590	USBP009417505
2017	USBP009418488	USBP009418481	USBP009417433

8. For CY 2009-2017, H5435 CARE IMPROVEMENT PLUS SOUTH CENTRAL INSURANCE COMPANY entered into Private Fee-for-Service (“PFFS”) contracts. The PFFS contracts had the terms included in the documents in the table below:

Year	Bates Number
2009	USBP009866901
2010	USBP009866901
2011	USBP009427636
2012	USBP009425668

2013	USBP009423731
2014	USBP009422007
2015	USBP009420324
2016	USBP009419115
2017	USBP009418065

9. For CY 2014-2017, H2531 UNITEDHEALTHCARE COMMUNITY PLAN OF OHIO, INC. entered into Medicare-Medicaid Plan (“MMP”) contracts. The MMP contracts had the terms included in the documents in the table below:

Year	Bates Number
2014	USBP009865290
2015	USBP009865290
2016	USBP009865495
2017	USBP009866017

10. For CY 2015-2017, H7833 UNITEDHEALTHCARE COMMUNITY PLAN OF TEXAS, LLC entered into MMP contracts. The MMP contracts had the terms included in the documents in the table below:

Year	Bates Number
2015	USBP009866581
2016	USBP009866233
2017	USBP009865709

11. For 2013-2017 Contract Years (“CY”), UnitedHealth sent emails to Cheri Rice in conjunction with the execution of its Attestations. CMS employees responded to each of those emails.

- MARA1296257 is an accurate record of the email sent by Steve Nelson in conjunction with UnitedHealth’s 2013 CY Attestation and Cheri Rice’s response to that email from Steve Nelson.

- 1 • USBP001354165 is an accurate record of the email sent by Steve Nelson in
2 conjunction with UnitedHealth's 2014 CY Attestation and Cheri Rice's response
3 to that email from Steve Nelson.
- 4 • USBP001354107 is an accurate record of the email sent by Steve Nelson in
5 conjunction with UnitedHealth's 2015 CY Attestation and Cheri Rice's response
6 to that email from Steve Nelson.
- 7 • USBP058101090 is an accurate record of the email sent by Brian Thompson in
8 conjunction with UnitedHealth's 2016 and 2017 CY Attestations.
- 9 • USBP009866579 is an accurate record of the letter sent from Jennifer Shapiro to
10 Brian Thompson in response to Mr. Thompson's email found at USBP058101090.

11 **Related Entities**

12 12. The UnitedHealth MAOs are all owned by UnitedHealth Group, Inc., either
13 directly or through one or more subsidiaries.

14 13. United HealthCare Services, Inc. is also owned by UnitedHealth Group, Inc.,
15 either directly or through one or more subsidiaries.

16 14. United HealthCare Services, Inc. performed management functions for the
17 UnitedHealth MAOs pursuant to management services agreements with those MAOs.

18 15. United HealthCare Services, Inc. is a "Related Entity" to the each of the
19 UnitedHealth MAOs, as defined by 42 C.F.R. §§ 422.2 & 422.500.

20 16. United Healthcare Services, Inc., in turn delegated some management functions
21 for the UnitedHealth MAOs to its subsidiary Optum, Inc., either directly or through
22 OptumInsight, Inc.

23 17. Optum, Inc. is owned by UnitedHealth Group, Inc., either directly or through one
24 or more subsidiaries.

25 18. Optum, Inc. is a "Related Entity" to the each of the UnitedHealth MAOs, as
26 defined by 42 C.F.R. §§ 422.2 & 422.500.

19. OptumInsight, Inc. is owned by UnitedHealth Group, Inc., either directly or through one or more subsidiaries.

20. OptumInsight, Inc. is a “Related Entity” to the each of the UnitedHealth MAOs, as defined by 42 C.F.R. §§ 422.2 & 422.500.

Dated: May 28, 2024

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EXHIBIT P-1A

**CONTRACT WITH ELIGIBLE MEDICARE ADVANTAGE (MA) ORGANIZATION
PURSUANT TO SECTIONS 1851 THROUGH 1859 OF THE SOCIAL SECURITY ACT
FOR THE OPERATION OF A MEDICARE ADVANTAGE COORDINATED CARE PLAN(S)**

CONTRACT (H2226)

Between

Centers for Medicare & Medicaid Services (hereinafter referred to as CMS);

and

UNITEDHEALTHCARE INSURANCE COMPANY
(hereinafter referred to as the MA Organization)

CMS and the MA Organization, an entity which has been determined to be an eligible Medicare Advantage Organization by the Administrator of the Centers for Medicare & Medicaid Services under 42 CFR 5422.503, agree to the following for the purposes of §§ 1851 through 1859 of the Social Security Act (hereinafter referred to as the Act):

(NOTE: Citations indicated in brackets are placed in the text of this contract to note the regulatory authority for certain contract provisions. All references to Part 422 are to 42 CFR Part 422.)

**Article I
Term of Contract**

The term of this contract shall be from the date of signature by CMS' authorized representative through December 31, 2017, after which this contract may be renewed for successive one-year periods in accordance with 42 CFR 5422.505(c) and as discussed in Paragraph A of Article VII below. [422.505]

This contract governs the respective rights and obligations of the parties as of the effective date set forth above, and supersedes any prior agreements between the MA Organization and CMS as of such date. MA organizations offering Part D benefits also must execute an Addendum to the Medicare Managed Care Contract Pursuant to §§ 1860D-1 through 1860D-43 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan (hereafter the "Part D Addendum"). For MA Organizations offering MA-PD plans, the Part D Addendum governs the rights and obligations of the parties relating to the provision of Part D benefits, in accordance with its terms, as of its effective date.

**Article II
Coordinated Care Plan**

A. The MA Organization agrees to operate one or more coordinated care plans as defined in 42 CFR 5422.4(a)(1)(ii), including at least one MA-PD plan as required under 42 CFR 422.4(c), as described in its final Plan Benefit Package (PBP) bid submission (benefit and price bid) proposal as approved by CMS and as attested to in the Medicare Advantage Attestation of Benefit Plan and Price, and in compliance with the requirements of this contract and applicable Federal statutes, regulations, and policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual, etc.).

B. Except as provided in paragraph (C) of this Article, this contract is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract and any regulations or policies implementing or interpreting such statutory provisions.

C. CMS will not implement, other than at the beginning of a calendar year, requirements under 42 CFR Part 422 that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute. [422.521]

D. If the MA Organization had a contract with CMS for Contract Year 2016 under the contract ID number designated above, this document is considered a renewal of the existing contract. While the terms of this document supersede the terms of the 2016 contract, the parties' execution of this contract does not extinguish or interrupt any pending obligations or actions that may have arisen under the 2016 or prior year contracts.

E. This contract is in no way intended to supersede or modify 42 CFR, Part 422. Failure to reference a regulatory requirement in this contract does not effect the applicability of such requirements to the MA organization and CMS.

**Article III
Functions To Be Performed By Medicare Advantage Organization**

A. PROVISION OF BENEFITS

1. The MA Organization agrees to provide enrollees in each of its MA plans the basic benefits as required under 42 CFR 5422.101 and, to the extent applicable, supplemental benefits under 42 CFR 5422.102 and as established in the MA Organization's final benefit and price bid proposal as approved by CMS and listed in the MA Organization Plan Attestation of Benefit Plan and Price, which is attached to this contract. The MA Organization agrees to provide access to such benefits as required under subpart C in a manner consistent with professionally recognized standards of health care and according to the access standards stated in 42 CFR 5422.112.

2. The MA Organization agrees to provide post-hospital extended care services, should an MA enrollee elect such coverage, through a home skilled nursing facility, as defined at 42 CFR 5422.133(b), according to the requirements of § 1852(l) of the Act and 42 CFR 5422.133. [422.133; 422.504(a)(3)]

B. ENROLLMENT REQUIREMENTS

1. The MA Organization agrees to accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in 42 CFR Part 422, Subpart B.

2. The MA Organization shall comply with the provisions of 42 CFR 5422.110 concerning prohibitions against discrimination in beneficiary enrollment, other than in enrolling eligible beneficiaries in a CMAA-approved special needs plan that exclusively enrolls special needs individuals as consistent with 42 CFR 55422.2, 422.4(a)(1)(iv) and 422.52. [422.504(a)(2)]

C. BENEFICIARY PROTECTIONS

1. The MA Organization agrees to comply with all requirements in 42 CFR Part 422, Subpart M governing coverage determinations, grievances, and appeals. [422.504(a)(7)]

2. The MA Organization agrees to comply with the confidentiality and enrollee record accuracy requirements in 42 CFR 5422.118.

3. **Beneficiary Financial Protections.** The MA Organization agrees to comply with the following requirements:

(3.a) Each MA Organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the MA Organization. To meet this requirement the MA Organization must—

(3.a.i) Ensure that all contractual or other written arrangements with providers prohibit the Organization's providers from holding any beneficiary enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and

(3.a.ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the MA Organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA Organization, to provide services to the organization's beneficiary enrollees.

[422.504(g)(1)]

(3.b) The MA Organization must provide for continuation of enrollee health care benefits-

(3.b.i) For all enrollees, for the duration of the contract period for which CMS payments have been made; and

(3.b.ii) For enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of the MA Organization's insolvency, through the date of discharge. **[422.504(g)(2)]**

(3.c) In meeting the requirements of this paragraph, other than the provider contract requirements specified in subparagraph 3(a) of this paragraph, the MA Organization may use-

(3.c.i) Contractual arrangements;

(3.c.ii) Insurance acceptable to CMS;

(3.c.iii) Financial reserves acceptable to CMS; or

(3.c.iv) Any other arrangement acceptable to CMS. **[422.504(g)(3)]**

D. PROVIDER PROTECTIONS

1. The MA Organization agrees to comply with all applicable provider requirements in 42 CFR Part 422 Subpart E, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans. **[422.504(a)(6)]**

2. Prompt Payment.

(2.a) The MA Organization must pay 95 percent of "clean claims" within 30 days of receipt if they are claims for covered services that are not furnished under a written agreement between the organization and the provider.

(i) The MA Organization must pay interest on clean claims that are not paid within 30 days in accordance with §§ 1816(c)(2) and 1842(c)(2) of the Act.

(ii) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request. **[422.520(a)]**

(2.b) Contracts or other written agreements between the MA Organization and its providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA Organization and the relevant provider. **[422.520(b)]**

(2.c) If CMS determines, after giving notice and opportunity for hearing, that the MA Organization has failed to make payments in accordance with subparagraph (2)(a) of this paragraph, CMS may provide-

(2.c.i) For direct payment of the sums owed to providers; and

(2.c.ii) For appropriate reduction in the amounts that would otherwise be paid to the MA Organization, to reflect the amounts of the direct payments and the cost of making those payments. **[422.520(c)]**

E. QUALITY IMPROVEMENT PROGRAM

1. The MA Organization agrees to operate, for each plan that it offers, an ongoing quality improvement program as stated in accordance with § 1852(e) of the Social Security Act and 42 CFR §422.152.

2. The MA Organization agrees to develop and operate a chronic care improvement program in accordance with the requirements of 42 CFR §422.152(c).

3. Performance Measurement and Reporting: The MA Organization shall measure performance under its MA plans using standard measures required by CMS, and report (at the organization level) its performance to CMS. The standard measures required by CMS during the term of this contract will be uniform data collection and reporting instruments, to include the Health Plan and Employer Data Information Set (HEDIS), Consumer Assessment of Health Plan Satisfaction (CAHPS) survey, and Health Outcomes Survey (HOS). These measures will address clinical areas, including effectiveness of care, enrollee perception of care and use of services, and non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics. **[422.152(b)(1), (e)]**

4. Utilization Review

(4.a) An MA Organization for an MA coordinated care plan must use written protocols for utilization review and policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and have in effect mechanisms to detect both underutilization and over utilization of services. **[422.152(b)]**

(4.b) For MA regional preferred provider organizations (RPOs) and MA local preferred provider organizations (LPOs) that are offered by an organization that is not licensed or organized under State law as an HMO, if the MA Organization uses written protocols for utilization review, those policies and procedures must reflect current standards of medical practice in processing requests for initial or continued authorization of services and include mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation. **[422.152(e)]**

5. Information Systems:

(5.a) The MA Organization must:

(5.a.i) Maintain a health information system that collects, analyzes and integrates the data necessary to implement its quality improvement program;

(5.a.ii) Ensure that the information entered into the system (particularly that received from providers) is reliable and complete;

(5.a.iii) Make all collected information available to CMS. **[422.152(f)(1)]**

6. External Review: The MA Organization will comply with any requests by Quality Improvement Organizations to review the MA Organization's medical records in connection with appeals of discharges from hospitals, skilled nursing facilities, and home health agencies.

7. The MA Organization agrees to address complaints received by CMS against the MA Organization as required in 42 CFR §422.504(a)(15) by:

(7.a) Addressing and resolving complaints in the CMS complaint tracking system; and

(7.b) Displaying a link to the electronic complaint form on the Medicare.gov Internet Web site on the MA plan's main Web page.

F. COMPLIANCE PLAN

The MA Organization agrees to implement a compliance plan in accordance with the requirements of 42 CFR §422.503(b)(4)(vi). **[422.503(b)(4)(vi)]**

G. COMPLIANCE DEEMED ON THE BASIS OF ACCREDITATION

CMS may deem the MA Organization to have met the quality improvement requirements of §1852(e) of the Act and 42 CFR §422.152, the confidentiality and accuracy of enrollee records requirements of §1852(h) of the Act and 42 CFR §422.118, the anti-discrimination requirements of §1852(b) of the Act and 42 CFR §422.110, the access to services requirements of §1852(d) of the Act and 42 CFR §422.112, the advance directives requirements of §1852(i) of the Act and 42 CFR §422.128, the provider participation requirements of §1852(j) of the Act and 42 CFR Part 422, Subpart E, and the applicable requirements described in 42 CFR §423.156, if the MA Organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by CMS and the accreditation organization used the standards approved by CMS for the purposes of assessing the MA Organization's compliance with Medicare requirements. The

provisions of 42 CFR §422.155 shall govern the MA Organization's use of deemed status to meet MA program requirements.

H. PROGRAM INTEGRITY

1. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS of any integrity items related to payments from governmental entities, both federal and state, for healthcare or prescription drug services. These items include any investigations, legal actions or matters subject to arbitration brought involving the MA Organization (or MA Organization's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.

2. The MA Organization agrees to provide notice based on best knowledge, information, and belief to CMS in the event the MA Organization or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent activities or is sanctioned under any Federal program involving the provision of health care or prescription drug services.

I. MARKETING

1. The MA Organization may not distribute any marketing materials, as defined in 42 CFR §422.2260 and in the Marketing Materials Guidelines for Medicare Advantage-Prescription Drug Plans and Prescription Drug Plans (Medicare Marketing Guidelines), unless they have been filed with and not disapproved by CMS in accordance with 42 CFR §422.2264. The file and use process set out at 42 CFR §422.2262 must be used, unless the MA organization notifies CMS that it will not use this process.

2. CMS and the MA Organization shall agree upon language setting forth the benefits, exclusions and other language of the Plan. The MA Organization bears full responsibility for the accuracy of its marketing materials. CMS, in its sole discretion, may order the MA Organization to print and distribute the agreed upon marketing materials, in a format approved by CMS. The MA Organization must disclose the information to each enrollee electing a plan as outlined in 42 CFR §422.111.

3. The MA Organization agrees that any advertising material, including that labeled promotional material, marketing materials, or supplemental literature, shall be truthful and not misleading. All marketing materials must include the Contract number. All membership identification cards must include the Contract number on the front of the card.

4. The MA Organization must comply with the Medicare Marketing Guidelines, as well as all applicable statutes and regulations, including and without limitation § 1851(h) of the Act and 42 CFR § 422.111, 42 CFR Part 422 Subpart V and 42 CFR Part 423 Subpart V. Failure to comply may result in sanctions as provided in 42 CFR Part 422 Subpart O.

Article IV CMS Payment to MA Organization

A. The MA Organization agrees to develop its annual benefit and price bid proposal and submit to CMS all required information on premiums, benefits, and cost sharing, as required under 42 CFR Part 422 Subpart F. **[422.504(a)(10)]**

B. METHODOLOGY

CMS agrees to pay the MA Organization under this contract in accordance with the provisions of § 1853 of the Act and 42 CFR Part 422 Subpart G. **[422.504(a)(9)]**

C. ELECTRONIC HEALTH RECORDS INCENTIVE PROGRAM PAYMENTS

The MA Organization agrees to abide by the requirements in 42 CFR §§495.200 et seq. and §1853(l) and (m) of the Act, including the fact that payment will be made directly to MA-affiliated hospitals that are certified Medicare hospitals through the Medicare FFS hospital incentive payment program.

D. ATTESTATION OF PAYMENT DATA (Attachments A, B, and C).

As a condition for receiving a monthly payment under paragraph B of this article, and 42 CFR Part 422 Subpart G, the MA Organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on the forms attached hereto as Attachment A (enrollment attestation) and Attachment B (risk adjustment data) which attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) the accuracy, completeness, and truthfulness of the data identified on these attachments. The Medicare Advantage Plan Attestation of Benefit Plan and Price must be signed and attached to the executed version of this contract.

(NOTE: The forms included as attachments to this contract are for reference only. CMS will provide instructions for the completion and submission of the forms in separate documents. MA Organizations should not take any action on the forms until appropriate CMS instructions become available.)

1. Attachment A requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest based on best knowledge, information, and belief that each enrollee for whom the MA Organization is requesting payment is validly enrolled, or was validly enrolled during the period for which payment is requested, in an MA plan offered by the MA Organization. The MA Organization shall submit completed enrollment attestation forms to CMS, or its contractor, on a monthly basis.

2. Attachment B requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest to (based on best knowledge, information and belief, as of the date specified on the attestation form) that the risk adjustment data it submits to CMS under 42 CFR §422.310 are accurate, complete, and truthful. The MA Organization shall make annual attestations to this effect for risk adjustment data on Attachment B and according to a schedule to be published by CMS. If such risk adjustment data are generated by a related entity, contractor, or subcontractor of an MA Organization, such entity, contractor, or subcontractor must also attest to (based on best knowledge, information, and belief, as of the date specified on the attestation form) the accuracy, completeness, and truthfulness of the data. **[422.504(l)]**

3. The Medicare Advantage Plan Attestation of Benefit Plan and Price (an example of which is attached hereto as Attachment C) requires that the CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must attest (based on best knowledge, information and belief, as of the date specified on the attestation form) that the information and documentation comprising the bid submission proposal is accurate, complete, and truthful and fully conforms to the Bid Form and Plan Benefit Package requirements; and that the benefits described in the CMS-approved proposed bid submission agree with the benefit package the MA Organization will offer during the period covered by the proposed bid submission. This document is being sent separately to the MA Organization and must be signed and attached to the executed version of this contract, and is incorporated herein by reference. **[422.504(f)]**

4. The MA Organization must certify based on best knowledge, information, and belief, that the information provided for the purposes of reporting and returning of overpayments under 42 CFR §422.326 is accurate, complete, and truthful. The form for this certification will be determined by CMS. **[422.504(f)]**

Article V MA Organization Relationship with Related Entities, Contractors, and Subcontractors

A. Notwithstanding any relationship(s) that the MA Organization may have with related entities, contractors, or subcontractors, the MA Organization maintains full responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. **[422.504(l)(1)]**

B. The MA Organization agrees to require all related entities, contractors, or subcontractors to agree that—

1. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and related entities related to CMS' contract with the MA organization;

2. HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph B (1) of this Article directly from any first tier, downstream, or related entity;

3. For records subject to review under paragraph B(2) of this Article, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated; and

4. HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent information for any particular contract period for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later. **[422.504(f)(2)]**

C. The MA Organization agrees that all contracts or written arrangements into which the MA Organization enters with providers, related entities, contractors, or subcontractors (first tier and downstream entities) shall contain the following elements:

1. Enrollee protection provisions that provide—

(1.a) Consistent with Article III, paragraph C, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the legal obligation of the MA Organization; and

(1.b) Consistent with Article III, paragraph C, provision for the continuation of benefits.

2. Accountability provisions that indicate that the MA Organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph D of this Article.

3. A provision requiring that any services or other activity performed by a first tier, downstream, or related entity in accordance with a contract or written agreement will be consistent and comply with the MA Organization's contractual obligations. **[422.504(f)(3)]**

D. If any of the MA Organization's activities or responsibilities under this contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, or related entity:

1. Each and every contract must specify delegated activities and reporting responsibilities.

2. Each and every contract must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the MA Organization determine that such parties have not performed satisfactorily.

3. Each and every contract must specify that the performance of the parties is monitored by the MA Organization on an ongoing basis.

4. Each and every contract must specify that either—

(4.a) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the MA Organization; or

(4.b) The credentialing process will be reviewed and approved by the MA Organization and the MA Organization must audit the credentialing process on an ongoing basis.

5. Each and every contract must specify that the first tier, downstream, or related entity comply with all applicable Medicare laws, regulations, and CMS instructions. **[422.504(f)(4)]**

E. If the MA Organization delegates selection of the providers, contractors, or subcontractors to another organization, the MA Organization's contract with that organization must state that the CMS-contracting MA Organization retains the right to approve, suspend, or terminate any such arrangement. **[422.504(f)(5)]**

F. As of the date of this contract and throughout its term, the MA Organization

1. Agrees that any physician incentive plan it operates meets the requirements of 42 CFR 5422.208, and

2. Has assured that all physicians and physician groups that the MA Organization's physician incentive plan places at substantial financial risk have adequate stop-loss protection in accordance with 42 CFR 5422.208(f). **[422.208]**

Article VI Records Requirements

A. MAINTENANCE OF RECORDS

1. The MA Organization agrees to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that—

(1.a) Are sufficient to do the following:

(1.a.i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the benefit and price bid) of the MA Organization.

(1.a.ii) Enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the MA Organization.

(1.a.iii) Enable CMS to audit and inspect any books and records of the MA Organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(1.a.iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the benefit and price bid proposal.

(1.a.v) Establish component rates of the benefit and price bid for determining additional and supplementary benefits.

(1.a.vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(1.b) Include at least records of the following:

(1.b.i) Ownership and operation of the MA Organization's financial, medical, and other record keeping systems.

(1.b.ii) Financial statements for the current contract period and ten prior periods.

(1.b.iii) Federal income tax or informational returns for the current contract period and ten prior periods.

(1.b.iv) Asset acquisition, lease, sale, or other action.

(1.b.v) Agreements, contracts (including, but not limited to, with related or unrelated prescription drug benefit managers) and subcontracts.

(1.b.vi) Franchise, marketing, and management agreements.

(1.b.vii) Schedules of charges for the MA Organization's fee-for-service patients.

(1.b.viii) Matters pertaining to costs of operations.

(1.b.ix) Amounts of income received, by source and payment.

(1.b.x) Cash flow statements.

(1.b.xi) Any financial reports filed with other Federal programs or State authorities. **[422.504(d)]**

2. Access to facilities and records. The MA Organization agrees to the following:

(2.a) The Department of Health and Human Services (HHS), the Comptroller General, or their designee may evaluate, through inspection or other means—

(2.a.i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(2.a.ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(2.a.iii) The facilities of the MA Organization; and

(2.a.iv) The enrollment and disenrollment records for the current contract period and ten prior periods.

(b) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, documents, papers, patient care documentation, and other records of the MA Organization, related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(c) The MA Organization agrees to make available, for the purposes specified in paragraph A of this Article, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require, in a manner that meets CMS record maintenance requirements.

(2.d) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the final date of the contract period or completion of audit, whichever is later unless—

(2.d.i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the MA Organization at least 30 days before the normal disposition date;

(2.d.ii) There has been a termination, dispute, or fraud or similar fault by the MA Organization, in which case the retention may be extended to 10 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(2.d.iii) HHS, the Comptroller General, or their designee determines that there is a reasonable possibility of fraud, in which case they may inspect, evaluate, and audit the MA Organization at any time. **[422.504(e)]**

B. REPORTING REQUIREMENTS

1. The MA Organization shall have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information as described in the remainder of this paragraph. **[422.516(a)]**

2. The MA Organization agrees to submit to CMS certified financial information that must include the following:

(2.a) Such information as CMS may require demonstrating that the organization has a fiscally sound operation, including:

(2.a.i) The cost of its operations;

(2.a.ii) A description, submitted to CMS annually and within 120 days of the end of the fiscal year, of significant business transactions (as defined in 42 CFR §422.500) between the MA Organization and a party in interest showing that the costs of the transactions listed in subparagraph (2)(a)(v) of this paragraph do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(2.a.iii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2.a.iv) A combined financial statement for the MA Organization and a party in interest if either of the following conditions is met:

(2.a.iv.aa) Thirty five percent or more of the costs of operation of the MA Organization go to a party in interest.

(2.a.iv.bb) Thirty five percent or more of the revenue of a party in interest is from the MA Organization. **[422.516(b)]**

(2.a.v) Requirements for combined financial statements.

(2.a.v.aa) The combined financial statements required by this subparagraph must display in separate columns the financial information for the MA Organization and each of the parties in interest.

(2.a.v.bb) Inter-entity transactions must be eliminated in the consolidated column.

(2.a.v.cc) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(2.a.v.dd) Upon written request from the MA Organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this subparagraph with respect to a particular entity. **[422.516(c)]**

(2.a.vi) A description of any loans or other special financial arrangements the MA Organization makes with contractors, subcontractors, and related entities. **[422.516(e)]**

(2.b) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA Organization. **[422.504(f)]**

(2.c) Patterns of utilization of the MA Organization's services. **[422.516(a)(2)]**

3. The MA Organization agrees to participate in surveys required by CMS and to submit to CMS all information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(3.a) The benefits covered under the MA plan;

(3.b) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan.

(3.c) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(3.d) Plan quality and performance indicators for the benefits under the plan including —

(3.d.i) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(3.d.ii) Information on Medicare enrollee satisfaction;

(3.d.iii) The patterns of utilization of plan services;

(3.d.iv) The availability, accessibility, and acceptability of the plan's services;

(3.d.v) Information on health outcomes and other performance measures required by CMS;

- (3.d.vi) The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and
- (3.d.vii) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA plans and traditional Medicare;
- (3.d.viii) Information about beneficiary appeals and their disposition;
- (3.d.ix) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;
- (3.d.x) Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program. **[422.504(f)(2)]**
4. The MA Organization agrees to provide to its enrollees and upon request, to any individual eligible to elect an MA plan, all informational requirements under 42 CFR §422.64 and, upon an enrollee's request, the financial disclosure information required under 42 CFR §422.516. **[422.504(f)(3)]**
5. Reporting and disclosure under ERISA –
- (5.a) For any employees' health benefits plan that includes an MA Organization in its offerings, the MA Organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the MA Organization) under the Employee Retirement Income Security Act of 1974 (ERISA).
- (5.b) The MA Organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA. **[422.516(d)]**
6. Electronic communication. The MA Organization must have the capacity to communicate with CMS electronically. **[422.504(b)]**
7. Risk Adjustment data. The MA Organization agrees to comply with the requirements in 42 CFR §422.310 for submitting risk adjustment data to CMS. **[422.504(a)(8)]**
8. The MA Organization acknowledges that CMS releases to the public summary reconciled Part D Payment data after the reconciliation of Part C and Part D Payments for the contract year as provided in 42 CFR §422.504(n) and, for Part D plan sponsors, 42 CFR §423.505(e).
9. The MA Organization agrees that it must subject information collected pursuant to 42 CFR §422.516(a) to a yearly independent audit to determine their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS. **[422.516(g)]**

Article VII Renewal of the MA Contract

A. RENEWAL OF CONTRACT

In accordance with 42 CFR §422.505, following the initial contract period, this contract is renewable annually only if –

1. The MA Organization has not provided CMS with a notice of intention not to renew; **[422.506(a)]**
2. CMS and the MA Organization reach agreement on the bid under 42 CFR Part 422, Subpart F; and **[422.505(d)]**
3. CMS informs the MA Organization that it authorizes a renewal.

B. NONRENEWAL OF CONTRACT

1. Nonrenewal by the Organization.

(1.a) In accordance with 42 CFR §422.506, the MA Organization may elect not to renew its contract with CMS as of the end of the term of the contract for any reason, provided it meets the time frames for doing so set forth in this subparagraph.

(1.b) If the MA Organization does not intend to renew its contract, it must notify –

(1.b.i) CMS, in writing, by the first Monday in June of the year in which the contract would end, pursuant to 42 CFR §422.506

(1.b.ii) Each Medicare enrollee by mail, at least 90 calendar days before the date on which the nonrenewal is effective. This notice must include a written description of all alternatives available for obtaining Medicare services within the service area including alternative MA plans, MA-PD plans, Medigap options, and original Medicare and prescription drug plans and must receive CMS approval prior to issuance.

(1.c) CMS may accept a nonrenewal notice submitted after the applicable annual non-renewal notice deadline if –

- (1.c.i) The MA Organization notifies its Medicare enrollees and the public in accordance with subparagraph (1)(b)(ii) of this paragraph; and
- (1.c.ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(1.d) If the MA Organization does not renew a contract under this subparagraph, CMS may deny an application for a new contract or a service area expansion from the Organization or with any organization whose covered persons, as defined at 42 CFR §422.506(a)(5), also served as covered persons for the non-renewing MA Organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. **[422.506(a)]**

2. CMS decision not to renew.

(2.a) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(2.a.i) For any of the reasons listed in 42 CFR §422.510(a) which would also permit CMS to terminate the contract.

(2.a.ii) The MA Organization has committed any of the acts in 42 CFR §422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under 42 CFR Part 422 Subpart D.

(2.a.iii) The MA Organization did not submit a benefit and price bid or the benefit and price bid was not acceptable **[422.505(d)]**

(2.b) Notice. CMS shall provide notice of its decision whether to authorize renewal of the contract as follows:

(2.b.i) To the MA Organization by August 1 of the contract year, except in the event described in subparagraph (2)(a)(iii) of this paragraph, for which notice will be sent by September 1.

(2.b.ii) To the MA Organization's Medicare enrollees by mail at least 90 days before the end of the current calendar year.

(2.c) Notice of appeal rights. CMS shall give the MA Organization written notice of its right to reconsideration of the decision not to renew in accordance with 42 CFR §422.644. **[422.506(b)]**

Article VIII Modification or Termination of the Contract

A. MODIFICATION OR TERMINATION OF CONTRACT BY MUTUAL CONSENT

1. This contract may be modified or terminated at any time by written mutual consent.

(1.a) If the contract is modified by written mutual consent, the MA Organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within time frames specified by CMS. [422.508(a)(2)]

(1.b) If the contract is terminated by written mutual consent, except as provided in subparagraph 2 of this paragraph, the MA Organization must provide notice to its Medicare enrollees and the general public as provided in paragraph B, subparagraph 2(b) of this Article. [422.508(a)(1)]

2. If this contract is terminated by written mutual consent and replaced the day following such termination by a new MA contract, the MA Organization is not required to provide the notice specified in paragraph B of this Article. [422.508(b)]

3. As a condition of the consent to a mutual termination, CMS will require as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. [422.508(c)]

B. TERMINATION OF THE CONTRACT BY CMS OR THE MA ORGANIZATION

1. Termination by CMS.

(1.a) CMS may at any time terminate a contract if CMS determines that the MA Organization meets any of the following:

(1.a.i) has failed substantially to carry out the terms of its contract with CMS,

(1.a.ii) is carrying out its contract in a manner that is inconsistent with the efficient and effective implementation of 42 CFR Part 422,

(1.a.iii) no longer substantially meets the applicable conditions of 42CFR Part 422.

(1.b) CMS may make a determination under paragraph B(1)(a)(i), (ii), or (iii) of this Article if the MA Organization has had one or more of the following occur:

(1.b.i) based on credible evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care program, including submission of false or fraudulent data,

(1.b.ii) experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists,

(1.b.iii) substantially failed to comply with the requirements in 42 CFR Part 422 Subpart M relating to grievances and appeals,

(1.b.iv) failed to provide CMS with valid data as required under 42 CFR §§422.310,

(1.b.v) failed to implement an acceptable quality assessment and performance improvement program as required under 42 CFR Part 422 Subpart D,

(1.b.vi) substantially failed to comply with the prompt payment requirements in 42 CFR §422.520,

(1.b.vii) substantially failed to comply with the service access requirements in 42 CFR §422.112,

(1.b.viii) failed to comply with the requirements of 42 CFR §422.208 regarding physician incentive plans,

(1.b.ix) substantially failed to comply with the marketing requirements in 42 CFR Part 422 Subpart V,

(1.b.x) Failed to comply with regulatory requirements contained in 42 CFR Parts 422 or 423 or both,

(1.b.xi) Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in 42 CFR Parts 422 or 423 or both,

(1.b.xii) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years,

(1.b.xiii) Has failed to report RLR data in a timely and accurate manner in accordance with 42 CFR §422.2460,

(1.c) Notice. If CMS decides to terminate a contract, it will give notice of the termination as follows:

(1.c.i) CMS will notify the MA Organization in writing at least 45 calendar days before the intended date of the termination,

(1.c.ii) The MA Organization will notify its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination,

(1.c.iii) The MA Organization will notify the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site,

(1.d) Expedited termination of contract by CMS.

(1.d.i) For terminations based on violations prescribed in subparagraph 1(b)(i) or (b)(ii) of this paragraph or if CMS determines that a delay in termination would pose an imminent and serious threat to the health of the individuals enrolled with the MA Organization, CMS will notify the MA Organization in writing that its contract has been terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA Organization covering the period of the month following the contract termination.

(1.d.ii) CMS will notify the MA Organization's Medicare enrollees in writing of CMS' decision to terminate the MA Organization's contract. This notice will occur no later than 30 days after CMS notifies the plan of its decision to terminate this contract. CMS will simultaneously inform the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA Organizations in a similar geographic area and original Medicare.

(1.d.iii) CMS will notify the general public of the termination no later than 30 days after notifying the MA Organization of CMS' decision to terminate this contract. This notice will be published in one or more newspapers of general circulation in each community or county located in the MA Organization's service area.

(1.e) Corrective action plan

(1.e.i) General. Before providing a notice of intent to terminate a contract for reasons other than the grounds specified in subparagraph 1(a)(iv) or (v) of this paragraph, CMS will provide the MA Organization with notice specifying the MA Organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement an approved corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(1.e.ii) Exceptions. If a contract is terminated under subparagraph 1(a)(iv) or (v) of this paragraph, the MA Organization will not be provided with the opportunity to develop and implement a corrective action plan.

(1.f) Appeal rights. If CMS decides to terminate this contract, it will send written notice to the MA Organization informing it of its termination appeal rights in accordance with 42 CFR Part 422 Subpart N. [422.510(d)]

2. Termination by the MA Organization

(2.a) Cause for termination. The MA Organization may terminate this contract if CMS fails to substantially carry out the terms of the contract.

(2.b) Notice. The MA Organization must give advance notice as follows:

(2.b.i) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA Organization is requesting

contract termination.

(2.b.ii) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA and MA-PD plans, PDP plans, Medigap options, and original Medicare and must receive CMS approval.

(2.b.iii) To the general public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA Organization's geographic area.

(2.c) Effective date of termination. The effective date of the termination will be determined by CMS and will be at least 90 days after the date CMS receives the MA Organization's notice of intent to terminate.

(2.d) CMS' liability. CMS' liability for payment to the MA Organization ends as of the first day of the month after the last month for which the contract is in effect, but CMS shall make payments for amounts owed prior to termination but not yet paid.

(2.e) Effect of termination by the organization. CMS (2.e) may deny an application for a new contract or service area expansion from the MA Organization or with an organization whose covered persons, as defined in 42 CFR §422.512(e)(2), also served as covered persons for the terminating MA Organization for a period of two years from the date the Organization has terminated this contract, unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type, or service area of the previous contract. **[422.512]**

Article IX Requirements of Other Laws and Regulations

A. The MA Organization agrees to comply with—

1. Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 USC §3729 et seq.), and the anti-kickback statute (§ 1128B(b) of the Act); and

2. HIPAA administrative simplification rules at 45 CFR Parts 160, 162, and 164. **[422.504(h)]**

B. Pursuant to § 13112 of the American Recovery and Reinvestment Act of 2009 (ARRA), the MA Organization agrees that as it implements, acquires, or upgrades its health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under § 3004 of the Public Health Service Act, as amended by § 13101 of the ARRA.

C. The MA Organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS, notwithstanding any relationship(s) that the MA Organization may have with related entities, contractors, or subcontractors. **[422.504(i)]**

D. In the event that any provision of this contract conflicts with the provisions of any statute or regulation applicable to an MA Organization, the provisions of the statute or regulation shall have full force and effect.

E. The MA Organization agrees to comply with the requirements relating to Nondiscrimination in Health Programs and Activities in 45 CFR Part 92, including submitting assurances that the MA Organization's health programs and activities will be operated in compliance with the nondiscrimination requirements, as required in 45 CFR §92.5.

Article X Severability

The MA Organization agrees that, upon CMS' request, this contract will be amended to exclude any MA plan or State-licensed entity specified by CMS, and a separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made. **[422.504(k)]**

Article XI Miscellaneous

A. DEFINITIONS

Terms not otherwise defined in this contract shall have the meaning given to such terms in 42 CFR Part 422.

B. ALTERATION TO ORIGINAL CONTRACT TERMS

The MA Organization agrees that it has not altered in any way the terms of this contract presented for signature by CMS. The MA Organization agrees that any alterations to the original text the MA Organization may make to this contract shall not be binding on the parties.

C. APPROVAL TO BEGIN MARKETING AND ENROLLMENT

The MA Organization agrees that it must complete CMS operational requirements prior to receiving CMS approval to begin Part C marketing and enrollment activities. Such activities include, but are not limited to, establishing and successfully testing connectivity with CMS systems to process enrollment applications (or contracting with an entity qualified to perform such functions on the MA Organization's Sponsor's behalf) and successfully demonstrating capability to submit accurate and timely price comparison data. To establish and successfully test connectivity, the MA Organization must, 1) establish and test physical connectivity to the CMS data center, 2) acquire user identifications and passwords, 3) receive, store, and maintain data necessary to perform enrollments and send and receive transactions to and from CMS, and 4) check and receive transaction status information.

D. MA Organization agrees to maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities) as required in 42 CFR § 422.504(a)(14).

E. MA Organization agrees to maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services as required by 42 CFR §422.504(a)(17).

F. MA Organization agrees to maintain a Part C summary plan rating score of at least 3 stars as required by 42 CFR §422.504(a)(18).

G. CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance. If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations. **[422.504(m)]**

H. **Business Continuity:** The MA organization agrees to develop, maintain, and implement a business continuity plan as required by 42 CFR §422.504(o).

ATTACHMENT A

ATTESTATION OF ENROLLMENT INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization

acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This attestation shall not be considered a waiver of the MA Organization's right to seek payment adjustments from CMS based on information or data which does not become available until after the date the MA Organization submits this attestation.

1. The MA Organization has reported to CMS for the month of (INDICATE MONTH AND YEAR) all new enrollments, disenrollments, and appropriate changes in enrollees' status with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The MA Organization has reviewed the CMS monthly membership report and reply listing for the month of (INDICATE MONTH AND YEAR) for the above-stated MA plans and has reported to CMS any discrepancies between the report and the MA Organization's records. For those portions of the monthly membership report and the reply listing to which the MA Organization raises no objection, the MA Organization, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief as of the date indicated below, to its accuracy, completeness, and truthfulness.

ATTACHMENT B

**ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO
CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION**

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and (INSERT NAME OF MA ORGANIZATION), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage plans (INSERT PLAN IDENTIFICATION NUMBERS HERE), the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS during the period of (INDICATE DATES) all (INDICATE TYPE - DIAGNOSIS/ENCOUNTER) risk adjustment data available to the MA Organization with respect to the above-stated MA plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

ATTACHMENT C - Medicare Advantage Plan Attestation of Benefit Plan and Price

In witness whereof, the parties hereby execute this contract.

This document has been electronically signed by:

FOR THE MA ORGANIZATION

LISA IVERSON

Contracting Official Name

8/30/2016 11:45:56 AM

Date

UNITEDHEALTHCARE INSURANCE COMPANY

Organization

185 Asylum Street
Hartford, CT 061030450

Address

FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES



Kathryn A. Coleman
Director
Medicare Drug and Health
Plan Contract Administration Group,
Center for Medicare

9/15/2016 3:03:52 PM

Date

EXHIBIT P-1B

[The following text is extremely faint and largely illegible due to the quality of the scan. It appears to be a series of paragraphs or a list of items, but the specific content cannot be accurately transcribed.]

The first part of the paper discusses the importance of the
 Journal of Management Education in the field of management
 education. It highlights the journal's role in providing
 a platform for the dissemination of research findings and
 the advancement of the discipline. The second part of the
 paper focuses on the journal's commitment to diversity and
 inclusion, emphasizing the need for a more equitable and
 inclusive research agenda. The third part of the paper
 discusses the journal's efforts to promote the use of
 research in management education, highlighting the
 importance of evidence-based practice. The fourth part of
 the paper discusses the journal's commitment to
 transparency and accountability, emphasizing the need for
 open access and the sharing of research data. The fifth
 part of the paper discusses the journal's commitment to
 the future of management education, highlighting the
 need for innovation and the development of new
 research paradigms. The final part of the paper
 discusses the journal's commitment to the management
 education community, emphasizing the need for
 collaboration and the sharing of resources.

• • • • •

[illegible]
$$\vdots$$

[The body of the document contains several paragraphs of text that are extremely faint and illegible due to low contrast or scanning quality. The text appears to be organized into multiple sections, possibly separated by headings or subheadings, but the specific content cannot be discerned.]



EXHIBIT P-1C





Medicare+Choice Organization

Electronic Data Interchange Enrollment Form

MANAGED CARE ELECTRONIC DATA INTERCHANGE (EDI) ENROLLMENT FORM

ONLY for the Collection of Risk Adjustment Data and/or

With Medicare+Choice Eligible Organizations

The eligible organization agrees to the following provisions for submitting Medicare risk adjustment data electronically to The Centers for Medicare & Medicaid Services (CMS) or to CMS's contractors.

A. The Eligible Organization Agrees:

1. That it will be responsible for all Medicare risk adjustment data submitted to CMS by itself, its employees, or its agents.
2. That it will not disclose any information concerning a Medicare beneficiary to any other person or organization, except CMS and/or its contractors, without the express written permission of the Medicare beneficiary or his/her parent or legal guardian, or where required for the care and treatment of a beneficiary who is unable to provide written consent, or to bill insurance primary or supplementary to Medicare, or as required by State or Federal law.
3. That it will ensure that every electronic entry can be readily associated and identified with an original source document. Each source document must reflect the following information:
 - Beneficiary's name,
 - Beneficiary's health insurance claim number,
 - Date(s) of service,
 - Diagnosis/nature of illness
4. That the Secretary of Health and Human Services or his/her designee and/or the contractor has the right to audit and confirm information submitted by the eligible organization and shall have access to all original source documents and medical records related to the eligible organization's submissions, including the beneficiary's authorization and signature.
5. Based on best knowledge, information, and belief, that it will submit risk adjustment data that are accurate, complete, and truthful.
6. That it will retain all original source documentation and medical records pertaining to any such particular Medicare risk adjustment data for a period of at least 6 years, 3 months after the risk adjustment data is received and processed.
7. That it will affix the CMS-assigned unique identifier number of the eligible organization on each risk adjustment data electronically transmitted to the contractor.
8. That the CMS-assigned unique identifier number constitutes the eligible organization's legal electronic signature.
9. That it will use sufficient security procedures to ensure that all transmissions of documents are authorized and protect all beneficiary-specific data from improper access.
10. That it will establish and maintain procedures and controls so that information concerning Medicare beneficiaries, or any information obtained from CMS or its contractor, shall not be used by agents, officers, or employees of the billing service except as provided by the contractor (in accordance with §1106(a) of the Act).
11. That it will research and correct risk adjustment data discrepancies.
12. That it will notify the contractor or CMS within 2 business days if any transmitted data are received in an unintelligible or garbled form.

B. The Centers for Medicare & Medicaid Services Agrees To:

1. Transmit to the eligible organization an acknowledgment of risk adjustment data receipt.
2. Affix the intermediary/carrier number, as its electronic signature, on each response/report sent to the eligible organization.
3. Ensure that no contractor may require the eligible organization to purchase any or all electronic services from the contractor or from any subsidiary of the contractor or from any company for which the contractor has an interest.
4. The contractor will make alternative means available to any electronic biller to obtain such services.
5. Ensure that all Medicare electronic transmitters have equal access to any services that CMS requires Medicare contractors to make available to eligible organizations or their billing services, regardless of the electronic billing technique or service they choose. Equal access will be granted to any services the contractor sells directly, indirectly, or by arrangement.
6. Notify the provider within 2 business days if any transmitted data are received in an unintelligible or garbled form.

NOTICE:

Federal law shall govern both the interpretation of this document and the appropriate jurisdiction and venue for appealing any final decision made by CMS under this document.

This document shall become effective when signed by the eligible organization. The responsibilities and obligations contained in this document will remain in effect as long as Medicare risk adjustment data are submitted to CMS or the contractor. Either party may terminate this arrangement by giving the other party (30) days written notice of its intent to terminate. In the event that the notice is mailed, the written notice of termination shall be deemed to have been given upon the date of mailing, as established by the postmark or other appropriate evidence of transmittal.

C. Signature:

I am authorized to sign this document on behalf of the indicated party and I have read and agree to the foregoing provisions and acknowledge same by signing below.

Eligible Organization's Name:

PACIFICARE LIFE + HEALTH
A UNITED HEALTHCARE COMPANY

Contract Number:

H5435

Signature:

Name:

JIM HIGGINS

Title:

DIRECTOR

Address:

3100 LAKE CENTER DR
SANTA ANA, CA 92704

City/State/ZIP:

Phone:

714-825-5979

Email:

JIM.HIGGINS@PHR.COM

Date: JULY 6, 2006

cc: Regional Offices

Please retain a copy of all forms submitted for your records.

Complete and mail this form with original signature to:

**M+CO EDI Enrollment
CSSC Operations AG-570
P.O. Box 100275
Columbia, SC 29202-3275**

**Phone (877) 534-2772
<http://www.csscoperations.com/>**



MEDICARE
CSSC OPERATIONS

CSSC Risk Adjustment Data Submitter Application

Plan Number (Hnnnn):	H5435
Plan Name:	PACIFICARE LIFE & HEALTH
Address:	3100 LAKE CENTER, SANTA ANA, CA
Fax Number:	714-825-5979
Operations Contact Person:	JIM HIGGINS
E-Mail address:	JIM.HIGGINS@PHB.COM
Phone Number:	714-825-5425
Technical Contact Person:	PAT RASMUSSEN
E-Mail address:	PAT.RASMUSSEN@PHB.COM
Phone Number:	972-860-1553

92704

What format do you plan to use to submit Risk Adjustment Data?

- ☒ RAPS Format
- ☐ M+CO NSF Format
- ☐ UB 92 version 6.0
- ☐ ANSI 837 4010

What Connection Type is established via the Medicare Data Communications Network (MDCN)?

Lease Line _____

☒ IP _____ FOR SH0151

NDM _____

Dial up / Modem _____

Please list any additional Plan numbers your organization will submit data for:

Plan _____ Plan _____ Plan _____

Plan _____ Plan _____ Plan _____

Plan _____ Plan _____ Plan _____

Please return the completed submitter application, EDI Agreement and NDM specifications to CSSC Operations at the address below.

1-877-534-CSSC

www.mcoservice.com

FAX: 1-803-935-0171

EXHIBIT P-1D

Message

From: Rice, Cheri M. (CMS/CM) [/O=HHS EES/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=CHERI.RICE.CMS59728027]
Sent: 7/30/2015 9:56:36 PM
To: steve_nelson@uhc.com
Subject: RE: 2013 CMS RAF Attestation

Steve,

With this email, we are acknowledging receipt of your email dated 6/26/15. However, neither the receipt of your email nor any acknowledgment of such receipt should be interpreted as acquiescence by the Government to any purported modification to the Attestations of Risk Adjustment Data submitted by United or to any of the arrangements described in or statements made in your email, or as a release of any of United's present or future liability to the Government. As you know, both regulation and the MA organizations' contracts with CMS prescribe the specific language of this Attestation, and the MA organizations' execution and submission of the Attestation as specified is a condition of payment by the Medicare Program.

With respect to your fifth point, as we noted last year in response to a similar email from you, there are laws and contractual provisions that impose standards, requirements and responsibilities on MA organizations in connection with federal payments, including risk adjustment payments, they receive from the Medicare Program. We cannot provide legal advice to United about whether its current or proposed courses of action are compliant with such laws and obligations, but we do wish to remind you that MA organizations are required to implement effective compliance programs that prevent, detect and correct non-compliance with CMS program requirements, to exercise reasonable diligence in identifying overpayments, and to report and return such overpayments to the Medicare Program within 60 days. MA organizations cannot delegate these legal obligations to others.

Cheri Rice
Director, Medicare Plan Payment Group
Centers for Medicare and Medicaid Services

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Friday, June 26, 2015 12:42 PM
To: Rice, Cheri M. (CMS/CM)
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

EXHIBIT

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~~4008~~

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

This e-mail, including attachments, may include confidential and/or proprietary information, and may be used only by the person or entity to which it is addressed. If the reader of this e-mail is not the intended recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this e-mail in error, please notify the sender by replying to this message and delete this e-mail immediately.

EXHIBIT P-1E

Message

Sent: 8/22/2016 1:54:59 AM
To: Nelson, Steve H [steve_nelson@uhc.com]
BCC: Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Jennifer.harlow.cms20728073]; Chaudhuri, Ilina (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Ilina.Chaudhuri.CMS]; Reed-Asante, Monica (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=Monica.Reed.CMS]; Paul, Rebecca (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=rebecca.paul.cms55708697]; Simons, Kellie M. (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Kellie.Gombeski.CMS]; Kreisel, Johanna (OS/OGC) [/O=HHS EES/OU=EXternal (FYDIBOHF25SPDLT)/cn=Recipients/cn=b191e47b8d7d42b8a6a6460de4a4eabb]; Burke, Sherry Lynn (HHS/OGC) [/O=HHS EES/OU=EXternal (FYDIBOHF25SPDLT)/cn=Recipients/cn=65433f2bbb034833b76096f08ab6184f]
Subject: RE: 2014 CMS RAF Attestation

Steve,

With this email, we are acknowledging receipt of your email dated 6/7/16. However, neither the receipt of your email nor any acknowledgment of such receipt should be interpreted as acquiescence by the Government to any purported modification to the Attestations of Risk Adjustment Data submitted by United or to any of the arrangements described in or statements made in your email, or as a release of any of United's present or future liability to the Government. As you know, both regulation and the MA organizations' contracts with CMS prescribe the specific language of this Attestation, and the MA organizations' execution and submission of the Attestation as specified is a condition of payment by the Medicare Program.

With respect to your fifth point, as we noted last year in response to a similar email from you, there are laws and contractual provisions that impose standards, requirements and responsibilities on MA organizations in connection with federal payments, including risk adjustment payments, they receive from the Medicare Program. We cannot provide legal advice to United about whether its current or proposed courses of action are compliant with such laws and obligations, but we do wish to remind you that MA organizations are required to implement effective compliance programs that prevent, detect and correct non-compliance with CMS program requirements, to exercise reasonable diligence in identifying overpayments, and to report and return such overpayments to the Medicare Program within 60 days. MA organizations cannot delegate these legal obligations to others.

Cheri Rice
Director, Medicare Plan Payment Group
Centers for Medicare and Medicaid Services

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Tuesday, June 7, 2016 10:21 AM
To: Rice, Cheri M. (CMS/CM) <Cheri.Rice@cms.hhs.gov>
Subject: 2014 CMS RAF Attestation

Cheri,

EXHIBIT

649

4011

USBP001354107

As we have done the past several years, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you in the past, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing regarding our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our prior discussion and understanding regarding the certifications.

- ◆ As with our past certifications, the 2014 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.
- ◆ The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.
- ◆ The certifications only cover risk adjustment data for 2014 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- ◆ As we have mentioned to you previously, we are continuously engaged in the ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2014 dates of service that we ultimately determine should be deleted consistent with this email.
- ◆ CMS issued a proposed rule two years ago that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed at that time, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS two years ago, CMS's withdrawal of the proposed rule, and CMS's announced plans to use a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision at the time. That decision remains operative for 2014 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT P-1F

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



MEDICARE PLAN PAYMENT GROUP

May 28, 2020

Brian Thompson
Chief Executive Officer
United Healthcare
Medicare & Retirement
9800 Health Care Lane
MN006-E010
Minnetonka, MN 55343

Dear Mr. Thompson:

Thank you for your communications regarding Medicare Advantage risk adjustment. We appreciate your taking time to share your views. This letter is in response to all correspondence related to Medicare Advantage risk adjustment data certifications and the Electronic Data Interchange (EDI) enrollment forms that the Medicare Plan Payment Group has received from your organization to date.

In CMS' view any caveats that United sends are non-binding and do not alter any existing agreements or any other statutory, regulatory, and contractual obligations. To the extent that your communication seeks "advice" regarding United's legal obligations, it is not CMS' practice to modify the established legal and contractual obligations of MA organizations through informal "advice."

We remind you that there are existing laws and contractual provisions that impose standards, requirements, and responsibilities on MA organizations in connection with federal payments, including risk adjustment payments, they receive from the Medicare Program. As you know, the decision in 2014 by CMS not to finalize the proposed amendment to 42 CFR § 422.310(e) did "not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS." 79 Fed. Reg. 29,844, 29,926 (May 23, 2014). Nor did it change the requirement that all diagnosis codes submitted for risk adjustment payments must be documented in the beneficiaries' medical records pursuant to the ICD-9 and -10 Guidelines for Coding and Reporting with which HHS and Medicare regulations require compliance. CMS has not stated otherwise to United.

Furthermore, the agency's positions on the issues raised in your communications also are public and can be found in, among other places, the government's briefs in the *UnitedHealth Group* cases pending in the District of Columbia and in California. CMS reserves all its rights and remedies associated with United's submission of invalid risk adjustment data. The agency's

receipt of United's communications and the acknowledgement of such receipt should not be interpreted as a release of any administrative, civil, or criminal liability arising from United's failure to comply with its legal and regulatory obligations relating to the submission of risk adjustment data to and receipt of risk adjustment payments from the Medicare Program (including, without limitation, any potential liability arising from the matters currently under DOJ investigation).

Sincerely,

A handwritten signature in dark ink, reading "Jennifer R. Shapiro". The signature is written in a cursive, flowing style.

Jennifer R. Shapiro
Director

Cc: Kristin Lehrke, Benjamin Eklo, Joshua Streich, Jean Benson

EXHIBIT P-1G



Risk Adjustment Certification Reports - Payment Year 2017 (Dates of Service 2016)

Confirmation #: 422

ATTACHMENT B

ATTESTATION OF RISK ADJUSTMENT DATA INFORMATION RELATING TO CMS PAYMENT TO A MEDICARE ADVANTAGE ORGANIZATION, MEDICARE MEDICAID PLAN OR PACE ORGANIZATION

Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and UNITEDHEALTHCARE INSURANCE COMPANY (H2226), hereafter referred to as the MA Organization, governing the operation of the following Medicare Advantage and Medicare Advantage-Prescription Drug plans 001, the MA Organization hereby requests payment under the contract, and in doing so, makes the following attestation concerning CMS payments to the MA Organization. The MA Organization acknowledges that the information described below directly affects the calculation of CMS payments to the MA Organization or additional benefit obligations of the MA Organization and that misrepresentation to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution.

The MA Organization has reported to CMS for the period of January 1, 2016, to December 31, 2016, all risk adjustment data (*inpatient hospital, outpatient hospital, and physician*) available to the MA Organization, Medicare Medicaid Plan or PACE Organization as of the applicable deadline(s), with respect to the above-stated MA, MMP, and MA-PD plans. Based on best knowledge, information, and belief as of the date indicated below, all information submitted to CMS in this report is accurate, complete, and truthful.

TIMOTHY NOEL on behalf of

UNITEDHEALTHCARE INSURANCE COMPANY (H2226)

10/12/2018

Close

EXHIBIT P-2

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel. BENJAMIN POEHLING,

Plaintiff,

vs.

UNITEDHEALTH GROUP, INC.,
et al.,

Defendants.

No. CV 16-08697 FMO

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 1

DEPOSITION OF BIGGS T. CANNON, III

As 30(b)(6) Designee 6 of UHC of California, Inc.,
OptumInsight, Inc.
UnitedHealthcare, Inc.

Washington, DC
June 6, 2023

Reported by: John L. Harmonson, RPR

Job No. 983690

Page 30	Page 32
1 to answer. 2 MS. GLOVER: You're going to instruct 3 him not to answer based on -- his company has been 4 paid a certain amount for him to appear here today, 5 and he's still being paid by his company. It is 6 relevant in calculating the number of hours and how 7 much, approximately, his time is worth to be here 8 today. 9 MS. DO: He's already testified twice 10 now that he's paid a salary that is not impacted by 11 the hourly rate. It has no relevance. It's 12 outside the scope. 13 MS. GLOVER: It goes to his credibility 14 and bias. 15 MS. DO: It's outside the scope. 16 MS. GLOVER: Relevance is not an 17 appropriate basis for instructing him not to 18 answer. 19 MS. DO: You have an hourly rate. Move 20 on. 21 BY MS. GLOVER: 22 Q. Are you going to answer my question? 23 A. Counsel has instructed me not to answer 24 that question. 25 MS. GLOVER: And I will say for the	1 BY MS. GLOVER: 2 Q. Sure. 3 Is it your understanding that 4 UnitedHealthcare retains Optum to manage and 5 process the data that providers submit to 6 UnitedHealthcare, UnitedHealthcare's plans? 7 MS. DO: Outside the scope, and also 8 vague. 9 THE WITNESS: UnitedHealthcare -- Optum 10 supports UnitedHealthcare through the submissions 11 of a portion of their Medicare Advantage 12 beneficiaries. 13 BY MS. GLOVER: 14 Q. Does Optum process data submitted by 15 providers to UnitedHealthcare, Inc.? 16 A. What do you mean by process? 17 Q. Receive the data and assimilate it into 18 a system. 19 MS. DO: Outside the scope. Object to 20 form. 21 THE WITNESS: United providers do not 22 submit directly to Optum, no. 23 BY MS. GLOVER: 24 Q. Do they submit to systems, systems that 25 you've been asked to prepare on today, that
Page 31	Page 33
1 record that it is an inappropriate instruction not 2 to answer because it is not on the basis of 3 privilege. 4 BY MS. GLOVER: 5 Q. Okay. So let's -- we will move on for 6 now. All right. So just so that I understand, you 7 are here to testify on behalf of those three 8 entities that we've discussed, OptumInsight, UHC of 9 California, and UnitedHealthcare, Inc.; correct? 10 A. Yes. 11 Q. And at a high level, Optum submits risk 12 adjustment data on behalf of UnitedHealthcare, 13 Inc.'s Medicare Advantage plans; is that correct? 14 A. It's a portion of their business, yes. 15 Q. Okay. And UHC of California, Inc., is 16 one of those plans on whose behalf Optum submits 17 risk adjustment data to CMS. Is that correct? 18 A. Yes. 19 Q. All right. And is it your understanding 20 that UnitedHealthcare retains Optum to manage and 21 process data submitted by providers to 22 UnitedHealthcare -- to UnitedHealthcare's plans? 23 MS. DO: Object to form. Vague. 24 THE WITNESS: Can you repeat the 25 question?	1 ultimately load data into OptumInsight systems? 2 MS. DO: Outside the scope. And object 3 to form. 4 THE WITNESS: Yes, some data received by 5 providers of Medicare Advantage -- to Medicare 6 Advantage beneficiaries can end up in Optum 7 systems. 8 BY MS. GLOVER: 9 Q. And some of those Medicare beneficiaries 10 are enrolled in UnitedHealthcare, Inc.'s plans; 11 correct? 12 A. Medicare Advantage beneficiaries. 13 Q. Yes. 14 A. Yes. 15 Q. And Medicare Part D beneficiaries as 16 well; right? 17 MS. DO: Outside the scope. And object 18 to form. 19 THE WITNESS: I believe Optum may 20 receive part -- a portion of Part D data related to 21 Medicare Advantage beneficiaries. 22 BY MS. GLOVER: 23 Q. And a portion of data which includes 24 ICD-9 or 10 codes, diagnosis codes; right? 25 MS. DO: Object to form. Also outside

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1 chart review data that may have been extracted from 2 ChartSync during that time. 3 BY MS. GLOVER: 4 Q. And what was the purpose of the compare? 5 MS. DO: Objection; outside the scope. 6 And objection to the form. 7 THE WITNESS: I'm not sure I can speak 8 to why they ran the analysis they did. Just a 9 comparison was done between the two datasets. 10 MS. DO: We've gone well over an hour. 11 I believe we're also hitting the seven-hour mark. 12 Would you like a break? 13 THE WITNESS: Ideally. I don't know if 14 we're close to seven hours. 15 MS. GLOVER: Let's go off the record. 16 THE VIDEOGRAPHER: Off the record. The 17 time is 7:27. 18 (Off the record.) 19 THE VIDEOGRAPHER: This concludes 20 today's video deposition. We are recessing until 21 9:00 a.m. tomorrow morning. 22 (Deposition recessed at 7:29 p.m., to be 23 reconvened on June 7, 2023, at 9:00 a.m.) 24 25	1 C E R T I F I C A T E 2 3 DISTRICT OF COLUMBIA 4 I, JOHN L. HARMONSON, a Notary Public 5 within and for the District of Columbia, do hereby 6 certify that BIGGS T. CANNON, III, the witness 7 whose deposition is hereinbefore set forth, was 8 duly sworn by me and that such deposition is a true 9 record of the testimony given by such witness. 10 That before completion of the 11 proceedings, review and signature of the transcript 12 was reserved. 13 I further certify that I am not related 14 to any of the parties to this action by blood or 15 marriage; and that I am in no way interested in the 16 outcome of this matter. 17 IN WITNESS WHEREOF, I have hereunto set 18 my hand this 8th day of June, 2023. 19 20 21 <u>JOHN L. HARMONSON, RPR</u> 22 My commission expires: 04/14/26 23 24 25
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1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, BIGGS T. CANNON, III, have read or have had 4 the foregoing testimony read to me and hereby 5 certify that it is a true and correct transcription 6 of my testimony with the exception of any attached 7 corrections or changes. 8 9 10 _____ 11 BIGGS T. CANNON, III 12 [] No corrections 13 [] Correction sheet(s) enclosed 14 15 SUBSCRIBED AND SWORN TO BEFORE ME, the 16 undersigned authority, by the witness, BIGGS T. 17 CANNON, III, on this the ____ day of 18 _____, _____. 19 20 21 22 23 24 25	1 ERRATA SHEET 2 CASE: USA v. UnitedHealthcare Group, et al. 3 DATE: June 6, 2023 4 WITNESS: BIGGS T. CANNON, III, Vol. 1 5 Reason Codes: 6 1. To clarify the record. 7 2. To conform to the facts. 8 3. To correct transcription errors. 9 Pg. Ln. Now Reads Should Read Reason 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 21 <u>Signature of Deponent</u> 22 SUBSCRIBED AND SWORN BEFORE ME 23 THIS ____ DAY OF _____, _____ 24 _____ 25 (Notary Public) MY COMMISSION EXPIRES: _____

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EXHIBIT P-3

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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

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RISK ADJUSTMENT METHODOLOGY

disabled and smaller perhaps than some people expect because the final measure is plan liability rather than spending.

Figure 1C illustrates the calculation of the Part D Direct Subsidy.

Figure 1C – Calculation of Part D Direct Subsidy



1.4 Parts C and D Final Submission of Risk Adjustment Data (Reconciliation)

Reconciliation is used to complete the implementation of payments, with CMS calculating final risk adjustment factors and beneficiary status based on complete data. CMS continues to allow a period (approximately 13 months after the data collection year) for submitting final RAPS data for the appropriate data collection period. Data not received or submitted by the initial submission deadline for a data collection period can be submitted by the final submission deadline (reconciliation). In addition to incorporating new RAPS and fee-for-service diagnoses, reconciliation takes into account necessary adjustments to institutional status and demographic data for enrollees.

Note: CMS reconciles risk-adjusted payments for a calendar year only one time. When submitting risk adjustment data for reconciliation, plans may submit as well as correct data that was previously submitted.

1.4.1 Parts C and D Risk Adjustment Schedule & Elimination of the Payment Lag

Risk adjusted payments were originally implemented with a 6-month payment lag from the end of the collection period to the start of revised payments, based on the data collected.



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

MODULE 2 – RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

Purpose

The success of Medicare Advantage (MA) risk adjustment is dependent upon organizations understanding the process of collecting and submitting accurate risk adjustment data. The purpose of this module is to provide participants with important terms, key resources, and schedule information that will provide the foundation for this training.

Learning Objectives

At the completion of this module, participants will be able to:

- Define common risk adjustment terminology.
- Demonstrate knowledge in interpreting key components of the risk adjustment process.
- Interpret the risk adjustment schedule.
- Identify the Centers for Medicare & Medicaid Services (CMS) outreach efforts available to organizations.

ICON KEY	
Example	
Reminder	
Resource	

2.1 Common Risk Adjustment Terms (Slide 7)

Table 2A provides descriptions of common risk adjustment terminology.

TABLE 2A – RISK ADJUSTMENT COMMON TERMS

TERM	DESCRIPTION
FERAS	Risk adjustment submitters send data to Palmetto through the Front-End Risk Adjustment System .
RAPS	Risk adjustment data are processed by the Risk Adjustment Processing System .
RAS	The Risk Adjustment System calculates the risk score.
MARx	The Medicare Advantage Prescription Drug System calculates the risk payment.
Common UI	The Common UI maintains Medicare beneficiary eligibility data.
HPMS	The Health Plan Management System is a CMS MA information system that contains health plan-level data.
Required Diagnosis	ICD-9-CM diagnosis codes required to be submitted for the CMS Hierarchical Condition Category (HCC) model and for future model development.



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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2 Risk Adjustment Process Overview

Hospital inpatient, hospital outpatient, and physician risk adjustment data must be submitted at least quarterly. Risk adjustment data are processed through RAPS.

2.2.1 Risk Adjustment Data Requirements (Slide 8)

- The data required under the risk adjustment process include:
 - Health Insurance Claim (HIC) number.
 - Diagnosis code.
 - Service from date.
 - Service through date.
 - Provider type (hospital inpatient, hospital outpatient, physician).
- MA organizations must submit data at least quarterly to CMS.
- Each quarterly submission should represent approximately one-fourth of the data that the MA organization will submit during a data collection year. MA organizations will be monitored to ensure compliance.
- All beneficiary ICD-9-CM diagnosis codes required for the CMS-HCC risk adjustment model must be reported at least once per enrollee in the data collection period.

2.2.2 Risk Adjustment Data Collection (Slide 9)

- MA organizations may choose to collect data from providers in a variety of formats:
 - Standard fee-for-service claim or encounter formats
 - Uniform Billing Form (UB-94)
 - HCFA 1500
 - National Standard Format (NSF) v3.01
 - American National Standards Institute (ANSI) X12 837 v30.5; or v40.10. Health Insurance Portability and Accountability Act (HIPAA) mandated transactions must use v40.10.
 - Superbill
 - RAPS format
 - HIC number
 - Provider type
 - Diagnosis code
 - Service from date
 - Service through date

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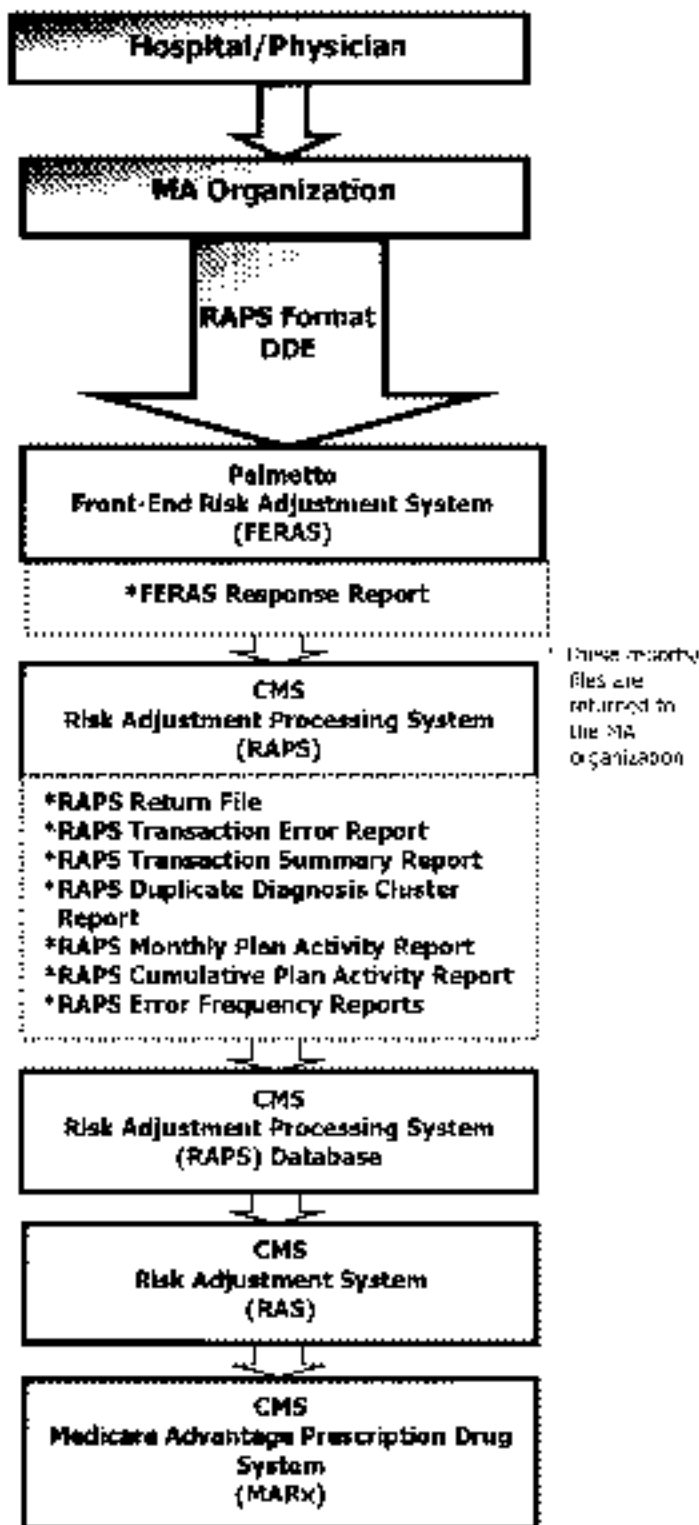
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RISK ADJUSTMENT SUBMISSION PROCESS OVERVIEW

2.2.4 Risk Adjustment Dataflow (Slide 11)

- Hospital/physician submits data to MA organization via:
 - Full or abbreviated UB-04, ICD-9 (SDD), NCHS v3 PL, ANSI x837 v30.51 or v10.10, Superbel or RAPS format.
- The MA organization submits these data at least quarterly to Palmetto G&A.
- The MA organization submits the data via Direct Data Entry or in the RAPS format.
- The data are sent to FERAS for processing where the file level data, batch level data, and first and last detail records are checked.
- If any data are rejected, then data are reported on the FERAS Response Report.
- After passing the FERAS checks, the file is submitted to RAPS where detail editing is performed.
- The RAPS Return File is returned daily and shows all records approved and where errors occurred.
- The RAPS Transaction Error Report displays records on which errors occurred.
- The RAPS Transaction Summary Report is sent to the MA organization daily and identifies data that have been finalized in RAPS database.
- The Duplicate Diagnosis Cluster Report identifies diagnosis clusters submitted with information that duplicates a stored cluster.
- The RAPS Monthly Plan Activity Report and Cumulative Plan Activity Report provides a summary of all diagnoses stored for a given time period.
- Distributed monthly and quarterly, the Error Frequency Report provides an overview of all errors associated with files submitted in test and production.
- RAPS database stores all finalized diagnosis clusters.
- RAS calculates the Risk Adjuster Factors by executing the CMS-HCC model.
- MARx is used in the calculation of payments and determination of plan payments. MARx replaced Medicare Managed Care System (MMCS) on November 15, 2005.

Figure 2A – Risk Adjustment Dataflow





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DATA COLLECTION

3.2.4 Alternative Data Sources

Alternative data sources (ADS) include diagnostic data from sources other than hospital inpatient, hospital outpatient, and physician services. MA organizations may use ADS as a **check** to ensure that all required diagnoses have been submitted to CMS for risk adjustment purposes, such as pharmacy records and information provided to national or state cancer registries. The MA organization may not, however, use ADS as substitutes for documenting diagnoses from a hospital/physician. As in all diagnoses submitted, there must be medical record documentation to support the diagnosis as having been documented as a result of a hospital inpatient stay, a hospital outpatient visit, or a physician face-to-face visit during the data collection period.

For example, a prescription for an ACE inhibitor, alone, is not considered sufficient for the sole data source of "clinical evidence" of congestive heart failure (CHF); instead, the medical record needs to document an appropriate clinician's diagnosis of CHF during the data collection period (e.g., where an "appropriate clinician" is a physician/nurse practitioner/physician assistant). A laboratory test showing one reading of high blood sugar is not considered sufficient "clinical evidence" of diabetes—the medical record needs to document a clinician's diagnosis of diabetes during the data collection period.

3.2.5 Excluded Providers

Medicare will not pay for items or services rendered to beneficiaries and recipients by an excluded provider or by entities owned or managed by an excluded provider. Providers are excluded for the following reasons: a program related crime, patient abuse or neglect, health care fraud in any health care program, and convictions relating to controlled substances.

1. The HHS monthly exclusion notification can be found at <http://oig.hhs.gov/fraud/exclusions.html>.

3.3 Data Collection Formats and Considerations

There are several formats that MA organizations can accept when collecting data from medical providers. Table 3I lists the formats by provider type.

3.3.1 Data Collection Formats (Slide 16)

For facility services, the standard billing format is UB-04 (Uniform Billing Form—2004 version). The HCFA 1500 form is the standard format for physician services.

TABLE 3I — DATA COLLECTION FORMATS

HOSPITAL INPATIENT/HOSPITAL OUTPATIENT	• UB-04 • ANSI X12 837 4010 • RAPS Format
PHYSICIAN	• HCFA 1500 • NSF 3.01 • ANSI X12 837 4010 • RAPS Format • Superbill



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DATA SUBMISSION

4.13 Deleting Diagnosis Clusters (Slide 16)

Each diagnosis cluster ("Diagnosis Code," "From Date," "Through Date," and "Provider Type") is stored separately as a unique cluster associated with a beneficiary's HIC number. If a diagnosis was submitted in error and needs to be corrected, the original diagnosis cluster must be resubmitted with a delete indicator in the appropriate field. **Delete transactions may only be submitted using the RAPS format or the DDE function.** When a delete record is received, CMS maintains the original diagnosis cluster on file and adds a delete indicator to it and the date of the deletion.

4.14 Reasons to Delete a Diagnosis Cluster (Slide 17)

There are three reasons MA organizations may delete a diagnosis cluster:

- Diagnosis cluster submitted erroneously (e.g., data from an interim bill was submitted for hospital inpatient).
- Incorrect HIC number used for submission of a beneficiary's diagnostic information.
- An error in a diagnosis cluster field (i.e., "Provider Type," "Dates of Service," "Diagnosis Code").

MA organizations submit deletions within a file, batch, or record containing previously submitted risk adjustment data.

4.15 Steps for Deleting a Diagnosis Cluster (Slides 18-20)

Before deleting an error, verify that the diagnosis cluster appears on the RAPS Return File. Only diagnosis clusters accepted by RAPS and stored in the RAPS database may be deleted.

There are two methods for deleting diagnosis clusters:

Method 1 for Deleting Clusters

1. Submit RAPS format using normal submission process with appropriate HIC number included.
2. Enter information in the diagnosis cluster fields (9.0, 9.1, 9.2, 9.4, 9.5) exactly as it appeared in the original submission.
3. In field 9.3 enter a "D" for delete.
4. Enter the appropriate information in all other records to ensure the submission file is complete.
5. Transmit the file to FERAS. (See www.cmsoperations.com for details.)

Method 2 for Deleting Clusters

1. Create a file using the DDE screens available through FERAS at Palmetto (detailed information about the DDE process is located in Section 4.20).
2. Enter information exactly as it appeared in the original submission.
3. In the DDE "CCC" record screen, hit the down arrow key and select "D."
4. Proceed with entering all appropriate information.
5. Upload the file created in DDE to FERAS at Palmetto.



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DATA SUBMISSION

4.16 MA Organization Responsibilities Regarding Deletions (Slide 21)

- MA organizations must submit delete records when an erroneous diagnosis cluster has been accepted by RAPS and stored in the RAPS database.
- If a diagnosis cluster is deleted for the purpose of correcting data, the MA organization is responsible for submitting the correct diagnosis cluster. Conversely, if the MA organization submits corrected data, the MA organization must submit the appropriate deletion record. That is, if the correct diagnosis cluster is submitted, the erroneous diagnosis cluster cannot be ignored.
- If a correction applies to the same beneficiary as the deletion, the correction may be included in the same "CCC" record as the deletion. (Do not exceed 10 diagnosis clusters per "CCC" record.)
- If only one of several clusters within the CCC record requires modification, do not resubmit all other associated clusters. If clusters are resubmitted exactly the same without the delete indicator, the plans will generate a duplicate cluster error.
- If the corrected diagnosis cluster belongs to a different beneficiary than the deleted diagnosis cluster, the correct diagnosis cluster may be submitted in the same file as the deletion.

MA organizations should not delete a diagnosis code or record repeatedly on the same day and on the same record. MA organizations should implement a process to ensure that only one instance of a specific diagnosis cluster (either add or delete) is submitted on a given day.

4.17 Direct Data Entry (Slide 22)

MA organizations have the option of manually entering diagnostic information via the DDE application offered by Palmetto. DDE instructions are illustrated in the screen shots below. DDE is available in FERAS at Palmetto via the Medicare Data Communications Network (MDCN).

- DDE entries allow for deletion of records for corrections even if another submission format was used.
- The DDE screens, as shown in Figures 4B through 4G, automatically prevent the placement of incorrect data characters (e.g., alpha characters will not be accepted in the "From" or "Through Date" fields).
- After the user has entered all relevant data, the user will click on the "Create File" button in FERAS. This will create a file on the user's local PC.
- After the file is created on the local PC, the user must upload the file to FERAS in order to complete the process.
- Files created in DDE and uploaded to FERAS will receive a FERAS Response Report, which may be downloaded from the MA organization's electronic mailbox.



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DIAGNOSIS CODES & RISK ADJUSTMENT

The source medical record documentation that supports each coded diagnosis must be obtainable and demonstrate adherence to official coding guidelines.

Required diagnoses are defined as those diagnoses collected from one of the three provider types that are used in the Risk Adjustment models (i.e., CMS-HCC, ESRD, and RxHCC models), and those diagnoses required for payment simulation.

This module emphasizes physician documentation and reporting of diagnosis codes. Historically, physician reimbursement in fee-for-service is primarily based on procedures or services rather than diagnoses, and physicians are very familiar with documentation guidelines for procedures and services. Physicians generally are not as familiar with diagnosis codes and their associated documentation guidelines as they are with procedure coding rules. The Risk Adjustment models depend upon accurate diagnosis coding, which means that physicians must fully understand and comply with documentation and coding guidelines for reporting diagnoses.

6.1.1 Benefit to the MA Organization and Physician

Benefits to the MA organization and physician are illustrated in Table 6A.

TABLE 6A – BENEFITS TO MA ORGANIZATIONS AND PHYSICIANS

A basic understanding of ICD-9-CM process and guidelines assists MA organizations in:
• Interpreting and designing management reports. • Determining possible causes of ICD-9-CM errors. • Communicating diagnosis-related collection issues to the provider staff. • Developing and maintaining information systems that meet the clinical data collection needs of the organization. • Understanding clinical issues important to beneficiaries. • Planning for future MA organization services.
Medical record documentation and coding impact several issues important to the physician and MA organization including:
• Accurate reimbursement. ICD-9-CM codes are the basis of the Risk Adjustment models. Accurate diagnosis codes are a result of clear, consistent, and complete documentation. CMS may verify the accuracy of the diagnoses submitted relative to the medical record documentation. • Communication among all members of the health care team. • Evaluation of the care provided. • Research and education. • Practice patterns.

6.2 Structure and Terminology of ICD-9-CM

ICD-9-CM diagnosis codes are 3- to 5-digit codes used to describe the clinical reason for a patient's treatment. They do not describe the service performed, just the patient's medical condition. For any



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DIAGNOSIS CODES & RISK ADJUSTMENT

classification system to be reliable, the application of the codes must be consistent across users. Therefore, CMS, the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), and the National Center for Health Statistics (NCHS) together have developed official coding guidelines. These guidelines are available on: <http://www.cdc.gov/nchs/data/wh/ftpserver/ftp/cd9/icdguide07.pdf>. The diagnosis portion of ICD-9-CM consists of two volumes: the Disease Tabular and the Disease Index.

- **The Disease Tabular (Numeric)** is also known as Volume I of ICD-9-CM. It is a numeric listing of codes organized primarily by body system. The Disease Tabular provides much more detail than the Alphabetic Index on conditions included and excluded in the code selected. Another code in the same category may represent the diagnostic description better than the one indicated in the Disease Index.
- **The Disease Index (Alphabetic)** is also known as Volume II of ICD-9-CM. It is an index of all diseases and injuries categorized in ICD-9-CM. When a code is listed after the description, it means the reader should look up that code in the Disease Tabular section to determine if that is the most specific code to describe the diagnosis. The index is organized by main terms and subterms that further describes or specifies the main term. In general, the main term is the condition, disease, symptom, or eponym (i.e., disease named after a person), not the organ or body system involved.

6.2.1 Special Notes and Abbreviations

Throughout the ICD-9-CM publication, there are notes and cross references to assist the coder in arriving at the most accurate code according to official coding guidelines. Examples include:

Excludes notes: Informs the coder which diagnosis codes are not included in the code selected

Use Additional Code notes: Informs the coder that more than one code is needed to fully describe the condition and gives examples of common associated conditions.

Not otherwise specified (NOS): Basically means "unspecified." The documentation does not provide additional information to assign a more specific code in the particular category. In many (but not all) code categories, the fourth digit "9" signifies an unspecified code.

Not elsewhere classified (NEC): Also is present in ICD-9-CM. It is used when the medical record documents a condition to a level of specificity not identified by a specific ICD-9-CM code. In some cases the fifth digit "8" represents an NEC code.

6.2.2 Supplemental Classifications and Tables

Included in Volumes I and II are supplemental classifications and special tables that provide additional guidance in determining the most accurate code.

- **V codes** are a section of ICD-9-CM diagnosis codes that represent factors that influence health status or describe contact with health services. They are used to describe those circumstances or reasons for encounter other than for disease or injury. Selected V codes are included in the Risk Adjustment models and are described later in this module.



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DIAGNOSIS CODES & RISK ADJUSTMENT

6.5 Supporting Documentation Summary

Accurate coding begins with complete documentation. Characteristics of effective documentation include quality documentation as a team effort that may require some intervention by the MA organization. Table 6C lists documentation considerations.

TABLE 6C – DOCUMENTATION CONSIDERATIONS

Documentation Guidelines
- Reported diagnoses must be supported with medical record documentation. - Medical records and codes are subject to CMS validation. - Characteristics of acceptable documentation include: - Clear - Concise. - Consistent. - Complete. - Legible.
Physician Documentation and Communication Tips
- Document and report co-existing diagnoses. - Communicate issues regarding inadequate documentation. - Adhere to proper methods for appending (late entries) or correcting inaccurate data entries. - Lab/Radiology results. - Strike through, initial, and date. Do not obliterate. - Use only standard abbreviations. - Identify patient and date on each page of the record.
SOAP Notes
- SOAP note format assists both the physician and record reviewer/coder in identifying key documentation elements. SOAP stands for: Subjective: How the patients describe their problem or illness. Objective: Data obtained from examinations, lab results, vital signs, etc. Assessment: Listing of the patient's current condition and status of all chronic conditions. How the objective data relate to the patient's acute problem. Plan: Next steps in diagnosing problem further, prescriptions, consultation referrals, patient education, and recommended time to return for followup.

6.6 Provider and Staff Training

Remaining current on medical record documentation and coding guidelines is important to ensure accurate risk adjustment payment. Table 6D provides examples of resources available for medical record documentation and coding guidelines.



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RISK ADJUSTMENT DATA VALIDATION

**MODULE 7 – RISK ADJUSTMENT DATA VALIDATION
(MEDICAL RECORD REVIEW)**

Presentation Purpose (Slide 2)

To provide participants with an understanding of:

- The risk adjustment data validation (RADV) process AND
- CMS' approaches for:
 - Identifying risk adjustment discrepancies,
 - Estimating payment error, and
 - Conducting contract-level payment adjustments

Presentation Objectives (Slide 3)

Define

- Purpose and objectives of risk adjustment data validation (RADV)
- New RADV policies and parameters
- RADV stages and requirements
- Documentation Dispute
- Payment adjustment implementation approach
- Appeals

ICON KEY	
Example	
Reminder	
Resource	...

7.1 Risk Adjustment Data Validation (RADV)

7.1.1 RADV – Purpose, Method, and Objectives (Slide 4)

Risk adjustment data validation (RADV) occurs after the final risk adjustment data submission deadline for the MA contract payment year. The purpose of RADV is to ensure risk adjusted payment integrity and accuracy. CMS reviews medical records from hospital (inpatient and outpatient) and physician providers to validate enrollee CMS-HCCs that were assigned based on risk adjustment diagnoses submitted by MA organizations for payment. As a basic risk adjustment rule, all risk adjustment diagnosis codes submitted by MA organizations must be supported by medical record documentation.

The primary objectives of RADV are to:

- Verify enrollee CMS-HCCs used for payment
- Identify risk adjustment discrepancies
- Calculate enrollee-level payment error
- Estimate national and contract-level payment errors
- Implement contract-level payment adjustments



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VERIFYING RISK SCORES

MODULE 8– VERIFYING RISK SCORES

Purpose (Slide 2)

The risk score calculation is based on data captured from a variety of systems. To ensure that accurate payments are made, Medicare Advantage (MA) organizations may verify the components of the risk score calculation throughout the year. This module is designed to explain the systems involved in the risk score calculations and introduce MA organizations to a variety of verification tools available to them.

Learning Objectives (Slide 3)

At the completion of this module, participants will:

- Understand the systems and processes used to calculate the risk scores.
- Determine how the organizations can use risk adjustment processing and management reports to ensure the accuracy of payment.
- Identify the components and uses of the Non-Drug and Drug Monthly Membership Reports (MMRs).
- Explain the Part C Risk Adjustment and New RXHCC Model Output Report (MOR).

ICON KEY	
Example	
Reminder	
Resource	

8.1 Calculating Risk Scores (Slides 5-7)

The risk score used in calculating payments under the Centers for Medicare & Medicaid Services (CMS)-HCC model includes demographics as part of the risk model as well as different disease groups or HCCs. The risk score calculation gathers the critical data from a variety of systems, including risk adjustment data from the Risk Adjustment Processing System (RAPS) database, Fee-For-Service (FFS) information from the National Medicare Utilization Database (NMUD), and demographic data captured from the Common Tables.

The risk score calculation considers the following:

- Demographics
- Disease groups
- Disease interactions
- Disease hierarchies
- Disabled indicators
- Residence in a long-term care institution
- End-Stage Renal Disease (ESRD) Status

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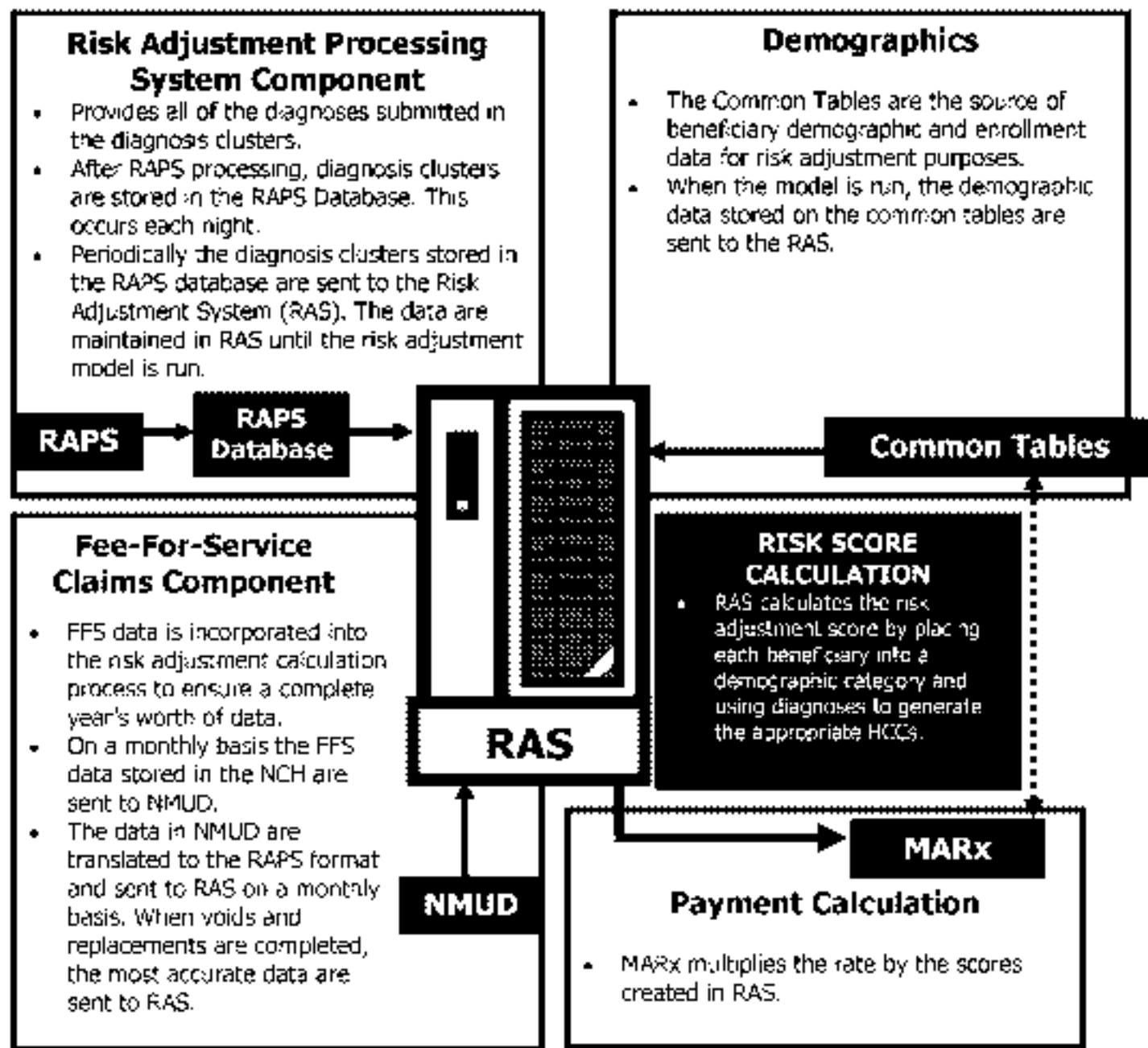


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VERIFYING RISK SCORES

Figure 8A illustrates the flow of data used to calculate the risk score.

Figure 8A - Risk Score Calculation Process





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VERIFYING RISK SCORES

Table 8A describes the eight steps in the risk score calculation.

TABLE 8A - RISK SCORE CALCULATION STEPS

STEP	DESCRIPTION
1 Define Cohort	Each year CMS defines a cohort of beneficiaries for whom risk scores will be calculated and used for making payments beginning the following January. Typically, CMS calculates scores for all Medicare beneficiaries.
2 Obtain Beneficiary Specific Information	For this cohort, CMS obtains beneficiary-specific information from Medicare's enrollment databases. Beneficiary information includes the months of enrollment in Part A and Part B, age, sex, original reason for Medicare entitlement, etc. for each beneficiary in the cohort. Medicaid information is obtained from the third-party payor file. In addition, plan-submitted Medicaid status information is included and beneficiaries with an ESRD flag are identified. CMS ensures that all Health Insurance Claim (HIC) numbers associated with each individual in the file have been identified. CMS uses all of this information to create a beneficiary demographic input file.
3 Extract Long-term Institutional Information from MDS	Next, for this cohort, CMS extracts assessments from the Minimum Data Set (MDS). CMS identifies the beneficiaries who have resided in a long-term institution for 90 days or more and classifies these individuals as long-term institutional beneficiaries. CMS passes beneficiary long-term institutional file to the RAS system.
4 Obtain Diagnosis Information	Next, CMS obtains all diagnostic information from Medicare data files for the cohort. These data include all diagnoses for the data collection period from the three types of data sources: physician services, hospital outpatient, and hospital inpatient. These diagnoses come from the RAPS database as well as Medicare fee-for-service files. From these data, CMS creates a beneficiary diagnosis input file.
5 Run the Model	The beneficiary demographic and beneficiary diagnosis input files are used to run the CMS-HCC and ESRD models and the Prescription Drug HCC (RxHCC) model. The ESRD model is run only on those beneficiaries with ESRD flags from the Common Tables. Each model determines a new enrollee factor for individuals who had fewer than 12 months of Part B enrollment during the data collection period. The model filters out diagnoses that do not correlate, such as ovarian cancer in a male patient. For individuals with 12 months of Part B enrollment, the software produces two risk scores: one based on the community model and one on the institutional model. In addition, for individuals with ESRD, the ESRD model will create additional risk scores appropriate to that model. The software also shows which HCC group (as well as which demographics, interactions, etc.) is associated with the risk scores. Only the most severe disease classification within a hierarchy is shown in the output. Based on this information, an output file is created and sent to the payment system.



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VERIFYING RISK SCORES

TABLE 8A – RISK SCORE CALCULATION STEPS (CONTINUED)

STEP	DESCRIPTION
6 Send Model Output to MARx	The output from the CMS-HCC model is provided to MARx for use in making payments to plans. In addition, the model output serves as the basis for the MMR reports provided to plans and the risk adjustment MOR.
7 Apply Additional Payment Factors	Plan-level instructions are provided to MARx to determine which factors should be used in actually making payments.
8 Calculate Payment	MARx identifies individuals enrolled in an organization for a particular month. Then it accesses the risk factor file to retrieve the appropriate risk factor for each individual. MARx uses the individual's state and county code to determine the correct county capitation rate and then multiplies the risk factor by that rate. After calculating the correct demographic payment for the same individual, MARx then calculates the correct payment by blending the appropriate proportion of risk and demographic payments. Then the demographic and risk adjusted amounts are totaled.

Note: For each risk adjustment model run, the process is repeated, updating the data used for the model to include new diagnoses received for the data collection period, as well as changes in any of the demographic factors. During final reconciliation, long term institutional status is determined for each month during the payment year, and ESRD status is reconciled to obtain the most precise month-by-month status.

8.2 Risk Score Verification Tools (Slide 8)

CMS offers a variety of tools that MA organizations can use at various stages in the risk adjustment process to ensure that the risk score reported by CMS is in close alignment with the score that the organization expects to receive. This section of the training module describes each of the tools, identifies the method of access and timeframe, and provides information on how an organization can use the tool to increase the accuracy of payment projections.

The verification tools include:

- RAPS Return File/RAPS Transaction Error Report
- RAPS Monthly and Cumulative Plan Activity Reports
- SAS CMS-HCC Model Program
- MMR
- Part C MOR (Non-Drug) and the new RAS RxHCC MOR

Information on the tools are illustrated in Table 8B

EXHIBIT P-4

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
_____)

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VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
TAMMY DICKEY
(Taken virtually)
9:02 a.m. Eastern
Tuesday, May 24, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 recall exactly. Somewhere in there, 2010, '11 to
2 I think the end of 2012 --

3 Q. Okay.

4 A. -- early 2013.

5 Q. Okay. And when did you -- sorry, I
6 think I missed this.

7 When did you first starting working at
8 AIM?

9 A. 2008.

10 Q. Okay. And prior to working as a coder
11 for a contractor for AIM, did you have experience
12 as a medical record coder?

13 A. I did.

14 Q. Okay. And how long had you worked as
15 a medical record coder prior to becoming a
16 contractor for AIM?

17 A. Probably 2001 or '02 until 2007. I
18 worked in a physician's office.

19 Q. Okay. And you mentioned the word "QA"
20 when you were describing some of your roles and
21 responsibilities. Does that stand for quality
22 assurance?

23 A. Yes.

24 Q. Okay. And what is QA for -- what's
25 the QA process for coding at Optum?

1 also referring to Ingenix which was sort of the
2 forerunner for Optum?

3 A. Yes.

4 Q. Okay. And if you need to clarify at
5 any point that something applies to Ingenix but
6 does not apply to Optum, please let me know. I
7 want to make sure the record is clear on that.

8 A. Okay.

9 Q. Okay. Ms. Dickey, are you -- are you
10 familiar with the program called Medicare
11 Advantage?

12 A. I am.

13 Q. It's sometimes called Part C; right?

14 A. Yes.

15 Q. Are you familiar with Part D of
16 Medicare?

17 A. Yes.

18 Q. And Part D includes drug benefits for
19 beneficiaries enrolled in the Part D program; is
20 that correct?

21 A. To my knowledge, yes.

22 Q. So as a certified coder, you are
23 certified to assess whether an ICD-9 or ICD-10
24 diagnosis code is documented in a medical record;
25 right?

1 MS. MADDUX: Objection. Form.

2 THE WITNESS: No, that's not correct.

3 BY MS. GLOVER:

4 Q. Oh, can you tell me what is correct
5 about what your certification means?

6 A. Well, the ICD-9 or 10, it is not
7 documented in the medical record. The diagnosis
8 is documented in the medical record.

9 Q. That's a valid point. So is it -- is
10 it helpful instead of saying ICD-9 or ICD-10,
11 which I understand to be the code, is it better --
12 would it be more understandable to you to say that
13 the diagnosis code is documented in the medical
14 record?

15 A. It's not -- that's not correct, the
16 diagnosis is documented in the medical record. A
17 coder then translates that diagnosis into the
18 ICD-9 or ICD-10 code.

19 Q. Understood. So is it fair to say then
20 that as a certified coder you're certified to
21 assess whether a diagnosis is documented in a
22 medical record and translate that diagnosis to an
23 ICD-9 or ICD-10 code as applicable?

24 A. That's correct.

25 MS. GLOVER: Okay. And, actually,

1 supported by medical record documentation. And we
2 talked about some guidance, whether it was from
3 CMS or the coding clinic or the ICD guidelines.
4 Is this -- this statement here that reported
5 diagnoses must be supported with medical record
6 documentation some of the guidance that you were
7 thinking about earlier?

8 MS. MADDUX: Objection. Form.

9 THE WITNESS: Not specifically this,
10 but more just the -- I would say like
11 golden rule of coding, that if it's not
12 documented, then you don't code it.

13 BY MS. GLOVER:

14 Q. Have you ever heard the phrase used at
15 Optum if it's not in the medical record, it didn't
16 happen?

17 MS. MADDUX: Objection. Form.

18 THE WITNESS: I don't know if I -- I've
19 heard that before, but not specifically at
20 Optum. I know I've heard it at my other
21 roles and just in the coding world.

22 BY MS. GLOVER:

23 Q. Understood. But you agree that
24 reported diagnoses must be supported with medical
25 record documentation?

1 been -- since that was implemented that there's
2 always been something in place.

3 Q. Okay. And do you know why Optum
4 requires new coders to do practice chart audits
5 before they can move into production?

6 MS. MADDUX: Objection. Form. Calls
7 for speculation.

8 THE WITNESS: So generally coders, when
9 coming onboard, they may not have had risk
10 adjustment coding experience and may have
11 only coded in a provider's office or
12 radiology or things like that and may not
13 be used to reading a full medical record
14 and coding from that medical record. A lot
15 of coders may be coding like an operative
16 note, why did the patient come in for an
17 operation. They don't necessarily read
18 that full note to make the code assignment.
19 And that's just an example.

20 BY MS. GLOVER:

21 Q. And at Optum in the chart review
22 program, you instruct the coders to read the full
23 record when conducting a chart review; is that
24 right?

25 MS. MADDUX: Objection. Form. Vague.

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified
Court Reporter within and for the State of
Georgia, do hereby certify:

That the foregoing deposition was
taken before me on the date and at the time and
location stated on Page 1 of this transcript; that
the deponent was duly sworn to testify to the
truth, the whole truth and nothing but the truth;
that the testimony of the deponent and all
objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed; that the foregoing
deposition as typed is a true, accurate and
complete record of the testimony of the deponent
and of all objections made at the time of the
examination to the best of my ability.

I further certify that I am neither
related to nor counsel for any party to the cause
pending or interested in the events thereof.
Witness my hand, this 26th day of May, 2022.

Christine A. Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT P-5

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

_____	)	
UNITED STATES OF AMERICA	)	
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiff,	)	No. CV 16-08697 FMO
	)	
vs.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER
(With Redactions)

DEPOSITION OF MELISSA SEDOR
As 30(b)(6) Designee 1 of
OptumInsight, Inc.
UnitedHealthcare, Inc.
Washington, DC
June 29, 2023

Reported by: John L. Harmonson, RPR
Job No. 988356

1 THE WITNESS: The actual payment is
2 based on the actual risk score of each member and
3 that 1.0 bid that we submitted in the bid filing.

4 BY MS. GLOVER:

5 Q. Okay. And so if -- are you familiar
6 with the term "benchmark"?

7 A. I've heard the term. I probably
8 couldn't define it for you.

9 Q. Okay. I know earlier you mentioned the
10 county rates.

11 A. Uh-huh.

12 Q. And how do county rates factor in to
13 payment in Medicare Advantage?

14 A. This is probably a little more detailed
15 than I'm prepared to speak to, but my understanding
16 is on the Part C side the county rates are not as
17 impactful or included in our bids but they are
18 included on the D side as well as the ESRD bids.

19 Q. Okay. Now, you spoke a little bit about
20 timing earlier, and I said we would do it in a few
21 minutes. You submit diagnosis codes to CMS at
22 various intervals in order to receive payment under
23 the risk adjustment payment process; right?

24 A. That's correct.

25 Q. Okay. And there's an initial

1 calculation of a beneficiary's risk score, a
2 midyear calculation, and then a final calculation;
3 correct?

4 A. That's correct.

5 Q. Okay. And for the initial calculation,
6 you are actually submitting six months of
7 diagnostic data from a prior date of service year
8 as well as six months of diagnostic information
9 from the current date of service year to calculate
10 that initial payment; correct?

11 A. I would say it is six months and six
12 months. I maybe am unsure how you're using prior
13 and current because they're actually both prior to
14 the year the payment is being based on.

15 Q. That's very fair. Let's clarify. Maybe
16 an example will help.

17 So let's say that for 2011 payment year,
18 to calculate the initial risk score you would use
19 six months of diagnostic data from 2009 and six
20 months of diagnostic data from 2010; is that
21 correct?

22 A. That's correct. You use the last six
23 months of 2009 and the first six months of 2010 for
24 the initial payment.

25 Q. Okay. And then for the midyear

1 calculation, you use actually in this example the
2 full 2010 date of service year data; correct?

3 A. Yes, correct.

4 Q. Okay. And then for the final -- the
5 final calculation of the risk score, you also use
6 the full date of service year, in this example 2010
7 worth of data, to calculate that score; correct?

8 A. Yes.

9 Q. Okay. And the final -- the final
10 calculation is sometimes called the final
11 reconciliation; right?

12 A. Yes.

13 Q. Okay. And in advance of the final
14 reconciliation, there is a couple of things that
15 have to happen including, one, the submission of
16 data; correct?

17 A. Yes.

18 Q. And two, there is a final submission
19 deadline that happens in advance of that. Are you
20 familiar with that term?

21 A. Yes, I am.

22 Q. Okay. And in advance of the final
23 submission deadline, you had to submit all of the
24 diagnostic data for a given beneficiary by that
25 date; is that right?

1 A. That is correct.

2 Q. And generally that date is set for 13
3 months after the conclusion of a given date of
4 service year. So in this example, it may be
5 January 31 or beyond of 2012 when the final
6 submission deadline occurs; is that right?

7 A. Correct.

8 Q. Okay. And sometimes CMS has moved -- in
9 the past, has moved the final submission deadline
10 forward and given plans additional time to submit
11 data; is that correct?

12 A. That's correct.

13 Q. And after the final submission deadline,
14 plans are no longer able to submit additional
15 codes, diagnosis codes, that might increase a
16 beneficiary's risk score; right?

17 A. That's correct.

18 Q. Okay. But they are able to delete
19 diagnosis codes that were previously submitted that
20 the plan has determined were submitted in error;
21 right?

22 MR. JONES: Objection; form.

23 THE WITNESS: Correct. CMS's process
24 allows for what they would call as a closed period
25 delete which occurs after that sweep window has

1 closed, or reconciliation window has closed.

2 BY MS. GLOVER:

3 Q. And that's actually helpful.

4 Today as we talk about things, are you
5 comfortable if I use the term "open period" to
6 define the period prior to the final submission
7 deadline, and the "closed period" to apply to
8 information or things happening after the final
9 submission deadline?

10 A. Yes, I'm fine with that.

11 Q. Okay. And before -- after the final
12 submission deadline but before the final
13 reconciliation that CMS does, plans also submit
14 something called an annual attestation; correct?

15 A. Yes.

16 Q. And that attestation is something that's
17 required by the contract that they had entered into
18 with CMS the prior September; right?

19 MR. JONES: Objection; outside the
20 scope.

21 THE WITNESS: Yes, it's an attestation
22 required by the contract.

23 BY MS. GLOVER:

24 Q. Okay. And the attestation is a request
25 for payment under the Medicare Advantage payment

1 knowledge our risk adjustment submissions were
2 accurate, complete and truthful.

3 BY MS. GLOVER:

4 Q. Okay. And you also understood that you
5 as the Medicare Advantage organization had the
6 ultimate responsibility for the accuracy of the
7 data that you submitted to CMS; right?

8 MR. JONES: Objection; outside the scope
9 as to her responsibilities.

10 THE WITNESS: Yes.

11 BY MS. GLOVER:

12 Q. And that's true specifically for
13 diagnosis codes that you submitted for payment to
14 CMS; right?

15 A. That it was our responsibility to --

16 Q. To ensure the accuracy of the data, the
17 diagnosis codes that you submitted to CMS.

18 MR. JONES: Objection; outside the scope
19 of the notice.

20 THE WITNESS: Yes. With regard to
21 diagnosis codes submitted, it was our
22 responsibility to ensure that they were accurate
23 and complete to the best of our knowledge.

24 BY MS. GLOVER:

25 Q. Okay. And are you familiar with

1 something called a hierarchical condition category,
2 sometimes called an HCC?

3 A. I am.

4 Q. Okay. And what, at a high level, is an
5 HCC?

6 A. An HCC is, I would say, the mechanism
7 CMS uses to group like diagnosis codes using either
8 ICD-9 or ICD-10. There are, I think, tens of
9 thousands of diagnosis codes, and rather than
10 giving us a risk score component for tens of
11 thousands of ICD codes, they group them into HCCs,
12 and then that HCC is what dictates the component or
13 the numerical value that goes into your risk score.

14 Q. Okay. And earlier you mentioned a
15 couple of things that make up a risk score. One of
16 those things is demographics; is that correct?

17 A. Yes, that's correct.

18 Q. Okay. And demographics includes things
19 like age, sex, disability status, Medicaid status,
20 et cetera; right?

21 A. Correct.

22 Q. Okay. And then there is also a health
23 status portion of the risk score; right?

24 A. Correct.

25 Q. And do HCCs make up the health status

1 portion of the risk score?

2 A. Yes, they do.

3 Q. Okay. And so you understood that in
4 calculating the payments that you received from CMS
5 for the beneficiaries enrolled in your Medicare
6 Advantage and Medicare Advantage Part D plans that
7 CMS would use the HCCs to calculate the payments
8 that you received; right?

9 A. Yes, they use the HCC to calculate the
10 risk score, which is a component of the payment we
11 receive.

12 Q. Okay. And we talked a little bit about
13 the diagnosis codes that make up those HCCs. The
14 CMS HCC risk adjustment model as well as the Part D
15 model applies something called a hierarchy; right?

16 A. Yes.

17 Q. What does that mean?

18 A. A hierarchy describes -- it dictates
19 which condition you'll get paid for if there are
20 instances where two conditions are similar. An
21 example would be I believe one HCC would be for
22 diabetes while another HCC is diabetes with
23 complications. The hierarchy table explains which
24 one of them trumps the other one. You're not going
25 to get paid for both diabetes and diabetes with

1 complications. The hierarchy table explains to
2 you, if the member has two or three, which one is
3 the highest one that they're going to get paid on
4 instead of getting paid on all of them.

5 Q. Okay. And so for example, if you submit
6 a diagnosis code that maps to, let's say, HCC 19,
7 which is sort of garden-variety diabetes, as well
8 as HCC 15, which is diabetes with some severe
9 complications, in that scenario you would only be
10 paid for the diagnosis code that you submitted for
11 HCC 15 because it is the more severe form of
12 diabetes; is that right?

13 A. Correct.

14 Q. Okay. And so sometimes when you submit
15 a diagnosis code, it doesn't actually impact the
16 risk score in that it doesn't raise it higher
17 because a diagnosis code mapping to an HCC higher
18 in the hierarchy has also been submitted; is that
19 right?

20 A. That's correct.

21 Q. Okay. So as we're talking, if I say --
22 if I ask you questions with the premise that it's
23 something that impacts the risk score, you'll
24 understand what I mean?

25 A. Yes.

1 Q. Okay. Now, the CMS HCC risk adjustment
2 model as well as the Part D model account for
3 interactions between conditions as well; right?

4 A. Yes, that's correct.

5 Q. And you receive additional payments if
6 there are certain interactions of conditions;
7 right?

8 A. Correct. Certain interactions give you
9 an additional lift in your risk score.

10 Q. Okay. And so that piece of it is an
11 additional component to the risk score; is that
12 right?

13 A. Yes.

14 Q. It falls within health status, but let's
15 say that your risk score is 2.0. It may be that
16 disease interactions accounts for .2, but it's a
17 portion of it?

18 A. Correct, yes.

19 Q. Does that make sense?

20 A. Yes.

21 Q. All right. And you understood that the
22 CMS HCC risk adjustment model as well as the Part D
23 model are prospective models; right?

24 MR. JONES: Objection; form.

25 BY MS. GLOVER:

1 Q. And if you don't understand what I mean
2 by prospective, I can explain.

3 A. Yeah, can you explain?

4 Q. Certainly.

5 What I mean is that they use diagnoses
6 submitted from a prior date of service year to
7 anticipate the cost of caring for the beneficiary
8 in the next year.

9 A. Yes, I would agree with that.

10 Q. Okay. And so we've sort of talked about
11 this a little bit. But the way that the model
12 worked is that you would use information from one
13 year to calculate the payments that you received in
14 the next year?

15 A. That is correct.

16 Q. Okay. And earlier with Mr. Voldman you
17 referred to per member per month payments; right?

18 A. Yes.

19 Q. And what are per member per month
20 payments?

21 A. It would be the average -- if you're
22 looking at each individual member, it is the
23 premium that you are getting paid for that member
24 for one month of coverage.

25 Q. Okay. And when we spoke about the

1 timing of the initial risk score calculation, the
2 midyear calculation and the final reconciliation,
3 what happens in each of those calculations is
4 essentially your -- CMS is calculating how much you
5 will be paid for a given beneficiary on a per
6 member per month basis; right?

7 A. That's correct.

8 Q. And in the midyear run, for example,
9 based on the information that has been submitted
10 for the entire date of service year at issue, CMS
11 retroactively adjusts the per member per month
12 payments that were received by the plan based on
13 the initial calculation; right?

14 A. Correct. They go back and adjust your
15 payments for, generally speaking, January through
16 June is usually the timing.

17 Q. And then for the final reconciliation,
18 what CMS is doing is it's a similar process but
19 essentially what CMS does is they retroactively
20 adjust the payments that were received for the
21 entire payment year based on what was submitted for
22 the full date of service year; right?

23 A. That's correct.

24 Q. Okay. Are you familiar with something
25 called a rerun?

1 A. Yes, I am.

2 Q. What is a rerun?

3 A. In my experience, CMS has used rerun to
4 refer to when they're truing up the risk scores for
5 a payment year after that final reconciliation has
6 been received, which usually means that they're
7 processing closed period deletes and then rerunning
8 that payment year.

9 Q. Okay. And when you say their processing
10 closed period deletes, that is because you can't
11 submit additional codes after the final submission
12 deadline, but I think as you testified earlier you
13 can submit deletes; right?

14 A. Correct.

15 Q. Okay. And functionally, what the rerun
16 does is it's a rerun of that final reconciliation;
17 is that right?

18 A. Yes.

19 Q. Okay. So functionally, it's
20 retroactively adjusting the per member per month
21 payments that the plan received for a given
22 beneficiary in a given payment year; right?

23 A. Yes, that's correct.

24 Q. Okay. Now, sometimes those reruns don't
25 happen immediately; right?

1 A. They usually do not happen immediately,
2 yes.

3 Q. They can take a couple of years or a few
4 years; right?

5 A. Yes.

6 MR. JONES: Objection; form.

7 THE WITNESS: Yes. In my experience,
8 they usually take a number of years before the
9 reruns occur.

10 BY MS. GLOVER:

11 Q. Okay. And CMS announces a rerun in
12 advance of performing that rerun; correct?

13 MR. JONES: Objection; form. Outside
14 the scope.

15 THE WITNESS: That has been their
16 process of probably the past three to five years.
17 I don't know that in the time frame in question
18 that they were always announcing when they were
19 making reruns.

20 MS. GLOVER: I'm going to mark another
21 exhibit here. This is going to be marked
22 Exhibit 733, and the attachment will be 733-1.

23 (Exhibit 733 and 733-1 marked for
24 identification and attached hereto.)

25 BY MS. GLOVER:

1 Q. Feel free to take a look at that. I
2 don't know if you've seen this document, but let me
3 know if you have.

4 A. Okay.

5 Q. And the cover email, for the record, is
6 MAPL000172139, and the attachment is MAPL000172140.

7 Do you see that this is an announcement
8 of a rerun?

9 A. Yes, I do.

10 Q. And it's from September 18, 2013?

11 A. Yes.

12 Q. Does that refresh your memory that rerun
13 announcements were made during the relevant time
14 period?

15 MR. JONES: Objection; form.

16 THE WITNESS: I guess I would look at
17 this and say they're telling us on September 18th
18 that they're taking a rerun on September 30th and
19 not necessarily view that as advance notice. I
20 mean, that was less than two weeks, give or take,
21 of notice. Whereas their new process, they publish
22 it probably a year in advance. They say this is
23 what we're going to do.

24 BY MS. GLOVER:

25 Q. Oh, I see what you're saying. So they

1 may have always given notice but it may not have
2 had as much of a lead time as it does now?

3 A. Correct.

4 Q. All right. And so in -- I guess I want
5 to understand a little bit more about what happens
6 in the rerun.

7 So if you submit deletes -- closed
8 period deletes I think you referred to them as --
9 after the final reconciliation but before the
10 rerun, the new per member per month payment after
11 the rerun accounts for the new universe of HCCs
12 that apply to that beneficiary; is that right?

13 MR. JONES: Objection; form.

14 THE WITNESS: The rerun would create a
15 new risk score for each beneficiary based on the
16 most up-to-date information, which would include
17 the closed period deletes that we submitted.

18 BY MS. GLOVER:

19 Q. Okay. And if the closed period deletes
20 that you made impact the risk score, then that will
21 reduce the per member per month payments; correct?

22 A. That is correct.

23 Q. Okay. Similarly, in the open period, if
24 you submit diagnosis codes that increase the risk
25 score, that will increase the per member per month

1 payments that you receive from CMS; right?

2 A. If they are new and unique diagnosis
3 codes to that member and not a repeat of something
4 they're already getting paid on, then yes, that
5 would increase the risk score.

6 Q. Okay. And let's talk about that a
7 little bit. You do have to submit a diagnosis code
8 that maps to an HCC that impacts the risk score
9 once every year, right, at least?

10 A. Correct, at least once a year you have
11 to submit the diagnosis code.

12 Q. Okay. So you can't use diagnosis codes
13 that were submitted in prior years to determine the
14 payment that's going to be -- that's going to be
15 received for a date of service year that follows
16 it? Does that make sense?

17 A. Yes, that makes sense. And that is
18 correct. You have to recapture that diagnosis code
19 and submit it to CMS every year to get payment for
20 it.

21 Q. Okay. And so for example, if you submit
22 a diagnosis code that maps up to HCC 19, which we
23 established was diabetes, and you submit that based
24 on an encounter in date of service year 2010, you
25 have to resubmit it for 2011 as well; right?

1 A. That is correct.

2 Q. When you resubmit it for 2011, can it
3 still be based on the encounter that took place in
4 2010?

5 A. No.

6 MR. JONES: Objection; form.

7 THE WITNESS: No, it has to be based on
8 an encounter that happened in 2011.

9 BY MS. GLOVER:

10 Q. Okay. So there has to be separate
11 documentation in a medical record each year if
12 you're going to submit a diagnosis code to CMS?

13 MR. JONES: Objection; form.

14 THE WITNESS: There has to be a separate
15 submission from the physician or provider each year
16 on, say, a claim in order for us to resubmit it to
17 CMS.

18 BY MS. GLOVER:

19 Q. Okay. And in submitting diagnosis codes
20 for payment to CMS, sometimes you submitted
21 diagnosis codes based on a claim or an encounter
22 that you received from a physician or a hospital;
23 right?

24 A. Correct.

25 Q. And sometimes you submitted diagnosis

1 codes that were based on a review of medical
2 records; correct?

3 A. Correct.

4 Q. Okay. And either one of those sources
5 could be a source for a diagnosis code that you
6 submitted for payment; right?

7 A. That's correct.

8 Q. Okay. Now, were there certain diagnosis
9 codes that you couldn't submit based on the source
10 of that diagnosis code?

11 MR. JONES: Objection to form. Vague.

12 THE WITNESS: Yeah, I'm not sure I fully
13 know the answer to that, and it's very broad. I
14 would say with RAPS, with the RAPS submissions
15 versus EDS that we've started to shift to, there
16 were requirements by CMS such as the visit had to
17 be face-to-face with a provider. So if the visit
18 was not face-to-face, we would not or could not
19 submit it. I'm not sure if that's what you were
20 asking.

21 BY MS. GLOVER:

22 Q. That's exactly what I was asking. You
23 read my mind.

24 So for example, you couldn't submit a
25 diagnosis code that was based on a lab or a

1 radiology visit. It had to be a face-to-face visit
2 with a provider; right?

3 A. Correct.

4 Q. Okay. And every diagnosis code that you
5 submitted for payment to CMS, in order for CMS to
6 pay for it it had to be supported by documentation
7 in the medical record; correct?

8 MR. JONES: Objection; form. Vague.

9 THE WITNESS: The expectation is that
10 every diagnosis code is supported in the medical
11 record, yes.

12 BY MS. GLOVER:

13 Q. Okay. And so similarly, just the
14 converse of that, the expectation was that you were
15 not going to be paid for diagnosis codes that were
16 not supported by the medical record; right?

17 MR. JONES: Objection; form. Outside
18 the scope.

19 THE WITNESS: The expectation is that
20 every diagnosis code we submit is supported by a
21 medical record, so we would expect to only get paid
22 on a diagnosis supported by a medical record.

23 BY MS. GLOVER:

24 Q. Okay. And you can't just make up a
25 diagnosis code and submit it to CMS for payment;

1 right?

2 A. Correct.

3 Q. Did you also understand that diagnosis
4 codes that you submitted for payment, the medical
5 record that supported them had to be signed or have
6 the credential for the physician included on the
7 face of the medical record?

8 MR. JONES: Objection; form.

9 THE WITNESS: Yes, it's my understanding
10 that a medical record has to be signed by a
11 physician to be adequate documentation.

12 BY MS. GLOVER:

13 Q. Okay. We've covered some of this, so I
14 just want to speed things along.

15 Earlier, you mentioned CMS's model
16 software.

17 A. Uh-huh.

18 Q. Did you utilize the model software?

19 A. Not personally, but as an organization
20 we used the model software, yes.

21 Q. And I should be clear, every time I say
22 "you," I'm actually referring to the organizations.
23 But thank you for the clarification.

24 A. Yes, we utilize their model software.
25 We download it and utilize it.

1 Q. And what does the model software allow
2 you to do?

3 A. The model software assists with
4 projecting a member's risk score based on the
5 diagnosis codes that are being submitted to CMS.

6 Q. So essentially the model software, if
7 you put in the components for a given beneficiary,
8 will spit out what the anticipated risk score will
9 be for that beneficiary?

10 A. That's correct.

11 Q. Okay. And did you utilize that to
12 determine what your expected payments would be from
13 CMS for the beneficiaries enrolled in your MA and
14 MAPD plans?

15 A. Yes. As standard accounting principles,
16 we needed to attempt to accrue for the midyear and
17 final reconciliation in the coverage period that
18 they were occurring. So we used that tool and
19 would use that as one of the components to look at
20 what was submitted that we hadn't been paid on yet
21 and estimate what our accrual needed to be for the
22 CMS risk adjustment true-ups.

23 Q. And you understood which diagnosis codes
24 were risk adjusting for a given date of service
25 year; correct?

1 A. Correct. That was published by CMS.

2 Q. Okay. And you utilized the information
3 published by CMS so that you were aware of which
4 diagnosis codes could be used for risk adjustment
5 purposes and for which you could receive payment?

6 A. Yes.

7 Q. And we've talked about diagnosis codes.
8 Diagnosis codes can map to an HCC but they can also
9 map to something called an RxHCC; right?

10 A. That's correct. That's the Part D
11 component of it, yes.

12 Q. And there are some diagnosis codes that
13 map to both an RxHCC and an HCC; correct?

14 A. Yes, there's overlap.

15 Q. And then there's some that only map to
16 an HCC or only map to an RxHCC; right?

17 A. That's correct.

18 Q. Okay. So if you submit a diagnosis code
19 that maps to an HCC and an RxHCC and it impacts the
20 risk score under both models, then you could
21 receive additional payment under both models;
22 correct?

23 A. Yes, that's correct.

24 Q. Okay. And similarly, if you delete a
25 diagnosis code that maps to both an HCC and an

1 service or traditional side of Medicare; right?

2 A. Yes.

3 Q. And that was always true during the
4 relevant time period; right?

5 A. Yes. CMS utilizes the fee for service
6 data to arrive at their coefficients.

7 Q. Okay. So in the advance notice and rate
8 announcement that we talked about, as well as other
9 information provided by CMS, it was clear that CMS
10 was using fee for service data to calculate the
11 factors that would be used in a given risk score;
12 right?

13 A. Yes.

14 Q. Okay. Now, the final submission
15 deadline, you are supposed to make efforts to
16 submit all of the data that you have for a given
17 beneficiary before that deadline; right?

18 A. Yes.

19 Q. But CMS allows for submission of
20 deletions after that deadline; right?

21 A. Correct.

22 Q. And you understood that if you
23 identified something that needed to be deleted, you
24 were supposed to delete that after the final
25 submission deadline even though that deadline had

1 passed; right?

2 MR. JONES: Objection; form. Outside
3 the scope.

4 THE WITNESS: Yes. If we identified
5 something that we had submitted erroneously, it was
6 the expectation that we would submit a delete.

7 BY MS. GLOVER:

8 Q. Okay. And when you say "erroneously,"
9 what do you mean?

10 MR. JONES: Objection; form.

11 THE WITNESS: If as an organization we
12 had knowledge that we submitted a risk -- I'm
13 sorry, a diagnosis code that was in error, if we
14 had knowledge that the diagnosis code was in error
15 and unsupported, we would submit a delete.

16 BY MS. GLOVER:

17 Q. What do you mean by unsupported?

18 A. In an instance where we looked for
19 documentation or support for that diagnosis code
20 and could not find it, that's what I mean by
21 unsupported.

22 Q. I see. So in instances where you looked
23 at, like, the medical record documentation and you
24 couldn't find documentation for that specific
25 diagnosis code, it was your understanding that you

1 BY MS. GLOVER:

2 Q. Okay. And you were responsible for the
3 accuracy of your data, and so you felt that you
4 needed to correct it based on that as well?

5 MR. JONES: Objection; form as to
6 obligations. Outside the scope. And calls for a
7 legal conclusion.

8 THE WITNESS: Yeah, I can't speak
9 legally to what obligations we had to do. I can
10 just say as our practice, as our good business
11 practice, we felt we had to correct something that
12 we found was in error.

13 BY MS. GLOVER:

14 Q. Okay. And we spoke briefly about RAPS.
15 RAPS includes five different fields; right?

16 A. Yes.

17 Q. What fields does RAPS contain?

18 A. I believe they contain a provider ID, a
19 from date, through date, the member identifier, and
20 the diagnosis code.

21 Q. Okay. And you had to submit all five
22 elements into RAPS in order to get paid for a
23 diagnosis code that impacted a beneficiary's risk
24 score; right?

25 A. Correct.

1 Q. Okay. And if one of those fields was
2 missing, the CMS system would reject that code;
3 right?

4 A. That's correct.

5 Q. And did you submit diagnosis codes to a
6 system called FERAS, F-E-R-A-S?

7 A. I'm honestly not sure about that.

8 Q. I think it stands for Front End Risk
9 Adjustment System and feeds into RAPS.

10 A. Yes, then we did submit to that.

11 Q. Okay. And if CMS was rejecting a given
12 diagnosis code as well as the other elements that
13 you mentioned, it sent you an error message saying
14 that it could not accept that code; right?

15 A. Correct.

16 Q. And similarly, if it accepted a given
17 diagnosis code and the other RAPS elements, it
18 would send a message saying that it had accepted
19 that code; right?

20 A. Correct.

21 Q. And for purposes of maybe ease, are you
22 familiar with the term "diagnosis cluster"?

23 A. I am.

24 Q. What is a diagnosis cluster?

25 A. My understanding is that the term

1 "diagnosis cluster" refers to the combination of
2 the five fields on the RAP submission.

3 Q. Okay. And so if it's okay with you,
4 I'll just refer to the RAP submission as a
5 diagnosis cluster.

6 A. Okay.

7 Q. So you submitted diagnosis clusters to
8 CMS into the FERAS system, which fed into the RAP
9 system. And then is it your understanding that
10 after being processed in the RAP system it would go
11 into a system to calculate the risk score based on
12 the diagnosis codes that had been -- the diagnosis
13 clusters that had been submitted for the given
14 beneficiary?

15 A. Yes, that's my understanding.

16 Q. Are you familiar with a system called
17 RAS, R-A-S?

18 A. I am not.

19 Q. Do you know the name of the system that
20 calculated the risk score for the given
21 beneficiary?

22 A. No. On the CMS side?

23 Q. Yes.

24 A. No, I do not.

25 Q. Are you familiar with a system called

1 MARX, M-A-R-X?

2 A. Yes.

3 Q. And what is that system used for?

4 A. The MARX system is a CMS system that
5 they utilize to generate the payments on a monthly
6 basis.

7 Q. Okay. And so after a risk score is
8 calculated for a given beneficiary, was it your
9 understanding that MARX would then take that risk
10 score and calculate the payment that should be paid
11 to the plan based on that risk score?

12 A. Yes, that was my understanding.

13 Q. Are you familiar with something called a
14 RAPS return file?

15 A. Yes.

16 Q. What is a RAPS return file?

17 A. The RAPS return files were the -- when
18 we would submit something to CMS, when we would
19 submit a RAPS submission to CMS, the RAPS return
20 file would come back telling us if that submission
21 was accepted or if it errored out.

22 Q. So you were able to tell or you were
23 able to know what diagnosis clusters CMS had
24 accepted and which it had rejected; correct?

25 A. Correct.

1 Q. Now, if you were going to delete a
2 diagnosis cluster, you had to submit a delete flag
3 with that cluster; is that right?

4 A. Correct.

5 Q. Okay. And that delete flag or -- I
6 don't know what term you used -- an indicator would
7 signify to CMS that that particular cluster had to
8 be deleted; right?

9 A. That's correct.

10 Q. Okay. Now, if you submitted a diagnosis
11 cluster and later learned that it was an error and
12 needed to submit a new diagnosis cluster, you
13 understood that you first had to delete the
14 original diagnosis cluster that was submitted in
15 error and then replace it with the new diagnosis
16 cluster; right?

17 MR. JONES: Objection; outside the
18 scope. Calls for a legal conclusion.

19 THE WITNESS: Yes, my understanding --
20 our understanding and practice would be to delete
21 the one that was in error before we submitted the
22 other one, assuming that we're in an open period.

23 BY MS. GLOVER:

24 Q. Okay. And that was because you couldn't
25 just leave the -- you couldn't leave the incorrect

1 diagnosis cluster in the system and simply replace
2 it without indicating a delete first; right?

3 A. Correct.

4 Q. Okay. And I want to talk briefly about
5 EDPS.

6 A. Okay.

7 Q. And when I say EDPS, I mean the
8 Encounter Data Processing System. Are you familiar
9 with that term?

10 A. Yes.

11 Q. And you're aware that in approximately
12 2014, CMS started using encounter data to calculate
13 payments that it was making to Medicare Advantage
14 organizations for the beneficiaries enrolled in
15 their MA or MAPD plans; right?

16 A. Yes.

17 Q. Okay. Now, as opposed to the five RAPS
18 fields, there are a lot of fields that are
19 submitted into EDPS; right?

20 A. Correct.

21 Q. But you still submit diagnosis codes
22 into EDPS; right?

23 A. Yes, that's correct.

24 Q. And similar to the RAP system, there was
25 a way that you could delete previously submitted

1 Q. Okay. And then the non-allowable data
2 sources, I think we talked about these. Earlier,
3 you confirmed that you couldn't identify diagnosis
4 codes based on labs; right?

5 A. That's correct. It has to be a
6 face-to-face visit.

7 Q. And do you know what it means by
8 diagnostic?

9 MR. JONES: Objection; form. Outside
10 the scope.

11 THE WITNESS: I'm not a hundred percent
12 certain. I believe in this instance, diagnostic
13 would mean like a radiology technician kind of
14 saying to you: Oh, I think everything looks good,
15 or I think you have a problem. You know, that's
16 kind of their diagnostic opinion, but they're not a
17 certified provider from a CMS standpoint to allow
18 you to submit that information.

19 BY MS. GLOVER:

20 Q. Understood.

21 And similarly, you couldn't submit
22 diagnosis codes for payment to CMS under the risk
23 adjustment payment process for Part D if it was
24 like a rule-out or probable condition but hadn't
25 been confirmed by the provider; right?

1 MR. JONES: Objection; form.

2 THE WITNESS: I'm not -- I'm not sure
3 how we would even know of a probable condition
4 until it was confirmed by the provider.

5 BY MS. GLOVER:

6 Q. I see. I see what you're saying.

7 So if in the medical record
8 documentation the condition hasn't yet been
9 confirmed, you couldn't code that or submit that
10 diagnosis code for the probable condition until it
11 was confirmed; right?

12 MR. JONES: Objection; outside the
13 scope.

14 THE WITNESS: That's correct.

15 BY MS. GLOVER:

16 Q. Okay. And similarly, if an individual
17 had a history of a condition and it wasn't
18 currently documented in their medical record as a
19 current condition, you couldn't submit a diagnosis
20 code based on that for payment to CMS in the risk
21 adjustment payment process; right?

22 A. In our process around chart review, if
23 the member had -- if it's listed in the medical
24 record as a prior condition that is a lifelong
25 condition or a chronic condition that you cannot

1 get rid of, our process is to use that medical
2 record to submit the diagnosis code.

3 Q. Okay. So if it's documented -- if it's
4 documented in a -- earlier we talked about you had
5 to have an encounter each date of service year --

6 A. Correct.

7 Q. -- on which a diagnosis was based;
8 right?

9 A. Correct.

10 Q. Okay. So you couldn't base -- if it
11 said they have this diagnosis in 2010 but they
12 don't say they have it in 2011 when you look at the
13 medical record, you can't just submit the code
14 because there was a history of that condition
15 documented in 2010; right?

16 MR. JONES: Objection; outside the
17 scope. Form.

18 THE WITNESS: That is correct. You
19 would need a medical record with a visit from 2011
20 to document that that person had a provider visit
21 and had that condition.

22 BY MS. GLOVER:

23 Q. Okay. Let's go to the last page that
24 we'll do today, which is page 36. And you can go
25 directly to the page if you use the numbers at the

1 Q. Okay. And in a self-conducted chart
2 review they sometimes identified deletes; is that
3 right?

4 A. They could identify deletes through a
5 self-conducted chart review, yes.

6 Q. Do you know how those self-conducted
7 reviews were conducted?

8 MR. JONES: Outside the scope.

9 THE WITNESS: I have a general sense,
10 although I imagine every provider group could be a
11 little different. But from a general sense,
12 they're conducted by our capitated providers. And
13 the reason for that is the capitated providers do
14 not submit claims to us. So we're not getting
15 diagnosis codes from the claims themselves because
16 they don't submit the claims to us. They're in a
17 separate payment arrangement.

18 We require them to submit encounter data
19 to us to provide the diagnosis codes. The
20 providers often towards the end of a sweep window
21 closing, so either the midyear or the final
22 deadline approaching, the providers will look at
23 their systems and their medical records to ensure
24 that they did in fact provide us all the diagnosis
25 codes from their patients as an encounter record.

1 providers were supported or otherwise validated by
2 documentation in the associated medical records?

3 MR. JONES: Objection; form. Outside
4 the scope.

5 THE WITNESS: I'm not aware of -- if we
6 did conduct them I'm not aware of them. So I'm not
7 prepared to talk about them.

8 BY MS. GLOVER:

9 Q. Okay. How about the RACCR program?
10 What is that?

11 A. RACCR is the Risk Adjustment Coding
12 Compliance Review, and that is a risk adjustment
13 program that we use to monitor both our capitated
14 providers as well as our providers that were in an
15 accountable care organization.

16 Q. Okay. Was it used to monitor diagnosis
17 codes submitted by fee for service providers?

18 A. The accountable care organization
19 component of it would be considered a fee for
20 service provider. The capitation side of it would
21 not be.

22 Q. What is an accountable care
23 organization?

24 A. It is a provider network that we have
25 entered into some sort of risk sharing or gain

1 sharing arrangement where if they're able to manage
2 the member's care to decrease kind of the overall
3 spend by doing a better job managing it, we will
4 share in the savings with them.

5 Q. Okay. And did RACCR -- did RACCR review
6 diagnosis codes submitted by just your everyday fee
7 for service provider who was not involved in an
8 accountable care organization?

9 A. No. The RACCR program was intended to
10 monitor provider groups that potentially had an
11 incentive to over-submit because they were paid
12 some component of the percentage of revenue.

13 Q. Okay. And if you identified diagnosis
14 codes that weren't supported by the medical record
15 in the RACCR program, you deleted those codes;
16 correct?

17 A. That is correct.

18 Q. Now, the other program listed here is
19 CV, which I think you've mentioned today. Claims
20 verification; right?

21 A. Correct.

22 Q. And was that a program that was -- that
23 falls under Topic 10 here as a program to determine
24 whether diagnosis codes that were submitted to you
25 by fee for service providers were supported or

1 A. Yes.

2 Q. So I specifically want to talk to you
3 about the first part of that definition just as it
4 relates to Topic 10. Was chart review another
5 program where you were assessing whether diagnosis
6 codes submitted by providers were supported by
7 medical record documentation?

8 A. No.

9 Q. So in the chart review program, there
10 were some diagnosis codes that were identified as
11 being supported by the medical record that had
12 already been submitted by the provider; right?

13 MR. JONES: Objection; form.

14 THE WITNESS: Yes, that is correct.

15 BY MS. GLOVER:

16 Q. Okay. So in that way, chart review was
17 confirming diagnosis codes that had been submitted
18 by providers were supported by the medical record
19 documentation; right?

20 A. No. They were two separate and distinct
21 processes, and the results of chart review were not
22 necessarily bumped up against the claim to confirm
23 whether or not they matched.

24 Q. Are you familiar with something called a
25 new and unique HCC?

1 A. I am.

2 Q. Okay. And do you understand that a new
3 and unique HCC was identified if a chart reviewer
4 identified a diagnosis code that mapped to a new
5 and unique HCC that had not been submitted by a
6 provider before?

7 A. Yes.

8 Q. Okay. And so in that process to
9 identify a new and unique HCC, isn't it correct
10 that you were comparing the diagnosis codes that
11 had been submitted by a provider with what had been
12 found in the chart review?

13 MR. JONES: Objection; form.

14 BY MS. GLOVER:

15 Q. And the delta there, if it hadn't been
16 submitted by a provider, was a new and unique HCC?

17 A. So I would say that the chart review
18 process identified all HCCs, and then a separate
19 process that was not part of the chart review
20 program itself but was part of the submission
21 process would identify which of those codes from a
22 chart review were new and unique for submission.

23 Q. Okay. So do you understand what is
24 meant here when it says that "chart review is
25 performed at least once every two years to validate

1 Q. Okay. And so if you delete a diagnosis
2 code -- and by delete I mean you submit it to CMS
3 as a deletion -- and that diagnosis code impacts
4 the risk score and moves it down, is it correct
5 that when CMS accounts for that, they are
6 essentially -- like the plan is essentially paying
7 money back to CMS to account for the change in risk
8 score?

9 A. Yes. When a deletion results in a lower
10 risk score and, for example, they process a rerun,
11 the plan is -- CMS is recouping money back from the
12 plan. The plan is paying that money to CMS.

13 Q. I see. Okay.

14 All right. I want to move on to
15 Topic 11 which, from the sounds of your background,
16 may be very much in your wheelhouse.

17 And I know that the parties have made an
18 agreement to narrow this topic, and so one of the
19 things that you're prepared to testify about is the
20 quarterly roll forward schedules showing the total
21 CV-related accruals recorded and the reserves
22 released for the four quarters of 2013 and the
23 first two quarters of 2014 and their supporting
24 schedules, as well as the specific CV accruals that
25 were released in or around April and May of 2014,

1 including information regarding the release of
2 those reserves, their amounts, their inclusion in
3 the general ledger and monthly close reports
4 related to the release of CV reserves for April,
5 May and June of 2014.

6 Is that a correct description of what
7 you're prepared on?

8 A. Yes, it is.

9 Q. Okay. And as we sort of discuss this, I
10 want to make sure that I understand terms that are
11 used in this description just so that we can talk
12 about things a bit more freely.

13 A. Okay.

14 Q. So first of all, what is an accrual?

15 A. An accrual is an amount you would post
16 into the general ledger where cash has not settled
17 yet. So you're awaiting -- it could be you're
18 awaiting revenue and you haven't received that cash
19 yet. It could be that you're waiting to pay a
20 legal bill and you're accruing for it but you have
21 not received the bill and paid the cash out yet.

22 An accrual is something you post in the
23 general ledger to try to follow your accounting
24 principles and post it when you've accrued it even
25 though the cash has not come in or gone out yet.

1 Q. So it's almost like a placeholder so
2 that you know if you have money coming in or money
3 that's going to go out based on an event that has
4 happened now?

5 A. Correct.

6 Q. Okay. And what is a reserve?

7 A. A reserve is the same thing but in the
8 opposite direction. So from a revenue standpoint,
9 an accrual would be if you're expecting revenue in.
10 A reserve would be if you're expecting to pay
11 revenue out. On your balance sheet, you would call
12 that a reserve instead of an accrual just because
13 it's going the opposite direction.

14 Q. Okay. So with claims verification, is
15 it actually more accurate to say that there were
16 reserves given that you were making deletions based
17 on claims verification?

18 A. Yes, we would have called them reserves
19 within our general ledger and all our
20 documentation.

21 Q. Okay. So I know that you are prepared
22 to testify about CV-related accruals recorded and
23 reserves released. Were there accruals recorded
24 for CV?

25 A. No. Technically, it should probably say

1 CV reserves record and released.

2 Q. Okay. And then you mentioned something
3 called a general ledger. What is a general ledger?

4 A. A general ledger is your -- anybody's
5 accounting system that tracks their monthly profit
6 and loss statements. So your revenue in, your
7 income and expenses -- sorry, your revenue in, your
8 expenses out. They are all part of a financial
9 statement, and the general ledger is just a system
10 that manages your financial statements.

11 Q. Okay. And did you use a general ledger
12 to manage your financial statements?

13 A. Yes.

14 Q. Okay. And in order to make a reserve,
15 you mentioned something about accounting
16 principles.

17 A. Uh-huh.

18 Q. What were you referencing there?

19 A. Well, overarching, it's called GAAP,
20 Generally Accepted Accounting Principles, and
21 there's hundreds of them I would say that dictate
22 your rules of what you are and are not supposed to
23 do to follow standard accounting within your
24 general ledger.

25 Q. And is one of the principles that in

1 order to -- and maybe I should correct this. Is it
2 book a reserve?

3 A. Sure, you could say that.

4 Q. In order to book a reserve, that the
5 amount you'll have to -- that you are anticipating
6 paying out is probable and estimable?

7 A. Estimatable, yes. Yes, that is correct.
8 Part of the rule if you're booking a reserve is
9 that it's probable and -- it might be estimable.

10 Q. Estimable?

11 A. Yes. I always struggle with that word.
12 Estimable, estimatable, I'm not sure which it is.
13 But you have to be able to estimate it.

14 Q. I love that. Okay.

15 And basically, like that means that it's
16 probable or estimable that more likely than not
17 you're going to have to pay that money out; is that
18 right?

19 A. Correct.

20 Q. Okay. And are you familiar with the
21 term "contra revenue"?

22 A. Yes.

23 Q. What is that?

24 A. It's an accounting term for sort of a
25 reduction to your revenue. You could refer to a

1 delete reserve as a contra revenue. We just
2 internally refer to it as a reserve versus
3 contra revenue. But really it's revenue that's
4 going out. It's the direction. It's reducing
5 revenue instead of increasing revenue.

6 Q. Okay. So a reserve and a contra revenue
7 are conceptually the same in that both mean that
8 money will be paid out?

9 A. Correct.

10 Q. Okay. And then I'm still in the
11 definition of what we're going to be talking about.

12 A. Okay.

13 Q. I'm not an accountant.

14 What is a quarterly roll forward
15 schedule?

16 A. A quarterly roll forward schedule is
17 usually prepared on a balance sheet account, which
18 is sort of your running total of items you owe out
19 or receivables that are owed in to you. Your
20 balance sheet is that running total from month to
21 month to month. It just increases or decreases.

22 And a roll forward is usually a summary
23 of the activity that occurred in that account. For
24 example, if you started -- ended a year
25 December 31st with balance of zero and then the end

1 of the first quarter your balance was a hundred,
2 the roll forward details the activity that got you
3 to a hundred. It could be that you accrued 200 but
4 paid 100. You know, that net activity gets you to
5 your ending balance, but the roll forward details
6 that activity as it occurs to explain what happened
7 in that account.

8 Q. Does the roll forward -- if you take a
9 reserve on something, does the roll forward show
10 that as having happened? Or is there some
11 indication that it's a placeholder but the money
12 has not been taken out or accounted for yet?

13 A. A roll forward is a more general term,
14 and you can -- internally, someone creating a roll
15 forward can kind of make it do whatever they want.
16 As long as in concept it's showing your beginning
17 balance and your ending balance and what has
18 occurred, you can set it up to show any kind of
19 activity that you want, whether you want to show
20 that you put up a reserve or that a reserve paid
21 out or anything like that. It's really at the
22 discretion of who's creating it.

23 Q. I see.

24 Now, you're here to talk about the
25 claims verification roll forward schedules for

1 certain quarters in 2013 and 2014. How did you use
2 the roll forward schedules?

3 A. The roll forward schedule was created on
4 our entire risk adjustment receivable account which
5 is at times, depending on the time of year, could
6 be a very large account. Within that risk
7 adjustment receivable account we're accruing for
8 the midyear reconciliation, the final
9 reconciliation. We have reserves against it for
10 possible deletes that we're paying out. So across
11 our entire Medicare Advantage business, that
12 balance can be pretty large.

13 So the roll forward is actually
14 detailing that entire RAF receivable account and
15 then breaking it down into subcategories of what is
16 in that account based on the supporting schedules
17 that add up to those balances.

18 Q. What do you mean by supporting
19 schedules?

20 A. The schedules that -- within any account
21 reconciliation you really should have support for a
22 balance. You can't just accrue a million dollars
23 without some sort of support. So within the RAF
24 receivable account, as I said, at any given time
25 you could have multiple types of accruals. Let's

1 say it's March and you have a midyear accrual, plus
2 a final accrual, plus the final accrual from the
3 year previous because that hasn't settled yet, plus
4 a delete reserve, each one of those is going to
5 have a different supporting schedule.

6 Q. I see.

7 So does claims verification have its own
8 supporting schedule?

9 A. It was part of supporting schedules
10 depending on the payment type.

11 Q. What does that mean?

12 A. If -- when we were in an open period, it
13 would have been part of our overall accrual for
14 the, say, 2013 final reconciliation payment. So
15 within that support for the 2013 final
16 reconciliation payment, there would be a column or
17 something in the spreadsheet specific to claims
18 verification.

19 Q. Okay. And if there is a column in
20 claims verification -- sorry, in the roll forward
21 schedule for claims verification, is that
22 indicating a reserve for deletes that you
23 anticipate needing -- or sorry. No.

24 Is that a reserve for money that you
25 anticipate CMS taking back based on deletes?

1 A. It is the estimated anticipated payment
2 back to CMS for deletes related to the claims
3 verification program. But at any given time not
4 all of those deletes have yet been submitted.
5 There could be a subset of them that have or have
6 not been submitted based on the time of year and
7 where we sit within a reconciliation.

8 Q. I see.

9 So because some deletes identified
10 pursuant to claims verification were in fact
11 submitted to CMS, some portion of the roll forward
12 schedule line devoted to CV is -- could be
13 attributable to deletes that have already been
14 submitted and you're waiting for CMS to take the
15 money back, and some portion could be attributable
16 to deletes that you anticipate needing to make the
17 probable and estimable but you haven't submitted
18 them to CMS yet. Is that right?

19 A. Generally, yes. I guess I would add
20 that even for the ones not submitted to CMS, I
21 would add a distinction that not only have they not
22 been submitted but there is some subset of a
23 balance where the work hasn't even occurred yet.
24 We're just estimating future work that will occur.

25 Q. I see. I see.

1 So for example, work in claims
2 verification on 2013 date of service had not yet
3 begun when the program was canceled by
4 UnitedHealth; right? UnitedHealthcare?

5 A. So 2013 dates of service, May 2014
6 payment year?

7 Q. Correct.

8 A. Yes, that's correct.

9 Q. And so did the roll forward schedules
10 for the time that you're testifying about have
11 reserves in place for 2013 date of service?

12 A. Up until the month where we would have
13 released the accruals, there was an inherent
14 balance for claims verification on our roll
15 forwards, yes.

16 Q. And specifically for claims verification
17 for 2013 date of service?

18 A. Yes. As of -- so as of the quarters in
19 question for 2013, there would be nothing for 2014
20 payment year because we haven't hit that year yet.
21 So each quarter of 2013 would not have had any
22 reserve for '14 payment year because we haven't hit
23 '14 yet. But then for Q1 and Q2 of 2014 there
24 would be a balance for claims verification.

25 Q. I see.

1 So when did you -- what had to happen
2 before you put a reserve in place for -- or what
3 had to happen in order for you to put a reserve in
4 place for 2013 date of service in 2014 payment
5 year?

6 MR. JONES: Objection; form.

7 THE WITNESS: In the beginning of the
8 year, the way it works for the first quarter of any
9 year, because at that point minimal data has been
10 submitted because of the timing of the different
11 sweep periods. The first quarter of any year is
12 using an estimated PMPM based on what had occurred
13 the year prior. So in your question, in the first
14 quarter of 2014 we would have been using PMPMs from
15 2013 which baked into them had a reserve for claims
16 verification.

17 So by using a number that had claims
18 verification inside of it, we were basically
19 accruing to a claims verification balance in Q1 of
20 2014 as well even though no work had started yet.

21 BY MS. GLOVER:

22 Q. I see.

23 How did you know how much to put in the
24 estimated reserve for 2013 date of service CV?

25 MR. JONES: Objection; form.

1 your question, you're asking me if we did claims
2 verification before we did claims verification. So
3 I'm not sure I understand the question.

4 BY MS. McMAHON:

5 Q. Well, I certainly did see the look of
6 confusion on your face, so I do want to clear it
7 up.

8 My question is prior to -- prior to
9 implementation of the claims verification, did you
10 do any other process that would have served the
11 same purpose as you just described it, that would
12 have served the same purpose that CV served?

13 MR. JONES: Objection; outside the scope
14 of Judge Segal's order.

15 THE WITNESS: We complied with all
16 audits such as RADV audits and they're now called
17 improper payment audits, IPM -- I'm blanking on the
18 name it was years ago. But we complied with all
19 CMS audits which would have asked us to produce
20 medical records to support diagnosis codes. So
21 that would have been what we would have done to
22 compare diagnosis to medical records.

23 BY MS. McMAHON:

24 Q. But you didn't do anything in particular
25 with respect to the charts that had gone through

1 chart review, right, to make sure that anything
2 that the coders did not find as supported to try to
3 validate any of those codes; correct?

4 MR. JONES: Objection; outside the
5 scope.

6 THE WITNESS: Correct.

7 BY MS. McMAHON:

8 Q. And I would say by definition, if you
9 didn't have that type of process, then you were not
10 submitting deletes that would have -- that would
11 have resulted; correct?

12 MR. JONES: Objection; outside the scope
13 of Judge Segal's order.

14 THE WITNESS: Correct. Without a
15 program to identify the deletes, we would not have
16 been submitting deletes.

17 BY MS. McMAHON:

18 Q. Right, of course.

19 So my question is what was your -- what
20 was your decision to not submit deletes for codes
21 that were not identified in chart review but that
22 were on the provider's claim on the charts that
23 went through claims verification -- I mean, I'm
24 sorry, that went through chart review, what was
25 your decision based on to not have a program that

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that MELISSA SEDOR, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was not requested.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 3rd day of July, 2023.

19

20

21


JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT P-6

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.
BENJAMIN POEHLING,

Plaintiffs,

vs.

UNITEDHEALTH GROUP, INC., et al.,

No.

16-08697 FMO

Defendants.

VIDEOTAPED DEPOSITION OF TIMOTHY RENJILIAN

March 21, 2024, 9:07 a.m.

Alston & Bird

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Michelle R. Lowe, RPR, CCR-2748

1 can't just make up diagnosis codes and report them
2 because they want to.

3 BY MR. MASON:

4 Q They can only submit what you call
5 appropriate diagnosis codes?

6 A Yeah. Again, not speaking as a lawyer,
7 but, yes, that's consistent with my understanding.

8 Q Okay. And diagnosis codes submitted for
9 risk adjustment must be adequately documented in a
10 medical record from a face-to-face encounter with a
11 medical provider; right?

12 A I'm sorry. Are you reading from my
13 report, or was that --

14 Q I'm just asking you a question.

15 A Oh.

16 Q Diagnosis codes submitted for risk
17 adjustment must be adequately documented in a
18 medical record from a face-to-face encounter with a
19 medical provider; right?

20 MR. JONES: Objection. Form.

21 A Well, again, I'm not speaking as a lawyer.

22 So I understand that ultimately if a code
23 is reviewed, it should have appropriate medical
24 record support. The MAO doesn't gather underlying
25 medical record data or retain it for all codes and

1 so it wouldn't necessarily have that kind of data,
2 you know, at its immediate disposal. But
3 ultimately, to the extent that codes are being
4 reviewed, they should have adequate support.

5 BY MR. MASON:

6 Q In a medical record from a face-to-face
7 encounter?

8 A Correct.

9 Q Okay. And you said that -- Paragraph 35,
10 when you use appropriate clinical diagnosis codes,
11 you're referring to the statements that you made in
12 the preceding paragraphs; right?

13 A I believe so. Let me just make sure we're
14 clear. Let me take a second and just take a look to
15 make sure.

16 Yes. I -- I think that I'm using that
17 term there as -- as a bit of a catchall for the
18 various criteria that are expressed in the preceding
19 several paragraphs, at least back up through
20 Paragraph 31. So appropriate is referring to
21 those -- those preceding paragraphs.

22 Q Okay. And let's look at Paragraph 31. In
23 Paragraph 31, you say: Diagnosis codes -- sorry.

24 You say: According to the CMS 2012 Risk
25 Adjustment Regional Technical Assistance Participant

1 Guide.

2 I might refer to that just as the
3 participant guide. Is that okay with you?

4 A Yeah, that -- that's fine. I think, just
5 as a caution, there may be a couple of different
6 participant guides that are that referred to across
7 the different reports.

8 Q Fair point. So I will refer to that as
9 the 2012 participant guide.

10 A Okay. Thank you.

11 Q So what you say in Paragraph 31 is:
12 According to the 2012 participant guide, diagnosis
13 codes included in risk adjustment data must be based
14 on clinical medical record documentation from a
15 face-to-face encounter, coded according to the
16 applicable coding guidelines, paren, ICD-9-CM or
17 ICD-10, closed paren, assigned based on dates of
18 service within the data collection period, and
19 submitted to the MAO from an acceptable source and
20 acceptable provider type.

21 Did I read that correctly?

22 A Yes. You read that very well.

23 Q Okay. And that requirement is part of
24 what makes a diagnosis code appropriate, as you use
25 it in your report; right?

1 MR. JONES: Objection. Form.

2 A That's what the participant guide says. I
3 understand there could be different views of
4 requirements. And I'm not opining as a lawyer, but,
5 yes, what -- what we read is consistent with my
6 understanding of the 2012 participant guide.

7 BY MR. MASON:

8 Q And it's part of what you meant when you
9 said appropriate diagnosis codes in Paragraph 35?

10 A As a general proposition, yes. I mean,
11 I -- we're probably focusing more attention on the
12 specific word appropriate than I did at the time
13 that I selected that.

14 But, yeah, what I'm intending to do in
15 this section is to provide a general overview just
16 for background-setting purposes. It's not meant to
17 be an exhaustive recitation of legal or other
18 requirements associated with the submission of
19 codes. It's really intended just to be sort of a
20 foundation-setting discussion.

21 Q Right. This section -- well, what is the
22 purpose of this section?

23 A As I said, just to provide some
24 foundational background for understanding my report.

25 Q And -- and this section accurately sets

1 forth what your understanding of how the program
2 works; right?

3 MR. JONES: Objection. Form.

4 A Well, again, as I said, it's meant to
5 be -- not meant to be an exhaustive recitation of
6 all of the requirements or nuances inside of those.
7 It's a -- meant to be a simplified background
8 explanation of my understanding.

9 BY MR. MASON:

10 Q And you reference here the 2012
11 participant guide. Can you explain what that is.

12 A Yes. That -- that was a guide that was
13 put out by CMS that just, you know, provided
14 additional training and guidance around the use of
15 risk assessment and the submission of codes and that
16 sort of thing.

17 Q You said risk assessment. Do you mean
18 risk adjustment?

19 A I'm sorry. Risk adjustment, yeah. Thank
20 you. Sorry.

21 Q I'm just trying to make sure the
22 transcript is clear.

23 A I appreciate that. Sorry. I do a lot of
24 risk assessment work as well so that just flowed a
25 little too naturally.

1 supported or not appropriate for submission, you
2 know, my recommendation from a compliance standpoint
3 would typically be to delete that code.

4 BY MR. MASON:

5 Q Go on. Sorry.

6 A No. I'm sorry. Go ahead.

7 Q Why would that be a recommendation?

8 A I think that's the -- you know, probably
9 the safest course of action. It's not necessarily
10 the legal requirement, which I know that's the next
11 part of your question -- and I'll tell you now, I
12 don't know strictly from a legal standpoint what the
13 actual technical requirement would be.

14 But if you have definitive knowledge that
15 a code is not correct and, you know, impacts
16 payment, et cetera, et cetera, then I would say, you
17 know, the safest course from a compliance standpoint
18 is to delete it.

19 Q You would only recommend that MAOs delete
20 codes if they've learned that it impacted the
21 payment?

22 A No, not necessarily, because, frankly,
23 determining whether a code impacted payment, you
24 know, may be unknowable for quite some period of
25 time.

1 So, yeah, again, I mean, I think it's
2 probably a facts and circumstances determination
3 rather than an abstract discussion. But, generally
4 speaking, if -- if, you know, I had a client who
5 said they had identified codes as being not
6 supported, I would suggest that they delete those
7 codes.

8 Q And you said -- when I asked you why, you
9 said because that would be the safest course of
10 action. What do you mean by that?

11 A Well, I think it would be hard for anybody
12 to object to the deletion of codes, whereas not
13 deleting them at least opens you up to, you know,
14 additional questioning in those circumstances.

15 Q What type of additional questioning are
16 you referring to?

17 MR. JONES: Objection. Form.

18 A Could be any kind of form, you know,
19 coming out of an OIG audit, a CMS audit, an internal
20 audit, et cetera. I mean, there are all sorts of
21 people who are scrutinizing what happens in the
22 healthcare industry.

23 BY MR. MASON:

24 Q And you said you don't know what the
25 participant guide says as to this question?

1 Q And what CMS does is they calculate the
2 risk score for the beneficiary, excluding whatever
3 diagnosis code submission was deleted?

4 MR. JONES: Objection.

5 A That's right.

6 MR. JONES: Form.

7 BY MR. MASON:

8 Q Sorry. I didn't catch the answer.

9 A I'm sorry. Yeah. Again, some -- I have
10 not reviewed in detail the internal mechanics of
11 CMS's process, but that would be my general
12 understanding.

13 Q Okay. So, in other words, the next time
14 CMS calculates a risk score -- wherever we are in
15 the year, the next time CMS calculates a risk score
16 that specific submission that was deleted won't be
17 included in that calculation?

18 A Presumably.

19 Q And that would generally result in a
20 downward adjustment in the payment that the MAO
21 receives; right?

22 A No.

23 Q And are you saying no because it depends
24 on whether the diagnosis code that's deleted maps to
25 a risk adjusting HCC is duplicated by another

1 diagnosis code that was submitted or is duplicated
2 at the HCC level by another diagnosis code that was
3 submitted?

4 A Yes, all of those reasons, at least within
5 the initial processing of -- you know, by CMS.

6 It's also possible, of course, that, you
7 know, if a code is deleted there was another
8 unsubmitted code that was appropriate that -- that
9 could have been submitted that might take the place
10 of that or that other records are found if the -- a
11 code is, you know, audited and reviewed.

12 But in the strict sort of mechanical
13 processing, you know, if a code is taken out of
14 CMS's RAS system at that level, you know, the HCC
15 impact would flow from there in whatever way is
16 appropriate, but there may not be an HCC impact.

17 Q And you mentioned unsubmitted codes.
18 Those unsubmitted codes can never be part of the
19 risk score that's calculated by CMS; right?

20 MR. JONES: Objection. Form. Foundation.
21 Incomplete hypothetical.

22 A If they weren't submitted, they would not
23 be considered as part of the -- the basic RAPS and
24 RAS processing, you know, flow that we just
25 discussed. But they may ultimately come into play

1 at some point, for example, through an audit process
2 or if a -- you know, a code is deleted and it's
3 found that another unsubmitted code that could
4 properly be submitted can be submitted in its place.

5 BY MR. MASON:

6 Q We're going to talk about RADV and audits
7 later.

8 Right now I'm just talking about what
9 happens in the ordinary payment model --

10 A Okay.

11 Q -- the CMS-HCC model when MAOs submit adds
12 or submit deletes. Okay?

13 A Okay.

14 Q So in the ordinary CMS-HCC model
15 unsubmitted codes are never part of the calculation
16 of a risk score; right?

17 MR. JONES: Objection. Form. Foundation.
18 Asked and answered.

19 A If a code hasn't been submitted, CMS won't
20 know about it.

21 BY MR. MASON:

22 Q And therefore it can't be part of the
23 calculation of a risk score; right?

24 A If it's not been submitted, it wouldn't be
25 factored into that initial risk score calculation.

1 Q Or the final risk score calculation?

2 MR. JONES: Objection. Form. Incomplete
3 hypothetical.

4 A Yeah. Again, at the risk score
5 calculation level if a code is not submitted, an
6 unsubmitted code would not be considered in that
7 calculation process.

8 BY MR. MASON:

9 Q And you mentioned that if the diagnosis
10 code is duplicated either at the HCC level or at the
11 diagnosis code level by another submitted code, then
12 the deletion would not have a financial impact in
13 the calculation of risk scores in the ordinary
14 CMS-HCC model; right?

15 MR. JONES: Objection. Form. Incomplete
16 hypothetical.

17 A That's one example of why a deleted code
18 might not have a payment impact at the beneficiary
19 level.

20 BY MR. MASON:

21 Q And does CMS undertake any extra steps to
22 account for or search for or identify whether codes
23 are duplicated at the diagnosis code or HCC level?

24 MR. JONES: Objection. Form. Incomplete
25 hypothetical. Foundation.

1 A Okay.

2 Q Do you understand?

3 A Okay. Yes.

4 Q So you haven't offered an expert opinion
5 that the methodology that Dr. Garthwaite used to
6 identify which encounters had charts go through
7 Chart Review was flawed, have you?

8 A I have not offered such an expert opinion.

9 Q And you haven't offered an expert opinion
10 that the conclusions that Dr. Garthwaite reached
11 regarding which provider encounters had charts go
12 through Chart Review was incorrect -- or were
13 incorrect?

14 MR. JONES: Objection. Form.

15 A That's not a question that I felt I needed
16 to evaluate in detail for purposes of my opinion.
17 So it's not that I don't have thoughts on that, but
18 I have not expressed an expert opinion on that.

19 BY MR. MASON:

20 Q Okay. And you -- you haven't identified
21 any specific encounters that Dr. Garthwaite says
22 their charts went through Chart Review that you say
23 he got it wrong; right?

24 A Not something that I sought to do as part
25 of my expert reports.

1 Q You have an understanding of the
2 methodology that Dr. Garthwaite used to identify
3 which diagnosis codes were submitted by United to
4 CMS for risk adjustment by analyzing United's IRADS
5 and EDPS data?

6 A We're talking just about his analysis of
7 what codes were submitted irrespective of whether
8 they link to Chart Review?

9 Q Yeah.

10 A Generally I understand that he was looking
11 at the same sorts of data that I was.

12 Q And you're not offering an expert opinion
13 that Dr. Garthwaite did that part incorrectly, are
14 you?

15 MR. JONES: Objection. Form.

16 A Again, I don't think that my opinions go
17 down to that level of detailed mechanics. So I
18 didn't seek to identify where he may have gotten
19 that wrong.

20 I do point out, I think as I described his
21 methodology, some of the assumptions inherent in
22 that process, but I haven't expressed specific
23 expert opinions as to the degree to which he may
24 have gotten it wrong.

25 BY MR. MASON:

1 Q And you're familiar with the methodology
2 that Dr. Garthwaite used to identify which diagnosis
3 codes were recorded by Chart Review coders in the
4 Chart Review databases?

5 MR. JONES: Objection. Form.

6 A Yes, generally I'm -- I'm familiar with
7 how he did that.

8 BY MR. MASON:

9 Q And have you analyzed whether the
10 diagnosis codes that Dr. Garthwaite identifies as
11 found in Chart Review were, in fact, recorded in the
12 Chart Review databases?

13 MR. JONES: Objection. Form.

14 A Again, not a question that I sought to
15 answer for purposes of my expert report; so I don't
16 have an opinion on that.

17 BY MR. MASON:

18 Q Okay. So you're -- you don't have an
19 expert opinion that Dr. Garthwaite misidentifies or
20 makes an error in identifying the diagnosis codes
21 that the Chart Review coders found?

22 A I haven't expressed an opinion on that.

23 You know, again, I'd say that, you know, I
24 think he had to employ a number of significant
25 assumptions in that process, but I haven't sought

1 exhaustively to rebut those assumptions or formed
2 a -- or expressed a particular expert opinion about
3 the extent to which those assumptions may drive his
4 calculations.

5 Q And you're not offering an expert opinion
6 that -- that any of the diagnosis codes that he
7 identifies as found in Chart Review -- that -- that
8 he made any errors in identifying codes that were
9 found in Chart Review?

10 A I haven't expressed opinions, one way or
11 the other. So it shouldn't be meant to -- to
12 suggest that I agree --

13 Q That's --

14 A -- with him. It's -- but I have not
15 expressed direct opinions saying that I disagree
16 with those -- those analyses.

17 Q Sorry for interrupting.

18 Fair point. I'm not trying to put words
19 in your mouth. I'm just trying to close off, like,
20 what you did and did not analyze. So I'm not
21 trying to suggest that you have agreed with
22 Dr. Garthwaite on any of these things. I'm just
23 trying to understand and make sure that I understand
24 what you have and haven't opined on.

25 So when I say you don't have an expert

1 opinion on something, I'm not -- I'm not suggesting
2 that you have an expert opinion that it's correct.
3 Okay?

4 A Okay. No. That's fair and I appreciate
5 that. I also just want to make sure --

6 Q Yeah.

7 A -- the record is clear after the fact --

8 Q Sure.

9 A -- so --

10 Q You have a familiarity with the
11 methodology that Dr. Garthwaite used to compare the
12 diagnosis codes that United submitted associated
13 with the provider claim to the diagnosis codes that
14 United chart reviewers found in a Chart Review of
15 the corresponding chart; right?

16 A Again, he employs a bunch of assumptions
17 in there; so I don't want to say that -- that
18 there's a definitive way of knowing which chart --
19 which diagnoses were actually reviewed in Chart
20 Review, but I have not expressed opinions about the
21 mechanics of his specific analyses in that regard.

22 Q You don't have an expert opinion that
23 Dr. Garthwaite performed that comparison
24 incorrectly?

25 MR. JONES: Objection. Form.

1 A Well, I have not expressed opinions on
2 that, one way or the other.

3 BY MR. MASON:

4 Q Are you familiar with how -- are you
5 familiar with the fact that FTI supported United in
6 execute -- or implementing the claims verification
7 program?

8 MR. JONES: Objection. Form. Foundation.

9 A Actually, I don't think I was aware of
10 that, no.

11 BY MR. MASON:

12 Q Do you know what the claims verification
13 program is?

14 A I do.

15 Q Can you just describe it at a high level.

16 A Sure. At a high level, it was a program
17 that was in effect from 2011 to 2012, I believe, in
18 which the intent was to try to identify what I think
19 United referred to as exclusive codes that had gone
20 through Chart Review and not been independently
21 identified in the course of that chart review. That
22 was the subjective intent.

23 I think the -- I further understand that
24 the implementation of that was -- was difficult and
25 not always precise, but that's, at a high level, my

1 that leads you to believe that.

2 MR. JONES: Objection. Form.

3 A So I'm looking at -- as one example, I'm
4 looking at Paragraph 6 of my initial report from
5 December 3rd: The first interrogatory requested
6 that the government identify certain information
7 related to each and every diagnosis code the
8 government alleges United knowingly and improperly
9 failed to delete or otherwise return to Medicare --
10 to the Medicare program as an overpayment.

11 And then the government produced data
12 tables comprising of approximately 28 million
13 records of data.

14 That's one example.

15 BY MR. MASON:

16 Q And that doesn't say anything about the
17 methodology that the government used to compile the
18 diagnosis codes on the first interrogatory response,
19 does it?

20 MR. JONES: Objection. Form. Misstates
21 the testimony.

22 A So I'm not -- I don't know what other way
23 the government could have done that, but to try to
24 come up with some way of matching datasets to figure
25 out which charts may have been subjected to Chart

1 Review and which codes from those charts may have
2 been identified or not identified by chart reviewers
3 and which chart -- and which codes had or had not
4 been deleted.

5 I mean, there is some sort of matching
6 mechanism that I believe has to be inherent to that
7 process and that would be consistent with my
8 understanding of all the data requests and the data
9 that was produced.

10 If you're telling me that there was some
11 other way the government did that, okay. But I --
12 you know, the government hasn't disclosed its
13 methodology for compiling the first interrogatory
14 response, but from everything I've seen I believe
15 that's how it had to have been done in some form or
16 fashion.

17 BY MR. MASON:

18 Q So just to make sure that we're clear on
19 the record, you don't have any knowledge of the
20 methodology that the government used; right?

21 A The government --

22 MR. JONES: Objection.

23 A -- has not disclosed its methodology.

24 BY MR. MASON:

25 Q So therefore you don't have any knowledge

1 of how the -- how the codes on Interrogatory Number
2 1 were compiled; right?

3 MR. JONES: Objection. Form. Misstates
4 the testimony.

5 A You know, I -- I have my insights based on
6 my understanding of the data and the objective of
7 the exercise and the way the government has
8 characterized it. I have not seen anything from the
9 government that says, this is exactly how we did it.

10 BY MR. MASON:

11 Q And those insights are that the only way
12 to answer this question being asked in Interrogatory
13 Number 1 would be to evaluate through matching data
14 elements what charts went through Chart Review and
15 identify what codes were submitted based on provider
16 claims that weren't subsequently found in Chart
17 Review?

18 MR. JONES: Objection. Form. Misstates
19 the testimony.

20 A I'm saying it's the only way that I can
21 discern the government could have come up with the
22 FIR, based on the information that's been produced.

23 BY MR. MASON:

24 Q Just going back to how you've written it
25 here in the Opinion 1 section on Page 8 of your

1 rebuttal report. Do you see the sentence that
2 begins with specifically?

3 A I do.

4 Q Specifically, the data available from
5 CMS's RADV audits in payment years 2011 to 2015
6 shows that 91 percent of the diagnosis codes in the
7 government's first interrogatory response -- which
8 are diagnosis codes the government alleges should
9 have deleted -- United should have deleted as
10 overpayments because they were not found in Chart
11 Review -- mapped to health conditions that were
12 confirmed to be supported by the government in the
13 RADV audits.

14 Did I read that correctly?

15 A You read that correctly.

16 Q And the way that you've written this,
17 you've said that the RADV data shows that 91 percent
18 of the diagnosis codes on the government's first
19 interrogatory response map to health conditions that
20 were confirmed to be supported by the government in
21 RADV audits; right?

22 A Yes, that is what it says there. I think
23 I make the basis for that 91 percent clearer in the
24 subsequent paragraphs of the report itself, which
25 makes clear that what I'm referring to is the codes

1 from the FIR that overlap with RADV audits.

2 Q Right. What you've referred to as the
3 RADV overlap?

4 A Correct.

5 Q So this 91 -- as it's written, this isn't
6 quite correct; right?

7 MR. JONES: Objection. Form.

8 BY MR. MASON:

9 Q When I say this, I mean the -- the last
10 sentence in your Opinion 1.

11 MR. JONES: Objection. Form. Misstates
12 the testimony.

13 A I think the basis of the opinion becomes
14 clearer, but I -- I agree that it would be clearer
15 in this bolded section of Opinion 1 if it said 91
16 percent of the diagnosis codes in the government's
17 first interrogatory response which overlapped with
18 the RADV audits, and then continued on from there.

19 BY MR. MASON:

20 Q And -- and we'll talk about this later,
21 but I -- I think we're going to -- you're using
22 shorthand, and I've used it to, what you referred to
23 as the RADV overlap. Can you explain what you mean
24 by a RADV overlap.

25 A Sure. Those would be diagnosis codes that

1 are included in whatever relevant body of diagnosis
2 codes we're talking about, whether it's the FIR or
3 the Garthwaite deletes, that map to HCCs that were
4 reviewed by auditors as part of the RADV audit
5 program, which was in effect across -- or for which
6 we have relevant data across five years from the
7 audit years 2011 through 2015.

8 Q So the diagnosis codes on the first
9 interrogatory response and the Garthwaite's delete
10 list are diagnosis code instances; right?

11 A Yes. The --

12 MR. JONES: Objection. Form.

13 THE WITNESS: I apologize.

14 A Yes. The individual line items in the FIR
15 or in the Garthwaite deletes are expressed as
16 diagnosis codes, that's right.

17 BY MR. MASON:

18 Q But they're not just the diagnosis codes.
19 They're the instances of the diagnosis codes.

20 In other words, the corresponding date of
21 service, provider information, et cetera.

22 A So --

23 MR. JONES: Objection. Form.

24 A Yes. So they are expressed as instances
25 of a given diagnosis code. There's multiple fields

1 there: Member, provider, year, and I think HCC as
2 well.

3 BY MR. MASON:

4 Q And so it's not that -- it's not that that
5 whole -- that that specific diagnosis code instance
6 was reviewed in RADV. It's just that the specific
7 diagnosis code itself maps to an HCC that CMS RADV
8 audits analyzed?

9 A The -- the basis of the RADV audits was
10 the HCC. And so -- yes, so when we're looking at
11 what the RADV auditors reviewed, they reviewed at
12 the HCC level. And I have linked the diagnoses from
13 the different lists to those HCCs to identify which
14 diagnoses mapped to the HCCs that were reviewed by
15 the RADV auditors.

16 Q I think I'm asking this question in a way
17 that's not clear; so I -- I'm going to try again.
18 I'm sorry.

19 What's set forth on both the first
20 interrogatory response and the Dr. Garthwaite delete
21 list are not just diagnosis codes; right? They're
22 rows that include a diagnosis code, a date, a
23 provider, a member, a specific instance of a
24 diagnosis code that United submitted to CMS; right?

25 A Generally speaking, yeah, that's a fair

1 characterization.

2 Q And when you say that there's a RADV
3 overlap, just to be clear, you're not saying that --
4 that that entire -- or that exact diagnosis code
5 instance -- the date of service, the provider, that
6 encounter that's associated with all of that -- was
7 reviewed in RADV; right?

8 MR. JONES: Objection. Form.

9 A Yeah, what I'm saying is that those
10 diagnoses mapped to an HCC that was reviewed by the
11 RADV auditors.

12 And -- yeah, so that's right.

13 BY MR. MASON:

14 Q Okay. You're not offering an opinion that
15 that 91 percent rate that you've calculated at which
16 you -- you've concluded that the RADV overlap
17 resulted in finding a validation of the HCC --
18 you're not offering an expert opinion that that rate
19 should apply to the entire population of the first
20 interrogatory response, are you?

21 A Well, certainly not as a statistical
22 matter. I'm not saying that that 91 percent rate
23 can be extrapolated out to any full population of
24 claims or of diagnoses.

25 The way I'm using the RADV information,

1 you know, in particular here is as rebutting the
2 presumption that diagnosis codes not independently
3 identified by a chart reviewer were necessarily
4 unsupported.

5 Q Okay. And, likewise, you're not offering
6 an expert opinion that the 55 percent that you
7 calculated for the Garthwaite RADV overlap should be
8 applied to the entire population of the Garthwaite
9 delete list; right?

10 A Again, I'm using that principally to rebut
11 Dr. Garthwaite's presumption that the codes on his
12 delete list were necessarily unsupported.

13 Q So you agree then that you're not offering
14 an expert opinion that the 55 percent rate that you
15 calculated for the Garthwaite delete list should be
16 applied across the entire Garthwaite delete
17 population?

18 A Well, when you say should be applied, I
19 mean, I think it's -- as I've, I think, termed it in
20 my report -- it's an instructive basis on which to
21 think about that grouping, but it's not a
22 statistically valid extrapolable [sic] rate that
23 you could say with any sort of mathematical
24 confidence reflects, you know, anything about the
25 larger population of Garthwaite deletes.

1 Q If one were to opine that the validation
2 rate of 55 percent from the Garthwaite RADV overlap
3 that you calculated should be applied to the entire
4 Garthwaite delete list, then that would also mean
5 that 45 percent of the diagnosis codes on
6 Garthwaite's list map to member-HCC combinations
7 that would not be validated in RADV; right?

8 MR. JONES: Objection. Form.

9 A Well, as I've said, I don't think the RADV
10 overlap can statistically or mathematically be
11 extrapolated to any population, which means just as
12 I wouldn't assert that that means that some certain
13 percentage of the codes are supported, it would be
14 inappropriate to conclude that that definitively
15 means that some certain percentage of the codes were
16 not supported. And that's -- I think that's
17 important.

18 Nonetheless, my view, just based on what
19 we have in the RADV overlap, that some of the HCCs
20 to which the questioned diagnoses map were found to
21 be validated definitively rebuts Dr. Garthwaite's
22 presumption that the codes on his list are
23 necessarily unsupported, but you can't do the
24 converse and say, and here's the percentage that is
25 or is not supported.

1 I think the other thing I would just throw
2 in there is that the RADV results, you know, are
3 also subject to appeal. So we don't know whether or
4 to what extent the RADV audit findings might be
5 changed by appeals that United might pursue, and I
6 haven't seen that data.

7 BY MR. MASON:

8 Q In your experience, is 45 percent of a
9 RADV audit not validating considered high?

10 MR. JONES: Objection. Form. Foundation.
11 Misstates the testimony.

12 A I don't -- I don't think there's enough
13 information here to make a judgment about that, one
14 way or the other.

15 I mean, at some level, right, if you did
16 enough work, you could find a population that had an
17 error rate of 100 percent, right, if you went all
18 the way through and did everything you needed to do.
19 That, to me, probably isn't the relevant way to
20 think about an error rate and there's not an
21 absolute standard as to what sort of error is too
22 high or not high enough. There's judgment inherent
23 in those determinations.

24 So I don't have a clear answer for you on
25 that.

1 BY MR. MASON:

2 Q You said a minute ago if you did
3 everything you needed to do you could find a
4 population with 100 percent. Can you explain what
5 you meant by that.

6 MR. JONES: Objection. Form. Misstates
7 the testimony. Incomplete hypothetical.

8 A Sure. So conceptually if you took a group
9 of -- well, let's just say, you know, emergency
10 department admissions and you did a 100 percent
11 thorough audit of every admission and you -- or on
12 every encounter and you ended up finding 20 that
13 were coded incorrectly. The error rate associated
14 with those 20 is 100 percent. Those 20 may be a
15 small percentage of the body that you looked at.

16 So as a framing device, there's 100
17 percent error rate associated with 20, but if that's
18 out of 100,000 emergency department encounters, say,
19 that's a -- I would probably -- you know, again in
20 my hypothetical -- characterize that as a low error
21 rate.

22 But as you tighten the lens, you can
23 artificially construct smaller and smaller
24 subpopulations that would logically have higher and
25 higher error rate percentages.

1 So the framing, I think, is important.

2 MR. MASON: Okay. You know what? This is
3 a decent breaking spot. Why don't we go off the
4 record?

5 THE VIDEOGRAPHER: We are going off the
6 record. The time is 12:06 p.m.

7 (Recess taken from 12:06 p.m. to 1:19
8 p.m.)

9 THE VIDEOGRAPHER: We are now back on the
10 record. The time is 1:19 p.m.

11 BY MR. MASON:

12 Q Good afternoon, Mr. Renjilian.

13 When we left off before lunch, we were
14 discussing your Opinion 1 in your rebuttal report;
15 right?

16 A Right.

17 Q And I'd like to pick up there,
18 specifically discussing your opinions regarding the
19 diagnosis codes in the RADV overlap that, as you put
20 it, were validated in RADV. Okay?

21 A Okay.

22 Q And when you say that a diagnosis code
23 is -- was validated in RADV, what you mean is that
24 the RADV of the member-HCC combination that maps to
25 the same as the diagnosis code in the RADV

1 overlap -- that that RADV found some diagnosis that
2 maps to the same HCC. Did I get that right?

3 A I think so, yeah. So what -- what I mean,
4 just to rephrase, is that the HCC to which a
5 diagnosis mapped was a HCC that was validated by the
6 RADV auditor. So in that circumstance, in my
7 tallies on a diagnosis basis, I -- I think I sort of
8 shorthand described that as a validated diagnosis.

9 Q And so a diagnosis code can be validated
10 under those terms in RADV by any diagnosis code that
11 maps to the same HCC; right?

12 A Yes. It's really saying that the HCC is
13 validated, because we don't know specifically what
14 diagnosis the RADV auditor looked at. And they
15 wouldn't necessarily look at all of the diagnoses.
16 They would stop when they got to one that supported
17 the HCC.

18 Q Okay. And so RADV does not actually
19 assess whether the specific diagnosis codes
20 submitted by an MAO are supported by medical
21 records?

22 MR. JONES: Objection. Form.

23 A Yeah. I don't think we know, one way or
24 the other, which specific diagnosis was found by the
25 RADV auditors to be supported, but it's just that

1 the HCC was supported. And therefore then in my
2 analysis any of those diagnoses that I sort of
3 describe as validated had no payment impact and, you
4 know, couldn't have affected the -- the -- the risk
5 scoring of the -- of the member affected.

6 BY MR. MASON:

7 Q And there are multiple diagnosis codes
8 that map to each of the HCCs in the CMS-HCC model;
9 right?

10 A Certainly at least for most. I don't
11 remember if every one of them has multiple, but
12 probably so.

13 Q Sometimes hundreds of diagnosis codes that
14 map to the same HCC?

15 A There can certainly be many.

16 Q And so RADV does not assess whether the
17 specific diagnosis code that the MAO submitted was
18 supported?

19 MR. JONES: Objection. Form. Misstates
20 the testimony.

21 A Again, the RADV audit is focused on the
22 condition level -- on the HCC and the condition code
23 and -- and they are looking at the diagnoses
24 underneath that, but we don't know from the data
25 which specific diagnosis the RADV auditors may have

1 What I'm looking at is the impact of the
2 codes that were submitted and that are alleged here
3 to have been problematic.

4 BY MR. MASON:

5 Q Okay. But I'm just trying to see if you
6 agree that it's possible for a code that is
7 validated at the RADV -- in a RADV audit or
8 validated at the HCC level, as you're putting it,
9 to -- nevertheless, that specific diagnosis code is
10 not adequately documented in the medical record from
11 the face-to-face encounter that it's associated
12 with?

13 MR. JONES: Objection. Form. Asked and
14 answered. Calls for a legal conclusion.

15 A It is certainly possible, for example, if
16 multiple codes were submitted that all mapped to the
17 same HCC, that some of those weren't supported.

18 That's certainly possible. It's not
19 something I've evaluated. Well, it's certainly
20 possible and I don't know that it's relevant to my
21 conclusions, but it's certainly possible.

22 BY MR. MASON:

23 Q Okay. And so it would be incorrect to
24 state that the RADV results confirmed that the
25 specific diagnosis codes that the MAO submitted were

1 documented in any medical record; right?

2 MR. JONES: Objection. Form. Asked and
3 answered.

4 A We can't know or don't know which specific
5 diagnoses the RADV auditors reviewed to get to their
6 conclusion that a given HCC was supported; so we
7 don't know, one way or the other.

8 What we can say is that diagnoses that map
9 to an HCC that was found to be validated by the RADV
10 auditors is either supported or had no impact.

11 BY MR. MASON:

12 Q Can you say that again.

13 A Sure.

14 Q What we can say is?

15 A We can say that for all of the diagnoses
16 that map to an HCC that was validated by the RADV
17 auditors -- those codes were either supported or
18 they had no impact.

19 Q When -- when you say they had no impact,
20 that's -- that's not true in terms of the impact to
21 the CMS payment process; right?

22 MR. JONES: Objection. Form. Asked and
23 answered.

24 A It is completely true.

25 You only need one code -- one diagnosis

1 that maps to a given HCC in order for that HCC to be
2 calculated within CMS's system.

3 BY MR. MASON:

4 Q Right.

5 A If you submitted five codes that map to
6 the same HCC and four of them turned out to have
7 been a problem for some reason, if the fifth one is
8 okay, the other four didn't have an impact --

9 Q What if you only --

10 A -- on that calculation.

11 Q But what if you only submitted one
12 diagnosis code?

13 MR. JONES: Objection. Form. Asked and
14 answered.

15 A And I think that's a different
16 hypothetical. We were talking about a hypothetical
17 where the HCC has been validated, but we don't know
18 which diagnosis code.

19 If -- is your question what happens if a
20 diagnosis code that uniquely supports an HCC was
21 determined definitively to be incorrect, would that
22 affect the payment model of CMS? Is that your
23 question?

24 BY MR. MASON:

25 Q Well, go ahead and answer that one.

1 MR. JONES: Objection. Form. Incomplete
2 hypothetical.

3 A So within the confines of the -- the RAPS
4 and RAS model and without considering things like
5 the impact of unsubmitted but supported codes and
6 all of that and what actually constitutes an
7 overpayment, which are a couple of other levels of
8 consideration here -- strictly within the mechanics
9 of the model, if a single diagnosis code uniquely
10 supported an HCC and that diagnosis code was
11 definitively determined not to be supported or to be
12 inappropriate, then re -- the removal of that
13 diagnosis code would presumably affect the risk
14 calculation score that comes out of CMS's system.

15 BY MR. MASON:

16 Q And that answer could hold true even if a
17 RADV found the HCC that that diagnosis code maps to
18 as supported by some other chart?

19 MR. JONES: Objection. Form. Asked and
20 answered.

21 A No. Because in that scenario that code
22 wouldn't have mattered. That diagnosis wouldn't
23 have mattered, because if that diagnosis maps to the
24 HCC and there's another supported diagnosis that
25 maps to that HCC, the HCC is supported and therefore

1 the problematic code couldn't have had an impact.

2 BY MR. MASON:

3 Q But in the CMS payment model there's no
4 opportunity to add additional diagnosis codes that
5 were unsubmitted after the final submission
6 deadline?

7 A I don't think that's --

8 MR. JONES: Objection.

9 A -- what we're talking about. I think
10 we're talking --

11 THE COURT REPORTER: Was that an
12 objection?

13 THE WITNESS: I'm sorry.

14 MR. JONES: Objection. Form.

15 A I think we were talking about a scenario
16 where multiple codes support an HCC or multiple
17 codes were submitted and -- I'm sorry.

18 Please clarify your question, because I
19 think we got something lost there.

20 BY MR. MASON:

21 Q Why don't we come back to that?

22 A diagnosis code can be validated in RADV
23 by any medical record that's presented by the MAO
24 for RADV; right?

25 A You mean an HCC can be validated?

1 Q Fair enough.

2 A Yes. So an HCC can be validated by any of
3 the -- I think up to five different records that a
4 MAO may provide to the RADV auditors.

5 Q You -- you object to the phrase a
6 diagnosis code being validated in RADV?

7 MR. JONES: Objection. Form.

8 A Well, what I'm saying is that submissions
9 aren't made to support individual diagnoses
10 necessarily. Support -- submissions are made to
11 support the HCC, because the level at which the RADV
12 audit is being performed.

13 BY MR. MASON:

14 Q But you consider a diagnosis code to be
15 validated in RADV if RADV auditors find any other
16 diagnosis code that maps to the same HCC; right?

17 MR. JONES: Objection. Form. Asked and
18 answered.

19 A Yeah. I tried to be clear on what my
20 calculations are saying. They're saying that when
21 I'm calculating what we've called a validation rate
22 at the diagnosis code level, if the HCC to which the
23 diagnosis maps is validated, then I count that in
24 that rubric as a validated diagnosis.

25 I'm not saying that that specific -- any

1 specific diagnosis code from a specific provider on
2 a specific date was validated.

3 What I'm saying is that either all of
4 those diagnoses were supported or had no impact on
5 payment.

6 BY MR. MASON:

7 Q Okay. So CMS allows MAOs to go and
8 investigate all of the members' medical records for
9 the whole year and submit up to five medical records
10 that the MAO believes supports the HCC; right?

11 MR. JONES: Objection. Form.

12 A That's generally consistent with my
13 understanding. Again, not something I studied in
14 detail, but that sounds right.

15 BY MR. MASON:

16 Q Even if none of those medical records are
17 associated with any RAPS submission that the MAO
18 made?

19 MR. JONES: Objection. Form. Asked and
20 answered.

21 A Yes. My understanding is that the MAO can
22 support -- can submit any medical records in support
23 of the HCC and they don't necessarily need to relate
24 to a specific diagnosis that was submitted. So
25 there could be another record that supports an

1 unsubmitted diagnosis code that gets submitted by
2 the MAO and therefore yields a validated HCC from
3 the RADV auditors.

4 BY MR. MASON:

5 Q So it's possible to be validated in RADV
6 even if no diagnosis codes that map to that HCC were
7 adequately documented in the specific medical record
8 that was associated with the RAPS submission?

9 MR. JONES: Objection. Form. Asked and
10 answered.

11 A It is possible that -- that a RADV auditor
12 considers a record that is not associated with a
13 submitted diagnosis code and finds that record to
14 support the HCC.

15 BY MR. MASON:

16 Q And did you do anything to analyze whether
17 the RADV audits that you reference in your opinion
18 made any finding about the specific medical record
19 from the face-to-face encounter associated with
20 United's submission to CMS?

21 A As I think we've discussed, we can't know
22 which specific diagnosis codes the RADV auditors
23 looked at. What I know is that the RADV auditors
24 validated the HCC.

25 Q Sorry. No. I'm not asking about which

1 specific --

2 A Oh.

3 Q -- diagnosis code here.

4 I'm asking about --

5 A Sorry.

6 Q -- which specific medical record.

7 So my question is: Did you do anything to
8 analyze whether the RADV audits that you reference
9 in your opinion made any finding about the specific
10 medical record from the face-to-face encounter that
11 was associated with United's submission to CMS?

12 A I have not looked at the medical records
13 that the HCC -- I'm sorry -- that the RADV reviewers
14 reviewed at all. I mean, that's really not relevant
15 to my analysis.

16 Q Okay. So you haven't looked at the
17 medical records; right?

18 A That's correct, yeah, nor has
19 Dr. Garthwaite.

20 Q But have you done anything to analyze
21 whether the RADV audits that you reference in your
22 opinion made any finding about the specific medical
23 record from the face-to-face encounter associated
24 with United's submission to CMS?

25 A I haven't looked on a specific basis. I

1 have to conclude that the RADV auditors saw a
2 medical record that they agreed supported the HCC.
3 I don't know which one they saw.

4 Q You don't know which one they saw and so
5 you don't know whether it was the same -- whether it
6 was the same one that was associated with United's
7 submission?

8 MR. JONES: Objection. Form.

9 A There could be dozens that were associated
10 with United's submission. So I don't know which one
11 you're talking about when you say one.

12 BY MR. MASON:

13 Q But you don't even know if it was any of
14 those dozens?

15 A That's correct. I -- as I've said, I
16 don't know which medical record the RADV auditors
17 relied on to conclude that the HCC was supported.

18 And, again, that wasn't relevant to my
19 analysis which is really about whether or not these
20 diagnoses had any payment impact.

21 Q And so you're not making an opinion
22 that -- you're not offering an expert opinion that
23 the RADV results show that United's chart reviewers
24 missed codes that were actually supported by the
25 charts that they were looking at; right?

1 MR. JONES: Objection. Misstates the
2 testimony. Form.

3 A Yeah. I don't think I know on that front.
4 I know that the RADV auditors found codes that were
5 supported but not submitted. I don't know the
6 extent to which those may have been ones that were
7 on charts that were reviewed as part of chart
8 review.

9 BY MR. MASON:

10 Q So it could be that the chart reviewers
11 didn't miss anything on the chart that they
12 reviewed, but that RADV reviewers found it on some
13 other chart?

14 A I think that's one possibility.

15 Q Okay. And you don't know -- it's one
16 possibility and you don't know, one way or the
17 other, whether it's correct?

18 MR. JONES: Objection. Form.

19 A Yeah. I don't think anybody knows which
20 charts the RADV -- I'm sorry -- yeah -- the RADV
21 auditors reviewed and -- and concluded on.

22 BY MR. MASON:

23 Q And you've also mentioned, I think a
24 couple of times, that RADV accounts for or credits
25 MAOs for additional supported and unsubmitted HCCs

1 that they identify in the charts that they look at
2 in RADV; right?

3 A Yes, that's right.

4 Q You agree that that's not part of the CMS
5 payment process; right?

6 MR. JONES: Objection. Form. Asked and
7 answered.

8 A When you say CMS payment process, can you
9 just be more specific what you mean there?

10 BY MR. MASON:

11 Q I'm referring to the process by which
12 we -- that we discussed earlier today by which CMS
13 pays monthly payments to MAOs based on the diagnosis
14 data and demographic information that MAOs submit to
15 CMS for risk adjustment.

16 A To my knowledge, the -- the mechanics of
17 that system do not consider diagnoses that haven't
18 been submitted. But I do think that the RADV
19 findings with respect to supported but unsubmitted
20 diagnoses and their related impact is relevant to an
21 evaluation of whether an MAO has been paid too much.

22 Q And so the question you were assessing was
23 not how would -- the payments had been computed
24 differently had the diagnosis codes that were
25 unsupported been deleted, understanding you have

1 about to make sure that we get to the right
2 determinations on those.

3 BY MR. MASON:

4 Q So walk me through how that -- how that
5 works.

6 A I think I just did. Sorry. That's the --

7 Q Oh, can you add any more specificity to
8 how -- to how -- how that process ultimately arrives
9 at a conclusion whether the provider -- the codes
10 recorded by the provider are documented or
11 supported?

12 A Sure. And, again, I -- I thought I
13 covered this.

14 But so -- you know, as one example, if I
15 have the parallel review process: One coder looks
16 at it; another coder looks at it. It may be the
17 case that one coder says, I don't think this code
18 was supported. And the other one thinks that was
19 supported.

20 In that circumstance then I would convene
21 the coders and say, let's -- you know, let's go
22 through the medical record as a group and let's
23 figure out, you know, why one of you found it and
24 one of you didn't, to make sure that we've actually
25 got it right.

1 And then through that process -- with me
2 essentially as facilitator, but not as coder -- we
3 would reach the conclusion as to whether or not the
4 code that we were reviewing was actually supported.

5 MR. MASON: Okay. Good time for a break.
6 Why don't we go off the record here?

7 THE VIDEOGRAPHER: We are going off the
8 record. The time is 3:19 p.m.

9 (Recess taken from 3:19 p.m. to 3:44 p.m.)

10 THE VIDEOGRAPHER: We are now back on the
11 record. The time is 3:44 p.m.

12 BY MR. MASON:

13 Q Mr. Renjilian, before the break we were
14 talking about your experience supervising teams and
15 conducting inter-rater reliability.

16 A Yes.

17 Q Is that -- am I saying that right?

18 A You are, yes.

19 Q When you -- in your experience in IRR --
20 can I call it that?

21 A Sure.

22 Q Are -- are the reviews being done blind?

23 MR. JONES: Objection. Form. Foundation.

24 A So there -- there are going to be sort of
25 different approaches, but one of the approaches I

1 discussed was -- I think what I would characterize
2 as a blind approach to the extent that I would have
3 two different reviewers independently reviewing the
4 same record and then comparing the results that they
5 each independently came up with. And that's one of
6 those quality control techniques that I utilized.

7 BY MR. MASON:

8 Q Okay. And you mentioned that if those
9 reviewers disagree, then you have a process for
10 convening them together and working out the
11 disagreement; right?

12 A Correct.

13 Q And if both of them agree that a code is
14 supported, what happens?

15 A Then we would conclude that it was
16 supported.

17 Q And if neither of them record a code is
18 supported, what happens?

19 A Then we would conclude that -- that
20 whatever the code is and whatever kind of claim
21 is -- is not supported or --

22 Q Without any other steps?

23 MR. JONES: Objection. Form.

24 A Again, I'm speaking in general terms.

25 There -- there can be other steps, you

1 know, in theory.

2 So, for example, if we presented the
3 interim results of our work to the client and the
4 client said, well, hold on a second, you know, that
5 can't be right, or, look, we found in this cabinet
6 another medical record.

7 That kind of thing could get considered in
8 the process as well.

9 But, yeah, generally speaking, part of the
10 point of that kind of parallel process is that if
11 they both agree on a finding, you can be pretty
12 comfortable that that's the appropriate finding and
13 if they disagree, you need to figure that out.

14 BY MR. MASON:

15 Q We're still in your rebuttal report. I'd
16 like to go to Paragraph 37. You say: The notion
17 that valid diagnosis codes can nonetheless be missed
18 by Chart Review coders is further supported by
19 the --

20 And then you refer to the RADV
21 underpayments; right?

22 A Yes, yeah. That's a summary of the -- of
23 that first couple of lines of Paragraph 37.

24 Q And can you identify any result from the
25 RADV overlap that shows that a Chart Review coder

1 A This was the publicly disseminated result
2 of their audits.

3 Q Your understanding is that these results
4 were publicly disseminated?

5 A Well, I know that they were reflected
6 within a RADV audit summary that -- that I have
7 referenced in my report. I don't actually recall
8 whether that was generally publicly available,
9 available only through a FOYA request. I don't
10 recall exactly how it was obtained.

11 Q Why -- why did you refer to it as publicly
12 disseminated?

13 A Well, I apologize if that's a
14 misstatement. My understanding was that that
15 information is available and it's been incorporated
16 into my work.

17 Q Okay. So your understanding is that this
18 was a finding by CMS?

19 A Yes, that the results of their RADV audits
20 showed that 13 of those 15 contracts had negative
21 net recovery amounts or negative recovery amounts.

22 Q And do you have an understanding whether
23 that result was finalized by CMS?

24 MR. JONES: Objection. Form.

25 A I don't know what the current status is or

1 whether any appeals that United may have pursued
2 with respect to the findings of that -- of those
3 audits, you know, may also impact those results. So
4 I don't know.

5 BY MR. MASON:

6 Q You don't know that CMS considers those
7 preliminary results?

8 MR. JONES: Objection. Form.

9 A I do under -- I guess I do understand that
10 they are not final-final. My corresponding
11 understanding would be that they're not likely to
12 get worse from the MAO's perspective, but, rather,
13 that they are open to an appeal process that can be
14 initiated by the MAOs which may reverse some of the
15 adverse findings from those audits.

16 BY MR. MASON:

17 Q So let me just back up.

18 Do -- do you have an under --
19 understanding whether these results were finalized
20 by CMS?

21 MR. JONES: Objection. Form. Asked and
22 answered.

23 A I don't believe that they were
24 final-final.

25 BY MR. MASON:

1 whether the financial impact of deletes should be
2 offset by recalculating MLR remittances?

3 MR. JONES: Objection. Form.

4 A Not necessarily, because I think what
5 we're looking at here is, in some respects, a
6 but-for world.

7 So, in other words, modeling -- I think in
8 Dr. Garthwaite's work he's modeled what he believes
9 reimbursement might have looked like had these
10 things been deleted. And in that process, among
11 other things, as we discussed earlier, has taken
12 into account unsubmitted codes that were never
13 submitted, by definition, but that he's factored
14 those into his analysis because they could have been
15 taken into account at the time, had things
16 progressed the way he believes they should have
17 progressed.

18 So the basis for my MLR calculation here
19 is similar to say, you know, had all of that
20 happened, then also there would have been this
21 impact on the MLR calculation.

22 It's similar, I think, in many respects to
23 the work that he did around the risk corridors in
24 Part D, taking that into account in his work. So
25 this is predicated on the notion of if at the time

Video Deposition

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1 DISCLOSURE OF COURT REPORTER

2
3 Pursuant to Article 10.B of the Rules and
4 Regulations of the Board Of Court Reporting of the
5 Judicial Council of Georgia, I make the following
6 disclosures:

7 That I am not disqualified for a
8 relationship of interest under the provisions of
9 OCGA Section 9-11-28(c); that I am a Georgia
10 Certified Court Reporter; that I am a representative
11 of MLowe Reporting, LLC; that MLowe Reporting, LLC,
12 was contacted by Regency-Brentano, Inc. to provide
13 court reporting services for this deposition; that
14 all financial arrangements beyond the usual and
15 customary rates have been disclosed and offered to
16 all parties; and that I will not be taking this
17 deposition under any contract prohibited by Georgia
18 law.

19
20 This the 22st day of March 2024.

21
22 
23

24 MICHELLE LOWE, RPR, CCR-2748
25

EXHIBIT P-7

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

- - - - -X
:
UNITED STATES OF AMERICA, ex rel.:
BENJAMIN POEHLING, :
:
Plaintiff, :
:
Case No.
vs. : 2:16-cv-08697-FMO-SS
:
UNITEDHEALTH GROUP, INC., et al., :
:
Defendants. :
:
- - - - -X

VOLUME I
VIDEOTAPED RULE 30(b)(6) DEPOSITION OF
OPTUMINSIGHT, INC. AND UNITEDHEALTHCARE, INC.,
BY THEIR DESIGNEE, KATHLEEN O. BAKER

Washington, D.C.
May 30, 2023

Reported by:
Misty Klapper, RMR, CRR
Job No.: 982005

1 are you referring to?

2 A. UnitedHealthcare's risk adjustment
3 health plan members, Medicare Advantage health
4 plan members.

5 Q. And you're here today to testify
6 about certain aspects of Optum's chart review
7 program; is that right?

8 A. The retrospective chart review
9 program, yes.

10 Q. Okay. So broadly speaking, what is
11 Optum's retrospective chart review program?

12 A. Optum's retrospective chart review
13 program is a program where we submit a more
14 complete health status from medical records
15 collected on a member for appropriate payment
16 from CMS.

17 Q. Okay. So what is the purpose of
18 Optum's chart review program?

19 A. To submit more complete health
20 statuses to CMS on risk adjustment members.

21 Q. Okay. And what do you -- what do you
22 mean when you say more complete risk adjustment

1 MS. MADDUX: Objection,
2 mischaracterizes testimony.

3 THE WITNESS: As part of the
4 retrospective chart review program we have
5 quality assurance's programs that look at
6 what our coders code and ensure -- to
7 ensure or to work towards a 95 percent
8 industry standard, which is what we all
9 do.

10 BY MS. ZUPAC:

11 Q. A 95 industry -- a 95 percent
12 industry standard in terms of accuracy?

13 A. Correct.

14 Q. Okay.

15 A. For what our coders code.

16 Q. Okay. I just want to make sure that
17 we're operating under the same definition of
18 accurate.

19 What is -- what is Optum's
20 understanding of the term accurate?

21 A. For -- for -- well, it -- it would
22 vary. And if I could go to my --

1 And then once we get validation from
2 there, typically we either fax or we would secure
3 E-mail the complete list of the members. And
4 then, based upon the number, we'd work with them
5 to schedule either on site or they could
6 themselves decide to send us the charts them --
7 back because they don't want people -- or they
8 wouldn't want somebody on site or various
9 permutations of that.

10 Q. Okay. And prior to this retrieval
11 process that you just described, there is a chart
12 targeting process, correct?

13 A. Correct.

14 Q. Okay. So Optum began by targeting
15 certain charts to pull, correct?

16 A. Began chart review?

17 Q. Yes.

18 A. We would -- actually, as part of the
19 targeting -- targeting was one of the first
20 steps, yes, not the -- not the first, first step,
21 because there's suspecting that you have to do
22 and then out of suspecting you go into targeting.

1 But, yes, it was part of that.

2 Q. Okay. So we can actually go
3 backwards in time.

4 You mentioned that the first step
5 that Optum did was suspecting.

6 A. Um-hmm.

7 Q. And what is suspecting?

8 A. You know, part of suspecting was just
9 taking a look at the whole universe of -- of
10 members. And so you think about that, it's like
11 the whole universe and then targeting as you're
12 picking specific ones, right?

13 And so, like, from a suspecting
14 perspective, we'd take a look at information that
15 we have from CMS on -- on -- like, for instance
16 from the MOR, the Model Output Report, or other
17 CMS documentation that would tell us what health
18 statuses a member has, had either in the prior
19 year or the current year.

20 We would look at lab information.
21 We'd look at medications. We'd look at encounter
22 information or claims information if we had it,

1 knowing that, again, this information, especially
2 if it comes from an MOR, could have come from
3 other health plans, right, because the member
4 could have not been in our health plan the prior
5 year.

6 You know, we take a look at
7 information such as, like, disease management
8 programs that our members belong to. So, like,
9 you know, if someone was in diabetes, they would
10 probably be in a diabetes program; cancer, an
11 oncology program. You know we take a look at
12 certain information like that.

13 And then, you know, as we look at
14 information regarding the different types of --
15 of health statuses that member either previously
16 had or currently has or how they interact with
17 one another, we would then compare that to the
18 claims information that we would have.

19 Or, in some cases, if we didn't have
20 claims information -- because, again -- I mean,
21 again, we -- we may not -- get a capitated
22 provider, a provider that -- or somehow we don't

1 have information on that member, we may have just
2 made a request to a -- an assigned provider
3 panel, if that makes sense, patient panel to a
4 provider.

5 And then once we get to the universe
6 of what member-provider combinations there could
7 be, then we would go through a -- a -- you know,
8 a targeting process of saying okay, let's look
9 for these member-provider combinations based upon
10 health statuses, based upon their -- their health
11 risk status.

12 Q. Okay.

13 MS. ZUPAC: I'm going to pull up a
14 new exhibit, Tab 4. So this exhibit will
15 be marked 608.

16 (Exhibit 608 was marked for
17 identification.)

18 THE WITNESS: Thank you.

19 BY MS. ZUPAC:

20 Q. So this exhibit was produced in
21 native, so the individual slides don't have Bates
22 numbers. But the Bates number of the document is

1 of go, so that the question is not compound, and
2 talk about each one.

3 Generally speaking, I -- I'm trying
4 to ask whether or not Optum targeted charts for
5 outpatient provider visits, inpatient charts from
6 hospital admissions, nursing homes or any other
7 type of chart. So that's generally what I'm
8 getting at.

9 A. We would look at the CMS level
10 face-to-face encounter types, which are -- which
11 do include some of the examples that you just
12 gave or the examples that you just gave.

13 Q. Okay. So what's -- what -- what
14 types of visits specifically did the face-to-face
15 encounters include?

16 A. Physician encounters, in-office
17 encounters or provider encounters, let's say,
18 like if it's a nurse practitioner, and then,
19 like, hospital reviews like you were just
20 describing. Those are some of the examples.

21 Q. Are there any other examples that you
22 can think of?

1 from CMS.

2 Q. And we've been discussing Optum's
3 suspecting and targeting processes, correct?

4 A. Yes.

5 Q. Okay. Did -- did UnitedHealthcare,
6 Inc. -- was UnitedHealthcare, Inc. aware that
7 Optum was using suspecting logic to target
8 particular charts for retrieval?

9 A. We would have conversations with
10 UnitedHealthcare on the logic we would use and
11 targeting to make sure we were generally aligned.

12 Q. Okay. And did UnitedHealthcare, Inc.
13 sign off on or approve the suspect logic that
14 Optum used?

15 A. We would have conversations with them
16 and we would generally receive their approval on
17 the -- on the logic that we would deploy.

18 Q. Okay. And did Optum decide which
19 charts to target for retrieval based on their
20 chart score group?

21 A. Chart score group was a consideration
22 on doing retrievals, but it was not the only

1 consideration.

2 So, for instance, timing was a
3 consideration, like meaning -- the way the risk
4 adjustment program works, you have only until
5 January of the following year after the year that
6 the data collection period ended to submit that.
7 So you have about 13 months, you know, to submit
8 it.

9 And so with claims, if we're using it
10 for targeting and claims lag and -- and run out,
11 sometimes targeting wouldn't start until May of a
12 year and retrievals wouldn't start until summer.
13 So you had less time to do retrievals. Right?
14 So just the timing of things would have had a
15 consideration. Other things would have been
16 operational capacity.

17 So, you know, you could retrieve all
18 the charts you want, but if you can't code the
19 charts, then there's no -- you can't -- you can't
20 code them. And so we would also have to take a
21 look at seeing if we only had the ability to code
22 1,000 charts, you know, you know, which 1,000

1 does it make sense for us to look after.

2 And there could have been other
3 constraints, such as onshore/offshore
4 restrictions. So not all charts could be sent
5 offshore for coding. And so there is kind of
6 business rules that we had to take a look at, if
7 that makes sense.

8 So there's other things that we took
9 a look at as well.

10 Q. Um-hmm. The one thing you mentioned
11 is that Optum may have limited resources or
12 certain resources to code charts, correct?

13 A. We have -- we had operational
14 considerations when you're looking at it,
15 production plans and operational capacity plans,
16 yes.

17 Q. Okay. So did Optum use the chart
18 score group information as part of its
19 consideration for which charts to retrieve?

20 A. We -- chart score group was one of
21 the considerations, but not the only
22 consideration.

1 going to be 100 percent complete in what
2 they pick up.

3 BY MS. ZUPAC:

4 Q. And then with all the caveats that
5 you've mentioned on multiple answers, was it also
6 UnitedHealthcare, Inc.'s expectation that coders
7 working on its retrospective chart review
8 programs would code as accurately as possible?

9 MS. MADDUX: Objection, form,
10 asked and answered.

11 THE WITNESS: Can you maybe
12 restate?

13 MS. ZUPAC: Can you read back my
14 question.

15 (The record was read as requested.)

16 THE WITNESS: I'd say UHC's
17 expectations were aligned with Optum's
18 with the fact that, you know, we both knew
19 that, you know, theory versus practice,
20 100 percent is never going to be the case.
21 But for what we -- for what our individual
22 risk adjustment coders were doing in the

1 context of retrospective chart review,
2 that our program was designed to have what
3 they were coding to be at 95 percent or
4 above accuracy.

5 BY MS. ZUPAC:

6 Q. Okay. And both Optum and HCC,
7 under -- or sorry.

8 Both Optum and UHC understood that
9 the HCCs for members submitted to CMS were used
10 to determine risk adjustment payments to the
11 Medicare Advantage organization, correct?

12 MS. MADDUX: Objection, out of
13 scope.

14 THE WITNESS: The risk adjustment
15 model underlying it is health statuses
16 tied to HCCs for appropriate payment. But
17 not all HCCs submitted to CMS are there to
18 establish appropriate payment. I mean,
19 like when -- let me clarify that.

20 It's like you could send the same
21 HCC 15 times and not -- it -- it's only
22 one of those occurrence that matters. So

1 only worked in a paper and had not
2 navigated EM&R -- sorry -- EMR, so just
3 kind of, you know, various as a good
4 practice in terms of those types of sets
5 that we'd show to them.

6 BY MS. ZUPAC:

7 Q. And in order for coders going through
8 training to move into production, they had to
9 achieve certain chart audit or quality audit
10 standards, correct?

11 A. We would -- again, in terms of
12 retrospect chart review, release a coder into
13 production after they had demonstrated their
14 ability to meet or exceed that 95 percent
15 accuracy based upon what they coded.

16 Q. And that was true of all date of
17 service years from 2008 to 2016?

18 A. The 95 percent industry standard has
19 been in effect that time frame.

20 Q. But I'm specifically asking was it
21 always Optum's policy that coders had to meet a
22 certain quality standard before they could be

1 THE WITNESS: We required that our
2 coders be certified coders. And then from
3 there, we provided them training on risk
4 adjustment coding.

5 But every coder came with varying
6 degrees of -- of experience coding and
7 then experience coding diagnosis coding.
8 Right?

9 And so when a coder started with
10 us, they may have only done
11 fee-for-service coding and done CPT and
12 REV code coding, where they only have to
13 provide, like, the primary diagnosis code
14 or something like that in order for the
15 provider to get reimbursement. Or they
16 could have been a -- again, a coder like
17 I -- I described earlier, that was more
18 familiar with cardiology. Or they could
19 have been a coder that did radiology
20 billing, which has a very finite set.

21 And so our goal of our program for
22 training was to give them a baseline so

1 that everybody was hearing the same thing,
2 to have the same training, you know, to be
3 able to get them to get them prepared to
4 be able to do their job.

5 But in regards to what your
6 question is, you know, all coders met our
7 job requirements, but they also come with
8 different levels of experience and skill
9 sets.

10 MS. ZUPAC: All right. Why don't
11 we break for lunch now. Go off the
12 record.

13 VIDEO OPERATOR: Off the record.
14 The time is 12:49.

15 (Thereupon, at 12:49 p.m. EDT, a
16 lunch recess was taken.)

17
18
19
20
21
22

1 A. I see that.

2 Q. And as you've testified, ChartSync
3 was the program used to conduct retrospective
4 chart review for dates of service 2010, 2011,
5 2012 and some of 2013, correct?

6 A. Yes.

7 Q. All right. So down at the bottom
8 there's a heading 2.5, Standard Operating
9 Procedure, and 2.5.1, Review ChartSync specific
10 coding guidelines.

11 Do you see that?

12 A. I do.

13 Q. All right. All right. So there are
14 certain instructions or notes here in bullet
15 points. So that first bullet point states one
16 date of service, DOS, is considered an encounter,
17 correct?

18 A. I see that.

19 Q. Okay. So charts could, and often
20 did, include multiple encounters or dates of
21 service, correct?

22 MS. MADDUX: Objection, form.

1 THE WITNESS: A chart could contain
2 multiple dates of services.

3 BY MS. ZUPAC:

4 Q. Okay. So I just want to go over the
5 setup in ChartSync for coding a chart, including
6 the -- multiple dates of service. So that's what
7 we're going to be going over in the next few --

8 A. Okay.

9 Q. -- set of questions.

10 This SOP also notes that an encounter
11 can have multiple diagnoses, right?

12 A. That's what it states.

13 Q. Okay. And it can also have multiple
14 error and admission codes, correct?

15 A. That's what it states.

16 Q. Okay. So this third bullet point
17 notes that coders will only code ICD-9 codes that
18 map to HCC or RxHCC codes, correct?

19 A. That's what it states.

20 Q. Because, as you've testified, there
21 were something like 15,000 ICD-9 diagnosis codes
22 and not all of them mapped to an HCC, correct?

1 A. I mean, the member name and that --
2 that -- correct. I mean, it's industry standard
3 to start with blind coding.

4 Q. But I just want to make sure I
5 understand what exactly blind coding entails.

6 A. Um-hmm.

7 Q. So -- so in blind coding a coder
8 would not be informed, for example, about
9 diagnoses that the member is suspected to have,
10 correct?

11 MS. MADDUX: Objection, form.

12 THE WITNESS: The -- in blind
13 coding a coder's given no additional
14 information, other than the image of the
15 chart to -- to code to the best of their
16 ability.

17 BY MS. ZUPAC:

18 Q. And in blind coding a coder would not
19 be informed about diagnosis codes previously
20 submitted by a provider for that member, correct?

21 A. The -- the -- in blind coding a
22 coder's is given no information.

1 do it.

2 BY MS. ZUPAC:

3 Q. Okay. And so we've been talking
4 about the recode project, but at a high level,
5 what was the recode project?

6 A. The recode project was a project
7 where we had to take another look at our charts
8 due to a new coding policy application.

9 Q. And which charts specifically were
10 subject to the recode project?

11 A. The 2012 project year charts. So
12 they are the 2011 dates of services due that
13 January 2013.

14 Q. Okay. And so the recode project
15 entailed taking charts that were coded in the
16 2012 project year and coding them again with a
17 changed coding policy?

18 MS. MADDUX: Objection, form.

19 THE WITNESS: With a new coding
20 policy application.

21 BY MS. ZUPAC:

22 Q. Okay. And those -- those charts from

1 that you're mentioning that you tried to do
2 informed coding on in the 2013 date of service
3 year were not ultimately coded using informed
4 coding, correct?

5 A. Correct.

6 Q. Okay. So then -- so then I -- I
7 guess I can modify my question to ask, are there
8 any other instances of charts successfully coded
9 using informed coding in the retrospective chart
10 review program that have not been marked with the
11 recode flag?

12 MS. MADDUX: Objection, form.

13 THE WITNESS: Not that I'm aware of
14 in regards to the retrospective chart
15 review program.

16 BY MS. ZUPAC:

17 Q. Okay. Okay. So aside from the
18 charts marked with the recode flag discussed
19 here, Optum coded charts for UnitedHealthcare's
20 chart review program using blind coding for the
21 2008 to 2016 dates of service, correct?

22 A. Yes.

1 Q. Okay. And why is that? Why were
2 the -- why were charts other than those subject
3 to the recode program coded using blind coding?

4 A. It's just how it organically evolved.
5 I mean, from the very beginning, there weren't --
6 there wasn't tools or processes or even claims
7 information available to be able to provide that
8 information from a blind -- or sorry -- from a --
9 from a -- a -- from a non-blind perspective.

10 And then as chart review --
11 retrospective chart review became industry
12 standard, it also just became industry standard
13 to do blind coding as part of its natural method
14 for doing it.

15 Q. I believe you testified about --
16 at -- at the beginning there wasn't -- there
17 weren't other data sources to -- used to use
18 informed coding, correct?

19 MS. MADDUX: Objection, form.

20 THE WITNESS: There weren't --
21 there wasn't an ability to tie, you know,
22 a -- like a -- a claim to a -- a chart,

1 second-level review, quality assurance and
2 overread, correct?

3 A. Yes.

4 Q. Okay. So what is your understanding
5 of second-level review?

6 A. Because we, you know, established
7 that every -- that not every coder -- that coders
8 won't get to 100 percent completeness and that,
9 based upon the coder's own individual skill sets
10 and experience and the complexity of the chart,
11 we would have that chart coded by a second coder
12 for a second level of review.

13 Q. Okay. And when did -- when did you
14 start performing second-level review?

15 A. In recode we started coding 2LR or
16 second-level review.

17 Q. Okay. Let me make sure I understand
18 that.

19 During the recode project that
20 you've --

21 A. During the recode project, yes.

22 Q. Okay. And then subsequent to the

1 recode project, did Optum start sending some
2 charts to second-level review automatically?

3 A. We would send charts to second-level
4 review based upon the information that we saw,
5 where again, depending upon the coder's
6 experience -- the complexity of the chart, the
7 type of chart, if it was EMR or if it was
8 handwritten -- that we would send it to
9 second-level review.

10 Q. Okay. And so the basic process for
11 second-level review is a chart was reviewed and
12 coded once by a production coder, correct?

13 Step one, sorry. Let's -- let's put
14 it that way.

15 A. Okay.

16 Q. All right. So step one of the
17 second-level review process was that a chart was
18 reviewed and coded by a production coder once,
19 correct?

20 A. First-time coding.

21 Q. Okay. It was referred to as
22 first-time coding?

1 A. First-time coding --

2 Q. Okay. All right.

3 A. -- FTC, yes --

4 Q. Okay.

5 A. -- or 1LR.

6 Q. 1LR, okay.

7 So the first step was to conduct --
8 for the -- for a coder to conduct first-time
9 coding or basically just review the code the
10 first time and using the normal blind coding
11 process, correct?

12 MS. MADDUX: Objection, form.

13 THE WITNESS: We would code the
14 chart using our standard process, which
15 was the -- a -- a blind code.

16 BY MS. ZUPAC:

17 Q. Okay. And then a chart that was
18 subject to second-level review would be assigned
19 to a different coder; is that right?

20 A. It would be assigned to a different
21 coder.

22 Q. And that -- that second-level

1 reviewer, that second-level coder, would then
2 conduct a second blind review of that chart?

3 A. A second blind review of that chart.

4 Q. Okay. And so did -- did Optum
5 perform second-level review on charts at a time
6 when ChartSync was operational?

7 A. I mean, while technically ChartSync
8 was operational during recode, we just didn't use
9 ChartSync.

10 Q. Okay. So I -- I -- I guess let me
11 ask my question a different way.

12 Was second-level review performed
13 using ChartSync at all?

14 A. Not that I recall.

15 Q. Okay. So what was the general
16 process for conducting second-level review? Was
17 it conducted on paper with results later uploaded
18 to a database or some other method?

19 A. In the 2013 project year it was based
20 upon the -- the paper and spreadsheet process,
21 yes.

22 Q. Um-hmm.

1 So then let's move on to the next
2 quality score, which is the completeness quality
3 score.

4 What does that refer to?

5 A. So the completeness quality score is
6 in -- if, in their review of the encounter
7 information, that the QA auditor identified
8 another diagnosis code that could have been coded
9 by the production coder because it would have
10 been picked up -- or sorry -- because the
11 documentation supported it, they would have noted
12 that diagnosis code and that would have been
13 noted on their -- the coder's QA feedback.

14 Q. Okay. So again, just trying to
15 figure out mechanically how this would work and
16 be calculated.

17 So start -- again, back to Mary, the
18 production coder identified diagnosis code or
19 codes that mapped to HCC 15 for diabetes.

20 A. Um-hmm.

21 Q. Okay?

22 And then the QA coder is reviewing

1 CERTIFICATE OF NOTARY

2 I, MISTY KLAPPER, the officer before whom
3 the foregoing deposition was taken, do hereby
4 certify that the witness whose testimony appears in
5 the foregoing deposition was duly sworn by me; that
6 the testimony of said witness was taken by me in
7 shorthand and thereafter reduced to typewriting by
8 me; that said deposition is a true record of the
9 testimony given by said witness; that I am neither
10 counsel for, related to, nor employed by any of the
11 parties to the action in which this deposition was
12 taken; and, further, that I am not a relative or
13 employee of any attorney or counsel employed by the
14 parties hereto, nor financially or otherwise
15 interested in the outcome of this action.

16

17

Misty Klapper

Misty Klapper, RMR, CRR

18

Notary Public in and for

the District of Columbia

19

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21

22

EXHIBIT P-8

Medicare Managed Care Manual

Chapter 7 – Risk Adjustment

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10 - Introduction

(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

This manual chapter addresses the policies and operations related to the data collection for, calculation of, and use of risk scores in Part C and Part D payments through 2011. For detailed information on payment policies and formulas, refer to Chapter 8 for Part C payment (a chapter for Part D payment is forthcoming). CMS risk adjusts Part C payments made to Medicare Advantage (MA) plans and Program of All Inclusive Care for The Elderly (PACE) organizations, and Part D payments made to Part D sponsors, including Medicare Advantage-Prescription Drug plans (MA-PDs) and standalone Prescription Drug Plans (PDPs).

20 - Purpose of Risk Adjustment

(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an enrollee. Risk scores measure individual beneficiaries' relative risk and risk scores are used to adjust payments for each beneficiary's expected expenditures. By risk adjusting plan bids, CMS is able to use standardized bids as base payments to plans.

30 - Statutory and Regulatory Authority for Risk Adjustment

(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The Medicare Advantage (MA) program provides Parts A and B services under Part C of Title XVIII of the Social Security Act ("the Act"). CMS administers risk adjusted payments to MA organizations in accordance with Subpart G of 42 CFR §422.304. This regulatory provision is based on sections 1853, 1854, and 1858 of the Act. CMS risk adjusts Part C payments made to MA plans under Section 1853(a) (3) of the Act; these rules are codified at 42 CFR 422.310. CMS risk adjusts payments to PACE organizations under 1894(d) (2).

MA plans include MA-only plans, MA-PD plans, regional plans, employer group health plans, and Special Needs Plans (SNPs). CMS risk adjusts certain demonstration plan payments, such as the Part C payments made to the dual demonstration plans (Wisconsin Partnership Program, MassHealth Senior Care Options, and Minnesota Senior Health Options and Minnesota Disability Health Options), and Social Health Maintenance Organizations (SHMOs).

CMS risk adjusts Part D payments to Medicare Advantage Prescription Drugs plans (MA-PDs), standalone Prescription Drug Plans (PDPs), and PACE organizations under 1860(d); these rules are codified at 42 CFR 423.

40 - Role and Responsibilities of Plan Sponsors

(Rev. 118; Effective: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010); Implementation: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010))

MA organizations, PACE organizations, 1876 Cost HMOs/Competitive Medical Plans (CMPs), and starting in 2012, Health Care Prepayment Plans (HCPPs) like the United Mine Workers of America Health and Retirement Funds, must submit risk adjustment data, as required by CMS.

This section provides a high-level checklist of plan requirements. Detailed information about risk adjustment data collection, submission, reporting, and validation are outlined in later sections within this chapter.

Risk Adjustment Data Submission Requirements – Plan Sponsors (Medicare Advantage Organizations (MAOs), PACE organizations, and 1876 Cost HMO/CMPs) must:

- Ensure the accuracy and integrity of risk adjustment data submitted to CMS. All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to *International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting*.
- Implement procedures to ensure that diagnoses are from acceptable data sources. The only acceptable data sources are hospital inpatient facilities, hospital outpatient facilities, and physicians. Plan sponsors are responsible for determining provider type based on the source of the data.
- Submit the required data elements from acceptable data sources according to the coding guidelines.
- Submit all required diagnosis codes for each beneficiary and submit unique diagnoses at least once during the risk adjustment data-reporting period. Submitters must filter diagnosis data to eliminate the submission of duplicate diagnosis clusters.
 - For Part B-only beneficiaries enrolled in a plan, the plan sponsor must submit diagnosis codes under the same rules as for a beneficiary with both Parts A and B. The plan should also submit *diagnosis* codes for Part A services provided under a non-Medicare contract.

If upon conducting an internal review of submitted diagnosis codes, the plan sponsor determines that any diagnosis codes that have been submitted do not meet risk adjustment submission requirements, the plan sponsor is responsible for deleting the submitted diagnosis codes as soon as possible.

- Receive and reconcile CMS Risk Adjustment Reports in a timely manner. Plan sponsors must track their submission and deletion of diagnosis codes on an ongoing basis.
- Once CMS calculates the final risk scores for a payment year, plan sponsors may request a recalculation of payment upon discovering the submission of inaccurate diagnosis codes that CMS used to calculate a final risk score for a previous payment year and that

had an impact on the final payment. Plan sponsors must inform CMS immediately upon such a finding.

50 - History of Risk Adjustment

(Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The Balanced Budget Act of 1997 (BBA) mandated that a risk adjustment payment methodology, incorporating information on beneficiaries' health status, be implemented in the Medicare+Choice (M+C) program (now the Medicare Advantage program) no later than January 2000. Under the BBA, risk adjustment of M+C payments was initially to be based only on data from enrollees' inpatient hospital stays, with later implementation of risk adjustment based on data from additional sites of care. CMS selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method to be implemented in 2000. This model recognizes diagnoses for which inpatient care is most frequently appropriate and which are predictive of higher future costs.

To assist managed care organizations, CMS provided for a gradual phase-in of risk adjusted payment, initially adjusting only a portion of the total payment based on the PIP-DCG methodology - and later the CMS Hierarchical Condition Category (HCC) methodology - with the remainder still adjusted under the pre-BBA method based only on demographic information. This phase in was intended to provide more stable payments to M+C organizations.

The phase in schedule was as follows:

Payment year	MA plans	Evercare*	SHMO*	PACE and dual demonstrations*
2000-2003	10% risk/90% demographic	100% demographic	100% demographic	100% demographic
2004	30% risk/70% demographic			10% risk/90% demographic
2005	50% risk/50% demographic		30% risk/70% demographic	
2006	75% risk/25% demographic		50% risk/50% demographic	
2007	100% risk/0% demographic		75% risk/25% demographic	
2008 and later			100% risk/0% demographic	

*Note: For MA plans (formerly M+C plans), the demographic-only portion of the payment was adjusted for age, gender, Medicaid eligibility, institutional status, and working aged status. For certain demonstrations, the non-risk portion of the payment may have involved a demonstration-specific payment methodology.

ESRD risk adjustment was implemented at 100% in 2005. Part D risk adjustment was implemented at 100% in 2006.

120.2 - Submission and Flow of Risk Adjustment Data (Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

The following outlines the flow of risk adjustment data:

- Hospital/Physician submits data to MA organization using standard claims formats, or through review of medical records.
- The MA organization submits required data at least quarterly to FERAS via Direct Data Entry (DDE) or RAPS format.
- FERAS checks the file-level data, batch-level data, and first and last detail records on each Batch Record within the file.
- If any data are rejected, the rejections are reported on the FERAS Response Report.
- After passing the FERAS checks, the file is submitted to RAPS where detail editing is performed and applicable reports are generated.
- The RAPS Return File contains the entire submitted transaction and identifies errors.
- The RAPS Transaction Error Report communicates errors found in CCC records during processing.
- The RAPS Transaction Summary Report summarizes the disposition of the diagnosis clusters.
- The Duplicate Diagnosis Cluster Report identifies diagnosis clusters with the 502-error message. Duplicate clusters are accepted but not stored.
- The RAPS Monthly Plan Activity Report and Cumulative Plan Activity Report provides a summary of the status of submissions by submitter ID and plan number.
- Distributed monthly and quarterly, the Error Frequency Report provides an overview of all errors associated with files submitted in test and productions.
- RAPS database stores all finalized diagnosis clusters.
- RAS calculates the Risk Adjuster Factors by executing the CMS-HCC model.
- MARx is used in the calculation of payments and determination of plan payments.

120.2.1 - Data Exchange Requirements (Rev. 114, Issued; 06-07-13, Effective: 06- 07-13, Implementation: 06-07-13)

Prior to submitting risk adjustment data to CMS, CMS requires MAOs to:

- Complete and submit an Electronic Data Interchange (EDI) Agreement to the Customer Service and Support Center (CSSC) within 1 month of their contract's HPMS effective date.
 - o The EDI Agreement is a contract between the MAO and CMS attesting to the accuracy of the data submitted.
 - o An officer (e.g., CEO) that represents the MAO must sign the EDI Agreement
- Submit test data within three months of the HPMS effective date.
- Submit production files within four months of the HPMS effective date and continue to submit at least one time per quarter.

If the MAO uses a third party submitter:

- A Letter of Authorization on company letterhead from the plan is required indicating that the third party vendor is going to submit on their behalf.
- The MAO must complete the EDI Agreement.
- The third party submitter must complete the Submitter ID Application Form.

If the MAO establishes a new contract number, the MAO must submit a new EDI agreement. If the submitter's system successfully submitted test data previously, CMS does not require additional testing.

Note: CMS holds the MA organization accountable for the content of submissions regardless of who submits the data.

120.2.2 - Format

(Rev. 118; Effective: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010); Implementation: ICD-10: Upon Implementation of ICD-10, ASC X12: January 1, 2012 (for ASC X12 5010))

In accordance with CMS' 2008 Call Letter, MA organizations must submit risk adjustment data electronically using one of two formats to enable CMS to more efficiently process the data at CSSC and ensure appropriate payment under the risk adjustment payment models. MA organizations must submit data electronically using either the RAPS format or the Direct Data Entry (DDE) option. Both of these formats are used for all provider types.

Table 20 describes each field of the current RAPS file layout.

EXHIBIT P-9

CMS Manual System

Pub. 100-16 Medicare Managed Care

Transmittal: 57

**Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)**

Date: AUGUST 13, 2004

I. SUMMARY OF CHANGES:

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 13, 2004

Table of Contents - Added new line for new Exhibit 30.

Section 55 - Coverage of Clinical Trials:

In first paragraph, updated years "2002 through 2003" to read "2002 through 2005."

In second paragraph, updated reference to the Medicare National Coverage Determinations manual and the web address.

Deleted previously fourth and fifth paragraphs regarding payment of clinical trial items and services on a fee-for-service basis.

Added fifth paragraph referring reader to Exhibit 2, the Medicare National Coverage Determinations Manual, and Program Memorandum AB-01-142 for information on billing for clinical trial services.

Deleted the previously last two paragraphs which together provided reference to Program Memorandum and instructions on submitting claims for clinical trial services.

Miscellaneous changes throughout section.

Section 111.1 - Hospital Inpatient Data - Updated citation in last sentence to read "Exhibit 30" for new exhibit instead of "the section of these instructions titled Coexisting Conditions."

Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks - Added new exhibit.

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information and not the entire table of contents.

To aid in determining whether or not a provider is a Medicare-certified hospital inpatient facility, the M+C organization may refer to the Medicare provider number. The Medicare provider number has a two-digit state code followed by four digits that identify the type of provider and the specific provider number. Exhibit 25 outlines the number ranges for all facility types that CMS considers to be Medicare hospital inpatient facilities. If the facility's Medicare provider number is unknown, the M+C organization may verify the provider number with the facility's billing department.

Some hospitals also operate Skilled Nursing Facilities (SNFs) as separate components within the hospital or have components with "swing beds" that can be used for either hospital inpatient or SNF stays. The M+C organizations shall not submit any diagnoses for stays in the SNF component of a hospital or from swing bed stays when the swing beds were utilized as SNF beds. Stays in both of these circumstances qualify as SNF stays and do not qualify as hospital inpatient stays. If the Medicare provider number is on the incoming transaction from the facility, the M+C organization may distinguish the SNF or SNF swing-bed stays by the presence of a U, W, Y, or Z in the third position of the Medicare provider number (e.g., 11U001).

Principal Hospital Inpatient and Other Hospital Inpatient Diagnoses

The M+C organizations must differentiate between the principal hospital inpatient diagnosis and all other hospital inpatient diagnoses when coding the provider type on the risk adjustment transaction. According to the Official ICD-9 CM Guidelines for Coding and Reporting, the principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." The principal diagnosis as reported by the hospital shall be coded as Provider Type 01, Principal Hospital Inpatient. The CMS strongly recommends that M+C organizations continue to collect electronic encounter data or claims from hospital inpatient stays to ensure the proper identification of the principal diagnosis.

The remaining diagnoses from a hospital inpatient stay shall be coded as Provider Type 02, Other Hospital Inpatient. The guidance for coding other conditions appears in Official ICD-9 CM Guidelines for Coding and Reporting, as well as in Exhibit 30.

Exhibit 30 - Diagnostic Coding and Guidelines for Data Collection from Provider Networks

(Rev. 57, 08-13-04)

Medicare utilizes ICD-9-CM as the official diagnosis code set for all lines of business. The "Official ICD-9 CM Guidelines for Coding and Reporting" provides guidance on diagnosis coding. This document provides guidelines for hospital inpatient, hospital outpatient and physician services. In accordance with this policy, CMS will utilize ICD-9

diagnosis codes in the determination of risk adjustment factors, M+C organizations must submit for each beneficiary all relevant ICD-9 codes that are utilized in the risk adjustment model. M+C organizations must submit each relevant diagnosis at least once during a risk adjustment data reporting period, with the first period being July 1, 2002 – June 30, 2003. See <http://www.cms.hhs.gov/paymentsystems/icd9/default.asp> for information regarding ICD-9-CM codes.

At a minimum, the submitted ICD-9 codes must be sufficiently specific to allow appropriate grouping of the diagnoses in the risk adjustment model. For the complete list of diagnoses used in the risk adjustment model, as well as the list of minimal ICD-9 codes required to group diagnoses for risk adjustment, see <http://www.cms.hhs.gov/healthplans/riskadj/>. In all cases, coding to the highest degree of specificity provides the most accurate coding and ensures appropriate grouping in the risk adjustment model.

M+C organizations must apply the following guidelines when collecting data from their provider networks. If the M+C organization utilizes an abbreviated method of collecting diagnoses, such as a superbill, the diagnoses may be coded to the highest level of specificity or to the level of specificity necessary to group the diagnosis appropriately for risk adjusted payments. If the M+C organization collects data using an encounter or claim format, the codes should already be at the highest level of specificity. CMS encourages M+C organizations to utilize the full level of specificity in submitting risk adjustment data. Regardless of the level of specificity of submitted diagnoses, a medical record must substantiate all diagnostic information provided to CMS.

Coexisting Conditions

Physicians and providers should use the “Official ICD-9-CM Guidelines for Coding and Reporting” (found at <http://www.cms.hhs.gov/paymentsystems/icd9/default.asp>) and Medicare fee-for-service rules when submitting risk adjustment data to M+C organizations. The official guidelines that govern those coexisting conditions that may be coded and reported by hospital inpatient, hospital outpatient and physician providers are summarized below. The guidelines for inpatient hospital stays are as follows:

“...all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or length of stay. Diagnoses that relate to an earlier episode which have no bearing on the current hospital stay are to be excluded.”

The guidelines for coexisting conditions that should be coded for hospital outpatient and physician services are as follows:

“Code all documented conditions that coexist at time of the encounter/visit, and require or affect patient care treatment or management. Do not code conditions that were previously treated and no longer exist. However, history codes (V10-V19) may be used as secondary

codes if the historical condition or family history has an impact on current care or influences treatment."

Physicians and hospital outpatient departments shall not code diagnoses documented as "probable," "suspected," "questionable," "rule out," or "working" diagnosis. Rather, physicians and hospital outpatient departments shall code the condition(s) to the highest degree of certainty for that encounter/visit, such as symptoms, signs, abnormal test results, or other reason for the visit.

EXHIBIT P-10

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videotaped Deposition of
CHERI RICE
Given Remotely
Wednesday, August 3, 2022
9:01 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 reading this e-mail, saying that we could define
2 specific steps that a plan must take to meet
3 that requirement; for example, we could
4 self-audit -- require them to self-audit their
5 own RADV audits, or we could revive the NPRM
6 proposal we had, that if a plan is checking a
7 medical record for underpayments, they must also
8 look for overpayments.

9 BY MR. GALLAGHER:

10 Q. All right. So you -- you don't have
11 anywhere in this e-mail any reference to
12 subregulatory guidance that defines this requirement,
13 do you?

14 MS. McMAHON: Objection.

15 THE WITNESS: No, I don't reference the
16 reasonable diligence standard, because that
17 was -- that was in regulation.

18 BY MR. GALLAGHER:

19 Q. Right. And -- and you also don't say,
20 "Well, we don't need to" -- sorry, my light keeps
21 turning off.

22 You also don't say in here, "Well, we
23 don't need regulation on this to define what we mean
24 by 'reasonable diligence,' or define what the
25 requirements are, because we have manuals and -- and

1 technical guidance and other subregulatory guidance
2 out there." Right?

3 MS. McMAHON: Objection. The document
4 speaks for itself.

5 MR. GALLAGHER: I actually need the
6 witness to speak, because I can't hear the
7 document.

8 MS. McMAHON: That's interesting. Love
9 your colleagues can when they make that
10 objection.

11 THE WITNESS: So there are general
12 requirements for plans in terms of -- or
13 expectations around submitting accurate data,
14 right? So we have -- we have to have a
15 compliance program. We have attestations. We
16 have language in the managed care manual.

17 So setting aside this reasonable diligence
18 standard, there still is overall framework about
19 specifying that -- the various requirements for
20 diagnosis to be valid and, you know, what our
21 expectations are generally about plans'
22 obligations to -- to use a good faith effort to
23 submit accurate data.

24 I think what I'm talking about here is
25 specifying specific steps that we would

1 prescribe for plans to meet that obligation, and
2 whether that's requiring them to do their sort
3 of own RADV audits or reviving the medical
4 record review regulation that we -- that we had
5 not finalized.

6 BY MR. GALLAGHER:

7 Q. Right. And these were all -- so the
8 things you mention here -- and I'll go through
9 them -- are all things that you -- that would require
10 a regulation change if you wanted to set those as
11 specific requirements for plans, right?

12 MR. BULAND: Objection.

13 MS. McMAHON: Objection.

14 THE WITNESS: No, I don't think we would
15 need to do it through regulation. I suggested
16 doing it through regulation, but we had
17 specified other requirements outside of
18 regulation that were expectations for plans.

19 So it's -- we can enforce manual chapters,
20 subregulatory guidance; so it -- it doesn't just
21 have to be through regulation.

22 BY MR. GALLAGHER:

23 Q. So let's -- let's take a look at one of
24 these. You say you could, through regulation, define
25 specific steps a plan must take, at a minimum, to

1 the part of plans.

2 A. Uh-huh.

3 Q. So with that framework, is the -- was the
4 fact that -- that audits demonstrated some error rate
5 in the -- in Medicare Advantage diagnosis codings and
6 the support for codes and the support for them, was
7 that enough, in your mind, to trigger an obligation
8 to conduct medical record review, or to confirm the
9 support for diagnosis codes, above and beyond the
10 general requirement that you think exists?

11 MS. McMAHON: Objection. Vague.

12 THE WITNESS: No, I don't think so. I
13 think -- I mean, there's an understanding that
14 some subset of Medicare Advantage codes are --
15 are not going to be valid in a medical record,
16 most likely. And so the -- the fact that a plan
17 was RADV'd in one year wouldn't really change
18 that.

19 But again, it doesn't -- it's not
20 necessarily holding those plans to a higher
21 standard in subsequent years, but it doesn't --
22 it also doesn't change the underlying
23 expectation that when we're not RADV, that their
24 plan has to do -- has some proactive
25 responsibilities to take a good faith effort to

1 make sure that -- that the data that they're
2 submitting are correct.

3 BY MR. GALLAGHER:

4 Q. So earlier, you were -- you were
5 mentioning some -- I think you called it obligation
6 to -- to investigate whether codes were supported,
7 based on some knowledge a plan might have. So I want
8 to go back to that question and the process you were
9 talking about.

10 So -- so I understand it, you believe
11 that -- that in some -- in some way, if a plan has
12 reason to believe, I'll call it, that -- that codes
13 might not be supported, they have an obligation, a
14 more specific obligation to do something about that.
15 Is that right? Is that your belief?

16 A. Yes.

17 Q. And what triggers that obligation? What
18 sort of knowledge triggers this obligation, in your
19 mind? What do they have to know in order to have
20 this obligation to do more?

21 A. So we do not specify the details of what
22 "knowledge" means in our -- at least in our Medicare
23 Advantage regulations. But if -- if a plan is, for
24 example, looking at a medical record, and they don't
25 see a diagnosis that they had previously supported

1 for that medical record, that, to me, would indicate
2 there could be a problem here, and would warrant
3 additional follow-up by the plan to determine whether
4 that -- that code was actually valid or not.

5 Q. At what point in that process, if they're
6 following up, at what point does a plan have to
7 delete the code?

8 MS. McMAHON: Objection. Vague.

9 BY MR. GALLAGHER:

10 Q. Let me ask it this way: Under -- under
11 your rules, as you understand them --

12 A. Uh-huh?

13 Q. -- at what point in that process does a
14 plan have to delete the code?

15 A. So again, we have not been specific about
16 that. But if the plan has information that suggests
17 that perhaps this code is not documented, that they
18 need to take steps to double-check on whether that is
19 accurate or not. And if -- if there is still an
20 issue with it not being valid, then they need to
21 correct it.

22 So we don't -- we aren't prescriptive
23 about the five steps that the plan needs to take,
24 because you -- you can't regulate all the different
25 scenarios, the universe's scenarios. So we don't --

1 we don't get into being prescriptive there.

2 Q. Earlier I asked you about the example of
3 sort of RADV audits and whether the knowledge of --
4 of the results of those might create some obligation
5 in subsequent years. If a -- if a plan, for whatever
6 reason, has done its own internal audit for one year,
7 and -- and appreciated from that that there was a
8 certain rate at which their providers had, you know,
9 coded things that were not supported by the medical
10 records, does that, in your view, create an
11 obligation in subsequent years to do something?

12 MR. BULAND: Objection.

13 MS. McMAHON: Objection.

14 THE WITNESS: I think there -- again,
15 the -- there is -- regardless of whether they --
16 what they found in the particular year, there's
17 a general requirement and expectation that
18 they're going to take a good faith effort to
19 validate the validity of the -- of the diagnoses
20 that they submit.

21 BY MR. GALLAGHER:

22 Q. I'm -- I'm sort of setting aside what
23 you've described as a general expectation that --
24 that you believe exists for plans, and I -- I want to
25 ask more specifically: Do you at CMS -- let me put

1 have to delete it because it's not supported by the
2 radiology record, but it would still be available for
3 risk adjustment purposes?

4 A. Yes.

5 Q. And -- and therefore deleting it wouldn't
6 affect payment?

7 A. Correct.

8 Q. Do you agree that there's a difference
9 between knowing that a code is not supported by a
10 particular set of medical records and knowing that
11 that has resulted in an overpayment?

12 MS. McMAHON: Objection.

13 THE WITNESS: Yes. But our -- our
14 requirements are plans need to correct their
15 diagnosis data regardless of whether there's a
16 payment impact or not. So it's not up to them
17 to decide, "I'm not going to -- I'm not going to
18 correct this one because there's no payment
19 impact."

20 The data need to be corrected, and then it
21 will flow through our payments, and it may or
22 may not change, you know, the payment to the
23 plan. But the -- the plan needs to submit the
24 accurate diagnosis data, and then it flows
25 through our -- you know, our payment

1 methodology.

2 BY MR. GALLAGHER:

3 Q. Right. What I'm getting at is the
4 question that's kind of at issue in this lawsuit,
5 which is whether there's an overpayment. And that's
6 a different issue than whether you need to correct
7 the data, right?

8 MS. McMAHON: Objection.

9 BY MR. GALLAGHER:

10 Q. You can answer.

11 A. So -- I'm sorry, can you state your
12 question again?

13 Q. Yeah. What I'm trying to get at is that
14 there's a difference between whether there's an
15 overpayment, which is the -- which is what is alleged
16 to have happened in this lawsuit, and whether there
17 is simply a data correction that needs to be made for
18 a particular code or -- or set of data.

19 MS. McMAHON: Objection.

20 BY MR. GALLAGHER:

21 Q. Do you understand that, that distinction?

22 A. Yes. So there will be -- there could be
23 some set -- set of codes that get corrected and don't
24 have a payment impact.

25 Q. Yeah. Put another way, you can have data

1 A. Yes.

2 Q. So if you go to the next page, the bottom
3 section, "Model Calibration Factor," this is the
4 section where you're discussing that issue, the
5 extrapolation methodology and whether to apply a
6 fee-for-service adjuster, right?

7 A. Correct.

8 Q. And a fee-for-service adjuster, if you
9 could, just explain to us what that is.

10 A. So the -- the concept of the
11 fee-for-service adjuster is that in -- when we audit
12 a plan for RADV, we were taking a sample, reviewing
13 that sample of beneficiaries, reviewing the medical
14 records for all the diagnoses for those
15 beneficiaries, computing an error rate, and
16 extrapolating those results to the entire payment for
17 the plan.

18 So we were, in that context, basically
19 enforcing a -- what I call a perfection standard, of
20 100 percent enforcement of the -- all the risk
21 adjustment rules that -- that we have.

22 Plans had raised concerns, when we
23 announced that we were launching the RADV audits and
24 began them, that the data that we used to calibrate
25 the risk adjustment model is based on fee-for-service

1 spending and diagnostic information from the
2 fee-for-service program.

3 Plans raised the concern that we were not
4 subjecting the fee-for-service data that we were
5 using in the model calibration to a RADV-like audit.
6 So the model would include diagnoses that --
7 presumably some subset, that if we were to RADV-audit
8 those data, we would determine, don't -- you know,
9 requirements aren't -- aren't valid for risk
10 adjustment purposes.

11 And so the plans made -- raised that
12 concern, and made the argument that that -- because
13 there was this disconnect in the documentation
14 standard that we were applying and enforcing,
15 effectively through this extrapolation in RADV, and
16 the documentation and lack of auditing of that
17 documentation for the model calibration, that there
18 was a difference there; and that there was a -- there
19 would be a payment impact if you were to recalibrate
20 the model based on a RADV-like audit instead of
21 fee-for-service data.

22 So within the context of RADV, we
23 concluded that -- that conceptual argument made
24 sense, and that we should include a fee-for-service
25 adjuster. That was our recommendation, to include a

1 fee-for-service adjuster to take into account that
2 different enforcement of the documentation standard
3 between the two data sets in the extrapolation
4 methodology as part of the RADV program.

5 Q. All right. So to unpack that just a
6 little bit -- and I won't try to get the technical
7 details right. But for reasons having to do with the
8 fact that you were not conducting a RADV-type audit
9 of the fee-for-service data, the objection was raised
10 that if you were to extrapolate from the RADV audit
11 to change the payment to Medicare Advantage programs,
12 you would be disadvantaging them because of that
13 difference in documentation standard, right?

14 MS. McMAHON: Objection.

15 THE WITNESS: I'm not sure I would say
16 "disadvantaging." I think it's -- it's that we
17 should take into account, if we're applying this
18 standard uniformly throughout the whole payment
19 to the plan, that the recovery amount will be
20 different if we --

21 BY MR. GALLAGHER:

22 Q. Right.

23 A. -- were to audit the data.

24 And so this is an adjustment to take that
25 into account.

1 validates the accuracy of codes already submitted.

2 We did not finalize that regulation. So
3 we do not have a specific recipe for how plans are
4 supposed to meet their obligation of -- under the
5 False Claims Act, and our various requirements about
6 making sure their data are accurate. But we don't
7 have a specification that says you have to do
8 chart -- specifically, you have to do chart review,
9 and you have to do a specific kind of claims
10 verification program.

11 Q. Right. You've never specified in any
12 guidance, rule, regulation, subregulatory document,
13 that plans are required to look both ways?

14 MR. BULAND: Objection.

15 MS. McMAHON: Objection.

16 THE WITNESS: I would say -- well, that's
17 very broad. I would say there's a requirement
18 that plans have a good -- good faith compliance
19 program to validate the accuracy of diagnoses.
20 Doesn't have to be 100 percent; we're not saying
21 they have to do like a RADV of everything. But
22 they have to have some kind of protocols,
23 procedures in place to assess the accuracy of
24 the data that they're submitting.

25

1 BY MR. GALLAGHER:

2 Q. Doesn't even have to be a chart review,
3 though, I think you said earlier, right? You don't
4 require chart review?

5 A. Not specifically, no.

6 Q. And so a plan of deciding how to meet the
7 obligation that you say exists, you know, generally,
8 doesn't have any guidance from CMS that says
9 specifically, you have to look both ways, or design a
10 chart review program to validate the diagnoses
11 reported by --

12 MS. McMAHON: Objection.

13 BY MR. GALLAGHER:

14 Q. Right?

15 A. We don't say specifically, "Here are the
16 steps that you need to take." But we -- but we do
17 say, "If you have information that suggests that a
18 diagnosis isn't valid, that you've already submitted,
19 you need to take steps to correct it; to find out if
20 it's right or wrong, and to correct it if it's not.

21 Q. What sort of -- what sort of information
22 have you told plans triggers that obligation?

23 A. So we have not been specific, because
24 there are all sorts of circumstances and scenarios,
25 and didn't -- we didn't want to be prescriptive. And

1 so we have not done that. So there's general
2 obligation. We have not specified, "Here's the, you
3 know, the specific steps in all various scenarios
4 that you have to follow to meet your obligations
5 under the False Claims Act, or the other requirements
6 that we have, and specific to the MA program."

7 Q. Right. So you've not -- CMS has not
8 specified what type of information a plan might have
9 that would trigger an obligation to do some
10 additional assessment, right? You have not --

11 MS. McMAHON: Objection.

12 BY MR. GALLAGHER:

13 Q. You have not been specific in saying,
14 "Here's the type of thing that would trigger this
15 obligation to do something more"? Right?

16 MR. BULAND: Objection.

17 MS. McMAHON: Objection.

18 THE WITNESS: That's correct. We have not
19 been that specific.

20 BY MR. GALLAGHER:

21 Q. Have you -- have you generally informed
22 plans that there is such an obligation? And if so,
23 where?

24 A. Yes. So first we have in our regs that
25 the plans have to have a compliance program to do

1 internal monitoring.

2 We also have the managed care manual,
3 where we say they have to implement procedures to
4 make sure that the data that they submit for -- the
5 encounter data, which includes the diagnosis data --
6 have to be accurate.

7 We also have plans attest, every time they
8 submit data, that the data are accurate to their best
9 knowledge, information, and belief.

10 So there's -- and then we have participant
11 guides for encounter data submission, where we also
12 flag that if you're looking -- if you're looking at
13 records, and you're seeing additional codes, and
14 you're not -- you need to make sure that you're
15 correcting anything that isn't documented.

16 So we've said in multiple places, the
17 standard for an accurate diagnosis data is -- it has
18 to be documented in the medical record. And we've
19 said in multiple places, and I think including in the
20 contract for the plan, there is -- you can't just do
21 nothing. You have to do something. We have not been
22 specific about -- "Here's the precise formula"; but
23 you must take steps, good faith steps, to ensure that
24 the data that you're submitting is accurate.

25 Q. So just a few follow-up questions on that.

1 have identified that a code is not supported when
2 they know that there's no support for it in the
3 medical records, right?

4 MS. McMAHON: Objection.

5 BY MR. GALLAGHER:

6 Q. Let me see if it helps if I direct your
7 attention to the last full sentence on the -- in the
8 left-hand column: "Under this provision, the day
9 after the date on which the organization has
10 confirmed and identified overpayment -- because the
11 organization knows that the diagnosis is not
12 supported by documentation -- is the first day of the
13 60-day period for reporting." Right?

14 A. Right. So I -- I would say there that our
15 intention there was not to say you don't have to
16 correct diagnosis data because there's another
17 similar diag for that condition elsewhere.

18 Our point with this was, if you have a
19 payment -- a payment diagnosis -- or a diagnosis that
20 feeds into a payment HCC, you don't have to put a
21 dollar amount on it; that's -- that needs to be
22 corrected.

23 And not trying to make this nuanced
24 interpretation of -- "Well, yeah, it's a payment HCC,
25 but there's another diagnosis, so I don't have to

1 correct it."

2 Like that's -- that wasn't our intent in
3 this preamble language.

4 Q. Just focusing on the -- the obligation to
5 delete or correct the diagnosis code, without regard
6 to that.

7 A. Uh-huh.

8 Q. What you're telling -- the guidance you're
9 giving to plans here is that that obligation to
10 delete the code arises when they've confirmed and
11 know that there is no support for the code in the
12 medical records. Right?

13 MS. McMAHON: Objection.

14 THE WITNESS: Yes.

15 BY MR. GALLAGHER:

16 Q. Not when they suspect it might be,
17 but when they --

18 A. Well, no, I'm sorry. When -- we weren't
19 getting into what it means to know here. It was the
20 circumstances where there's a risk adjustment
21 diagnosis that's problematic, our point with this was
22 we're not going to have -- you don't need to do the
23 math of how it might affect payment. That -- that is
24 enough to say that needs to be corrected, and that's
25 when the clock starts. That was our intent with this

1 those comments in the preamble.

2 Q. And -- and to the extent that there is any
3 decision made about whether to finalize the rule or
4 withdraw it, do you have to then go through the same
5 chain of command of policymakers that you went
6 through to propose the rule in the first place?

7 A. So, yes. The final rule then goes through
8 the clearance process, where policy officials are
9 briefed on the comments, and any recommendations for
10 finalizing or modifying or -- however, you know,
11 whatever the scope of options for the final rule are.

12 Q. And you have the opportunity in that
13 process to make a recommendation about whether the
14 rule should be finalized, whether it should be
15 modified, or whether it should be withdrawn?

16 A. Uh-huh.

17 MS. McMAHON: Objection.

18 THE WITNESS: Yes.

19 BY MR. GALLAGHER:

20 Q. In the case of the medical record review
21 rule, what was your recommendation after the comment
22 period?

23 A. So we did not make a recommendation,
24 because a -- a decision was made that -- as I
25 mentioned, this -- this was a provision in a much

1 larger rule that had some provisions that were -- got
2 a lot of stakeholder concern and pushback. And so
3 the direction that we received was that the rule --
4 the final rule needed to include only those
5 provisions that had wide -- you know, widespread
6 stakeholder support.

7 So we did not move forward then with the
8 medical record review provision, not because we
9 didn't think it was the right thing to do or the
10 right policy, but because it had mixed reactions from
11 stakeholders. It didn't meet those criteria, and so
12 we didn't include it in the final rule.

13 Q. So you didn't withdraw -- you didn't make
14 the determination that the rule wasn't necessary?

15 MS. McMAHON: Objection.

16 BY MR. GALLAGHER:

17 Q. You made the determination that -- or
18 somebody made the determination, as a policy matter,
19 that they weren't going to go forward with it because
20 it had faced opposition?

21 MR. BULAND: Objection.

22 MS. McMAHON: Objection.

23 THE WITNESS: So we didn't make a
24 recommendation one way or the other, because of
25 the decision about what the scope of the final

1 BY MR. GALLAGHER:

2 Q. Now, there's a reference in -- still on
3 Exhibit 1061, on that first page, there's a reference
4 in that same Bullet Number 4, under "Meeting
5 Summary," to UHG representatives indicating that "in
6 light of the proposed rule and other discussions with
7 CMS, UHC had suspended its claims verification
8 process pending a decision by the company of whether
9 it was appropriate to submit additional deletes to
10 CMS that have been identified through the company's
11 claims verification process."

12 You see that?

13 A. Yes.

14 Q. Do you recall being informed by
15 UnitedHealth that they had in fact suspended this
16 program?

17 A. Not in the meeting, no.

18 Q. Do you recall being informed that later?

19 A. So there was an e-mail the next day, that
20 Steve Nelson sent me, where I believe he said that in
21 the e-mail.

22 Q. Right. So if we could have Exhibit 1063,
23 which is Tab 12. I think that's the e-mail you're
24 referring to.

25 (Exhibit 1063 was marked for identification.)

1 BY MR. GALLAGHER:

2 Q. So Exhibit 1063 is an e-mail exchange that
3 starts at the bottom of the first page with an e-mail
4 from Steve Nelson to you, on Wednesday, April 30th,
5 at 9:55 in the morning.

6 Is this the e-mail you're referring to?

7 A. Yes.

8 Q. And if you go to the next page, in the --
9 in the paragraph that starts, "Fifth," is -- is it in
10 this paragraph that you were informed -- or that
11 UnitedHealth had in fact suspended or stopped this
12 program, the claims verification or chart review
13 program looking for deletes?

14 A. Yes. Just rereading it again here.

15 Yes, so we suspended the process, yes,
16 right.

17 Q. So you were aware of that in -- in April
18 of 2014, that whatever process UnitedHealth had, that
19 it was asking for guidance on in this meeting, it had
20 decided to suspend that process?

21 A. Yes.

22 Q. What do you recall learning about what,
23 you know -- actually, let me ask this differently.

24 Do you recall ever learning what
25 UnitedHealth's decision was with respect to claims

1 obligations were with respect to conducting medical
2 record review or confirming the support for diagnosis
3 codes?

4 A. I don't remember the conversation. All I
5 can tell you is I remember feeling very uncomfortable
6 in the meeting, and -- and then when I saw
7 Mr. Nelson's e-mail the following day, I was very
8 concerned about how things were characterized.

9 And -- but again, I don't remember
10 specifically what was said in the -- in the meeting.

11 Q. So, for example, you don't recall anybody
12 from CMS informing UnitedHealth at this meeting that
13 they haven't any obligation, outside of whatever
14 might be imposed by the proposed medical record
15 review, to conduct medical record review looking for
16 deletes, or to design their compliance program to
17 conduct medical record review looking for deletes?

18 MR. BULAND: Objection.

19 THE WITNESS: The only thing I --

20 MS. McMAHON: Objection.

21 THE WITNESS: The only thing I -- I
22 remember feeling very uncomfortable, and I
23 believe I said something along the --
24 referencing the False Claims Act.

25 And -- and, you know, the -- that that is

1 still -- you know, is still in play, even
2 regardless of the medical record review rule,
3 but -- other than that, no.

4 BY MR. GALLAGHER:

5 Q. So tell me everything you recall saying
6 about the False Claims Act and how it came to bear
7 here, during this meeting in April of 2014.

8 A. I -- I honestly don't recall,
9 specifically. I just remember feeling very
10 uncomfortable with the conversation, and reminding
11 United about the False Claims Act. But the details,
12 I don't recall.

13 Q. With reference to the e-mail exchange you
14 had with Cynthia Tudor and Mr. Cavanaugh before the
15 meeting, which is Exhibit 1060 --

16 A. Uh-huh.

17 Q. -- do you recall that there was -- as part
18 of that exchange, discussion of -- of deleting or
19 correcting data that you know is wrong?

20 A. Yes.

21 Q. Was your reference to the False Claims
22 Act, if you remember, a reference to that obligation
23 or some obligation with respect to the -- the data
24 that was in review already?

25 MR. BULAND: Objection.

1 THE WITNESS: What was particularly
2 concerning to me was the data that had been
3 reviewed and not found, at that point in the
4 process, to be documented in medical records.
5 And that was very concerning to me, that they
6 appeared to be saying, "We're not going to do
7 anything more with that," and that was
8 concerning.

9 BY MR. GALLAGHER:

10 Q. So -- I'm sorry. I didn't mean to
11 interrupt you. Were you --

12 A. No, that's okay. Go ahead.

13 Q. The -- so do you think that when you were
14 -- that whatever it is you recall about saying about
15 the False Claims Act, it was in reference to that
16 data that was in review and some potential for the
17 need to delete had been identified for it?

18 A. Again, I don't -- I don't recall.

19 Q. Do you recall whether you had any --
20 whether you had any thought, even, that the False
21 Claims Act had any bearing on the decision whether to
22 stop the program and not continue it in further -- in
23 future years?

24 MR. BULAND: Objection.

25 THE WITNESS: Yeah, I don't recall.

1 inference that somehow CMS was blessing this --
2 these next steps that United was suggesting.
3 And so -- I was frankly alarmed by the e-mail,
4 and wanted to make -- respond in writing that we
5 were not blessing what they were suggesting they
6 were doing in Bullet 5, and that there were
7 other laws and requirements beyond the medical
8 record review rule that they needed to be in
9 compliance with.

10 And so I, again, was very, very concerned
11 with this e-mail.

12 BY MR. GALLAGHER:

13 Q. My question was, you don't dispute, in
14 your responsive e-mail, Mr. Nelson's characterization
15 of what was said by CMS and confirmed by CMS at the
16 meeting on the 29th?

17 MR. BULAND: Objection.

18 MS. McMAHON: Objection. Asked and
19 answered.

20 THE WITNESS: I think it is making clear
21 that they should not take away from that meeting
22 that we had said that it was okay to stop the
23 claims verification program, or that it was okay
24 not to continue to review and determine whether
25 those questionable diagnoses were accurate or

1 not.

2 BY MR. GALLAGHER:

3 Q. In April of 2014, had you issued any --
4 had CMS issued any guidance, rules, requirements,
5 subregulatory or otherwise, that required plans to
6 conduct any medical record review?

7 MS. McMAHON: Objection. Asked and
8 answered.

9 THE WITNESS: Again, not specifically. We
10 had general requirements about compliance
11 programs, language in our managed care manual,
12 et cetera. But in terms of a specific procedure
13 that plans were to follow to -- to meet their
14 obligations to submit correct data, no, we did
15 not have specific procedures that we were
16 telling plans to follow.

17 BY MR. GALLAGHER:

18 Q. And in your response to Mr. Nelson, do you
19 identify any rule, regulation, subregulatory
20 guidance, you know, communication from CMS that
21 imposes an obligation to conduct medical record
22 review specifically to look for deletes?

23 A. No.

24 Q. Do you know -- do you identify any
25 requirements with specificity in your response?

1 and communicate to them your expectations?

2 MR. BULAND: Objection.

3 MS. McMAHON: Objection.

4 THE WITNESS: Again, I think that not
5 knowing all the details, for example, of
6 United's claim verification program, for us to
7 be able to say, "Yes, it's fine," or "No, it's
8 not," or "What are all the steps that you went
9 through," we would have to have a lot more
10 information to be able to -- to weigh in, even
11 if that were appropriate, to be able to say
12 "Yes, it's okay," or "No, it's not."

13 And my purpose in sending that e-mail was
14 to make clear we're not -- we're not giving you
15 a blessing one way or the other; you need to
16 make that determination based on the laws and
17 requirements.

18 BY MR. GALLAGHER:

19 Q. All right. So -- I'm sorry. Go ahead.

20 A. I'm sorry. While we try to be as specific
21 and as helpful as we can, we can't always give a
22 specific yes or no. In this case, it would have
23 taken a lot more information to know exactly what the
24 scope is of what United was doing, what information
25 they had, how much due diligence they had done, and

1 wanted to make clear to them that they had an
2 obligation -- they might have an obligation under --
3 you know, setting aside the medical record review
4 rule, to follow up on those -- certainly on those --
5 on those diagnoses that, at least through the process
6 to date, didn't look like they were going to be
7 valid. So . . .

8 Q. So looking at your response to Mr. Nelson
9 in Exhibit 1063, the e-mail of May 2nd, 2014 --

10 A. Uh-huh.

11 Q. -- as we discussed earlier, you -- you
12 mentioned -- you say there are other laws that do
13 impose standards, requirements, and responsibilities,
14 but you don't identify what those laws are. Right?

15 A. That's correct.

16 Q. In Interrogatory Number 24, when
17 identifying the ways in which CMS would communicate
18 requirements that you believe are imposed by the --
19 by the regulation concerning a compliance program, or
20 due diligence generally, you indicate that you would
21 provide guidance -- provide that guidance in e-mails
22 and in-person communications. Right?

23 MS. McMAHON: Objection. Misstates the
24 witness's testimony, and the document.

25

1 specific set of circumstances, and that we were not
2 giving them an answer of up or down, but that they
3 needed to think carefully about whether their
4 proposed course of action was consistent with those
5 other laws and regs.

6 BY MR. GALLAGHER:

7 Q. Without identifying what those laws and
8 regs were with any specificity?

9 MR. BULAND: Objection.

10 THE WITNESS: (Nodding head up and down.)

11 BY MR. GALLAGHER:

12 Q. If you -- if, in May of 2014, you thought
13 there was some specific guidance, rule, regulation,
14 or requirement that United's proposed course of
15 action that they discussed with you would run afoul
16 of, why didn't you tell them what that rule was?

17 MR. BULAND: Objection.

18 MS. McMAHON: Objection.

19 THE WITNESS: And so we didn't know all
20 the details of their program, and all the
21 details of the work that they had done in terms
22 of the review of the diagnoses that they had --
23 at least initially -- identified as not being
24 supported in the medical record, so we didn't
25 have enough information to say, at that point,

1 it definitively is or is not in compliance with
2 these other laws and regulations.

3 BY MR. GALLAGHER:

4 Q. They -- they did tell you, United did, at
5 the meeting in April of 2014, or in Mr. Nelson's
6 e-mail following, that they were stopping the program
7 entirely, right?

8 MS. McMAHON: Objection.

9 BY MR. GALLAGHER:

10 Q. That they weren't going to continue with a
11 claims verification process that involved looking for
12 deletes?

13 A. Yes.

14 Q. And if you thought that violated some
15 requirement that you -- that CMS had imposed on
16 plans, by rule or regulation or otherwise, why didn't
17 you tell United that?

18 MR. BULAND: Objection.

19 MS. McMAHON: Objection. Asked and
20 answered. Argumentative.

21 THE WITNESS: Again, they're very well
22 aware we have these requirements, specifically
23 with reference laws and regs in their contract
24 they have to comply with. And so while we
25 didn't put a laundry list in there, we did say

1 A. Yes.

2 Q. And then it says, "During our
3 conversations last year before the proposed rule was
4 withdrawn, CMS confirmed to us that the proposed
5 requirements would not apply until the effective date
6 of the rule, and that MA plans were thus not required
7 to design their medical record reviews to determine
8 the accuracy of risk adjustment diagnoses."

9 Do you recognize that as basically the
10 same language that was in the 2014 e-mail that you
11 responded to on May 2nd, 2014?

12 A. Yes.

13 Q. And am I right that you never responded to
14 this e-mail from Mr. Nelson disputing that
15 characterization of the advice provided by CMS?

16 A. I don't recall if I responded or not. I
17 don't believe I did, but I don't recall.

18 Q. Right. But you don't recall ever
19 disputing it one way or the other?

20 A. Right. Yeah, that's correct.

21 Q. And then there's a sentence that begins
22 later, "Based on." It says, "Based on our
23 conversations with CMS last year, CMS's withdrawal of
24 the proposed rule, and CMS's ongoing consideration of
25 a fee-for-service adjuster to address diagnoses not

1 A. Yes.

2 Q. And then following that, it says,
3 "However, we emphasize that our decision to not
4 finalize this regulatory proposal does not change
5 CMS' existing contractual requirement that MA
6 organizations must certify (based on best knowledge,
7 information, and belief) the accuracy, completeness,
8 and truthfulness of the risk adjustment data they
9 submit to CMS. Further, this decision does not
10 change the longstanding risk adjustment data
11 requirement that a diagnosis submitted to CMS by an
12 MA organization for payment purposes must be
13 supported by medical record documentation."

14 Did I read that correctly?

15 A. Yes.

16 Q. And is -- is that a true statement?

17 A. Yes.

18 Q. And that is -- your understanding is that
19 despite not finalizing the medical record review
20 rule, you -- you are in agreement that -- that it
21 does not change CMS's longstanding existing
22 contractual requirements that MA organizations have,
23 correct?

24 MR. GALLAGHER: Objection. Leading.

25 THE WITNESS: Correct. Yes.

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

21

22

23

24

25

Karen Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-11

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**UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC. *et*
al.,

Defendants.

CASE NO. CV 16-08697 (SSx)

**UNITEDHEALTH'S FIRST
SUPPLEMENTAL RESPONSES AND
OBJECTIONS TO PLAINTIFF
UNITED STATES' SIXTH SET OF
INTERROGATORIES**

EXHIBIT

00381

1 information from multiple providers and multiple dates of services across different
2 data collection years and different provider encounters.

3 Subject to and without waiving the foregoing Specific and General
4 Objections, UnitedHealth states that it has previously produced information
5 responsive to this Interrogatory. Pursuant to Fed. R. Civ. P. 33(d), UnitedHealth
6 directs the government to UnitedHealth's prior productions of chart review data in
7 response to document request 4C. The relevant data is bates labeled:
8 MARA2160495, MARA2157337, and MARA2152918. There is a "Recode_Flag"
9 column in each document that denotes whether a chart was coded in UnitedHealth's
10 Chart Review program using "informed coding," as UnitedHealth interprets this
11 term. UnitedHealth is not aware of additional data responsive to this Interrogatory
12 that has not already been produced to the United States. The burden of determining
13 or ascertaining the answer is substantially the same for the United States as it is for
14 the United States.

15 **INTERROGATORY NO. 18:**

16 For each year, Identify the total amount of revenue Your MA Organizations
17 received from CMS as a result of Diagnoses submitted to CMS as a result of the
18 Chart Review Program.

19 **RESPONSE TO INTERROGATORY NO. 18:**

20 UnitedHealth incorporates by reference each of its General Objections and
21 Specific Objections to Definitions set forth above. UnitedHealth objects to this
22 Interrogatory on the grounds that it calls for UnitedHealth to provide information
23 already provided to the United States in connection with the *Poehling* Investigation
24 and to the extent it seeks information already in the possession of the United States.
25 UnitedHealth also objects to this Interrogatory as duplicative of discovery requests
26 issued during the *Poehling* Investigation, including but not limited to Interrogatory
27 1K.

1 UnitedHealth additionally objects to this Interrogatory to the extent it calls for
2 UnitedHealth to prepare documents and/or perform data analysis that does not
3 already exist.

4 UnitedHealth also objects to this Interrogatory as overly broad to the extent
5 “each year” is undefined and seeks information related to UnitedHealth’s Chart
6 Review program—and the chart review data UnitedHealth has produced—beyond
7 the date of service years at issue in the litigation. For the purpose of responding to
8 this Interrogatory, UnitedHealth interprets the request to seek information related to
9 UnitedHealth’s Chart Review program for date of service years 2008–2016.

10 UnitedHealth further objects to this Interrogatory to the extent the term
11 “Diagnoses,” as defined is unclear, mis-leading, confusing, vague, and ambiguous.
12 For the purposes of responding to this Interrogatory, UnitedHealth interprets the
13 term “Diagnoses” to refer to multiple diagnosis codes.

14 Subject to and without waiving the foregoing Special and General Objections,
15 UnitedHealth states that, as the government is well aware, during the Poehling
16 Investigation, it issued Interrogatory 1(K), which sought the “total monetary amount
17 of the RA payments made by CMS to UHG’s MA Plans based on the diagnosis codes
18 that were submitted to CMS based on CRs.” UnitedHealth responded to
19 Interrogatory 1(K) in 2015 and 2016 and provided the requested information for date
20 of service years 2009 through a portion of 2014. As UnitedHealth confirmed in a
21 December 21, 2015 cover letter, UnitedHealth “does not have sufficient data
22 available to provide a similar estimate for years prior to 2009 DOS.” UnitedHealth’s
23 response remains the same, and therefore UnitedHealth cannot perform the analysis
24 or provide the relevant data in response to this Interrogatory.

25 Subject to and without waiving the foregoing Specific and General
26 Objections, UnitedHealth further states that it has previously produced information
27 responsive to this Interrogatory related to UnitedHealth’s Chart Review program for
28 date of service years 2009 through part of 2014, including in a May 2, 2016 cover

letter and supplemental response to the government’s Interrogatory 1(K) issued during the *Poehling* Investigation. Nonetheless, UnitedHealth has included below a table that provides revised estimates of the total amount of revenue attributable to UnitedHealth’s Chart Review program for date of services years 2009 through 2013, which reflect the impact of closed period deletes. Given that UnitedHealth previously provided partial information for date of service year 2014 because the period was still open at the time of UnitedHealth’s May 2, 2016 response, UnitedHealth has also included below a revised estimate of the total amount of revenue attributable to UnitedHealth’s Chart Review program for date of service year 2014. Finally, UnitedHealth has provided in the table below the estimates of the total amount of revenue attributable to UnitedHealth’s Chart Review program for date of services years 2015 and 2016.

Date of Service Year	Total
2009 DOS	\$152,546,622
2010 DOS	\$421,010,415
2011 DOS	\$581,369,966
2012 DOS	\$713,432,228
2013 DOS	\$757,396,026
2014 DOS	\$1,466,271,322
2015 DOS	\$1,581,139,269
2016 DOS	\$1,864,349,540

INTERROGATORY NO. 19:

For each year, Identify all Diagnoses Deleted as part of or as a result of Claims Verification You performed for Your MA Organizations.

RESPONSE TO INTERROGATORY NO. 19:

UnitedHealth incorporates by reference each of its General Objections and Specific Objections to Definitions set forth above. UnitedHealth objects to this Interrogatory on the grounds that it calls for UnitedHealth to provide information already provided to the United States in connection with the *Poehling* Investigation and to the extent it seeks information already in the possession of the United States. UnitedHealth also objects to this Interrogatory as duplicative of discovery requests issued during the *Poehling* Investigation, including but not limited to document request 4C.vii.m.

UnitedHealth additionally objects to this Interrogatory to the extent it calls for UnitedHealth to prepare documents and/or perform data analysis that does not already exist.

UnitedHealth also objects to this Interrogatory as overly broad to the extent “each year” is undefined and seeks information for the entire time period of January 1, 2004 to May 16, 2017 when the Claims Verification program did not exist during the entirety of the time period. For the purposes of responding to this Interrogatory, UnitedHealth interprets the term “each year” to refer to the years during which UnitedHealth had a Claims Verification program.

UnitedHealth further objects to this Interrogatory to the extent the term “Diagnoses,” as defined is unclear, mis-leading, confusing, vague, and ambiguous. For the purposes of responding to this Interrogatory, UnitedHealth interprets the term “Diagnoses” to refer to multiple diagnosis codes.

Subject to and without waiving the foregoing Specific and General Objections, UnitedHealth states that it has previously produced information responsive to this Interrogatory. Pursuant to Fed. R. Civ. P. 33(d), UnitedHealth directs the government to UnitedHealth’s prior productions of chart review data in response to document request 4C. The relevant data is bates labeled: MARA2160498, MARA2157342, and MARA2152923. MARA2160498 is a

standalone file with the diagnosis codes that were deleted through UnitedHealth's Claims Verification program for date of service year 2010. There is a "Delete_Flag" column in MARA2157342 and MARA2152923 that denotes the diagnosis codes that were deleted through UnitedHealth's Claims Verification program for date of service years 2011 and 2012, respectively. UnitedHealth is not aware of additional data responsive to this Interrogatory that has not already been produced to the United States. The burden of determining or ascertaining the answer is substantially the same for the United States as it is for the United States.

INTERROGATORY NO. 20:

For each year, Identify what You understood to be the total monetary value of Diagnoses Deleted as part of or as a result of Claims Verification You performed for Your MA Organizations.

RESPONSE TO INTERROGATORY NO. 20:

UnitedHealth incorporates by reference each of its General Objections and Specific Objections to Definitions set forth above. UnitedHealth objects to this Interrogatory on the grounds that it calls for UnitedHealth to provide information already provided to the United States in connection with the *Poehling* Investigation and to the extent it seeks information already in the possession of the United States. UnitedHealth also objects to this Interrogatory as duplicative of discovery requests issued during the *Poehling* Investigation, including but not limited to document request 4C.

UnitedHealth additionally objects to this Interrogatory to the extent it calls for UnitedHealth to prepare documents and/or perform data analysis that does not already exist.

UnitedHealth also objects to this Interrogatory as overly broad to the extent "each year" is undefined and seeks information for the entire time period of January 1, 2004 to May 16, 2017 when the Claims Verification program did not exist during the entirety of the time period. For the purposes of responding to this Interrogatory,

UnitedHealth interprets the term “each year” to refer to the years during which UnitedHealth had a Claims Verification program.

UnitedHealth further objects to this Interrogatory to the extent the term “Diagnoses,” as defined is unclear, mis-leading, confusing, vague, and ambiguous. For the purposes of responding to this Interrogatory, UnitedHealth interprets the term “Diagnoses” to refer to multiple diagnosis codes.

UnitedHealth also objects to this Interrogatory to the extent the term “You understood” is vague and ambiguous as to the time period. Specifically, the term “You understood” is vague and ambiguous because it uses the past tense but is unclear as to what specific time period is at issue. For example, it is unclear if the government is requesting information related to UnitedHealth’s understanding in a particular year, at the time diagnoses were submitted for deletion, or at a different time period. For the purposes of responding to this Interrogatory, UnitedHealth is providing information currently available to it.

Subject to and without waiving the foregoing Specific and General Objections, UnitedHealth has provided below a table with the total monetary value of diagnosis codes it submitted for deletion as part of or as a result of its Claims Verification program for date of service years 2010, 2011, and 2012.

Date of Service Year	Total
2010 DOS	\$1,264,751
2011 DOS	\$183,375,164
2012 DOS	\$42,800,053

INTERROGATORY NO. 21:

Excluding Deletes made as part of the Claims Verification You performed for Your MA Organizations or the Chart Review Quality Assurance process, for each year, Identify all Diagnoses Deleted because the Diagnosis Codes were not supported by Chart documentation.

1 Given the breadth of the information sought by this Interrogatory,
2 UnitedHealth in good faith requested a meet and confer with the government to
3 discuss its current response to Interrogatory 25 and whether the government would
4 agree to narrow the scope of the interrogatory. On the parties' July 5, 2022 meet and
5 confer, UnitedHealth explained that it has already identified the relevant individuals
6 who may have provided risk adjustment services to the UnitedHealth MAOs,
7 including in its Initial Disclosures and on its custodian list, but that further
8 identification of all such employees for every year is overly burdensome because it
9 calls for every individual who may have provided broad categories of risk
10 adjustment services to UnitedHealth's MAOs over a 13-year time period. In light of
11 the parties' July 5, 2022 meet and confer, UnitedHealth understands that the
12 government plans to provide UnitedHealth with a proposal for narrowing the scope
13 of Interrogatory 25. UnitedHealth agrees to consider the government's proposal in
14 good faith and will, if appropriate, supplement its response to Interrogatory 25.
15 UnitedHealth is in receipt of and assessing the government's proposal in its July 15,
16 2022 email.

17
18 Dated: July 19, 2022

LATHAM & WATKINS LLP
DAVID J. SCHINDLER
MANUEL ABASCAL
DANIEL MERON
ABID R. QURESHI

21
22
23
24 By



David J. Schindler
Attorneys for UnitedHealth
Defendants

1 **PROOF OF SERVICE**

2
3 I am employed in the County of Los Angeles, State of California. I am
4 over the age of 18 years and not a party to this action. My business address is
Latham & Watkins LLP, 355 South Grand Avenue, Suite 100, Los Angeles, CA
90071-1560.

5 On **July 19, 2022**, I caused the service of a true copy of the following
6 document described as:

7 **UNITEDHEALTH'S FIRST SUPPLEMENTAL RESPONSES AND**
8 **OBJECTIONS TO PLAINTIFF UNITED STATES' SIXTH SET OF**
9 **INTERROGATORIES TO DEFENDANTS**

10 to be served in the following manner:

11 **BY ELECTRONIC MAIL**

12 The above-described document was transmitted via electronic mail to
13 the following party pursuant to written consent under Federal Rule of Civil
14 Procedure 5(b)(2)(E) on **July 19, 2022**:

15 **SEE ATTACHED SERVICE LIST**

16 I declare that I am employed in the office of a member of the Bar of,
17 or permitted to practice before, this Court at whose direction the service was made
and declare under penalty of perjury under the laws of the State of California that
the foregoing is true and correct.

18 **July 19, 2022**, at Los Angeles, California.

19
20 

21 _____
David J. Schindler

EXHIBIT P-12

Optum Medicare Risk Adjustment Operations

Policy Name: Chart Review Services for Medicare Advantage Plan Clients

Issue Date:
6/30/2014

Pages: 5

Approvals

Approved By:

Dave Thomas Optum Legal 5/26/2015

Name	Title	Date
Dave Thomas	Optum Legal	5/26/2015

Status
Approved
Effective
Retired

Date:
6/9/2015
6/9/2015
NA

Approved By:

Sean Heath Dir Compliance 5/26/2015

Name	Title	Date
Sean Heath	Dir Compliance	5/26/2015

Applicable To:

☒ Chart Review Services

Approved By:

Tim Trujillo VP Risk Adjustment 6/9/2015

Name	Title	Date
Tim Trujillo	VP Risk Adjustment	6/9/2015

PURPOSE

Optum Medicare Advantage Risk Adjustment Operations provides Chart Review services to Medicare Advantage Organizations (MAO) Clients that support risk adjustment submissions in accordance with CMS risk adjustment regulations, the Medicare Managed Care Manual and the CMS Risk Adjustment Participant Guide. This policy addresses standards for the review of medical record documentation that supports the diagnoses submitted to CMS for Medicare program risk adjustment.

SCOPE

This policy addresses Optum Medicare Advantage Risk Adjustment Operations Chart Review services.

DEFINITIONS

TERM	DESCRIPTION
Hierarchical Condition Category (HCC)	HCC is a disease group broadly organized into body systems. The HCC assigned to a disease group is determined by the ICD-CM diagnosis code.
MAO Client	Medicare Advantage Organization that holds a Medicare Advantage contract.
PCP	Primary Care Physician

POLICY

Where Optum Medicare Advantage Risk Adjustment Operations performs Chart Review services on behalf of its MAO Clients, it will do so in accordance with CMS standards. Optum Medicare Advantage Risk Adjustment Operations will abide by instructions in the applicable Medicare regulations, CMS Risk Adjustment Participant Guides and Medicare Managed Care Manual, CH. 7 addressing medical record documentation sources and content, coding review, coding standards and quality activities.

CHART REVIEW SERVICES

Chart Review services, which will be conducted if and as specified in the contract with the Client, include a number of programs that are designed to collect, assess and evaluate documentation that supports health plan risk adjustment submissions. Chart Review services are designed to review individual medical records to identify and capture risk adjusted member diagnoses and chronic conditions based on review of the member's medical record. Chart Review services include:

A. Standard Chart Review :

The standard chart review includes retrieval, review, coding and confirming signature and credential requirements of the medical record to capture the risk adjusted diagnosis information from the member's medical record documentation for a specific date of service or timeframe.

B. Attestations:

An optional Medicare risk adjustment chart review service a client may select to retrieve attestations from providers. Attestations capture a providers signature or credentials when absent from the chart documentation. The provider states in writing that the pre-existing medical record accurately reflects the care of a member in a given encounter.

Optum Medicare Advantage Risk Adjustment Chart Review Operations Team will follow Optum coding guidelines for Risk Adjustment submissions when reviewing medical record documentation as outlined in the Retrospective Services Standards section of this policy.

1. Standards for Reviewing Medical Records for Chart Review Services:

Optum Medicare Advantage Risk Adjustment Operations has developed standards for reviewing medical records based on CMS risk adjustment instructions. These standards include:

- A.** The diagnosis must be coded in accordance with the ICD-CM Coding Guidelines as mandated by CMS and Optum coding guidelines;

B. The medical record documentation meets the CMS medical records guidelines and includes the following risk adjustment information:

- The service was provided by an acceptable risk adjustment provider and physician type.
- Dates of service are within the data collection period.
- Diagnoses are supported by medical record documentation.
- A provider signature and credentials are documented for each note.
 - Client may exercise discretion, consistent with CMS guidance on attestation, as to how to address records that have not yet been fully authenticated by the treating practitioner at the time of chart review.
- Coding level specificity – 3-5 digit codes

2. Coding Review Requirements:

To meet this standard, Optum Medicare Advantage Risk Adjustment Operations has developed requirements for coding reviews based on the Medicare Advantage regulations, the Medicare Managed Care Manual and CMS Risk Adjustment Participant Guide. These requirements include:

- A. Optum Medicare Advantage Risk Adjustment Operations will utilize certified medical coders.
- B. The certified coders will use ICD-CM Diagnosis Codes Guidelines as mandated by CMS, Optum coding guidelines, and Coding Clinics published by American Hospital Association (AHA), and comply with Optum Medicare Advantage Diagnostic Coding Standards and any other applicable Optum Coding Compliance Policies when evaluating assigned medical charts.
- C. Certified coders will review medical records to identify risk adjusting conditions supported in the medical record documentation. When performing chart reviews, the certified coders will apply CMS standards for Medicare Risk Adjustment submissions as detailed above.
- D. Optum Medicare Advantage Risk Adjustment Operations will document and implement a procedure for receipt, research and response to coding questions from internal coders or its vendors.
- E. Optum Medicare Advantage Risk Adjustment Operations will provide training to its internal coding staff that specifically addresses the above standards. This training will be conducted for all new coding staff before they begin coding charts and on-going thereafter for all coding staff.
- F. Optum Medicare Advantage Risk Adjustment Operations will conduct coding accuracy reviews of its internal coding staff to validate that data is coded correctly and meets CMS standards

3. Chart Review Vendor Engagement and Oversight

Optum Medicare Advantage Risk Adjustment Operations will conduct reasonable due diligence on potential vendors that conduct chart reviews and may engage vendors to conduct chart reviews pursuant to a written agreement that meets business, legal and regulatory requirements. Optum Medicare Advantage Risk Adjustment Operations will follow appropriate procurement processes when engaging chart review vendors. When Optum Medicare Advantage Risk Adjustment Operations engages a vendor to conduct chart reviews, Optum Medicare Advantage Risk Adjustment Operations will follow the following standards:

A. Contract Standards:

The terms of a vendor agreement with Optum Medicare Advantage Risk Adjustment Operations will include: the specific retrospective program activities, measurement or performance standards, if applicable, auditing and monitoring rights and payment terms. The vendor agreement will also include a Business Associate Agreement (BAA) or other appropriate terms that describe the permitted and required uses of protected health information.

B. Coding Standards:

See coding standards guidelines from Section 1 Standards for Reviewing Medical Records.

4. Vendor Oversight:

Optum Medicare Advantage Risk Adjustment Operations will design and execute appropriate coding reviews for its external vendors as part of its overall quality review program. Optum Medicare Advantage Risk Adjustment Operations will establish performance measurements, corrective action and disciplinary action guidelines for vendors that do not meet the quality review standards.

5. Provider Communications Standards

Optum Medicare Advantage Risk Adjustment Operations will obtain prior review as required by Optum Legal and Compliance and prior approval from the Client for all provider correspondence related to the chart review process.

6. Privacy Standards

Optum Medicare Advantage Risk Adjustment Operations will only receive, use and disclose Protected Health Information pursuant to the Optum privacy and security standards, including the use of secure transmission methods.

7. Standards Management

The Director of Chart Review Programs is responsible for collaborating with Optum Compliance to identify changes to the standards for all risk adjustment data collection and submission and ensuring implementation of any new requirements.

- The policy will be reviewed for updates periodically or when changes are indicated by CMS.
- All policy changes will be approved by the policy owner, Compliance and Legal.

Version control will apply to all policies.

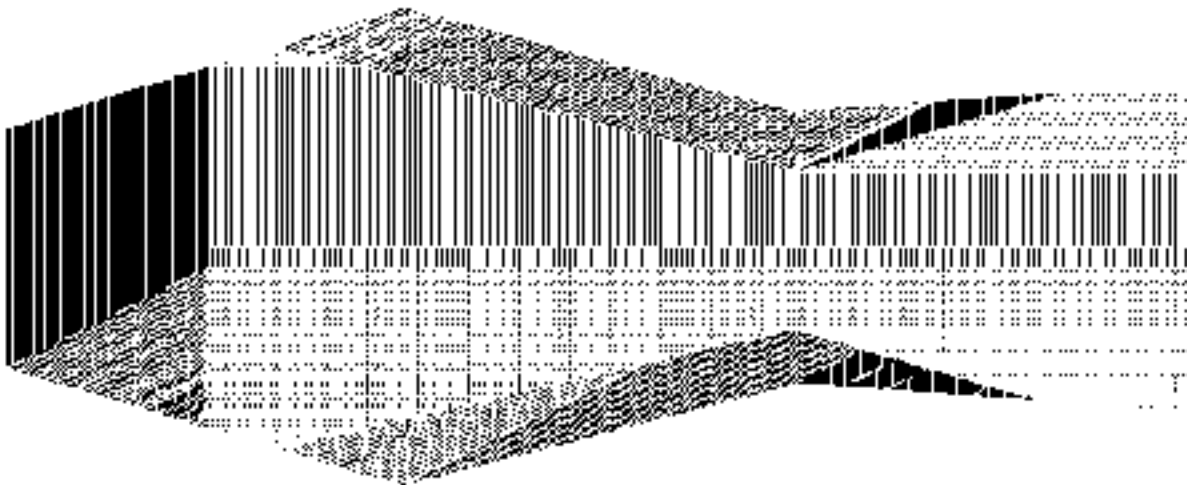
CHANGE CONTROL LOG

Date	Brief Description of Change	Author	Approver(s)
6/30/2014	Create new document	Baker	Thomas, Pettersen-Scott, Trujillo and Fabrizio
5/20/2015	2015 review and updates.	Baker	Thomas, Heath, Trujillo

EXHIBIT P-13



Medicare Advantage Coding Guide Training and Reference Material



10

EXHIBIT
00033B

4260

PARA1262848

OPTUM Right

Quality Audit Standard

Optum Right is committed to providing high quality care to our patients. We are committed to continuous improvement and to ensuring that our patients receive the best possible care. The following are the standards for quality care that we expect all of our providers to follow:

1. Patient Safety

Optum Right is committed to ensuring the safety of our patients. We expect all of our providers to follow the following standards:

Each Patient Audit Results	How to Improve QA Score	Assigned to Provider Score	QA Score for the Score	Assigned to Provider QA Score

Quality Audit

Audit Process

The audit process is a continuous process that involves the following steps:

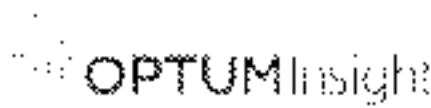
1. Identify the audit area.
2. Develop the audit plan.
3. Conduct the audit.
4. Analyze the results.
5. Implement the findings.
6. Monitor the results.

The audit process is a continuous process that involves the following steps:

1. Identify the audit area.
2. Develop the audit plan.
3. Conduct the audit.
4. Analyze the results.
5. Implement the findings.
6. Monitor the results.

EXHIBIT P-14

Optum Coding Policy



For information on how to use the OPTUMInsight
platform, please visit <https://www.optuminsight.com>
or contact your account manager.

Question 10: What is the difference between a "data source" and a "data stream"?

Answer: A data source is a location where data is stored, while a data stream is a continuous flow of data. Data sources are typically used for batch processing, while data streams are used for real-time processing.

Reference: <https://www.optuminsight.com/docs/data-sources-and-streams>

Further Clarification:

A data source is a location where data is stored, while a data stream is a continuous flow of data. Data sources are typically used for batch processing, while data streams are used for real-time processing.

Question 11: What is the difference between a "data source" and a "data stream"?

Answer: A data source is a location where data is stored, while a data stream is a continuous flow of data. Data sources are typically used for batch processing, while data streams are used for real-time processing.

Reference: <https://www.optuminsight.com/docs/data-sources-and-streams>

Further Clarification:

A data source is a location where data is stored, while a data stream is a continuous flow of data. Data sources are typically used for batch processing, while data streams are used for real-time processing.

Question 12: What is the difference between a "data source" and a "data stream"?

Answer: A data source is a location where data is stored, while a data stream is a continuous flow of data. Data sources are typically used for batch processing, while data streams are used for real-time processing.

EXHIBIT P-15

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

- - - - -X

UNITED STATES OF AMERICA, ex rel.:
BENJAMIN POEHLING, :

Plaintiff, :

: Case No.

vs. : 2:16-cv-08697-FMO-SS

UNITEDHEALTH GROUP, INC., et al., :

Defendants. :

- - - - -X

VOLUME II
CONTINUATION OF VIDEOTAPED
RULE 30(b)(6)DEPOSITION OF
OPTUMINSIGHT, INC. AND UNITEDHEALTHCARE, INC.,
BY THEIR DESIGNEE, KATHLEEN O. BAKER

Washington, D.C.

May 31, 2023

Reported by:
Misty Klapper, RMR, CRR
Job No.: 982006

1 when in that project year you reverted back to
2 instructing coders to record all RxHCCs?

3 MS. MADDUX: Objection, form.

4 THE WITNESS: Going into then --
5 after our first attempt at the CAT form,
6 we reverted back to the standard process
7 of coding all.

8 BY MS. ZUPAC:

9 Q. Okay. Was that approximately in July
10 of 2013?

11 A. Approximately.

12 Q. Okay. And then going forward for
13 subsequent date of service years, so date of --
14 dates of service 2013, 2014, 2015 and 2016, were
15 coders consistently instructed to record all
16 RxHCCs?

17 MS. MADDUX: Objection, form.

18 THE WITNESS: They were asked to
19 code all HCCs and RxHCCs that they could
20 identify in the chart according to their
21 ability, according to the chart difficulty
22 levels.

1 CERTIFICATE OF NOTARY

2 I, MISTY KLAPPER, the officer before whom
3 the foregoing deposition was taken, do hereby
4 certify that the witness whose testimony appears in
5 the foregoing deposition was duly sworn by me; that
6 the testimony of said witness was taken by me in
7 shorthand and thereafter reduced to typewriting by
8 me; that said deposition is a true record of the
9 testimony given by said witness; that I am neither
10 counsel for, related to, nor employed by any of the
11 parties to the action in which this deposition was
12 taken; and, further, that I am not a relative or
13 employee of any attorney or counsel employed by the
14 parties hereto, nor financially or otherwise
15 interested in the outcome of this action.

16

17



Misty Klapper, RMR, CRR

18

Notary Public in and for
the District of Columbia

19

20

21

22

EXHIBIT P-16

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 1
DEPOSITION OF JON H. BIRD
As 30(b)(6) Designee 2 of
OptumInsight, Inc.
UnitedHealthcare, Inc.
Washington, DC
June 22, 2023

Reported by: John L. Harmonson, RPR
Job No. 988356

1 programs continues.

2 Q. Okay.

3 MR. MASON: Why don't we go off the
4 record and take a break.

5 THE VIDEOGRAPHER: Going off the record
6 at 11:53.

7 (Recess taken.)

8 THE VIDEOGRAPHER: We are back on the
9 record at 12:11.

10 BY MR. MASON:

11 Q. Mr. Bird, another risk adjustment
12 program that Optum performed for UnitedHealthcare
13 was called claims verification; right?

14 A. Correct.

15 Q. Can you explain what the claims
16 verification program is?

17 A. It was a program that we operated during
18 a certain time frame that identified and reviewed
19 exclusive HCCs that were submitted by providers
20 that were part of the chart review program.

21 Q. And Optum performed that program for
22 UnitedHealthcare?

23 A. That's correct.

24 Q. When?

25 A. The program was in phases. The first

1 phase of the program was 2010 calendar year for
2 2009 dates of service that was limited to Ovations,
3 which was UnitedHealthcare population, and also
4 limited to one member one provider.

5 The second phase was a similar one
6 member one provider. It was moved from a manual
7 process into one that was within a system, and that
8 was in 2011 for 2010 dates of service.

9 And then Phase 3 of CV was for 2011 and
10 '12 dates of service. And that was looking at
11 multiple provider as opposed to one member one
12 provider criteria.

13 Q. And when was Phase 3 conducted?

14 A. Phase 3 -- and I may need to refer to
15 kind of a timeline on that. But typically it would
16 be done on a retrospective basis. So if we're
17 looking at 2011 dates of service, we would have
18 commenced that in 2012. And then it was ongoing
19 for 2011 and in 2012 until the program was
20 suspended and ultimately discontinued, which was
21 the spring of 2014.

22 Q. When specifically was it suspended?

23 A. There was -- so there was operational
24 suspensions from time to time based upon -- but in
25 terms of suspension leading to discontinuation of

1 the program, my understanding is it was around the
2 middle of April that there was -- I think I've seen
3 within the documentation I reviewed some
4 notification for the delete process to be put on
5 hold around April of -- on or around April 18th of
6 2014.

7 Q. And when you say suspended, you just
8 said that you suspended the delete process. Did
9 you suspend all of CV, or just the delete process?

10 A. The notification that I saw was in
11 relation to deletes. But my understanding is the
12 entire CV process was suspended at or around that
13 time.

14 Q. And it was terminated when?

15 A. The decision for termination, which is
16 based on the memorandum that came from Steve Nelson
17 to Scott Theisen, I think that was dated on
18 June 11th, and he references in there the decision
19 for termination of the program was made on
20 May 27th.

21 Q. And so is that your testimony as the
22 designee for UnitedHealthcare and Optum, that the
23 suspension of CV went into place on April 18, 2014,
24 and the termination of CV went into place on
25 May 27, 2014?

1 A. Yeah, my testimony is on or around
2 April 18th is when I saw notification of delete
3 processing, and I believe the program was also
4 suspended on or around that date.

5 And yeah, based upon the -- we have the
6 exhibit in here which is Steve Nelson's email or
7 memorandum to Scott Theisen. He indicates in there
8 that the decision was made to terminate on
9 May 27th, and then that memorandum was dated with
10 notification to Scott and others that was on
11 June 11th.

12 Q. And the dates that you were just
13 speaking of are in regards to the CV program that
14 Optum performed for UnitedHealthcare; right?

15 A. That's correct.

16 Q. Optum also performed CV for other MAO
17 clients; right?

18 A. That is correct.

19 Q. During what time period?

20 A. I don't actually -- within the materials
21 that I kind of reviewed, I didn't look at the
22 specific timelines related to commercial customers
23 or non-UHC customers. There were claims
24 verification processes in place for some MAO
25 clients as well as some HHS, you know, ACA risk

1 Q. What's the purpose of the claims
2 verification program?

3 A. The purpose is to identify exclusive
4 HCCs and review those that were submitted by
5 providers that were part of the chart review
6 program.

7 Q. What do you mean, and review them?

8 A. They would be subject to medical coder
9 review. So the CVA people that we spoke about
10 earlier, CV analysts.

11 Q. And when you say the purpose was to
12 identify exclusive -- did you say exclusive HCCs or
13 exclusive codes?

14 A. Exclusive HCCs.

15 Q. And what do you mean by that?

16 A. It would be an HCC or diagnoses that
17 mapped to an HCC and that HCC is submitted by one
18 and only one provider.

19 Q. So why?

20 MR. QURESHI: Objection to form.

21 BY MR. MASON:

22 Q. I was asking the purpose; right? And
23 you're telling me what CV did. CV looked at
24 exclusive codes and then had a CV analyst review
25 the chart associated with it to determine if it was

1 supported; right?

2 MR. QURESHI: Objection to form.

3 Mischaracterizes testimony.

4 THE WITNESS: It's the operational
5 purpose that the program was to identify and review
6 codes.

7 BY MR. MASON:

8 Q. Okay. Why was that the operational
9 purpose?

10 MR. QURESHI: Objection to form.
11 Outside the scope. He's answered the question
12 about purpose.

13 You can answer in your personal capacity
14 if you know the answer, Mr. Bird.

15 MR. MASON: That's an inappropriate
16 assertion. Please refrain from instructing the
17 witness how to answer. I'm allowed to ask
18 questions, and the witness can answer those to the
19 best of his ability. You can assert all the
20 objections you want out of scope, but it's
21 inappropriate to tell the witness how he should
22 answer.

23 MR. QURESHI: Once again I'm going to
24 object to your question as being outside the
25 scope --

1 supported in the corresponding medical chart
2 documentation. All diagnosis codes determined to
3 be adequately documented within the chart will" --
4 sorry, "not adequately documented within the chart
5 will be deleted."

6 Q. Is this statement a correct description
7 of the claims verification program?

8 MR. QURESHI: Objection to form.

9 THE WITNESS: They were the words of
10 whoever authored this document chose to describe it
11 at that particular time. As I kind of break it
12 down based upon my understanding of the program, I
13 see the programs between chart review and claims
14 verification as being separate programs as opposed
15 to part of the chart review program. It could have
16 been described or positioned in that way. But it
17 wasn't something that was part of a single program.

18 This does not mention exclusive HCCs.
19 But I think, yeah, my description, the purpose was
20 to identify exclusive HCCs. This doesn't mention
21 exclusive HCCs, but it does mention review of
22 diagnosis. I did mention review. And it would be
23 reviewed by a coder.

24 And to the extent that we've been
25 through every step of the claims verification

1 process as defined at any point in time, and we can
2 determine that the -- we have all of the
3 appropriate medical records and we have sufficient
4 evidence to overturn the diagnosis that was
5 submitted by the provider that takes care of the
6 patient, then they would be deleted.

7 It doesn't provide all of that detail
8 but a summarized version that they provide outside
9 of claims verification seems to cover most of the
10 main aspects of the program.

11 BY MR. MASON:

12 Q. So I'm just trying to make sure I
13 understand your answer. My question was: Is this
14 a correct description of the claims verification
15 program? You've mentioned some things, but I'm not
16 sure that you've answered my question.

17 MR. QURESHI: Objection to form.
18 Argumentative. And asked and answered.

19 THE WITNESS: What I'm trying to say is
20 there's a lot of different descriptions and
21 different documents written by different people.

22 BY MR. MASON:

23 Q. I'm asking about this one, though.

24 MR. QURESHI: Let him finish his answer.
25 If you're going to ask him questions, give him the

1 words than just "reviews chart."

2 BY MR. MASON:

3 Q. Okay. And I'm just trying to make sure
4 that I understand all of your knowledge.

5 So other than the disposition codes, is
6 there anything else that you know about as a step
7 in the coding review process?

8 MR. QURESHI: Objection to form.
9 Outside the scope.

10 THE WITNESS: I'm just going to refer to
11 some documents.

12 BY MR. MASON:

13 Q. Sure. Just let me know which ones,
14 please.

15 A. Yeah. Let me see if I can find -- so
16 this is process documentation titled "Claims
17 Verification, Business Requirements." It's Tab 4.
18 And I don't think the pages --

19 Q. So this is your Tab 4. So for the
20 record, we're looking at Exhibit 712-4.

21 MR. QURESHI: I think he was still
22 responding. I know you're trying to clarify the
23 record, but I think he's in the middle of
24 something.

25 THE WITNESS: Yeah. I was just about to

1 say these pages don't seem to be numbered. So the
2 section I was looking at goes to Section 10, "Chart
3 Review Discrepancies." So there is a Step 2.0,
4 which I think is one thing I mentioned, validate
5 member and providers listed in the chart.

6 BY MR. MASON:

7 Q. Sorry. Can you point me to where?

8 A. So under Section 10.0, review -- "Chart
9 Review Discrepancies," the second box, process box
10 in that diagram, "Validate member and provider
11 listed in chart match CV inventory list." So
12 that's one step to look at.

13 There were steps related to HCCs on the
14 chart, and hierarchy, which are kind of covered
15 further down in the process documentation.

16 There was steps related to E&O codes,
17 which is also in the process documentation.

18 There's querying ChartSync for
19 additional charts.

20 So I think what I was trying to depict
21 is on the chart view provided, it said review
22 medical record, which is very high level, and
23 within this document there's two and a half pages'
24 worth of process flows that describe some of the
25 steps that would have been taken at that point in

1 time.

2 So the point I was trying to make is
3 review is a step in the process, but that process
4 is actually quite detailed.

5 Q. Quite detailed. And the detail can be
6 found here on page 13 -- sorry, 12, 13 and 14 of --
7 sorry. Let me try that again. Can be found on
8 page 12, 13, 14 and 15 of Exhibit 712-4?

9 MR. QURESHI: Objection to form.
10 Mischaracterizes testimony. And outside the scope.

11 THE WITNESS: This was the process as
12 documented at the time that this business
13 requirements document was put together. As I
14 indicated earlier, things evolved and changed over
15 time.

16 BY MR. MASON:

17 Q. But this was accurate as of the time it
18 was written?

19 MR. QURESHI: Same objection to form and
20 scope.

21 THE WITNESS: I have no reason to
22 believe not.

23 BY MR. MASON:

24 Q. Okay. And you said this would describe
25 some of the steps. Are you aware of any other

1 A. "After a chart review is complete and it
2 has been determined that the member associated with
3 the chart is a candidate for claims verification,
4 the system will pull the member's claims data from
5 IRADS. The system will then determine if there are
6 discrepancies between the claims information in
7 IRADS and the data from chart review."

8 Q. And is that an accurate description of
9 the claims verification process as of 2010?

10 A. It's a high-level description of the
11 matching process, not the entire claims
12 verification process.

13 Q. I'm not asking if it covers everything
14 about the claims verification process. I'm just
15 asking whether it's accurate as to how the claims
16 verification process worked at this time.

17 MR. QURESHI: Objection to form.
18 Mischaracterizes testimony.

19 THE WITNESS: But I don't think this
20 describes the claims verification process. It's a
21 component of the claims verification process it's
22 describing. So if your question is is this --

23 BY MR. MASON:

24 Q. My question wasn't does this describe
25 the claims verification process. It was: Is this

1 Q. Okay. Why don't you go to page 3. Do
2 you see at the top under "Claims Verification -
3 Purpose"?

4 A. I see that.

5 Q. Can you read what's below that out loud,
6 please.

7 A. "The purpose of the claims verification
8 is twofold: (1) Enable the submission of 'delete
9 transactions' to CMS if HCCs that were supposed to
10 be evidenced in a chart were either not evidenced
11 in the chart, or not appropriately evidenced in the
12 chart, and

13 "(2) Enable the submission of 'add
14 transactions' to CMS if HCCs are evidenced in the
15 chart but are not evidenced in IRADS."

16 Q. So putting aside numeral 2, because I
17 think we have already spoken about the fact that
18 the add component was changed early on in the
19 implementation of CV. So putting aside part 2, do
20 you agree with the statement of the purpose of
21 claims verification in part 1?

22 MR. QURESHI: Objection to form.

23 THE WITNESS: I think it's consistent
24 with the explanation that I previously provided
25 outside of the detail related to exclusive HCCs.

1 MR. QURESHI: Objection to form.

2 THE WITNESS: It depends on which --
3 where the discrepancy exists, because this doesn't
4 make it clear in here whether this is post-CVA
5 review or pre-CVA review. So I think the words
6 "potential delete" were used interchangeably with
7 CV inventory. So where there was no match, as we
8 discussed earlier there would be a review and
9 coding process. Then once the delete had been
10 identified through this multistep process, such a
11 process, that would probably be called a delete.

12 So this doesn't make it clear in this
13 document of what point in the process it's
14 referring to.

15 BY MR. MASON:

16 Q. Right. So you don't know in this
17 definition whether you're talking about just after
18 the matching logic or after the CVA analysis?

19 A. Yeah, correct.

20 Q. And so if it's just after the matching
21 logic but before the CV analysis, you would call
22 that a potential delete?

23 A. That's what many people referred to it
24 as at the time.

25 Q. And after the CV analysis, you would

1 call it a delete?

2 A. I mean, it could be a -- it could be --
3 yeah, an identified delete and an actual process
4 delete. So typically there's some kind of
5 qualification to what stage in the process it's in.

6 Q. Okay. And if the stage of the process
7 it's in is after the CVA analysis, then you would
8 call it a delete?

9 A. If it's been through the steps of the
10 process, yeah.

11 Q. Okay. And so with that clarification in
12 mind, this definition is otherwise consistent with
13 how Optum and UHC used the term "delete" at the
14 time?

15 MR. QURESHI: Objection to form. Asked
16 and answered.

17 THE WITNESS: Well, I think the things
18 that I added in there kind of change it
19 fundamentally. So I wouldn't call this consistent
20 with our understanding of what a delete is. I
21 think it lacks detail to describe which part of the
22 process it's in.

23 BY MR. MASON:

24 Q. Okay. You have a different
25 understanding of what delete means than what's

1 So I wasn't going back to determine whether the
2 data elements that were available for CV 3 were
3 also available during the earlier dates of service
4 years.

5 Q. You don't know one way or the other?

6 MR. QURESHI: Objection; asked and
7 answered. And argumentative.

8 THE WITNESS: Yeah, I don't know what
9 data elements would have been available in earlier
10 years.

11 BY MR. MASON:

12 Q. Okay. And let's go down to Number 12,
13 "Matching Logic." This bullet refers to the fact
14 that the matching logic was done at the HCC level;
15 right?

16 A. That's correct.

17 Q. And we've talked about this, but
18 matching logic is looking for a match in diagnoses
19 between the claim and the chart review?

20 A. HCC, not diagnosis.

21 Q. Thank you. Matching logic is looking
22 for a match in the HCC between the claim and the
23 chart review?

24 A. Correct.

25 Q. Okay. And what you mean by at the HCC

1 THE WITNESS: It looks higher than my
2 recollection, actually.

3 BY MR. MASON:

4 Q. Your recollection is that the percentage
5 that made the exclusive HCC rule is lower than
6 that?

7 A. Yes, it is.

8 Q. Okay. And then the inner circle,
9 approximately 360,000 charts contains HCCs
10 requiring CV coding review. Do you see that?

11 A. I do.

12 Q. What would that refer to?

13 MR. QURESHI: Objection to form.

14 THE WITNESS: To be honest, I'm not
15 familiar with this particular slide or the way that
16 the data was put together. So it's -- I'm
17 struggling to interpret it.

18 BY MR. MASON:

19 Q. Okay. Why don't we zoom out just a
20 little bit. Just at a high level, you agree that
21 the number of charts that were eligible for the CV
22 program under Optum's rules was a small subset of
23 the overall number of charts that went through the
24 chart review program?

25 MR. QURESHI: Objection to form.

1 THE WITNESS: In terms of what
2 qualifies -- so the universe of charts and which
3 ones went through the eligibility and matching and
4 resulted in a review?

5 BY MR. MASON:

6 Q. Just that made it to the matching step.

7 A. To or through the matching step?

8 Q. Let's do to the matching step first and
9 then through the matching step.

10 A. The way I understand the process works
11 is all of the charts would be considered for CV
12 eligibility. Then it would be eligibility applied
13 in terms of which of those charts had an exclusive
14 HCC associated with them where there is a match and
15 whether you're able to see I've got a provider ID
16 match between the chart data and the claim data and
17 that the member is eligible and there is an
18 exclusive HCC.

19 So all of the charts are considered in
20 that step to try and get to what is going to be
21 eligible. And then from eligibility, all of the
22 ones that are eligible are considered for matching.
23 And then after the matching, anything that didn't
24 match would move on into the CV review process.

25 Q. Okay. And the number of charts that

1 were eligible was a small subset of the overall
2 number of charts that went through the chart review
3 program; right?

4 MR. QURESHI: Objection to form. Asked
5 and answered.

6 THE WITNESS: I don't know what the
7 percentage is exactly at the eligible level. But,
8 you know, it's a portion of the overall charts. I
9 don't know exactly what the percentage is, but it's
10 not all of the charts that make it through
11 eligibility.

12 BY MR. MASON:

13 Q. Less than 25 percent?

14 MR. QURESHI: Objection to form.

15 THE WITNESS: That's my recollection.

16 BY MR. MASON:

17 Q. Less than 10 percent?

18 MR. QURESHI: Same objection.

19 THE WITNESS: You know, I can say less
20 than 25 percent. I don't know whether it's less
21 than 10 percent.

22 BY MR. MASON:

23 Q. Okay. Let's go to slide 8.

24 A. Just to be clear on that, they're all in
25 process for analysis of eligibility. So it's the

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that JON H. BIRD, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was not requested.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 26th day of June, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

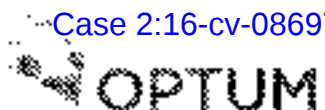
22

23

24

25

EXHIBIT P-17



PRODUCT SCORECARD

Clinical Performance & Compliance

Growth Lever: Business Services
Product Type: Service
Markets Served: Payer and Provider

Solution Description

Integrates existing systems of the client organization with a cloud-based platform to manage and enhance the delivery of member and clinical outcomes. The solution is designed to improve the quality of care and reduce costs.

Key Priorities

1. Population Health – Integrated Member/Provider Engagement
 - Integrated Assessments (in Office/Home)
 - Integrated Member Engagement (Assessments, Drug Adherence, CM-EM, etc.)
 - Big 4 Opportunities (Aetna/Coverity, Humana, Cigna and Health Net/Oscar)
2. Global Chart Management
 - Outcomes and Efficiency Improvements (MA Risk)
 - Workflow (Medicaid, PAH, Assessments, RADV/IDV, HEDIS, Hospital, Other Clinical)
 - Client Enablement and Transparency
 - Innovation: Clinical and embedded reviews linked to prospective
3. Submission and Compliance
 - MA Submissions (RAPs, EDRS)
 - Risk Adjustment Compliance (IDV, RADV, EM, etc.)
 - Other Compliance (Part C & D data validation, other consulting)
4. Quality/STARS
 - HEDIS Measurement and Chart Abstraction
 - STARS Enterprise Reporting and Other Quality Consulting
5. Integrated Platforms
 - Clinical Analytics (Risk, Quality, Utilization and Cost)
 - Campaign Management (Tracking Interventions)
 - Provider Data Sharing (One source of truth)

EXHIBIT

508A

1292

PRODUCT DETAILS

- 4293

EXHIBIT P-18

No tiff included for this record.

EXHIBIT
00201



Claims Verification Overview – March 7, 2013
John Martinez/Patty Brennan/Jim Colhour

Attorney Client Privilege

Current Industry Environment

- \$322M Settlement Agreement (August 2012)
- Page 3-4*:

“SCAN provided to the United States Centers for Medicare and Medicaid Services ("CMS"), as corrections, the diagnosis codes that the SCAN coding consultants had identified and that the physicians had not identified.

As to the diagnosis codes that the physicians had previously identified, but that the SCAN coding consultants had failed to identify, SCAN failed to inform CMS that such codes might have needed to be *withdrawn from SCAN's prior submissions* to CMS for the Encounters.

Had SCAN provided that information to CMS, Medicare Part C's capitated rate payments to SCAN based on the Encounters allegedly would have been lower than they were.”

*Source: http://oag.ca.gov/system/files/attachments/press_releases/SCAN-Settlement%20Agreement_0.pdf

EXHIBIT P-19

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
United States' 30(b)(6) Designee 1
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
At the Law Offices of Latham & Watkins
Thursday, May 25, 2023
10:24 a.m. Eastern

1 I'll put on that list is the June -- the response to
2 the comment in June of 2000, which is in Exhibit 164
3 at, you know, Page 40286.

4 Are there any other documents that should go
5 on this list that --

6 MS. LIKOFF: Object to --

7 BY MR. GALLAGHER:

8 Q -- you say support the rule you say exists?

9 MS. LIKOFF: Object to form. Objection.

10 Outside the scope of Topic 21. Topic 21 did not ask
11 the witness to prepare to identify all instances of
12 any communications.

13 THE DEPONENT: I would say that CMS has been
14 very clear, including in Ms. Rice's deposition, that
15 CMS does not provide recipes about how MAOs should
16 conduct their chart review programs. So CMS is not
17 going to provide a threshold for what information is
18 or a threshold for what best knowledge is. That is
19 the responsibility of the MAO when designing an
20 effective compliance program that ensures that it --
21 that the -- the organization is fulfilling all program
22 requirements including the payment ones and that

1 ensures that it is -- identified the key risks and is
2 monitoring them and auditing. So that -- it's the
3 MAO's responsibility.

4 So you're asking for something that M- --
5 that CMS has been clear they, on purpose, are not
6 doing. They are not providing a detailed series of
7 steps or a recipe for how to conduct and organize and
8 design a chart review program. CMS requires that
9 diagnoses be accurate, complete, and truthful. It's
10 the MAO's responsibility to figure out how to make
11 that truth which allows them to certify every year.

12 MR. GALLAGHER: I'm going to move to strike
13 that as not responsive.

14 BY MR. GALLAGHER:

15 Q My question is just, can you give me a list
16 of the documents you rely upon for the assertion that
17 there exists a duty for MAOs to investigate if they
18 have any information that a set of codes is not
19 supported?

20 MS. LIKOFF: Object to form. Asked and
21 answered.

22 Counsel, the fact that you don't like her

1 Because -- because CMS doesn't specify how to validate
2 risk adjustment data. I mean, you're using the word
3 "audit," so I guess you mean auditing risk adjustment
4 data. CMS doesn't tell MAOs how to audit risk
5 adjustment data. So the specificity -- you're looking
6 for a very specific link that doesn't make sense
7 because under the risk adjustment program, there is no
8 specific requirement for an audit. Under 422.503,
9 audit could mean something very general, even for risk
10 adjustment data. It doesn't have to be on diagnosis
11 codes.

12 BY MR. GALLAGHER:

13 Q My question is not whether you communicated
14 how you think they should conduct an audit.

15 My question is, can you point to anywhere
16 that CMS communicated to MAOs that there's an
17 obligation under 422.503(b)(4)(vi) to audit risk
18 adjustment data at all?

19 MS. LIKOFF: Objection to form.

20 THE DEPONENT: There's an obligation to have
21 accurate data, which is also under 422.504. So when
22 you go look at that one step in the compliance

1 programs, there are series of obligations described,
2 you know, monitoring audit, et cetera. So you're
3 looking for one very specific link when it -- that's
4 just not how CMS operates with this.

5 BY MR. GALLAGHER:

6 Q Earlier you testified that it's CMS's view
7 that 422.503(b)(4)(vi) creates an obligation for plans
8 to audit risk adjustment data to confirm the support
9 for codes.

10 And my question is just, can you point me
11 anywhere where CMS has communicated that view to
12 plans?

13 MS. LIKOFF: Objection to form.

14 THE DEPONENT: And I did -- I did not say
15 just audit. I was talking about the entire paragraph,
16 which is there should procedures for monitoring and
17 audit and -- oh, goodness, where is it? I want to
18 read --

19 BY MR. GALLAGHER:

20 Q I -- I don't need you to read it.

21 A -- that section.

22 Anyway, I didn't say just audit. I said the

1 whole kit and caboodle. There's a requirement to do a
2 risk assessment and then develop procedures to deal
3 with the problems at hand or areas that are always at
4 risk of error such as payment. And that you need to
5 develop monitoring protocols, select some audits in or
6 out, if that's useful, and just make sure that the
7 program is in full compliance with all of the program
8 guidelines, which is a statement at the beginning of
9 Paragraph -- Subparagraph 6.

10 Q Can -- can you point to me anywhere where
11 CMS has told plans that it's your view that
12 422.503(b)(4)(vi) imposes on them an obligation to
13 audit risk adjustment data?

14 A You know --

15 MS. LIKOFF: Objection to form.

16 THE DEPONENT: Yeah. You said my view, and
17 I'm -- I'm just not going to say anything else beside
18 what I said. I answered the question by saying the
19 implementation of that Subparagraph 6 depends on the
20 risk assessment results and on what the MAO decides
21 under 422.310 to do to validate its data, its risk
22 adjustment data.

1 BY MR. GALLAGHER:

2 Q Right.

3 And so the requirement is to do a risk
4 assessment; right?

5 A That's part of it.

6 Q And -- and what plans do, based on that risk
7 assessment, and -- and frankly whether they've done an
8 appropriate risk assessment, is something that the
9 government audits through MOEG; yes?

10 MS. LIKOFF: Objection to form. Objection.
11 Outside the scope to the extent you included the --
12 the term "government."

13 THE DEPONENT: What MOEG audits for CPE,
14 compliance program effectiveness, is, is there a
15 process in place? And then they find certain problems
16 that came up, and they track them through the process.
17 They don't comment on the nature of the process that
18 the MAOs put in place.

19 BY MR. GALLAGHER:

20 Q Right.

21 They -- they -- they -- but they will
22 comment if they find problems; right?

1 Here you're referring to your own personal
2 view, not something that you ascertained with advice
3 of counsel or with somebody higher up in the -- in
4 the -- in the chain of command at CMS; right?

5 A You mean the sentence I just said?

6 Q Yeah. The -- the --

7 A That -- the sentence I just said is CMS's
8 position on -- on using -- on the limits of using
9 group level -- level memos that are internal to a
10 group that never see the light of day anywhere outside
11 the group. And that CMS would say they're very --
12 there are limits to using that to mean anything.

13 Q Right. Right.

14 My -- my point is just that when -- when I
15 asked the best authority for the medical record review
16 rule that you referenced here, when you write this in
17 this email, you're referring to what you, Anne
18 Hornsby, think, not something that you have vetted
19 through the process at CMS or gotten advice of counsel
20 on; right?

21 A Of course not. This is just my memo done
22 with Jennifer that just reflects two people of the

1 many people within MPPG to present some approaches to
2 Cheri, the di- -- the group director. So this memo is
3 really not particularly meaningful from CMS's point of
4 view. It's -- you know, it's just a little staff
5 memo.

6 Q You say in the next sentence, "And I gather
7 we don't want to use that," referring to the
8 contracting requirement to have a routine process for
9 monitoring compliance risk; right? That's what you
10 say in the next sentence?

11 A That's what's written there.

12 Q Yeah.

13 Why -- why didn't you -- and -- and the "we"
14 there is a reference to MPPG not wanting to use that
15 contracting requirement as the authority for the
16 medical record review rule?

17 MS. LIKOFF: Objection to form.

18 THE DEPONENT: Speaking as Anne Hornsby, I
19 do not remember that. I -- I just don't.

20 BY MR. GALLAGHER:

21 Q So then you say, "So I've tried to write the
22 authority for requiring this using the contractual

1 BY MR. GALLAGHER:

2 Q Have you ever specified for plans the
3 circumstances in which you believe at CMS they are
4 obligated to investigate whether codes are or are not
5 supported by the medical records? Have you ever given
6 that specific guidance to plans whether it's in a rule
7 or regulation or any -- some regulatory guidance?

8 MS. LIKOFF: Objection to form.

9 THE DEPONENT: If CMS says, and for many
10 forms of this guidance you've listed, is that the data
11 has to be accurate and complete and truthful. So when
12 an MAO is doing chart reviews or medical record
13 reviews, they have a protocol, presumably. CMS knows
14 nothing about the MAO chart review protocols, but they
15 have a protocol presumably which gives them results.
16 And this is not rocket science. If there's something
17 that quacks like a duck, it probably is a duck, an
18 unsupported diagnosis. And the MAO knows that that
19 violates the regulation to submit accurate data.

20 Q Have you ever given MAOs specific guidance
21 on when it is you think they have to conduct a medical
22 record review or do further investigation to determine

1 REPORTER'S CERTIFICATE

2 DISTRICT OF COLUMBIA

3

4 I, Jeaninn Y. Alexis, a Notary Public of the
5 District of Columbia, do hereby certify that the
6 with-named witness personally appeared before me at
7 the time and place herein set out, and after having
8 been duly sworn by me, according to law, was examined
9 by counsel.

10 I further certify that the examination was recorded
11 stenographically by me, and that this transcript is a true
12 record of the proceedings.

13 I further certify that I am not of counsel to any of
14 the parties, nor an employee of counsel, nor related to any of
15 the parties nor in any way interested in the outcome of the
16 action.

17 As witness my hand and seal this 5th day of June, 2023.

18

19

20

21

22

Jeaninn Y. Alexis

JEANINN ALEXIS

My Commission Expires: 11/30/2023

EXHIBIT P-20

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

CONTAINS PORTIONS OF ATTORNEYS' EYES ONLY

Videotaped Deposition of
SEAN CAVANAUGH
Given Remotely
Thursday, February 17, 2022
9:02 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 fee-for-service, traditional claims data, and the
2 Medicare Advantage plans data, right?

3 A. Well, I think it was much more common, if
4 it was unsupported, to be on the side where it drove
5 financial advantage and Medicare Advantage. And if
6 it was omitted, it was much more likely to happen on
7 the fee-for-service side, where it didn't cause any
8 financial harm.

9 Q. Setting aside your belief about the extent
10 to which it occurred, you agree that both fee for
11 service and Medicare Advantage, you know, submitted
12 data included codes that were not supported by the
13 medical records, and omitted diagnostic codes that
14 would be supported by the medical records? Right?

15 MS. KRIEG: Object to form.

16 THE WITNESS: Yes, it was my understanding
17 that that was true.

18 BY MR. GALLAGHER:

19 Q. And you could refer to that as overcoding
20 and undercoding, right? Overcoding being assigning
21 codes that are not supported by the medical record,
22 and undercoding being omitting codes that would be
23 supported by the medical records. Fair?

24 A. Yes. They frequently -- they are
25 frequently referred to that way.

1 Q. And it was your understanding, as the
2 director for the Center for Medicare in 2014, 2017,
3 in that time frame, that overcoding and undercoding
4 was to some degree an issue with both traditional,
5 fee-for-service data and the data submitted by
6 Medicare Advantage plans. Right?

7 MS. KRIEG: Object to form.

8 THE WITNESS: Yes.

9 BY MR. GALLAGHER:

10 Q. Bear with me one second. I have an
11 outline, and I've covered some of it already. I
12 don't want to waste time, so -- just bear with me one
13 second.

14 So I want to direct your attention to the
15 article that we've marked as Exhibit 1002, and in
16 particular to page 5, at the top.

17 Are you on page 5?

18 A. I am.

19 Q. So do you see at the top, where
20 Mr. Kronick and Mr. Welch write in their article that
21 "However, fee-for-service coding is known to be both
22 incomplete and variable." Do you see that?

23 A. Yes.

24 Q. And this article was written in two
25 thousand -- or published in 2014. Do you agree with

1 was inaccurate, you had to do something, what did you
2 mean by "came across that knowledge"?

3 A. If by any mechanism, whether it's medical
4 record review or other -- I don't want to run through
5 hypothetical scenarios. I don't know everything that
6 goes into how they run their plans and their audits
7 and so forth. But they had an affirmative obligation
8 to make it correct.

9 Q. So are you saying that an affirmative
10 obligation, if they knew, from whatever mechanism,
11 that a code was not supported, to withdraw it?

12 A. Absolutely if they knew. I'm
13 less conversant in law and regulation on if they had
14 an affirmative obligation to take reasonable steps to
15 find out.

16 Q. Sitting here today, you can't identify any
17 rule or regulation that created an affirmative
18 obligation to audit the claims data submitted by
19 providers, or to proactively review medical records,
20 to ensure that the codes selected by providers were
21 supported?

22 A. I cannot. But I'm not an expert in the
23 area and don't work in that area.

24 Q. This rule that we're looking at in
25 Exhibit 1006, the medical records review rule that

1 BY MR. GALLAGHER:

2 Q. Right. And the provision of the medical
3 record review rule that would have required Medicare
4 Advantage organizations to design their medical
5 record reviews to determine the accuracy of
6 diagnoses -- in other words, to look for deletes --
7 that was one of -- that was the part that was
8 withdrawn and never finalized, right?

9 MS. KRIEG: Object to form.

10 THE WITNESS: This provision you referred
11 me to, 422.3.0 was not finalized.

12 BY MR. GALLAGHER:

13 Q. And you're not aware of any other rule or
14 regulation that imposes this requirement, are you?

15 A. Again, my understanding of the attestation
16 would cover similar ground. And in fact, you know, I
17 was always careful to tell United that, you know,
18 there are multiple rules and statutes that may apply,
19 and you should be careful to comply with all of them,
20 and you shouldn't focus solely on this proposed rule.

21 Q. There was no other -- there is no other
22 rule or regulation that specifically instructs
23 Medicare Advantage plans that they must conduct
24 medical record reviews to look for deletes, right?

25 A. I'm -- I'm not the right person to ask

1 Do you agree that you and Ms. Rice were
2 the appropriate people to be talking about this issue
3 with United?

4 A. Yes, among others.

5 Q. All right. So then -- let's go back to
6 the first page of Exhibit 1060, now that we have the
7 background for the meeting. And -- and do you see --
8 well, actually, first, I'm sorry, go back to page 2.
9 There's something I forgot to ask about.

10 A. Uh-huh.

11 Q. So Mr. Renfro indicates that "other
12 Medicare Advantage plans do not look for possible
13 deletions when reviewing medical records."

14 Did you know that in 2014? That
15 medical -- Medicare Advantage plans were conducting
16 medical record reviews, and for the most part, not
17 looking for deletes?

18 A. I did not know that.

19 Q. Did that surprise you --

20 MS. KRIEG: Object to form.

21 BY MR. GALLAGHER:

22 Q. -- when you learned?

23 MS. KRIEG: Object to form.

24 THE WITNESS: I don't recall how I reacted
25 to it.

1 What do you recall about who said what, if anything?

2 MS. KRIEG: Object to form.

3 BY MR. GALLAGHER:

4 Q. Actually, let me -- let me ask it
5 differently.

6 Do you have a specific recollection of who
7 said what at the meeting?

8 A. My recollections are much stronger on what
9 CMS said, because it was something we practiced and
10 something we agreed upon prior to going into the
11 meeting.

12 I am much weaker on my recollections of
13 specifically what United said and asked. But as I
14 told you previously, we had agreed that we would
15 consistently say that -- that, you know, they should
16 stay tuned to find out whether the proposed
17 regulation was finalized or not. However, that was
18 not the only applicable requirement on them to make
19 sure they submitted complete and accurate data in --
20 for risk adjustment, and that to the degree they were
21 posing questions to us that sought legal advice on
22 their obligations under the statute and regulations,
23 they should instead rely on their own counsel, and
24 not this meeting.

25 Q. Was that a mantra that you practiced in

1 advance? I mean, did you have a script for that?

2 A. I -- I probably would have had notes of
3 some sort, but it -- it was something -- it was
4 certainly something we talked amongst ourselves and
5 agreed to. I think -- you know, I think, as you read
6 from the e-mails, there was a concern that they might
7 be trying to get us to say something other than that.

8 Q. Can you give me the answer again, like
9 what -- what you recall about the meeting?

10 MS. KRIEG: Object to form.

11 THE WITNESS: About what I recall about
12 the meeting? Or --

13 BY MR. GALLAGHER:

14 Q. No, what you recall CMS said, because you
15 practiced it.

16 A. Yeah. I was better at this eight years
17 ago than I am now, but my recollection is it was
18 along the lines of, yes, there's a proposed
19 regulation. It may or may not be finalized. We
20 can't tell you one way or the other. However, if
21 you're solely focused on that, you should be aware
22 there are other statutes, regulations, requirements
23 that apply to your obligation to submit complete and
24 accurate data. You should make sure you're aware of
25 them, and if you're asking us questions about how to

1 specifically comply with the law, that's more
2 appropriately posed to your own counsel.

3 Q. Do you recall that there was -- there were
4 actually a couple of issues raised by United about
5 their -- about what the rule -- what the rules were;
6 that it wasn't just whether the medical record review
7 rule would be finalized, but also what to do with
8 their as-yet-not-completed medical record review that
9 they had been conducting for the 2012 year?

10 A. I -- in the vaguest sense, I do recall
11 something like that, yes.

12 Q. So you recall that there was discussion
13 about how United had been -- unlike other plans, had
14 been conducting medical record reviews and looking
15 for deletes, that they had a whole process around
16 that, and that they had not yet really completed it?

17 MR. LANGHAM: Objection. Form.

18 BY MR. GALLAGHER:

19 Q. Do you recall that?

20 A. I have a recollection that they did
21 describe their medical record review process in
22 some -- I forget how much detail, but they were
23 describing it.

24 Q. If you would look at Exhibit 1060, which
25 is the exchange you had with Cynthia Tudor and

1 Q. And you deny that Cheri Rice said that?

2 A. I -- yes. I deny that she said that. It
3 seems -- it's totally inconsistent with the approach
4 we took into that meeting, and what we agreed to say.

5 Q. So you claim that rather than saying that,
6 you stuck to the script that you gave us earlier, and
7 just repeated that mantra?

8 A. When it came to articulating any
9 obligation and duty, or duty they had, that was the
10 response we gave.

11 Q. Did you give that response more than once
12 in the meeting? Like multiple times?

13 A. Oh, yes. Yes.

14 Q. So it was a mantra that you repeated, you
15 claim, multiple times in response to questions from
16 United?

17 A. Yes.

18 Q. And you deny saying anything else besides
19 the mantra on the subject of what United's
20 obligations were before finalization of the medical
21 record review rule?

22 MR. LANGHAM: Objection. Form.

23 THE WITNESS: I deny saying anything else
24 about what their obligations were under either
25 the probes reg or existing requirements.

1 firsthand.

2 Q. So you actually don't recall one way or
3 the other whether Ms. Rice said this about what you
4 have to do if you have knowledge?

5 A. I don't have a specific recollection, as I
6 said, but it did seem more consistent with how we
7 prepared for the meeting.

8 Q. Okay. Let's go to page 2, and in -- and
9 in particular, the second bullet point.

10 A. The second bullet point?

11 Q. Yeah, that begins, "Cheri Rice then asked
12 some follow-up questions." Do you see that?

13 A. Yes, I see that.

14 Q. And do you see the sentence that reads,
15 near the end of that paragraph, "Sean Cavanaugh
16 stated that, under current rules, if UHG doesn't know
17 codes are inaccurate the company would not have to
18 delete them. He went on to state that if UHC does
19 not know until the end of its claims verification
20 process that a code is incorrect then there is no
21 requirement to delete the code until the effective
22 date of CMS's final rule." Do you see that?

23 A. I see that.

24 Q. You -- you deny saying that?

25 A. I deny it, absolutely.

1 BY MR. GALLAGHER:

2 Q. In the next sentence of his e-mail,
3 Mr. Nelson writes, "During our conversation yesterday
4 and other recent conversations, CMS confirmed to us
5 that these requirements do not apply until the
6 effective date of the rule." Do you see that?

7 A. I see that.

8 Q. And do you agree that the requirements of
9 the medical record review rule did not apply, or
10 would not apply, until the effective date of the
11 rule?

12 A. I agreed that -- well, actually, I think
13 I -- yes, I think I agree.

14 Q. And do you agree that that's something
15 that -- that somebody from CMS told United during
16 your meeting on April 29th, 2014?

17 A. I think if we'd been asked about the reg,
18 we would have said, again, what you see Cheri says,
19 what I called my mantra. But you also see in Cheri's
20 response, which is, you know, there are other
21 applicable laws that impose standards requirements
22 and responsibilities. I don't know that we would
23 have specifically given that response to him.

24 And the --

25 Q. So you deny that -- you deny -- sorry. Go

1 ahead.

2 A. No, go ahead, please.

3 Q. You deny confirming that the requirements
4 of the medical -- the proposed medical record review
5 rule do not apply until the effective date of the
6 rule, because you believe that instead of answering
7 that, you would have simply repeated the mantra that
8 you agreed to deliver at the meeting?

9 A. Correct. And as I told you previously, my
10 only specific recollection around this sort of topic
11 was in the abstract, about a regulation that is not
12 finalized.

13 Q. All right. Mr. Nelson writes that "CMS
14 confirmed to us that these requirements do not apply
15 until the effective date of the rule, and that
16 Medicare Advantage plans are thus not currently
17 required to design their medical record reviews to
18 determine the accuracy of risk adjustment diagnoses."

19 Do you see that?

20 A. I see that.

21 Q. And you deny saying that anybody from CMS
22 said that at the meeting, right?

23 A. Absolutely.

24 Q. All right. So let's -- let's look at --
25 because you had agreed to deliver the mantra, and

1 that's all you did, as you recall it?

2 A. But also, as phrased here, the reason why
3 my memory is so crystal clear, none of us would say,
4 if you're doing a medical record review, you
5 shouldn't -- you wouldn't be held to a standard of
6 trying to be accurate. Like that -- that's just not
7 a posture CMS would take.

8 Q. All right. So on page 1 -- well, sorry.
9 So there's two reasons you say you deny that you said
10 that.

11 One is because, as you said a few times,
12 you agreed to deliver the same mantra in response to
13 questions like that. And the second is, you believe
14 you would never have said such a thing because it's
15 not consistent with what, you know, your
16 understanding was?

17 A. Correct.

18 Q. Okay. All right. So on the first page of
19 Exhibit 1063, you have Mrs. Rice responding to
20 Mr. Nelson's e-mail, on May 2nd, 2014. Right?

21 A. Yes.

22 Q. Anywhere in this e-mail does she deny that
23 CMS confirmed, as Mr. Nelson set forth, that the
24 requirements of the medical record review rule do not
25 apply until the effective date of the rule, and that

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 SEAN CAVANAUGH was remotely sworn to testify to the
7 truth, the whole truth and nothing but the truth.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20



21

Karen K. Kidwell

22

Registered Merit Reporter
Certified Realtime Reporter
Notary Public

23

Dated: February 28, 2022

24

25

EXHIBIT P-21

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 3
DEPOSITION OF ANNE HORNSBY
As 30(b)(6) Designee 1 of
The United States

Washington, DC
November 21, 2023

Reported by: John L. Harmonson, RPR

1 Mr. Gardner during the Zoom session -- one of the
2 Zoom sessions that you had with him; correct?

3 MS. LIKOFF: Object to form. Asked and
4 answered.

5 THE WITNESS: Yes, that was an adequate
6 preparation because of what the answer was. The
7 fact that the answer was no results have been
8 released, the answer is there is nothing else to do
9 to prepare. I focused on preparing for CON14 and
10 CON15.

11 BY MR. MARTINEZ:

12 Q. Are you aware that CMS has released I
13 believe what it referred to as preliminary results
14 of the payment year 2011 through 2013 RADV audits
15 to MA plans?

16 MS. LIKOFF: Objection. Outside the
17 scope in terms of the time frame the witness has
18 been designated for.

19 THE WITNESS: I'm not prepared to
20 testify on behalf of CMS on this topic. It is out
21 of my scope.

22 BY MR. MARTINEZ:

23 Q. So my question is are you aware -- and
24 let me step back, because what you're telling me
25 now is that Mr. Gardner told you that the results,

1 the audit results for years prior to CON14 had not
2 been released as of the time you spoke to him. Is
3 that right?

4 MS. LIKOFF: Objection; asked and
5 answered.

6 THE WITNESS: That is a correct summary
7 of what Mr. Gardner said to me.

8 BY MR. MARTINEZ:

9 Q. Okay. And so then my follow-up question
10 is: Are you aware whether any results, whether
11 preliminary or final, have been released to MA
12 plans concerning the payment year 2011 through 2013
13 audits?

14 MS. LIKOFF: Objection; outside the
15 scope. Again, this witness was prepared on this
16 limited topic with respect to only the time period
17 post July 2021.

18 THE WITNESS: I'm not prepared to
19 testify on behalf of CMS for these previous audit
20 years with which I was not tasked.

21 BY MR. MARTINEZ:

22 Q. All right. You reviewed the deposition
23 testimonies you've indicated of the government's
24 Designee Witness 6 in preparation for today;
25 correct?

1 That's the system that the medical reviewers, the
2 reviewers look at.

3 So I asked -- so, you know, there is a
4 process within CDAT that gives MAOs continuous
5 report feedback. They can log in any time and see
6 where their medical record reviews are in the
7 process in CDAT. So that's all part of medical
8 record review.

9 That's separate from the analytical
10 piece of the RADV audit where you take all those
11 results, build all these massive datasets, crunch
12 them, and then eventually have a result for each
13 contract.

14 Q. So that second piece of analyzing all of
15 the results from the medical record reviews for
16 payment years 2014 and 2015, that piece has not
17 happened yet; correct?

18 A. That is correct. I asked Dave, and he
19 said there are no preliminary results for '14 or
20 '15 at this point.

21 Q. Who is the lead analytic contractor for
22 the payment year 2014 and 2015 RADVs?

23 A. Deloitte.

24 Q. All right. We've talked about some of
25 the documents that you reviewed in preparation for

1 from the provider or was instead added by the MAO
2 through chart review?

3 A. CMS does not know what kind of data
4 exists in MAOs, in the parent organizations. It
5 does not know; does not have that information. So
6 that means -- also, it means that with the RAPS
7 system, the abbreviated dataset, CMS cannot
8 distinguish between a provider-submitted diagnosis
9 and an additional diagnosis added by the MAO from
10 its own chart review. CMS cannot distinguish that.

11 With encounter data, you could partly
12 distinguish but not completely. So it's still not
13 something that could be relied on if that were of
14 interest.

15 Q. Is RADV, the RADV process that CMS is
16 performing, is it designed to separate inaccurate
17 codes that originate with providers as opposed to
18 inaccurate codes that were potentially added by the
19 plans themselves?

20 A. That is not CMS's intention. And as
21 I've explained, CMS cannot make that distinction in
22 any systematic way.

23 Q. If I was to look at the results of any
24 given RADV audit performed by CMS, then, it would
25 not tell me what percentage of the

1 provider-submitted codes were accurate?

2 MS. LIKOFF: Objection to form. Vague.

3 THE WITNESS: CMS is interested in
4 determining whether or not the HCC on which the MA
5 contract was paid is supported in the medical
6 record. That's what accurate is. Accurate means
7 supported, the diagnosis is supported in the
8 medical record.

9 BY MR. BAAK:

10 Q. To my question, though, if I look at the
11 results of any given RADV audit performed on a
12 contract by CMS, the purpose of that is not trying
13 to identify what percentage of the
14 provider-submitted codes were inaccurate on that
15 plan; right?

16 A. The purpose of the RADV audit is to
17 determine what enrollee HCCs are not validated by
18 coder review. That's -- that's it. That's what
19 CMS is looking for.

20 Q. And CMS is making no distinction in that
21 process between codes that originated with the
22 providers themselves versus codes that were added
23 downstream by the plans through chart review;
24 correct?

25 A. CMS doesn't have that information so it

1 would not be possible to incorporate it in the
2 sampling frame.

3 Q. You mentioned as your second category
4 the IPIA and IPERIA requirements. What is IPIA?

5 A. The Improper Payment Improvements Act,
6 which was the initial one in 2002. There are
7 amendments, I believe, to Department of Treasury
8 U.S. Code. And then Congress subsequently made two
9 more versions of it in the time frame of this
10 litigation. So the most recent, 2013, is IPERIA.
11 And I don't even remember what all the extra
12 letters stand for.

13 But the point was federal
14 government-wide to have programs that expend over a
15 certain dollar limit conduct a risk adjustment and
16 then every year conduct an analysis to come up with
17 an improper payment error rate for that program.

18 So CMS, being a very large organization,
19 has to do an improper payment error analysis for a
20 number of its programs: Medicare Advantage,
21 fee-for-service, Part D, Medicaid, SCHIP, so on.
22 That's where the term "improper payment" came into
23 common discourse in CMS. It's from those laws.

24 Q. Has CMS calculated an improper payment
25 amount on Medicare Advantage for every year from

1 to their medical record reviews in January of 2014?

2 A. That is correct.

3 Q. And then ultimately CMS opted not to
4 finalize this new proposed requirement on MA plans
5 related to how they conduct their medical record
6 reviews; right?

7 A. CMS opted not to finalize over 40
8 provisions in the proposed rule.

9 Q. And one of them --

10 A. And one of them was medical record
11 review proposal, yeah.

12 Q. So coming back to the attachment to your
13 email, the bottom part of the email says Issue 6.B,
14 and then it says: "Amend Section 422.310 to
15 require MA organizations conducting medical record
16 reviews to focus" -- "to not focus only on
17 identifying underpayments."

18 Do you see that?

19 A. I do see that sentence.

20 Q. So this is the section that's on what
21 ultimately became the proposed medical record
22 review rule; right?

23 A. Yes. This is an early draft.

24 Q. And you say -- this next statement under
25 6.B is that "Under existing regulation, there is no

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that ANNE HORNSBY, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

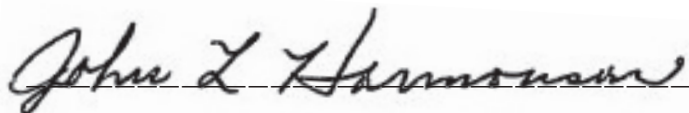
10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 27th day of November, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

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EXHIBIT P-22

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF

ANNE HORNSBY

(Taken virtually)

10:03 a.m. Eastern

Wednesday, May 18, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 have been a new obligation in the sense
2 that a continuous adequate compliance
3 review process conducted during the routine
4 course of business of an MAO should include
5 looking for diagnoses that are not
6 supported by the medical record and looking
7 for diagnoses that could be submitted for
8 payment that had been missed. So that
9 should have been seen as part of a rigorous
10 compliance process. And, in fact, you
11 know, CMS has a contract termination
12 requirement that if you don't submit valid
13 risk adjustment data, we can stop your --
14 terminate your contract. But, you know, a
15 lot of times people find that specifying
16 guidance more precisely, you know, is
17 helpful. So it's -- did that answer your
18 question?

19 BY MR. LEE:

20 Q. Yes. Even though the medical record
21 rule as proposed ultimately was not passed, was it
22 your understanding that MAOs had obligations to
23 CMS?

24 A. Yes.

25 MS. SCHEFFLER DO: Objection. Vague.

1 THE WITNESS: Do I --

2 BY MR. LEE:

3 Q. And were part of the obligations to
4 submit accurate, truthful, and complete data to
5 CMS?

6 A. Yeah, absolutely.

7 MS. SCHEFFLER DO: Objection. Lacks
8 foundation.

9 THE WITNESS: So I don't answer?

10 BY MR. LEE:

11 Q. You can answer.

12 MS. SCHEFFLER DO: You can -- yeah, let
13 me get my objection out, please, and then
14 you can go ahead and answer.

15 BY MR. LEE:

16 Q. And was it your understanding as part
17 of the obligations that MAOs had, that they were
18 required to delete submitted codes that they knew
19 were inaccurate?

20 MS. SCHEFFLER DO: Objection. Form.

21 THE WITNESS: Absolutely. Absolutely.

22 MS. SCHEFFLER DO: Lacks foundation.

23 THE WITNESS: That's part of the
24 compliance.

25 BY MR. LEE:

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified
Court Reporter within and for the State of
Georgia, do hereby certify:

That the foregoing deposition was
taken before me on the date and at the time and
location stated on Page 1 of this transcript; that
the deponent was duly sworn to testify to the
truth, the whole truth and nothing but the truth;
that the testimony of the deponent and all
objections made at the time of the examination
were recorded stenographically by me and were
thereafter transcribed; that the foregoing
deposition as typed is a true, accurate and
complete record of the testimony of the deponent
and of all objections made at the time of the
examination to the best of my ability.

I further certify that I am neither
related to nor counsel for any party to the cause
pending or interested in the events thereof.
Witness my hand, this 22nd day of May, 2022.

Christine Taylor

Christine A. Taylor, RPR
CCR-4736

EXHIBIT P-23

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex
rel. BENJAMIN POEHLING,
Plaintiffs,

vs.

No. CV 16-08697 FMO

UNITEDHEALTH GROUP, INC., et al,
Defendants.

_____ /

** CONTAINS CONFIDENTIAL PORTIONS **

REMOTE VIDEOCONFERENCE DEPOSITION OF
JONATHAN BLUM
March 4, 2022

Reported by:

Anne E. Vosburgh, CSR-6804, RPR, CRR

Job No. 789903

1 J. BLUM

2 seeing code growth was the behavior the
3 plans -- plans' different behaviors and
4 different tactics.

5 BY MR. SUMMERS:

6 Q. Right. And one of those behaviors
7 was one-way chart review, correct?

8 MS. LIKOFF: Objection to form.

9 Asked and answered. Vague.

10 A. I cannot speak to the operations
11 that a plan had. I can speak to the policy
12 that CMS set.

13 BY MR. SUMMERS:

14 Q. Okay. I know you can't speak with
15 firsthand knowledge to what MA plans were
16 doing. But at the risk of extreme repetition,
17 I'm asking you, did you have a general
18 awareness that one of the things that was
19 driving the increased coding was one-sided
20 chart review by MA plans?

21 MS. LIKOFF: Objection to form.

22 Asked and answered. Vague.

23 A. Again, chart review takes multiple
24 forms. There's not one common terminology
25 that I'm aware of.

1 J. BLUM

2 Typically CMS would finalize
3 regulations, then produce materials to
4 describe those final regulations. But, again,
5 I was not involved with the final
6 determination of that regulation.

7 BY MR. SUMMERS:

8 Q. And there were no regulations
9 explicitly requiring medical record reviews to
10 be two ways, right?

11 MS. LIKOFF: Object to form.

12 BY MR. SUMMERS:

13 Q. That's not controversial, is it?

14 MS. LIKOFF: Object to form. Vague.

15 Asked and answered.

16 A. My understanding of the regulations
17 that were in place, the plans had an
18 obligation to submit accurate diagnosis codes
19 to the Agency.

20 BY MR. SUMMERS:

21 Q. I'll take that as a no, there were no
22 such requirements explicitly, unless you'd like
23 to amend your remarks.

24 The --

25 MS. LIKOFF: Object to form.

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J. BLUM

C E R T I F I C A T E

I, ANNE E. VOSBURGH, Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, and Closed Captioner, hereby certify:

That JONATHAN BLUM, via remote videoconference, solemnly affirmed and agreed to testify to the truth, the whole truth and nothing but the truth; that all counsel stipulated to this process, notwithstanding the location of reporter or witness at time of deposition; and that this transcript is a true and correct record of testimony given.

I further certify that I am not related to any of the parties to this action and that I am in no way interested in the outcome of this matter.



ANNE E. VOSBURGH

Certified Shorthand Reporter No. 6804
Registered Professional Reporter
Certified Realtime Reporter

EXHIBIT P-24

Message

To: Cherl Rice@cms.hhs.gov
CC: Johnson, Thad C. [/O=UHC-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=21e0e185-77aa00a2-85256887-56b2c8]; Schumacher, Daniel J. [/O=UHC-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=f1a13511-1e478dc-852567a-520b3e]; Erickson, Karen L. [/O=UHC-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=2f9c139c-fc81e059-85256977-61819f]; Jennifer Harlow@cms.hhs.gov
BCC: Nelson, Steve H. [/O=UHC-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=steels50], Cosgriff, John W. [/O=UHC-EXCHANGEMAIL/OU=First Administrative Group/cn=Recipients/cn=45fd8f6b-8e-b0d608-8525702f-69b35]
Subject: 2012 Attestation and follow-up from yesterday's meeting

Cheri,

Thanks for your email, and please let us know if you need any additional information.

Steve

-----Original Message-----

From: Rice, Cheri M. (CMS:CM) [Cheri.Rice@cms.hhs.gov]
Sent: Friday, May 02, 2014 05:14 PM Central Standard Time
To: Nelson, Steve H.
Cc: Johnson, Thad C.; Schumacher, Daniel J.; Erickson, Karen L.; Harlow, Jennifer A. (CMS:CM)
Subject: RE: 2012 Attestation and follow-up from yesterday's meeting

Steve,

Thank you for your email and for our discussion earlier this week. With respect to your fifth point, I would note that regardless of the effective date of the proposed requirement related to medical record reviews, there are other laws that do impose standards, requirements and responsibilities on MA plans in connection with the federal payments they receive from CMS. We cannot provide advice to United about the scope of those other laws. Nor can we provide advice on whether United's plan course of action and/or purported limits on the scope of its attestation are compliant with such other laws. Your statement concerning the data submissions that have already been made and United's plans for future action will be included in our records and we will proceed with our evaluation and use of the risk adjustment data consistent with 42 CFR 422.308, 422.310, and other applicable law.

Thanks again.

Cheri

From: Nelson, Steve H. [mailto:steve_nelson@uhc.com]
Sent: Wednesday, April 30, 2014 9:55 AM
To: Rice, Cheri M. (CMS:CM)
Cc: Johnson, Thad C.; Schumacher, Daniel J.; Erickson, Karen L.; Nelson, Steve H.
Subject: 2012 Attestation and follow-up from yesterday's meeting

Dear Cheri,

I wanted to thank you and your colleagues for taking the time to meet with us yesterday. We appreciate the time and attention that you and others in CMS leadership have provided on the issue of our 2012 risk adjustment data.

EXHIBIT
00324

submissions and our annual risk adjustment data certifications. As we mentioned, prior annual certifications have been on paper, and we have thus had the ability to add notes explaining our understanding of the certifications and our ongoing data remediation efforts. This year, however, the certifications are electronic, and there does not appear to be an opportunity to reflect our understanding. The purpose of our meeting yesterday and this email is to explain our understanding of the certifications.

First, as with our past certifications, the 2012 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate.

Second, the certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.

Third, the certifications only cover risk adjustment data for 2012 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.

Fourth, as we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2012 dates of service that we ultimately determine should be deleted consistent with this email.

Fifth, as we discussed yesterday, CMS recently issued a proposed rule that would, if finalized, require MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. During our conversation yesterday and other recent conversations, CMS confirmed to us that these requirements do not apply until the effective date of the rule, and that MA plans are thus not currently required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. We currently have a process through which we review certain medical records to determine the accuracy of risk adjustment diagnoses and submit appropriate deletes. This process already has resulted in the identification of and, in some instances, the submission of deletes for 2012 dates of service. But based on the proposed rule, including the preamble, and recent conversations with CMS, we suspended that process for 2012 dates of service while we consider whether to make changes. Pursuant to our discussion, however, we will soon submit for deletion those diagnosis codes that have undergone a complete review and that we have therefore identified as appropriate deletes. In the near future, we will determine whether to continue our review process for the diagnosis codes which were still under review at the time we suspended our process. In the meantime, we will not delete these codes.

The certifications that we submit today are made subject to these clarifications. Please let us know if you have any questions. Again, thank you for your time and attention on this matter.

EXHIBIT P-25

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
STEVEN HALE NELSON
Given Remotely
Tuesday, July 26, 2022
10:10 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
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1 and we said, "Okay."

2 I mean, that's how I remember it.

3 Q. Okay. And we -- we are going to talk now
4 about sort of the substance of what took place at
5 that meeting, best we can.

6 A. Okay.

7 Q. So why don't we start out -- can you tell
8 me right now, sitting here today, what you remember
9 about what transpired at that meeting on
10 April 14th -- I'm sorry, April 29th, 2014, with CMS?

11 MR. SUMMERS: I'm just going to object to
12 form, since it's such an open-ended question.

13 But you can go ahead and do your best to
14 answer.

15 THE WITNESS: Okay.

16 Yeah, so I -- I remember opening up the
17 meeting, talking about what we wanted to
18 accomplish and what the objectives were of the
19 meeting, to get clarification on the proposed
20 rule, the timing of it, and -- and that we were
21 evaluating and trying to make a decision on our
22 claims verification program, and was that
23 required.

24 BY MS. McMAHON:

25 Q. Okay.

1 Q. Okay.

2 A. Yeah.

3 Q. And did you understand that she was making
4 clear that she was not providing you advice on that
5 course of action?

6 MR. SUMMERS: Objection. Form.
7 Mischaracterizes.

8 THE WITNESS: Yeah, I -- not -- I mean,
9 other than what I just said, I just think she
10 was trying to limit, you know, where -- where
11 she would weigh in on. But I -- it's hard to
12 completely -- you know, like interpret what --
13 what she meant by the "advice" word, if that's
14 what -- if that's the word you're specifically
15 focused on.

16 BY MS. McMAHON:

17 Q. Did you have an understanding, after the
18 meeting you had with CMS and after this
19 correspondence that you had with Ms. Rice, that CMS
20 was confirming or concurring with your potential
21 decision to not submit diagnosis codes that -- that
22 had been identified during your chart review program?

23 MR. SUMMERS: Objection. Form.

24 THE WITNESS: Yeah, the -- just to remind
25 you, the question we were there to discuss was

1 the status of the proposed rule and potential
2 timing, if they could give us any insight about
3 that. And then our question about the
4 requirement or not to have a claims verification
5 program.

6 And the -- the conclusion we reached after
7 the conversation was that we had no obligation
8 to proactively delete codes, or have a program
9 like the claims verification program.

10 So that was the -- that was the answer we
11 got. That's what we heard. We gave -- we were
12 super clear in our follow-up: This is what we
13 heard. This is what we intend to do. There's
14 no -- no -- no vagueness in -- in our letter
15 back.

16 And then -- and what we got this letter
17 was -- said, you know, "Thanks for your e-mail."
18 And -- and then, "I'd just like to remind you
19 that this" -- I'm paraphrasing her: "I'd like
20 to remind you that regardless of the
21 conversation we had, there's other laws you
22 should pay attention to, and you should be
23 thinking about that too."

24 And I take that as -- you know, whether
25 she meant it as advice or not, good advice; and

1 that's written right here, is an agreement that --
2 that CMS or she agreed with the information you put
3 in your fifth point, that she was somehow giving you
4 the -- her understanding that you could go ahead, and
5 CMS was okay with the -- the course of action that
6 you describe in your Point 5?

7 A. I think -- again, it -- sorry, but it's --
8 your -- your characterization is I think simplistic,
9 but how I -- I'll just try this again.

10 We went there seeking very specific
11 information and to very specific questions about
12 claims verification program, the -- and the entirety
13 of that conversation, that we've talked about several
14 times here. And in addition, the time -- timeliness
15 and -- and their thoughts about the proposed rule,
16 and the finalization or possibility of finalization
17 of that rule.

18 We had a discussion during the meeting
19 that -- that we concluded that they agreed with us
20 that it did not -- that MA plans did not need to
21 do -- have a program -- again, people probably called
22 it different things -- but our claims verification
23 program.

24 We then put that in a memo. We were very
25 specific about our plans. And we got this response

1 hitting a budget. I mean, that's -- that's just how
2 we have to run our business. There's no way around
3 that.

4 And then you have to find -- you know,
5 continue to run the business in a proper way. But
6 the compliance and consistent with CMS regulations,
7 there's no negotiation on that.

8 Q. After your meeting with CMS on April 29 of
9 2014, after that point in time, did CMS ever come to
10 you and say that you needed to reinstate claim
11 verification or risk being sued?

12 A. Not to my knowledge.

13 MR. SUMMERS: I have no further questions.
14 Thank you for your time.

15 MS. McMAHON: All right. I just -- give
16 me five minutes to see if I have any follow-up.
17 I think we have ten minutes left on record.

18 MR. SUMMERS: I think you only had like
19 two minutes left, according to our count. And
20 the count -- the witness has a -- a flight to
21 catch, so be as fast as you can, please.

22 MS. McMAHON: Well, I will go as fast as I
23 can, but I believe I have ten minutes, and I
24 believe that was made clear at the end of
25 Mr. Havian's --

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

21

22

23

24

25



Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-26

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
	)	
Defendants.	)	

CONFIDENTIAL
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videotaped Deposition of
ANNE HORNSBY
VOLUME I

Friday, May 19, 2023

Reported by: Traci M. Mertens, RDR, CRR, CSR

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1 more, to find more diagnosis codes and hopefully to
2 find sicker beneficiaries to enroll.

3 What I said is there wasn't a general
4 awareness in -- among CM leadership -- and Cynthia
5 Tutor also said this in her deposition. There
6 wasn't a general awareness that plans were -- were
7 going to medical records and only looking for
8 additional.

9 CMS supported the idea of chart review.
10 That -- that means confirming the accuracy of the
11 diagnoses you submit for payment and -- and
12 confirming that they are supported in the medical
13 record, and it can mean also, but not only, that you
14 find diagnoses that were -- had not been submitted
15 for payment.

16 Q. If you look at the middle of this page E4,
17 there's a paragraph that starts: "If we find that
18 MA plans code with high intensity, that does not
19 provide information about whether MA plans are
20 overcoding or whether fee-for-service providers are
21 undercoding. Similarly, one cannot infer whether MA
22 coding is any more or less accurate than
23 fee-for-service."

24 Do you see that?

25 A. I do.

1 compliance actions for marketing issues because
2 that's the -- the policy area for which they're
3 responsible.

4 And MDBG, M-D-B-G, will take some
5 compliance actions for issues related to the Part C
6 and D reporting because that's what they're
7 responsible for.

8 So that -- and then MOAG has its own set
9 of responsibilities for, for example, audits, audits
10 of plans to see if they're complying with CMS'
11 requirements. So I learned that from them, and I
12 learned about CMS' policy about termination from
13 them.

14 Q. What did you learn about CMS' policy for
15 termination from John Scott and Jerry Mulcahey?

16 A. I learned that CMS will terminate for
17 reasons of beneficiary harm. That is CMS' focus.
18 That is the goal. They want beneficiaries to have
19 continuity of coverage and to be protected and to
20 make sure that plans are handling the appeals and
21 grievances and determinations correctly, and that is
22 CMS' focus regarding termination.

23 (Exhibit 1446 was marked for
24 identification and attached hereto.)

25 Q. (By Mr. Jones) Ms. Hornsby, we're handing

1 Swoben case about United's risk adjustment practices
2 and the chart review practices, correct?

3 A. Some people in CMS, yes. Not everyone.

4 Q. Okay. And after finding out about those
5 issues, CMS continued to contract with United and
6 these United Health plans for the purposes of
7 providing services as Medicare -- as Medicare
8 Advantage organizations, right?

9 A. Yes. CMS' position is that beneficiary
10 harm is the overarching reason for termination and
11 that CMS has two other remedies for MAOs that are
12 not ensuring that they submit accurate data to CMS,
13 and those two remedies are RADV audits and -- and
14 the False Claims Act.

15 Q. Does CMS consider conducting one-way chart
16 reviews looking for codes that are supported by
17 medical records to add to risk adjustment payments,
18 does it consider that to be fraud?

19 MS. KRIEG: Object to form.

20 A. So the question is whether one-way review
21 is fraud?

22 Q. Sure. Does CMS consider United looking
23 for codes to add by looking at medical records as
24 part of chart review but not looking for deletes,
25 does it consider that to be fraud?

1 A. I'm just going to repeat myself. I mean,
2 CMS believes this is being handled by the Department
3 of Justice.

4 Q. So --

5 A. That is the appropriate way to handle
6 this.

7 Q. So instead of invoking the power to
8 terminate or the choice not to contract with United
9 plans, CMS has chosen to support the Department of
10 Justice's lawsuit instead of ending the
11 relationship?

12 A. Yes. United is the largest single MAO in
13 the program. You terminate all those beneficiaries
14 which fall outside of their provider networks, it's
15 not likely they could find new providers easily.
16 CMS is interested in protecting continuity of care
17 for beneficiaries.

18 Q. And so under CMS' view, CMS decided to
19 continue contracting with United plans
20 notwithstanding the allegations that CMS' risk
21 adjustment practices have cost the government
22 billions of dollars?

23 A. CMS' position is that this is being
24 handled by the Department of Justice.

25 Q. And you can't tell me one way or another

1 Q. The next sentence says: "In particular,
2 we did not use our previous process to determine
3 whether diagnosis codes submitted through claims are
4 unsupported in the medical record."

5 Do you see that?

6 A. Yeah, but that doesn't say anything.

7 Q. You don't think that -- well, CMS knew
8 that United was not using the previous process
9 discussed with Ms. Rice to review medical records to
10 determine whether diagnosis codes submitted through
11 claims are unsupported.

12 A. My understanding is that CMS' entire
13 discussion with United, with Steve Nelson in
14 particular, started with that April 2014 meeting and
15 is still continuing here, and CMS still doesn't know
16 exactly what United was doing. You know, were they
17 targeting a population? Were they doing blind
18 coding or not, you know? Who knows what that claims
19 verification program was? Who knows if there are
20 other parts of United, other MAOs that are still
21 doing some kind of review?

22 So CMS doesn't give specific
23 recommendations to MAOs in meetings like that. CMS
24 will restate CMS' position, and -- and that's it.

25 Q. Did CMS ask for any clarity on what

1 with Medicare Advantage plans about rules of the
2 road on chart review?

3 A. Could you tell me what transparent means?

4 Q. We just got a -- seen the email where
5 United is telling CMS what it's doing. Do you have
6 any view one way or another about whether CMS should
7 be transparent with MA plans and give guidance about
8 the rules of the road with respect to chart review
9 programs?

10 MS. KRIEG: Object to form and scope.

11 A. Well, first, I would say the fifth bullet
12 really has no information in it about United's
13 claims verification program. It's very vague. So
14 there's really -- it's -- even if CMS were to
15 respond in a meeting like that, there would be
16 nothing to respond to.

17 Secondly, CMS would not tell one company
18 special guidance that none of the others had access
19 to and give them that kind of leg up and advance.

20 Q. Here in this Exhibit 330, we already
21 established that United was asking for guidance from
22 CMS, that it was telling CMS what it was doing, and
23 CMS didn't ask for any clarification, right?

24 A. Exactly, because that's not what CMS would
25 do.

CERTIFICATE

I, TRACI M. MERTENS, Registered Diplomate Reporter and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was placed under oath to testify to the truth and nothing but the truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor counsel for any of the parties to this action in which this proceeding was taken, and further that I am not financially or otherwise interested in the outcome of this action.

Certified to by me on this 24th day of May, 2023.

Traci Mertens

Traci Mertens, RDR, CRR, CSR
Registered Diplomate Reporter
Certified Realtime Reporter
Certified Shorthand Reporter

EXHIBIT P-27

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

Videotaped Deposition of
CYNTHIA G. TUDOR, Ph.D.
Given Remotely
Tuesday, August 23, 2022
9:59 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 you don't recall the specifics. Do you recall in
2 general the April 2014 meeting you had with Steve
3 Nelson?

4 A. Well, only because people had asked for
5 what was in my Day-Timer at the time. And I looked
6 at my Day-Timer, and it told me that there had been
7 a meeting.

8 Q. You're referring to your Day-Timer.
9 Dr. Tudor, did you take notes at the meeting you
10 had with Steve Nelson and others from United in
11 April of 2014?

12 MS. CHEN: Object to form.

13 THE WITNESS: I don't know about the
14 date, but I know that there was a piece of paper
15 that had something on it.

16 BY MR. BAAK:

17 Q. Was it your practice to take notes of
18 meetings with -- your meetings with Steve Nelson?

19 A. No. Not necessarily. It'd depend upon
20 what the subject of the meeting was. It'd depend
21 upon who else was there, what role I was serving.
22 It's all sort of situational.

23 Q. Did reviewing the notes you took of the
24 April 2014 meeting in your Day-Timer, the meeting
25 with Steve Nelson and others from United, did it

1 refresh your recollection at all about what the
2 subject matter of that meeting was?

3 A. Well, my -- the way I remember that
4 piece of paper, it was pretty vague. And it -- you
5 know, there were other people there who knew more
6 than I did about these subjects. So I -- as my
7 general practice was, those people should take the
8 lead.

9 Q. And the subjects you just referenced,
10 what were the subjects of that April 2014 meeting,
11 as you recall?

12 A. I don't -- I don't --

13 MS. CHEN: Object to form.

14 THE WITNESS: I don't really remember
15 this April '14 meeting, so I don't think I can
16 answer that.

17 BY MR. BAAK:

18 Q. Do you recall how it was determined
19 that you would attend the April 2014 meeting with
20 Mr. Nelson and others from United?

21 A. Well, I was the deputy director, so I
22 was there. Because I'm sure that whoever was the
23 director -- I think it was Sean Cavanaugh at that
24 point -- told me to come, so I came.

25 Q. Do you recall what you said, if

1 MS. MCMAHON: Objection. Vague.

2 THE WITNESS: So my stance as deputy
3 director was my experts were the leads, and I was
4 there to elevate them and to sort of understand
5 whether CMS needed to do something. That's
6 generally where I stood.

7 BY MR. BAAK:

8 Q. My question is a little different,
9 Dr. Tudor. Just -- just in general, was it your
10 practice when you took notes at meetings,
11 recognizing you didn't take notes at all meetings,
12 to try to take accurate notes, to the best of your
13 ability?

14 MS. CHEN: Object to form.

15 THE WITNESS: Well, for example, I -- I
16 don't really -- the trouble with my notes -- and it
17 isn't just here -- is it's not clear sometimes who
18 said what and the sort of context of what they
19 said.

20 So I can't -- where -- I can't really
21 say whether or not they were accurate and whether
22 or not you can read anything into them.

23 Generally, my note-taking -- the only
24 thing that was really important to me for my
25 note-taking was whether CMS committed to do

1 something for a plan, and if so, it was a next
2 step.

3 And so, generally, the next steps, if I
4 put them in there, which I didn't here, would be
5 reliable. I wouldn't say that I would judge
6 anything else to be necessarily the verdict.

7 I tried to -- for example, on the
8 right-hand side of this, I tried to get their
9 numbers down. But they were going very fast, and
10 I'm not sure that they are even close to being
11 right.

12 BY MR. BAAK:

13 Q. In general, you tried to take accurate
14 notes, though, Dr. Tudor, at meetings when you
15 elected to take notes, right?

16 MS. MCMAHON: Objection.

17 MS. CHEN: Object to form.

18 THE WITNESS: I don't know what else I
19 can say on this. It -- it -- you know, I'm
20 admitting that my mind wasn't necessarily on
21 everything these people were saying --

22 BY MR. BAAK:

23 Q. Dr. Tudor, we'll talk about these
24 particular notes in just a second.

25 I'm asking, in general, it was your

1 During your time as the deputy director
2 of the Center for Medicare, did you understand that
3 Medicare Advantage plans were conducting chart
4 review to add diagnosis codes for the submission of
5 risk adjustment data?

6 MS. CHEN: Object to form.

7 THE WITNESS: I understood they were
8 doing chart reviews. To the extent to which they
9 were only adding and not -- not validating, if you
10 will, to what they had already submitted, I was not
11 aware. Chart review means both ways to me, but --
12 when it comes to encounter data, it means both
13 ways.

14 BY MR. BAAK:

15 Q. Let me just unpack that a little. Did
16 you understand, during the time you were the deputy
17 director of the Center for Medicare, that Medicare
18 Advantage plans were reviewing charts to add
19 diagnosis codes?

20 MS. MCMAHON: Objection. Asked and
21 answered.

22 BY MR. BAAK:

23 Q. You can answer it.

24 A. I think it's the same that I said
25 before. I -- I don't see how plans can attest the

1 hundreds of insurers at the time.

2 BY MR. BAAK:

3 Q. If a plan comes to CMS, its regulator,
4 and says, "Is what we're about to do permissible
5 under CMS rules and regulations?" do you agree that
6 it's reasonable of the plan to expect a clear
7 answer from CMS?

8 A. That --

9 MS. MCMAHON: Objection.

10 THE WITNESS: -- that's -- that's not
11 the way CMS operated.

12 BY MR. BAAK:

13 Q. So it would have been -- during your
14 time at CMS, if a plan came and had a question
15 about whether its course of action was permissible,
16 CMS, in your experience, did not feel like it owed
17 a clear answer to the plan, right?

18 A. That's not what I would --

19 MS. MCMAHON: Objection. Misstates.

20 THE WITNESS: That's not what I said.
21 And what -- CMS's practice was that they would
22 state the requirements. Here are the requirements.
23 It's up to you to make sure that those requirements
24 are consistent with CMS's requirements.

25 BY MR. BAAK:

CERTIFICATE OF REPORTER

I, Cindy A. Hayden, Registered Merit Reporter and Notary Public for the State of Maryland at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 26th day of August, 2022.

Cindy A. Hayden

Cindy A. Hayden, RMR, CRR

My Commission expires

April 26, 2025

EXHIBIT P-28

#23165

Case 1116 - Attorney General's Managed Discretion.

8/20/14

Office
 - Did not stay until the proposal; did not leave ^{specific} ~~procedural~~ _{substantive} responsibility

• 1st time laying out litigation

• Measures for not

Office

- not acceptable to not delete what we know

- If you have knowledge of secrets, you delete

Office

• "Statutory obligation" to report & report

False (class act) representations. "Secret"

Personal knowledge ~~prohibit~~ to limit or restrict on our judgment

Office

- Identification ~~own~~ in writing, no option to express our ~~substantive~~ ^{substantive} ~~content~~ ^{content}

→ Review on w/ other places and will have the law, government counsel to see if ok. Others have work involving that also need to be reviewed

OSS
 notes

EXHIBIT
 00317

4376

MAR2158615

EXHIBIT P-29

UNITED STATES DISTRICT COURT
FOR THE CENTAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

United States of America, ex rel.
Benjamin Poehling,

Plaintiffs,

vs.

No. 16-08697 FMO

UnitedHealth Group, Inc., et al.,

Defendants.

DEPOSITION

of Thad Johnson, taken pursuant to
notice to take oral deposition, at
Dorsey & Whitney LLP, 50 South Sixth
Street, Minneapolis, Minnesota 55402 on
the 17th day of November, 2022, before
Nathan D. Engen, a notary public in and
for the State of Minnesota.

(Confidential information,
subject to protective order)

1 A No.

2 Q When Ms. Rice talked about knowledge,
3 did you understand what she was saying?

4 MR. BAAK: Objection. I
5 instruct the witness not to answer his
6 mental impressions of Ms. Rice's
7 statements in the meeting. It calls
8 for privilege information.

9

10 By Mr. Buland:

11 Q But you certainly didn't ask her at the
12 meeting, 'What do you mean by
13 knowledge?'

14 MR. BAAK: Objection; asked
15 and answered.

16 THE WITNESS: I did not ask
17 her.

18 MR. BULAND: Okay.

19

20 By Mr. Buland:

21 Q Now, the next thing in Mr. Schumacher's
22 notes is, "Statutory obligation to
23 report and repay." Do you see that?

24 A Yes, I do.

25 Q Okay. And it says, "False Claims Act

1 implications." Do you see that?

2 A Yes, I do.

3 Q Okay. And did Ms. Rice say at the
4 meeting about -- in response to your
5 question about claims verification, and
6 by 'you,' I mean UnitedHealthcare, if
7 there were false claims identifications
8 to be issued?

9 MR. BAAK: Objection; form.

10 THE WITNESS: She said this
11 in response to the second part of the
12 conversation I was talking about where
13 we had the -- some deletes we
14 submitted, some were through the
15 process, some were in the middle of the
16 process.

17

18 By Mr. Buland:

19 Q So you're telling me that the false
20 claims identifications Ms. Rice talked
21 about were only in reference to the
22 buckets of codes already in the claims
23 verification process?

24 A That's how I understood the
25 conversation, yes.

1 STATE OF MINNESOTA)
2) ss.
3 CROW WING COUNTY)

6 I, Nathan D. Engen do hereby
7 certify that the foregoing transcript in
8 the matter of United States of America,
9 ex rel. Benjamin Poehling vs.
10 Unitedhealth Group, Inc., et al is true,
11 correct and accurate:

12 That said transcript was prepared
13 under my direction and control from my
14 stenographic shorthand notes.

15 That I am not related to any of
16 the parties in this matter, nor am I
17 interested in the outcome of this
18 action.

19
20 Witness my hand and seal this 29th day
21 of November, 2022.

22

23

24

25

Nathan D. Engen
Nathan D. Engen

EXHIBIT P-30

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex :
rel., BENJAMIN POEHLING, :
Plaintiffs, : Case No.:
VS. : CV-16-08697 FMO
UNITED HEALTH GROUP, INC., :
et al., :
Defendants. : Page 1-362

- - -

Friday, March 22, 2024

- - -

Videotaped deposition of JEAN ACEVEDO
taken at Latham & Watkins, 555 Eleventh Street, Suite
1000, Washington, DC commencing at 9:50 a.m., before
Sherry L. Brooks, Certified LiveNote Reporter and
Notary Public, in and for the District of Columbia.

- - -

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WWW.MAGNALS.COM

1 logical that any contracted entity should be aware of
2 what's expected of them.

3 BY MR. BAAK:

4 Q. We covered earlier some of your experience
5 in the consulting work you do in compliance. But
6 you're not offering any opinions in this case on the
7 compliance obligations of Medicare Advantage
8 organizations, right?

9 A. Correct.

10 Q. You are not offering any opinions in this
11 case about whether or not the Department of Justice's
12 allegations against United are, in fact, true, right?

13 A. Correct.

14 Q. And to get a little more specific, you're
15 not offering any opinions related to the design or
16 operation of United Health Group's chart review
17 program?

18 A. Correct.

19 Q. You're not offering any opinions about
20 whether United Health Group have been overpaid in any
21 way in connection with the Medicare Advantage
22 program?

1 A. Correct.

2 Q. You have not reviewed the details of
3 United Health Group's chart review programs, correct?

4 A. Correct.

5 Q. You're not familiar with the details of
6 those -- of United Health's chart review programs,
7 correct?

8 A. Correct.

9 Q. In connection with the expert testimony
10 you're offering in this case, you have not reviewed
11 any of the medical records underlying the diagnosis
12 codes that are in dispute between the Department of
13 Justice and United Health Group, right?

14 A. Correct.

15 MS. KRIEG: Object to form.

16 BY MR. BAAK:

17 Q. And, in fact, you have not reviewed any
18 specific medical records in connection with the
19 expert testimony you're offering in this case,
20 correct?

21 MS. KRIEG: Object to form. Foundation.

22 A. Correct.

1 ultimate outcome, correct?

2 MS. KRIEG: Object to form.

3 A. To improve the accuracy -- oh, of the
4 coder, yes. Um-hum.

5 BY MR. BAAK:

6 Q. When you have chart audits at Acevedo
7 Consulting that are designed with multiple layers of
8 coder review, do you set up a procedure for resolving
9 when the two coders disagree?

10 MS. KRIEG: Object to form. Foundation.

11 A. So I don't think the procedure would vary
12 based on a project versus how we work in general,
13 which is to reach out to someone.

14 And if, indeed, there were two assigned
15 coders to a project because of the checks and
16 balances that you just asked me about, having a
17 second coder review, invalidate or not the first
18 coder's work, they would still follow the same
19 guidelines that we would use at any particular time,
20 check the guidelines, what -- depending on what the
21 -- what was the cause of the disagreement.

22 Maybe query the provider, seek further

1 advice, use another resource. So all of those
2 options are always available.

3 BY MR. BAAK:

4 Q. Let me unpack that a little bit more.

5 A. Sure.

6 Q. So if you have two providers -- let me try
7 again.

8 If you have two coders who are reviewing a
9 chart as part of a chart audit, do you -- you don't
10 always assume that the second reviewer is the one who
11 got the correct answer?

12 A. No, not if that reviewer has at all -- so
13 if, indeed, that reviewer is darn certain, no, no,
14 this is it and I'll show you why, he or she has to be
15 able to say I'll show you why so that the first coder
16 sees the why and has his or her, what I call, aha
17 moment -- aha, forgot about that; aha, missed that;
18 misinterpreted that -- then of course not. That's
19 the whole idea of the second check.

20 Q. I'm going to try to simplify this, but I
21 want to get it right. It sounds like that when the
22 two coders in one of your chart audits disagree about

1 whether a code should be assigned, how that
2 disagreement is resolved depends on the
3 circumstances.

4 Is that accurate?

5 A. Yes.

6 Q. It is also, in fact, the case that when
7 you have more than one coder reviewing a medical
8 record you do have disagreements about whether a
9 diagnosis code is appropriately assigned, right?

10 MS. KRIEG: Object to form.

11 A. Yes. That can happen and does.

12 BY MR. BAAK:

13 Q. The first step at Acevedo Consulting when
14 you have such a disagreement, is that a dialogue
15 between the two coders about why they disagree about
16 whether a diagnosis code should be assigned?

17 A. Yes.

18 Q. If that process doesn't produce agreement,
19 what are the next steps at Acevedo Consulting for you
20 to resolve a disagreement between two of your coders
21 as to whether a diagnosis code should be assigned?

22 A. So one would be to make sure that they

1 have reviewed all of the available resources.
2 Depending on what's their root cause of any
3 disagreement such as if it happens to be
4 documentation in the clinical record that is unclear
5 to one or both of them or could be interpreted in
6 more than one way, then they should be eliciting a
7 physician query to get the clarification from the
8 provider.

9 They can always go to a more senior person
10 such as myself, use other resources that they hadn't
11 used before.

12 There was one -- one instance in my 25
13 years where none of that resolved and it was a mental
14 health code. And I actually brought in a
15 psychiatrist that would be able to explain to the
16 person who was resistant what that mental health
17 condition actually meant so that she could actually
18 have what I call her aha moment and say aha, got it,
19 I just didn't understand that.

20 Q. How frequently -- well, let me ask just to
21 follow up there.

22 In discussing how you resolve a

1 disagreement between two of your coders about whether
2 or not a code should be assigned, sometimes you're
3 brought in to break the tie between the two coders;
4 is that correct?

5 A. Yes.

6 Q. How frequently does that happen?

7 A. Not very frequently at all. I mean, these
8 things just don't happen very often in my
9 organization.

10 Q. Do you track how often when you have two
11 levels of coder review on a given medical record
12 there is disagreement?

13 A. It would only be tracked per project.

14 Q. Would you keep statistics on a given
15 project, the rate of disagreement between two coders?

16 A. Yes, I would keep -- yes.

17 Q. You mentioned potentially using other
18 resources that the coder didn't have before to
19 resolve a disagreement. And then I also see in
20 paragraph 54 a reference to providing coders with
21 resources to address coding questions.

22 What kind of resources do you have in mind

1 there?

2 A. So, again, the Coding Clinic, you know,
3 would be an example.

4 Q. The Coding Clinic is one example of a
5 resource that a coder might consult when there's
6 disagreement. Is there anything -- other guidance or
7 resource, rather, that you can identify that the
8 coder -- the coders might consult to resolve a
9 disagreement?

10 A. So, obviously, it would depend on what the
11 project actually was. But if we are speaking risk
12 adjustment, then they would also be encouraged if
13 they didn't do it on their own to use the participant
14 guide or the managed care manual.

15 Q. I want to come back to blind coding we
16 talked about a little bit earlier. But before we get
17 into blind coding, are you familiar with the term
18 "informed coding" or an "informed coding review"?

19 A. I've not used that term, so I wouldn't
20 want to guess at a definition.

21 Q. Well, I'm going to try my best to give us
22 a definition to use just so we can speak the same

1 front of them, that would not allow them to draw a
2 conclusion about the totality of the appropriate
3 diagnosis codes for that given patient, correct?

4 A. Correct. They could only assign diagnosis
5 codes for the medical records they had at hand.

6 Q. Do you have any experience with what -- or
7 do you track what percentage of time in the chart
8 retrieval process you're able to obtain a complete
9 set of the patient's medical records?

10 A. I don't track it, but I will tell you that
11 it's the overwhelming majority of the time with
12 electronic medical records.

13 Q. When did most practices switch to
14 electronic medical records?

15 A. Beginning in 2011, probably the majority
16 of -- because that's when the meaningful use program
17 and some government funding for implementing
18 electronic medical records started. And the adoption
19 -- I'm trying to think when seeing paper charts at
20 all for medical records was suddenly so very uncommon
21 for us. I can't picture when.

22 Q. Can you estimate just approximately when

1 there's an interface between the practice, if they
2 don't do in-house lab and the outside laboratory,
3 that the lab results just come into the practice
4 through an integration process.

5 So there's a lot of those issues, the most
6 important one being that one doesn't know where the
7 chart is, is eliminated in the electronic medical
8 records because it's always in the electronic medical
9 record.

10 Q. Even with the improvements in electronic
11 medical records over paper medical records, assuming
12 you agree that's an improvement, are there still
13 circumstances where you're unable to retrieve and a
14 complete set of a patient's electronic medical
15 records for various reasons?

16 MS. KRIEG: Object to form.

17 A. I would say that's extremely uncommon,
18 extremely uncommon.

19 BY MR. BAAK:

20 Q. Is it the case that providers always
21 respond to every request for medical records that you
22 make?

1 MS. KRIEG: Object to form.

2 A. The overwhelming majority of the time,
3 yes. Most definitely, yes.

4 BY MR. BAAK:

5 Q. But not always? Not all providers respond
6 to all requests for medical records, right?

7 A. No, but it's probably about 99 percent. I
8 mean, it's really rare that we don't have a provider
9 that provides to us what we need, even if what we
10 need, they say let me get you access to the EMR and
11 we find it ourselves. So yeah.

12 Q. Turn to paragraph 41 of your opening
13 report -- sorry -- paragraph 51.

14 A. 51?

15 Q. Yes. In paragraph 51 you discuss some of
16 the difficult coding scenarios that a coder might
17 encounter in assigning the appropriate diagnosis
18 code, correct?

19 A. Correct.

20 Q. And you list a couple things that we've
21 already covered. The first is skill level and
22 experience among the coders, right?

1 documentation in that, yes, that would be proper.

2 I don't know what you meant by --

3 Q. Maybe my question is a little confusing.

4 I'll try again. So I'll use your phrase. I think
5 you said available?

6 A. No. I don't think --

7 Q. Well, let me ask a more simple version.

8 Is it possible to determine whether a given diagnosis
9 code is supported without looking at any medical
10 records in your experience?

11 A. So I hope you don't mind, I'm going to
12 reverse it to hopefully say -- what I'm comfortable
13 saying is that the only way a diagnosis code can be
14 reported is if you have clinical documentation to
15 support it.

16 Q. And so the converse, though -- I want to
17 press on this because it's important.

18 A. All right.

19 Q. The converse is also true. You can't make
20 a determination in your experience of whether a
21 diagnosis code is unsupported without access to the
22 clinical documentation, right?

1 MS. KRIEG: Object to form.

2 A. So that statement infers that the
3 documentation exists and I just haven't been provided
4 with it. And until I'm provided with it, I can't
5 support the code.

6 BY MR. BAAK:

7 Q. And you can't determine that a code is
8 unsupported either, right?

9 A. Well, it's not supported until you provide
10 me with the documentation.

11 Q. Well, what if a code has been submitted by
12 a provider already? So I'm asking, can you
13 invalidate that code in your experience without
14 looking at the underlying clinical documentation?

15 A. If you cannot provide me with that
16 documentation, correct.

17 Q. Or you elect not to look at the
18 documentation. That would be another circumstance
19 where you would be unable to invalidate a provider's
20 submitted diagnosis code, right?

21 A. I want to go back for a second, because
22 the way I worded it, I want to make sure that what I

1 physician queries as a way to resolve uncertainty as
2 to whether or not to assign a diagnosis code?

3 A. Correct.

4 Q. Just explain briefly what a physician
5 query is.

6 A. A physician query is a -- just that, a
7 query, a question submitted to the provider of the
8 service asking for clarification.

9 It is not asking for any additional
10 documentation, et cetera. It's for the actual
11 provider who made the documentation in the clinical
12 record to clarify something that might, indeed, in
13 the record not be clear.

14 Q. Are physician queries something you use in
15 your consulting practice at Acevedo Consulting?

16 A. Yes.

17 Q. In your view, is it appropriate for a
18 Medicare Advantage plan when it's doing a coding
19 review itself to submit a physician query to try to
20 seek clarity?

21 MS. KRIEG: Object to form.

22 A. Assuming that that's something that

C E R T I F I C A T E

I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this

_____ day of _____, 2024.


Notary Public



EXHIBIT P-31

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

CASE NO. CV 16-08697 FMO

UNITED STATES OF AMERICA ex rel.,
BENJAMIN POEHLING,
Plaintiffs,

vs.

UNITED HEALTH GROUP, INC., et al.,
Defendants.

-----/

DEPOSITION OF BARBARA BLAIR
WEDNESDAY, APRIL 3, 2024
9:48 a.m. - 7:37 p.m.

TWO SOUTH BISCAYNE BOULEVARD, SUITE 1850
MIAMI, FLORIDA

- - -

Reported By:
Katiana Louis
Notary Public, State of Florida
Miami Office #1100998
Magna Legal Services
866-624-6221
Www.MagnaLS.com

1 A. Yes, that is what I would have been
2 doing.

3 Q. And had you done any work for
4 UnitedHealth prior to your employment with FTI?

5 A. Not that I'm aware of.

6 Q. And since the 2012 time frame you
7 provided, have you done any work for UnitedHealth
8 other than your work in this particular matter?

9 A. No, not that I'm aware of.

10 Q. Are you aware that UnitedHealth conducts
11 a chart review program by which it reviews the
12 medical records of its beneficiary he's to
13 identify additional codes that were not
14 previously submitted by providers?

15 MS. SOBEL: Objection to form.

16 THE WITNESS: I'm not aware of
17 United's program, no.

18 BY MS. LIKOFF:

19 Q. So, you have no familiarity with
20 UnitedHealth's chart review program; is that
21 correct?

22 A. That's correct.

23 Q. Do you have any familiarity with a
24 UnitedHealth program called Claims Verification?

25 A. I do.

1 Q. And would you advise your client on
2 whether those unsupported codes should be
3 deleted?

4 A. Again, my results go to my FTI team, and
5 the client and whoever else. I don't advise on
6 what gets added or what gets deleted.

7 Q. Do you know whether there's anyone on
8 the FTI team that provides that type of advice to
9 FTI's clients?

10 MS. SOBEL: Objection to form.
11 Lacks foundation. Calls for
12 speculation.

13 THE WITNESS: I would be
14 speculating. I honestly don't know what
15 our final is with the client.

16 BY MS. LIKOFF:

17 Q. I'm looking back to your CV, I think the
18 second page of your CV -- strike that.

19 During your time at FTI, have you done
20 any work for the United States government?

21 A. For the government, not that I'm aware
22 of.

23 Q. Now turning back to your second page of
24 your CV, I think you've mentioned this a couple
25 of times but I just want to unpack it a little

1 MS. SOBEL: Objection to form.

2 Asked and answered.

3 MS. LIKOFF: You can go ahead and
4 answer.

5 THE WITNESS: As I said before, to
6 assign a diagnosis code, it must be in
7 the medical record that you've received.

8 BY MS. LIKOFF:

9 Q. All right. And this was a principle
10 that you learned during your 25 years of
11 experience as a coder; correct?

12 A. Yes.

13 Q. And would you agree that this is a
14 principle that coders receive training on?

15 MS. SOBEL: Objection to form.

16 THE WITNESS: Again, I can't opine
17 to what training they received, but if I
18 were going to offer my experience, then
19 I would say that if they've received
20 formal training, they may have received
21 that.

22 BY MS. LIKOFF:

23 Q. And would you agree that ICD guidelines
24 require that all diagnosis codes that are
25 reported be based on documentation that shows

1 A. More often than not, yes.

2 Q. Can you think of any specific examples
3 in which you were not able to assign a code?

4 A. If I didn't have access to all of the
5 documentation, I would have to -- I wouldn't be
6 able to assign that code at that time.

7 Q. But in that case that you've just
8 described, the dispute would be resolved and it
9 would be resolved in determining that there was
10 no code that could be supported; correct?

11 A. No, I wouldn't be able to -- I guess,
12 one of the ways -- I couldn't -- I couldn't be
13 the determination on the two coders if I didn't
14 have access to the documentation to make that
15 determination.

16 Q. So what would happen in those cases?

17 A. Then, again, I would attempt to get the
18 documentation. So, that would be like the
19 initial immediate -- based on my e-mail, I'd have
20 to ask for more information. But ultimately
21 based on what I have, I would make a decision as
22 to which one -- which diagnosis code was
23 supported.

24 Q. So, based on your experience can you
25 think of any instance in which a coder

1 disagreement was not able to be resolved?

2 A. Not at this time.

3 Q. Turn back to paragraph 22 of your
4 report, you then opine that there are a variety
5 of reasons why coders may reach different
6 conclusions and you list six specific reasons in
7 your report; correct?

8 A. Correct.

9 Q. And we'll go through a number of these,
10 but first I just want to make sure that your
11 report provides a complete list of the reasons
12 you believe coders may reach different
13 conclusions. So in paragraph 22, I believe, you
14 list six of them.

15 So my question is: Whether there are
16 any other reasons you believe that coders may
17 disagree?

18 A. Well, there may be, but these are what
19 my opinion is upon. I can't opine to all of
20 them. I said, "including, but not limited to."
21 These are the ones I'm making the opinion on.

22 Q. I'm just trying to understand exactly
23 what you honed in on in the "including but not
24 limited to." So, I'm just trying to understand
25 if there are any other reasons that you are

1 A. Yes.

2 Q. And what is the basis for your opinion?

3 A. Again, my years of experience and myself
4 assigning a code in error.

5 Q. Can you point to any data regarding the
6 prevalence of human error in diagnosis coding?

7 A. I cannot.

8 Q. So you cannot point to any data
9 regarding the prevalence of human error in
10 diagnosis coding?

11 A. No.

12 Q. Can you point to any studies regarding
13 the prevalence of human error in diagnosis
14 coding?

15 A. I'm not aware of any.

16 Q. And can you point to any published
17 article regarding the prevalence of human error
18 in diagnosis coding?

19 A. I'm not aware of any.

20 Q. You then provided a number of factors
21 that you believe make human error more likely,
22 including long days, voluminous records, and
23 fatigue among coders; is that correct?

24 A. Correct.

25 Q. And you opine that all of these factors

1 can result in mistakes, including missed
2 diagnosis codes; is that correct?

3 A. Actually, I opine here that they may
4 miss records, mistakes including missed diagnosis
5 codes. So, mistakes meaning transposed,
6 assigning the wrong diagnosis code, and including
7 missed diagnoses, as I said.

8 Q. So, you would agree that human error in
9 coding could also lead a coder to assign codes
10 that are not in fact supported by the medical
11 record; correct?

12 A. I do speak to them assigning the wrong
13 code in that sentence. I do speak to that in my
14 report. I believe it's in paragraph 43 where I
15 say it's a simple transposition of a number, and
16 the code gets reported in error.

17 Q. Well, I understand in paragraph 43
18 you -- you're referring to mistyped codes;
19 correct?

20 A. Correct.

21 Q. So, separate from typographical errors,
22 I'm trying to understand whether you believe the
23 factors we mentioned before, long days,
24 voluminous records, fatigue among coders, could
25 also lead coders to assign codes that are not

1 supported by medical record documentation?

2 A. As I said, it states right there, "which
3 can result in mistakes."

4 Q. And you believe that these mistakes,
5 include missed diagnosis codes as well as
6 diagnosis codes that are not supported by the
7 medical record; is that correct?

8 A. Yes. Diagnosis codes that may not be
9 supported in the medical record, again because
10 they typed something wrong, they didn't read
11 through the entire 100 pages. It can happen,
12 yes.

13 Q. So, other than mistakes that involve
14 mistyping a diagnosis code, you are agreeing that
15 human error can lead to coders reporting codes
16 that are unsupported; correct?

17 A. Like I said, that can result in
18 mistakes. The code that would be reported would
19 more than likely be in error. It does not
20 necessarily mean that the documentation was not
21 there. They may have, again, misread something,
22 not read something further, but it could be that
23 they put something in error. Yes, there can be
24 mistakes.

25 Q. Again, I'm just trying to understand the

1 REPORTER'S DEPOSITION CERTIFICATE
2 STATE OF FLORIDA
COUNTY OF MIAMI-DADE

3
4 I, Katiana Louis, do hereby certify that
5 I was authorized to and did stenographically
6 report the foregoing deposition; and that the
7 transcript is a true and correct transcription of
8 the testimony given by the witness; and that the
9 reading and signing of the deposition were not
10 waived.

11
12 I further certify that I am not a
13 relative, employee, attorney or counsel of any of
14 the parties, nor am I a relative or employee of
15 any of the parties' attorney or counsel connected
16 with the action, nor am I financially interested
17 in the action.

18
19 Dated this 5th day of April 2024.

20
21

Katiana Louis

22 Katiana Louis

23
24
25

EXHIBIT P-32

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., *et al.*,

Defendants.

No. CV 16-08697 FMO-PVCx

DECLARATION OF Steven Ferraina

1 I, Steven Ferraina, declare and state as follows:

2
3 1. I am the Deputy Director for CMS' Center for Program Integrity (CPI), Audits
4 and Vulnerabilities Group. I have been in this position since September 2020. My
5 responsibilities include overseeing and implementing the Medicare Advantage Risk
6 Adjustment Data Validation (RADV) program in CPI. I submit this Declaration in
7 support of the United States' Opposition to UnitedHealth's Motion for Summary
8 Judgment. I have personal knowledge of the matters set forth herein and, if called to
9 testify, could and would testify competently thereto.

10 2. In connection with RADV Audits for Contract Year (CY) 2011 through CY 2013,
11 the Centers for Medicare & Medicaid Services (CMS) issued Plan Feedback Reports
12 (PFRs) to the plans being audited. The PFRs communicated initial feedback of the
13 agency's medical record reviews and provided an initial estimate of the portion of the
14 audited Hierarchical Condition Categories (HCCs) that were not found to be supported
15 by medical records submitted by the given plan.

16 3. CMS provided UnitedHealth initial access to PFRs for the UnitedHealth plans
17 included in CYs 2011, 2012, and 2013 RADV Audits beginning in April 2019.

18 4. CMS did not provide UnitedHealth with PFRs for plans included in the CYs 2014
19 and 2015 RADV Audits.

20 5. When conducting RADV Audits for CY 2014 and CY 2015, CMS gave the plans
21 being audited access to a portal to view the initial feedback of the agency's medical
22 record reviews, which CMS added to the portal as they became available.

23 6. CMS provided UnitedHealth with access to the portal for CY 2014 in April 2019.

24 7. CMS provided UnitedHealth with access to the portal for CY 2015 in January
25 2020.

26 8. The RADV Audits for CY 2011 through CY 2015 are not final. The initial results
27 of medical record reviews and estimates of the portion of the audited HCCs that were
28

found to be supported by medical records, provided to plans in the PFRs and through the portal, are not yet final and are subject to change. The portion of audited HCCs that were initially found to be supported by medical records submitted by a given plan may increase or decrease before the RADV Audits are finalized.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2024, Washington, D.C.

Steven J.
Ferraina -S

Digitally signed by Steven J.
Ferraina -S
Date: 2024.07.12 10:41:19 -04'00'

Steven Ferraina

EXHIBIT P-33

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

CONFIDENTIAL

Videotaped Rule 30(b)(6) Deposition of
UnitedHealthcare, Inc. and OptumInsight, Inc.,
Designee 4, by SCOTT THEISEN
Given Remotely
Tuesday, June 6, 2023
10:08 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. Yes. Exactly. So there, CMS indicates
2 that it addressed that concern in developing the
3 Medicare Advantage contract requirement by mandating
4 that the MA organizations certify the accuracy,
5 completeness, and truthfulness of its data based on
6 its best knowledge, information, and belief. Do you
7 see? Do you see that?

8 A. I do.

9 Q. Okay. And so this is -- do you understand
10 that this is where, and in response to what the best
11 knowledge, information, and belief standard was --
12 was adopted by CMS?

13 MR. BAAK: Objection. Calls for a legal
14 conclusion. Foundation.

15 THE WITNESS: Can you restate the
16 question, Linda?

17 BY MS. McMAHON:

18 Q. So do you understand that this is where
19 CMS was announcing this standard that it was creating
20 of best knowledge, information, and belief that was
21 applying to -- that applied to MA organizations'
22 obligation to certify the accuracy, completeness, and
23 truthfulness of their risk adjustment data?

24 MR. BAAK: Objection. Form. Calls for a
25 legal conclusion.

1 THE WITNESS: I do. I think it's
2 important to read the sentence following, for
3 context, which also says: "This language was
4 included in the 1999 contract forms in
5 recognition of the fact that the Medicare Plus
6 Choice organizations cannot reasonably be
7 expected to know that every piece of data is
8 correct, nor is the standard that HCFA, the OIG,
9 and DOJ believe is reasonable to enforce."

10 BY MS. McMAHON:

11 Q. Perfect. Yes. I -- thank you for
12 pointing that out.

13 So you did understand, as a result of
14 these requirements that are being developed right
15 here, you understood that you, indeed, were not being
16 asked to certify to the accuracy of every single
17 diagnosis code you submitted, correct?

18 A. Yes, that I would interpret this to mean
19 that there's a best efforts, good-faith,
20 reasonableness standard with regard to a plan's need
21 or ability to submit complete, accurate, and truthful
22 information, that there would be some limitations in
23 the plan's ability to -- to support that in a way
24 that's -- would not be requiring 100 percent
25 accuracy, but reasonable -- you know, not absolute,

1 but assurance of 100 percent of the data. But, yes,
2 I understand the concept.

3 Q. Okay. And what CMS is saying right here
4 is that in order to address that, in order to make --
5 to address the plan's concerns that you just
6 articulated, that it would be too difficult or maybe
7 impossible to certify every single piece of data;
8 that instead what they were asking you to do is to
9 certify based on your best knowledge, information,
10 and belief, correct?

11 A. That is correct.

12 Q. Okay. And then -- see. And CMS defines
13 for you here, correct, that the best knowledge,
14 information, and belief standard encompasses the
15 concept that you don't actually know or deliberately
16 ignore or recklessly disregard the fact that your
17 risk adjustment data submitted to CMS for payment was
18 not accurate, complete, and truthful, correct?

19 MR. BAAK: Objection. Mischaracterizes
20 the document. Calls for a legal conclusion.

21 THE WITNESS: I would just acknowledge how
22 it's written here. Generally, the federal
23 government can bring an action only when one of
24 three states of mind exist: actual knowledge of
25 falsity of a claim or information, reckless

1 disregard, or deliberate ignorance of
2 information supporting the truth or falsity of a
3 claim or other information. However, no
4 specific intent to defraud is required. The
5 best knowledge, information, and belief standard
6 of the Medicare Plus Choice contract
7 certification forms is consistent with these
8 standards.

9 BY MS. McMAHON:

10 Q. Okay. Thank you.

11 And that is something you, as an
12 organization, understood throughout your time
13 participating in the program, correct?

14 MR. BAAK: Object to the form.

15 THE WITNESS: Yeah, I would say the
16 company understands the terms and conditions of
17 the CMS regulations.

18 BY MS. McMAHON:

19 Q. Okay. And of course you did understand
20 that you had an obligation to take some steps to
21 ensure that the risk adjustment data you were
22 submitting was accurate, complete, and truthful,
23 correct?

24 MR. BAAK: Objection. Calls for a legal
25 conclusion.

1 We have an entire witness designated on the
2 RACCR program.

3 BY MS. McMAHON

4 Q. Sorry. Did you -- did you answer the
5 question? I couldn't hear.

6 A. Yeah, I read this -- I read this. And at
7 the time, can't speak specifically to the RACCR
8 program, but we certainly had a RACCR program in
9 place at the time of this letter.

10 Q. Right. And what I'm specifically asking
11 you now is, do you agree, sitting here today, that by
12 seeking to identify and delete diagnosis codes that
13 are not supported in the medical record, that you are
14 improving the accuracy of the data you submit to CMS?

15 MR. BAAK: Objection. Beyond the scope.

16 THE WITNESS: Yes, I would agree with
17 that. I would add that the RACCR program was
18 really -- was designed and -- to audit and have
19 quality assurance around capitated provider
20 groups, so those provider groups would be
21 different than a fee-for-service provider group,
22 just to be clear.

23 And the reason it was important to analyze
24 and do some analytical reviews and some auditing
25 of those records is that the value-based care

1 reimbursement to these providers was based upon
2 the revenue and medical costs of the members
3 they managed. So implicit in that could be --
4 is some level of potential incentive to code
5 completely and accurately.

6 And the purpose of the RACCR program was
7 to look at diagnoses, understand where a
8 particular provider might be an outlier to their
9 peers, and then there were subsequent audits
10 back to medical records on a select basis.

11 So I just wanted to be clear that as we're
12 talking about this letter, it's really the --
13 this subgroup of physicians we're talking about
14 are those that -- and this procedure and this
15 audit procedure was designed and specifically
16 targeted at those that were paid on a capitated
17 percentage of revenue basis for the members they
18 served.

19 BY MS. McMAHON:

20 Q. Okay. And I want to ask you, separate and
21 apart from the RACCR program, I am asking you if,
22 sitting here today, as a general proposition, that
23 seeking to identify and delete diagnosis codes that
24 are not supported in the medical record, that you are
25 improving the accuracy of the data that you submit to

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.





Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-34

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	No. 16-08697 FMO
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et	)	
al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL INFORMATION, SUBJECT TO PROTECTIVE ORDER

VIDEOTAPED VIDEOCONFERENCE ZOOM DEPOSITION OF
KAREN ERICKSON

August 2, 2022

9:32 a.m. Eastern Standard Time

Magna Legal Services
(866) 624-6221
www.MagnaLS.com

Prepared by:
Marcella Daughtry, RPR, RMR
CA CSR 14315
GA No. 6595-1471-3597-5424

1 MS. KRIEG: I had it in here as 320. If -- if
2 we have 319 prepared, we can pull it up.

3 MS. SOBEL: We can take a look. My notes could
4 be wrong, too.

5 MS. KRIEG: Let's see, we have 319 in here.
6 Okay. Here we go. So here is 319.

7 Q BY MS. KRIEG: 319 is from Thad Johnson to
8 Steve Nelson, Daniel Schumacher, Karen Erickson. I think
9 that's it. "Subject: Meeting Minutes. Attachment: CMS
10 meeting notes 4/29/14.

11 "Privileged and Confidential.

12 "Please let me know of any
13 corrections/clarifications or changes you may have to my
14 notes from the meeting today. Thanks."

15 Did I read that correctly?

16 A Yes.

17 Q And I think you have testified that you
18 received this e-mail?

19 A Yes.

20 Q Okay. Let's go to 320. And these are the
21 notes that you reviewed in anticipation of your
22 deposition today?

23 A Yes.

24 Q Okay. And again, you have no independent
25 recollection of the meeting, correct?

1 A I don't remember the specifics. I remember the
2 meeting itself and some of the -- some of the big topics,
3 but I don't remember the specifics.

4 Q And the big topics are?

5 A The rule that was proposed in January of 2014
6 and whether or not the Claims Verification program of
7 United was -- what their guidance would be in terms of
8 whether that was required or not.

9 Q Okay. And I want to direct you to the fourth
10 bullet from the top. And it says: "Cheri Rice added
11 that there is a False Claims Act requirement that plans
12 not knowingly keep overpayments so if you do not know
13 that there is an overpayment, you do not need to delete a
14 code."

15 Did I read that correctly?

16 A Which -- I'm sorry, which bullet are you on?

17 Q The fourth from the bottom on page 2.

18 MS. SOBEL: Oh, on page 2.

19 THE WITNESS: Oh, on page 2.

20 Q BY MS. KRIEG: I'm sorry, on page 2.

21 A Okay. Yes.

22 Q And do you agree that the inverse of this is
23 true, right? If you know there is an overpayment, you do
24 need to delete the code, right?

25 MS. SOBEL: Objection. Calls for a legal

1 STATE OF GEORGIA)
2 COUNTY OF DEKALB) ss:
3

4 I HEREBY CERTIFY that the foregoing deposition
5 was taken before me; that I was then and there a
6 Registered Professional Reporter and Registered Merit
7 Reporter, License No. 6595-1471-3597-5424 for the State
8 of Georgia, and License No. 14315 in the State of
9 California; that the witness before testifying was duly
10 sworn by me to testify to the whole truth; that the
11 questions propounded by counsel and the answers of the
12 witness thereto were taken down by me in shorthand and
13 thereafter transcribed under my direction; and that the
14 foregoing pages contain a full, true, and accurate
15 transcript of all deposition testimony and proceedings
16 had, all done to the best of my skill and ability.

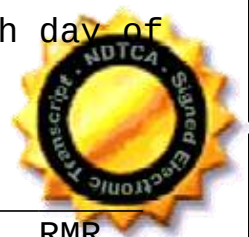
17 Signature requested.

18 I FURTHER CERTIFY that I am in no way related
19 to, nor employed by any of the parties hereto, nor am I
20 in any way interested in the outcome.

21 DATED at Dunwoody, Georgia, this 8th day of
22 August, 2022.

23
24
25


MARCELLA L. DAUGHTRY, RPR, RMR
GA License No. 6595-1471-3597-5424
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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 13 OF 14
EXHIBITS P-35 THROUGH P-94
PAGES 4428 THROUGH 5057**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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EXHIBIT P-35

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

Videotaped Deposition of
DANIEL J. SCHUMACHER
Given Remotely
Tuesday, September 20, 2022
9:04 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

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1 then articulated, as I mentioned, at the outset,
2 what the intent of it was, and then the fundamental
3 question we were there to ask, which was, "Boy, it
4 sure sounds like you're proposing that people might
5 need to start doing something. And that would
6 imply that we are doing more than we need to be
7 doing here." And that's what we were there to ask.

8 Q. So nobody at United suggested or gave
9 the impression that the chart review program and
10 the claims verification program were related in any
11 way?

12 A. I think we were clear to -- we were --
13 you know, my recollection was that we were clear to
14 say, "We have a chart review program. There's a
15 quality assurance around that." Because there was
16 a conversation about a meeting prior. So after we
17 did the general description, then we went into more
18 specific description.

19 Then Cheri Rice was in a meeting with
20 some folks from our organization. And I think she
21 was asking for a distinction between this meeting
22 and that meeting. And we were clear to say that,
23 you know, "Chart program is one thing. It has its
24 own QA process. We're not asking about that right
25 now. We're asking you about our claims

1 verification process."

2 Q. So, in other words, the chart review
3 program and the quality assurance related to the
4 chart review program, that's not -- that's not the
5 reason for the meeting today?

6 MR. SUMMERS: Objection. Form.

7 THE WITNESS: We were -- we were there
8 to ask the three things that I articulated before,
9 the first of which was: Do we have a proactive
10 obligation to do a two-way look when we're
11 reviewing a medical chart given that there was a
12 proposed rule that would -- if -- if and when
13 finalized, would then require it? And we were
14 already doing it, so we had suspended it. So we
15 wanted to know the answer to that question.

16 We also wanted to know: Okay. Then
17 what should we be doing with things that had
18 initiated the claims verification process and had
19 not gone through all the steps?

20 And then, lastly, we were quickly going
21 to be submitting bids for the 2015 bid year, and we
22 wanted to understand how we should be treating --
23 how we should be thinking about that in light of
24 this, you know, proposed regulation that says we
25 might have to start doing something that we were

1 Q. Do you have a memory of Sean Cavanaugh
2 saying what is attributed to him here? Aside from
3 what's written in the notes, do you remember him
4 saying it?

5 A. I have a recollection of Sean saying
6 something very closely to this effect. Whether or
7 not it's word for word, I -- I cannot recall.

8 Q. What does that mean, very -- something
9 very close to this?

10 A. I'm saying that the spirit of what is
11 reflected here is what was conveyed to us. Whether
12 he used every single word exactly as it's expressed
13 in this note, I cannot tell you.

14 Q. Okay. And so what's written here in
15 Thad Johnson's notes comports with your memory is
16 what you're saying?

17 A. Yes, it does.

18 Q. And it comports with your memory that
19 Cheri Rice raised the False Claims Act shortly
20 after the comment from Sean Cavanaugh?

21 MR. SUMMERS: Objection. Form.

22 THE WITNESS: That is a piece that
23 is -- in terms of timing, I -- I don't -- I don't
24 have a chronology in my notes, because it's -- my
25 notes are just not a comprehensive record. So

1 that's a question I have in my mind about whether
2 or not she said that after this or it was said
3 earlier.

4 BY MR. MASON:

5 Q. Well, okay. You agree that the way
6 Thad Johnson's notes set it forth, she -- she
7 said -- it -- it says: Cheri Rice added that there
8 is a False Claims Act requirement.

9 So you agree that Thad Johnson's notes
10 indicate that Cheri Rice made the False Claims Act
11 comment, adding onto Sean Cavanaugh's statement,
12 right?

13 A. Thad's notes reflect that.

14 Q. But you don't remember if that is
15 accurate or not?

16 A. I read this shortly after the meeting,
17 and I gave verbal and then written feedback that
18 it -- it comported with my recollection of the
19 meeting.

20 Q. Okay. Do you -- and -- and is that
21 still the case? As you read Thad Johnson's notes
22 today, do you find anything in there that is
23 inaccurate or incorrect?

24 A. I think that Thad's notes are a very
25 good reflection, a faithful reflection of -- of how

1 CERTIFICATE OF REPORTER

2

3 I, Cindy A. Hayden, Registered Merit
4 Reporter and Notary Public, do hereby certify that
5 the foregoing transcript is a true, accurate, and
6 complete record.

7 I further certify that I am neither
8 related to nor counsel for any party to the cause
9 pending or interested in the events thereof.

10 Witness my hand, this 23rd day of
11 September, 2022.

12

13

14

15

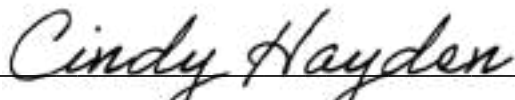
16

17

18

19

20


Cindy A. Hayden, RMR, CRR

21

22

23

24

25

EXHIBIT P-36

Message

From: Cavanaugh, Sean (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SEAN.CAVANAUGH.CMS]
Sent: 6/26/2015 5:18:53 PM
To: Rice, Cheri M. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=cheri.rice.cms59728027]; Tudor, Cynthia G. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=cynthia.tudor.cms06246732]; Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=jennifer.harlow.cms20728073]
Subject: Re: 2013 CMS RAF Attestation

I disagree that we stated the last part of this sentence beginning "...and that MA plans..."

"During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses."

From: Rice, Cheri M. (CMS/CM)
Sent: Friday, June 26, 2015 12:49 PM
To: Tudor, Cynthia G. (CMS/CM); Cavanaugh, Sean (CMS/CM); Harlow, Jennifer A. (CMS/CM)
Subject: Fw: 2013 CMS RAF Attestation

Sent from my BlackBerry Wireless Device

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Friday, June 26, 2015 12:41 PM
To: Rice, Cheri M. (CMS/CM)
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.

EXHIBIT

00331
4436

USBP000619443

- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

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EXHIBIT P-37

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al,

Defendants.

Case No. 16-cv-08697 FMO

**EXPERT DISCLOSURE OF PAUL SPITALNIC
JANUARY 29, 2024**

Expert Disclosure by Paul Spitalnic

I have been the Chief Actuary for the Centers for Medicare & Medicaid Services since 2013 where I am responsible for overseeing all actuarial work in the Agency including for the Medicare Advantage (MA) program. Prior to this role, I was the Director of the Parts C & D Actuarial Group where I was specifically responsible for overseeing all work related to the Medicare Advantage program, including the rate development and bidding processes. I have a Bachelor of Arts degree in Mathematics from Binghamton University and am an Associate of the Society of Actuaries and a member of the American Academy of Actuaries. I have not been retained or specially employed to provide expert testimony in this case, nor do my routine duties as an employee of CMS involve giving expert testimony. I am not being compensated in any way for this report, or any testimony I may give in this case, other than the salary I earn from my current position with CMS. I have prepared this expert opinion in response to statements in Julia Lambert's expert opinion. Attached as Appendix 1 is a list of the documents I relied on in forming these expert opinions.

Ms. Lambert claims that "Removing MAO payments related to unsupported codes fundamentally changes the application of the risk model. Whether or not an MAO was overpaid cannot be determined solely by the presence of unsupported medical conditions in its data. Rather, an MAO is overpaid only if its level of unsupported diagnosis codes exceeds or is not reasonably consistent with the level of unsupported diagnosis codes in the TM data used to develop the risk model."¹ She adds that "A decision that retrospectively removes a significant amount of UHG revenue related to unsupported diagnosis codes would materially change the payment rules and nullify the actuarial certification UHG submitted with the filing of MA plan benefits and premiums."²

Based on my roles and years of experience as an actuary working on the MA program and my knowledge of the Actuarial Standards of Practice (ASOPs) and the statute and regulations governing the MA program, it is my opinion that these statements are inaccurate. Specifically, (i) there is no actuarial soundness issue with the requirement that bids are to be prepared and certified in a manner consistent with the various published payment policies, (ii) MAOs would be overpaid if they are reimbursed for unsupported diagnoses and, (iii) the actuarial certification submitted by the actuary requires that they have complied with the

¹ Expert Report of Julia Lambert, dated September 29, 2023 ("Lambert Report") at P. 2.

² *Id.* at 3.

applicable laws, rules, bid instructions and CMS guidance and necessitates that they only include diagnoses that are expected to be included in payment. The following describes how I've reached these conclusions.

1. The risk adjustment model used in MA payment is proposed through the Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies; is subject to comment³; and is finalized in the Announcement of Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, prior to the bid submission deadline⁴.
2. MA bids must be prepared with projected risk scores that represent what the actuary reasonably expects to be used for payment. Since diagnoses submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation, the actuary must exclude from the bid development any knowingly unsupported codes that will not be included for payment. While the actuary does not have an obligation to audit the data used in the risk score projection development, they are obligated to review this data to ensure that the data is reasonable and consistent for purposes of the assignment⁵
3. The risk adjustment model development and the MA bidding and payment process does follow the data consistency standard described in ASOP #45 – The Use of Health Status Based Risk Adjustment Methodologies⁶. The ASOP considers two areas of consistent treatment consideration.
 - a. The first is that “The actuary should consider if the population and program to which the model is being applied are reasonably consistent with those used to develop the model.” Since both the development and application of the model are applicable to Medicare beneficiaries, this standard has been satisfied⁷.

³ For example, USBP067351461 is the Advance Notice of Methodological Changes for the Calendar Year (CY) 2015 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

⁴ USBP067351609 is the Announcement Medicare Advantage (MA) Capitation Rates of Calendar Year (CY) 2015 and Part C and Part D Payment Policies

⁵ American Academy of Actuaries, Actuarial Standard of Practice (“ASOP”) No. 23, https://www.actuarialstandardsboard.org/wp-content/uploads/2017/01/asop023_185.pdf.

⁶ American Academy of Actuaries, Actuarial Standard of Practice (“ASOP”) No. 45, https://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf.

⁷ *Id.* at § 3.1.4.

- b. The second is that “The type of input data that is used in the application of risk adjustment should be reasonably consistent with the type of data used to develop the model. Also, the type of input data should be reasonably consistent across organizations, populations, and time periods.” The risk model development and the application of the risk model in the bid and payment processes both rely on health care diagnoses which are wholly consistent. The reliance on unaudited Traditional Medicare (using the same terminology as used by Ms. Lambert -an inter-changeable term is Medicare Fee-for-Service) data for determining the relative and predictive values of the various condition categories used in the risk model doesn’t invalidate the reasonability of those values. The risk model development process is subject to public comment and there have been no substantive comments rejecting the model development because of the unaudited nature of the underlying data nor have there been reasonable suggestions of alternative data sources that would provide for better predictability. Relying on unaudited data for the risk model development and requiring support for diagnoses submitted for payment does not result in an unreasonable or inconsistent application of risk adjustment⁸.
4. As stated above, it is my opinion that the data consistency standard described in ASOP #45 is followed in the application of the risk adjustment model to Medicare Advantage payments. Even if an actuary believed that there was an inconsistency between the data used as the basis of the risk model development and the data used for plan payment, the Actuarial Standards allow for the actuary to depart from the guidance set forth in the prescribed standard in order to comply with applicable law (statutes, regulations, and other legally binding authority) and to disclose if any material assumption or method was prescribed by applicable law (statutes, regulations, and other legally binding authority)⁹. Thus, the Actuarial Standards of Practice allow the actuary to perform their work in a manner prescribed by the law, regulations and other guidance related to the Medicare Advantage program, including the requirement that payment will only be made for diagnoses that are supported by a medical record.
5. Once again, it is my opinion that the data consistency standard described in ASOP #45 is followed in the application of the risk adjustment model to

⁸ *Id.* at § 3.2.

⁹ *Id.* at §§ 4.1-4.2.

Medicare Advantage payments. However, even if there were data inconsistencies resulting from the reliance on unaudited diagnosis data used in the development of the risk adjustment model, this potential inconsistency would not result in an underpayment to Medicare Advantage plans.

Specifically:

- An audit of the medical records for the Traditional Medicare diagnoses used in the risk model development would result in unsupported diagnoses being eliminated and unrecorded diagnoses being added.
- If the risk model was recalibrated based on the audited Traditional Medicare data, it is uncertain if this would lead to a net increase or decrease in cumulative diagnoses codes as the audit would result in some codes being added and others being deleted.
- If this change resulted in a change in average Traditional Medicare risk scores, the calibration of the model coefficients will change, and the calculated normalization factor would also need to change to return the average Traditional Medicare risk score to 1.0 in the payment year since normalization always gets back to a projected 1.0 score for the average Traditional Medicare beneficiary.
- Similarly, such a recalibration of the risk adjustment model would result in a change to the measure of coding intensity, or roughly the difference between average MA and Traditional Medicare risk scores. Even if just unsupported claims were removed, as in Ms. Lambert's illustration, the measured coding intensity adjustment would increase commensurately.
- As described in the preceding bullets, any change in a theorized risk adjustment model based on audited Traditional Medicare data would directly affect the risk model coefficient values, normalization, and coding intensity factors, all of which affect MA plan payments. A more complete consideration of any potential effects of including unsupported diagnoses in the calibration of the risk adjustment model would negate most, if not all, of any potential payment difference identified in Ms. Lambert's illustration.
- All these considerations are theoretical as the program is dependent on the finalization of the published risk adjustment model that serves as the foundation for the bidding and payments of the Medicare Advantage program.

- Once the bid is finalized, even if there are known changes that would materially affect the assumptions underlying the bid development, no changes to the bid are permitted.
6. Actuaries preparing bids are required to be familiar with the laws, regulations, and instructions of the program. They are required to include in their certification¹⁰ that “the actuary is familiar with the requirements for preparing Medicare Advantage and Prescription Drug bid submissions and meets the Academy’s qualification standards for doing so¹¹” and that they attest “that the bid was prepared in compliance with the current standards of practice, as promulgated by the Actuarial Standards Board of the American Academy of Actuaries, and that the bid complies with the appropriate ASOPs”.¹²

Based on the considerations summarized in points 1-6 above, it is my opinion that there is no actuarial soundness issue with the requirement that bids are to be prepared and certified in a manner consistent with the various published payment policies. Specifically, (i) there is no actuarial soundness issue with the requirement that bids are to be prepared and certified in a manner consistent with the various published payment policies, (ii) MAOs would be overpaid if they are reimbursed for unsupported diagnoses and, (iii) the actuarial certification submitted by the actuary requires that they have complied with the applicable laws, rules, bid instructions and CMS guidance and necessitates that they only include diagnoses that are expected to be included in payment.

Now, I’ll respond to a few other statements in Ms. Lambert’s report.

7. Ms. Lambert’s report states that “retrospectively removing unsupported diagnosis codes and the associated revenue would materially change the assumed payment methodology relied on in the bid submission process, nullify the actuarial certification, and underpay MAOs for the benefits offered.”¹³ Ms. Lambert’s opinion that “retrospectively removing unsupported diagnosis codes and the associated revenue would ... nullify the actuarial certification” is incorrect. The actuarial certification is not affected by events that occur after the

¹⁰ The CMS Bid pricing tool instructions for the Calendar Year (CY) 2015 was produced in this litigation as USBP057538571.

¹¹ USBP057538571 at p. 100.

¹² USBP057538571 at p. 101.

¹³ Lambert Report at P. 30.

certification. Actual results may vary from the assumptions and projections. The actuarial certification remains in effect based on what was known at that time. As noted above, the certifying actuary is required to prepare the bid in accordance with compliance with the applicable laws, rules, bid instructions, and guidance. This requirement should preclude an actuary from certifying a bid when they are aware of unsupported diagnoses included in the projected risk scores.

8. Ms. Lambert's report also states that "UHG projected risk scores without validating them in the medical record, and CMS accepted those bids under these assumptions."¹⁴ Given this statement, I believe it is relevant to note that acceptance of the bid submission by CMS is not a justification or guarantee that the bid submission is entirely correct or without issues. The certifying actuary is responsible for the assumptions, methodologies, and inputs for each bid pricing submission. To emphasize this position, the bid pricing instructions state that: "The objective of obtaining an actuarial certification is to place greater responsibility on the actuary's professional judgment and to hold him/her accountable for the reasonableness of the assumptions and projections."¹⁵ The following assertions cited by Ms. Lambert do not diminish the certifying actuary's and MA organization's responsibility because CMS may (i) not have reviewed this specific information or (ii) only reviewed this information to check compliance with disclosure requirements in the ASOPs:

- In every year during the Review Period: "As part of the preparation of the bids, we did not attempt to validate any actual or projected risk scores through a review of applicable medical records or of the systems used to submit RAF data to CMS."
- And starting with the BPT submissions in 2015: "We also adjusted projected risk scores to account for changes in our medical record review processes. Specifically, based on multiple conversations with CMS and CMS's treatment of medical record review in its recent rulemaking process, the health plan has decided to cease one of its prior processes that identified and deleted certain diagnoses codes through the medical record review process."¹⁶

¹⁴ *Id.* at P. 39.

¹⁵ USBP067812968 at P. 99.

¹⁶ Lambert Report at P. 32.

An actuary cannot disclaim that they are knowingly violating the rules of the program. The actuarial certification requires that they are familiar with the laws, regulations, and instructions of the program.

9. Finally, Ms. Lambert’s report includes the following statement, “In addition, approximately one third of the bids go through a rigorous audit procedure where an actuary hired by CMS reviews the calculations and checks the bid information, including the supporting data and assumptions for compliance with CMS’s instructions, guidance, and regulations (called “Bid Audits”).¹⁷” This statement is incorrect. The CMS audit of “one third of the bids” is a process that is independent of and separate from the “Bid Audits.” The Bid Audits are significantly smaller in scope than one third of the bids. Regardless of the number of bid audits performed, the actuarial certification requirement that a bid is to be prepared in accordance with the applicable law, regulations and guidance, including the requirement that diagnoses provided by the plan for payment purposes to be supported by a medical record, is unchanged.

Paul

Spitalnic -S

Digitally signed by
Paul Spitalnic -S
Date: 2024.01.25
16:48:16 -05'00'

Paul I. Spitalnic
Director and Chief Actuary,
Centers for Medicare &
Medicaid Services

Date

¹⁷ *Id* at 5.

Appendix 2

Materials Relied Upon

Produced in Litigation

USBP067351461

USBP067351609

USBP057538571

USBP067812968

Publicly Available

American Academy of Actuaries, Actuarial Standard of Practice (“ASOP”) No. 23,
https://www.actuarialstandardsboard.org/wp-content/uploads/2017/01/asop023_185.pdf

American Academy of Actuaries, Actuarial Standard of Practice (“ASOP”) No. 45,
https://www.actuarialstandardsboard.org/wp-content/uploads/2014/02/asop045_164.pdf

EXHIBIT P-38

UNITED STATES DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF)
AMERICA, ex rel.) Case No.:
BENJAMIN POEHLING,) No. 16-08697-FMO
Plaintiffs,)
V.)
UNITEDHEALTH GROUP,)
INC., et al.,)
Defendants.)
-----/

CONFIDENTIAL

CONTAINS ATTORNEYS' EYES ONLY PORTIONS

The Videotaped, In-Person, Remote deposition of KIRK LIMMER was held on Wednesday, June 21, 2023, commencing at 10:40 a.m., at the Law Offices of DLA Piper, 650 South Exeter Street, Suite 1100, Baltimore, Maryland 21202 before Susan Wootton, Notary Public.

REPORTED BY: Susan Wootton, RPR, CLR

1 risk scores to account for changes in our medical
2 record review processes, specifically based on
3 multiple conversations with CMS and CMS's
4 treatment of medical record review in its
5 reasonable making process.

6 The health plan has decided to cease
7 one of its prior processes that identified and
8 deleted certain diagnosis codes through the
9 medical record review process. Do you see that?

10 A Yes.

11 Q So what this paragraph is saying is
12 that the plan has adjusted its projected risk
13 score to account for cessation of a prior process
14 that identified and deleted certain diagnosis
15 codes, correct?

16 MS. ZUPAC: Object to form.

17 A It says they've decided to cease one
18 of its prior processes that identified and deleted
19 certain diagnoses codes. Yes. It does say that.

20 Q And it also says that it adjusted its
21 projected risk scores to account for that.

22 A It says: We also adjusted projected
23 risk scores to account for changes in our medical
24 review process.

25 Q And then it says: Specifically,

1 we've -- the plan has decided to cease one of its
2 prior processes and delete codes. Correct?

3 MS. ZUPAC: Object to form.

4 A Yes. It does say that.

5 Q And CMS understands, right, that an
6 adjustment to a projected risk score -- to account
7 for cessation of a process to identify and delete
8 diagnosis codes -- would be an upward adjustment
9 in the risk score, correct?

10 MS. ZUPAC: Object to form.

11 Q All else being equal?

12 A So given the -- the brief context of
13 what is provided here, I don't know if I would
14 know the -- the scope of the entire -- the entire
15 change or the magnitude.

16 I think that the -- and there --
17 there's -- there's very little information in here
18 in terms -- to make an assessment on what -- you
19 know, the -- the entirety of what's happening
20 here.

21 This doesn't really state any
22 quantitative assessment. But that's not required.
23 I mean, the Standards of Practice don't
24 necessarily require that the actuary quantify some
25 of these coding things.

1 there may be a number of different changes going
2 on simultaneously during the course of the year
3 which are projected for the next year.

4 A Yes.

5 Q And those changes might cumulatively
6 point in various different directions.

7 A Okay.

8 Q Is that right?

9 A Yes.

10 Q That's what you're saying? But what
11 I'm asking is -- holding all the others constant,
12 whatever those others are -- the incremental
13 impact -- CMS would understand, right, that the
14 incremental impact of ceasing a process of
15 identifying and deleting diagnosis codes -- in
16 terms of the risk score -- would have to be in an
17 upward direction, correct?

18 MS. ZUPAC: Object to form.

19 A So you're asking for this -- under
20 this bid submission under this here, whether CMS
21 would have known about that question you just
22 asked?

23 So -- so I did inquire -- so I have
24 maybe some background. I did inquire with Tova
25 Labell, the one, the one from -- from Korn Ferry.

1 I checked with her, and I checked with
2 other -- the points of contact in 2015 and 2012,
3 if they recalled a review of this, and I was not
4 able to confirm that anyone ever recalled or heard
5 or saw it.

6 I also checked under -- so under this
7 one, 2015, I did check the documentation that was
8 uploaded to HPMS as part of the Korn Ferry's
9 review and their documentation, and I was unable
10 to find any reference to this.

11 So in -- in doing that, I -- I
12 searched on, like, key words, like the word --
13 words that would stand out in here, like the word
14 "cease" and the word "process," I believe, RAD --
15 the RADV, and the word "adjustor."

16 So I did try to find if this was
17 reviewed. I was not able to find any of that in
18 the -- in the -- the contractor's documentation
19 that they necessarily looked at this.

20 Q So just to understand, so your
21 testimony is that CMS is not sure whether or not,
22 one way or another, this particular language was
23 reviewed by a bid reviewer as part of the review
24 of United's bids; is that your testimony?

25 A Correct. I was not able to confirm

1 it, whether or not it was actually -- it wasn't
2 documented, and no one -- no one had a
3 recollection.

4 It's kind of -- it was kind of hard
5 too, because the people at Korn Ferry, that staff
6 is gone.

7 So they -- they weren't able to
8 really -- talking to them, to them directly, I
9 wasn't able to provide any information there.

10 Q So they may have reviewed it and found
11 it was okay, but you just don't know one way or
12 the other?

13 A Correct.

14 Q Okay. And then -- my question,
15 though, was a little different, which is -- my
16 original question, which was: Do you agree -- do
17 you understand that, that an up -- an adjustment
18 to a risk score projection -- everything else held
19 constant -- an adjustment to a risk score
20 projection to account for the cessation of a
21 program to identify and delete diagnosis codes
22 would be an upward adjustment?

23 MS. ZUPAC: Object to form.

24 A I believe that depends on which codes
25 are being deleted in that, that hierarchal

1 State of Maryland

2 County of Baltimore, to wit:

3 I, Susan M. Wootton, a Notary Public of the
4 State of Maryland, County of Baltimore, do hereby
5 certify that the within-named witness personally
6 appeared before me at the time and place herein set
7 out, and after having been duly sworn by me, according
8 to law, was examined by counsel.

9 I further certify that the examination was
10 recorded stenographically by me and this is a verbatim
11 transcript of the testimony, as taken stenographically
12 by me, to the best of my ability.

13

14 As witness my hand this _____ day of
15 _____, 2023.

16

Susan M. Wootton

SUSAN WOOTTON

17

Notary Public

18

19 My Commission Expires:

20 June 12, 2027

21

22

23

24

25

EXHIBIT P-39



About Us

CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.

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Who we are

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CMS Organizational Chart (PDF) [see more](#)

Administrator

Chiquita Brooks-LaSure is the Administrator for the Centers for Medicare and Medicaid... [see more](#)

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7500 Security Boulevard, Baltimore, MD 21244

EXHIBIT P-40

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July 1, 2014

VIA E-MAIL

Carol Wallack
Trial Attorney
Civil Division, Fraud Section
U.S. Department of Justice
601 D Street, NW, Room 9128
Washington, D.C. 20004

Re: UnitedHealth Group Updates

Dear Ms. Wallack:

I write to update you on several issues concerning UnitedHealth Group ("UHG").

First, we received your June 16, 2014 email with suggested revisions to the search term proposal outlined in our May 16, 2014 letter. We are reviewing the proposed revisions and analyzing how the changes may impact the amount of potentially responsive documents subject to review. We appreciate the fact that you offered to prioritize certain searches and custodians, and we are focusing our collection and production efforts accordingly. We plan to produce additional documents to you shortly, and on a rolling basis, for all custodians for whom we have active data. This includes all the additional custodians identified by the government except the following individuals: Ken Burdick, Ken Fasola, Ronnie Grower, Pamela Leal, and Kathleen Linder. Each of these individuals ended their respective employment with UHG before the government issued its first request for documents. Nonetheless, UHG intends to produce any responsive communications that any of these individuals had with other custodians for whom active data exists.

Second, on June 13, 2014, UHG provided the government with a catalogue of documents and audio recordings subject to the attorney-client privilege and/or attorney work product protection. We are confident that the government will remain mindful of its ethical obligations and associated policies regarding the treatment of privileged materials and will report on any developments regarding this issue so UHG may take appropriate steps. We appreciate your candor with respect to this issue thus far.

EXHIBIT

00327

4462

Carol Wallace
July 1, 2014
Page 2

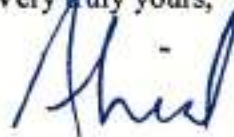
LATHAM & WATKINS LLP

Third, I wanted to provide you with an update on the Claims Verification program OptumInsight developed to analyze certain diagnosis codes submitted in provider claims data. This program was described during our September 14, 2012 meeting with your colleagues Dick Nicholson, Gretchen Wylegala, Peggy Glynn, Teresa Tetlow, Peggy McFarland, and Jessica Rogers. As Claims Verification has continued to evolve, and based on a number of factors, UnitedHealthcare recently decided to discontinue its utilization of the program. We would be pleased to discuss this development with you or your colleagues if you have any questions or concerns, including as part of a broader discussion of this matter.

* * * *

Thank for your continued courtesies. Please do not hesitate to contact me if you have any questions or concerns.

Very truly yours,



Abid R. Qureshi
of LATHAM & WATKINS LLP

cc: Gretchen Wylegala
Peggy B. Glynn
Roger S. Goldman
Daniel Meron

EXHIBIT P-41

(d) Hospice care; election; waiver of rights; revocation; change of election

(1) Payment under this part may be made for hospice care provided with respect to an individual only during two periods of 90 days each and an unlimited number of subsequent periods of 60 days each during the individual's lifetime and only, with respect to each such period, if the individual makes an election under this paragraph to receive hospice care under this part provided by, or under arrangements made by, a particular hospice program instead of certain other benefits under this subchapter.

(2)(A) Except as provided in subparagraphs (B) and (C) and except in such exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this subchapter with respect to-

(i) hospice care provided by another hospice program (other than under arrangements made by the particular hospice program) during the period, and

(ii) services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be-

(I) related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made or

(II) equivalent to (or duplicative of) hospice care;

except that clause (ii) shall not apply to physicians' services furnished by the individual's attending physician (if not an employee of the hospice program) or to services provided by (or under arrangements made by) the hospice program.

(B) After an individual makes such an election with respect to a 90-day period or a subsequent 60-day period, the individual may revoke the election during the period, in which case-

(i) the revocation shall act as a waiver of the right to have payment made under this part for any hospice care benefits for the remaining time in such period and (for purposes of subsection (a)(4) of this section and subparagraph (A)) the individual shall be deemed to have been provided such benefits during such entire period, and

(ii) the individual may at any time after the revocation execute a new election for a subsequent period, if the individual otherwise is entitled to hospice care benefits with respect to such a period.

(C) An individual may, once in each such period, change the hospice program with respect to which the election is made and such change shall not be considered a revocation of an election under subparagraph (B).

(D) For purposes of this subchapter, an individual's election with respect to a hospice program shall no longer be considered to be in effect with respect to that hospice program after the date the individual's revocation or change of election with respect to that election takes effect.

EXHIBIT P-42

42 USC 1395x: Definitions

Text contains those laws in effect on June 27, 2024

From Title 42-THE PUBLIC HEALTH AND WELFARE

CHAPTER 7-SOCIAL SECURITY

SUBCHAPTER XVIII-HEALTH INSURANCE FOR AGED AND DISABLED

Part E-Miscellaneous Provisions

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§1395x. Definitions

For purposes of this subchapter-

(a) Spell of illness

The term "spell of illness" with respect to any individual means a period of consecutive days-

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1395i-3(a)(1) of this title or subsection (y)(1).

(b) Inpatient hospital services

The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital-

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however-

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s) (2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by-

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this subchapter for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this subchapter.

(c) Inpatient psychiatric hospital services

individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician-

- (A) physicians' services;
- (B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;
- (C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;
- (D) social and psychological services;
- (E) nursing care provided by or under the supervision of a registered professional nurse;
- (F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;
- (G) supplies and durable medical equipment; and
- (H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this subchapter.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which-

- (A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;
- (B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in subsection (r)(1), who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;
- (C) maintains clinical records on all patients;
- (D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);
- (E) has a requirement that every patient must be under the care of a physician;
- (F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;
- (G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;
- (H) has in effect an overall plan and budget that meets the requirements of subsection (z);
- (I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000; and
- (J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

(dd) Hospice care; hospice program; definitions; certification; waiver by Secretary

(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program-

- (A) nursing care provided by or under the supervision of a registered professional nurse,
- (B) physical or occupational therapy, or speech-language pathology services,
- (C) medical social services under the direction of a physician,
- (D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,
- (E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,
- (F) physicians' services,
- (G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,
- (H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and
- (I) any other item or service which is specified in the plan and for which payment may otherwise be made under this subchapter.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally

ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which-

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1395d(a)(5) of this title,

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that-

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1395d(d) of this title with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which-

(i) includes at least-

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker, marriage and family therapist, or mental health counselor,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3)(A) An individual is considered to be "terminally ill" if the individual has a medical prognosis that the individual's life expectancy is 6 months or less.

(B) The term "attending physician" means, with respect to an individual, the physician (as defined in subsection (r)(1)), the nurse practitioner (as defined in subsection (aa)(5)), or the physician assistant (as defined in such subsection), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4)(A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this subchapter so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1395cc of this title and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this subchapter.

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization-

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such

request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A) or (C) shall not preclude the granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization-

- (i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and
- (ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

(ee) Discharge planning process

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this subchapter and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this subchapter and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1395a of this title, the discharge plan shall-

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization-

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i) ⁹, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

(ff) Partial hospitalization services; intensive outpatient services

(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week and provided under a program described in paragraph (3) under the

EXHIBIT P-43

Risk Model Diagnoses for 2012 Payment Year (2011 data collection year)

CMS-HCC (MA), CMS-HCC (ESRD, PACE) and RxHCC models (updated March 26, 2012)

Note: Includes Fiscal Year 2012 ICD-9-CM code revisions.

Note: Cost plans include \$1876 cost HMOs/CMPs and \$1833 HCPPPs.

ICD-9-CM Code	ICD-9-CM Description	CMS-HCC Model Category (MA and cost plans aged/disabled)	CMS-HCC Model Category (ESRD, PACE)	RxHCC Model Category	CMS-HCC Model -- MA and cost plans. Calendar Year 2012 Payment	CMS-HCC Model -- ESRD, PACE. Calendar Year 2012 Payment	RxHCC Model Calendar Year 2012 Payment
0031	Salmonella septicemia	2	2		Yes	Yes	No
00322	Salmonella pneumonia	112	115		Yes	Yes	No
00323	Salmonella arthritis	37	39		Yes	Yes	No
00324	Salmonella osteomyelitis	37	39		Yes	Yes	No
0064	Amebic lung abscess	112	115	106	Yes	Yes	Yes
0074	Cryptosporidiosis	5	6	5	Yes	Yes	Yes
0202	Septicemic plague	2	2		Yes	Yes	No
0203	Primary pneumonic plague	112	115		Yes	Yes	No
0204	Secondary pneumon plague	112	115		Yes	Yes	No
0205	Pneumonic plague NOS	112	115		Yes	Yes	No
0212	Pulmonary tularemia	112	115		Yes	Yes	No
0221	Pulmonary anthrax	112	115		Yes	Yes	No
0223	Anthrax septicemia	2	2		Yes	Yes	No
0310	Pulmonary mycobacteria	5	6	5	Yes	Yes	Yes
0312	DMAC bacteremia	5	6	5	Yes	Yes	Yes
03283	Diphtheritic peritonitis	31	33		Yes	Yes	No
0362	Meningococemia	2	2		Yes	Yes	No
0363	Meningococc adrenal synd		23	19	No	Yes	Yes
03682	Meningococc arthropathy	37	39		Yes	Yes	No
0380	Streptococcal septicemia	2	2		Yes	Yes	No
03810	Staphylococc septicem NOS	2	2		Yes	Yes	No
03811	Meth susc Staph aur sept	2	2		Yes	Yes	No
03812	MRSA septicemia	2	2		Yes	Yes	No
03819	Staphylococc septicem NEC	2	2		Yes	Yes	No
0382	Pneumococcal septicemia	2	2		Yes	Yes	No
0383	Anaerobic septicemia	2	2		Yes	Yes	No
03840	Gram-neg septicemia NOS	2	2		Yes	Yes	No
03841	H. influenzae septicemia	2	2		Yes	Yes	No
03842	E coli septicemia	2	2		Yes	Yes	No
03843	Pseudomonas septicemia	2	2		Yes	Yes	No
03844	Serratia septicemia	2	2		Yes	Yes	No
03849	Gram-neg septicemia NEC	2	2		Yes	Yes	No
0388	Septicemia NEC	2	2		Yes	Yes	No
0389	Septicemia NOS	2	2		Yes	Yes	No
0391	Pulmonary actinomycosis	112	115		Yes	Yes	No
0400	Gas gangrene	104	106		Yes	Yes	No
0402	Whipple's disease	32		31	Yes	No	Yes
04082	Toxic shock syndrome	2	2		Yes	Yes	No
042	Human immuno virus dis	1	1	1	Yes	Yes	Yes
0460	Kuru		52	55	No	Yes	Yes
04611	Vamt Creutzfeldt-Jakob		52	55	No	Yes	Yes
04619	Creutzfldt-Jakob NEC/NOS		52	55	No	Yes	Yes
0462	Subac scleros panenceph		52	55	No	Yes	Yes
0463	Prog multifoc leukoencep		52	55	No	Yes	Yes
04671	Gerstm-Straus-Schnk syn		52	55	No	Yes	Yes
04672	Fatal familial insomnia		52	55	No	Yes	Yes
04679	Prion dis of CNS NEC/NOS		52	55	No	Yes	Yes
0468	Cns slow virus infec NEC		52	55	No	Yes	Yes
0469	Cns slow virus infec NOS		52	55	No	Yes	Yes
0522	Postvaricella myelitis		72	72	No	Yes	Yes
05310	H zoster nerv syst NOS			83	No	No	Yes

05311	Geniculate herpes zoster			83	No	No	Yes
05312	Postherpes trigem neural			83	No	No	Yes
05313	Postherpes polyneuropath			83	No	No	Yes
05314	Herpes zoster myelitis		72	72	No	Yes	Yes
05319	H zoster nerv syst NEC			83	No	No	Yes
0545	Herpetic septicemia	2	2		Yes	Yes	No
05474	Herpes simplex myelitis		72	72	No	Yes	Yes
05671	Arthritis due to rubella	37	39		Yes	Yes	No
07022	Hpt B chrn coma wo dlta	27	29	25	Yes	Yes	Yes
07023	Hpt B chrn coma w dlta	27	29	25	Yes	Yes	Yes
07032	Hpt B chrn wo cm wo dlta	27	29	25	Yes	Yes	Yes
07033	Hpt B chrn wo cm w dlta	27	29	25	Yes	Yes	Yes
07044	Chrc hpt C w hepat Coma	27	29	25	Yes	Yes	Yes
07054	Chrc hpt C wo hpat coma	27	29	25	Yes	Yes	Yes
0723	Mumps pancreatitis	32			Yes	No	No
0785	Cytomegaloviral disease	5	6	5	Yes	Yes	Yes
0786	Hem nephrosonephritis	132	141	126	Yes	Yes	Yes
07953	Hiv-2 infection oth dis	1	1	1	Yes	Yes	Yes
09487	Syph rupt cereb aneurysm	95	99		Yes	Yes	No
09850	Gonococcal arthritis	37	39		Yes	Yes	No
09851	Gonococcal synovitis	37	39		Yes	Yes	No
09852	Gonococcal bursitis	37	39		Yes	Yes	No
09853	Gonococcal spondylitis	37	39		Yes	Yes	No
09859	Gc infect joint NEC	37	39		Yes	Yes	No
09886	Gonococcal peritonitis	31	33		Yes	Yes	No
0993	Reiter's disease		40	41	No	Yes	Yes
1026	Yaws of bone & joint	37	39		Yes	Yes	No
1124	Candidiasis of lung	5	6	5	Yes	Yes	Yes
1125	Disseminated candidiasis	5	6	5	Yes	Yes	Yes
11284	Candidal esophagitis	5	6	5	Yes	Yes	Yes
1140	Primary coccidioidomycos	112	115	106	Yes	Yes	Yes
1144	Ch pl coccidioidomycosis	112	115	106	Yes	Yes	Yes
1145	Pl coccidioidomycosis NOS	112	115	106	Yes	Yes	Yes
11505	Histoplasma caps pneumon	112	115	106	Yes	Yes	Yes
11515	Histoplasma dub pneumonia	112	115	106	Yes	Yes	Yes
11595	Histoplasmosis pneumonia	112	115	106	Yes	Yes	Yes
1173	Aspergillosis	5	6	5	Yes	Yes	Yes
1175	Cryptococcosis	5	6	5	Yes	Yes	Yes
1177	Zygomycosis	5	6	5	Yes	Yes	Yes
118	Opportunistic mycoses		6	5	No	Yes	Yes
1212	Paragonimiasis	112	115	106	Yes	Yes	Yes
1221	Echinococc granul lung	112	115	106	Yes	Yes	Yes
1300	Toxoplasma meningoenceph	5	6	5	Yes	Yes	Yes
1304	Toxoplasma pneumonitis	112	6	5	Yes	Yes	Yes
1308	Multisystem toxoplasmos	5	6	5	Yes	Yes	Yes
135	Sarcoidosis		112		No	Yes	No
1361	Behcet's syndrome	38	40	41	Yes	Yes	Yes
1363	Pneumocystosis	5	6	5	Yes	Yes	Yes
1410	Mal neo tongue base	9	11		Yes	Yes	No
1411	Mal neo dorsal tongue	9	11		Yes	Yes	No
1412	Mal neo tip/lat tongue	9	11		Yes	Yes	No
1413	Mal neo ventral tongue	9	11		Yes	Yes	No
1414	Mal neo ant 2/3 tongue	9	11		Yes	Yes	No
1415	Mal neo tongue junction	9	11		Yes	Yes	No
1416	Mal neo lingual tonsil	9	11		Yes	Yes	No
1418	Malig neo tongue NEC	9	11		Yes	Yes	No
1419	Malig neo tongue NOS	9	11		Yes	Yes	No
1420	Malig neo parotid	9	11		Yes	Yes	No
1421	Malig neo submandibular	9	11		Yes	Yes	No
1422	Malig neo sublingual	9	11		Yes	Yes	No
1428	Mal neo maj salivary NEC	9	11		Yes	Yes	No
1429	Mal neo salivary NOS	9	11		Yes	Yes	No
1430	Malig neo upper gum	9	11		Yes	Yes	No
1431	Malig neo lower gum	9	11		Yes	Yes	No

1438	Malig neo gum NEC	9	11		Yes	Yes	No
1439	Malig neo gum NOS	9	11		Yes	Yes	No
1440	Mal neo ant floor mouth	9	11		Yes	Yes	No
1441	Mal neo lat floor mouth	9	11		Yes	Yes	No
1448	Mal neo mouth floor NEC	9	11		Yes	Yes	No
1449	Mal neo mouth floor NOS	9	11		Yes	Yes	No
1450	Mal neo cheek mucosa	9	11		Yes	Yes	No
1451	Mal neo mouth vestibule	9	11		Yes	Yes	No
1452	Malig neo hard palate	9	11		Yes	Yes	No
1453	Malig neo soft palate	9	11		Yes	Yes	No
1454	Malignant neoplasm uvula	9	11		Yes	Yes	No
1455	Malignant neo palate NOS	9	11		Yes	Yes	No
1456	Malig neo retromolar	9	11		Yes	Yes	No
1458	Malig neoplasm mouth NEC	9	11		Yes	Yes	No
1459	Malig neoplasm mouth NOS	9	11		Yes	Yes	No
1460	Malignant neopl tonsil	9	11		Yes	Yes	No
1461	Mal neo tonsillar fossa	9	11		Yes	Yes	No
1462	Mal neo tonsil pillars	9	11		Yes	Yes	No
1463	Malign neopl vallecula	9	11		Yes	Yes	No
1464	Mal neo ant epiglottis	9	11		Yes	Yes	No
1465	Mal neo epiglottis junct	9	11		Yes	Yes	No
1466	Mal neo lat oropharynx	9	11		Yes	Yes	No
1467	Mal neo post oropharynx	9	11		Yes	Yes	No
1468	Mal neo oropharynx NEC	9	11		Yes	Yes	No
1469	Malig neo oropharynx NOS	9	11		Yes	Yes	No
1470	Mal neo super nasopharynx	9	11		Yes	Yes	No
1471	Mal neo post nasopharynx	9	11		Yes	Yes	No
1472	Mal neo lat nasopharynx	9	11		Yes	Yes	No
1473	Mal neo ant nasopharynx	9	11		Yes	Yes	No
1478	Mal neo nasopharynx NEC	9	11		Yes	Yes	No
1479	Mal neo nasopharynx NOS	9	11		Yes	Yes	No
1480	Mal neo postcricoid	9	11		Yes	Yes	No
1481	Mal neo pyriform sinus	9	11		Yes	Yes	No
1482	Mal neo aryepiglott fold	9	11		Yes	Yes	No
1483	Mal neo post hypopharynx	9	11		Yes	Yes	No
1488	Mal neo hypopharynx NEC	9	11		Yes	Yes	No
1489	Mal neo hypopharynx NOS	9	11		Yes	Yes	No
1490	Mal neo pharynx NOS	9	11		Yes	Yes	No
1491	Mal neo waldeyer's ring	9	11		Yes	Yes	No
1498	Mal neo oral/pharynx NEC	9	11		Yes	Yes	No
1499	Mal neo orophryn ill-def	9	11		Yes	Yes	No
1500	Mal neo cervical esophag	8	9		Yes	Yes	No
1501	Mal neo thoracic esophag	8	9		Yes	Yes	No
1502	Mal neo abdomin esophag	8	9		Yes	Yes	No
1503	Mal neo upper 3rd esoph	8	9		Yes	Yes	No
1504	Mal neo middle 3rd esoph	8	9		Yes	Yes	No
1505	Mal neo lower 3rd esoph	8	9		Yes	Yes	No
1508	Mal neo esophagus NEC	8	9		Yes	Yes	No
1509	Mal neo esophagus NOS	8	9		Yes	Yes	No
1510	Mal neo stomach cardia	8	9	10	Yes	Yes	Yes
1511	Malignant neo pylorus	8	9	10	Yes	Yes	Yes
1512	Mal neo pyloric antrum	8	9	10	Yes	Yes	Yes
1513	Mal neo stomach fundus	8	9	10	Yes	Yes	Yes
1514	Mal neo stomach body	8	9	10	Yes	Yes	Yes
1515	Mal neo stom lesser curv	8	9	10	Yes	Yes	Yes
1516	Mal neo stom great curv	8	9	10	Yes	Yes	Yes
1518	Malig neopl stomach NEC	8	9	10	Yes	Yes	Yes
1519	Malig neopl stomach NOS	8	9	10	Yes	Yes	Yes
1520	Malignant neopl duodenum	8	9	11	Yes	Yes	Yes
1521	Malignant neopl jejunum	8	9	11	Yes	Yes	Yes
1522	Malignant neoplasm ileum	8	9	11	Yes	Yes	Yes
1523	Mal neo meckel's divert	8	9	11	Yes	Yes	Yes
1528	Mal neo small bowel NEC	8	9	11	Yes	Yes	Yes
1529	Mal neo small bowel NOS	8	9	11	Yes	Yes	Yes

1530	Mal neo hepatic flexure	10	11		Yes	Yes	No
1531	Mal neo transverse colon	10	11		Yes	Yes	No
1532	Mal neo descend colon	10	11		Yes	Yes	No
1533	Mal neo sigmoid colon	10	11		Yes	Yes	No
1534	Malignant neoplasm cecum	10	11		Yes	Yes	No
1535	Malignant neo appendix	10	11		Yes	Yes	No
1536	Malig neo ascend colon	10	11		Yes	Yes	No
1537	Mal neo splenic flexure	10	11		Yes	Yes	No
1538	Malignant neo colon NEC	10	11		Yes	Yes	No
1539	Malignant neo colon NOS	10	11		Yes	Yes	No
1540	Mal neo rectosigmoid jct	10	11		Yes	Yes	No
1541	Malignant neopl rectum	10	11		Yes	Yes	No
1542	Malig neopl anal canal	10	11		Yes	Yes	No
1543	Malignant neo anus NOS	10	11		Yes	Yes	No
1548	Mal neo rectum/anus NEC	10	11		Yes	Yes	No
1550	Mal neo liver, primary	8	9	10	Yes	Yes	Yes
1551	Mal neo intrahepat ducts	8	9	10	Yes	Yes	Yes
1552	Malignant neo liver NOS	8	9	10	Yes	Yes	Yes
1560	Malig neo gallbladder	8	9	11	Yes	Yes	Yes
1561	Mal neo extrahepat ducts	8	9	11	Yes	Yes	Yes
1562	Mal neo ampulla of vater	8	9	11	Yes	Yes	Yes
1568	Malig neo biliary NEC	8	9	11	Yes	Yes	Yes
1569	Malig neo biliary NOS	8	9	11	Yes	Yes	Yes
1570	Mal neo pancreas head	8	9	10	Yes	Yes	Yes
1571	Mal neo pancreas body	8	9	10	Yes	Yes	Yes
1572	Mal neo pancreas tail	8	9	10	Yes	Yes	Yes
1573	Mal neo pancreatic duct	8	9	10	Yes	Yes	Yes
1574	Mal neo islet langerhans	8	9	10	Yes	Yes	Yes
1578	Malig neo pancreas NEC	8	9	10	Yes	Yes	Yes
1579	Malig neo pancreas NOS	8	9	10	Yes	Yes	Yes
1580	Mal neo retroperitoneum	8	9	11	Yes	Yes	Yes
1588	Mal neo peritoneum NEC	8	9	11	Yes	Yes	Yes
1589	Mal neo peritoneum NOS	8	9	11	Yes	Yes	Yes
1590	Malig neo intestine NOS	10	11		Yes	Yes	No
1591	Malignant neo spleen NEC	10	11		Yes	Yes	No
1598	Mal neo gi/intra-abd NEC	10	11		Yes	Yes	No
1599	Mal neo GI tract ill-def	10	11		Yes	Yes	No
1600	Mal neo nasal cavities	9	11		Yes	Yes	No
1601	Malig neo middle ear	9	11		Yes	Yes	No
1602	Mal neo maxillary sinus	9	11		Yes	Yes	No
1603	Mal neo ethmoidal sinus	9	11		Yes	Yes	No
1604	Malig neo frontal sinus	9	11		Yes	Yes	No
1605	Mal neo sphenoid sinus	9	11		Yes	Yes	No
1608	Mal neo access sinus NEC	9	11		Yes	Yes	No
1609	Mal neo access sinus NOS	9	11		Yes	Yes	No
1610	Malignant neo glottis	9	11		Yes	Yes	No
1611	Malig neo supraglottis	9	11		Yes	Yes	No
1612	Malig neo subglottis	9	11		Yes	Yes	No
1613	Mal neo cartilage larynx	9	11		Yes	Yes	No
1618	Malignant neo larynx NEC	9	11		Yes	Yes	No
1619	Malignant neo larynx NOS	9	11		Yes	Yes	No
1620	Malignant neo trachea	8	9	10	Yes	Yes	Yes
1622	Malig neo main bronchus	8	9	10	Yes	Yes	Yes
1623	Mal neo upper lobe lung	8	9	10	Yes	Yes	Yes
1624	Mal neo middle lobe lung	8	9	10	Yes	Yes	Yes
1625	Mal neo lower lobe lung	8	9	10	Yes	Yes	Yes
1628	Mal neo bronch/lung NEC	8	9	10	Yes	Yes	Yes
1629	Mal neo bronch/lung NOS	8	9	10	Yes	Yes	Yes
1630	Mal neo parietal pleura	8	9	10	Yes	Yes	Yes
1631	Mal neo visceral pleura	8	9	10	Yes	Yes	Yes
1638	Malig neopl pleura NEC	8	9	10	Yes	Yes	Yes
1639	Malig neopl pleura NOS	8	9	10	Yes	Yes	Yes
1640	Malignant neopl thymus	9	11		Yes	Yes	No
1641	Malignant neopl heart	9	11		Yes	Yes	No

1642	Mal neo ant mediastinum	9	11		Yes	Yes	No
1643	Mal neo post mediastinum	9	11		Yes	Yes	No
1648	Mal neo mediastinum NEC	9	11		Yes	Yes	No
1649	Mal neo mediastinum NOS	9	11		Yes	Yes	No
1650	Mal neo upper resp NOS	9	11		Yes	Yes	No
1658	Mal neo thorax/resp NEC	9	11		Yes	Yes	No
1659	Mal neo resp system NOS	9	11		Yes	Yes	No
1700	Mal neo skull/face bone	9	10	11	Yes	Yes	Yes
1701	Malignant neo mandible	9	10	11	Yes	Yes	Yes
1702	Malig neo vertebrae	9	10	11	Yes	Yes	Yes
1703	Mal neo ribs/stern/clav	9	10	11	Yes	Yes	Yes
1704	Mal neo long bones arm	9	10	11	Yes	Yes	Yes
1705	Mal neo bones wrist/hand	9	10	11	Yes	Yes	Yes
1706	Mal neo pelvic girdle	9	10	11	Yes	Yes	Yes
1707	Mal neo long bones leg	9	10	11	Yes	Yes	Yes
1708	Mal neo bones ankle/foot	9	10	11	Yes	Yes	Yes
1709	Malig neopl bone NOS	9	10	11	Yes	Yes	Yes
1710	Mal neo soft tissue head	9	10	10	Yes	Yes	Yes
1712	Mal neo soft tissue arm	9	10	10	Yes	Yes	Yes
1713	Mal neo soft tissue leg	9	10	10	Yes	Yes	Yes
1714	Mal neo soft tis thorax	9	10	10	Yes	Yes	Yes
1715	Mal neo soft tis abdomen	9	10	9	Yes	Yes	Yes
1716	Mal neo soft tis pelvis	9	10	10	Yes	Yes	Yes
1717	Mal neopl trunk NOS	9	10	10	Yes	Yes	Yes
1718	Mal neo soft tissue NEC	9	10	10	Yes	Yes	Yes
1719	Mal neo soft tissue NOS	9	10	10	Yes	Yes	Yes
1720	Malig melanoma lip	10	12		Yes	Yes	No
1721	Malig melanoma eyelid	10	12		Yes	Yes	No
1722	Malig melanoma ear	10	12		Yes	Yes	No
1723	Mal melanom face NEC/NOS	10	12		Yes	Yes	No
1724	Mal melanoma scalp/neck	10	12		Yes	Yes	No
1725	Malig melanoma trunk	10	12		Yes	Yes	No
1726	Malig melanoma arm	10	12		Yes	Yes	No
1727	Malig melanoma leg	10	12		Yes	Yes	No
1728	Malig melanoma skin NEC	10	12		Yes	Yes	No
1729	Malig melanoma skin NOS	10	12		Yes	Yes	No
1740	Malig neo nipple	10	12	10	Yes	Yes	Yes
1741	Mal neo breast-central	10	12	10	Yes	Yes	Yes
1742	Mal neo breast up-inner	10	12	10	Yes	Yes	Yes
1743	Mal neo breast low-inner	10	12	10	Yes	Yes	Yes
1744	Mal neo breast up-outer	10	12	10	Yes	Yes	Yes
1745	Mal neo breast low-outer	10	12	10	Yes	Yes	Yes
1746	Mal neo breast-axillary	10	12	10	Yes	Yes	Yes
1748	Malign neopl breast NEC	10	12	10	Yes	Yes	Yes
1749	Malign neopl breast NOS	10	12	10	Yes	Yes	Yes
1750	Mal neo male nipple	10	12	10	Yes	Yes	Yes
1759	Mal neo male breast NEC	10	12	10	Yes	Yes	Yes
1760	Skin - kaposi's sarcoma	9	10	10	Yes	Yes	Yes
1761	Sft tissue - kpsi's srcma	9	10	10	Yes	Yes	Yes
1762	Palate - kpsi's sarcoma	9	10	10	Yes	Yes	Yes
1763	GI sites - kpsi's srcoma	9	10	10	Yes	Yes	Yes
1764	Lung - kaposi's sarcoma	9	10	10	Yes	Yes	Yes
1765	Lym nds - kpsi's sarcoma	9	10	10	Yes	Yes	Yes
1768	Spf sts - kpsi's sarcoma	9	10	10	Yes	Yes	Yes
1769	Kaposi's sarcoma NOS	9	10	10	Yes	Yes	Yes
179	Malig neopl uterus NOS	10	12		Yes	Yes	No
1800	Malig neo endocervix	10	11		Yes	Yes	No
1801	Malig neo exocervix	10	11		Yes	Yes	No
1808	Malig neo cervix NEC	10	11		Yes	Yes	No
1809	Mal neo cervix uteri NOS	10	11		Yes	Yes	No
181	Malignant neopl placenta	9	10		Yes	Yes	No
1820	Malig neo corpus uteri	10	12		Yes	Yes	No
1821	Mal neo uterine isthmus	10	12		Yes	Yes	No
1828	Mal neo body uterus NEC	10	12		Yes	Yes	No

1830	Malign neopl ovary	9	10		Yes	Yes	No
1832	Mal neo fallopian tube	9	10		Yes	Yes	No
1833	Mal neo broad ligament	9	10		Yes	Yes	No
1834	Malig neo parametrium	9	10		Yes	Yes	No
1835	Mal neo round ligament	9	10		Yes	Yes	No
1838	Mal neo adnexa NEC	9	10		Yes	Yes	No
1839	Mal neo adnexa NOS	9	10		Yes	Yes	No
1840	Malign neopl vagina	10	11		Yes	Yes	No
1841	Mal neo labia majora	10	11		Yes	Yes	No
1842	Mal neo labia minora	10	11		Yes	Yes	No
1843	Malign neopl clitoris	10	11		Yes	Yes	No
1844	Malign neopl vulva NOS	10	11		Yes	Yes	No
1848	Mal neo female genit NEC	10	11		Yes	Yes	No
1849	Mal neo female genit NOS	10	11		Yes	Yes	No
185	Malign neopl prostate	10	12	11	Yes	Yes	Yes
1860	Mal neo undescend testis	10	12		Yes	Yes	No
1869	Malig neo testis NEC	10	12		Yes	Yes	No
1871	Malign neopl prepuce	10	12		Yes	Yes	No
1872	Malig neo glans penis	10	12		Yes	Yes	No
1873	Malig neo penis body	10	12		Yes	Yes	No
1874	Malig neo penis NOS	10	12		Yes	Yes	No
1875	Malig neo epididymis	10	12		Yes	Yes	No
1876	Mal neo spermatic cord	10	12		Yes	Yes	No
1877	Malign neopl scrotum	10	12		Yes	Yes	No
1878	Mal neo male genital NEC	10	12		Yes	Yes	No
1879	Mal neo male genital NOS	10	12		Yes	Yes	No
1880	Mal neo bladder-trigone	10	11		Yes	Yes	No
1881	Mal neo bladder-dome	10	11		Yes	Yes	No
1882	Mal neo bladder-lateral	10	11		Yes	Yes	No
1883	Mal neo bladder-anterior	10	11		Yes	Yes	No
1884	Mal neo bladder-post	10	11		Yes	Yes	No
1885	Mal neo bladder neck	10	11		Yes	Yes	No
1886	Mal neo ureteric orifice	10	11		Yes	Yes	No
1887	Malig neo urachus	10	11		Yes	Yes	No
1888	Malig neo bladder NEC	10	11		Yes	Yes	No
1889	Malig neo bladder NOS	10	11		Yes	Yes	No
1890	Malig neopl kidney	10	11	10	Yes	Yes	Yes
1891	Malig neo renal pelvis	10	11	10	Yes	Yes	Yes
1892	Malign neopl ureter	10	11		Yes	Yes	No
1893	Malign neopl urethra	10	11		Yes	Yes	No
1894	Mal neo paraurethral	10	11		Yes	Yes	No
1898	Mal neo urinary NEC	10	11		Yes	Yes	No
1899	Mal neo urinary NOS	10	11		Yes	Yes	No
1900	Malign neopl eyeball	10	12		Yes	Yes	No
1901	Malign neopl orbit	10	12		Yes	Yes	No
1902	Mal neo lacrimal gland	10	12		Yes	Yes	No
1903	Mal neo conjunctiva	10	12		Yes	Yes	No
1904	Malign neopl cornea	10	12		Yes	Yes	No
1905	Malign neopl retina	10	12		Yes	Yes	No
1906	Malign neopl choroid	10	12		Yes	Yes	No
1907	Mal neo lacrimal duct	10	12		Yes	Yes	No
1908	Malign neopl eye NEC	10	12		Yes	Yes	No
1909	Malign neopl eye NOS	10	12		Yes	Yes	No
1910	Malign neopl cerebrum	9	10	11	Yes	Yes	Yes
1911	Malig neo frontal lobe	9	10	11	Yes	Yes	Yes
1912	Mal neo temporal lobe	9	10	11	Yes	Yes	Yes
1913	Mal neo parietal lobe	9	10	11	Yes	Yes	Yes
1914	Mal neo occipital lobe	9	10	11	Yes	Yes	Yes
1915	Mal neo cereb ventricle	9	10	11	Yes	Yes	Yes
1916	Mal neo cerebellum NOS	9	10	11	Yes	Yes	Yes
1917	Mal neo brain stem	9	10	11	Yes	Yes	Yes
1918	Malig neo brain NEC	9	10	11	Yes	Yes	Yes
1919	Malig neo brain NOS	9	10	11	Yes	Yes	Yes
1920	Mal neo cranial nerves	9	10	11	Yes	Yes	Yes

1921	Mal neo cerebral mening	9	10	11	Yes	Yes	Yes
1922	Mal neo spinal cord	9	10	11	Yes	Yes	Yes
1923	Mal neo spinal meninges	9	10	11	Yes	Yes	Yes
1928	Mal neo nervous syst NEC	9	10	11	Yes	Yes	Yes
1929	Mal neo nervous syst NOS	9	10	11	Yes	Yes	Yes
193	Malign neopl thyroid	10	12	11	Yes	Yes	Yes
1940	Malign neopl adrenal	9	10	11	Yes	Yes	Yes
1941	Malig neo parathyroid	10	12	11	Yes	Yes	Yes
1943	Malig neo pituitary	9	10	11	Yes	Yes	Yes
1944	Malign neo pineal gland	9	10	11	Yes	Yes	Yes
1945	Mal neo carotid body	10	12	11	Yes	Yes	Yes
1946	Mal neo paraganglia NEC	10	12	11	Yes	Yes	Yes
1948	Mal neo endocrine NEC	10	12	11	Yes	Yes	Yes
1949	Mal neo endocrine NOS	10	12	11	Yes	Yes	Yes
1950	Mal neo head/face/neck	10	12		Yes	Yes	No
1951	Malign neopl thorax	10	12		Yes	Yes	No
1952	Malig neo abdomen	10	12		Yes	Yes	No
1953	Malign neopl pelvis	10	12		Yes	Yes	No
1954	Malign neopl arm	10	12		Yes	Yes	No
1955	Malign neopl leg	10	12		Yes	Yes	No
1958	Malig neo site NEC	10	12		Yes	Yes	No
1960	Mal neo lymph-head/neck	7	8		Yes	Yes	No
1961	Mal neo lymph-intrathor	7	8		Yes	Yes	No
1962	Mal neo lymph intra-abd	7	8		Yes	Yes	No
1963	Mal neo lymph-axilla/arm	7	10	11	Yes	Yes	Yes
1965	Mal neo lymph-inguin/leg	7	8		Yes	Yes	No
1966	Mal neo lymph-intrapelv	7	8		Yes	Yes	No
1968	Mal neo lymph node-mult	7	8		Yes	Yes	No
1969	Mal neo lymph node NOS	7	10	11	Yes	Yes	Yes
1970	Secondary malig neo lung	7	8	10	Yes	Yes	Yes
1971	Sec mal neo mediastinum	7	8	10	Yes	Yes	Yes
1972	Second malig neo pleura	7	8	10	Yes	Yes	Yes
1973	Sec malig neo resp NEC	7	8	10	Yes	Yes	Yes
1974	Sec malig neo sm bowel	7	8	10	Yes	Yes	Yes
1975	Sec malig neo lg bowel	7	8	10	Yes	Yes	Yes
1976	Sec mal neo peritoneum	7	8	10	Yes	Yes	Yes
1977	Second malig neo liver	7	8	10	Yes	Yes	Yes
1978	Sec mal neo GI NEC	7	8	10	Yes	Yes	Yes
1980	Second malig neo kidney	7	8	11	Yes	Yes	Yes
1981	Sec malig neo urin NEC	7	8	11	Yes	Yes	Yes
1982	Secondary malig neo skin	7	10		Yes	Yes	No
1983	Sec mal neo brain/spine	7	8		Yes	Yes	No
1984	Sec malig neo nerve NEC	7	8		Yes	Yes	No
1985	Secondary malig neo bone	7	8	10	Yes	Yes	Yes
1986	Second malig neo ovary	7	8	11	Yes	Yes	Yes
1987	Second malig neo adrenal	7	8	11	Yes	Yes	Yes
19881	Second malig neo breast	7	10		Yes	Yes	No
19882	Second malig neo genital	7	10		Yes	Yes	No
19889	Secondary malig neo NEC	7	8	11	Yes	Yes	Yes
1990	Malig neo disseminated	7	8	11	Yes	Yes	Yes
1991	Malignant neoplasm NOS	10	12		Yes	Yes	No
1992	Malig neopl-transp organ	10	12		Yes	Yes	No
20000	Retclsrc unsp xtrndl org	9	10		Yes	Yes	No
20001	Reticulosarcoma head	9	10		Yes	Yes	No
20002	Reticulosarcoma thorax	9	10		Yes	Yes	No
20003	Reticulosarcoma abdom	9	10		Yes	Yes	No
20004	Reticulosarcoma axilla	9	10		Yes	Yes	No
20005	Reticulosarcoma inguin	9	10		Yes	Yes	No
20006	Reticulosarcoma pelvic	9	10		Yes	Yes	No
20007	Reticulosarcoma spleen	9	10		Yes	Yes	No
20008	Reticulosarcoma mult	9	10		Yes	Yes	No
20010	Lymphsrc unsp xtrndl org	9	10		Yes	Yes	No
20011	Lymphosarcoma head	9	10		Yes	Yes	No
20012	Lymphosarcoma thorax	9	10		Yes	Yes	No

20013	Lymphosarcoma abdom	9	10		Yes	Yes	No
20014	Lymphosarcoma axilla	9	10		Yes	Yes	No
20015	Lymphosarcoma inguin	9	10		Yes	Yes	No
20016	Lymphosarcoma pelvic	9	10		Yes	Yes	No
20017	Lymphosarcoma spleen	9	10		Yes	Yes	No
20018	Lymphosarcoma mult	9	10		Yes	Yes	No
20020	Brkt tmr unsp xtrndl org	9	10		Yes	Yes	No
20021	Burkitt's tumor head	9	10		Yes	Yes	No
20022	Burkitt's tumor thorax	9	10		Yes	Yes	No
20023	Burkitt's tumor abdom	9	10		Yes	Yes	No
20024	Burkitt's tumor axilla	9	10		Yes	Yes	No
20025	Burkitt's tumor inguin	9	10		Yes	Yes	No
20026	Burkitt's tumor pelvic	9	10		Yes	Yes	No
20027	Burkitt's tumor spleen	9	10		Yes	Yes	No
20028	Burkitt's tumor mult	9	10		Yes	Yes	No
20030	Marginl zone lym xtrndl	9	10		Yes	Yes	No
20031	Margin zone lym head	9	10		Yes	Yes	No
20032	Margin zone lym thorax	9	10		Yes	Yes	No
20033	Margin zone lym abdom	9	10		Yes	Yes	No
20034	Margin zone lym axilla	9	10		Yes	Yes	No
20035	Margin zone lym inguin	9	10		Yes	Yes	No
20036	Margin zone lym pelvic	9	10		Yes	Yes	No
20037	Margin zone lymph spleen	9	10		Yes	Yes	No
20038	Margin zone lymph multip	9	10		Yes	Yes	No
20040	Mantle cell lym xtrndl	9	10		Yes	Yes	No
20041	Mantle cell lymph head	9	10		Yes	Yes	No
20042	Mantle cell lymph thorax	9	10		Yes	Yes	No
20043	Mantle cell lymph abdom	9	10		Yes	Yes	No
20044	Mantle cell lymph axilla	9	10		Yes	Yes	No
20045	Mantle cell lymph inguin	9	10		Yes	Yes	No
20046	Mantle cell lymph pelvic	9	10		Yes	Yes	No
20047	Mantle cell lymph spleen	9	10		Yes	Yes	No
20048	Mantle cell lymph multip	9	10		Yes	Yes	No
20050	Primary CNS lymph xtrndl	9	10		Yes	Yes	No
20051	Primary CNS lymph head	9	10		Yes	Yes	No
20052	Primary CNS lymph thorax	9	10		Yes	Yes	No
20053	Primary CNS lymph abdom	9	10		Yes	Yes	No
20054	Primary CNS lymph axilla	9	10		Yes	Yes	No
20055	Primary CNS lym inguin	9	10		Yes	Yes	No
20056	Primary CNS lymph pelvic	9	10		Yes	Yes	No
20057	Primary CNS lymph spleen	9	10		Yes	Yes	No
20058	Primary CNS lymph multip	9	10		Yes	Yes	No
20060	Anaplastic lymph xtrndl	9	10		Yes	Yes	No
20061	Anaplastic lymph head	9	10		Yes	Yes	No
20062	Anaplastic lymph thorax	9	10		Yes	Yes	No
20063	Anaplastic lymph abdom	9	10		Yes	Yes	No
20064	Anaplastic lymph axilla	9	10		Yes	Yes	No
20065	Anaplastic lymph inguin	9	10		Yes	Yes	No
20066	Anaplastic lymph pelvic	9	10		Yes	Yes	No
20067	Anaplastic lymph spleen	9	10		Yes	Yes	No
20068	Anaplastic lymph multip	9	10		Yes	Yes	No
20070	Large cell lymph xtrndl	9	10		Yes	Yes	No
20071	Large cell lymphoma head	9	10		Yes	Yes	No
20072	Large cell lymph thorax	9	10		Yes	Yes	No
20073	Large cell lymph abdom	9	10		Yes	Yes	No
20074	Large cell lymph axilla	9	10		Yes	Yes	No
20075	Large cell lymph inguin	9	10		Yes	Yes	No
20076	Large cell lymph pelvic	9	10		Yes	Yes	No
20077	Large cell lymph spleen	9	10		Yes	Yes	No
20078	Large cell lymph multip	9	10		Yes	Yes	No
20080	Oth varn unsp xtrndl org	9	10		Yes	Yes	No
20081	Mixed lymphosarc head	9	10		Yes	Yes	No
20082	Mixed lymphosarc thorax	9	10		Yes	Yes	No
20083	Mixed lymphosarc abdom	9	10		Yes	Yes	No

20084	Mixed lymphosarc axilla	9	10		Yes	Yes	No
20085	Mixed lymphosarc inguin	9	10		Yes	Yes	No
20086	Mixed lymphosarc pelvic	9	10		Yes	Yes	No
20087	Mixed lymphosarc spleen	9	10		Yes	Yes	No
20088	Mixed lymphosarc mult	9	10		Yes	Yes	No
20100	Hdgk prg unsp xtrndl org	9	10		Yes	Yes	No
20101	Hodgkins paragran head	9	10		Yes	Yes	No
20102	Hodgkins paragran thorax	9	10		Yes	Yes	No
20103	Hodgkins paragran abdom	9	10		Yes	Yes	No
20104	Hodgkins paragran axilla	9	10		Yes	Yes	No
20105	Hodgkins paragran inguin	9	10		Yes	Yes	No
20106	Hodgkins paragran pelvic	9	10		Yes	Yes	No
20107	Hodgkins paragran spleen	9	10		Yes	Yes	No
20108	Hodgkins paragran mult	9	10		Yes	Yes	No
20110	Hdgk grn unsp xtrndl org	9	10		Yes	Yes	No
20111	Hodgkins granulom head	9	10		Yes	Yes	No
20112	Hodgkins granulom thorax	9	10		Yes	Yes	No
20113	Hodgkins granulom abdom	9	10		Yes	Yes	No
20114	Hodgkins granulom axilla	9	10		Yes	Yes	No
20115	Hodgkins granulom inguin	9	10		Yes	Yes	No
20116	Hodgkins granulom pelvic	9	10		Yes	Yes	No
20117	Hodgkins granulom spleen	9	10		Yes	Yes	No
20118	Hodgkins granulom mult	9	10		Yes	Yes	No
20120	Hdgk src unsp xtrndl org	9	10		Yes	Yes	No
20121	Hodgkins sarcoma head	9	10		Yes	Yes	No
20122	Hodgkins sarcoma thorax	9	10		Yes	Yes	No
20123	Hodgkins sarcoma abdom	9	10		Yes	Yes	No
20124	Hodgkins sarcoma axilla	9	10		Yes	Yes	No
20125	Hodgkins sarcoma inguin	9	10		Yes	Yes	No
20126	Hodgkins sarcoma pelvic	9	10		Yes	Yes	No
20127	Hodgkins sarcoma spleen	9	10		Yes	Yes	No
20128	Hodgkins sarcoma mult	9	10		Yes	Yes	No
20140	Lym-hst unsp xtrndl orgn	9	10		Yes	Yes	No
20141	Hodg lymph-histio head	9	10		Yes	Yes	No
20142	Hodg lymph-histio thorax	9	10		Yes	Yes	No
20143	Hodg lymph-histio abdom	9	10		Yes	Yes	No
20144	Hodg lymph-histio axilla	9	10		Yes	Yes	No
20145	Hodg lymph-histio inguin	9	10		Yes	Yes	No
20146	Hodg lymph-histio pelvic	9	10		Yes	Yes	No
20147	Hodg lymph-histio spleen	9	10		Yes	Yes	No
20148	Hodg lymph-histio mult	9	10		Yes	Yes	No
20150	Ndr sclr unsp xtrndl org	9	10		Yes	Yes	No
20151	Hodg nodul sclero head	9	10		Yes	Yes	No
20152	Hodg nodul sclero thorax	9	10		Yes	Yes	No
20153	Hodg nodul sclero abdom	9	10		Yes	Yes	No
20154	Hodg nodul sclero axilla	9	10		Yes	Yes	No
20155	Hodg nodul sclero inguin	9	10		Yes	Yes	No
20156	Hodg nodul sclero pelvic	9	10		Yes	Yes	No
20157	Hodg nodul sclero spleen	9	10		Yes	Yes	No
20158	Hodg nodul sclero mult	9	10		Yes	Yes	No
20160	Mxd celr unsp xtrndl org	9	10		Yes	Yes	No
20161	Hodgkins mix cell head	9	10		Yes	Yes	No
20162	Hodgkins mix cell thorax	9	10		Yes	Yes	No
20163	Hodgkins mix cell abdom	9	10		Yes	Yes	No
20164	Hodgkins mix cell axilla	9	10		Yes	Yes	No
20165	Hodgkins mix cell inguin	9	10		Yes	Yes	No
20166	Hodgkins mix cell pelvic	9	10		Yes	Yes	No
20167	Hodgkins mix cell spleen	9	10		Yes	Yes	No
20168	Hodgkins mix cell mult	9	10		Yes	Yes	No
20170	Lym dplt unsp xtrndl org	9	10		Yes	Yes	No
20171	Hodg lymph deplet head	9	10		Yes	Yes	No
20172	Hodg lymph deplet thorax	9	10		Yes	Yes	No
20173	Hodg lymph deplet abdom	9	10		Yes	Yes	No
20174	Hodg lymph deplet axilla	9	10		Yes	Yes	No

20175	Hodg lymph deplet inguin	9	10		Yes	Yes	No
20176	Hodg lymph deplet pelvic	9	10		Yes	Yes	No
20177	Hodg lymph deplet spleen	9	10		Yes	Yes	No
20178	Hodg lymph deplet mult	9	10		Yes	Yes	No
20190	Hdgk dis unsp xtrndl org	9	10		Yes	Yes	No
20191	Hodgkins dis NOS head	9	10		Yes	Yes	No
20192	Hodgkins dis NOS thorax	9	10		Yes	Yes	No
20193	Hodgkins dis NOS abdom	9	10		Yes	Yes	No
20194	Hodgkins dis NOS axilla	9	10		Yes	Yes	No
20195	Hodgkins dis NOS inguin	9	10		Yes	Yes	No
20196	Hodgkins dis NOS pelvic	9	10		Yes	Yes	No
20197	Hodgkins dis NOS spleen	9	10		Yes	Yes	No
20198	Hodgkins dis NOS mult	9	10		Yes	Yes	No
20200	Ndlr lym unsp xtrndl org	9	10		Yes	Yes	No
20201	Nodular lymphoma head	9	10		Yes	Yes	No
20202	Nodular lymphoma thorax	9	10		Yes	Yes	No
20203	Nodular lymphoma abdom	9	10		Yes	Yes	No
20204	Nodular lymphoma axilla	9	10		Yes	Yes	No
20205	Nodular lymphoma inguin	9	10		Yes	Yes	No
20206	Nodular lymphoma pelvic	9	10		Yes	Yes	No
20207	Nodular lymphoma spleen	9	10		Yes	Yes	No
20208	Nodular lymphoma mult	9	10		Yes	Yes	No
20210	Mycs fng unsp xtrndl org	9	10		Yes	Yes	No
20211	Mycosis fungoides head	9	10		Yes	Yes	No
20212	Mycosis fungoides thorax	9	10		Yes	Yes	No
20213	Mycosis fungoides abdom	9	10		Yes	Yes	No
20214	Mycosis fungoides axilla	9	10		Yes	Yes	No
20215	Mycosis fungoides inguin	9	10		Yes	Yes	No
20216	Mycosis fungoides pelvic	9	10		Yes	Yes	No
20217	Mycosis fungoides spleen	9	10		Yes	Yes	No
20218	Mycosis fungoides mult	9	10		Yes	Yes	No
20220	Szry dis unsp xtrndl org	9	10		Yes	Yes	No
20221	Sezary's disease head	9	10		Yes	Yes	No
20222	Sezary's disease thorax	9	10		Yes	Yes	No
20223	Sezary's disease abdom	9	10		Yes	Yes	No
20224	Sezary's disease axilla	9	10		Yes	Yes	No
20225	Sezary's disease inguin	9	10		Yes	Yes	No
20226	Sezary's disease pelvic	9	10		Yes	Yes	No
20227	Sezary's disease spleen	9	10		Yes	Yes	No
20228	Sezary's disease mult	9	10		Yes	Yes	No
20230	Mlg hist unsp xtrndl org	9	10		Yes	Yes	No
20231	Mal histiocytosis head	9	10		Yes	Yes	No
20232	Mal histiocytosis thorax	9	10		Yes	Yes	No
20233	Mal histiocytosis abdom	9	10		Yes	Yes	No
20234	Mal histiocytosis axilla	9	10		Yes	Yes	No
20235	Mal histiocytosis inguin	9	10		Yes	Yes	No
20236	Mal histiocytosis pelvic	9	10		Yes	Yes	No
20237	Mal histiocytosis spleen	9	10		Yes	Yes	No
20238	Mal histiocytosis mult	9	10		Yes	Yes	No
20240	Lk rtctl unsp xtrndl org	9	10		Yes	Yes	No
20241	Hairy-cell leukem head	9	10		Yes	Yes	No
20242	Hairy-cell leukem thorax	9	10		Yes	Yes	No
20243	Hairy-cell leukem abdom	9	10		Yes	Yes	No
20244	Hairy-cell leukem axilla	9	10		Yes	Yes	No
20245	Hairy-cell leukem inguin	9	10		Yes	Yes	No
20246	Hairy-cell leukem pelvic	9	10		Yes	Yes	No
20247	Hairy-cell leukem spleen	9	10		Yes	Yes	No
20248	Hairy-cell leukem mult	9	10		Yes	Yes	No
20250	Ltr-siwe unsp xtrndl org	9	10		Yes	Yes	No
20251	Letterer-siwe dis head	9	10		Yes	Yes	No
20252	Letterer-siwe dis thorax	9	10		Yes	Yes	No
20253	Letterer-siwe dis abdom	9	10		Yes	Yes	No
20254	Letterer-siwe dis axilla	9	10		Yes	Yes	No
20255	Letterer-siwe dis inguin	9	10		Yes	Yes	No

20256	Letterer-siwe dis pelvic	9	10		Yes	Yes	No
20257	Letterer-siwe dis spleen	9	10		Yes	Yes	No
20258	Letterer-siwe dis mult	9	10		Yes	Yes	No
20260	Mlg mast unsp xtrndl org	9	10		Yes	Yes	No
20261	Mal mastocytosis head	9	10		Yes	Yes	No
20262	Mal mastocytosis thorax	9	10		Yes	Yes	No
20263	Mal mastocytosis abdom	9	10		Yes	Yes	No
20264	Mal mastocytosis axilla	9	10		Yes	Yes	No
20265	Mal mastocytosis inguin	9	10		Yes	Yes	No
20266	Mal mastocytosis pelvic	9	10		Yes	Yes	No
20267	Mal mastocytosis spleen	9	10		Yes	Yes	No
20268	Mal mastocytosis mult	9	10		Yes	Yes	No
20270	Periph T cell lym xtrndl	9	10		Yes	Yes	No
20271	Periph T cell lymph head	9	10		Yes	Yes	No
20272	Periph T cell lym thorax	9	10		Yes	Yes	No
20273	Periph T cell lym abdom	9	10		Yes	Yes	No
20274	Periph T cell lym axilla	9	10		Yes	Yes	No
20275	Periph T cell lym inguin	9	10		Yes	Yes	No
20276	Periph T cell lym pelvic	9	10		Yes	Yes	No
20277	Periph T cell lym spleen	9	10		Yes	Yes	No
20278	Periph T cell lym multip	9	10		Yes	Yes	No
20280	Oth lym unsp xtrndl org	9	10		Yes	Yes	No
20281	Lymphomas NEC head	9	10		Yes	Yes	No
20282	Lymphomas NEC thorax	9	10		Yes	Yes	No
20283	Lymphomas NEC abdom	9	10		Yes	Yes	No
20284	Lymphomas NEC axilla	9	10		Yes	Yes	No
20285	Lymphomas NEC inguin	9	10		Yes	Yes	No
20286	Lymphomas NEC pelvic	9	10		Yes	Yes	No
20287	Lymphomas NEC spleen	9	10		Yes	Yes	No
20288	Lymphomas NEC mult	9	10		Yes	Yes	No
20290	Unsp lym unsp xtrndl org	9	10		Yes	Yes	No
20291	Lymphoid mal NEC head	9	10		Yes	Yes	No
20292	Lymphoid mal NEC thorax	9	10		Yes	Yes	No
20293	Lymphoid mal NEC abdom	9	10		Yes	Yes	No
20294	Lymphoid mal NEC axilla	9	10		Yes	Yes	No
20295	Lymphoid mal NEC inguin	9	10		Yes	Yes	No
20296	Lymphoid mal NEC pelvic	9	10		Yes	Yes	No
20297	Lymphoid mal NEC spleen	9	10		Yes	Yes	No
20298	Lymphoid mal NEC mult	9	10		Yes	Yes	No
20300	Mult mye w/o achv rmson	9	9	9	Yes	Yes	Yes
20301	Mult myelm w remission	9	9	9	Yes	Yes	Yes
20302	Mult myeloma in relapse	9	9	9	Yes	Yes	Yes
20310	Pls cl leu w/o achv rmsn	9	9	9	Yes	Yes	Yes
20311	Plsm cell leuk w rmson	9	9	9	Yes	Yes	Yes
20312	Plsm cel leuk in relapse	9	9	9	Yes	Yes	Yes
20380	Oth immo npl wo ach rmsn	9	9	9	Yes	Yes	Yes
20381	Oth immprfl npl w rmsn	9	9	9	Yes	Yes	Yes
20382	Oth immprfl neo-relapse	9	9	9	Yes	Yes	Yes
20400	Ac lym leuk wo achv rmsn	7	8	11	Yes	Yes	Yes
20401	Act lym leuk w rmsion	7	8	11	Yes	Yes	Yes
20402	Act lym leuk in relapse	7	8	11	Yes	Yes	Yes
20410	Ch lym leuk wo achv rmsn	9	10		Yes	Yes	No
20411	Chr lym leuk w rmsion	9	10		Yes	Yes	No
20412	Chr lym leuk in relapse	9	10		Yes	Yes	No
20420	Sbac lym leu wo ach rmsn	9	10		Yes	Yes	No
20421	Sbac lym leuk w rmsion	9	10		Yes	Yes	No
20422	Sbac lym leuk in relapse	9	10		Yes	Yes	No
20480	Oth lym leu wo achv rmsn	9	10		Yes	Yes	No
20481	Oth lym leuk w rmsion	9	10		Yes	Yes	No
20482	Oth lym leuk in relapse	9	10		Yes	Yes	No
20490	Uns lym leu wo ach rmsn	9	10		Yes	Yes	No
20491	Uns lym leuk w rmsion	9	10		Yes	Yes	No
20492	Lymp leuk NOS relapse	9	10		Yes	Yes	No
20500	Ac myl leuk wo achv rmsn	7	8		Yes	Yes	No

20501	Act myl leuk w rmsion	7	8		Yes	Yes	No
20502	Act myel leuk in relapse	7	8		Yes	Yes	No
20510	Ch myl leuk wo achv rmsn	8	9	8	Yes	Yes	Yes
20511	Chr myl leuk w rmsion	8	9	8	Yes	Yes	Yes
20512	Chr myel leuk in relapse	8	9	8	Yes	Yes	Yes
20520	Sbac myl leu wo ach rmsn	8	9	8	Yes	Yes	Yes
20521	Sbac myl leuk w rmsion	8	9	8	Yes	Yes	Yes
20522	Sbac myl leuk in relapse	8	9	8	Yes	Yes	Yes
20530	Myl sarcoma wo achv rmsn	8	9	8	Yes	Yes	Yes
20531	Myl srcoma w rmsion	8	9	8	Yes	Yes	Yes
20532	Myel sarcoma in relapse	8	9	8	Yes	Yes	Yes
20580	Oth my leuk wo achv rmsn	8	9	8	Yes	Yes	Yes
20581	Oth myl leuk w rmsion	8	9	8	Yes	Yes	Yes
20582	Oth myel leuk in relapse	8	9	8	Yes	Yes	Yes
20590	Uns my leu wo ach rmsn	8	9	8	Yes	Yes	Yes
20591	Uns myl leuk w rmsion	8	9	8	Yes	Yes	Yes
20592	Myel leuk NOS in relapse	8	9	8	Yes	Yes	Yes
20600	Ac mono leu wo achv rmsn	7	8	11	Yes	Yes	Yes
20601	Act mono leuk w rmsion	7	8	11	Yes	Yes	Yes
20602	Act mono leuk in relapse	7	8	11	Yes	Yes	Yes
20610	Ch mono leu wo achv rmsn	8	9	8	Yes	Yes	Yes
20611	Chr mono leuk w rmsion	8	9	8	Yes	Yes	Yes
20612	Chr mono leuk in relapse	8	9	8	Yes	Yes	Yes
20620	Sbac mno leu wo ach rmsn	8	9	8	Yes	Yes	Yes
20621	Sbac mono leuk w rmsion	8	9	8	Yes	Yes	Yes
20622	Sbac mono leu in relapse	8	9	8	Yes	Yes	Yes
20680	Ot mono leu wo achv rmsn	8	9	8	Yes	Yes	Yes
20681	Oth mono leuk w rmsion	8	9	8	Yes	Yes	Yes
20682	Oth mono leuk in relapse	8	9	8	Yes	Yes	Yes
20690	Uns mno leu wo ach rmsn	8	9	8	Yes	Yes	Yes
20691	Uns mono leuk w rmsion	8	9	8	Yes	Yes	Yes
20692	Mono leuk NOS relapse	8	9	8	Yes	Yes	Yes
20700	Ac erth/erlk wo ach rmsn	7	8	11	Yes	Yes	Yes
20701	Act erth/erylk w rmson	7	8	11	Yes	Yes	Yes
20702	Ac erth/erylk in relapse	7	8	11	Yes	Yes	Yes
20710	Chr erythrm w/o ach rmsn	8	9	8	Yes	Yes	Yes
20711	Chr erythrm w remision	8	9	8	Yes	Yes	Yes
20712	Chr erythrmia in relapse	8	9	8	Yes	Yes	Yes
20720	Mgkrcyt leuk wo ach rmsn	8	9	8	Yes	Yes	Yes
20721	Mgkrcyt leuk w rmsion	8	9	8	Yes	Yes	Yes
20722	Mgkrcyt leuk in relapse	8	9	8	Yes	Yes	Yes
20780	Oth leuk w/o achv rmsn	8	9	8	Yes	Yes	Yes
20781	Oth spf leuk w remision	8	9	8	Yes	Yes	Yes
20782	Oth spf leuk in relapse	8	9	8	Yes	Yes	Yes
20800	Ac leu un cl wo ach rmsn	7	8	11	Yes	Yes	Yes
20801	Act leuk uns cl w rmson	7	8	11	Yes	Yes	Yes
20802	Ac leuk uns cl relapse	7	8	11	Yes	Yes	Yes
20810	Ch leu un cl wo ach rmsn	9	10		Yes	Yes	No
20811	Chr leuk uns cl w rmson	9	10		Yes	Yes	No
20812	Ch leu uns cl in relapse	9	10		Yes	Yes	No
20820	Sbc leu un cl wo ah rmsn	9	10		Yes	Yes	No
20821	Sbac leuk uns cl w rmson	9	10		Yes	Yes	No
20822	Sbac leu uns cl-relapse	9	10		Yes	Yes	No
20880	Ot leu un cl wo ach rmsn	9	10		Yes	Yes	No
20881	Oth leuk uns cl w rmson	9	10		Yes	Yes	No
20882	Oth leuk uns cl-relapse	9	10		Yes	Yes	No
20890	Leuk NOS w/o achv rmsn	9	10		Yes	Yes	No
20891	Leukemia NOS w remission	9	10		Yes	Yes	No
20892	Leukemia NOS in relapse	9	10		Yes	Yes	No
20900	Mal crcnoid sm intst NOS	10	12	11	Yes	Yes	Yes
20901	Malig carcinoid duodenum	10	12	11	Yes	Yes	Yes
20902	Malig carcinoid jejunum	10	12	11	Yes	Yes	Yes
20903	Malig carcinoid ileum	10	12	11	Yes	Yes	Yes
20910	Mal crcnoid lg intst NOS	10	12	11	Yes	Yes	Yes

20911	Malig carcinoid appendix	10	12	11	Yes	Yes	Yes
20912	Malig carcinoid cecum	10	12	11	Yes	Yes	Yes
20913	Mal crcnoid ascend colon	10	12	11	Yes	Yes	Yes
20914	Mal crcnoid transv colon	10	12	11	Yes	Yes	Yes
20915	Mal carcinoid desc colon	10	12	11	Yes	Yes	Yes
20916	Mal carcinoid sig colon	10	12	11	Yes	Yes	Yes
20917	Malig carcinoid rectum	10	12	11	Yes	Yes	Yes
20920	Mal crcnid prim site unkn	10	12	11	Yes	Yes	Yes
20921	Mal carcinoid bronc/lung	10	12	11	Yes	Yes	Yes
20922	Malig carcinoid thymus	10	12	11	Yes	Yes	Yes
20923	Malig carcinoid stomach	10	12	11	Yes	Yes	Yes
20924	Malig carcinoid kidney	10	12	11	Yes	Yes	Yes
20925	Mal carcoid foregut NOS	10	12	11	Yes	Yes	Yes
20926	Mal carcinoid midgut NOS	10	12	11	Yes	Yes	Yes
20927	Mal carcoid hindgut NOS	10	12	11	Yes	Yes	Yes
20929	Malig carcinoid oth site	10	12	11	Yes	Yes	Yes
20930	Malig neuroendo ca NOS	10	12	11	Yes	Yes	Yes
20931	Merkel cell ca-face	10	12	11	Yes	Yes	Yes
20932	Merkel cell ca-sclp/neck	10	12	11	Yes	Yes	Yes
20933	Merkel cell ca-up limb	10	12	11	Yes	Yes	Yes
20934	Merkel cell ca-low limb	10	12	11	Yes	Yes	Yes
20935	Merkel cell ca-trunk	10	12	11	Yes	Yes	Yes
20936	Merkel cell ca-oth sites	10	12	11	Yes	Yes	Yes
20970	Sec neuroendo tumor NOS	7	8	11	Yes	Yes	Yes
20971	Sec neuroend tu dist lym	7	8		Yes	Yes	No
20972	Sec neuroend tumor-liver	7	8	10	Yes	Yes	Yes
20973	Sec neuroendo tumor-bone	7	8	10	Yes	Yes	Yes
20974	Sec neuroendo tu-periton	7	8	10	Yes	Yes	Yes
20975	Secondary Merkel cell ca	7	8	11	Yes	Yes	Yes
20979	Sec neuroend tu oth site	7	8	11	Yes	Yes	Yes
2250	Benign neoplasm brain	10	12	11	Yes	Yes	Yes
2251	Benign neo cranial nerve	10	12	11	Yes	Yes	Yes
2252	Ben neo cerebr meninges	10	12	11	Yes	Yes	Yes
2253	Benign neo spinal cord	10	12	11	Yes	Yes	Yes
2254	Ben neo spinal meninges	10	12	11	Yes	Yes	Yes
2258	Benign neo nerv sys NEC	10	12	11	Yes	Yes	Yes
2259	Benign neo nerv sys NOS	10	12	11	Yes	Yes	Yes
2273	Benign neo pituitary	10	12	11	Yes	Yes	Yes
2274	Ben neopl pineal gland	10	12	11	Yes	Yes	Yes
22802	Hemangioma intracranial	10	12	11	Yes	Yes	Yes
2370	Unc behav neo pituitary	10	12		Yes	Yes	No
2371	Unc behav neo pineal	10	12		Yes	Yes	No
2373	Unc behav neo paragang	10	12		Yes	Yes	No
2375	Unc beh neo brain/spinal	10	12		Yes	Yes	No
2376	Unc behav neo meninges	10	12		Yes	Yes	No
23770	Neurofibromatosis NOS	10	12		Yes	Yes	No
23771	Neurofibromatosis type I	10	12		Yes	Yes	No
23772	Neurofibromatosis typ II	10	12		Yes	Yes	No
23773	Schwannomatosis	10	12		Yes	Yes	No
23779	Neurofibromatosis NEC	10	12		Yes	Yes	No
2379	Unc beh neo nerv sys NEC	10	12		Yes	Yes	No
2384	Polycythemia vera		48		No	Yes	No
2386	Plasmacytoma NOS			9	No	No	Yes
23871	Essntial thrombocythemia		48		No	Yes	No
23872	Low grde myelody syn les	44	46	48	Yes	Yes	Yes
23873	Hi grde myelodys syn les	44	46	9	Yes	Yes	Yes
23874	Myelodyspls syn w 5q del	44	46	9	Yes	Yes	Yes
23875	Myelodysplastic synd NOS	44	46	48	Yes	Yes	Yes
23876	Myelofi w myelo metaplas		46	9	No	Yes	Yes
23877	Post tp lymphprolif dis		48	50	No	Yes	Yes
23879	Lymph/hematpoitc tis NEC		48	50	No	Yes	Yes
2396	Brain neoplasm NOS	10	12		Yes	Yes	No
2400	Simple goiter			20	No	No	Yes
2409	Goiter NOS			20	No	No	Yes

2410	Nontox uninodular goiter			20	No	No	Yes
2411	Nontox multinodul goiter			20	No	No	Yes
2419	Nontox nodul goiter NOS			20	No	No	Yes
24200	Tox dif goiter no crisis			20	No	No	Yes
24201	Tox dif goiter w crisis			20	No	No	Yes
24210	Tox uninod goit no cris			20	No	No	Yes
24211	Tox uninod goit w crisis			20	No	No	Yes
24220	Tox multnod goit no cris			20	No	No	Yes
24221	Tox multnod goit w cris			20	No	No	Yes
24230	Tox nod goiter no crisis			20	No	No	Yes
24231	Tox nod goiter w crisis			20	No	No	Yes
24240	Thyrotax-ect nod no cris			20	No	No	Yes
24241	Thyrotax-ect nod w cris			20	No	No	Yes
24280	Thyrtox orig NEC no cris			20	No	No	Yes
24281	Thyrotax orig NEC w cris			20	No	No	Yes
24290	Thyrotax NOS no crisis			20	No	No	Yes
24291	Thyrotax NOS w crisis			20	No	No	Yes
243	Congenital hypothyroidism			20	No	No	Yes
2440	Postsurgical hypothyroid			20	No	No	Yes
2441	Postablat hypothy NEC			20	No	No	Yes
2442	Iodine hypothyroidism			20	No	No	Yes
2443	Iatrogen hypothyroid NEC			20	No	No	Yes
2448	Acquired hypothyroid NEC			20	No	No	Yes
2449	Hypothyroidism NOS			20	No	No	Yes
2450	Acute thyroiditis			20	No	No	Yes
2451	Subacute thyroiditis			20	No	No	Yes
2452	Chr lymphocyt thyroidit			20	No	No	Yes
2453	Chr fibrous thyroiditis			20	No	No	Yes
2454	Iatrogenic thyroiditis			20	No	No	Yes
2458	Chr thyroiditis NEC/NOS			20	No	No	Yes
2459	Thyroiditis NOS			20	No	No	Yes
2460	Dis thyrocalciton secret			20	No	No	Yes
2461	Dyshormonogenic goiter			20	No	No	Yes
2462	Cyst of thyroid			20	No	No	Yes
2463	Hemorr/infarc thyroid			20	No	No	Yes
2468	Disorders of thyroid NEC			20	No	No	Yes
2469	Disorder of thyroid NOS			20	No	No	Yes
24900	Sec DM wo cmp nt st uncn	19	19	15	Yes	Yes	Yes
24901	Sec DM wo comp uncontrld	19	19	15	Yes	Yes	Yes
24910	Sec DM keto nt st uncntr	17	17	14	Yes	Yes	Yes
24911	Sec DM ketoacd uncntrld	17	17	14	Yes	Yes	Yes
24920	Sec DM hpros nt st uncnr	17	17	14	Yes	Yes	Yes
24921	Sec DM hprosmr uncntrld	17	17	14	Yes	Yes	Yes
24930	Sec DM ot cma nt st uncn	17	17	14	Yes	Yes	Yes
24931	Sec DM oth coma uncntrld	17	17	14	Yes	Yes	Yes
24940	Sec DM renl nt st uncntr	15	18	14	Yes	Yes	Yes
24941	Sec DM renal uncntrld	15	18	14	Yes	Yes	Yes
24950	Sec DM ophth nt st uncn	18	18	14	Yes	Yes	Yes
24951	Sec DM ophth uncntrld	18	18	14	Yes	Yes	Yes
24960	Sec DM neuro nt st uncn	16	18	14	Yes	Yes	Yes
24961	Sec DM neuro uncntrld	16	18	14	Yes	Yes	Yes
24970	Sec DM circ nt st uncntr	15	18	14	Yes	Yes	Yes
24971	Sec DM circ uncntrld	15	18	14	Yes	Yes	Yes
24980	Sec DM oth nt st uncntr	16	18	14	Yes	Yes	Yes
24981	Sec DM other uncntrld	16	18	14	Yes	Yes	Yes
24990	Sec DM unsp nt st uncon	18	18	14	Yes	Yes	Yes
24991	Sec DM unsp uncontrold	18	18	14	Yes	Yes	Yes
25000	DMII wo cmp nt st uncntr	19	19	15	Yes	Yes	Yes
25001	DMI wo cmp nt st uncntrl	19	19	15	Yes	Yes	Yes
25002	DMII wo cmp uncntrld	19	19	15	Yes	Yes	Yes
25003	DMI wo cmp uncntrld	19	19	15	Yes	Yes	Yes
25010	DMII keto nt st uncntrld	17	17	14	Yes	Yes	Yes
25011	DMI keto nt st uncntrld	17	17	14	Yes	Yes	Yes
25012	DMII ketoacd uncontrold	17	17	14	Yes	Yes	Yes

25013	DMI ketoacd uncontrold	17	17	14	Yes	Yes	Yes
25020	DMII hprsm nt st uncntrl	17	17	14	Yes	Yes	Yes
25021	DMI hprsm nt st uncntrld	17	17	14	Yes	Yes	Yes
25022	DMII hprosmrlr uncontrold	17	17	14	Yes	Yes	Yes
25023	DMI hprosmrlr uncontrold	17	17	14	Yes	Yes	Yes
25030	DMII o cm nt st uncntrld	17	17	14	Yes	Yes	Yes
25031	DMI o cm nt st uncntrld	17	17	14	Yes	Yes	Yes
25032	DMII oth coma uncontrold	17	17	14	Yes	Yes	Yes
25033	DMI oth coma uncontrold	17	17	14	Yes	Yes	Yes
25040	DMII renl nt st uncntrld	15	18	14	Yes	Yes	Yes
25041	DMI renl nt st uncntrld	15	18	14	Yes	Yes	Yes
25042	DMII renal uncntrld	15	18	14	Yes	Yes	Yes
25043	DMI renal uncntrld	15	18	14	Yes	Yes	Yes
25050	DMII ophth nt st uncntrl	18	18	14	Yes	Yes	Yes
25051	DMI ophth nt st uncntrld	18	18	14	Yes	Yes	Yes
25052	DMII ophth uncntrld	18	18	14	Yes	Yes	Yes
25053	DMI ophth uncntrld	18	18	14	Yes	Yes	Yes
25060	DMII neuro nt st uncntrl	16	18	14	Yes	Yes	Yes
25061	DMI neuro nt st uncntrld	16	18	14	Yes	Yes	Yes
25062	DMII neuro uncntrld	16	18	14	Yes	Yes	Yes
25063	DMI neuro uncntrld	16	18	14	Yes	Yes	Yes
25070	DMII circ nt st uncntrld	15	18	14	Yes	Yes	Yes
25071	DMI circ nt st uncntrld	15	18	14	Yes	Yes	Yes
25072	DMII circ uncntrld	15	18	14	Yes	Yes	Yes
25073	DMI circ uncntrld	15	18	14	Yes	Yes	Yes
25080	DMII oth nt st uncntrld	16	18	14	Yes	Yes	Yes
25081	DMI oth nt st uncntrld	16	18	14	Yes	Yes	Yes
25082	DMII oth uncntrld	16	18	14	Yes	Yes	Yes
25083	DMI oth uncntrld	16	18	14	Yes	Yes	Yes
25090	DMII unspf nt st uncntrl	18	18	14	Yes	Yes	Yes
25091	DMI unspf nt st uncntrld	18	18	14	Yes	Yes	Yes
25092	DMII unspf uncntrld	18	18	14	Yes	Yes	Yes
25093	DMI unspf uncntrld	18	18	14	Yes	Yes	Yes
2510	Hypoglycemic coma		23		No	Yes	No
2514	Abn secretion glucagon	32		31	Yes	No	Yes
2515	Abnorm secretion gastrin	32		31	Yes	No	Yes
2518	Pancreatic disorder NEC	32		31	Yes	No	Yes
2519	Pancreatic disorder NOS	32		31	Yes	No	Yes
25200	Hyperparathyroidism NOS		23	19	No	Yes	Yes
25201	Primary hyperparathyroid		23	19	No	Yes	Yes
25202	Sec hyprprthyrd nonrenal		23	19	No	Yes	Yes
25208	Hyperparathyroidism NEC		23	19	No	Yes	Yes
2521	Hypoparathyroidism		23	19	No	Yes	Yes
2528	Parathyroid disorder NEC		23	19	No	Yes	Yes
2529	Parathyroid disorder NOS		23	19	No	Yes	Yes
2530	Acromegaly and gigantism		23	18	No	Yes	Yes
2531	Ant pituit hyperfunc NEC		23	18	No	Yes	Yes
2532	Panhypopituitarism		23	18	No	Yes	Yes
2533	Pituitary dwarfism		23	18	No	Yes	Yes
2534	Anter pituitary dis NEC		23	18	No	Yes	Yes
2535	Diabetes insipidus		23	18	No	Yes	Yes
2536	Neurohypophysis dis NEC		23	19	No	Yes	Yes
2537	Iatrogenic pituitary dis		23	19	No	Yes	Yes
2538	Pituitary disorder NEC		23	19	No	Yes	Yes
2539	Pituitary disorder NOS		23	19	No	Yes	Yes
2540	Persist hyperplas thymus		23	19	No	Yes	Yes
2541	Abscess of thymus		23	19	No	Yes	Yes
2548	Diseases of thymus NEC		23	19	No	Yes	Yes
2549	Disease of thymus NOS		23	19	No	Yes	Yes
2550	Cushing's syndrome		23	19	No	Yes	Yes
25510	Hyperaldosteronism NOS		23	19	No	Yes	Yes
25511	Glucrtcod-rem aldsterism		23	19	No	Yes	Yes
25512	Conn's syndrome		23	19	No	Yes	Yes
25513	Bartter's syndrome		23	19	No	Yes	Yes

25514	Secondry aldostermsm NEC		23	19	No	Yes	Yes
2552	Adrenogenital disorders		23	19	No	Yes	Yes
2553	Corticoadren overact NEC		23	19	No	Yes	Yes
25541	Glucocorticoid deficient		23	19	No	Yes	Yes
25542	Mineralcorticoid defcnt		23	19	No	Yes	Yes
2555	Adrenal hypofunction NEC		23	19	No	Yes	Yes
2556	Medulloadrenal hyperfunc		23	19	No	Yes	Yes
2558	Adrenal disorder NEC		23	19	No	Yes	Yes
2559	Adrenal disorder NOS		23	19	No	Yes	Yes
25801	Mult endo neoplas type I		23	19	No	Yes	Yes
25802	Mult endo neop type IIA		23	19	No	Yes	Yes
25803	Mult endo neop type IIB		23	19	No	Yes	Yes
2581	Comb endocr dysfunct NEC		23	19	No	Yes	Yes
2588	Polyglandul dysfunc NEC		23	19	No	Yes	Yes
2589	Polyglandul dysfunc NOS		23	19	No	Yes	Yes
2592	Carcinoid syndrome	10	12	11	Yes	Yes	Yes
260	Kwashiorkor	21	21		Yes	Yes	No
261	Nutritional marasmus	21	21		Yes	Yes	No
262	Oth severe malnutrition	21	21		Yes	Yes	No
2630	Malnutrition mod degree	21	21		Yes	Yes	No
2631	Malnutrition mild degree	21	21		Yes	Yes	No
2632	Arrest devel d/t malnutr	21	21		Yes	Yes	No
2638	Protein-cal malnutr NEC	21	21		Yes	Yes	No
2639	Protein-cal malnutr NOS	21	21		Yes	Yes	No
2680	Rickets, active			45	No	No	Yes
2682	Osteomalacia NOS			45	No	No	Yes
2700	Amino-acid transport dis		23	19	No	Yes	Yes
2701	Phenylketonuria - pku		23	19	No	Yes	Yes
2702	Arom amin-acid metab NEC		23	19	No	Yes	Yes
2703	Bran-chain amin-acid dis		23	19	No	Yes	Yes
2704	Sulph amino-acid met dis		23	19	No	Yes	Yes
2705	Dis histidine metabolism		23	19	No	Yes	Yes
2706	Dis urea cycle metabol		23	19	No	Yes	Yes
2707	Straig amin-acid met NEC		23	19	No	Yes	Yes
2708	Dis amino-acid metab NEC		23	19	No	Yes	Yes
2709	Dis amino-acid metab NOS		23	19	No	Yes	Yes
2710	Glycogenosis		23	18	No	Yes	Yes
2711	Galactosemia		23	19	No	Yes	Yes
2714	Renal glycosuria		23	19	No	Yes	Yes
2718	Dis carbohydr metab NEC		23	19	No	Yes	Yes
2719	Dis carbohydr metab NOS		23	19	No	Yes	Yes
2720	Pure hypercholesterolem			23	No	No	Yes
2721	Pure hyperglyceridemia			23	No	No	Yes
2722	Mixed hyperlipidemia			23	No	No	Yes
2723	Hyperchylomicronemia			23	No	No	Yes
2724	Hyperlipidemia NEC/NOS			23	No	No	Yes
2725	Lipoprotein deficiencies			23	No	No	Yes
2727	Lipidoses		23		No	Yes	No
2728	Lipoid metabol dis NEC			23	No	No	Yes
2729	Lipoid metabol dis NOS			23	No	No	Yes
2732	Paraproteinemia NEC		23		No	Yes	No
2733	Macroglobulinemia		23		No	Yes	No
2734	Alpha-1-antitrypsin def		23	18	No	Yes	Yes
27501	Heredit hemochromatosis		23	19	No	Yes	Yes
27503	Hemochromatosis NEC			19	No	No	Yes
27509	Disord iron metablsm NEC			19	No	No	Yes
2751	Dis copper metabolism			19	No	No	Yes
2753	Dis phosphorus metabol			19	No	No	Yes
27700	Cystic fibros w/o ileus	107	110	103	Yes	Yes	Yes
27701	Cystic fibrosis w ileus	107	110	103	Yes	Yes	Yes
27702	Cystic fibros w pul man	107	110	103	Yes	Yes	Yes
27703	Cystic fibrosis w GI man	107	110	103	Yes	Yes	Yes
27709	Cystic fibrosis NEC	107	110	103	Yes	Yes	Yes
2771	Dis porphyrin metabolism		23	19	No	Yes	Yes

2772	Purine/pyrimid dis NEC		23	19	No	Yes	Yes
27730	Amyloidosis NOS		23		No	Yes	No
27731	Fam Mediterranean fever		23		No	Yes	No
27739	Amyloidosis NEC		23		No	Yes	No
2775	Mucopolysaccharidosis		23	18	No	Yes	Yes
2776	Defic circul enzyme NEC		23	18	No	Yes	Yes
27781	Primary carnitine defncy		23	19	No	Yes	Yes
27782	Cmitne def d/t nb met		23	19	No	Yes	Yes
27783	Iatrogenic carnitine def		23	19	No	Yes	Yes
27784	Sec carnitine defncy NEC		23	19	No	Yes	Yes
27785	Disorders acid oxidation		23	19	No	Yes	Yes
27786	Peroxisomal disorders		23	19	No	Yes	Yes
27787	Dis mitochondrial metab		23	19	No	Yes	Yes
27789	Metabolism disorder NEC		23	19	No	Yes	Yes
27801	Morbid obesity		22	21	No	Yes	Yes
27803	Obesity hypovent synd		22	21	No	Yes	Yes
27900	Hypogammaglobulinem NOS	45	47	49	Yes	Yes	Yes
27901	Selective iga immunodef	45	47	49	Yes	Yes	Yes
27902	Selective IgM immunodef	45	47	49	Yes	Yes	Yes
27903	Selective ig defic NEC	45	47	49	Yes	Yes	Yes
27904	Cong hypogammaglobulinem	45	47	49	Yes	Yes	Yes
27905	Immunodef w hyper-igm	45	47	49	Yes	Yes	Yes
27906	Common variabl immunodef	45	47	49	Yes	Yes	Yes
27909	Humoral immunity def NEC	45	47	49	Yes	Yes	Yes
27910	Immunodef t-cell def NOS	45	47	49	Yes	Yes	Yes
27911	Digeorge's syndrome	45	47	49	Yes	Yes	Yes
27912	Wiskott-aldrich syndrome	45	47	49	Yes	Yes	Yes
27913	Nezelof's syndrome	45	47	49	Yes	Yes	Yes
27919	Defic cell immunity NOS	45	47	49	Yes	Yes	Yes
2792	Combined immunity defic	45	47	49	Yes	Yes	Yes
2793	Immunity deficiency NOS	45	47	49	Yes	Yes	Yes
27941	Autoimmun lymphprof synd	45	47	49	Yes	Yes	Yes
27949	Autoimmune disease NEC	45	47	49	Yes	Yes	Yes
27950	Graft-versus-host NOS	45	47	49	Yes	Yes	Yes
27951	Ac graft-versus-host dis	45	47	49	Yes	Yes	Yes
27952	Chronc graft-vs-host dis	45	47	49	Yes	Yes	Yes
27953	Ac on chrn grft-vs-host	45	47	49	Yes	Yes	Yes
2798	Immune mechanism dis NEC	45	47	49	Yes	Yes	Yes
2799	Immune mechanism dis NOS	45	47	49	Yes	Yes	Yes
2820	Hereditary spherocytosis		48		No	Yes	No
2821	Heredit elliptocytosis		48		No	Yes	No
2822	Glutathione dis anemia		48		No	Yes	No
2823	Enzyme defic anemia NEC		48		No	Yes	No
28241	Thalasema Hb-S w/o crisis	44	46	50	Yes	Yes	Yes
28242	Thalassemia Hb-S w crisis	44	46	50	Yes	Yes	Yes
28243	Alpha thalassemia		48		No	Yes	No
28244	Beta thalassemia		48		No	Yes	No
28245	Delta-beta thalassemia		48		No	Yes	No
28247	Hgb E-beta thalassemia		48		No	Yes	No
28249	Thalassemia NEC		48		No	Yes	No
2825	Sickle-cell trait		48		No	Yes	No
28260	Sickle cell disease NOS	44	46	50	Yes	Yes	Yes
28261	Hb-SS disease w/o crisis	44	46	47	Yes	Yes	Yes
28262	Hb-SS disease w crisis	44	46	47	Yes	Yes	Yes
28263	Hb-SS/hb-C dis w/o crsis	44	46	50	Yes	Yes	Yes
28264	Hb-S/Hb-C dis w crisis	44	46	50	Yes	Yes	Yes
28268	Hb-S dis w/o crisis NEC	44	46	50	Yes	Yes	Yes
28269	Hb-SS dis NEC w crisis	44	46	50	Yes	Yes	Yes
2827	Hemoglobinopathies NEC		48		No	Yes	No
2828	Hered hemolytic anem NEC		48		No	Yes	No
2829	Hered hemolytic anem NOS		48		No	Yes	No
2830	Autoimmun hemolytic anem	44	46	50	Yes	Yes	Yes
28310	Nonauto hem anemia NOS	44	46	50	Yes	Yes	Yes
28311	Hemolytic uremic synd	44	46	50	Yes	Yes	Yes

28319	Oth nonauto hem anemia	44	46	50	Yes	Yes	Yes
2832	Hemolytic hemoglobinuria	44	46	50	Yes	Yes	Yes
2839	Acq hemolytic anemia NOS	44	46	50	Yes	Yes	Yes
28401	Constitution RBC aplasia	44	46	50	Yes	Yes	Yes
28409	Const aplastic anemia NEC	44	46	50	Yes	Yes	Yes
2841	Pancytopenia	44	46	50	Yes	Yes	Yes
28411	Antin chemo indcd pancyt	45	47		Yes	Yes	No
28412	Oth drg indcd pancytopna	45	47		Yes	Yes	No
28419	Other pancytopenia	45	47		Yes	Yes	No
2842	Myelophthisis	44	46	50	Yes	Yes	Yes
28481	Red cell aplasia	44	46	50	Yes	Yes	Yes
28489	Aplastic anemias NEC	44	46	50	Yes	Yes	Yes
2849	Aplastic anemia NOS	44	46	50	Yes	Yes	Yes
2850	Sideroblastic anemia		48	50	No	Yes	Yes
2860	Cong factor viii diord	44	46	50	Yes	Yes	Yes
2861	Cong factor IX disorder	44	46	50	Yes	Yes	Yes
2862	Cong factor xi disorder		48		No	Yes	No
2863	Cong def clot factor NEC		48		No	Yes	No
2864	Von willebrand's disease		48		No	Yes	No
2865	Intr circul anticoag dis		48		No	Yes	No
28652	Acquired hemophilia		48		No	Yes	No
28653	Antiphospholipid w hemor		48		No	Yes	No
28659	Ot hem d/t circ anticoag		48		No	Yes	No
2866	Defibrination syndrome		48		No	Yes	No
2867	Acq coagul factor defic		48		No	Yes	No
2869	Coagulat defect NEC/NOS		48		No	Yes	No
2870	Allergic purpura		48		No	Yes	No
2871	Thrombocytopathy		48		No	Yes	No
2872	Purpura NOS		48		No	Yes	No
28730	Prim thrombocytopen NOS		48		No	Yes	No
28731	Immune thrombocyt purpra		48		No	Yes	No
28732	Evans' syndrome		48		No	Yes	No
28733	Cong/herid thromb purpra		48		No	Yes	No
28739	Prim thrombocytopen NEC		48		No	Yes	No
2875	Thrombocytopenia NOS		48		No	Yes	No
2878	Hemorrhagic cond NEC		48		No	Yes	No
2879	Hemorrhagic cond NOS		48		No	Yes	No
28800	Neutropenia NOS	45	47		Yes	Yes	No
28801	Congenital neutropenia	45	47		Yes	Yes	No
28802	Cyclic neutropenia	45	47		Yes	Yes	No
28803	Drug induced neutropenia	45	47		Yes	Yes	No
28804	Neutropenia d/t infectn	45	47		Yes	Yes	No
28809	Neutropenia NEC	45	47		Yes	Yes	No
2881	Function dis neutrophils	45	47		Yes	Yes	No
2882	Genetic anomaly leukocyt	45	47		Yes	Yes	No
2884	Hemophagocytic syndromes	45	47		Yes	Yes	No
28952	Splenic sequestration	44	46	50	Yes	Yes	Yes
28981	Prim hypercoagulable st		48	50	No	Yes	Yes
28982	Sec hypercoagulable st		48	50	No	Yes	Yes
28983	Myelofibrosis		46	9	No	Yes	Yes
28984	Heparin-indu thrombocyto		48		No	Yes	No
2900	Senile dementia uncomp		52	55	No	Yes	Yes
29010	Presenile dementia		52	55	No	Yes	Yes
29011	Presenile delirium		51	55	No	Yes	Yes
29012	Presenile delusion		51	55	No	Yes	Yes
29013	Presenile depression		51	55	No	Yes	Yes
29020	Senile delusion		51	55	No	Yes	Yes
29021	Senile depressive		51	55	No	Yes	Yes
2903	Senile delirium		51	55	No	Yes	Yes
29040	Vascular dementia,uncomp		52	55	No	Yes	Yes
29041	Vasc dementia w delirium		51	55	No	Yes	Yes
29042	Vasc dementia w delusion		51	55	No	Yes	Yes
29043	Vasc dementia w depressn		51	55	No	Yes	Yes
2908	Senile psychosis NEC		52	55	No	Yes	Yes

2909	Senile psychot cond NOS		52	55	No	Yes	Yes
2910	Delirium tremens	51	54		Yes	Yes	No
2911	Alcohol amnestic disordr	51	54		Yes	Yes	No
2912	Alcohol persist dementia	51	54		Yes	Yes	No
2913	Alcoh psy dis w hallucin	51	54		Yes	Yes	No
2914	Pathologic alcohol intox	51	54		Yes	Yes	No
2915	Alcoh psych dis w delus	51	54		Yes	Yes	No
29181	Alcohol withdrawal	51	54		Yes	Yes	No
29182	Alcoh induce sleep disor	51	54		Yes	Yes	No
29189	Alcohol mental disor NEC	51	54		Yes	Yes	No
2919	Alcohol mental disor NOS	51	54		Yes	Yes	No
2920	Drug withdrawal	51	54		Yes	Yes	No
29211	Drug psych disor w delus	51	54		Yes	Yes	No
29212	Drug psy dis w hallucin	51	54		Yes	Yes	No
2922	Pathologic drug intox	51	54		Yes	Yes	No
29281	Drug-induced delirium	51	54		Yes	Yes	No
29282	Drug persisting dementia	51	54		Yes	Yes	No
29283	Drug persist amnestic dis	51	54		Yes	Yes	No
29284	Drug-induced mood disord	51	54		Yes	Yes	No
29285	Drug induced sleep disor	51	54		Yes	Yes	No
29289	Drug mental disorder NEC	51	54		Yes	Yes	No
2929	Drug mental disorder NOS	51	54		Yes	Yes	No
2940	Amnestic disord oth dis		52	55	No	Yes	Yes
29410	Dementia w/o behav dist		52	55	No	Yes	Yes
29411	Dementia w behavior dist		51	55	No	Yes	Yes
29420	Demens NOS w/o behv distrb		52	55	No	Yes	Yes
29421	Demens NOS w behav distrb		51	55	No	Yes	Yes
2948	Mental disor NEC oth dis		52	55	No	Yes	Yes
2949	Mental disor NOS oth dis		52	55	No	Yes	Yes
29500	Simpl schizophren-unspec	54	57	58	Yes	Yes	Yes
29501	Simpl schizophren-subchr	54	57	58	Yes	Yes	Yes
29502	Simple schizophren-chr	54	57	58	Yes	Yes	Yes
29503	Simp schiz-subchr/exacer	54	57	58	Yes	Yes	Yes
29504	Simpl schizo-chr/exacerb	54	57	58	Yes	Yes	Yes
29505	Simpl schizophren-remiss	54	57	58	Yes	Yes	Yes
29510	Hebephrenia-unspec	54	57	58	Yes	Yes	Yes
29511	Hebephrenia-subchronic	54	57	58	Yes	Yes	Yes
29512	Hebephrenia-chronic	54	57	58	Yes	Yes	Yes
29513	Hebephren-subchr/exacerb	54	57	58	Yes	Yes	Yes
29514	Hebephrenia-chr/exacerb	54	57	58	Yes	Yes	Yes
29515	Hebephrenia-remission	54	57	58	Yes	Yes	Yes
29520	Catatonia-unspec	54	57	58	Yes	Yes	Yes
29521	Catatonia-subchronic	54	57	58	Yes	Yes	Yes
29522	Catatonia-chronic	54	57	58	Yes	Yes	Yes
29523	Catatonia-subchr/exacerb	54	57	58	Yes	Yes	Yes
29524	Catatonia-chr/exacerb	54	57	58	Yes	Yes	Yes
29525	Catatonia-remission	54	57	58	Yes	Yes	Yes
29530	Paranoid schizo-unspec	54	57	58	Yes	Yes	Yes
29531	Paranoid schizo-subchr	54	57	58	Yes	Yes	Yes
29532	Paranoid schizo-chronic	54	57	58	Yes	Yes	Yes
29533	Paran schizo-subchr/exac	54	57	58	Yes	Yes	Yes
29534	Paran schizo-chr/exacerb	54	57	58	Yes	Yes	Yes
29535	Paranoid schizo-remiss	54	57	58	Yes	Yes	Yes
29540	Schizophreniform dis NOS	54	57	58	Yes	Yes	Yes
29541	Schizophrenic dis-subchr	54	57	58	Yes	Yes	Yes
29542	Schizophren dis-chronic	54	57	58	Yes	Yes	Yes
29543	Schizo dis-subchr/exacer	54	57	58	Yes	Yes	Yes
29544	Schizophr dis-chr/exacer	54	57	58	Yes	Yes	Yes
29545	Schizophrenic dis-remiss	54	57	58	Yes	Yes	Yes
29550	Latent schizophren-unsp	54	57	58	Yes	Yes	Yes
29551	Lat schizophren-subchr	54	57	58	Yes	Yes	Yes
29552	Latent schizophren-chr	54	57	58	Yes	Yes	Yes
29553	Lat schizo-subchr/exacer	54	57	58	Yes	Yes	Yes
29554	Latent schizo-chr/exacer	54	57	58	Yes	Yes	Yes

29555	Lat schizophren-remiss	54	57	58	Yes	Yes	Yes
29560	Schizophr dis resid NOS	54	57	58	Yes	Yes	Yes
29561	Schizophr dis resid-subch	54	57	58	Yes	Yes	Yes
29562	Schizophr dis resid-chr	54	57	58	Yes	Yes	Yes
29563	Schizo resid subchr/exac	54	57	58	Yes	Yes	Yes
29564	Schizophr resid-chro/exac	54	57	58	Yes	Yes	Yes
29565	Schizophr dis resid-remis	54	57	58	Yes	Yes	Yes
29570	Schizoaffective dis NOS	54	57	58	Yes	Yes	Yes
29571	Schizoaffectv dis-subchr	54	57	58	Yes	Yes	Yes
29572	Schizoaffective dis-chr	54	57	58	Yes	Yes	Yes
29573	Schizoaffectv dis-subchr/exac	54	57	58	Yes	Yes	Yes
29574	Schizoaffectv dis-chr/exac	54	57	58	Yes	Yes	Yes
29575	Schizoaffective dis-remis	54	57	58	Yes	Yes	Yes
29580	Schizophrenia NEC-unspec	54	57	58	Yes	Yes	Yes
29581	Schizophrenia NEC-subchr	54	57	58	Yes	Yes	Yes
29582	Schizophrenia NEC-chr	54	57	58	Yes	Yes	Yes
29583	Schizo NEC-subchr/exacer	54	57	58	Yes	Yes	Yes
29584	Schizo NEC-chr/exacerb	54	57	58	Yes	Yes	Yes
29585	Schizophrenia NEC-remiss	54	57	58	Yes	Yes	Yes
29590	Schizophrenia NOS-unspec	54	57	58	Yes	Yes	Yes
29591	Schizophrenia NOS-subchr	54	57	58	Yes	Yes	Yes
29592	Schizophrenia NOS-chr	54	57	58	Yes	Yes	Yes
29593	Schizo NOS-subchr/exacer	54	57	58	Yes	Yes	Yes
29594	Schizo NOS-chr/exacerb	54	57	58	Yes	Yes	Yes
29595	Schizophrenia NOS-remiss	54	57	58	Yes	Yes	Yes
29600	Bipol I single manic NOS	55	58	59	Yes	Yes	Yes
29601	Bipol I single manic-mild	55	58	59	Yes	Yes	Yes
29602	Bipol I single manic-mod	55	58	59	Yes	Yes	Yes
29603	Bipol I sing-sev w/o psy	55	58	59	Yes	Yes	Yes
29604	Bipo I sin man-sev w psy	55	58	59	Yes	Yes	Yes
29605	Bipol I sing man rem NOS	55	58	59	Yes	Yes	Yes
29606	Bipol I single manic rem	55	58	59	Yes	Yes	Yes
29610	Recur manic dis-unspec	55	58	59	Yes	Yes	Yes
29611	Recur manic dis-mild	55	58	59	Yes	Yes	Yes
29612	Recur manic dis-mod	55	58	59	Yes	Yes	Yes
29613	Recur manic dis-severe	55	58	59	Yes	Yes	Yes
29614	Recur manic-sev w psycho	55	58	59	Yes	Yes	Yes
29615	Recur manic-part remiss	55	58	59	Yes	Yes	Yes
29616	Recur manic-full remiss	55	58	59	Yes	Yes	Yes
29620	Depress psychosis-unspec	55	58	60	Yes	Yes	Yes
29621	Depress psychosis-mild	55	58	60	Yes	Yes	Yes
29622	Depressive psychosis-mod	55	58	60	Yes	Yes	Yes
29623	Depress psychosis-severe	55	58	60	Yes	Yes	Yes
29624	Depr psychos-sev w psych	55	58	60	Yes	Yes	Yes
29625	Depr psychos-part remiss	55	58	60	Yes	Yes	Yes
29626	Depr psychos-full remiss	55	58	60	Yes	Yes	Yes
29630	Recurr depr psychos-unsp	55	58	60	Yes	Yes	Yes
29631	Recurr depr psychos-mild	55	58	60	Yes	Yes	Yes
29632	Recurr depr psychos-mod	55	58	60	Yes	Yes	Yes
29633	Recurr depr psych-severe	55	58	60	Yes	Yes	Yes
29634	Rec depr psych-psychotic	55	58	60	Yes	Yes	Yes
29635	Recur depr psyc-part rem	55	58	60	Yes	Yes	Yes
29636	Recur depr psyc-full rem	55	58	60	Yes	Yes	Yes
29640	Bipol I currnt manic NOS	55	58	59	Yes	Yes	Yes
29641	Bipol I currnt manic-mild	55	58	59	Yes	Yes	Yes
29642	Bipol I currnt manic-mod	55	58	59	Yes	Yes	Yes
29643	Bipol I manic-sev w/o psy	55	58	59	Yes	Yes	Yes
29644	Bipol I manic-sev w psy	55	58	59	Yes	Yes	Yes
29645	Bipol I cur man part rem	55	58	59	Yes	Yes	Yes
29646	Bipol I cur man full rem	55	58	59	Yes	Yes	Yes
29650	Bipol I cur depress NOS	55	58	59	Yes	Yes	Yes
29651	Bipol I cur depress-mild	55	58	59	Yes	Yes	Yes
29652	Bipol I cur depress-mod	55	58	59	Yes	Yes	Yes
29653	Bipol I curr dep w/o psy	55	58	59	Yes	Yes	Yes

29654	Bipol I currnt dep w psy	55	58	59	Yes	Yes	Yes
29655	Bipol I cur dep rem NOS	55	58	59	Yes	Yes	Yes
29656	Bipol I currnt dep remis	55	58	59	Yes	Yes	Yes
29660	Bipol I currnt mixed NOS	55	58	59	Yes	Yes	Yes
29661	Bipol I currnt mix-mild	55	58	59	Yes	Yes	Yes
29662	Bipol I currnt mixed-mod	55	58	59	Yes	Yes	Yes
29663	Bipol I cur mix w/o psy	55	58	59	Yes	Yes	Yes
29664	Bipol I cur mixed w psy	55	58	59	Yes	Yes	Yes
29665	Bipol I cur mix-part rem	55	58	59	Yes	Yes	Yes
29666	Bipol I cur mixed remiss	55	58	59	Yes	Yes	Yes
2967	Bipolar I current NOS	55	58	59	Yes	Yes	Yes
29680	Bipolar disorder NOS	55	58	59	Yes	Yes	Yes
29681	Atypical manic disorder	55	58	59	Yes	Yes	Yes
29682	Atypical depressive dis	55	58	59	Yes	Yes	Yes
29689	Bipolar disorder NEC	55	58	59	Yes	Yes	Yes
29690	Episodic mood disord NOS	55	58	59	Yes	Yes	Yes
29699	Episodic mood disord NEC	55	58	59	Yes	Yes	Yes
2970	Paranoid state, simple	55	58		Yes	Yes	No
2971	Delusional disorder	55	58		Yes	Yes	No
2972	Paraphrenia	55	58		Yes	Yes	No
2973	Shared psychotic disord	55	58		Yes	Yes	No
2978	Paranoid states NEC	55	58		Yes	Yes	No
2979	Paranoid state NOS	55	58		Yes	Yes	No
29900	Autistic disord-current			65	No	No	Yes
29901	Autistic disord-residual			65	No	No	Yes
29910	Childhd disintegr-active			65	No	No	Yes
29911	Childhd disintegr-resid			65	No	No	Yes
29980	Pervasv dev dis-cur NEC			65	No	No	Yes
29981	Pervasv dev dis-res NEC			65	No	No	Yes
29990	Pervasv dev dis-cur NOS			65	No	No	Yes
29991	Pervasv dev dis-res NOS			65	No	No	Yes
30001	Panic dis w/o agorophobia			63	No	No	Yes
30002	Generalized anxiety dis			63	No	No	Yes
30010	Hysteria NOS			63	No	No	Yes
30011	Conversion disorder			63	No	No	Yes
30012	Dissociative amnesia			61	No	No	Yes
30013	Dissociative fugue			61	No	No	Yes
30014	Dissociative identity dis			61	No	No	Yes
30015	Dissociative react NOS			61	No	No	Yes
30016	Factitious dis w symptom			63	No	No	Yes
30019	Factitious ill NEC/NOS			63	No	No	Yes
30020	Phobia NOS			63	No	No	Yes
30021	Agoraphobia w panic dis			63	No	No	Yes
30022	Agoraphobia w/o panic			63	No	No	Yes
30023	Social phobia			63	No	No	Yes
30029	Isolated/spec phobia NEC			63	No	No	Yes
3003	Obsessive-compulsive dis			61	No	No	Yes
3004	Dysthymic disorder			62	No	No	Yes
3006	Depersonalization disord			61	No	No	Yes
3007	Hypochondriasis			63	No	No	Yes
30081	Somatization disorder			63	No	No	Yes
30082	Undiff somatoform disrdr			63	No	No	Yes
30089	Somatoform disorders NEC			63	No	No	Yes
30110	Affectiv personality NOS			62	No	No	Yes
30111	Chronic hypomanic person			62	No	No	Yes
30112	Chr depressive person			62	No	No	Yes
30113	Cyclothymic disorder			62	No	No	Yes
3013	Explosive personality			61	No	No	Yes
3014	Obsessive-compulsive dis			61	No	No	Yes
30183	Borderline personality			61	No	No	Yes
30300	Ac alcohol intox-unspec	52	55		Yes	Yes	No
30301	Ac alcohol intox-contin	52	55		Yes	Yes	No
30302	Ac alcohol intox-episod	52	55		Yes	Yes	No
30303	Ac alcohol intox-remiss	52	55		Yes	Yes	No

30390	Alcoh dep NEC/NOS-unspec	52	55		Yes	Yes	No
30391	Alcoh dep NEC/NOS-contin	52	55		Yes	Yes	No
30392	Alcoh dep NEC/NOS-episod	52	55		Yes	Yes	No
30393	Alcoh dep NEC/NOS-remiss	52	55		Yes	Yes	No
30400	Opioid dependence-unspec	52	55		Yes	Yes	No
30401	Opioid dependence-contin	52	55		Yes	Yes	No
30402	Opioid dependence-episod	52	55		Yes	Yes	No
30403	Opioid dependence-remiss	52	55		Yes	Yes	No
30410	Sed,hyp,anxiolyt dep-NOS	52	55		Yes	Yes	No
30411	Sed,hyp,anxiolyt dep-con	52	55		Yes	Yes	No
30412	Sed,hyp,anxiolyt dep-epi	52	55		Yes	Yes	No
30413	Sed,hyp,anxiolyt dep-rem	52	55		Yes	Yes	No
30420	Cocaine depend-unspec	52	55		Yes	Yes	No
30421	Cocaine depend-contin	52	55		Yes	Yes	No
30422	Cocaine depend-episodic	52	55		Yes	Yes	No
30423	Cocaine depend-remiss	52	55		Yes	Yes	No
30430	Cannabis depend-unspec	52	55		Yes	Yes	No
30431	Cannabis depend-contin	52	55		Yes	Yes	No
30432	Cannabis depend-episodic	52	55		Yes	Yes	No
30433	Cannabis depend-remiss	52	55		Yes	Yes	No
30440	Amphetamin depend-unspec	52	55		Yes	Yes	No
30441	Amphetamin depend-contin	52	55		Yes	Yes	No
30442	Amphetamin depend-episod	52	55		Yes	Yes	No
30443	Amphetamin depend-remiss	52	55		Yes	Yes	No
30450	Hallucinogen dep-unspec	52	55		Yes	Yes	No
30451	Hallucinogen dep-contin	52	55		Yes	Yes	No
30452	Hallucinogen dep-episod	52	55		Yes	Yes	No
30453	Hallucinogen dep-remiss	52	55		Yes	Yes	No
30460	Drug depend NEC-unspec	52	55		Yes	Yes	No
30461	Drug depend NEC-contin	52	55		Yes	Yes	No
30462	Drug depend NEC-episodic	52	55		Yes	Yes	No
30463	Drug depend NEC-in rem	52	55		Yes	Yes	No
30470	Opioid/other dep-unspec	52	55		Yes	Yes	No
30471	Opioid/other dep-contin	52	55		Yes	Yes	No
30472	Opioid/other dep-episod	52	55		Yes	Yes	No
30473	Opioid/other dep-remiss	52	55		Yes	Yes	No
30480	Comb drug dep NEC-unspec	52	55		Yes	Yes	No
30481	Comb drug dep NEC-contin	52	55		Yes	Yes	No
30482	Comb drug dep NEC-episod	52	55		Yes	Yes	No
30483	Comb drug dep NEC-remiss	52	55		Yes	Yes	No
30490	Drug depend NOS-unspec	52	55		Yes	Yes	No
30491	Drug depend NOS-contin	52	55		Yes	Yes	No
30492	Drug depend NOS-episodic	52	55		Yes	Yes	No
30493	Drug depend NOS-remiss	52	55		Yes	Yes	No
3071	Anorexia nervosa			61	No	No	Yes
30723	Tourette's disorder			61	No	No	Yes
3073	Stereotypic movement dis			61	No	No	Yes
30751	Bulimia nervosa			61	No	No	Yes
3091	Prolong depressive react			62	No	No	Yes
30981	Posttraumatic stress dis			61	No	No	Yes
311	Depressive disorder NEC			62	No	No	Yes
31200	Unsocial aggress-unspec			61	No	No	Yes
31201	Unsocial aggression-mild			61	No	No	Yes
31202	Unsocial aggression-mod			61	No	No	Yes
31203	Unsocial aggress-severe			61	No	No	Yes
31210	Unsocial unaggress-unsp			61	No	No	Yes
31211	Unsocial unaggress-mild			61	No	No	Yes
31212	Unsocial unaggress-mod			61	No	No	Yes
31213	Unsocial unaggr-severe			61	No	No	Yes
31220	Social conduct dis-unsp			61	No	No	Yes
31221	Social conduct dis-mild			61	No	No	Yes
31222	Social conduct dis-mod			61	No	No	Yes
31223	Social conduct dis-sev			61	No	No	Yes
31230	Impulse control dis NOS			61	No	No	Yes

31231	Pathological gambling			61	No	No	Yes
31232	Kleptomania			61	No	No	Yes
31233	Pyromania			61	No	No	Yes
31234	Intermitt explosive dis			61	No	No	Yes
31235	Isolated explosive dis			61	No	No	Yes
31239	Impulse control dis NEC			61	No	No	Yes
3124	Mix dis conduct/emotion			61	No	No	Yes
31281	Cndct dsrdr chldhd onst			61	No	No	Yes
31282	Cndct dsrdr adlscnt onst			61	No	No	Yes
31289	Other conduct disorder			61	No	No	Yes
3129	Conduct disturbance NOS			61	No	No	Yes
31381	Opposition defiant disor			61	No	No	Yes
31400	Attn defic nonhyperact			61	No	No	Yes
31401	Attn deficit w hyperact			61	No	No	Yes
3141	Hyperkinet w devel delay			61	No	No	Yes
3142	Hyperkinetic conduct dis			61	No	No	Yes
3148	Other hyperkinetic synd			61	No	No	Yes
3149	Hyperkinetic synd NOS			61	No	No	Yes
317	Mild intellect disability			68	No	No	Yes
3180	Mod intellect disability			67	No	No	Yes
3181	Sev intellect disability			66	No	No	Yes
3182	Profnd intellct disability			66	No	No	Yes
319	Intellect disability NOS			68	No	No	Yes
3210	Cryptococcal meningitis	5	6	5	Yes	Yes	Yes
32302	Myelitis-oth viral dis		72	72	No	Yes	Yes
32342	Oth myelitis ot inf else		72	72	No	Yes	Yes
32352	Myelitis follwg immune		72	72	No	Yes	Yes
32363	Postinfectious myelitis		72	72	No	Yes	Yes
32372	Toxic myelitis		72	72	No	Yes	Yes
32382	Myelitis cause NEC		72	72	No	Yes	Yes
3300	Leukodystrophy		52	55	No	Yes	Yes
3301	Cerebral lipidoses		52	55	No	Yes	Yes
3302	Cereb degen in lipidosis		52	55	No	Yes	Yes
3303	Cereb deg chld in oth dis		52	55	No	Yes	Yes
3308	Cereb degen in child NEC		52	55	No	Yes	Yes
3309	Cereb degen in child NOS		52	55	No	Yes	Yes
3310	Alzheimer's disease		52	54	No	Yes	Yes
33111	Pick's disease		52	55	No	Yes	Yes
33119	Frontotemp dementia NEC		52	55	No	Yes	Yes
3312	Senile degenerat brain		52	55	No	Yes	Yes
3313	Communicat hydrocephalus		51		No	Yes	No
3314	Obstructiv hydrocephalus		51		No	Yes	No
3315	Norml pressure hydroceph		51		No	Yes	No
3316	Corticobasal degeneration		52	55	No	Yes	Yes
3317	Cereb degen in oth dis		52	55	No	Yes	Yes
33181	Reye's syndrome		52	55	No	Yes	Yes
33182	Dementia w Lewy bodies		52	55	No	Yes	Yes
33189	Cereb degeneration NEC		52	55	No	Yes	Yes
3319	Cereb degeneration NOS		52	55	No	Yes	Yes
3320	Paralysis agitans	73	78	76	Yes	Yes	Yes
3321	Secondary parkinsonism	73	78	76	Yes	Yes	Yes
3330	Degen basal ganglia NEC	73	78		Yes	Yes	No
3334	Huntington's chorea	73	78		Yes	Yes	No
33371	Athetoid cerebral palsy	101	74		Yes	Yes	No
3340	Friedreich's ataxia	69	72	72	Yes	Yes	Yes
3341	Hered spastic paraplegia	69	72	72	Yes	Yes	Yes
3342	Primary cerebellar degen	69	72	72	Yes	Yes	Yes
3343	Cerebellar ataxia NEC	69	72	72	Yes	Yes	Yes
3344	Cerebel atax in oth dis	69	72	72	Yes	Yes	Yes
3348	Spinocerebellar dis NEC	69	72	72	Yes	Yes	Yes
3349	Spinocerebellar dis NOS	69	72	72	Yes	Yes	Yes
3350	Werdnig-hoffmann disease	67	72	72	Yes	Yes	Yes
33510	Spinal muscl atrophy NOS	67	72	72	Yes	Yes	Yes
33511	Kugelberg-welander dis	67	72	72	Yes	Yes	Yes

33519	Spinal muscl atrophy NEC	67	72	72	Yes	Yes	Yes
33520	Amyotrophic sclerosis	67	73	71	Yes	Yes	Yes
33521	Prog muscular atrophy	67	73	71	Yes	Yes	Yes
33522	Progressive bulbar palsy	67	73	71	Yes	Yes	Yes
33523	Pseudobulbar palsy	67	73	71	Yes	Yes	Yes
33524	Prim lateral sclerosis	67	73	71	Yes	Yes	Yes
33529	Motor neuron disease NEC	67	73	71	Yes	Yes	Yes
3358	Ant horn cell dis NEC	67	72	72	Yes	Yes	Yes
3359	Ant horn cell dis NOS	67	72	72	Yes	Yes	Yes
3360	Syringomyelia	69	72	72	Yes	Yes	Yes
3361	Vascular myelopathies	69	72	72	Yes	Yes	Yes
3362	Comb deg cord in oth dis	69	72	72	Yes	Yes	Yes
3363	Myelopathy in oth dis	69	72	72	Yes	Yes	Yes
3368	Myelopathy NEC	69	72	72	Yes	Yes	Yes
3369	Spinal cord disease NOS	69	72	72	Yes	Yes	Yes
33700	Idio perph auto neur NOS	71	75	74	Yes	Yes	Yes
33701	Carotid sinus syndrome		75	74	No	Yes	Yes
33709	Idio perph auto neur NEC	71	75	74	Yes	Yes	Yes
3371	Aut neuropthy in oth dis	71	75	74	Yes	Yes	Yes
33720	Unsp rflx symph dystroph	71	75	74	Yes	Yes	Yes
33721	Rflx sym dystroph up limb	71	75	74	Yes	Yes	Yes
33722	Rflx sym dystroph lwr lmb	71	75	74	Yes	Yes	Yes
33729	Rflx sym dystroph oth st	71	75	74	Yes	Yes	Yes
3373	Autonomic dysreflexia	71	75	74	Yes	Yes	Yes
3379	Autonomic nerve dis NEC	71	75	74	Yes	Yes	Yes
340	Multiple sclerosis	72	77	75	Yes	Yes	Yes
3410	Neuromyelitis optica	72	77	75	Yes	Yes	Yes
3411	Schilder's disease	72	77	75	Yes	Yes	Yes
34120	Acute myelitis NOS		72	72	No	Yes	Yes
34121	Acute myelitis oth cond		72	72	No	Yes	Yes
34122	Idiopathic trans myelitis		72	72	No	Yes	Yes
3418	Cns demyelination NEC	72	77		Yes	Yes	No
3419	Cns demyelination NOS	72	77		Yes	Yes	No
34200	Flccd hmiplga unspf side	100	103		Yes	Yes	No
34201	Flccd hmiplga domnt side	100	103		Yes	Yes	No
34202	Flccd hmiplg nondmnt sde	100	103		Yes	Yes	No
34210	Spstc hmiplga unspf side	100	103	98	Yes	Yes	Yes
34211	Spstc hmiplga domnt side	100	103	98	Yes	Yes	Yes
34212	Spstc hmiplg nondmnt sde	100	103	98	Yes	Yes	Yes
34280	Ot sp hmiplga unspf side	100	103		Yes	Yes	No
34281	Ot sp hmiplga domnt side	100	103		Yes	Yes	No
34282	Ot sp hmiplg nondmnt sde	100	103		Yes	Yes	No
34290	Unsp hmiplga unspf side	100	103		Yes	Yes	No
34291	Unsp hmiplga domnt side	100	103		Yes	Yes	No
34292	Unsp hmiplga nondmnt sde	100	103		Yes	Yes	No
3430	Congenital diplegia	68	74		Yes	Yes	No
3431	Congenital hemiplegia	100	74		Yes	Yes	No
3432	Congenital quadriplegia	67	74		Yes	Yes	No
3433	Congenital monoplegia	101	74		Yes	Yes	No
3434	Infantile hemiplegia	100	74		Yes	Yes	No
3438	Cerebral palsy NEC	101	74		Yes	Yes	No
3439	Cerebral palsy NOS	101	74		Yes	Yes	No
34400	Quadriplegia, unspcifd	67	70		Yes	Yes	No
34401	Quadrplg c1-c4, complete	67	70		Yes	Yes	No
34402	Quadrplg c1-c4, incomplt	67	70		Yes	Yes	No
34403	Quadrplg c5-c7, complete	67	70		Yes	Yes	No
34404	Quadrplg c5-c7, incomplt	67	70		Yes	Yes	No
34409	Other quadriplegia	67	70		Yes	Yes	No
3441	Paraplegia NOS	68	71		Yes	Yes	No
3442	Diplegia of upper limbs	101	104		Yes	Yes	No
34430	Monplga lwr lmb unsp sde	101	104		Yes	Yes	No
34431	Monplga lwr lmb dmnt sde	101	104		Yes	Yes	No
34432	Mnplg lwr lmb nondmnt sd	101	104		Yes	Yes	No
34440	Monplga upr lmb unsp sde	101	104		Yes	Yes	No

34441	Monplga upr lmb dmnt sde	101	104		Yes	Yes	No
34442	Mnplg upr lmb nondmnt sd	101	104		Yes	Yes	No
3445	Monoplegia NOS	101	104		Yes	Yes	No
34460	Cauda equina synd NOS	69	72	72	Yes	Yes	Yes
34461	Neurogenic bladder	69	72	72	Yes	Yes	Yes
34481	Locked-in state	67	104		Yes	Yes	No
34489	Oth spcf paralytic synd	101	104		Yes	Yes	No
3449	Paralysis NOS	101	104		Yes	Yes	No
34500	Gen noncv ep w/o intr ep	74	79	79	Yes	Yes	Yes
34501	Gen nonconv ep w intr ep	74	79	78	Yes	Yes	Yes
34510	Gen cnv epil w/o intr ep	74	79	79	Yes	Yes	Yes
34511	Gen cnv epil w intr epil	74	79	78	Yes	Yes	Yes
3452	Petit mal status	74	79	79	Yes	Yes	Yes
3453	Grand mal status	74	79	79	Yes	Yes	Yes
34540	Psymotr epil w/o int epi	74	79	79	Yes	Yes	Yes
34541	Psymotr epil w intr epil	74	79	78	Yes	Yes	Yes
34550	Part epil w/o intr epil	74	79	79	Yes	Yes	Yes
34551	Part epil w intr epil	74	79	78	Yes	Yes	Yes
34560	Inf spasm w/o intr epil	74	79	79	Yes	Yes	Yes
34561	Inf spasm w intract epil	74	79	78	Yes	Yes	Yes
34570	Epil par cont w/o int ep	74	79	79	Yes	Yes	Yes
34571	Epil par cont w intr epi	74	79	78	Yes	Yes	Yes
34580	Epilep NEC w/o intr epil	74	79	79	Yes	Yes	Yes
34581	Epilepsy NEC w intr epil	74	79	78	Yes	Yes	Yes
34590	Epilep NOS w/o intr epil	74	79	79	Yes	Yes	Yes
34591	Epilepsy NOS w intr epil	74	79	78	Yes	Yes	Yes
34600	Mgrn w aura wo ntrc mgrn			81	No	No	Yes
34601	Mgrn w aura w ntrc mgrn			81	No	No	Yes
34602	Mgrn w aur wo ntrc mgrn			81	No	No	Yes
34603	Mgrn w aura w ntrc mgrn			81	No	No	Yes
34610	Mgrn wo aura wo ntrc mgr			81	No	No	Yes
34611	Mgrn wo aura w ntrc mgrn			81	No	No	Yes
34612	Mgrn wo aura wo ntrc mgr			81	No	No	Yes
34613	Mgrn wo aura w ntrc mgrn			81	No	No	Yes
34620	Vrnt mgrn wo ntr mgr NEC			81	No	No	Yes
34621	Vrnt mgrn w ntrc mgr NEC			81	No	No	Yes
34622	Var mgr NEC wo ntrc mgr			81	No	No	Yes
34623	Var mgrn NEC w ntrc mgr			81	No	No	Yes
34630	Hmplg mgr wo ntrc wo st			81	No	No	Yes
34631	Hmplg mgrn w ntrc wo st			81	No	No	Yes
34632	Hemplg mgr wo ntrc w st			81	No	No	Yes
34633	Hmplg mgrn w ntrc w st			81	No	No	Yes
34640	Menst mgr wo ntrc wo st			81	No	No	Yes
34641	Menstl mgrn w ntrc wo st			81	No	No	Yes
34642	Menstl mgr wo ntrc w st			81	No	No	Yes
34643	Menstl mgrn w ntrc w st			81	No	No	Yes
34650	Prst aura wo inf/ntr/st			81	No	No	Yes
34651	Prs ara w ntr wo inf/st			81	No	No	Yes
34652	Prs ara wo inf/ntr w st			81	No	No	Yes
34653	Prs ara wo inf w ntr/st			81	No	No	Yes
34660	Prs ara w inf wo ntr/st			81	No	No	Yes
34661	Prs ara w/inf/ntr wo st			81	No	No	Yes
34662	Prs ara wo ntr w inf/st			81	No	No	Yes
34663	Prst ara w inf w ntr/st			81	No	No	Yes
34670	Ch mgr wo ar wo nt wo st			81	No	No	Yes
34671	Ch mgr wo ara w nt wo st			81	No	No	Yes
34672	Ch mgr wo ara wo nt w st			81	No	No	Yes
34673	Ch mgr wo ara w ntr w st			81	No	No	Yes
34680	Othr migrne wo ntrc mgrn			81	No	No	Yes
34681	Othr migrne w ntrc mgrne			81	No	No	Yes
34682	Oth mgr wo ntrc w st mgr			81	No	No	Yes
34683	Oth mgr w ntrc w st mgr			81	No	No	Yes
34690	Migrne unsp wo ntrc mgrn			81	No	No	Yes
34691	Mgrn unsp w ntrc mgr std			81	No	No	Yes

34692	Mgr NOS wo ntrc w st mgr			81	No	No	Yes
34693	Mgrm NOS w ntrc w st mgr			81	No	No	Yes
34700	Narcolepsy w/o cataplexy			156	No	No	Yes
34701	Narcolepsy w cataplexy			156	No	No	Yes
34710	Narclpsy w/o cat oth dis			156	No	No	Yes
34711	Narcolepsy w cat oth dis			156	No	No	Yes
3481	Anoxic brain damage	75	80		Yes	Yes	No
3484	Compression of brain	75	80		Yes	Yes	No
3485	Cerebral edema	75	80		Yes	Yes	No
3491	Complication cns device	164	176		Yes	Yes	No
3501	Trigeminal neuralgia			83	No	No	Yes
3502	Atypical face pain			83	No	No	Yes
3508	Trigeminal nerve dis NEC			83	No	No	Yes
3509	Trigeminal nerve dis NOS			83	No	No	Yes
3536	Phantom limb (syndrome)	177	189		Yes	Yes	No
3560	Hered periph neuropathy	71	75	74	Yes	Yes	Yes
3561	Peroneal muscle atrophy	71	75	74	Yes	Yes	Yes
3562	Hered sensory neuropathy	71	75	74	Yes	Yes	Yes
3563	Refsum's disease	71	75	74	Yes	Yes	Yes
3564	Idio prog polyneuropathy	71	75	74	Yes	Yes	Yes
3568	Idio periph neurphy NEC	71	75	74	Yes	Yes	Yes
3569	Idio periph neurphy NOS	71	75	74	Yes	Yes	Yes
3570	Ac infect polyneuritis	71	75	74	Yes	Yes	Yes
3571	Neurphy in col vasc dis	71	75	74	Yes	Yes	Yes
3572	Neuropathy in diabetes	71	75	74	Yes	Yes	Yes
3573	Neuropathy in malig dis	71	75	74	Yes	Yes	Yes
3574	Neuropathy in other dis	71	75	74	Yes	Yes	Yes
3575	Alcoholic polyneuropathy	71	75	74	Yes	Yes	Yes
3576	Neuropathy due to drugs	71	75	74	Yes	Yes	Yes
3577	Neurphy toxic agent NEC	71	75	74	Yes	Yes	Yes
35781	Chr inflam polyneuritis	71	75	74	Yes	Yes	Yes
35782	Crit illness neuropathy	71	75	74	Yes	Yes	Yes
35789	Inflam/tox neurophy NEC	71	75	74	Yes	Yes	Yes
3579	Inflam/tox neurophy NOS	71	75	74	Yes	Yes	Yes
35800	Mysthna grvs w/o ac exac	71	75	71	Yes	Yes	Yes
35801	Myasthna gravs w ac exac	71	75	71	Yes	Yes	Yes
3581	Myasthenia in oth dis	71	75	71	Yes	Yes	Yes
3582	Toxic myoneural disorder	71	75	71	Yes	Yes	Yes
35830	Lambert-Eaton synd NOS	71	75	71	Yes	Yes	Yes
35831	Lambert-Eaton synd neopl	71	75	71	Yes	Yes	Yes
35839	Lambert-Eaton syn ot dis	71	75	71	Yes	Yes	Yes
3588	Myoneural disorders NEC	71	75	71	Yes	Yes	Yes
3589	Myoneural disorders NOS	71	75	71	Yes	Yes	Yes
3590	Cong hered musc dystrophy	70	76		Yes	Yes	No
3591	Hered prog musc dystrophy	70	76		Yes	Yes	No
35921	Myotonic musclr dystrophy	70	76		Yes	Yes	No
35922	Myotonia congenita	71	75	74	Yes	Yes	Yes
35923	Myotonic chondrodystrophy	71	75	74	Yes	Yes	Yes
35924	Drug induced myotonia	71	75	74	Yes	Yes	Yes
35929	Myotonic disorder NEC	71	75	74	Yes	Yes	Yes
3593	Periodic paralysis	71	75	74	Yes	Yes	Yes
3594	Toxic myopathy	71	75	74	Yes	Yes	Yes
3595	Myopathy in endocrin dis	71	75	74	Yes	Yes	Yes
3596	Infl myopathy in oth dis	71	75	74	Yes	Yes	Yes
35971	Inclusion body myositis	71	75	74	Yes	Yes	Yes
35979	Inflm/immune myopath NEC	71	75	74	Yes	Yes	Yes
35981	Critical illness myopathy	71	75	74	Yes	Yes	Yes
35989	Myopathies NEC	71	75	74	Yes	Yes	Yes
3599	Myopathy NOS	71	75	74	Yes	Yes	Yes
36201	Diabetic retinopathy NOS		18	111	No	Yes	Yes
36202	Prolif diab retinopathy	119	122	111	Yes	Yes	Yes
36203	Nonprolf db retnoph NOS		18	111	No	Yes	Yes
36204	Mild nonprolf db retnoph		18	111	No	Yes	Yes
36205	Mod nonprolf db retnoph		18	111	No	Yes	Yes

36206	Sev nonprolf db retinoph		18	111	No	Yes	Yes
36207	Diabetic macular edema		18	111	No	Yes	Yes
36252	Exudative macular degen		124		No	Yes	No
36510	Open-angle glaucoma NOS			113	No	No	Yes
36511	Prim open angle glaucoma			113	No	No	Yes
36512	Low tension glaucoma			113	No	No	Yes
36513	Pigmentary glaucoma			113	No	No	Yes
36514	Glaucoma of childhood			113	No	No	Yes
36515	Residual opn ang glaucma			113	No	No	Yes
36641	Diabetic cataract		18	14	No	Yes	Yes
37923	Vitreous hemorrhage	119	122		Yes	Yes	No
39891	Rheumatic heart failure		85	87	No	Yes	Yes
4010	Malignant hypertension			88	No	No	Yes
4011	Benign hypertension			88	No	No	Yes
4019	Hypertension NOS			88	No	No	Yes
40200	Mal hyp ht dis w/o hf			88	No	No	Yes
40201	Mal hypert hrt dis w hf	80	85	87	Yes	Yes	Yes
40210	Benign hyp ht dis w/o hf			88	No	No	Yes
40211	Benign hyp ht dis w hf	80	85	87	Yes	Yes	Yes
40290	Hyp hrt dis NOS w/o hf			88	No	No	Yes
40291	Hyp ht dis NOS w ht fail	80	85	87	Yes	Yes	Yes
40300	Mal hy kid w cr kid I-IV		139	125	No	Yes	Yes
40301	Mal hyp kid w cr kid V	131	136	122	Yes	Yes	Yes
40310	Ben hy kid w cr kid I-IV		139	125	No	Yes	Yes
40311	Ben hyp kid w cr kid V	131	136	122	Yes	Yes	Yes
40390	Hy kid NOS w cr kid I-IV		139	125	No	Yes	Yes
40391	Hyp kid NOS w cr kid V	131	136	122	Yes	Yes	Yes
40400	Mal hy ht/kd I-IV w/o hf		139	125	No	Yes	Yes
40401	Mal hyp ht/kd I-IV w hf	80	139	125	Yes	Yes	Yes
40402	Mal hy ht/kd st V w/o hf	131	136	122	Yes	Yes	Yes
40403	Mal hyp ht/kd stg V w hf	131	136	122	Yes	Yes	Yes
40410	Ben hy ht/kd I-IV w/o hf		139	125	No	Yes	Yes
40411	Ben hyp ht/kd I-IV w hf	80	139	125	Yes	Yes	Yes
40412	Ben hy ht/kd st V w/o hf	131	136	122	Yes	Yes	Yes
40413	Ben hyp ht/kd stg V w hf	131	136	122	Yes	Yes	Yes
40490	Hy ht/kd NOS I-IV w/o hf		139	125	No	Yes	Yes
40491	Hyp ht/kd NOS I-IV w hf	80	139	125	Yes	Yes	Yes
40492	Hy ht/kd NOS st V w/o hf	131	136	122	Yes	Yes	Yes
40493	Hyp ht/kd NOS st V w hf	131	136	122	Yes	Yes	Yes
40501	Mal renovasc hypertens			88	No	No	Yes
40509	Mal second hyperten NEC			88	No	No	Yes
40511	Benign renovasc hyperten			88	No	No	Yes
40519	Benign second hypert NEC			88	No	No	Yes
40591	Renovasc hypertension			88	No	No	Yes
40599	Second hypertension NEC			88	No	No	Yes
41000	AMI anterolateral,unspec	82	87	89	Yes	Yes	Yes
41001	AMI anterolateral, init	81	86	89	Yes	Yes	Yes
41002	AMI anterolateral,subseq	82	87	89	Yes	Yes	Yes
41010	AMI anterior wall,unspec	82	87	89	Yes	Yes	Yes
41011	AMI anterior wall, init	81	86	89	Yes	Yes	Yes
41012	AMI anterior wall,subseq	82	87	89	Yes	Yes	Yes
41020	AMI inferolateral,unspec	82	87	89	Yes	Yes	Yes
41021	AMI inferolateral, init	81	86	89	Yes	Yes	Yes
41022	AMI inferolateral,subseq	82	87	89	Yes	Yes	Yes
41030	AMI inferopost, unspec	82	87	89	Yes	Yes	Yes
41031	AMI inferopost, initial	81	86	89	Yes	Yes	Yes
41032	AMI inferopost, subseq	82	87	89	Yes	Yes	Yes
41040	AMI inferior wall,unspec	82	87	89	Yes	Yes	Yes
41041	AMI inferior wall, init	81	86	89	Yes	Yes	Yes
41042	AMI inferior wall,subseq	82	87	89	Yes	Yes	Yes
41050	AMI lateral NEC, unspec	82	87	89	Yes	Yes	Yes
41051	AMI lateral NEC, initial	81	86	89	Yes	Yes	Yes
41052	AMI lateral NEC, subseq	82	87	89	Yes	Yes	Yes
41060	True post infarct,unspec	82	87	89	Yes	Yes	Yes

41061	True post infarct, init	81	86	89	Yes	Yes	Yes
41062	True post infarct,subseq	82	87	89	Yes	Yes	Yes
41070	Subendo infarct, unspec	82	87	89	Yes	Yes	Yes
41071	Subendo infarct, initial	81	86	89	Yes	Yes	Yes
41072	Subendo infarct, subseq	82	87	89	Yes	Yes	Yes
41080	AMI NEC, unspecified	82	87	89	Yes	Yes	Yes
41081	AMI NEC, initial	81	86	89	Yes	Yes	Yes
41082	AMI NEC, subsequent	82	87	89	Yes	Yes	Yes
41090	AMI NOS, unspecified	82	87	89	Yes	Yes	Yes
41091	AMI NOS, initial	81	86	89	Yes	Yes	Yes
41092	AMI NOS, subsequent	82	87	89	Yes	Yes	Yes
4110	Post MI syndrome	82	87	89	Yes	Yes	Yes
4111	Intermed coronary synd	82	87	89	Yes	Yes	Yes
41181	Acute cor occlsn w/o MI	82	87	89	Yes	Yes	Yes
41189	Ac ischemic hrt dis NEC	82	87	89	Yes	Yes	Yes
412	Old myocardial infarct	83		89	Yes	No	Yes
4130	Angina decubitus	83	88	89	Yes	Yes	Yes
4131	Prinzmetal angina	83	88	89	Yes	Yes	Yes
4139	Angina pectoris NEC/NOS	83	88	89	Yes	Yes	Yes
41400	Cor ath unsp vsf ntv/gft			89	No	No	Yes
41401	Crnry athrscf natve vssl			89	No	No	Yes
41402	Crn ath atlg vn bps grft			89	No	No	Yes
41403	Crn ath nonatlg blg grft			89	No	No	Yes
41404	Cor ath artry bypas grft			89	No	No	Yes
41405	Cor ath bypass graft NOS			89	No	No	Yes
41406	Cor ath natv art tp hrt			89	No	No	Yes
41407	Cor ath bps graft tp hrt			89	No	No	Yes
41410	Aneurysm of heart			89	No	No	Yes
41411	Aneurysm coronary vessel			89	No	No	Yes
41412	Dissection cor artery			89	No	No	Yes
41419	Aneurysm of heart NEC			89	No	No	Yes
4142	Chr tot occlus cor artry			89	No	No	Yes
4143	Cor ath d/t lpd rch plaq			89	No	No	Yes
4144	Cor ath d/t calc cor lsn			89	No	No	Yes
4148	Chr ischemic hrt dis NEC			89	No	No	Yes
4149	Chr ischemic hrt dis NOS			89	No	No	Yes
4150	Acute cor pulmonale	80	85	86	Yes	Yes	Yes
41511	Iatrogen pulm emb/infarc	104	107	100	Yes	Yes	Yes
41512	Septic pulmonary embolism	104	107	100	Yes	Yes	Yes
41513	Saddle embol pulmon art	104	107	100	Yes	Yes	Yes
41519	Pulm embol/infarct NEC	104	107	100	Yes	Yes	Yes
4160	Prim pulm hypertension	80	85	86	Yes	Yes	Yes
4161	Kyphoscoliotic heart dis	80	85	86	Yes	Yes	Yes
4162	Chr pulmonary embolism	104	107	100	Yes	Yes	Yes
4168	Chr pulmon heart dis NEC	80	85	86	Yes	Yes	Yes
4169	Chr pulmon heart dis NOS	80	85	86	Yes	Yes	Yes
4170	Arterioven fistu pul ves	80	85	86	Yes	Yes	Yes
4171	Pulmon artery aneurysm	80	85	86	Yes	Yes	Yes
4178	Pulmon circulat dis NEC	80	85	86	Yes	Yes	Yes
4179	Pulmon circulat dis NOS	80	85	86	Yes	Yes	Yes
4250	Endomyocardial fibrosis	80	85	87	Yes	Yes	Yes
4251	Hypertrophic cardiomyop	80	85	87	Yes	Yes	Yes
42511	Hypertrophic obst cardiomy	80	85	87	Yes	Yes	Yes
42518	Oth hypertrophic cardiomy	80	85	87	Yes	Yes	Yes
4252	Obstructive cardiomyopath	80	85	87	Yes	Yes	Yes
4253	Endocard fibroelastosis	80	85	87	Yes	Yes	Yes
4254	Prim cardiomyopathy NEC	80	85	87	Yes	Yes	Yes
4255	Alcoholic cardiomyopathy	80	85	87	Yes	Yes	Yes
4257	Metabolic cardiomyopathy	80	85	87	Yes	Yes	Yes
4258	Cardiomyopath in oth dis	80	85	87	Yes	Yes	Yes
4259	Second cardiomyopath NOS	80	85	87	Yes	Yes	Yes
4260	Atriovent block complete	92	96		Yes	Yes	No
4270	Parox atrial tachycardia	92	96	93	Yes	Yes	Yes
4271	Parox ventric tachycard	92	96		Yes	Yes	No

4272	Parox tachycardia NOS	92	96	93	Yes	Yes	Yes
42731	Atrial fibrillation	92	96	93	Yes	Yes	Yes
42732	Atrial flutter	92	96	93	Yes	Yes	Yes
42741	Ventricular fibrillation	79	84		Yes	Yes	No
42742	Ventricular flutter	79	84		Yes	Yes	No
4275	Cardiac arrest	79	84		Yes	Yes	No
42781	Sinoatrial node dysfunct	92	96		Yes	Yes	No
4280	CHF NOS	80	85	87	Yes	Yes	Yes
4281	Left heart failure	80	85	87	Yes	Yes	Yes
42820	Systolic hrt failure NOS	80	85	87	Yes	Yes	Yes
42821	Ac systolic hrt failure	80	85	87	Yes	Yes	Yes
42822	Chr systolic hrt failure	80	85	87	Yes	Yes	Yes
42823	Ac on chr syst hrt fail	80	85	87	Yes	Yes	Yes
42830	Diastolic hrt failure NOS	80	85	87	Yes	Yes	Yes
42831	Ac diastolic hrt failure	80	85	87	Yes	Yes	Yes
42832	Chr diastolic hrt fail	80	85	87	Yes	Yes	Yes
42833	Ac on chr diast hrt fail	80	85	87	Yes	Yes	Yes
42840	Syst/diast hrt fail NOS	80	85	87	Yes	Yes	Yes
42841	Ac syst/diastol hrt fail	80	85	87	Yes	Yes	Yes
42842	Chr syst/diastl hrt fail	80	85	87	Yes	Yes	Yes
42843	Ac/chr syst/dia hrt fail	80	85	87	Yes	Yes	Yes
4289	Heart failure NOS	80	85	87	Yes	Yes	Yes
4290	Myocarditis NOS	80	85	87	Yes	Yes	Yes
4291	Myocardial degeneration	80	85	87	Yes	Yes	Yes
4295	Chordae tendinae rupture	81	86	89	Yes	Yes	Yes
4296	Papillary muscle rupture	81	86	89	Yes	Yes	Yes
430	Subarachnoid hemorrhage	95	99		Yes	Yes	No
431	Intracerebral hemorrhage	95	99		Yes	Yes	No
4320	Nontraum extradural hem	95	99		Yes	Yes	No
4321	Subdural hemorrhage	95	99		Yes	Yes	No
4329	Intracranial hemorr NOS	95	99		Yes	Yes	No
43300	Ocl bslr art wo infrc			97	No	No	Yes
43301	Ocl bslr art w infrc	96	100	97	Yes	Yes	Yes
43310	Ocl crtd art wo infrc			97	No	No	Yes
43311	Ocl crtd art w infrc	96	100	97	Yes	Yes	Yes
43320	Ocl vrtb art wo infrc			97	No	No	Yes
43321	Ocl vrtb art w infrc	96	100	97	Yes	Yes	Yes
43330	Ocl mlt bi art wo infrc			97	No	No	Yes
43331	Ocl mlt bi art w infrc	96	100	97	Yes	Yes	Yes
43380	Ocl spcf art wo infrc			97	No	No	Yes
43381	Ocl spcf art w infrc	96	100	97	Yes	Yes	Yes
43390	Ocl art NOS wo infrc			97	No	No	Yes
43391	Ocl art NOS w infrc	96	100	97	Yes	Yes	Yes
43400	Crbl thrms wo infrc			97	No	No	Yes
43401	Crbl thrms w infrc	96	100	97	Yes	Yes	Yes
43410	Crbl emblm wo infrc			97	No	No	Yes
43411	Crbl emblm w infrc	96	100	97	Yes	Yes	Yes
43490	Crbl art oc NOS wo infrc			97	No	No	Yes
43491	Crbl art ocl NOS w infrc	96	100	97	Yes	Yes	Yes
4350	Basilar artery syndrome			97	No	No	Yes
4351	Vertebral artery syndrom			97	No	No	Yes
4352	Subclavian steal syndrom			97	No	No	Yes
4353	Vertbrobaslr artery synd			97	No	No	Yes
4358	Trans cereb ischemia NEC			97	No	No	Yes
4359	Trans cereb ischemia NOS			97	No	No	Yes
436	Cva	96	100	97	Yes	Yes	Yes
4370	Cerebral atherosclerosis			97	No	No	Yes
4371	Ac cerebrovasc insuf NOS			97	No	No	Yes
4372	Hypertens encephalopathy			88	No	No	Yes
4374	Cerebral arteritis			97	No	No	Yes
4375	Moyamoya disease			97	No	No	Yes
4376	Nonpyogen thrombos sinus			97	No	No	Yes
4378	Cerebrovasc disease NEC			97	No	No	Yes
4379	Cerebrovasc disease NOS			97	No	No	Yes

43820	Late ef-hemiplga side NOS	100	103		Yes	Yes	No
43821	Late ef-hemiplga dom side	100	103		Yes	Yes	No
43822	Late ef-hemiplga non-dom	100	103		Yes	Yes	No
43830	Late ef-mplga up lmb NOS	101	104		Yes	Yes	No
43831	Late ef-mplga up lmb dom	101	104		Yes	Yes	No
43832	Lt ef-mplga uplmb nondom	101	104		Yes	Yes	No
43840	Lte ef-mplga low lmb NOS	101	104		Yes	Yes	No
43841	Lte ef-mplga low lmb dom	101	104		Yes	Yes	No
43842	Lt ef-mplga lowlmb nondm	101	104		Yes	Yes	No
43850	Lt ef oth paral side NOS	101	104		Yes	Yes	No
43851	Lt ef oth paral dom side	101	104		Yes	Yes	No
43852	Lt ef oth parals non-dom	101	104		Yes	Yes	No
43853	Lt ef oth parals-bilat	101	104		Yes	Yes	No
4400	Aortic atherosclerosis	105	108	101	Yes	Yes	Yes
4401	Renal artery atheroscler	105	108	101	Yes	Yes	Yes
44020	Athsc l extrm ntv art NOS	105	108	101	Yes	Yes	Yes
44021	Ath ext ntv at w claudct	105	108	101	Yes	Yes	Yes
44022	Ath ext ntv at w rst pn	105	108	101	Yes	Yes	Yes
44023	Ath ext ntv art ulcrcton	104	106		Yes	Yes	No
44024	Ath ext ntv art gngrene	104	106		Yes	Yes	No
44029	Athrsc extrm ntv art oth	105	108	101	Yes	Yes	Yes
44030	Athsc l extrm bps gft NOS	105	108	101	Yes	Yes	Yes
44031	Ath ext autologs bps gft	105	108	101	Yes	Yes	Yes
44032	Ath ext nonautlg bps gft	105	108	101	Yes	Yes	Yes
4404	Chr tot occl art extrem	105	108	101	Yes	Yes	Yes
44100	Dsct of aorta unsp site	104	107		Yes	Yes	No
44101	Dsct of thoracic aorta	104	107		Yes	Yes	No
44102	Dsct of abdominal aorta	104	107		Yes	Yes	No
44103	Dsct of thoracoabd aorta	104	107		Yes	Yes	No
4411	Ruptur thoracic aneurysm	104	107		Yes	Yes	No
4412	Thoracic aortic aneurysm	105	108		Yes	Yes	No
4413	Rupt abd aortic aneurysm	104	107		Yes	Yes	No
4414	Abdom aortic aneurysm	105	108		Yes	Yes	No
4415	Rupt aortic aneurysm NOS	104	107		Yes	Yes	No
4416	Thoracoabd aneurysm rupt	104	107		Yes	Yes	No
4417	Thracabd anurysm wo rupt	105	108		Yes	Yes	No
4419	Aortic aneurysm NOS	105	108		Yes	Yes	No
4420	Upper extremity aneurysm	105	108		Yes	Yes	No
4421	Renal artery aneurysm	105	108		Yes	Yes	No
4422	Iliac artery aneurysm	105	108		Yes	Yes	No
4423	Lower extremity aneurysm	105	108		Yes	Yes	No
44281	Aneurysm of neck	105	108		Yes	Yes	No
44282	Subclavian aneurysm	105	108		Yes	Yes	No
44283	Splenic artery aneurysm	105	108		Yes	Yes	No
44284	Visceral aneurysm NEC	105	108		Yes	Yes	No
44289	Aneurysm NEC	105	108		Yes	Yes	No
4429	Aneurysm NOS	105	108		Yes	Yes	No
4431	Thromboangiit obliterans	105	108	101	Yes	Yes	Yes
44321	Dissect carotid artery	104	107		Yes	Yes	No
44322	Dissection iliac artery	104	107		Yes	Yes	No
44323	Dissection renal artery	104	107		Yes	Yes	No
44324	Dissect vertebral artery	104	107		Yes	Yes	No
44329	Dissection artery NEC	104	107		Yes	Yes	No
44381	Angiopathy in other dis	105	108	101	Yes	Yes	Yes
44382	Erythromelalgia	105	108	101	Yes	Yes	Yes
44389	Periph vascular dis NEC	105	108	101	Yes	Yes	Yes
4439	Periph vascular dis NOS	105	108	101	Yes	Yes	Yes
4440	Abd aortic embolism	104	107		Yes	Yes	No
44401	Saddle embolus abd aorta	104	107		Yes	Yes	No
44409	Ot art emb/thrm abd aort	104	107		Yes	Yes	No
4441	Thoracic aortic embolism	104	107		Yes	Yes	No
44421	Upper extremity embolism	104	107		Yes	Yes	No
44422	Lower extremity embolism	104	107		Yes	Yes	No
44481	Iliac artery embolism	104	107		Yes	Yes	No

44489	Arterial embolism NEC	104	107		Yes	Yes	No
4449	Arterial embolism NOS	104	107		Yes	Yes	No
44501	Atheroembolism,upper ext	104	107		Yes	Yes	No
44502	Atheroembolism,lower ext	104	107		Yes	Yes	No
44581	Atheroembolism, kidney	104	107		Yes	Yes	No
44589	Atheroembolism, site NEC	104	107		Yes	Yes	No
4460	Polyarteritis nodosa	38	40	42	Yes	Yes	Yes
4461	Mucocutan lymph node syn	38	40	42	Yes	Yes	Yes
44620	Hypersensit angiitis NOS	38	40	42	Yes	Yes	Yes
44621	Goodpasture's syndrome	38	40	42	Yes	Yes	Yes
44629	Hypersensit angiitis NEC	38	40	42	Yes	Yes	Yes
4463	Lethal midline granuloma	38	40	42	Yes	Yes	Yes
4464	Wegener's granulomatosis	38	40	42	Yes	Yes	Yes
4465	Giant cell arteritis	38	40	42	Yes	Yes	Yes
4466	Thrombot microangiopathy	38	40	42	Yes	Yes	Yes
4467	Takayasu's disease	38	40	42	Yes	Yes	Yes
4470	Acq arterioven fistula	105	108		Yes	Yes	No
4471	Stricture of artery	105	108		Yes	Yes	No
4472	Rupture of artery	105	108		Yes	Yes	No
4473	Renal artery hyperplasia	105	108		Yes	Yes	No
4474	Celiac art compress syn	105	108		Yes	Yes	No
4475	Necrosis of artery	105	108		Yes	Yes	No
4476	Arteritis NOS	105	108		Yes	Yes	No
44770	Aortic ectasia, site NOS	105	108		Yes	Yes	No
44771	Thoracic aortic ectasia	105	108		Yes	Yes	No
44772	Abdominal aortic ectasia	105	108		Yes	Yes	No
44773	Thoracoabd aortic ectasia	105	108		Yes	Yes	No
4478	Arterial disease NEC	105	108		Yes	Yes	No
4479	Arterial disease NOS	105	108		Yes	Yes	No
4480	Heredit hemorr telangiec	105	108		Yes	Yes	No
449	Septic arterial embolism	104	107		Yes	Yes	No
45111	Femoral vein phlebitis	105	108	100	Yes	Yes	Yes
45119	Deep phlebitis-leg NEC	105	108	100	Yes	Yes	Yes
45181	Iliac thrombophlebitis	105	108	100	Yes	Yes	Yes
45183	Phlbt deep vn up extrm	105	108	100	Yes	Yes	Yes
4530	Budd-chiari syndrome	105	108	100	Yes	Yes	Yes
4532	Oth inf vena cava thromb	105	108	100	Yes	Yes	Yes
4533	Renal vein thrombosis	105	108	100	Yes	Yes	Yes
45340	Ac DVT/embl low ext NOS	105	108	100	Yes	Yes	Yes
45341	Ac DVT/emb prox low ext	105	108	100	Yes	Yes	Yes
45342	Ac DVT/emb distl low ext	105	108	100	Yes	Yes	Yes
45350	Ch DVT/embl low ext NOS	105	108	100	Yes	Yes	Yes
45351	Ch DVT/embl prox low ext	105	108	100	Yes	Yes	Yes
45352	Ch DVT/embl dstl low ext	105	108	100	Yes	Yes	Yes
45372	Ch DVT/embl up ext	105	108	100	Yes	Yes	Yes
45374	Ch emblsm axillary veins	105	108	100	Yes	Yes	Yes
45375	Ch emblsm subclav veins	105	108	100	Yes	Yes	Yes
45376	Ch embl internl jug vein	105	108	100	Yes	Yes	Yes
45377	Ch embl thorac vein NEC	105	108	100	Yes	Yes	Yes
45382	Ac DVT/embl up ext	105	108	100	Yes	Yes	Yes
45384	Ac emblsm axillary veins	105	108	100	Yes	Yes	Yes
45385	Ac embl subclav veins	105	108	100	Yes	Yes	Yes
45386	Ac embl internl jug vein	105	108	100	Yes	Yes	Yes
45387	Ac embl thorac vein NEC	105	108	100	Yes	Yes	Yes
4540	Leg varicosity w ulcer		107		No	Yes	No
4542	Varicos leg ulcer/inflam		107		No	Yes	No
4560	Esophag varices w bleed	25	27		Yes	Yes	No
4561	Esoph varices w/o bleed	25	27		Yes	Yes	No
45620	Bleed esoph var oth dis	25	27		Yes	Yes	No
45621	Esoph varice oth dis NOS	25	27		Yes	Yes	No
45911	Postphlebtc synd w ulcer		107		No	Yes	No
45913	Postphl syn w ulc&inflam		107		No	Yes	No
45931	Chr venous hyper w ulcer		107		No	Yes	No
45933	Chr ven hyp w ulc&inflam		107		No	Yes	No

481	Pneumococcal pneumonia	112	115		Yes	Yes	No
4820	K. pneumoniae pneumonia	111	114	106	Yes	Yes	Yes
4821	Pseudomonal pneumonia	111	114	106	Yes	Yes	Yes
4822	H.influenzae pneumonia	112	115		Yes	Yes	No
48230	Streptococcal pneumn NOS	112	115		Yes	Yes	No
48231	Pneumonia strptococcus a	112	115		Yes	Yes	No
48232	Pneumonia strptococcus b	112	115		Yes	Yes	No
48239	Pneumonia oth strep	112	115		Yes	Yes	No
48240	Staphylococcal pneu NOS	111	114	106	Yes	Yes	Yes
48241	Meth sus pneum d/t Staph	111	114	106	Yes	Yes	Yes
48242	Meth res pneu d/t Staph	111	114	106	Yes	Yes	Yes
48249	Staph pneumonia NEC	111	114	106	Yes	Yes	Yes
48281	Pneumonia anaerobes	111	114	106	Yes	Yes	Yes
48282	Pneumonia e coli	111	114	106	Yes	Yes	Yes
48283	Pneumo oth grm-neg bact	111	114	106	Yes	Yes	Yes
48284	Legionnaires' disease	111	114	106	Yes	Yes	Yes
48289	Pneumonia oth spcf bact	111	114	106	Yes	Yes	Yes
4841	Pneum w cytomeg incl dis	5	6	5	Yes	Yes	Yes
4846	Pneum in aspergillosis	112	6	5	Yes	Yes	Yes
4847	Pneum in oth sys mycoses	112	115	106	Yes	Yes	Yes
4910	Simple chr bronchitis	108	111	104	Yes	Yes	Yes
4911	Mucopurul chr bronchitis	108	111	104	Yes	Yes	Yes
49120	Obst chr bronc w/o exac	108	111	104	Yes	Yes	Yes
49121	Obs chr bronc w(ac) exac	108	111	104	Yes	Yes	Yes
49122	Obs chr bronc w ac bronc	108	111	104	Yes	Yes	Yes
4918	Chronic bronchitis NEC	108	111	104	Yes	Yes	Yes
4919	Chronic bronchitis NOS	108	111	104	Yes	Yes	Yes
4920	Emphysematous bleb	108	111	104	Yes	Yes	Yes
4928	Emphysema NEC	108	111	104	Yes	Yes	Yes
49300	Extrinsic asthma NOS			104	No	No	Yes
49301	Ext asthma w status asth			104	No	No	Yes
49302	Ext asthma w(acute) exac			104	No	No	Yes
49310	Intrinsic asthma NOS			104	No	No	Yes
49311	Int asthma w status asth			104	No	No	Yes
49312	Int asthma w (ac) exac			104	No	No	Yes
49320	Chronic obst asthma NOS	108	111	104	Yes	Yes	Yes
49321	Ch ob asthma w stat asth	108	111	104	Yes	Yes	Yes
49322	Ch obst asth w (ac) exac	108	111	104	Yes	Yes	Yes
49381	Exercse ind bronchospasm			104	No	No	Yes
49382	Cough variant asthma			104	No	No	Yes
49390	Asthma NOS			104	No	No	Yes
49391	Asthma w status asthmat			104	No	No	Yes
49392	Asthma NOS w (ac) exac			104	No	No	Yes
4940	Bronchiectas w/o ac exac		112	105	No	Yes	Yes
4941	Bronchiectasis w ac exac		112	105	No	Yes	Yes
4950	Farmers' lung		112		No	Yes	No
4951	Bagassosis		112		No	Yes	No
4952	Bird-fanciers' lung		112		No	Yes	No
4953	Suberosis		112		No	Yes	No
4954	Malt workers' lung		112		No	Yes	No
4955	Mushroom workers' lung		112		No	Yes	No
4956	Mapl bark-stripprs' lung		112		No	Yes	No
4957	"ventilation" pneumonit		112		No	Yes	No
4958	Allerg alveol/pneum NEC		112		No	Yes	No
4959	Allerg alveol/pneum NOS		112		No	Yes	No
496	Chr airway obstruct NEC	108	111	104	Yes	Yes	Yes
500	Coal workers' pneumocon		112		No	Yes	No
501	Asbestosis		112		No	Yes	No
502	Silica pneumocon NEC		112		No	Yes	No
503	Inorg dust pneumocon NEC		112		No	Yes	No
504	Dust pneumonopathy NEC		112		No	Yes	No
505	Pneumoconiosis NOS		112		No	Yes	No
5060	Fum/vapor bronc/pneumon		112		No	Yes	No
5061	Fum/vapor ac pulm edema		112		No	Yes	No

5062	Fum/vapor up resp inflam		112		No	Yes	No
5063	Fum/vap ac resp cond NEC		112		No	Yes	No
5064	Fum/vapor chr resp cond		112		No	Yes	No
5069	Fum/vapor resp cond NOS		112		No	Yes	No
5070	Food/vomit pneumonitis	111	114		Yes	Yes	No
5071	Oil/essence pneumonitis	111	114		Yes	Yes	No
5078	Solid/liq pneumonit NEC	111	114		Yes	Yes	No
5080	Ac pul manif d/t radiat		112	105	No	Yes	Yes
5081	Chr pul manif d/t radiat		112	105	No	Yes	Yes
5082	Resp cond dt smoke inhal		112	105	No	Yes	Yes
5088	Resp cond: ext agent NEC		112	105	No	Yes	Yes
5089	Resp cond: ext agent NOS		112	105	No	Yes	Yes
5100	Empyema with fistula	112	115	106	Yes	Yes	Yes
5109	Empyema w/o fistula	112	115	106	Yes	Yes	Yes
5130	Abscess of lung	112	115	106	Yes	Yes	Yes
5131	Abscess of mediastinum	112	115	106	Yes	Yes	Yes
515	Postinflam pulm fibrosis		112	105	No	Yes	Yes
5160	Pul alveolar proteinosis		112	105	No	Yes	Yes
5161	Idio pulm hemosiderosis		112	105	No	Yes	Yes
5162	Pulm alveolar microlith		112	105	No	Yes	Yes
5163	Idio fibros alveolitis		112	105	No	Yes	Yes
51630	Idiopath inters pneu NOS		112	105	No	Yes	Yes
51631	Idiopath pulmon fibrosis		112	105	No	Yes	Yes
51632	Idio non-spec inter pneu		112	105	No	Yes	Yes
51633	Acute interstitial pneum		112	105	No	Yes	Yes
51634	Resp brncio interst lung		112	105	No	Yes	Yes
51635	Idiopath lym interst pneu		112	105	No	Yes	Yes
51636	Cryptogenic organiz pneu		112	105	No	Yes	Yes
51637	Desquamativ interst pneu		112	105	No	Yes	Yes
5164	Lymphangioleiomyomatosis		112	105	No	Yes	Yes
5165	Adlt pul Langs cell hist		112	105	No	Yes	Yes
51661	Neuroend cell hyprpl inf		112	105	No	Yes	Yes
51662	Pulm interstitl glycogen		112	105	No	Yes	Yes
51663	Surfactant mutation lung		112	105	No	Yes	Yes
51664	Alv cap dysp w vn misaln		112	105	No	Yes	Yes
51669	Oth intrst lung dis chld		112	105	No	Yes	Yes
5168	Alveol pneumonopathy NEC		112	105	No	Yes	Yes
5169	Alveol pneumonopathy NOS		112	105	No	Yes	Yes
5171	Rheumatic pneumonia		112	105	No	Yes	Yes
5172	Syst sclerosis lung dis		112	105	No	Yes	Yes
5173	Acute chest syndrome	44	46	50	Yes	Yes	Yes
5178	Lung involv in oth dis		112	105	No	Yes	Yes
5181	Interstitial emphysema	108	111	104	Yes	Yes	Yes
5182	Compensatory emphysema	108	111	104	Yes	Yes	Yes
5183	Pulmonary eosinophilia		112		No	Yes	No
5184	Acute lung edema NOS	79	84		Yes	Yes	No
5185	Post traum pulm insuffic	79	84		Yes	Yes	No
51851	Ac resp flr fol trma/srg	79	84		Yes	Yes	No
51852	Ot pul insuf fol trm/srg	79	84		Yes	Yes	No
51853	Ac/chr rsp flr fol tr/sg	79	84		Yes	Yes	No
5186	Alrgc brncpul asprglosis		112	105	No	Yes	Yes
51881	Acute respiratry failure	79	84		Yes	Yes	No
51882	Other pulmonary insuff	79	84		Yes	Yes	No
51883	Chronic respiratory fail	79	84		Yes	Yes	No
51884	Acute & chronc resp fail	79	84		Yes	Yes	No
51900	Tracheostomy comp NOS	77	82		Yes	Yes	No
51901	Tracheostomy infection	77	82		Yes	Yes	No
51902	Tracheostomy - mech comp	77	82		Yes	Yes	No
51909	Tracheostomy comp NEC	77	82		Yes	Yes	No
5300	Achalasia & cardiospasm			33	No	No	Yes
53010	Esophagitis, unspecified			33	No	No	Yes
53011	Reflux esophagitis			33	No	No	Yes
53012	Acute esophagitis			33	No	No	Yes
53013	Eosinophilic esophagitis			33	No	No	Yes

53019	Other esophagitis			33	No	No	Yes
5303	Esophageal stricture			33	No	No	Yes
5304	Perforation of esophagus			33	No	No	Yes
5305	Dyskinesia of esophagus			33	No	No	Yes
5306	Acq esophag diverticulum			33	No	No	Yes
53081	Esophageal reflux			33	No	No	Yes
53083	Esophageal leukoplakia			33	No	No	Yes
53084	Tracheoesophageal fstula			33	No	No	Yes
53085	Barrett's esophagus			33	No	No	Yes
53086	Esophagostomy infection	176	188		Yes	Yes	No
53087	Mech comp esophagostomy	176	188		Yes	Yes	No
53089	Other dsrdrs esophagus			33	No	No	Yes
5309	Esophageal disorder NOS			33	No	No	Yes
53110	Ac stomach ulcer w perf	31	33		Yes	Yes	No
53111	Ac stom ulc w perf-obst	31	33		Yes	Yes	No
53120	Ac stomach ulc w hem/perf	31	33		Yes	Yes	No
53121	Ac stom ulc hem/perf-obs	31	33		Yes	Yes	No
53150	Chr stomach ulcer w perf	31	33		Yes	Yes	No
53151	Chr stom ulc w perf-obst	31	33		Yes	Yes	No
53160	Chr stomach ulc hem/perf	31	33		Yes	Yes	No
53161	Chr stom ulc hem/perf-ob	31	33		Yes	Yes	No
53210	Ac duodenal ulcer w perf	31	33		Yes	Yes	No
53211	Ac duoden ulc perf-obstr	31	33		Yes	Yes	No
53220	Ac duoden ulc w hem/perf	31	33		Yes	Yes	No
53221	Ac duod ulc hem/perf-obs	31	33		Yes	Yes	No
53250	Chr duoden ulcer w perf	31	33		Yes	Yes	No
53251	Chr duoden ulc perf-obst	31	33		Yes	Yes	No
53260	Chr duoden ulc hem/perf	31	33		Yes	Yes	No
53261	Chr duod ulc hem/perf-ob	31	33		Yes	Yes	No
53310	Ac peptic ulcer w perfor	31	33		Yes	Yes	No
53311	Ac peptic ulc w perf-obs	31	33		Yes	Yes	No
53320	Ac peptic ulc w hem/perf	31	33		Yes	Yes	No
53321	Ac pept ulc hem/perf-obs	31	33		Yes	Yes	No
53350	Chr peptic ulcer w perf	31	33		Yes	Yes	No
53351	Chr peptic ulc perf-obst	31	33		Yes	Yes	No
53360	Chr pept ulc w hem/perf	31	33		Yes	Yes	No
53361	Chr pept ulc hem/perf-ob	31	33		Yes	Yes	No
53410	Ac marginal ulcer w perf	31	33		Yes	Yes	No
53411	Ac margin ulc w perf-obs	31	33		Yes	Yes	No
53420	Ac margin ulc w hem/perf	31	33		Yes	Yes	No
53421	Ac marg ulc hem/perf-obs	31	33		Yes	Yes	No
53450	Chr marginal ulc w perf	31	33		Yes	Yes	No
53451	Chr margin ulc perf-obst	31	33		Yes	Yes	No
53460	Chr margin ulc hem/perf	31	33		Yes	Yes	No
53461	Chr marg ulc hem/perf-ob	31	33		Yes	Yes	No
53640	Gastrostomy comp NOS	176	188		Yes	Yes	No
53641	Gastrostomy infection	176	188		Yes	Yes	No
53642	Gastrostomy comp - mech	176	188		Yes	Yes	No
53649	Gastrostomy comp NEC	176	188		Yes	Yes	No
5550	Reg enteritis, sm intest	33	35	32	Yes	Yes	Yes
5551	Reg enteritis, lg intest	33	35	32	Yes	Yes	Yes
5552	Reg enterit sm/lg intest	33	35	32	Yes	Yes	Yes
5559	Regional enteritis NOS	33	35	32	Yes	Yes	Yes
5560	Ulcerative enterocolitis	33	35	32	Yes	Yes	Yes
5561	Ulcerative ileocolitis	33	35	32	Yes	Yes	Yes
5562	Ulcerative proctitis	33	35	32	Yes	Yes	Yes
5563	Ulcervte prctosigmoiditis	33	35	32	Yes	Yes	Yes
5564	Pseudopolyposis colon	33	35	32	Yes	Yes	Yes
5565	Lftsded ulcervte colitis	33	35	32	Yes	Yes	Yes
5566	Univrsl ulcervte colitis	33	35	32	Yes	Yes	Yes
5568	Other ulcerative colitis	33	35	32	Yes	Yes	Yes
5569	Ulceratve colitis unspcf	33	35	32	Yes	Yes	Yes
5570	Ac vasc insuff intestine	104	107		Yes	Yes	No
5571	Chr vasc insuff intest	105	108		Yes	Yes	No

5579	Vasc insuff intest NOS	105	108		Yes	Yes	No
5600	Intussusception	31	33		Yes	Yes	No
5601	Paralytic ileus	31	33		Yes	Yes	No
5602	Volvulus of intestine	31	33		Yes	Yes	No
56030	Impaction intestine NOS	31	33		Yes	Yes	No
56031	Gallstone ileus	31	33		Yes	Yes	No
56032	Fecal impaction	31	33		Yes	Yes	No
56039	Impaction intestine NEC	31	33		Yes	Yes	No
56081	Intestinal adhes w obstr	31	33		Yes	Yes	No
56089	Intestinal obstruct NEC	31	33		Yes	Yes	No
5609	Intestinal obstruct NOS	31	33		Yes	Yes	No
5670	Peritonitis in infec dis	31	33		Yes	Yes	No
5671	Pneumococcal peritonitis	31	33		Yes	Yes	No
56721	Peritonitis (acute) gen	31	33		Yes	Yes	No
56722	Peritoneal abscess	31	33		Yes	Yes	No
56723	Spontan bact peritonitis	31	33		Yes	Yes	No
56729	Suppurat peritonitis NEC	31	33		Yes	Yes	No
56731	Psoas muscle abscess	31	33		Yes	Yes	No
56738	Retroperiton abscess NEC	31	33		Yes	Yes	No
56739	Retroperiton infect NEC	31	33		Yes	Yes	No
56781	Choleperitonitis	31	33		Yes	Yes	No
56782	Sclerosing mesenteritis	31	33		Yes	Yes	No
56789	Peritonitis NEC	31	33		Yes	Yes	No
5679	Peritonitis NOS	31	33		Yes	Yes	No
56960	Colostomy/enter comp NOS	176	188		Yes	Yes	No
56961	Colosty/enterost infectn	176	188		Yes	Yes	No
56962	Colosty/enter comp-mech	176	188		Yes	Yes	No
56969	Colstmy/enteros comp NEC	176	188		Yes	Yes	No
56971	Pouchitis	176	188		Yes	Yes	No
56979	Comp intest pouch NEC	176	188		Yes	Yes	No
56983	Perforation of intestine	31	33		Yes	Yes	No
5712	Alcohol cirrhosis liver	26	28		Yes	Yes	No
5713	Alcohol liver damage NOS	26	28		Yes	Yes	No
57140	Chronic hepatitis NOS	27	29		Yes	Yes	No
57141	Chr persistent hepatitis	27	29		Yes	Yes	No
57142	Autoimmune hepatitis	27	29		Yes	Yes	No
57149	Chronic hepatitis NEC	27	29		Yes	Yes	No
5715	Cirrhosis of liver NOS	26	28		Yes	Yes	No
5716	Biliary cirrhosis	26	28		Yes	Yes	No
5722	Hepatic encephalopathy	25	27		Yes	Yes	No
5723	Portal hypertension	25	27		Yes	Yes	No
5724	Hepatorenal syndrome	25	27		Yes	Yes	No
5728	Oth sequela, chr liv dis	25	27		Yes	Yes	No
5735	Hepatopulmonary syndrome	25	27		Yes	Yes	No
5770	Acute pancreatitis	32			Yes	No	No
5771	Chronic pancreatitis	32	34	30	Yes	Yes	Yes
5772	Pancreat cyst/pseudocyst	32		31	Yes	No	Yes
5778	Pancreatic disease NEC	32		31	Yes	No	Yes
5779	Pancreatic disease NOS	32		31	Yes	No	Yes
5790	Celiac disease	32		31	Yes	No	Yes
5791	Tropical sprue	32		31	Yes	No	Yes
5792	Blind loop syndrome	32		31	Yes	No	Yes
5793	Intest postop nonabsorb	32		31	Yes	No	Yes
5794	Pancreatic steatorrhea	32		31	Yes	No	Yes
5798	Intest malabsorption NEC	32		31	Yes	No	Yes
5799	Intest malabsorption NOS	32		31	Yes	No	Yes
5800	Ac proliferat nephritis	132	141	126	Yes	Yes	Yes
5804	Ac rapidly progr nephrit	132	141	126	Yes	Yes	Yes
58081	Ac nephritis in oth dis	132	141	126	Yes	Yes	Yes
58089	Acute nephritis NEC	132	141	126	Yes	Yes	Yes
5809	Acute nephritis NOS	132	141	126	Yes	Yes	Yes
5810	Nephrotic syn, prolifer	132	141	126	Yes	Yes	Yes
5811	Epimembranous nephritis	132	141	126	Yes	Yes	Yes
5812	Membranoprolif nephrosis	132	141	126	Yes	Yes	Yes

5813	Minimal change nephrosis	132	141	126	Yes	Yes	Yes
58181	Nephrotic syn in oth dis	132	141	126	Yes	Yes	Yes
58189	Nephrotic syndrome NEC	132	141	126	Yes	Yes	Yes
5819	Nephrotic syndrome NOS	132	141	126	Yes	Yes	Yes
5820	Chr proliferat nephritis	132	141	126	Yes	Yes	Yes
5821	Chr membranous nephritis	132	141	126	Yes	Yes	Yes
5822	Chr membranoprolif nephrit	132	141	126	Yes	Yes	Yes
5824	Chr rapid progr nephrit	132	141	126	Yes	Yes	Yes
58281	Chr nephritis in oth dis	132	141	126	Yes	Yes	Yes
58289	Chronic nephritis NEC	132	141	126	Yes	Yes	Yes
5829	Chronic nephritis NOS	132	141	126	Yes	Yes	Yes
5830	Proliferat nephritis NOS	132	141	126	Yes	Yes	Yes
5831	Membranous nephritis NOS	132	141	126	Yes	Yes	Yes
5832	Membranoprolif nephrit NOS	132	141	126	Yes	Yes	Yes
5834	Rapidly prog nephrit NOS	132	141	126	Yes	Yes	Yes
5836	Renal cort necrosis NOS	132	141	126	Yes	Yes	Yes
5837	Nephros NOS/medull necros	132	141	126	Yes	Yes	Yes
58381	Nephritis NOS in oth dis	132	141	126	Yes	Yes	Yes
58389	Nephritis NEC	132	141	126	Yes	Yes	Yes
5839	Nephritis NOS	132	141	126	Yes	Yes	Yes
5845	Ac kidney fail, tubr necr	131	135		Yes	Yes	No
5846	Ac kidney fail, cort necr	131	135		Yes	Yes	No
5847	Ac kidney fail, medu necr	131	135		Yes	Yes	No
5848	Acute kidney failure NEC	131	135		Yes	Yes	No
5849	Acute kidney failure NOS	131	135		Yes	Yes	No
5851	Chro kidney dis stage I	131	139	125	Yes	Yes	Yes
5852	Chro kidney dis stage II	131	139	125	Yes	Yes	Yes
5853	Chr kidney dis stage III	131	138	124	Yes	Yes	Yes
5854	Chr kidney dis stage IV	131	137	123	Yes	Yes	Yes
5855	Chron kidney dis stage V	131	136	122	Yes	Yes	Yes
5856	End stage renal disease	131	136	121	Yes	Yes	Yes
5859	Chronic kidney dis NOS	131	139	125	Yes	Yes	Yes
586	Renal failure NOS	131	140		Yes	Yes	No
5880	Renal osteodystrophy			45	No	No	Yes
5881	Nephrogen diabetes insip		23	18	No	Yes	Yes
58881	Sec hyperparathyrd-renal		23	19	No	Yes	Yes
59381	Renal vascular disorder	104	107		Yes	Yes	No
59681	Infection of cystostomy	164	176		Yes	Yes	No
59682	Mech comp of cystostomy	164	176		Yes	Yes	No
59683	Other comp of cystostomy	164	176		Yes	Yes	No
62931	Eros imp vag mesh in tis	164	176		Yes	Yes	No
6944	Pemphigus			145	No	No	Yes
69513	Stevens-Johnson syndrome		162		No	Yes	No
69514	Stevens-Johnson-TEN syn		162		No	Yes	No
69515	Toxic epidrm necrolysis		162		No	Yes	No
6960	Psoriatic arthropathy		40	40	No	Yes	Yes
6961	Other psoriasis			147	No	No	Yes
6962	Parapsoriasis			147	No	No	Yes
70700	Pressure ulcer, site NOS	148	160		Yes	Yes	No
70701	Pressure ulcer, elbow	148	160		Yes	Yes	No
70702	Pressure ulcer, upr back	148	160		Yes	Yes	No
70703	Pressure ulcer, low back	148	160		Yes	Yes	No
70704	Pressure ulcer, hip	148	160		Yes	Yes	No
70705	Pressure ulcer, buttock	148	160		Yes	Yes	No
70706	Pressure ulcer, ankle	148	160		Yes	Yes	No
70707	Pressure ulcer, heel	148	160		Yes	Yes	No
70709	Pressure ulcer, site NEC	148	160		Yes	Yes	No
70710	Ulcer of lower limb NOS	149	161	142	Yes	Yes	Yes
70711	Ulcer of thigh	149	161	142	Yes	Yes	Yes
70712	Ulcer of calf	149	161	142	Yes	Yes	Yes
70713	Ulcer of ankle	149	161	142	Yes	Yes	Yes
70714	Ulcer of heel & midfoot	149	161	142	Yes	Yes	Yes
70715	Ulcer other part of foot	149	161	142	Yes	Yes	Yes
70719	Ulcer oth part low limb	149	161	142	Yes	Yes	Yes

70720	Pressure ulcer,stage NOS	148	160		Yes	Yes	No
70721	Pressure ulcer, stage I	148	160		Yes	Yes	No
70722	Pressure ulcer, stage II	148	159		Yes	Yes	No
70723	Pressure ulcer,stage III	148	158		Yes	Yes	No
70724	Pressure ulcer, stage IV	148	157		Yes	Yes	No
70725	Pressure ulcer,unstagebl	148	158		Yes	Yes	No
7078	Chronic skin ulcer NEC	149	161	142	Yes	Yes	Yes
7079	Chronic skin ulcer NOS	149	161	142	Yes	Yes	Yes
7100	Syst lupus erythematosus	38	40	42	Yes	Yes	Yes
7101	Systemic sclerosis	38	40	42	Yes	Yes	Yes
7102	Sicca syndrome	38	40	42	Yes	Yes	Yes
7103	Dermatomyositis	38	40	42	Yes	Yes	Yes
7104	Polymyositis	38	40	42	Yes	Yes	Yes
7105	Eosinophilia myalgia snd	38	40	42	Yes	Yes	Yes
7108	Diff connect tis dis NEC	38	40	42	Yes	Yes	Yes
7109	Diff connect tis dis NOS	38	40	42	Yes	Yes	Yes
71100	Pyogen arthritis-unspec	37	39		Yes	Yes	No
71101	Pyogen arthritis-shlder	37	39		Yes	Yes	No
71102	Pyogen arthritis-up/arm	37	39		Yes	Yes	No
71103	Pyogen arthritis-forearm	37	39		Yes	Yes	No
71104	Pyogen arthritis-hand	37	39		Yes	Yes	No
71105	Pyogen arthritis-pelvis	37	39		Yes	Yes	No
71106	Pyogen arthritis-l/leg	37	39		Yes	Yes	No
71107	Pyogen arthritis-ankle	37	39		Yes	Yes	No
71108	Pyogen arthritis NEC	37	39		Yes	Yes	No
71109	Pyogen arthritis-mult	37	39		Yes	Yes	No
71110	Reiter arthritis-unspec	37	40	41	Yes	Yes	Yes
71111	Reiter arthritis-shlder	37	40	41	Yes	Yes	Yes
71112	Reiter arthritis-up/arm	37	40	41	Yes	Yes	Yes
71113	Reiter arthritis-forearm	37	40	41	Yes	Yes	Yes
71114	Reiter arthritis-hand	37	40	41	Yes	Yes	Yes
71115	Reiter arthritis-pelvis	37	40	41	Yes	Yes	Yes
71116	Reiter arthritis-l/leg	37	40	41	Yes	Yes	Yes
71117	Reiter arthritis-ankle	37	40	41	Yes	Yes	Yes
71118	Reiter arthritis NEC	37	40	41	Yes	Yes	Yes
71119	Reiter arthritis-mult	37	40	41	Yes	Yes	Yes
71120	Behcet arthritis-unspec	37	40	41	Yes	Yes	Yes
71121	Behcet arthritis-shlder	37	40	41	Yes	Yes	Yes
71122	Behcet arthritis-up/arm	37	40	41	Yes	Yes	Yes
71123	Behcet arthritis-forearm	37	40	41	Yes	Yes	Yes
71124	Behcet arthritis-hand	37	40	41	Yes	Yes	Yes
71125	Behcet arthritis-pelvis	37	40	41	Yes	Yes	Yes
71126	Behcet arthritis-l/leg	37	40	41	Yes	Yes	Yes
71127	Behcet arthritis-ankle	37	40	41	Yes	Yes	Yes
71128	Behcet arthritis NEC	37	40	41	Yes	Yes	Yes
71129	Behcet arthritis-mult	37	40	41	Yes	Yes	Yes
71130	Dysenter arthrit-unspec	37	39		Yes	Yes	No
71131	Dysenter arthrit-shlder	37	39		Yes	Yes	No
71132	Dysenter arthrit-up/arm	37	39		Yes	Yes	No
71133	Dysenter arthrit-forearm	37	39		Yes	Yes	No
71134	Dysenter arthrit-hand	37	39		Yes	Yes	No
71135	Dysenter arthrit-pelvis	37	39		Yes	Yes	No
71136	Dysenter arthrit-l/leg	37	39		Yes	Yes	No
71137	Dysenter arthrit-ankle	37	39		Yes	Yes	No
71138	Dysenter arthrit NEC	37	39		Yes	Yes	No
71139	Dysenter arthrit-mult	37	39		Yes	Yes	No
71140	Bact arthritis-unspec	37	39		Yes	Yes	No
71141	Bact arthritis-shlder	37	39		Yes	Yes	No
71142	Bact arthritis-up/arm	37	39		Yes	Yes	No
71143	Bact arthritis-forearm	37	39		Yes	Yes	No
71144	Bact arthritis-hand	37	39		Yes	Yes	No
71145	Bact arthritis-pelvis	37	39		Yes	Yes	No
71146	Bact arthritis-l/leg	37	39		Yes	Yes	No
71147	Bact arthritis-ankle	37	39		Yes	Yes	No

71148	Bact arthritis NEC	37	39		Yes	Yes	No
71149	Bact arthritis-mult	37	39		Yes	Yes	No
71150	Viral arthritis-unspec	37	39		Yes	Yes	No
71151	Viral arthritis-shlder	37	39		Yes	Yes	No
71152	Viral arthritis-up/arm	37	39		Yes	Yes	No
71153	Viral arthritis-forearm	37	39		Yes	Yes	No
71154	Viral arthritis-hand	37	39		Yes	Yes	No
71155	Viral arthritis-pelvis	37	39		Yes	Yes	No
71156	Viral arthritis-l/leg	37	39		Yes	Yes	No
71157	Viral arthritis-ankle	37	39		Yes	Yes	No
71158	Viral arthritis NEC	37	39		Yes	Yes	No
71159	Viral arthritis-mult	37	39		Yes	Yes	No
71160	Mycotic arthritis-unspec	37	39		Yes	Yes	No
71161	Mycotic arthritis-shlder	37	39		Yes	Yes	No
71162	Mycotic arthritis-up/arm	37	39		Yes	Yes	No
71163	Mycotic arthrit-forearm	37	39		Yes	Yes	No
71164	Mycotic arthritis-hand	37	39		Yes	Yes	No
71165	Mycotic arthritis-pelvis	37	39		Yes	Yes	No
71166	Mycotic arthritis-l/leg	37	39		Yes	Yes	No
71167	Mycotic arthritis-ankle	37	39		Yes	Yes	No
71168	Mycotic arthritis NEC	37	39		Yes	Yes	No
71169	Mycotic arthritis-mult	37	39		Yes	Yes	No
71170	Helminth arthrit-unspec	37	39		Yes	Yes	No
71171	Helminth arthrit-shlder	37	39		Yes	Yes	No
71172	Helminth arthrit-up/arm	37	39		Yes	Yes	No
71173	Helminth arthrit-forearm	37	39		Yes	Yes	No
71174	Helminth arthrit-hand	37	39		Yes	Yes	No
71175	Helminth arthrit-pelvis	37	39		Yes	Yes	No
71176	Helminth arthrit-l/leg	37	39		Yes	Yes	No
71177	Helminth arthrit-ankle	37	39		Yes	Yes	No
71178	Helminth arthrit NEC	37	39		Yes	Yes	No
71179	Helminth arthrit-mult	37	39		Yes	Yes	No
71180	Inf arthritis NEC-unspec	37	39		Yes	Yes	No
71181	Inf arthritis NEC-shlder	37	39		Yes	Yes	No
71182	Inf arthritis NEC-up/arm	37	39		Yes	Yes	No
71183	Inf arthrit NEC-forearm	37	39		Yes	Yes	No
71184	Inf arthritis NEC-hand	37	39		Yes	Yes	No
71185	Inf arthritis NEC-pelvis	37	39		Yes	Yes	No
71186	Inf arthritis NEC-l/leg	37	39		Yes	Yes	No
71187	Inf arthritis NEC-ankle	37	39		Yes	Yes	No
71188	Inf arthrit NEC-oth site	37	39		Yes	Yes	No
71189	Inf arthritis NEC-mult	37	39		Yes	Yes	No
71190	Inf arthritis NOS-unspec	37	39		Yes	Yes	No
71191	Inf arthritis NOS-shlder	37	39		Yes	Yes	No
71192	Inf arthritis NOS-up/arm	37	39		Yes	Yes	No
71193	Inf arthrit NOS-forearm	37	39		Yes	Yes	No
71194	Inf arthrit NOS-hand	37	39		Yes	Yes	No
71195	Inf arthrit NOS-pelvis	37	39		Yes	Yes	No
71196	Inf arthrit NOS-l/leg	37	39		Yes	Yes	No
71197	Inf arthrit NOS-ankle	37	39		Yes	Yes	No
71198	Inf arthrit NOS-oth site	37	39		Yes	Yes	No
71199	Inf arthritis NOS-mult	37	39		Yes	Yes	No
7140	Rheumatoid arthritis	38	40	41	Yes	Yes	Yes
7141	Felty's syndrome	38	40	41	Yes	Yes	Yes
7142	Syst rheum arthritis NEC	38	40	41	Yes	Yes	Yes
71430	Juv rheum arthritis NOS	38	40	41	Yes	Yes	Yes
71431	Polyart juv rheum arthr	38	40	41	Yes	Yes	Yes
71432	Pauciar juv rheum arthr	38	40	41	Yes	Yes	Yes
71433	Monoart juv rheum arthr	38	40	41	Yes	Yes	Yes
7144	Chr postreum arthritis	38	40	41	Yes	Yes	Yes
71481	Rheumatoid lung	38	40	41	Yes	Yes	Yes
71489	Inflamm polyarthrop NEC	38	40	41	Yes	Yes	Yes
7149	Inflamm polyarthrop NOS	38	40	41	Yes	Yes	Yes
7200	Ankylosing spondylitis	38	40	42	Yes	Yes	Yes

7201	Spinal enthesopathy	38	40	42	Yes	Yes	Yes
7202	Sacroiliitis NEC	38	40	42	Yes	Yes	Yes
72081	Spondylopathy in oth dis	38	40	42	Yes	Yes	Yes
72089	Inflam spondylopathy NEC	38	40	42	Yes	Yes	Yes
7209	Inflam spondylopathy NOS	38	40	42	Yes	Yes	Yes
725	Polymyalgia rheumatica	38	40		Yes	Yes	No
72886	Necrotizing fasciitis	37	39		Yes	Yes	No
73000	Ac osteomyelitis-unspec	37	39		Yes	Yes	No
73001	Ac osteomyelitis-shlder	37	39		Yes	Yes	No
73002	Ac osteomyelitis-up/arm	37	39		Yes	Yes	No
73003	Ac osteomyelitis-forearm	37	39		Yes	Yes	No
73004	Ac osteomyelitis-hand	37	39		Yes	Yes	No
73005	Ac osteomyelitis-pelvis	37	39		Yes	Yes	No
73006	Ac osteomyelitis-l/leg	37	39		Yes	Yes	No
73007	Ac osteomyelitis-ankle	37	39		Yes	Yes	No
73008	Ac osteomyelitis NEC	37	39		Yes	Yes	No
73009	Ac osteomyelitis-mult	37	39		Yes	Yes	No
73010	Chr osteomyelitis-unsp	37	39		Yes	Yes	No
73011	Chr osteomyelit-shlder	37	39		Yes	Yes	No
73012	Chr osteomyelit-up/arm	37	39		Yes	Yes	No
73013	Chr osteomyelit-forearm	37	39		Yes	Yes	No
73014	Chr osteomyelit-hand	37	39		Yes	Yes	No
73015	Chr osteomyelit-pelvis	37	39		Yes	Yes	No
73016	Chr osteomyelit-l/leg	37	39		Yes	Yes	No
73017	Chr osteomyelit-ankle	37	39		Yes	Yes	No
73018	Chr osteomyelit NEC	37	39		Yes	Yes	No
73019	Chr osteomyelit-mult	37	39		Yes	Yes	No
73020	Osteomyelitis NOS-unspec	37	39		Yes	Yes	No
73021	Osteomyelitis NOS-shlder	37	39		Yes	Yes	No
73022	Osteomyelitis NOS-up/arm	37	39		Yes	Yes	No
73023	Osteomyelit NOS-forearm	37	39		Yes	Yes	No
73024	Osteomyelitis NOS-hand	37	39		Yes	Yes	No
73025	Osteomyelitis NOS-pelvis	37	39		Yes	Yes	No
73026	Osteomyelitis NOS-l/leg	37	39		Yes	Yes	No
73027	Osteomyelitis NOS-ankle	37	39		Yes	Yes	No
73028	Osteomyelit NOS-oth site	37	39		Yes	Yes	No
73029	Osteomyelitis NOS-mult	37	39		Yes	Yes	No
73030	Periostitis-unspec	37	39		Yes	Yes	No
73031	Periostitis-shlder	37	39		Yes	Yes	No
73032	Periostitis-up/arm	37	39		Yes	Yes	No
73033	Periostitis-forearm	37	39		Yes	Yes	No
73034	Periostitis-hand	37	39		Yes	Yes	No
73035	Periostitis-pelvis	37	39		Yes	Yes	No
73036	Periostitis-l/leg	37	39		Yes	Yes	No
73037	Periostitis-ankle	37	39		Yes	Yes	No
73038	Periostitis NEC	37	39		Yes	Yes	No
73039	Periostitis-mult	37	39		Yes	Yes	No
73070	Polio osteopathy-unspec	37	39		Yes	Yes	No
73071	Polio osteopathy-shlder	37	39		Yes	Yes	No
73072	Polio osteopathy-up/arm	37	39		Yes	Yes	No
73073	Polio osteopathy-forearm	37	39		Yes	Yes	No
73074	Polio osteopathy-hand	37	39		Yes	Yes	No
73075	Polio osteopathy-pelvis	37	39		Yes	Yes	No
73076	Polio osteopathy-l/leg	37	39		Yes	Yes	No
73077	Polio osteopathy-ankle	37	39		Yes	Yes	No
73078	Polio osteopathy NEC	37	39		Yes	Yes	No
73079	Polio osteopathy-mult	37	39		Yes	Yes	No
73080	Bone infect NEC-unspec	37	39		Yes	Yes	No
73081	Bone infect NEC-shlder	37	39		Yes	Yes	No
73082	Bone infect NEC-up/arm	37	39		Yes	Yes	No
73083	Bone infect NEC-forearm	37	39		Yes	Yes	No
73084	Bone infect NEC-hand	37	39		Yes	Yes	No
73085	Bone infect NEC-pelvis	37	39		Yes	Yes	No
73086	Bone infect NEC-l/leg	37	39		Yes	Yes	No

73087	Bone infect NEC-ankle	37	39		Yes	Yes	No
73088	Bone infect NEC-oth site	37	39		Yes	Yes	No
73089	Bone infect NEC-mult	37	39		Yes	Yes	No
73090	Bone infect NOS-unsp site	37	39		Yes	Yes	No
73091	Bone infect NOS-shlder	37	39		Yes	Yes	No
73092	Bone infect NOS-up/arm	37	39		Yes	Yes	No
73093	Bone infect NOS-forearm	37	39		Yes	Yes	No
73094	Bone infect NOS-hand	37	39		Yes	Yes	No
73095	Bone infect NOS-pelvis	37	39		Yes	Yes	No
73096	Bone infect NOS-l/leg	37	39		Yes	Yes	No
73097	Bone infect NOS-ankle	37	39		Yes	Yes	No
73098	Bone infect NOS-oth site	37	39		Yes	Yes	No
73099	Bone infect NOS-mult	37	39		Yes	Yes	No
73300	Osteoporosis NOS			45	No	No	Yes
73301	Senile osteoporosis			45	No	No	Yes
73302	Idiopathic osteoporosis			45	No	No	Yes
73303	Disuse osteoporosis			45	No	No	Yes
73309	Osteoporosis NEC			45	No	No	Yes
73310	Path fx unspecified site			45	No	No	Yes
73311	Path fx humerus			45	No	No	Yes
73312	Path fx dsl radius ulna			45	No	No	Yes
73313	Path fx vertebrae	157	169	45	Yes	Yes	Yes
73314	Path fx neck of femur	158	170	45	Yes	Yes	Yes
73315	Path fx oth spcf prt fmr	158	170	45	Yes	Yes	Yes
73316	Path fx tibia fibula			45	No	No	Yes
73319	Path fx oth specif site			45	No	No	Yes
73340	Asept necrosis bone NOS	37	39	38	Yes	Yes	Yes
73341	Aseptic necrosis humerus	37	39	38	Yes	Yes	Yes
73342	Aseptic necrosis femur	37	39	38	Yes	Yes	Yes
73343	Asept necro femur condyl	37	39	38	Yes	Yes	Yes
73344	Aseptic necrosis talus	37	39	38	Yes	Yes	Yes
73345	Aseptic necrosis of jaw	37	39	38	Yes	Yes	Yes
73349	Asept necrosis bone NEC	37	39	38	Yes	Yes	Yes
7400	Anencephalus	69	72	72	Yes	Yes	Yes
7401	Craniorachischisis	69	72	72	Yes	Yes	Yes
7402	Iniencephaly	69	72	72	Yes	Yes	Yes
74100	Spin bif w hydroceph NOS	69	72	72	Yes	Yes	Yes
74101	Spin bif w hydrceph-cerv	69	72	72	Yes	Yes	Yes
74102	Spin bif w hydrceph-dors	69	72	72	Yes	Yes	Yes
74103	Spin bif w hydrceph-lumb	69	72	72	Yes	Yes	Yes
74190	Spina bifida	69	72	72	Yes	Yes	Yes
74191	Spina bifida-cerv	69	72	72	Yes	Yes	Yes
74192	Spina bifida-dorsal	69	72	72	Yes	Yes	Yes
74193	Spina bifida-lumbar	69	72	72	Yes	Yes	Yes
7420	Encephalocele	69	72	72	Yes	Yes	Yes
7421	Microcephalus	69	72	72	Yes	Yes	Yes
7422	Reduction deform, brain	69	72	72	Yes	Yes	Yes
7423	Congenital hydrocephalus	69	72	72	Yes	Yes	Yes
7424	Brain anomaly NEC	69	72	72	Yes	Yes	Yes
74251	Diastatomyelia	69	72	72	Yes	Yes	Yes
74253	Hydromyelia	69	72	72	Yes	Yes	Yes
74259	Spinal cord anomaly NEC	69	72	72	Yes	Yes	Yes
7428	Nervous system anom NEC	69	72	72	Yes	Yes	Yes
7429	Nervous system anom NOS	69	72	72	Yes	Yes	Yes
74685	Coronary artery anomaly			89	No	No	Yes
75314	Polycyst kid-autosom rec	131	139	125	Yes	Yes	Yes
75683	Ehlers-danlos syndrome			42	No	No	Yes
7581	Patau's syndrome			68	No	No	Yes
7582	Edwards' syndrome			68	No	No	Yes
75831	Cri-du-chat syndrome			68	No	No	Yes
75832	Velo-cardio-facial synd			68	No	No	Yes
75833	Microdeletions NEC			68	No	No	Yes
75839	Autosomal deletions NEC			68	No	No	Yes
7585	Autosomal anomalies NEC			68	No	No	Yes

7595	Tuberous sclerosis	10	12	10	Yes	Yes	Yes
7596	Hamartoses NEC	10	12	10	Yes	Yes	Yes
75981	Prader-will syndrome			68	No	No	Yes
75982	Marfan syndrome			42	No	No	Yes
75983	Fragile x syndrome			68	No	No	Yes
77181	NB septicemia [sepsis]	2	2		Yes	Yes	No
78001	Coma	75	80		Yes	Yes	No
78003	Persistent vegtv state	75	80		Yes	Yes	No
78031	Febrile convulsions NOS	74	79	80	Yes	Yes	Yes
78032	Complx febrile convulsns	74	79	80	Yes	Yes	Yes
78033	Post traumatic seizures	74	79	80	Yes	Yes	Yes
78039	Convulsions NEC	74	79	80	Yes	Yes	Yes
78072	Functional quadriplegia	67	70		Yes	Yes	No
7854	Gangrene	104	106		Yes	Yes	No
78550	Shock NOS	79	84		Yes	Yes	No
78551	Cardiogenic shock	79	84		Yes	Yes	No
78552	Septic shock	2	2		Yes	Yes	No
78559	Shock w/o trauma NEC	2	2		Yes	Yes	No
7980	Sudden infant death synd	79	84		Yes	Yes	No
7981	Instantaneous death	79	84		Yes	Yes	No
7982	Death within 24 hr sympt	79	84		Yes	Yes	No
7989	Unattended death	79	84		Yes	Yes	No
79901	Asphyxia	79			Yes	No	No
79902	Hypoxemia	79			Yes	No	No
7991	Respiratory arrest	78	83		Yes	Yes	No
7994	Cachexia	21	21		Yes	Yes	No
80000	Closed skull vault fx	155	167		Yes	Yes	No
80001	Cl skull vlt fx w/o coma	155	167		Yes	Yes	No
80002	Cl skull vlt fx-brf coma	155	167		Yes	Yes	No
80003	Cl skull vlt fx-mod coma	154	166		Yes	Yes	No
80004	Cl skl vlt fx-proln coma	154	166		Yes	Yes	No
80005	Cl skul vlt fx-deep coma	154	166		Yes	Yes	No
80006	Cl skull vlt fx-coma NOS	155	167		Yes	Yes	No
80009	Cl skl vlt fx-concus NOS	155	167		Yes	Yes	No
80010	Cl skl vlt fx/cerebr lac	155	167		Yes	Yes	No
80011	Cl skull vlt fx w/o coma	155	167		Yes	Yes	No
80012	Cl skull vlt fx-brf coma	155	167		Yes	Yes	No
80013	Cl skull vlt fx-mod coma	154	166		Yes	Yes	No
80014	Cl skl vlt fx-proln coma	154	166		Yes	Yes	No
80015	Cl skul vlt fx-deep coma	154	166		Yes	Yes	No
80016	Cl skull vlt fx-coma NOS	155	167		Yes	Yes	No
80019	Cl skl vlt fx-concus NOS	155	167		Yes	Yes	No
80020	Cl skl vlt fx/mening hem	155	167		Yes	Yes	No
80021	Cl skull vlt fx w/o coma	155	167		Yes	Yes	No
80022	Cl skull vlt fx-brf coma	155	167		Yes	Yes	No
80023	Cl skull vlt fx-mod coma	154	166		Yes	Yes	No
80024	Cl skl vlt fx-proln coma	154	166		Yes	Yes	No
80025	Cl skul vlt fx-deep coma	154	166		Yes	Yes	No
80026	Cl skull vlt fx-coma NOS	155	167		Yes	Yes	No
80029	Cl skl vlt fx-concus NOS	155	167		Yes	Yes	No
80030	Cl skull vlt fx/hem NEC	155	167		Yes	Yes	No
80031	Cl skull vlt fx w/o coma	155	167		Yes	Yes	No
80032	Cl skull vlt fx-brf coma	155	167		Yes	Yes	No
80033	Cl skull vlt fx-mod coma	154	166		Yes	Yes	No
80034	Cl skl vlt fx-proln coma	154	166		Yes	Yes	No
80035	Cl skul vlt fx-deep coma	154	166		Yes	Yes	No
80036	Cl skull vlt fx-coma NOS	155	167		Yes	Yes	No
80039	Cl skl vlt fx-concus NOS	155	167		Yes	Yes	No
80040	Cl skl vlt fx/br inj NEC	155	167		Yes	Yes	No
80041	Cl skull vlt fx w/o coma	155	167		Yes	Yes	No
80042	Cl skull vlt fx-brf coma	155	167		Yes	Yes	No
80043	Cl skull vlt fx-mod coma	154	166		Yes	Yes	No
80044	Cl skl vlt fx-proln coma	154	166		Yes	Yes	No
80045	Cl skul vlt fx-deep coma	154	166		Yes	Yes	No

80046	Cl skull vlt fx-coma NOS	155	167		Yes	Yes	No
80049	Cl skl vlt fx-concus NOS	155	167		Yes	Yes	No
80050	Opn skull vault fracture	155	167		Yes	Yes	No
80051	Opn skul vlt fx w/o coma	155	167		Yes	Yes	No
80052	Opn skul vlt fx-brf coma	155	167		Yes	Yes	No
80053	Opn skul vlt fx-mod coma	154	166		Yes	Yes	No
80054	Opn skl vlt fx-proln com	154	166		Yes	Yes	No
80055	Opn skl vlt fx-deep coma	154	166		Yes	Yes	No
80056	Opn skul vlt fx-coma NOS	155	167		Yes	Yes	No
80059	Op skl vlt fx-concus NOS	155	167		Yes	Yes	No
80060	Opn skl vlt fx/cereb lac	155	167		Yes	Yes	No
80061	Opn skul vlt fx w/o coma	155	167		Yes	Yes	No
80062	Opn skul vlt fx-brf coma	155	167		Yes	Yes	No
80063	Opn skul vlt fx-mod coma	154	166		Yes	Yes	No
80064	Opn skl vlt fx-proln com	154	166		Yes	Yes	No
80065	Opn skl vlt fx-deep coma	154	166		Yes	Yes	No
80066	Opn skul vlt fx-coma NOS	155	167		Yes	Yes	No
80069	Op skl vlt fx-concus NOS	155	167		Yes	Yes	No
80070	Opn skl vlt fx/menin hem	155	167		Yes	Yes	No
80071	Opn skul vlt fx w/o coma	155	167		Yes	Yes	No
80072	Opn skul vlt fx-brf coma	155	167		Yes	Yes	No
80073	Opn skul vlt fx-mod coma	154	166		Yes	Yes	No
80074	Opn skl vlt fx-proln com	154	166		Yes	Yes	No
80075	Opn skl vlt fx-deep coma	154	166		Yes	Yes	No
80076	Opn skul vlt fx-coma NOS	155	167		Yes	Yes	No
80079	Op skl vlt fx-concus NOS	155	167		Yes	Yes	No
80080	Opn skull vlt fx/hem NEC	155	167		Yes	Yes	No
80081	Opn skul vlt fx w/o coma	155	167		Yes	Yes	No
80082	Opn skul vlt fx-brf coma	155	167		Yes	Yes	No
80083	Opn skul vlt fx-mod coma	154	166		Yes	Yes	No
80084	Opn skl vlt fx-proln com	154	166		Yes	Yes	No
80085	Opn skl vlt fx-deep coma	154	166		Yes	Yes	No
80086	Opn skul vlt fx-coma NOS	155	167		Yes	Yes	No
80089	Op skl vlt fx-concus NOS	155	167		Yes	Yes	No
80090	Op skl vlt fx/br inj NEC	155	167		Yes	Yes	No
80091	Opn skul vlt fx w/o coma	155	167		Yes	Yes	No
80092	Opn skul vlt fx-brf coma	155	167		Yes	Yes	No
80093	Opn skul vlt fx-mod coma	154	166		Yes	Yes	No
80094	Opn skl vlt fx-proln com	154	166		Yes	Yes	No
80095	Op skul vlt fx-deep coma	154	166		Yes	Yes	No
80096	Opn skul vlt fx-coma NOS	155	167		Yes	Yes	No
80099	Op skl vlt fx-concus NOS	155	167		Yes	Yes	No
80100	Clos skull base fracture	155	167		Yes	Yes	No
80101	Cl skul base fx w/o coma	155	167		Yes	Yes	No
80102	Cl skul base fx-brf coma	155	167		Yes	Yes	No
80103	Cl skul base fx-mod coma	154	166		Yes	Yes	No
80104	Cl skl base fx-prol coma	154	166		Yes	Yes	No
80105	Cl skl base fx-deep coma	154	166		Yes	Yes	No
80106	Cl skul base fx-coma NOS	155	167		Yes	Yes	No
80109	Cl skull base fx-concuss	155	167		Yes	Yes	No
80110	Cl skl base fx/cereb lac	155	167		Yes	Yes	No
80111	Cl skul base fx w/o coma	155	167		Yes	Yes	No
80112	Cl skul base fx-brf coma	155	167		Yes	Yes	No
80113	Cl skul base fx-mod coma	154	166		Yes	Yes	No
80114	Cl skl base fx-prol coma	154	166		Yes	Yes	No
80115	Cl skl base fx-deep coma	154	166		Yes	Yes	No
80116	Cl skul base fx-coma NOS	155	167		Yes	Yes	No
80119	Cl skull base fx-concuss	155	167		Yes	Yes	No
80120	Cl skl base fx/menin hem	155	167		Yes	Yes	No
80121	Cl skul base fx w/o coma	155	167		Yes	Yes	No
80122	Cl skul base fx/brf coma	155	167		Yes	Yes	No
80123	Cl skul base fx-mod coma	154	166		Yes	Yes	No
80124	Cl skl base fx-prol coma	154	166		Yes	Yes	No
80125	Cl skl base fx-deep coma	154	166		Yes	Yes	No

80126	Cl skul base fx-coma NOS	155	167		Yes	Yes	No
80129	Cl skull base fx-concuss	155	167		Yes	Yes	No
80130	Cl skull base fx/hem NEC	155	167		Yes	Yes	No
80131	Cl skul base fx w/o coma	155	167		Yes	Yes	No
80132	Cl skul base fx-brf coma	155	167		Yes	Yes	No
80133	Cl skul base fx-mod coma	154	166		Yes	Yes	No
80134	Cl skl base fx-prol coma	154	166		Yes	Yes	No
80135	Cl skl base fx-deep coma	154	166		Yes	Yes	No
80136	Cl skul base fx-coma NOS	155	167		Yes	Yes	No
80139	Cl skull base fx-concuss	155	167		Yes	Yes	No
80140	Cl sk base fx/br inj NEC	155	167		Yes	Yes	No
80141	Cl skul base fx w/o coma	155	167		Yes	Yes	No
80142	Cl skul base fx-brf coma	155	167		Yes	Yes	No
80143	Cl skul base fx-mod coma	154	166		Yes	Yes	No
80144	Cl skl base fx-prol coma	154	166		Yes	Yes	No
80145	Cl skl base fx-deep coma	154	166		Yes	Yes	No
80146	Cl skul base fx-coma NOS	155	167		Yes	Yes	No
80149	Cl skull base fx-concuss	155	167		Yes	Yes	No
80150	Open skull base fracture	155	167		Yes	Yes	No
80151	Opn skl base fx w/o coma	155	167		Yes	Yes	No
80152	Opn skl base fx-brf coma	155	167		Yes	Yes	No
80153	Opn skl base fx-mod coma	154	166		Yes	Yes	No
80154	Op skl base fx-prol coma	154	166		Yes	Yes	No
80155	Op skl base fx-deep coma	154	166		Yes	Yes	No
80156	Opn skl base fx-coma NOS	155	167		Yes	Yes	No
80159	Opn skul base fx-concuss	155	167		Yes	Yes	No
80160	Op skl base fx/cereb lac	155	167		Yes	Yes	No
80161	Opn skl base fx w/o coma	155	167		Yes	Yes	No
80162	Opn skl base fx-brf coma	155	167		Yes	Yes	No
80163	Opn skl base fx-mod coma	154	166		Yes	Yes	No
80164	Op skl base fx-prol coma	154	166		Yes	Yes	No
80165	Op skl base fx-deep coma	154	166		Yes	Yes	No
80166	Opn skl base fx-coma NOS	155	167		Yes	Yes	No
80169	Opn skul base fx-concuss	155	167		Yes	Yes	No
80170	Op skl base fx/menin hem	155	167		Yes	Yes	No
80171	Opn skl base fx w/o coma	155	167		Yes	Yes	No
80172	Opn skl base fx-brf coma	155	167		Yes	Yes	No
80173	Opn skl base fx-mod coma	154	166		Yes	Yes	No
80174	Op skl base fx-prol coma	154	166		Yes	Yes	No
80175	Op skl base fx-deep coma	154	166		Yes	Yes	No
80176	Opn skl base fx-coma NOS	155	167		Yes	Yes	No
80179	Opn skul base fx-concuss	155	167		Yes	Yes	No
80180	Opn skul base fx/hem NEC	155	167		Yes	Yes	No
80181	Opn skl base fx w/o coma	155	167		Yes	Yes	No
80182	Opn skl base fx-brf coma	155	167		Yes	Yes	No
80183	Opn skl base fx-mod coma	154	166		Yes	Yes	No
80184	Op skl base fx-prol coma	154	166		Yes	Yes	No
80185	Op skl base fx-deep coma	154	166		Yes	Yes	No
80186	Opn skl base fx-coma NOS	155	167		Yes	Yes	No
80189	Opn skul base fx-concuss	155	167		Yes	Yes	No
80190	Op sk base fx/br inj NEC	155	167		Yes	Yes	No
80191	Op skul base fx w/o coma	155	167		Yes	Yes	No
80192	Opn skl base fx-brf coma	155	167		Yes	Yes	No
80193	Opn skl base fx-mod coma	154	166		Yes	Yes	No
80194	Op skl base fx-prol coma	154	166		Yes	Yes	No
80195	Op skl base fx-deep coma	154	166		Yes	Yes	No
80196	Opn skl base fx-coma NOS	155	167		Yes	Yes	No
80199	Opn skul base fx-concuss	155	167		Yes	Yes	No
80220	Mandible fx NOS-closed	155	167		Yes	Yes	No
80221	Fx condyl proc mandib-cl	155	167		Yes	Yes	No
80222	Subcondylar fx mandib-cl	155	167		Yes	Yes	No
80223	Fx coron proc mandib-cl	155	167		Yes	Yes	No
80224	Fx ramus NOS-closed	155	167		Yes	Yes	No
80225	Fx angle of jaw-closed	155	167		Yes	Yes	No

80226	Fx symphy mandib body-cl	155	167		Yes	Yes	No
80227	Fx alveolar bord mand-cl	155	167		Yes	Yes	No
80228	Fx mandible body NEC-cl	155	167		Yes	Yes	No
80229	Mult fx mandible-closed	155	167		Yes	Yes	No
80230	Mandible fx NOS-open	155	167		Yes	Yes	No
80231	Fx condyl proc mand-open	155	167		Yes	Yes	No
80232	Subcondyl fx mandib-open	155	167		Yes	Yes	No
80233	Fx coron proc mandib-opn	155	167		Yes	Yes	No
80234	Fx ramus NOS-open	155	167		Yes	Yes	No
80235	Fx angle of jaw-open	155	167		Yes	Yes	No
80236	Fx symphy mandib bdy-opn	155	167		Yes	Yes	No
80237	Fx alv bord mand bdy-opn	155	167		Yes	Yes	No
80238	Fx mandible body NEC-opn	155	167		Yes	Yes	No
80239	Mult fx mandible-open	155	167		Yes	Yes	No
8024	Fx malar/maxillary-close	155	167		Yes	Yes	No
8025	Fx malar/maxillary-open	155	167		Yes	Yes	No
8026	Fx orbital floor-closed	155	167		Yes	Yes	No
8027	Fx orbital floor-open	155	167		Yes	Yes	No
8028	Fx facial bone NEC-close	155	167		Yes	Yes	No
8029	Fx facial bone NEC-open	155	167		Yes	Yes	No
80300	Close skull fracture NEC	155	167		Yes	Yes	No
80301	Cl skull fx NEC w/o coma	155	167		Yes	Yes	No
80302	Cl skull fx NEC-brf coma	155	167		Yes	Yes	No
80303	Cl skull fx NEC-mod coma	154	166		Yes	Yes	No
80304	Cl skl fx NEC-proln coma	154	166		Yes	Yes	No
80305	Cl skul fx NEC-deep coma	154	166		Yes	Yes	No
80306	Cl skull fx NEC-coma NOS	155	167		Yes	Yes	No
80309	Cl skull fx NEC-concuss	155	167		Yes	Yes	No
80310	Cl skl fx NEC/cerebr lac	155	167		Yes	Yes	No
80311	Cl skull fx NEC w/o coma	155	167		Yes	Yes	No
80312	Cl skull fx NEC-brf coma	155	167		Yes	Yes	No
80313	Cl skull fx NEC-mod coma	154	166		Yes	Yes	No
80314	Cl skl fx NEC-proln coma	154	166		Yes	Yes	No
80315	Cl skul fx NEC-deep coma	154	166		Yes	Yes	No
80316	Cl skull fx NEC-coma NOS	155	167		Yes	Yes	No
80319	Cl skull fx NEC-concuss	155	167		Yes	Yes	No
80320	Cl skl fx NEC/mening hem	155	167		Yes	Yes	No
80321	Cl skull fx NEC w/o coma	155	167		Yes	Yes	No
80322	Cl skull fx NEC-brf coma	155	167		Yes	Yes	No
80323	Cl skull fx NEC-mod coma	154	166		Yes	Yes	No
80324	Cl skl fx NEC-proln coma	154	166		Yes	Yes	No
80325	Cl skul fx NEC-deep coma	154	166		Yes	Yes	No
80326	Cl skull fx NEC-coma NOS	155	167		Yes	Yes	No
80329	Cl skull fx NEC-concuss	155	167		Yes	Yes	No
80330	Cl skull fx NEC/hem NEC	155	167		Yes	Yes	No
80331	Cl skull fx NEC w/o coma	155	167		Yes	Yes	No
80332	Cl skull fx NEC-brf coma	155	167		Yes	Yes	No
80333	Cl skull fx NEC-mod coma	154	166		Yes	Yes	No
80334	Cl skl fx NEC-proln coma	154	166		Yes	Yes	No
80335	Cl skul fx NEC-deep coma	154	166		Yes	Yes	No
80336	Cl skull fx NEC-coma NOS	155	167		Yes	Yes	No
80339	Cl skull fx NEC-concuss	155	167		Yes	Yes	No
80340	Cl skl fx NEC/br inj NEC	155	167		Yes	Yes	No
80341	Cl skull fx NEC w/o coma	155	167		Yes	Yes	No
80342	Cl skull fx NEC-brf coma	155	167		Yes	Yes	No
80343	Cl skull fx NEC-mod coma	154	166		Yes	Yes	No
80344	Cl skl fx NEC-proln coma	154	166		Yes	Yes	No
80345	Cl skul fx NEC-deep coma	154	166		Yes	Yes	No
80346	Cl skull fx NEC-coma NOS	155	167		Yes	Yes	No
80349	Cl skull fx NEC-concuss	155	167		Yes	Yes	No
80350	Open skull fracture NEC	155	167		Yes	Yes	No
80351	Opn skul fx NEC w/o coma	155	167		Yes	Yes	No
80352	Opn skul fx NEC-brf coma	155	167		Yes	Yes	No
80353	Opn skul fx NEC-mod coma	154	166		Yes	Yes	No

80354	Opn skl fx NEC-prol coma	154	166		Yes	Yes	No
80355	Opn skl fx NEC-deep coma	154	166		Yes	Yes	No
80356	Opn skul fx NEC-coma NOS	155	167		Yes	Yes	No
80359	Opn skull fx NEC-concuss	155	167		Yes	Yes	No
80360	Opn skl fx NEC/cereb lac	155	167		Yes	Yes	No
80361	Opn skul fx NEC w/o coma	155	167		Yes	Yes	No
80362	Opn skul fx NEC-brf coma	155	167		Yes	Yes	No
80363	Opn skul fx NEC-mod coma	154	166		Yes	Yes	No
80364	Opn skl fx NEC-proln coma	154	166		Yes	Yes	No
80365	Opn skl fx NEC-deep coma	154	166		Yes	Yes	No
80366	Opn skul fx NEC-coma NOS	155	167		Yes	Yes	No
80369	Opn skull fx NEC-concuss	155	167		Yes	Yes	No
80370	Opn skl fx NEC/menin hem	155	167		Yes	Yes	No
80371	Opn skul fx NEC w/o coma	155	167		Yes	Yes	No
80372	Opn skul fx NEC-brf coma	155	167		Yes	Yes	No
80373	Opn skul fx NEC-mod coma	154	166		Yes	Yes	No
80374	Opn skl fx NEC-prol coma	154	166		Yes	Yes	No
80375	Opn skl fx NEC-deep coma	154	166		Yes	Yes	No
80376	Opn skul fx NEC-coma NOS	155	167		Yes	Yes	No
80379	Opn skull fx NEC-concuss	155	167		Yes	Yes	No
80380	Opn skull fx NEC/hem NEC	155	167		Yes	Yes	No
80381	Opn skul fx NEC w/o coma	155	167		Yes	Yes	No
80382	Opn skul fx NEC-brf coma	155	167		Yes	Yes	No
80383	Opn skul fx NEC-mod coma	154	166		Yes	Yes	No
80384	Opn skl fx NEC-prol coma	154	166		Yes	Yes	No
80385	Opn skl fx NEC-deep coma	154	166		Yes	Yes	No
80386	Opn skul fx NEC-coma NOS	155	167		Yes	Yes	No
80389	Opn skull fx NEC-concuss	155	167		Yes	Yes	No
80390	Op skl fx NEC/br inj NEC	155	167		Yes	Yes	No
80391	Opn skul fx NEC w/o coma	155	167		Yes	Yes	No
80392	Opn skul fx NEC-brf coma	155	167		Yes	Yes	No
80393	Opn skul fx NEC-mod coma	154	166		Yes	Yes	No
80394	Opn skl fx NEC-prol coma	154	166		Yes	Yes	No
80395	Opn skl fx NEC-deep coma	154	166		Yes	Yes	No
80396	Opn skul fx NEC-coma NOS	155	167		Yes	Yes	No
80399	Opn skull fx NEC-concuss	155	167		Yes	Yes	No
80400	Cl skul fx w oth bone fx	155	167		Yes	Yes	No
80401	Cl skl w oth fx w/o coma	155	167		Yes	Yes	No
80402	Cl skl w oth fx-brf coma	155	167		Yes	Yes	No
80403	Cl skl w oth fx-mod coma	154	166		Yes	Yes	No
80404	Cl skl/oth fx-proln coma	154	166		Yes	Yes	No
80405	Cl skul/oth fx-deep coma	154	166		Yes	Yes	No
80406	Cl skl w oth fx-coma NOS	155	167		Yes	Yes	No
80409	Cl skul w oth fx-concuss	155	167		Yes	Yes	No
80410	Cl sk w oth fx/cereb lac	155	167		Yes	Yes	No
80411	Cl skl w oth fx w/o coma	155	167		Yes	Yes	No
80412	Cl skl w oth fx-brf coma	155	167		Yes	Yes	No
80413	Cl skl w oth fx-mod coma	154	166		Yes	Yes	No
80414	Cl skl/oth fx-proln coma	154	166		Yes	Yes	No
80415	Cl skul/oth fx-deep coma	154	166		Yes	Yes	No
80416	Cl skl w oth fx-coma NOS	155	167		Yes	Yes	No
80419	Cl skul w oth fx-concuss	155	167		Yes	Yes	No
80420	Cl skl/oth fx/mening hem	155	167		Yes	Yes	No
80421	Cl skl w oth fx w/o coma	155	167		Yes	Yes	No
80422	Cl skl w oth fx-brf coma	155	167		Yes	Yes	No
80423	Cl skl w oth fx-mod coma	154	166		Yes	Yes	No
80424	Cl skl/oth fx-proln coma	154	166		Yes	Yes	No
80425	Cl skul/oth fx-deep coma	154	166		Yes	Yes	No
80426	Cl skl w oth fx-coma NOS	155	167		Yes	Yes	No
80429	Cl skul w oth fx-concuss	155	167		Yes	Yes	No
80430	Cl skul w oth fx/hem NEC	155	167		Yes	Yes	No
80431	Cl skl w oth fx w/o coma	155	167		Yes	Yes	No
80432	Cl skl w oth fx-brf coma	155	167		Yes	Yes	No
80433	Cl skl w oth fx-mod coma	154	166		Yes	Yes	No

80434	Cl skl/oth fx-proln coma	154	166		Yes	Yes	No
80435	Cl skul/oth fx-deep coma	154	166		Yes	Yes	No
80436	Cl skl w oth fx-coma NOS	155	167		Yes	Yes	No
80439	Cl skul w oth fx-concuss	155	167		Yes	Yes	No
80440	Cl skl/oth fx/br inj NEC	155	167		Yes	Yes	No
80441	Cl skl w oth fx w/o coma	155	167		Yes	Yes	No
80442	Cl skl w oth fx-brf coma	155	167		Yes	Yes	No
80443	Cl skl w oth fx-mod coma	154	166		Yes	Yes	No
80444	Cl skl/oth fx-proln coma	154	166		Yes	Yes	No
80445	Cl skul/oth fx-deep coma	154	166		Yes	Yes	No
80446	Cl skl w oth fx-coma NOS	155	167		Yes	Yes	No
80449	Cl skul w oth fx-concuss	155	167		Yes	Yes	No
80450	Opn skull fx/oth bone fx	155	167		Yes	Yes	No
80451	Opn skul/oth fx w/o coma	155	167		Yes	Yes	No
80452	Opn skul/oth fx-brf coma	155	167		Yes	Yes	No
80453	Opn skul/oth fx-mod coma	154	166		Yes	Yes	No
80454	Opn skl/oth fx-prol coma	154	166		Yes	Yes	No
80455	Opn skl/oth fx-deep coma	154	166		Yes	Yes	No
80456	Opn skul/oth fx-coma NOS	155	167		Yes	Yes	No
80459	Opn skull/oth fx-concuss	155	167		Yes	Yes	No
80460	Opn skl/oth fx/cereb lac	155	167		Yes	Yes	No
80461	Opn skul/oth fx w/o coma	155	167		Yes	Yes	No
80462	Opn skul/oth fx-brf coma	155	167		Yes	Yes	No
80463	Opn skul/oth fx-mod coma	154	166		Yes	Yes	No
80464	Opn skl/oth fx-prol coma	154	166		Yes	Yes	No
80465	Opn skl/oth fx-deep coma	154	166		Yes	Yes	No
80466	Opn skul/oth fx-coma NOS	155	167		Yes	Yes	No
80469	Opn skull/oth fx-concuss	155	167		Yes	Yes	No
80470	Opn skl/oth fx/menin hem	155	167		Yes	Yes	No
80471	Opn skul/oth fx w/o coma	155	167		Yes	Yes	No
80472	Opn skul/oth fx-brf coma	155	167		Yes	Yes	No
80473	Opn skul/oth fx-mod coma	154	166		Yes	Yes	No
80474	Opn skl/oth fx-prol coma	154	166		Yes	Yes	No
80475	Opn skl/oth fx-deep coma	154	166		Yes	Yes	No
80476	Opn skul/oth fx-coma NOS	155	167		Yes	Yes	No
80479	Opn skull/oth fx-concuss	155	167		Yes	Yes	No
80480	Opn skl w oth fx/hem NEC	155	167		Yes	Yes	No
80481	Opn skul/oth fx w/o coma	155	167		Yes	Yes	No
80482	Opn skul/oth fx-brf coma	155	167		Yes	Yes	No
80483	Opn skul/oth fx-mod coma	154	166		Yes	Yes	No
80484	Opn skl/oth fx-prol coma	154	166		Yes	Yes	No
80485	Opn skl/oth fx-deep coma	154	166		Yes	Yes	No
80486	Opn skul/oth fx-coma NOS	155	167		Yes	Yes	No
80489	Opn skull/oth fx-concuss	155	167		Yes	Yes	No
80490	Op skl/oth fx/br inj NEC	155	167		Yes	Yes	No
80491	Opn skul/oth fx w/o coma	155	167		Yes	Yes	No
80492	Opn skul/oth fx-brf coma	155	167		Yes	Yes	No
80493	Opn skul/oth fx-mod coma	154	166		Yes	Yes	No
80494	Opn skl/oth fx-prol coma	154	166		Yes	Yes	No
80495	Opn skl/oth fx-deep coma	154	166		Yes	Yes	No
80496	Opn skul/oth fx-coma NOS	155	167		Yes	Yes	No
80499	Opn skull/oth fx-concuss	155	167		Yes	Yes	No
80500	Fx cervical vert NOS-cl	157	169		Yes	Yes	No
80501	Fx c1 vertebra-closed	157	169		Yes	Yes	No
80502	Fx c2 vertebra-closed	157	169		Yes	Yes	No
80503	Fx c3 vertebra-closed	157	169		Yes	Yes	No
80504	Fx c4 vertebra-closed	157	169		Yes	Yes	No
80505	Fx c5 vertebra-closed	157	169		Yes	Yes	No
80506	Fx c6 vertebra-closed	157	169		Yes	Yes	No
80507	Fx c7 vertebra-closed	157	169		Yes	Yes	No
80508	Fx mult cervical vert-cl	157	169		Yes	Yes	No
80510	Fx cervical vert NOS-opn	157	169		Yes	Yes	No
80511	Fx c1 vertebra-open	157	169		Yes	Yes	No
80512	Fx c2 vertebra-open	157	169		Yes	Yes	No

80513	Fx c3 vertebra-open	157	169		Yes	Yes	No
80514	Fx c4 vertebra-open	157	169		Yes	Yes	No
80515	Fx c5 vertebra-open	157	169		Yes	Yes	No
80516	Fx c6 vertebra-open	157	169		Yes	Yes	No
80517	Fx c7 vertebra-open	157	169		Yes	Yes	No
80518	Fx mlt cervical vert-opn	157	169		Yes	Yes	No
8052	Fx dorsal vertebra-close	157	169		Yes	Yes	No
8053	Fx dorsal vertebra-open	157	169		Yes	Yes	No
8054	Fx lumbar vertebra-close	157	169		Yes	Yes	No
8055	Fx lumbar vertebra-open	157	169		Yes	Yes	No
8056	Fx sacrum/coccyx-closed	157	169		Yes	Yes	No
8057	Fx sacrum/coccyx-open	157	169		Yes	Yes	No
8058	Vertebral fx NOS-closed	157	169		Yes	Yes	No
8059	Vertebral fx NOS-open	157	169		Yes	Yes	No
80600	C1-c4 fx-cl/cord inj NOS	69	72		Yes	Yes	No
80601	C1-c4 fx-cl/com cord les	67	70		Yes	Yes	No
80602	C1-c4 fx-cl/ant cord syn	69	72		Yes	Yes	No
80603	C1-c4 fx-cl/cen cord syn	69	72		Yes	Yes	No
80604	C1-c4 fx-cl/cord inj NEC	69	72		Yes	Yes	No
80605	C5-c7 fx-cl/cord inj NOS	69	72		Yes	Yes	No
80606	C5-c7 fx-cl/com cord les	67	70		Yes	Yes	No
80607	C5-c7 fx-cl/ant cord syn	69	72		Yes	Yes	No
80608	C5-c7 fx-cl/cen cord syn	69	72		Yes	Yes	No
80609	C5-c7 fx-cl/cord inj NEC	69	72		Yes	Yes	No
80610	C1-c4 fx-op/cord inj NOS	69	72		Yes	Yes	No
80611	C1-c4 fx-op/com cord les	67	70		Yes	Yes	No
80612	C1-c4 fx-op/ant cord syn	69	72		Yes	Yes	No
80613	C1-c4 fx-op/cen cord syn	69	72		Yes	Yes	No
80614	C1-c4 fx-op/cord inj NEC	69	72		Yes	Yes	No
80615	C5-c7 fx-op/cord inj NOS	69	72		Yes	Yes	No
80616	C5-c7 fx-op/com cord les	67	70		Yes	Yes	No
80617	C5-c7 fx-op/ant cord syn	69	72		Yes	Yes	No
80618	C5-c7 fx-op/cen cord syn	69	72		Yes	Yes	No
80619	C5-c7 fx-op/cord inj NEC	69	72		Yes	Yes	No
80620	T1-t6 fx-cl/cord inj NOS	69	72		Yes	Yes	No
80621	T1-t6 fx-cl/com cord les	68	71		Yes	Yes	No
80622	T1-t6 fx-cl/ant cord syn	69	72		Yes	Yes	No
80623	T1-t6 fx-cl/cen cord syn	69	72		Yes	Yes	No
80624	T1-t6 fx-cl/cord inj NEC	69	72		Yes	Yes	No
80625	T7-t12 fx-cl/crd inj NOS	69	72		Yes	Yes	No
80626	T7-t12 fx-cl/com crd les	68	71		Yes	Yes	No
80627	T7-t12 fx-cl/ant crd syn	69	72		Yes	Yes	No
80628	T7-t12 fx-cl/cen crd syn	69	72		Yes	Yes	No
80629	T7-t12 fx-cl/crd inj NEC	69	72		Yes	Yes	No
80630	T1-t6 fx-op/cord inj NOS	69	72		Yes	Yes	No
80631	T1-t6 fx-op/com cord les	68	71		Yes	Yes	No
80632	T1-t6 fx-op/ant cord syn	69	72		Yes	Yes	No
80633	T1-t6 fx-op/cen cord syn	69	72		Yes	Yes	No
80634	T1-t6 fx-op/cord inj NEC	69	72		Yes	Yes	No
80635	T7-t12 fx-op/crd inj NOS	69	72		Yes	Yes	No
80636	T7-t12 fx-op/com crd les	68	71		Yes	Yes	No
80637	T7-t12 fx-op/ant crd syn	69	72		Yes	Yes	No
80638	T7-t12 fx-op/cen crd syn	69	72		Yes	Yes	No
80639	T7-t12 fx-op/crd inj NEC	69	72		Yes	Yes	No
8064	Cl lumbar fx w cord inj	69	72		Yes	Yes	No
8065	Opn lumbar fx w cord inj	69	72		Yes	Yes	No
80660	Fx sacrum-cl/crd inj NOS	69	72		Yes	Yes	No
80661	Fx sacr-cl/cauda equ les	69	72		Yes	Yes	No
80662	Fx sacr-cl/cauda inj NEC	69	72		Yes	Yes	No
80669	Fx sacrum-cl/crd inj NEC	69	72		Yes	Yes	No
80670	Fx sacrum-op/crd inj NOS	69	72		Yes	Yes	No
80671	Fx sacr-op/cauda equ les	69	72		Yes	Yes	No
80672	Fx sacr-op/cauda inj NEC	69	72		Yes	Yes	No
80679	Fx sacrum-op/crd inj NEC	69	72		Yes	Yes	No

8068	Vert fx NOS-cl w crd inj	69	72		Yes	Yes	No
8069	Vert fx NOS-op w crd inj	69	72		Yes	Yes	No
8080	Fracture acetabulum-clos	158	170		Yes	Yes	No
8081	Fracture acetabulum-open	158	170		Yes	Yes	No
8082	Fracture of pubis-closed	158	170		Yes	Yes	No
8083	Fracture of pubis-open	158	170		Yes	Yes	No
80841	Fracture of ilium-closed	158	170		Yes	Yes	No
80842	Fracture ischium-closed	158	170		Yes	Yes	No
80843	Pelv fx-clos/pelv disrup	158	170		Yes	Yes	No
80844	Pelv fx-cl w/o plv disrp	158	170		Yes	Yes	No
80849	Pelvic fracture NEC-clos	158	170		Yes	Yes	No
80851	Fracture of ilium-open	158	170		Yes	Yes	No
80852	Fracture of ischium-open	158	170		Yes	Yes	No
80853	Pelv fx-open/pelv disrup	158	170		Yes	Yes	No
80854	Pelv fx-opn w/o pelv dis	158	170		Yes	Yes	No
80859	Pelvic fracture NEC-open	158	170		Yes	Yes	No
8088	Pelvic fracture NOS-clos	158	170		Yes	Yes	No
8089	Pelvic fracture NOS-open	158	170		Yes	Yes	No
82000	Fx femur intrcaps NOS-cl	158	170		Yes	Yes	No
82001	Fx up femur epiphy-clos	158	170		Yes	Yes	No
82002	Fx femur, midcervic-clos	158	170		Yes	Yes	No
82003	Fx base femoral nck-clos	158	170		Yes	Yes	No
82009	Fx femur intrcaps NEC-cl	158	170		Yes	Yes	No
82010	Fx femur intrcap NOS-opn	158	170		Yes	Yes	No
82011	Fx up femur epiphy-open	158	170		Yes	Yes	No
82012	Fx femur, midcervic-open	158	170		Yes	Yes	No
82013	Fx base femoral nck-open	158	170		Yes	Yes	No
82019	Fx femur intrcap NEC-opn	158	170		Yes	Yes	No
82020	Trochanteric fx NOS-clos	158	170		Yes	Yes	No
82021	Intertrochanteric fx-cl	158	170		Yes	Yes	No
82022	Subtrochanteric fx-close	158	170		Yes	Yes	No
82030	Trochanteric fx NOS-open	158	170		Yes	Yes	No
82031	Intertrochanteric fx-opn	158	170		Yes	Yes	No
82032	Subtrochanteric fx-open	158	170		Yes	Yes	No
8208	Fx neck of femur NOS-cl	158	170		Yes	Yes	No
8209	Fx neck of femur NOS-opn	158	170		Yes	Yes	No
82100	Fx femur NOS-closed	158	170		Yes	Yes	No
82101	Fx femur shaft-closed	158	170		Yes	Yes	No
82110	Fx femur NOS-open	158	170		Yes	Yes	No
82111	Fx femur shaft-open	158	170		Yes	Yes	No
82120	Fx low end femur NOS-cl	158	170		Yes	Yes	No
82121	Fx femoral condyle-close	158	170		Yes	Yes	No
82122	Fx low femur epiphy-clos	158	170		Yes	Yes	No
82123	Supracondyl fx femur-cl	158	170		Yes	Yes	No
82129	Fx low end femur NEC-cl	158	170		Yes	Yes	No
82130	Fx low end femur NOS-opn	158	170		Yes	Yes	No
82131	Fx femoral condyle-open	158	170		Yes	Yes	No
82132	Fx low femur epiphy-open	158	170		Yes	Yes	No
82133	Supracondyl fx femur-opn	158	170		Yes	Yes	No
82139	Fx low end femur NEC-opn	158	170		Yes	Yes	No
83500	Dislocat hip NOS-closed	158	170		Yes	Yes	No
83501	Posterior disloc hip-cl	158	170		Yes	Yes	No
83502	Obturator disloc hip-cl	158	170		Yes	Yes	No
83503	Ant disloc hip NEC-clos	158	170		Yes	Yes	No
83510	Dislocation hip NOS-open	158	170		Yes	Yes	No
83511	Posterior disloc hip-opn	158	170		Yes	Yes	No
83512	Obturator disloc hip-opn	158	170		Yes	Yes	No
83513	Ant disloc hip NEC-open	158	170		Yes	Yes	No
8502	Concussion-moderate coma	155	167		Yes	Yes	No
8503	Concussion-prolong coma	155	167		Yes	Yes	No
8504	Concussion-deep coma	155	167		Yes	Yes	No
85100	Cerebral cortex contusion	155	167		Yes	Yes	No
85101	Cortex contusion-no coma	155	167		Yes	Yes	No
85102	Cortex contus-brief coma	155	167		Yes	Yes	No

85103	Cortex contus-mod coma	154	166		Yes	Yes	No
85104	Cortx contus-prolng coma	154	166		Yes	Yes	No
85105	Cortex contus-deep coma	154	166		Yes	Yes	No
85106	Cortex contus-coma NOS	155	167		Yes	Yes	No
85109	Cortex contus-concus NOS	155	167		Yes	Yes	No
85110	Cortex contusion/opn wnd	155	167		Yes	Yes	No
85111	Opn cortx contus-no coma	155	167		Yes	Yes	No
85112	Opn cort contus-brf coma	155	167		Yes	Yes	No
85113	Opn cort contus-mod coma	154	166		Yes	Yes	No
85114	Opn cort contu-prol coma	154	166		Yes	Yes	No
85115	Opn cort contu-deep coma	154	166		Yes	Yes	No
85116	Opn cort contus-coma NOS	155	167		Yes	Yes	No
85119	Opn cortx contus-concuss	155	167		Yes	Yes	No
85120	Cerebral cortex lacerat	155	167		Yes	Yes	No
85121	Cortex lacerat w/o coma	155	167		Yes	Yes	No
85122	Cortex lacera-brief coma	155	167		Yes	Yes	No
85123	Cortex lacerat-mod coma	154	166		Yes	Yes	No
85124	Cortex lacerat-prol coma	154	166		Yes	Yes	No
85125	Cortex lacerat-deep coma	154	166		Yes	Yes	No
85126	Cortex lacerat-coma NOS	155	167		Yes	Yes	No
85129	Cortex lacerat-concuss	155	167		Yes	Yes	No
85130	Cortex lacer w opn wound	155	167		Yes	Yes	No
85131	Opn cortex lacer-no coma	155	167		Yes	Yes	No
85132	Opn cortx lac-brief coma	155	167		Yes	Yes	No
85133	Opn cortx lacer-mod coma	154	166		Yes	Yes	No
85134	Opn cortx lac-proln coma	154	166		Yes	Yes	No
85135	Opn cortex lac-deep coma	154	166		Yes	Yes	No
85136	Opn cortx lacer-coma NOS	155	167		Yes	Yes	No
85139	Opn cortx lacer-concuss	155	167		Yes	Yes	No
85140	Cerebel/brain stm contus	155	167		Yes	Yes	No
85141	Cerebell contus w/o coma	155	167		Yes	Yes	No
85142	Cerebell contus-brf coma	155	167		Yes	Yes	No
85143	Cerebell contus-mod coma	154	166		Yes	Yes	No
85144	Cerebel contus-prol coma	154	166		Yes	Yes	No
85145	Cerebel contus-deep coma	154	166		Yes	Yes	No
85146	Cerebell contus-coma NOS	155	167		Yes	Yes	No
85149	Cerebell contus-concuss	155	167		Yes	Yes	No
85150	Cerebel contus w opn wnd	155	167		Yes	Yes	No
85151	Opn cerebe cont w/o coma	155	167		Yes	Yes	No
85152	Opn cerebe cont-brf coma	155	167		Yes	Yes	No
85153	Opn cerebe cont-mod coma	154	166		Yes	Yes	No
85154	Opn cerebe cont-prol com	154	166		Yes	Yes	No
85155	Opn cerebe cont-deep com	154	166		Yes	Yes	No
85156	Opn cerebe cont-coma NOS	155	167		Yes	Yes	No
85159	Opn cerebel cont-concuss	155	167		Yes	Yes	No
85160	Cerebel/brain stem lacer	155	167		Yes	Yes	No
85161	Cerebel lacerat w/o coma	155	167		Yes	Yes	No
85162	Cerebel lacer-brief coma	155	167		Yes	Yes	No
85163	Cerebel lacerat-mod coma	154	166		Yes	Yes	No
85164	Cerebel lacer-proln coma	154	166		Yes	Yes	No
85165	Cerebell lacer-deep coma	154	166		Yes	Yes	No
85166	Cerebel lacerat-coma NOS	155	167		Yes	Yes	No
85169	Cerebel lacer-concussion	155	167		Yes	Yes	No
85170	Cerebel lacer w open wnd	155	167		Yes	Yes	No
85171	Opn cerebel lac w/o coma	155	167		Yes	Yes	No
85172	Opn cerebel lac-brf coma	155	167		Yes	Yes	No
85173	Opn cerebel lac-mod coma	154	166		Yes	Yes	No
85174	Opn cerebe lac-prol coma	154	166		Yes	Yes	No
85175	Opn cerebe lac-deep coma	154	166		Yes	Yes	No
85176	Opn cerebel lac-coma NOS	155	167		Yes	Yes	No
85179	Opn cerebell lac-concuss	155	167		Yes	Yes	No
85180	Brain laceration NEC	155	167		Yes	Yes	No
85181	Brain lacer NEC w/o coma	155	167		Yes	Yes	No
85182	Brain lac NEC-brief coma	155	167		Yes	Yes	No

85183	Brain lacer NEC-mod coma	154	166		Yes	Yes	No
85184	Brain lac NEC-proln coma	154	166		Yes	Yes	No
85185	Brain lac NEC-deep coma	154	166		Yes	Yes	No
85186	Brain lacer NEC-coma NOS	155	167		Yes	Yes	No
85189	Brain lacer NEC-concuss	155	167		Yes	Yes	No
85190	Brain lac NEC w open wnd	155	167		Yes	Yes	No
85191	Opn brain lacer w/o coma	155	167		Yes	Yes	No
85192	Opn brain lac-brief coma	155	167		Yes	Yes	No
85193	Opn brain lacer-mod coma	154	166		Yes	Yes	No
85194	Opn brain lac-proln coma	154	166		Yes	Yes	No
85195	Open brain lac-deep coma	154	166		Yes	Yes	No
85196	Opn brain lacer-coma NOS	155	167		Yes	Yes	No
85199	Open brain lacer-concuss	155	167		Yes	Yes	No
85200	Traum subarachnoid hem	155	167		Yes	Yes	No
85201	Subarachnoid hem-no coma	155	167		Yes	Yes	No
85202	Subarach hem-brief coma	155	167		Yes	Yes	No
85203	Subarach hem-mod coma	154	166		Yes	Yes	No
85204	Subarach hem-prolng coma	154	166		Yes	Yes	No
85205	Subarach hem-deep coma	154	166		Yes	Yes	No
85206	Subarach hem-coma NOS	155	167		Yes	Yes	No
85209	Subarach hem-concussion	155	167		Yes	Yes	No
85210	Subarach hem w opn wound	155	167		Yes	Yes	No
85211	Opn subarach hem-no coma	155	167		Yes	Yes	No
85212	Op subarach hem-brf coma	155	167		Yes	Yes	No
85213	Op subarach hem-mod coma	154	166		Yes	Yes	No
85214	Op subarach hem-prol com	154	166		Yes	Yes	No
85215	Op subarach hem-deep com	154	166		Yes	Yes	No
85216	Op subarach hem-coma NOS	155	167		Yes	Yes	No
85219	Opn subarach hem-concuss	155	167		Yes	Yes	No
85220	Traumatic subdural hem	155	167		Yes	Yes	No
85221	Subdural hem w/o coma	155	167		Yes	Yes	No
85222	Subdural hem-brief coma	155	167		Yes	Yes	No
85223	Subdural hemorr-mod coma	154	166		Yes	Yes	No
85224	Subdural hem-prolng coma	154	166		Yes	Yes	No
85225	Subdural hem-deep coma	154	166		Yes	Yes	No
85226	Subdural hemorr-coma NOS	155	167		Yes	Yes	No
85229	Subdural hem-concussion	155	167		Yes	Yes	No
85230	Subdural hem w opn wound	155	167		Yes	Yes	No
85231	Open subdur hem w/o coma	155	167		Yes	Yes	No
85232	Opn subdur hem-brf coma	155	167		Yes	Yes	No
85233	Opn subdur hem-mod coma	154	166		Yes	Yes	No
85234	Opn subdur hem-prol coma	154	166		Yes	Yes	No
85235	Opn subdur hem-deep coma	154	166		Yes	Yes	No
85236	Opn subdur hem-coma NOS	155	167		Yes	Yes	No
85239	Opn subdur hem-concuss	155	167		Yes	Yes	No
85240	Traumatic extradural hem	155	167		Yes	Yes	No
85241	Extradural hem w/o coma	155	167		Yes	Yes	No
85242	Extradur hem-brief coma	155	167		Yes	Yes	No
85243	Extradural hem-mod coma	154	166		Yes	Yes	No
85244	Extradur hem-proln coma	154	166		Yes	Yes	No
85245	Extradural hem-deep coma	154	166		Yes	Yes	No
85246	Extradural hem-coma NOS	155	167		Yes	Yes	No
85249	Extadural hem-concuss	155	167		Yes	Yes	No
85250	Extradural hem w opn wnd	155	167		Yes	Yes	No
85251	Extradural hemor-no coma	155	167		Yes	Yes	No
85252	Extradur hem-brief coma	155	167		Yes	Yes	No
85253	Extradural hem-mod coma	154	166		Yes	Yes	No
85254	Extradur hem-proln coma	154	166		Yes	Yes	No
85255	Extradur hem-deep coma	154	166		Yes	Yes	No
85256	Extradural hem-coma NOS	155	167		Yes	Yes	No
85259	Extradural hem-concuss	155	167		Yes	Yes	No
85300	Traumatic brain hem NEC	155	167		Yes	Yes	No
85301	Brain hem NEC w/o coma	155	167		Yes	Yes	No
85302	Brain hem NEC-brief coma	155	167		Yes	Yes	No

85303	Brain hem NEC-mod coma	154	166		Yes	Yes	No
85304	Brain hem NEC-proln coma	154	166		Yes	Yes	No
85305	Brain hem NEC-deep coma	154	166		Yes	Yes	No
85306	Brain hem NEC-coma NOS	155	167		Yes	Yes	No
85309	Brain hem NEC-concussion	155	167		Yes	Yes	No
85310	Brain hem NEC w opn wnd	155	167		Yes	Yes	No
85311	Brain hem opn w/o coma	155	167		Yes	Yes	No
85312	Brain hem opn-brf coma	155	167		Yes	Yes	No
85313	Brain hem open-mod coma	154	166		Yes	Yes	No
85314	Brain hem opn-proln coma	154	166		Yes	Yes	No
85315	Brain hem open-deep coma	154	166		Yes	Yes	No
85316	Brain hem open-coma NOS	155	167		Yes	Yes	No
85319	Brain hem opn-concussion	155	167		Yes	Yes	No
85400	Brain injury NEC	155	167		Yes	Yes	No
85401	Brain injury NEC-no coma	155	167		Yes	Yes	No
85402	Brain inj NEC-brief coma	155	167		Yes	Yes	No
85403	Brain inj NEC-mod coma	154	166		Yes	Yes	No
85404	Brain inj NEC-proln coma	154	166		Yes	Yes	No
85405	Brain inj NEC-deep coma	154	166		Yes	Yes	No
85406	Brain inj NEC-coma NOS	155	167		Yes	Yes	No
85409	Brain inj NEC-concussion	155	167		Yes	Yes	No
85410	Brain injury w opn wnd	155	167		Yes	Yes	No
85411	Opn brain inj w/o coma	155	167		Yes	Yes	No
85412	Opn brain inj-brief coma	155	167		Yes	Yes	No
85413	Opn brain inj-mod coma	154	166		Yes	Yes	No
85414	Opn brain inj-proln coma	154	166		Yes	Yes	No
85415	Opn brain inj-deep coma	154	166		Yes	Yes	No
85416	Open brain inj-coma NOS	155	167		Yes	Yes	No
85419	Opn brain inj-concussion	155	167		Yes	Yes	No
8870	Amput below elb, unilat	161	173		Yes	Yes	No
8871	Amp below elb, unil-comp	161	173		Yes	Yes	No
8872	Amput abv elbow, unilat	161	173		Yes	Yes	No
8873	Amput abv elb, unil-comp	161	173		Yes	Yes	No
8874	Amputat arm, unilat NOS	161	173		Yes	Yes	No
8875	Amput arm, unil NOS-comp	161	173		Yes	Yes	No
8876	Amputation arm, bilat	161	173		Yes	Yes	No
8877	Amputat arm, bilat-compl	161	173		Yes	Yes	No
8950	Amputation toe	161	173		Yes	Yes	No
8951	Amputation toe-complicat	161	173		Yes	Yes	No
8960	Amputation foot, unilat	161	173		Yes	Yes	No
8961	Amput foot, unilat-compl	161	173		Yes	Yes	No
8962	Amputation foot, bilat	161	173		Yes	Yes	No
8963	Amputat foot, bilat-comp	161	173		Yes	Yes	No
8970	Amput below knee, unilat	161	173		Yes	Yes	No
8971	Amputat bk, unilat-compl	161	173		Yes	Yes	No
8972	Amput above knee, unilat	161	173		Yes	Yes	No
8973	Amput abv kn, unil-compl	161	173		Yes	Yes	No
8974	Amputat leg, unilat NOS	161	173		Yes	Yes	No
8975	Amput leg, unil NOS-comp	161	173		Yes	Yes	No
8976	Amputation leg, bilat	161	173		Yes	Yes	No
8977	Amputat leg, bilat-compl	161	173		Yes	Yes	No
9050	Late effec skull/face fx	155	167		Yes	Yes	No
9059	Late eff traumat amputat	177	189		Yes	Yes	No
9070	Lt eff intracranial inj	155	167		Yes	Yes	No
9072	Late eff spinal cord inj	69	72		Yes	Yes	No
94811	10-19% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94821	20-29% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94822	20-29% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94831	30-39% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94832	30-39% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94833	30-39% bdy brn/30-39% 3d	150	162		Yes	Yes	No
94841	40-49% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94842	40-49% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94843	40-49% bdy brn/30-39% 3d	150	162		Yes	Yes	No

94844	40-49% bdy brn/40-49% 3d	150	162		Yes	Yes	No
94851	50-59% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94852	50-59% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94853	50-59% bdy brn/30-39% 3d	150	162		Yes	Yes	No
94854	50-59% bdy brn/40-49% 3d	150	162		Yes	Yes	No
94855	50-59% bdy brn/50-59% 3d	150	162		Yes	Yes	No
94861	60-69% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94862	60-69% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94863	60-69% bdy brn/30-39% 3d	150	162		Yes	Yes	No
94864	60-69% bdy brn/40-49% 3d	150	162		Yes	Yes	No
94865	60-69% bdy brn/50-59% 3d	150	162		Yes	Yes	No
94866	60-69% bdy brn/60-69% 3d	150	162		Yes	Yes	No
94871	70-79% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94872	70-79% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94873	70-79% bdy brn/30-39% 3d	150	162		Yes	Yes	No
94874	70-79% bdy brn/40-49% 3d	150	162		Yes	Yes	No
94875	70-79% bdy brn/50-59% 3d	150	162		Yes	Yes	No
94876	70-79% bdy brn/60-69% 3d	150	162		Yes	Yes	No
94877	70-79% bdy brn/70-79% 3d	150	162		Yes	Yes	No
94881	80-89% bdy brn/10-19% 3d	150	162		Yes	Yes	No
94882	80-89% bdy brn/20-29% 3d	150	162		Yes	Yes	No
94883	80-89% bdy brn/30-39% 3d	150	162		Yes	Yes	No
94884	80-89% bdy brn/40-49% 3d	150	162		Yes	Yes	No
94885	80-89% bdy brn/50-59% 3d	150	162		Yes	Yes	No
94886	80-89% bdy brn/60-69% 3d	150	162		Yes	Yes	No
94887	80-89% bdy brn/70-79% 3d	150	162		Yes	Yes	No
94888	80-89% bdy brn/80-89% 3d	150	162		Yes	Yes	No
94891	90% + bdy brn/10-19% 3rd	150	162		Yes	Yes	No
94892	90% + bdy brn/20-29% 3rd	150	162		Yes	Yes	No
94893	90% + bdy brn/30-39% 3rd	150	162		Yes	Yes	No
94894	90% + bdy brn/40-49% 3rd	150	162		Yes	Yes	No
94895	90% + bdy brn/50-59% 3rd	150	162		Yes	Yes	No
94896	90% + bdy brn/60-69% 3rd	150	162		Yes	Yes	No
94897	90% + bdy brn/70-79% 3rd	150	162		Yes	Yes	No
94898	90% + bdy brn/80-89% 3rd	150	162		Yes	Yes	No
94899	90% + bdy brn/90% + 3rd	150	162		Yes	Yes	No
95200	C1-c4 spin cord inj NOS	69	72		Yes	Yes	No
95201	Complete les cord/c1-c4	67	70		Yes	Yes	No
95202	Anterior cord synd/c1-c4	69	72		Yes	Yes	No
95203	Central cord synd/c1-c4	69	72		Yes	Yes	No
95204	C1-c4 spin cord inj NEC	69	72		Yes	Yes	No
95205	C5-c7 spin cord inj NOS	69	72		Yes	Yes	No
95206	Complete les cord/c5-c7	67	70		Yes	Yes	No
95207	Anterior cord synd/c5-c7	69	72		Yes	Yes	No
95208	Central cord synd/c5-c7	69	72		Yes	Yes	No
95209	C5-c7 spin cord inj NEC	69	72		Yes	Yes	No
95210	T1-t6 spin cord inj NOS	69	72		Yes	Yes	No
95211	Complete les cord/t1-t6	68	71		Yes	Yes	No
95212	Anterior cord synd/t1-t6	69	72		Yes	Yes	No
95213	Central cord synd/t1-t6	69	72		Yes	Yes	No
95214	T1-t6 spin cord inj NEC	69	72		Yes	Yes	No
95215	T7-t12 spin cord inj NOS	69	72		Yes	Yes	No
95216	Complete les cord/t7-t12	68	71		Yes	Yes	No
95217	Anterior cord syn/t7-t12	69	72		Yes	Yes	No
95218	Central cord syn/t7-t12	69	72		Yes	Yes	No
95219	T7-t12 spin cord inj NEC	69	72		Yes	Yes	No
9522	Lumbar spinal cord injur	69	72		Yes	Yes	No
9523	Sacral spinal cord injur	69	72		Yes	Yes	No
9524	Cauda equina injury	69	72		Yes	Yes	No
9528	Spin cord inj-mult site	69	72		Yes	Yes	No
9529	Spinal cord injury NOS	69	72		Yes	Yes	No
9580	Air embolism	164	173		Yes	Yes	No
9581	Fat embolism	164	173		Yes	Yes	No
9582	Secondary/recur hemorr	164	173		Yes	Yes	No

9583	Posttraum wnd infec NEC	164	173		Yes	Yes	No
9584	Traumatic shock	164	173		Yes	Yes	No
9585	Traumatic anuria	164	173		Yes	Yes	No
9586	Volkman's isch contract	164	173		Yes	Yes	No
9587	Traum subcutan emphysema	164	173		Yes	Yes	No
9588	Early complic trauma NEC	164	173		Yes	Yes	No
95890	Compartment syndrome NOS	164	173		Yes	Yes	No
95891	Trauma comp synd up ext	164	173		Yes	Yes	No
95892	Trauma comp synd low ext	164	173		Yes	Yes	No
95893	Trauma compart synd abd	164	173		Yes	Yes	No
95899	Trauma compart synd NEC	164	173		Yes	Yes	No
99590	SIRS, NOS		2		No	Yes	No
99591	Sepsis		2		No	Yes	No
99592	Severe sepsis		2		No	Yes	No
99593	SIRS-noninf w/o ac or ds		2		No	Yes	No
99594	SIRS-noninf w ac org dys		2		No	Yes	No
99600	Malfunc card dev/grf NOS	164			Yes	No	No
99601	Malfunc cardiac pacemaker	164			Yes	No	No
99602	Malfunc prosth hrt valve	164			Yes	No	No
99603	Malfunc coron bypass grf	164			Yes	No	No
99604	Mch cmp autm mplnt dfbrl	164			Yes	No	No
99609	Malfunc card dev/grf NEC	164			Yes	No	No
9961	Malfunc vasc device/graf	164	176		Yes	Yes	No
9962	Malfun neuro device/graf	164	176		Yes	Yes	No
99630	Malfunc gu dev/graft NOS	164	176		Yes	Yes	No
99631	Malfunc urethral cath	164	176		Yes	Yes	No
99632	Malfunction iud	164			Yes	No	No
99639	Malfunc gu dev/graft NEC	164	176		Yes	Yes	No
99640	Cmp int orth dev/gft NOS	164	176		Yes	Yes	No
99641	Mech loosening pros jt	164	176		Yes	Yes	No
99642	Dislocate prosthetic jt	164	176		Yes	Yes	No
99643	Broke prosthtc jt implnt	164	176		Yes	Yes	No
99644	Periprosthetic fx-pros jt	164	176		Yes	Yes	No
99645	Periprosthetic osteolysis	164	176		Yes	Yes	No
99646	Articular wear prosth jt	164	176		Yes	Yes	No
99647	Mech com pros jt implant	164	176		Yes	Yes	No
99649	Mech com orth dev NEC	164	176		Yes	Yes	No
99651	Corneal grft malfunction	164			Yes	No	No
99652	Oth tissue graft malfunc	164			Yes	No	No
99653	Lens prosthesis malfunc	164			Yes	No	No
99654	Breast prosth malfunc	164			Yes	No	No
99655	Comp-artificial skin grf	164			Yes	No	No
99656	Comp-periton dialys cath	130	134	121	Yes	Yes	Yes
99657	Complication-insulin pump	164			Yes	No	No
99659	Malfunc oth device/graft	164			Yes	No	No
99660	Reaction-unsp devic/grft	164	176		Yes	Yes	No
99661	React-cardiac dev/graft	164	176		Yes	Yes	No
99662	React-oth vasc dev/graft	164	176		Yes	Yes	No
99663	React-nerv sys dev/graft	164	176		Yes	Yes	No
99664	React-indwell urin cath	164	176		Yes	Yes	No
99665	React-oth genitourin dev	164	176		Yes	Yes	No
99666	React-inter joint prost	164	176		Yes	Yes	No
99667	React-oth int ortho dev	164	176		Yes	Yes	No
99668	React-periton dialy cath	130	134	121	Yes	Yes	Yes
99669	React-int pros devic NEC	164	176		Yes	Yes	No
99670	Comp-unsp device/graft	164			Yes	No	No
99671	Comp-heart valve prosth	164			Yes	No	No
99672	Comp-oth cardiac device	164			Yes	No	No
99673	Comp-ren dialys dev/grft	130	134	121	Yes	Yes	Yes
99674	Comp-oth vasc dev/graft	164	176		Yes	Yes	No
99675	Comp-nerv sys dev/graft	164	176		Yes	Yes	No
99676	Comp-genitourin dev/grft	164	176		Yes	Yes	No
99677	Comp-internal joint pros	164	176		Yes	Yes	No
99678	Comp-oth int ortho devic	164	176		Yes	Yes	No

99679	Comp-int prost devic NEC	164			Yes	No	No
99681	Compl kidney transplant			120	No	No	Yes
99682	Compl liver transplant	174	186	167	Yes	Yes	Yes
99683	Compl heart transplant	174	186	167	Yes	Yes	Yes
99684	Compl lung transplant	174	186	166	Yes	Yes	Yes
99685	Compl marrow transplant	174	186	167	Yes	Yes	Yes
99686	Compl pancreas transplnt	174	186	168	Yes	Yes	Yes
99687	Comp intestine transplnt	174	186	167	Yes	Yes	Yes
99688	Comp tp organ-stem cell	174	186	167	Yes	Yes	Yes
99690	Comp reattach extrem NOS	161	173		Yes	Yes	No
99691	Compl reattached forearm	161	173		Yes	Yes	No
99692	Compl reattached hand	161	173		Yes	Yes	No
99693	Compl reattached finger	161	173		Yes	Yes	No
99694	Compl reattached arm NEC	161	173		Yes	Yes	No
99695	Compl reattached foot	161	173		Yes	Yes	No
99696	Compl reattached leg NEC	161	173		Yes	Yes	No
99699	Compl reattach part NEC	161	173		Yes	Yes	No
99700	Nervous syst comple NOS	164			Yes	No	No
99701	Surg complication - cns	164			Yes	No	No
99702	Iatrogen CV infarc/hmrhg	164	100	97	Yes	Yes	Yes
99709	Surg comp nerv systm NEC	164			Yes	No	No
9971	Surg compl-heart	164			Yes	No	No
9972	Surg comp-peri vasc syst	164			Yes	No	No
99731	Ventltr assoc pneumonia	164	114		Yes	Yes	No
99732	Postproc aspiration pneu	164			Yes	No	No
99739	Respiratory comp NEC	164			Yes	No	No
9974	Surg comp-digestv system	164			Yes	No	No
99749	Oth digestv system comp	164			Yes	No	No
9975	Surg compl-urinary tract	164			Yes	No	No
99760	Amputat stump compl NOS	177	189		Yes	Yes	No
99761	Neuroma amputation stump	177	189		Yes	Yes	No
99762	Infection amputat stump	177	189		Yes	Yes	No
99769	Amputat stump compl NEC	177	189		Yes	Yes	No
99771	Vasc comp mesenteric art	164			Yes	No	No
99772	Vasc comp renal artery	164			Yes	No	No
99779	Vascular comp vessel NEC	164			Yes	No	No
9980	Postoperative shock	164			Yes	No	No
99800	Postoperative shock, NOS	164			Yes	No	No
99801	Postop shock,cardiogenic	79	84		Yes	Yes	No
99802	Postop shock, septic	2	2		Yes	Yes	No
99809	Postop shock, other	164			Yes	No	No
9986	Persist postop fistula	164			Yes	No	No
E9500	Poison-analgesics	55	58		Yes	Yes	No
E9501	Poison-barbiturates	55	58		Yes	Yes	No
E9502	Poison-sedat/hypnotic	55	58		Yes	Yes	No
E9503	Poison-psychotropic agt	55	58		Yes	Yes	No
E9504	Poison-drug/medicin NEC	55	58		Yes	Yes	No
E9505	Poison-drug/medicin NOS	55	58		Yes	Yes	No
E9506	Poison-agricult agent	55	58		Yes	Yes	No
E9507	Poison-corrosiv/caustic	55	58		Yes	Yes	No
E9508	Poison-arsenic	55	58		Yes	Yes	No
E9509	Poison-solid/liquid NEC	55	58		Yes	Yes	No
E9510	Poison-piped gas	55	58		Yes	Yes	No
E9511	Poison-gas in container	55	58		Yes	Yes	No
E9518	Poison-utility gas NEC	55	58		Yes	Yes	No
E9520	Poison-exhaust gas	55	58		Yes	Yes	No
E9521	Poison-co NEC	55	58		Yes	Yes	No
E9528	Poison-gas/vapor NEC	55	58		Yes	Yes	No
E9529	Poison-gas/vapor NOS	55	58		Yes	Yes	No
E9530	Injury-hanging	55	58		Yes	Yes	No
E9531	Injury-suff w plas bag	55	58		Yes	Yes	No
E9538	Injury-strang/suff NEC	55	58		Yes	Yes	No
E9539	Injury-strang/suff NOS	55	58		Yes	Yes	No
E954	Injury-submersion	55	58		Yes	Yes	No

E9550	Injury-handgun	55	58		Yes	Yes	No
E9551	Injury-shotgun	55	58		Yes	Yes	No
E9552	Injury-hunting rifle	55	58		Yes	Yes	No
E9553	Injury-military firearm	55	58		Yes	Yes	No
E9554	Injury-firearm NEC	55	58		Yes	Yes	No
E9555	Injury-explosives	55	58		Yes	Yes	No
E9556	Self inflict acc-air gun	55	58		Yes	Yes	No
E9557	Self inj-paintball gun	55	58		Yes	Yes	No
E9559	Injury-firearm/expl NOS	55	58		Yes	Yes	No
E956	Injury-cut instrument	55	58		Yes	Yes	No
E9570	Injury-jump fm residence	55	58		Yes	Yes	No
E9571	Injury-jump fm struc NEC	55	58		Yes	Yes	No
E9572	Injury-jump fm natur sit	55	58		Yes	Yes	No
E9579	Injury-jump NEC	55	58		Yes	Yes	No
E9580	Injury-moving object	55	58		Yes	Yes	No
E9581	Injury-burn, fire	55	58		Yes	Yes	No
E9582	Injury-scald	55	58		Yes	Yes	No
E9583	Injury-extreme cold	55	58		Yes	Yes	No
E9584	Injury-electrocution	55	58		Yes	Yes	No
E9585	Injury-motor veh crash	55	58		Yes	Yes	No
E9586	Injury-aircraft crash	55	58		Yes	Yes	No
E9587	Injury-caustic substance	55	58		Yes	Yes	No
E9588	Injury-NEC	55	58		Yes	Yes	No
E9589	Injury-NOS	55	58		Yes	Yes	No
E959	Late eff of self-injury	55	58		Yes	Yes	No
V08	Asymp hiv infectn status	1	1	1	Yes	Yes	Yes
V420	Kidney transplant status			120	No	No	Yes
V421	Heart transplant status	174	186	167	Yes	Yes	Yes
V426	Lung transplant status	174	186	166	Yes	Yes	Yes
V427	Liver transplant status	174	186	167	Yes	Yes	Yes
V4281	Trnspl status-bne marrow	174	186	167	Yes	Yes	Yes
V4282	Trspls sts-perip stm cell	174	186	167	Yes	Yes	Yes
V4283	Trnspl status-pancreas	174	186	168	Yes	Yes	Yes
V4284	Trnspl status-intestines	174	186	167	Yes	Yes	Yes
V4321	Heart assist dev replace	174	186		Yes	Yes	No
V4322	Artificial heart replace	174	186		Yes	Yes	No
V440	Tracheostomy status	77	82		Yes	Yes	No
V441	Gastrostomy status	176	188		Yes	Yes	No
V442	Ileostomy status	176	188		Yes	Yes	No
V443	Colostomy status	176	188		Yes	Yes	No
V444	Enterostomy status NEC	176	188		Yes	Yes	No
V4450	Cystostomy status NOS	176	188		Yes	Yes	No
V4451	Cutaneous-vesicos status	176	188		Yes	Yes	No
V4452	Appendico-vesicos status	176	188		Yes	Yes	No
V4459	Cystostomy status NEC	176	188		Yes	Yes	No
V446	Urinostomy status NEC	176	188		Yes	Yes	No
V448	Artif open status NEC	176	188		Yes	Yes	No
V449	Artif open status NOS	176	188		Yes	Yes	No
V4511	Renal dialysis status	130	134	121	Yes	Yes	Yes
V4512	Noncmplnt w renal dialys	130	134	121	Yes	Yes	Yes
V4611	Respirator depend status	77	82		Yes	Yes	No
V4612	Resp depend-powr failure	77	82		Yes	Yes	No
V4613	Weaning from respirator	77	82		Yes	Yes	No
V4614	Mech comp respirator	77	82		Yes	Yes	No
V4970	Status amput lwr lmb NOS	177	189		Yes	Yes	No
V4971	Status amput great toe	177	189		Yes	Yes	No
V4972	Status amput othr toe(s)	177	189		Yes	Yes	No
V4973	Status amput foot	177	189		Yes	Yes	No
V4974	Status amput ankle	177	189		Yes	Yes	No
V4975	Status amput below knee	177	189		Yes	Yes	No
V4976	Status amput above knee	177	189		Yes	Yes	No
V4977	Status amput hip	177	189		Yes	Yes	No
V521	Fitting artificial leg	177	189		Yes	Yes	No
V550	Atten to tracheostomy	77	82		Yes	Yes	No

V551	Atten to gastrostomy	176	188		Yes	Yes	No
V552	Atten to ileostomy	176	188		Yes	Yes	No
V553	Atten to colostomy	176	188		Yes	Yes	No
V554	Atten to enterostomy NEC	176	188		Yes	Yes	No
V555	Atten to cystostomy	176	188		Yes	Yes	No
V556	Atten to urinostomy NEC	176	188		Yes	Yes	No
V558	Attn to artif open NEC	176	188		Yes	Yes	No
V559	Attn to artif open NOS	176	188		Yes	Yes	No
V560	Renal dialysis encounter	130	134	121	Yes	Yes	Yes
V561	Ft/adj xtrcorp dial cath	130	134	121	Yes	Yes	Yes
V562	Fit/adj perit dial cath	130	134	121	Yes	Yes	Yes
V5631	Hemodialysis testing	130	134	121	Yes	Yes	Yes
V5632	Peritoneal dialysis test	130	134	121	Yes	Yes	Yes
V568	Dialysis encounter, NEC	130	134	121	Yes	Yes	Yes
V5867	Long-term use of insulin	19	19	15	Yes	Yes	Yes
V8541	BMI 40.0-44.9, adult		22	21	No	Yes	Yes
V8542	BMI 45.0-49.9, adult		22	21	No	Yes	Yes
V8543	BMI 50.0-59.9, adult		22	21	No	Yes	Yes
V8544	BMI 60.0-69.9, adult		22	21	No	Yes	Yes
V8545	BMI 70 and over, adult		22	21	No	Yes	Yes

EXHIBIT P-44

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *
ex rel, BENJAMIN POEHLING, *

Plaintiffs, *

VS. * CASE NO:

UNITEDHEALTHCARE GROUP, * CV 16-08697 FMO
et al, *

Defendants. *

* * * * *

VIDEOTAPED 30(b)(6) DEPOSITION OF:

CONNIE LYNN LEONARD,

was held on Friday, May 26, 2023, commencing
at 10:04 a.m., at Latham & Watkins, 555 11th
Street, Washington, D.C., reported by
Barbara Moore, CRR, RMR.

* * *

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1 identified for that given year?

2 MS. GLOVER: Objection. Form.

3 Scope.

4 THE WITNESS: So a claim comes in
5 to Medicare fee for service. The claim
6 processes through the system that I talked
7 about, the claim is paid. Somewhere down
8 the road a Medicare review contractor
9 decides to review the claim and maybe they
10 review it on its face. That doesn't matter
11 one way or the other.

12 And they review the claim, and
13 the -- they adjust the claim in some form.
14 Maybe they downcode. They change the
15 diagnosis code. We will stick to the
16 diagnosis codes. Maybe they changed the
17 diagnosis code.

18 If that was a post-claim claim,
19 what happens is that claim is adjusted and
20 the provider gets a demand letter to send
21 back whatever the difference between the

1 actual payment was and what the new payment
2 amount would be. And that claim is
3 adjusted. And when that claim is adjusted,
4 that claim, that final adjustment goes into
5 the claim, claims history, into the claims
6 data. If it was a prepaid claim, then that
7 adjustment happens, and then when the claim
8 goes into the national claims history,
9 that's the final claim action.

10 So whenever they pull that data,
11 June 30 is the date that they pulled the
12 data, all they're pulling is the current
13 status of that claim. So when I use the
14 term "adjustment," I mean that the claim has
15 actually been adjusted, the medical record
16 has been reviewed, or somebody has adjusted
17 it, but somebody has reviewed the claim and
18 wanted to make a change to the previous
19 final action and they reopen the claim. The
20 claim was adjusted, and now it's a new final
21 form.

1 CERTIFICATE OF COURT REPORTER

2 I, BARBARA MOORE, do hereby
3 certify that the proceedings were recorded
4 by me stenographically and electronically at
5 the time and place mentioned on the cover
6 sheet thereof, and, thereafter, transcribed;
7 that said hearing is a true record of the
8 statements made; that I am neither counsel
9 for, related to, nor employed by any of the
10 parties to this proceeding;

11 And further, that I am not
12 financially or otherwise interested in the
13 outcome of this matter.

14 As Witnessed by my hand and
15 signature as indicated below.

16

17

18

19

Barbara Moore

BARBARA MOORE, CRR, RMR

20

21 My Commission Expires: July 31, 2023

EXHIBIT P-45

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel.	)	
BEN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
VS.	)	CASE NO.
	)	2:16-08687 FMO
	)	
UNITED HEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

VIDEOTAPED DEPOSITION OF JANICE REDMOND
Costa Mesa, California
Friday, July 29, 2022

Job No.: 835270

Reported by:

Shirley R. Lynn, C.S.R. NO. 13784

1 A I've heard of it.

2 Q Did you ever attend any ICE events?

3 A No.

4 Q Do you know who at Optum did attend ICE
5 events?

6 MS. ZUCKERMAN: Objection. Calls for
7 speculation.

8 THE WITNESS: Pam Leal that reported to me
9 was active in that organization.

10 BY MS. GLOVER:

11 Q Okay. I'm going to mark another exhibit
12 here.

13 This is 358. You can let me know when it's on
14 your screen. This is a two-page e-mail, although I
15 think all the text is on the first page. So if you want
16 to give a read to the e-mail chain, and we'll talk about
17 it in a minute.

18 (Exhibit 358 was marked for
19 identification.)

20 THE WITNESS: Okay.

21 BY MS. GLOVER:

22 Q Okay. Ms. Redmond, are you familiar with
23 the term "capitated provider"?

24 A Yes.

25 Q How about "gainsharing provider"?

1 A Yes.

2 Q What is a capitated provider?

3 A A provider that gets paid per member per

4 month.

5 Q To care for certain beneficiaries?

6 A Yes.

7 Q Okay. And what is a gainsharing provider?

8 (Court reporter clarification.)

9 MS. GLOVER: Gain, like g-a-i-n, yeah.

10 Yeah.

11 THE WITNESS: I'm familiar with the term.

12 I don't recall the specifics of the gainshare.

13 BY MS. GLOVER:

14 Q Are you familiar with the term

15 "fee-for-service" --

16 A Yes.

17 Q -- "provider"?

18 A Yes.

19 Q What's a fee-for-service provider?

20 A A provider that gets paid transactionally

21 as a member comes through the door, so based on

22 every encounter separately.

23 Q And in market consultation, did -- did you

24 work with capitated and gainsharing providers?

25 A Yes.

CERTIFICATE
OF
SHORTHAND REPORTER

* * * *

I, Shirley Lynn, CSR No. 13784, a Certified
Shorthand Reporter in and for the State of California,
do hereby certify:

That prior to being examined, the witness
named in the foregoing proceedings declared under
penalty of perjury to testify to the truth, the whole
truth, and nothing but the truth;

That said proceedings were taken by me in
shorthand at the time and place herein named and were
thereafter transcribed into typewriting under my
direction, said transcript being a true and correct
transcription of my shorthand notes;

Pursuant to Federal Rule 30(e), transcript
review was requested;

I further certify that I have no interest in
the outcome of this action.


SHIRLEY LYNN
CSR NO. 13784

EXHIBIT P-46

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex :
rel., BENJAMIN POEHLING, :
Plaintiffs, : Case No.:
VS. : CV-16-08697 FMO
UNITED HEALTH GROUP, INC., :
et al., :
Defendants. : Page 1-258

- - -

Thursday, March 14, 2024

- - -

Videotaped deposition of MELVIN JULES
INGBER, PH.D. taken at DLAPiper, 650 South Exeter
Street, Suite 1100, Baltimore, MD commencing at 9:42
a.m., before Sherry L. Brooks, Certified LiveNote
Reporter and Notary Public, in and for the State of
Maryland.

- - -

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1 take into account that -- I'm sorry. Are you saying
2 providers? I'm sorry. I need to understand the
3 question. Can you repeat it? I'm missing a word.

4 Q. Right. So do you know what percentage of
5 Medicare Advantage providers are paid by -- or have
6 increased payments based upon their diagnosis coding?

7 A. I do not have a study that gives me that
8 percentage.

9 Q. And you don't have any empirical analysis
10 or any basis to say what portion of Medicare
11 Advantage payments or Medicare Advantage providers
12 are based on diagnosis codes as opposed to
13 procedures?

14 A. I cannot quantify it.

15 Q. Are any providers in the fee-for-service
16 side of Medicare compensated at all based upon
17 diagnoses that are coded?

18 MS. MCMAHON: Objection. Calls for
19 speculation.

20 A. If we're talking in fee-for-service, the
21 hospital fee-for-service claims are paid partly on
22 procedures and partly on which diagnosis they put

1 first on a claim.

2 So hospitals have an incentive to choose
3 among the diagnoses they have for the patient which
4 one they put first because that is a basic part of
5 the DRG payment system, diagnostic-related group
6 payment system for hospitals.

7 BY MR. JONES:

8 Q. And as part of the DRG payment system for
9 hospitals, the diagnosis being put first matters
10 because more cost-intensive diagnoses lead to higher
11 reimbursement rates for those hospitals, right?

12 A. In the fee-for-service side they -- how
13 they order them would determine the amount that
14 they're paid, yes. But I want to just add that in
15 risk adjustment we don't care what order they're in.
16 But for what you said, it is true.

17 Q. Sure. And so those hospitals have
18 incentives to code first the most cost intensive
19 diagnosis that a patient they are seeing in the
20 fee-for-service Medicare has, right?

21 A. You could, indeed, say that they have an
22 incentive and also that the work is being done by

1 certified coders who have rules for themselves. So,
2 yes, there is an incentive but also the people doing
3 the coding are libel in some sense for fudging.

4 Q. Okay. And -- but you don't know, one way
5 or another, whether there is more compensation on the
6 MA side of the house for diagnosis coding compared to
7 the fee-for-service payments that are tied to DRGs
8 and diagnoses in hospital stays, do you?

9 A. Yes.

10 MS. MCMAHON: Objection. Form.

11 A. The hospitals are a relatively small
12 contributor to the diagnosis coding. And, as I said,
13 that would increase their payments so that the
14 fee-for-service costs might go up. When we do the
15 model and add up all the dollars, the fee-for-service
16 costs might go up.

17 However, as far as the risk adjustment is
18 concerned, it takes them in any order. On the side
19 of Medicare Advantage it is a lot of the time the
20 physicians who are in the position and not just
21 hospitals who do it for an entirely different reason.

22 And I can tell you that my experience in

1 talking with physicians who are in large systems,
2 they -- when they do their coding, the ones that do
3 have electronic systems are reminded of codes
4 particularly because of the HCC model that they
5 should be coding.

6 They literally when they sit down to code
7 a patient -- and I have (sic) this from personal
8 conversation that we've had over the years with
9 consulting physicians -- they are prodded to and
10 let's say reminded that this person also has
11 something.

12 But the guidelines, of course, for normal
13 fee-for-service is not just to code anything that the
14 person has. The guidelines are a bit different
15 there. It's supposed to be relevant.

16 So yeah, there's something going on with
17 physicians just the way the electronic systems work
18 today, specifically oriented towards HCCs to remind
19 people to code thoroughly. Let's put it that way.

20 BY MR. JONES:

21 Q. Sir, my question, respectfully, didn't
22 have anything to do with reminders.

1 What I'm interested in -- you mentioned
2 incentives for coding.

3 A. You mean paid --

4 Q. For payment.

5 A. Yeah.

6 Q. In terms of the differences in -- or the
7 -- let me -- let me start over.

8 You don't have any basis to quantify the
9 difference between payments in providers for Medicare
10 Advantage that are tied to diagnoses compared to
11 payments for providers in the fee-for-service side
12 that are tied to diagnoses?

13 A. I cannot quantify that.

14 Q. And you can't say whether the payments on
15 the MA side are materially higher than the payments
16 for diagnoses as part of the DRG payments for
17 Medicare fee-for-service are (sic), right?

18 MS. MCMAHON: Objection. Form.

19 A. When I use the term "payments," I want to
20 be very specific because the payments that are put on
21 encounter records, which are the source of the
22 diagnoses used, they're like claims that are

1 submitted by managed care plans. Those payments are
2 not the payments I'm talking about.

3 And the payments I'm talking about do not
4 appear anywhere that would make it possible to
5 quantify it. If a payment is made by somebody
6 writing a check to somebody, there's no record of
7 that. So the payments on claims are not affected.
8 So that, yes, I can't quantify that at all.

9 BY MR. JONES:

10 Q. Okay. And just to have the -- make sure I
11 got the question and answer right, you can't say
12 whether payments to providers who see MA patients
13 that are tied to diagnoses are any different or
14 materially higher than the payments to
15 fee-for-service hospitals that are tied to DRGs or
16 diagnoses, right?

17 MS. MCMAHON: Objection. Form.

18 A. The payments that I can talk about in a
19 quantitative way are payments on the encounter
20 records similar to claims. I can't say anything
21 about comparing payments that are made not through
22 the standard payment system for providers.

1 BY MR. JONES:

2 Q. So is the answer to my question no, that
3 you can't say whether payments from MA plans to
4 providers that are tied to diagnoses like the example
5 you provided are materially higher than the payments
6 to fee-for-service hospitals from the government that
7 are tied to DRGs or diagnoses?

8 A. I would like to answer the question, but I
9 have to keep saying that the word "payments" is a
10 little bit -- has a double meaning because there are
11 -- you're saying payments tied to diagnoses. And
12 payments tied to diagnoses means payments made
13 without a record of them.

14 I cannot talk about that. Payments made
15 in fee-for-service based on diagnoses are almost
16 entirely related to the actual payment system and are
17 on the records, the claims. The payments I'm talking
18 about based on diagnoses are not on the claims at
19 all. So I just want to be careful about the word
20 "payments." That's all.

21 Q. Sure. Is there another term that would --
22 that I should -- that would be better for me to use

1 to compare? I just want to make sure I know what
2 your testimony is in terms of that -- the example
3 that you gave of the provider who suggested that he
4 was compensated or that his group was compensated
5 because of more complete coding, what is the kind of
6 payment term that you'd prefer me to use so that I
7 can get the -- your -- your testimony?

8 A. It would be payments not related to the
9 claims, per se, because payments are made to
10 providers based on whatever system -- usually a
11 fee-for-service type system for most managed care
12 plans with the risk capitation.

13 But those payments of record are not the
14 ones we're speaking of, and it's only the payments
15 made to providers based on diagnoses that are beyond
16 those that are external to what is paid on claims.
17 So those are the payments that I would be talking
18 about that I cannot quantify at all.

19 Q. Okay. So let me try this again: You
20 don't have any way of saying whether the payments for
21 diagnosis coding that are not based on claims are any
22 -- materially higher in the Medicare Advantage world

1 than payments to hospitals on the fee-for-service
2 side that are based on diagnoses for DRGs, for
3 example?

4 A. I'm sorry. We're -- on one side or the
5 other we have hospitals and then we have a more vague
6 term on the Medicare Advantage side.

7 The hospital claims on both sides may or
8 may not be paid similarly based on diagnoses. I
9 don't know what a particular plan does. We do know
10 what Medicare fee-for-service does. The diagnosis
11 matters and so do the procedures. Okay?

12 On the managed care side, they may or may
13 not pay on DRGs. So the diagnosis may or may not
14 matter on the claim itself because there are many
15 ways to pay hospitals.

16 So, you know, not knowing the specifics of
17 any case, I couldn't say. But then there is the
18 other payment which can be made outside of the
19 hospital world all together and having some sort of a
20 -- on the one hand physicians who are not paid --
21 physicians provide the diagnosis codes for most
22 beneficiaries because hospitalizations are relatively

1 rare.

2 So most people get only physician-based
3 codes with some hospitals also. So if we're talking
4 about the other half of the world, which is not a
5 hospital, for physicians -- physicians there in
6 fee-for-service, the diagnoses are not a basis of
7 payment.

8 On the managed care side what they pay
9 physicians on a claim may or may not have anything to
10 do with the diagnoses they put on. But if there is a
11 -- an additional on top of that for increasing the
12 diagnoses, I cannot quantify that. I just know that
13 it exists. I can't quantify that.

14 Bonus payment -- let's go with the bonus
15 payment to make it clearer.

16 Q. Okay. But in terms of the comparison of
17 any payment that depends on a diagnosis as opposed to
18 a procedure, can you say, one way or another, whether
19 the payments on the Medicare Advantage side as a
20 general matter are materially higher that depend on a
21 diagnosis rather than a procedure than the payments
22 on the Medicare fee-for-service side that depend on a

1 diagnosis rather than a procedure?

2 A. If we're looking on the claim itself I
3 can't say that the hospitals -- and that's exactly
4 what we're talking about at this point -- that the
5 hospitals are coding differently for their own
6 benefit depending on how they're being paid by the
7 plan.

8 But if they were getting paid by DRGs,
9 they would have the same incentives. And if there
10 was a bonus payment, I can't see that at all in
11 there. So I'm not saying that in hospitals there's a
12 big difference because if the plan does pay with DRGs
13 based on diagnoses -- if they don't pay -- I know
14 from history that there are hospitals that have been
15 paid per diems, and it's an entirely different
16 situation from DRGs.

17 So, no, I can't speak too specifically
18 what's on the claim. I don't think there's a big
19 difference there.

20 But if there's any bonus for coding more
21 comorbidities or something like that outside of the
22 claim, which doesn't affect the payment on the claim,

1 I cannot say firmly how much that is.

2 Q. Sir, I'm just trying to understand whether
3 you have any data or quantification that would
4 suggest, one way or another, whether payments to
5 providers based on diagnoses for MA plans are any
6 materially different than payments to providers based
7 on diagnoses, not procedures, in the fee-for-service
8 side of Medicare.

9 MS. MCMAHON: Objection. Asked and
10 answered.

11 A. For hospitals -- that is the group you're
12 referring to -- I cannot quantify that there is a
13 difference, correct.

14 BY MR. JONES:

15 Q. And can you quantify that there is any
16 difference overall including hospitals or all
17 providers with respect to payments tied to diagnoses
18 for MA plans as opposed to payments tied to diagnoses
19 in the fee-for-service Medicare?

20 A. I cannot quantify that, no.

21 MR. JONES: We've been going about an
22 hour. Do you want to take a break now or do you want

C E R T I F I C A T E

I do hereby certify that I am a Notary Public in good standing, that the aforesaid testimony was taken before me, pursuant to notice, at the time and place indicated; that said deponent was by me duly sworn to tell the truth, the whole truth, and nothing but the truth; that the testimony of said deponent was correctly recorded in machine shorthand by me and thereafter transcribed under my supervision with computer-aided transcription; that the deposition is a true and correct record of the testimony given by the witness; and that I am neither of counsel nor kin to any party in said action, nor interested in the outcome thereof.

WITNESS my hand and official seal this _____ day of _____, 2024.


Notary Public



EXHIBIT P-47

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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex*
rel. BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., a
Delaware corporation; UNITED
HEALTHCARE SERVICES, INC., a
Minnesota corporation; UNITED
HEALTHCARE, INC., a Delaware
corporation; OVATIONS, INC., a
Delaware corporation; OPTUM, INC., a
Delaware corporation;
OPTUMINSIGHT, INC., a Delaware
corporation; AMERICHOICE OF NEW

No. CV 16-08697 MWF (SSx)

UNITED STATES' AMENDED
COMPLAINT-IN-PARTIAL-
INTERVENTION AND DEMAND FOR
JURY TRIAL

JERSEY, INC., a New Jersey corporation; ARIZONA PHYSICIANS IPA, INC., an Arizona corporation; CARE IMPROVEMENT PLUS OF MARYLAND, INC., a Maryland corporation; CARE IMPROVEMENT PLUS OF TEXAS INSURANCE COMPANY, a Texas insurance company; CARE IMPROVEMENT PLUS SOUTH CENTRAL INSURANCE CO., an Arkansas insurance company; CARE IMPROVEMENT PLUS WISCONSIN INSURANCE COMPANY, a Wisconsin insurance company; OPTUM INSURANCE CO., an Ohio corporation; CITRUS HEALTH CARE, INC., a Florida corporation; HEALTH PLAN OF NEVADA, INC., a Nevada corporation; MEDICA HEALTHCARE PLANS, INC., a Florida corporation; OXFORD HEALTH PLANS (CT), INC., a Connecticut corporation; OXFORD HEALTH PLANS (NJ), INC., a New Jersey corporation also known as Oxford Health Plans of New Jersey, Inc.; OXFORD HEALTH PLANS (NY), INC., a New York corporation; PACIFICARE LIFE AND HEALTH INSURANCE COMPANY, an Indiana insurance company; PACIFICARE OF ARIZONA, INC., an Arizona corporation; PACIFICARE OF COLORADO, INC., a Colorado corporation; PACIFICARE OF NEVADA, INC., a Nevada corporation also known as PacifiCare/UHC of Nevada; PHYSICIANS HEALTH CHOICE OF TEXAS, LLC, a Texas limited liability company; PREFERRED CARE PARTNERS, INC., a Florida corporation; ROCKY MOUNTAIN HEALTH MAINTENANCE ORGANIZATION, INC., a Colorado company; SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC., a Nevada corporation; SYMPHONIX HEALTH INSURANCE, INC., an Illinois insurance company; UNITEDHEALTHCARE OF CALIFORNIA, INC., a California corporation also known as UHC of California, Inc. and formerly known as PacifiCare of California, Inc. and PacifiCare of California/Secure Horizons; UNISON HEALTH PLAN OF

1 TENNESSEE, INC., a Tennessee
2 corporation; UNITED HEALTH CARE
3 INS. CO. AND UNITED NEW YORK, a
4 New York insurance company;
5 UNITEDHEALTHCARE BENEFITS
6 OF TEXAS, INC., a Texas corporation
7 formerly known as PacifiCare of Texas,
8 Inc.; UNITEDHEALTHCARE
9 COMMUNITY PLAN OF OHIO, INC.,
10 an Ohio corporation formerly known as
11 Unison Health Plan of Ohio, Inc.;
12 UNITEDHEALTHCARE
13 COMMUNITY PLAN OF TEXAS,
14 L.L.C., a Texas limited liability company
15 formerly known as Evercare of Texas,
16 LLC; UNITEDHEALTHCARE
17 COMMUNITY PLAN, INC., a Michigan
18 corporation also known as Great Lakes
19 Health Plan, Inc. and UnitedHealthcare
20 of the Great Lakes Health Plan, Inc.;
21 UNITEDHEALTHCARE INSURANCE
22 COMPANY, a Connecticut insurance
23 company also known as United
24 Healthcare Insurance Company;
25 UNITEDHEALTHCARE INSURANCE
26 COMPANY OF NEW YORK, a New
27 York insurance company also known as
28 United Healthcare Insurance Company of
New York; UNITEDHEALTHCARE OF
ALABAMA, INC., an Alabama
corporation also known as United
HealthCare of Alabama, Inc.;
UNITEDHEALTHCARE OF
ARIZONA, INC., an Arizona
corporation also known as United
HealthCare of Arizona, Inc.;
UNITEDHEALTHCARE OF
ARKANSAS, INC., an Arkansas
corporation also known as United
Healthcare of Arkansas, Inc.;
UNITEDHEALTHCARE OF
FLORIDA, INC., a Florida corporation
also known as United Healthcare of
Florida, Inc.; UNITEDHEALTHCARE
OF GEORGIA, INC., a Georgia
corporation also known as United
Healthcare of Georgia, Inc.;
UNITEDHEALTHCARE OF NEW
ENGLAND, INC., a Rhode Island
corporation also known as United
HealthCare of New England, Inc. and
United Health Plans of New England,
Inc.; UNITEDHEALTHCARE OF NEW
YORK, INC., a New York corporation
also known as AmeriChoice of New
York, Inc. and United Healthcare of New

York, Inc.; UNITEDHEALTHCARE OF NORTH CAROLINA, INC., a North Carolina corporation also known as United Healthcare of North Carolina, Inc.; UNITEDHEALTHCARE OF OHIO, INC., an Ohio corporation also known as United Healthcare of Ohio, Inc.; UNITEDHEALTHCARE OF OKLAHOMA, INC., an Oklahoma corporation formerly known as PacifiCare of Oklahoma, Inc.; UNITEDHEALTHCARE OF OREGON, INC., an Oregon corporation formerly known as PacifiCare of Oregon, Inc.; UNITEDHEALTHCARE OF PENNSYLVANIA, INC., a Pennsylvania corporation formerly known as Unison Health Plan of Pennsylvania, Inc.; UNITEDHEALTHCARE OF TENNESSEE, INC., a Tennessee corporation also known as United Healthcare of Tennessee, Inc.; UNITEDHEALTHCARE OF THE MIDLANDS, INC., a Nebraska corporation also known as United Healthcare of the Midlands, Inc.; UNITEDHEALTHCARE OF THE MIDWEST, INC., a Missouri corporation also known as United Healthcare of the Midwest, Inc.; UNITEDHEALTHCARE OF UTAH, INC., a Utah corporation also known as United Healthcare of Utah, Inc.; UNITEDHEALTHCARE OF WASHINGTON, INC., a Washington corporation formerly known as PacifiCare of Washington, Inc.; UNITEDHEALTHCARE OF WISCONSIN, INC., a Wisconsin corporation also known as United Healthcare of Wisconsin, Inc.; UNITEDHEALTHCARE PLAN OF THE RIVER VALLEY, INC., an Illinois corporation also known as United Healthcare Plan of the River Valley, Inc., UnitedHealth Care Plan of the River Valley, Inc., and United HealthCare of the River Valley, Inc.,

Defendants.

1 This is a civil fraud action brought by the United States of America (“United
2 States” or “Government”) to recover treble damages and civil penalties under the False
3 Claims Act (“FCA”), 31 U.S.C. §§ 3729-3733, as well as for restitution and common
4 law damages, for monies unlawfully obtained and retained by Defendant UnitedHealth
5 Group Inc. and various of its direct and indirect subsidiaries (“Defendants”) involved in
6 Parts C and D of the Medicare Program. Defendants knowingly submitted false claims
7 and made false statements to the Medicare Program. Moreover, Defendants have
8 knowingly and improperly avoided their obligations to repay significant sums of money
9 to the Medicare Program.

10 Having filed a notice of intervention pursuant to 31 U.S.C. § 3730(b)(4), the
11 United States alleges for its amended complaint-in-partial-intervention (the “Amended
12 Complaint”) as follows:

13 **INTRODUCTION**

14 1. Millions of elderly and disabled individuals throughout the United States receive
15 their Medicare benefits through Parts C and D of the Medicare Program, hereinafter
16 referred to as the Medicare Advantage (MA) Program, which is administered by the
17 Government agency called the Centers for Medicare and Medicaid Services (“CMS”). A
18 central, distinguishing feature of the MA Program is the provision of Medicare benefits
19 by private healthcare insurance organizations, which are called Medicare Advantage
20 Organizations (“MA Organizations”). Medicare beneficiaries enroll in managed
21 healthcare insurance plans called Medicare Advantage Plans (“MA Plans”) and
22 prescription drug plans (“PD Plans”) that are offered by these MA Organizations. The
23 MA Plans are packages of healthcare insurance benefits and the PD Plans are packages
24 of prescription drug benefits. Hereinafter MA Plans and PD Plans are collectively
25 referred to as “Plans.”

26 2. The Government pays each MA Organization a fixed monthly payment for each
27 Medicare beneficiary enrolled in its Plans. The Government adjusts these payments for
28 various risk factors that affect expected healthcare expenditures, including the age,

gender, and health status of each beneficiary. The adjustments are intended to ensure that MA Organizations are paid more for beneficiaries whose healthcare expenses are *expected* to be more and less for beneficiaries whose health care expenses are *expected* to be less. However, these adjustments to the fixed monthly payments are made regardless of the actual services provided to the beneficiaries and, thus, regardless of whether those beneficiaries expected to need more or more costly services actually obtain more or more costly services, and whether those beneficiaries expected to need less or less costly services actually obtain less or less costly services.

3. To obtain payments based on adjustments for health status, MA Organizations submit diagnosis codes to the Government for the beneficiaries in their Plans. These diagnosis codes are from the beneficiaries' medical encounters with healthcare providers (*e.g.*, physician office visits and hospital stays) during the year prior to the actual payment year (often referred to as the "data collection" year or the "date of service" year). Payments are based on diagnoses from the prior year because they are used to predict the *expected* needs of a beneficiary for more or less costly healthcare services during the payment year. Using these diagnosis codes submitted by or on behalf of MA Organizations, the Government calculates a risk score for each beneficiary. The beneficiary's risk score is then used to calculate monthly payments to the MA Organization for that beneficiary for the payment year. In general, the more numerous and severe the conditions identified by the diagnosis codes, the higher the risk score for a beneficiary and, thus, the greater the risk adjustment payments made to the MA Organization for that beneficiary for the payment year.

4. This payment model creates powerful incentives for MA Organizations and their owners and operators to exaggerate the expected healthcare costs for the beneficiaries in their Plans by submitting invalid diagnosis codes and failing to comply with their obligation to retract invalid diagnoses. In order to combat these incentives and protect the Government from overpaying MA Organizations, the Government requires that submitted diagnoses be unambiguously supported and, thus, validated by the

1 beneficiaries' medical records for medical encounters during the data collection year.
2 Medical records are the "source of truth" for the purpose of receiving and retaining risk
3 adjustment payments.

4 5. The medical records that must support the diagnosis codes are not provided to the
5 Government as part of the payment process. Instead, the Government requires that each
6 MA Organization expressly certify that the diagnosis codes it has submitted for risk
7 adjustment payments are accurate and truthful based on best knowledge, information,
8 and belief. 42 C.F.R. § 422.504(l)(2). Each MA Organization must exercise due
9 diligence in order to make this express certification. Each MA Organization must also
10 "[a]dopt and implement an effective compliance program, which must include measures
11 that prevent, detect, and correct non-compliance with [the Government's] program
12 requirements as well as measures that prevent, detect, and correct fraud, waste, and
13 abuse." 42 C.F.R. § 422.503(b)(4)(vi).

14 6. As explained by the United States Court of Appeals for the Ninth Circuit, CMS, in
15 2000, made clear that

16 Medicare Advantage organizations have always had "an obligation to take
17 steps to ensure the accuracy, completeness, and truthfulness of the
18 [medical] encounter data" [i.e., diagnoses] and "an obligation to undertake
19 'due diligence' to ensure the accuracy, completeness, and truthfulness of
20 encounter data submitted to [CMS]." . . . CMS made perfectly clear that
21 Medicare Advantage organizations would be "held responsible for making
22 good faith efforts to certify the accuracy, completeness, and truthfulness of
23 encounter data submitted."

24 *United States ex rel. Swoben v. UnitedHealthcare Ins. Co.*, 848 F.3d 1161, 1174 (9th Cir.
25 2016) (quoting 65 Fed. Reg. 40,170, 40,268 (June 29, 2000)). The Ninth Circuit further
26 explained that the requirement that MA Organizations take affirmative steps to address
27 errors in their data is further demonstrated by "§ 422.503, which since 2005 has required
28 Medicare Advantage organizations to have effective compliance programs in place,

1 including ‘[p]rocedures for internal monitoring and auditing’ and ‘for ensuring prompt
2 response to detected offenses’.” *Id.* (quoting 42 C.F.R. § 422.503(b)(4)(vi), (vi)(F),
3 (vi)(G) (2005)).

4 7. For many years, Defendant UnitedHealth Group Inc. (“UHG”) has been the
5 nation’s largest owner of MA Organizations. These organizations offer MA and PD
6 Plans throughout the country. Millions of elderly and disabled Medicare beneficiaries
7 throughout the United States are enrolled in MA and PD Plans that are offered by UHG
8 and the MA Organizations owned by it. In March 2017, approximately 229,000
9 Medicare beneficiaries in the Central District of California were enrolled in MA Plans
10 offered by Defendants UnitedHealthcare of California, Inc. (previously known as
11 PacifiCare of California, Inc.) and Sierra Health and Life Insurance Company, Inc.

12 8. UHG manages and operates the Defendant MA Organizations itself and through
13 its business divisions which, depending on the time period, were or are part of
14 Defendants UnitedHealthcare, Inc.; United HealthCare Services, Inc.; Ovations, Inc.;
15 Optum, Inc.; and OptumInsight, Inc. Hereinafter, UHG, UnitedHealthcare, Inc.; United
16 HealthCare Services, Inc.; Ovations, Inc.; Optum, Inc.; and OptumInsight, Inc. are
17 sometimes collectively referred to as the “UHG Managing Defendants,” based on their
18 roles in managing and operating the Defendant MA Organizations, as described more
19 fully herein. When the term “UHG Managing Defendants” is used in this Amended
20 Complaint in reference to specific facts (*e.g.*, meetings and communications), it refers to
21 those Defendants that managed and operated the Defendant MA Organizations at the
22 time relating to the facts alleged.

23 9. The Government pays billions of taxpayer dollars each year to the Defendant MA
24 Organizations for the Medicare beneficiaries enrolled in the Defendant MA
25 Organizations’ Plans. Risk adjustment payments account for a substantial percentage of
26 these dollars. The diagnoses submitted to the Government by the UHG Managing
27 Defendants on behalf of the Defendant MA Organizations drive a large percentage of the
28 payments that the Defendant MA Organizations receive from the Government.

1 Accordingly, it is not surprising that the UHG Managing Defendants and the Defendant
2 MA Organizations are not passive conduits of diagnoses from healthcare providers to the
3 Government. Rather, for many years, the UHG Managing Defendants have conducted
4 programs and engaged in other activities to increase the amount of risk adjustment
5 payments from the Government to the Defendant MA Organizations. This includes
6 programs and other efforts to directly influence both the number of diagnoses and the
7 severity of the medical conditions reported by providers (such as educating physicians
8 about diagnoses associated with greater risk adjustment payments). This also includes
9 programs and efforts that do not involve providers but nonetheless materially increase
10 the number of diagnoses submitted to the Government and, thus, the amount of risk
11 adjustment payments to the Defendant MA Organizations. Since 2005, the UHG
12 Managing Defendants and/or their predecessors have worked jointly to conduct these
13 programs and perform these activities.

14 10. In particular, since 2005, the UHG Managing Defendants have conducted a very
15 large national Chart Review Program to significantly increase the risk adjustment
16 payments that the Defendant MA Organizations receive from the Government. For
17 many years, this was their biggest effort aimed at increasing risk adjustment payments.
18 During the last ten years, they significantly increased the amount of risk adjustment
19 payments that the Defendant MA Organizations received from the Government by
20 collecting millions of medical records (also known as “charts”) from providers and then
21 employing diagnosis coders (also known as “chart reviewers”) to review the medical
22 records in order to mine them for diagnoses that the providers themselves did not report
23 to the Defendant MA Organizations for the beneficiaries in their Plans. The UHG
24 Managing Defendants then submitted these additional diagnosis codes (“ADDS”) to the
25 Government for billions of dollars of additional risk adjustment payments.

26 11. The UHG Managing Defendants’ national Chart Review Program was strictly a
27 one-sided revenue-generating program. The UHG Managing Defendants did not review
28 the beneficiaries’ medical records in good faith in order to obtain a true and accurate

1 picture of the health status of the beneficiaries in the Defendant MA Organizations’
2 Plans or to submit truthful and accurate risk adjustment data to the Government. They
3 used the results of the chart reviews to only increase payments, *i.e.*, to submit additional
4 diagnoses not reported by the providers. At the same time, they systematically ignored
5 the results of chart reviews that would have led to decreased payments, *i.e.*, results
6 showing that diagnoses reported by providers to them and then submitted by them to the
7 Government were not supported by the beneficiaries’ medical records.

8 12. Moreover, since at least 2005, the UHG Managing Defendants and/or their
9 predecessors have known that a significant percentage of diagnoses reported by
10 providers to them (hereinafter “provider-reported diagnoses”) are invalid because the
11 beneficiaries’ medical records do not substantiate that the beneficiaries had the medical
12 conditions identified by the diagnosis codes reported by the providers. They knew this
13 from audits conducted by the Government and from their own internal medical record
14 reviews. Despite this knowledge, they knowingly avoided “looking both ways” as part
15 of their national Chart Review Program, except for a very limited time period when they
16 “looked both ways” at some of the chart review results as part of their Claims
17 Verification (“CV”) Program. That is, they knowingly and improperly avoided
18 comparing the diagnoses reported by the providers and submitted by them to the
19 Government with the results of the coders’ chart reviews to identify those provider-
20 reported diagnoses that were not supported by the beneficiaries’ medical records. They
21 could and should have done this comparison and withdrawn their prior submission of
22 these unsupported diagnoses, that is, made “DELETES.” If they had done so, the
23 Government would not have made risk adjustment payments based on these unsupported
24 diagnoses or, if it had already made the payments, it would have recovered them from
25 the Defendant MA Organizations or the other Defendants.

26 13. By failing to “look both ways,” the UHG Managing Defendants generated and
27 reported skewed data artificially inflating beneficiaries’ risk scores, avoided negative
28 payment adjustments, and caused the Defendant MA Organizations to retain payments to

1 which they were not entitled. They did this “knowingly,” as that term is defined in the
2 FCA. The Government has conservatively estimated that, if the UHG Managing
3 Defendants had “looked both ways,” they would not have submitted on behalf of the
4 Defendant MA Organizations or, if submitted, they would have withdrawn hundreds of
5 thousands of invalid diagnoses on behalf of the Defendant MA Organizations, and the
6 Government would not have erroneously paid or would have recovered substantial sums
7 of money (*e.g.*, potentially over a billion dollars in risk adjustment payments for four
8 payment years) to which the Defendant MA Organizations were not entitled.

9 14. By failing to “look both ways,” the UHG Managing Defendants and the Defendant
10 MA Organizations knowingly submitted false certifications about the accuracy and
11 truthfulness of their data and knowingly and improperly avoided or decreased
12 obligations to repay (*i.e.*, return) monies owed to the Government in violation of the
13 FCA.

14 15. In addition, Defendants engaged in other conduct (unrelated to their Chart Review
15 Program) that violated the FCA. Defendants deliberately ignored or recklessly
16 disregarded information from their Risk Adjustment Coding Compliance Review
17 (“RACCR”) Program about invalid diagnoses. This information showed that significant
18 percentages of the diagnoses reported to the UHG Managing Defendants and the
19 Defendant MA Organizations by certain “financially incentivized” providers, including
20 certain capitated and gainsharing providers, were unsubstantiated by their patients’
21 medical records.

22 16. The UHG Managing Defendants and the Defendant MA Organizations paid
23 providers who cared for the beneficiaries in the Defendant MA Organizations’ MA Plans
24 through a variety of arrangements. They paid some healthcare providers on a fee-for-
25 service basis for each service (*e.g.*, office visit) they provided to a beneficiary. However,
26 they negotiated payment arrangements with large provider groups that were intended to
27 more closely align their financial interests. For example, the UHG Managing
28 Defendants and the Defendant MA Organizations paid many large provider groups a

1 “fixed” fee for each beneficiary cared for by these providers. These “capitated” fees
2 generally were not dependent on the amount of services rendered by these providers.
3 Instead, the “capitated” fees were often based on a percentage share of the payments that
4 the Defendant MA Organizations received from the Government for the beneficiaries
5 cared for by the providers. The UHG Managing Defendants and the Defendant MA
6 Organizations also entered into “gainsharing” agreements whereby they made incentive
7 payments to some of their fee-for-service providers. These incentive payments were
8 based in whole or part on total revenues that the Defendant MA Organizations received
9 from the Government for the beneficiaries cared for by these gainsharing providers.

10 17. The UHG Managing Defendants’ and the Defendant MA Organizations’
11 agreements with capitated and gainsharing providers incentivized these providers to
12 increase the number of diagnoses that they reported to the UHG Managing Defendants
13 and the Defendant MA Organizations and to report diagnoses for more severe medical
14 conditions. The more risk adjustment payments obtained by the Defendant MA
15 Organizations for the beneficiaries cared for by these providers, the more money the
16 UHG Managing Defendants and the Defendant MA Organizations paid to these
17 providers pursuant to the capitation and gainsharing agreements.

18 18. The UHG Managing Defendants knew that these capitated and gainsharing
19 providers had a financial incentive to report invalid diagnoses in order to increase their
20 own revenues. In fact, based on the results of their own data analyses and medical
21 record reviews conducted as part of their RACCR Program, they knew which
22 incentivized providers were actually or likely engaged in over-reporting diagnoses,
23 including a significant number of providers located in this District. But the UHG
24 Managing Defendants knowingly continued to submit diagnoses from these incentivized
25 providers to the Government and knowingly and improperly avoided repaying the
26 Government for risk adjustment payments based on invalid diagnoses from these
27 providers, all in violation of the FCA.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 because the United States is the Plaintiff. In addition, the Court has subject matter jurisdiction over the FCA claims for relief under 28 U.S.C. §§ 1331 and 1345 and 31 U.S.C. § 3732(a)-(b) and supplemental jurisdiction to entertain the common law and equitable claims for relief under 28 U.S.C. § 1367(a).

20. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because at least one of the Defendants can be found in, resides in, transacts business in, or has committed the alleged acts in the Central District of California.

21. Venue also lies in this District pursuant to 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because at least one of the Defendants can be found in, resides in, and transacts business in this District, a substantial part of the events or omissions giving rise to the claims occurred in this District, and/or all of the Defendants are subject to the Court's personal jurisdiction under the FCA.

PARTIES

I. Plaintiffs

22. Plaintiff is the United States of America, suing on behalf of the United States Department of Health and Human Services ("HHS"), which includes its operating division, the Centers for Medicare and Medicaid Services ("CMS"). At all times relevant to this Complaint, CMS administered and supervised the MA Program and made risk adjustment payments to MA Organizations, including the Defendant MA Organizations in this action, under Parts C and D of the Program. The United States filed its notice of partial intervention in this action on February 14, 2017.

23. The *qui tam* plaintiff ("Relator") is Benjamin Poehling, a former employee of United HealthCare Services, Inc. who was the Director of Finance for Oventions, the group that managed the Defendant MA Organizations until approximately 2010 and, after that, the Director of Finance for UnitedHealthcare Medicare & Retirement, which was the group at UnitedHealthcare, Inc. that succeeded Oventions in managing the

1 Defendant MA Organizations. From mid-2007 until he left at the end of 2012, Poehling
2 ran the risk adjustment team at Ovations and then at UnitedHealthcare Medicare &
3 Retirement, where he was one of the management employees responsible for the
4 submission of claims (*i.e.*, diagnoses) by the UHG Managing Defendants to the
5 Government for risk adjustment payments to the Defendant MA Organizations. He was
6 also one of the management employees responsible for risk adjustment revenue-
7 generating activities, including, but not limited to, the UHG Managing Defendants’
8 national Chart Review Program. Poehling expressed concerns to fellow executives
9 about the failure of the UHG Managing Defendants’ Chart Review Program to “look
10 both ways.” In March 2011, Poehling initiated this action by filing a complaint pursuant
11 to the *qui tam* provisions of the FCA. 31 U.S.C. § 3730(b)(1).

12 **II. Defendants**

13 24. Defendant UnitedHealth Group, Inc. (“UHG”) is a publicly traded Delaware
14 corporation. It is the parent company for all other Defendants in this action. UHG, the
15 other Defendants, and their affiliates have offices in various locations throughout the
16 United States, including in the Central District of California. UHG offers a broad
17 spectrum of products and services through two distinct primary direct corporate
18 subsidiaries (each of which has numerous direct and indirect subsidiaries of its own):
19 (1) UnitedHealthcare, Inc., a health benefits (*i.e.*, insurance) company, and (2) Optum,
20 Inc., a health services company. Accordingly, UHG’s healthcare insurance products,
21 including those under Parts C and D of the Medicare Program, are offered by, and
22 UHG’s MA and PD Plans are managed by, various entities that are UHG’s direct or
23 indirect subsidiaries, including, but not limited to, the other Defendants identified below.
24 UHG controls all of these entities.

25 25. UHG and its direct and indirect subsidiaries and affiliates operate MA
26 Organizations in all fifty states and the District of Columbia. Each of these MA
27 Organizations offers one or more MA Plans, that is, one or more packages of healthcare
28 insurance benefits under Part C of the Medicare Program. Many, if not all, of these MA

1 Organizations also offer PD Plans, that is, drug benefit packages under Part D of the
2 Medicare Program. As of December 31, 2008, UHG had approximately 1.5 million
3 Medicare beneficiaries enrolled in its MA Plans under Part C of the Medicare Program
4 and millions of additional beneficiaries enrolled in its PD Plans. As of December 31,
5 2009, UHG had approximately 1.8 million Medicare beneficiaries enrolled in its MA and
6 millions of additional beneficiaries enrolled in its PD Plans. As of December 31, 2010,
7 UHG had approximately 2.1 million beneficiaries in its MA Plans and millions of
8 additional beneficiaries in its PD Plans. As of December 31, 2011, UHG had 2.2 million
9 beneficiaries in its MA Plans and millions of additional beneficiaries in its PD Plans. As
10 of December 31, 2012, UHG had approximately 2.6 million beneficiaries in its MA
11 Plans and millions of additional beneficiaries in its PD Plans. In 2013, 2014, and 2015
12 United had approximately 3 million beneficiaries in its MA Plans and approximately 8
13 million in its PD Plans. In 2016, UHG had approximately 3.6 million beneficiaries in its
14 MA Plans, and approximately 8.6 million beneficiaries in its PD Plans. Annually,
15 UHG's revenues from the MA Program have been in the tens of billions of dollars.

16 26. All Defendant MA Organizations entered into one or more agreements with the
17 Government during the relevant time period to offer MA Plans and/or PD Plans to
18 Medicare beneficiaries under Parts C and D of the Medicare Program, presented or had
19 the UHG Managing Defendants present on their behalf claims to the Government for risk
20 adjustment payments under Parts C and D of the Medicare Program, submitted or had
21 the UHG Managing Defendants submit on their behalf one or more Risk Adjustment
22 Attestations to the Government for risk adjustment payments from the Medicare
23 Program, and received risk adjustment payments from the Government. These
24 Defendant MA Organizations include all MA Organizations acquired, owned, and
25 controlled directly or indirectly by UHG after 2005, including:

26 a. AmeriChoice of New Jersey, Inc., a New Jersey corporation, doing
27 business as AmeriChoice Personal Care Plus and UnitedHealthcare Community
28 Plan.

1 b. Arizona Physicians IPA, Inc., an Arizona corporation, doing business
2 as APIPA Personal Care Plus and UnitedHealthcare Community Plan.

3 c. Care Improvement Plus of Maryland, Inc., which is or was a
4 Maryland corporation, doing business as Care Improvement Plus.

5 d. Care Improvement Plus of Texas Insurance Company, which is a
6 Texas insurance company, doing business as Care Improvement Plus.

7 e. Care Improvement Plus South Central Insurance Co., which is an
8 Arkansas insurance company, doing business as Care Improvement Plus and
9 UnitedHealthcare.

10 f. Care Improvement Plus Wisconsin Insurance Company, which is a
11 Wisconsin insurance company, doing business as Care Improvement Plus and
12 UnitedHealthcare.

13 g. Optum Insurance Co., which is an Ohio corporation.

14 h. Citrus Health Care, Inc., which is or was a Florida corporation.

15 i. Health Plan of Nevada, Inc., which is a Nevada corporation.

16 j. Medica HealthCare Plans, Inc., which is a Florida corporation.

17 k. Oxford Health Plans (CT), Inc., which is a Connecticut corporation,
18 doing business as AARP MedicareComplete from SecureHorizons; Oxford
19 Medicare Advantage; SecureHorizons; SecureHorizons by UnitedHealthCare; and
20 UnitedHealthcare.

21 l. Oxford Health Plans (NJ), Inc., which is a New Jersey corporation,
22 also known as Oxford Health Plans of New Jersey, Inc., doing business as AARP
23 MedicareComplete from SecureHorizons; AARP MedicareComplete provided by
24 SecureHorizons; Evercare; Evercare by UnitedHealthcare; Evercare Health Plans;
25 Evercare Plan H; SecureHorizons; SecureHorizons by UnitedHealthCare; and
26 UnitedHealthcare.

1 m. Oxford Health Plans (NY), Inc. which is a New York corporation,
2 doing business as Oxford Medicare Advantage; SecureHorizons; SecureHorizons
3 by UnitedHealthcare; and UnitedHealthcare.

4 n. PacifiCare Life and Health Insurance Company, which is an Indiana
5 insurance company, doing business as SecureHorizons Direct and SecureHorizons
6 MedicareDirect.

7 o. PacifiCare of Arizona, Inc., which is an Arizona corporation doing
8 business as SecureHorizons Medicare Advantage Plan; SecureHorizons by
9 UnitedHealthcare; and UnitedHealthcare.

10 p. PacifiCare of Colorado, Inc., which is a Colorado corporation doing
11 business as AARP MedicareComplete from Secure Horizons; AARP
12 MedicareComplete provided by SecureHorizons; Secure Horizons Medicare
13 Advantage Plan; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

14 q. PacifiCare of Nevada, Inc., which is a Nevada corporation, also
15 known as PacifiCare/UHC of Nevada, doing business as AARP
16 MedicareComplete provided by SecureHorizons; PacifiCare/UHC of Nevada;
17 Secure Horizons Medicare Advantage Plan; SecureHorizons by UnitedHealthcare;
18 and UnitedHealthcare.

19 r. Physicians Health Choice of Texas, LLC, which is a Texas limited
20 liability company doing business as Physicians Health Choice.

21 s. Preferred Care Partners, Inc., which is a Florida corporation doing
22 business as UnitedHealthcare.

23 t. Rocky Mountain Health Maintenance Organization, Inc., which is a
24 Colorado company.

25 u. Sierra Health and Life Insurance Company, Inc., which is a Nevada
26 corporation doing business as Erickson Advantage and UnitedHealthcare.

27 v. Symphonix Health Insurance, Inc., which is an Illinois insurance
28 company doing business as Symphonix Health.

1 w. UnitedHealthcare of California, Inc., which is a California
2 corporation, also known as UHC of California, Inc. and formerly known as
3 PacifiCare of California, Inc. and PacifiCare of California/Secure Horizons, doing
4 business as SecureHorizons by UnitedHealthcare, Secure Horizons Medicare
5 Advantage Plan, and UnitedHealthcare.

6 x. Unison Health Plan of Tennessee, Inc., which is a Tennessee
7 corporation doing business as Unison Advantage and UnitedHealthcare
8 Community Plan.

9 y. United Health Care Ins. Co. and United New York, which is a New
10 York insurance company doing business as UnitedHealthcare.

11 z. UnitedHealthcare Benefits of Texas, Inc., which is a Texas
12 corporation, formerly known as PacifiCare of Texas, Inc., doing business as
13 SecureHorizons Medicare Advantage Plan; SecureHorizons by UnitedHealthcare;
14 and UnitedHealthcare.

15 aa. UnitedHealthcare Community Plan of Ohio, Inc., which is an Ohio
16 corporation, formerly known as Unison Health Plan of Ohio, Inc., doing business
17 as Unison Advantage and UnitedHealthcare Community Plan.

18 bb. UnitedHealthcare Community Plan of Texas, L.L.C., which is a
19 Texas limited liability company, formerly known as Evercare of Texas, LLC,
20 doing business as Evercare by UnitedHealthcare and Evercare Health Plans; and
21 UnitedHealthcare.

22 cc. UnitedHealthcare Community Plan, Inc., which is a Michigan
23 corporation, also known as Great Lakes Health Plan, Inc. and UnitedHealthcare of
24 the Great Lakes Health Plan, Inc., doing business as Great Lakes Personal Care
25 Plus and UnitedHealthcare Community Plan.

26 dd. UnitedHealthcare Insurance Company, which is a Connecticut
27 insurance company, also known as United Healthcare Insurance Company, doing
28 business as AARP MedicareComplete from SecureHorizons; Erickson Advantage;

1 Evercare by UnitedHealthcare; Evercare Health Plans; Evercare Senior Care
2 Options; SecureHorizons; SecureHorizons by UnitedHealthcare; SecureHorizons
3 MedicareDirect; United Health Group; UnitedHealthcare; and UnitedHealthcare
4 Community Plan.

5 ee. UnitedHealthcare Insurance Company of New York, which is a New
6 York insurance company, also known as United Healthcare Insurance Company of
7 New York, doing business as SecureHorizons; SecureHorizons MedicareDirect;
8 SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

9 ff. UnitedHealthcare of Alabama, Inc., which is an Alabama
10 corporation, also known as United HealthCare of Alabama, Inc., doing business as
11 SecureHorizons; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

12 gg. UnitedHealthcare of Arizona, Inc., which is an Arizona corporation,
13 also known as United HealthCare of Arizona, Inc., doing business as
14 SecureHorizons; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

15 hh. UnitedHealthcare of Arkansas, Inc., which is an Arkansas
16 corporation, also known as United Healthcare of Arkansas, Inc., doing business as
17 SecureHorizons; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

18 ii. UnitedHealthcare of Florida, Inc., which is a Florida corporation, also
19 known as United Healthcare of Florida, Inc. doing business as AmeriChoice;
20 Evercare at Home; SecureHorizons; SecureHorizons by UnitedHealthcare; and
21 UnitedHealthcare.

22 jj. UnitedHealthcare of Georgia, Inc., which is a Georgia corporation,
23 also known as United Healthcare of Georgia, Inc., doing business as
24 SecureHorizons; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

25 kk. UnitedHealthcare of New England, Inc., which is a Rhode Island
26 corporation, also known as United HealthCare of New England, Inc. and United
27 Health Plans of New England, Inc., doing business as AARP MedicareComplete
28

1 provided by SecureHorizons; AARP MedicareComplete from SecureHorizons;
2 SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

3 ll. UnitedHealthcare of New York, Inc., which is a New York
4 corporation, also known as AmeriChoice of New York, Inc. and United
5 Healthcare of New York, Inc. doing business as AmeriChoice Personal Care Plus;
6 SecureHorizons; SecureHorizons by UnitedHealthcare; UnitedHealthcare; and
7 UnitedHealthcare Community Plan.

8 mm. UnitedHealthcare of North Carolina, Inc., which is a North Carolina
9 corporation, also known as United Healthcare of North Carolina, Inc., doing
10 business as SecureHorizons; SecureHorizons by UnitedHealthcare, and
11 UnitedHealthcare.

12 nn. UnitedHealthcare of Ohio, Inc., which is an Ohio corporation, also
13 known as United Healthcare of Ohio, Inc., doing business as SecureHorizons,
14 SecureHorizons by UnitedHealthcare, and UnitedHealthcare.

15 oo. UnitedHealthcare of Oklahoma, Inc., which is an Oklahoma
16 corporation, formerly known as PacifiCare of Oklahoma, Inc., doing business as
17 Secure Horizons Medicare Advantage Plan; SecureHorizons by UnitedHealthcare,
18 and UnitedHealthcare.

19 pp. UnitedHealthcare of Oregon, Inc., which is an Oregon corporation,
20 formerly known as PacifiCare of Oregon, Inc., doing business as AARP
21 MedicareComplete from SecureHorizons; AARP MedicareComplete provided by
22 SecureHorizons; SecureHorizons Medicare Advantage Plan; SecureHorizons by
23 UnitedHealthCare; and UnitedHealthcare.

24 qq. UnitedHealthcare of Pennsylvania, Inc., which is a Pennsylvania
25 corporation, formerly known as Unison Health Plan of Pennsylvania, Inc., doing
26 business as Unison Advantage; UnitedHealthcare Community Plan; and
27 UnitedHealthcare.
28

1 rr. UnitedHealthcare of Tennessee, Inc., which is a Tennessee
2 corporation, also known as United Healthcare of Tennessee, Inc., doing business
3 as AARP MedicareComplete from SecureHorizons; AARP MedicareComplete
4 provided by SecureHorizons; SecureHorizons; and SecureHorizons by
5 UnitedHealthcare.

6 ss. UnitedHealthcare of the Midlands, Inc., which is a Nebraska
7 corporation, also known as United Healthcare of the Midlands, Inc., doing
8 business as SecureHorizons by UnitedHealthcare and UnitedHealthcare.

9 tt. UnitedHealthcare of the Midwest, Inc., which is a Missouri
10 corporation, also known as United Healthcare of the Midwest, Inc., doing business
11 as SecureHorizons; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

12 uu. UnitedHealthcare of Utah, Inc., which is a Utah corporation, also
13 known as United Healthcare of Utah, Inc., doing business as SecureHorizons;
14 SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

15 vv. UnitedHealthcare of Washington, Inc., which is a Washington
16 corporation, formerly known as PacifiCare of Washington, Inc., doing business as
17 AARP MedicareComplete from SecureHorizons; Secure Horizons Medicare
18 Advantage Plan; SecureHorizons by UnitedHealthcare; and UnitedHealthcare.

19 ww. UnitedHealthcare of Wisconsin, Inc., which is a Wisconsin
20 corporation, also known as United Healthcare of Wisconsin, Inc. doing business as
21 SecureHorizons; SecureHorizons by UnitedHealthcare; UnitedHealthcare
22 Community Plan; UnitedHealthcare Personal Care Plus; and UnitedHealthcare.

23 xx. UnitedHealthcare Plan of the River Valley, Inc., which is an Illinois
24 corporation, also known as United Healthcare Plan of the River Valley, Inc.,
25 UnitedHealth Care Plan of the River Valley, Inc., and United HealthCare of the
26 River Valley, Inc., doing business as AmeriChoice Secure Plus Complete;
27 SecureHorizons by UnitedHealthcare; UnitedHealthcare; and UnitedHealthcare
28 Community Plan.

yy. Any other MA Organizations acquired, owned, or controlled by UHG since 2005.

27. Defendant United HealthCare Services, Inc. (“United HealthCare Services”) is a Minnesota corporation. It is a direct subsidiary of Defendant UHG. United HealthCare Services is the successor to PacifiCare Health Systems and PacifiCare Health Plan Administrators, Inc., which managed some of the Defendant MA Organizations. See *infra* paragraph 37. As previously stated, United HealthCare Services also employed Relator Poehling and, on information and belief, employed other individuals who held titles and positions within the other UHG Managing Defendants and who performed work on behalf of the Defendant MA Organizations.

28. Defendant Ovations, Inc. (“Ovations”) is a Delaware corporation. It is a direct subsidiary of Defendant United HealthCare Services and an indirect subsidiary of Defendant UHG. Until approximately 2010, one or more of the groups that managed some of the Defendant MA Organizations were located within Defendant Ovations.

29. Defendant UnitedHealthcare, Inc. (“UnitedHealthcare”) is a Delaware corporation, and a direct subsidiary of Defendant UHG. UnitedHealthcare is the UHG business entity which owns, operates, and offers health insurance plans to governmental customers. Various UnitedHealthcare subsidiaries operate health benefit plans and provide healthcare benefits to millions of Medicare beneficiaries under the MA Program. UnitedHealthcare also is the UHG subsidiary which contracts (through its subsidiaries) with the Government to provide insurance benefits to MA beneficiaries, submits the annual Risk Adjustment Attestations to the Government, submits claims for payment to the Government, and receives payment from the Government.

30. Defendants Optum, Inc. and OptumInsight, Inc. are health services companies. They are Delaware corporations. They are direct or indirect subsidiaries of Defendant UHG. In 2011, OptumInsight became the successor to Ingenix, Inc. (“Ingenix”). Thereafter, OptumInsight operated as part of Optum. For the purposes of this Amended Complaint, Optum, Inc. and OptumInsight, Inc. will be referred to as “Optum.”

1 Furthermore, to the extent that the United States is uncertain whether an act or statement
2 is attributable to Ingenix or its successor, Optum, the United States will refer to the entity
3 as “Ingenix/Optum.” Since 2007, the group within Ingenix and then Optum that
4 performed risk adjustment-related work had various names. For purposes of this
5 Amended Complaint, it is referred to as the “Risk Adjustment Group.”

6 31. Defendants United HealthCare Services, Ovations, UnitedHealthcare, and Optum
7 (and Optum’s predecessor, Ingenix) are or were “Related Entities” under the federal
8 regulations that govern the MA Program. As explained more fully below, each of them
9 has or had its own legal obligations to the MA Program relating to, among other things,
10 the submission of valid risk adjustment data and the deletion or withdrawal of invalid
11 data.

12 32. The Defendant MA Organizations were not autonomous and do not appear to have
13 had any management or any other employees who ran them or had any decision-making
14 authority (if they had any of their own management or employees at all). Instead, UHG
15 had various groups that managed and had oversight responsibilities and decision-making
16 authority for the Defendant MA Organizations. At various times relevant to this
17 Amended Complaint, these groups were located within Defendants United HealthCare
18 Services (and/or its predecessors), Ovations, and UnitedHealthcare. Depending on the
19 time period, the groups were known by the names Secure Horizons, Evercare, the Public
20 & Senior Markets Group (“PSMG”), the Public Sector Market Group (also “PSMG”),
21 Ovations, Ovations Part D, and AmeriChoice. Prior to approximately 2010, these groups
22 were located in Defendants United HealthCare Services (and/or its predecessors) and
23 Ovations. Since approximately 2010, these groups have been located within Defendant
24 UnitedHealthcare and are referred to as UnitedHealthcare Medicare & Retirement and
25 UnitedHealthcare Community & State. Among other things, these groups oversaw risk
26 adjustment-related activities such as the submission of risk adjustment data (including
27 diagnoses) to the Government on behalf of the Defendant MA Organizations, the
28 retraction of invalid data that they had submitted to the Government on behalf of the

1 Defendant MA Organizations, and the Chart Review, Claims Verification, and RACCR
2 Programs that they had conducted on behalf of the Defendant MA Organizations. As
3 explained more fully below, Defendants United HealthCare Services (and/or its
4 predecessors), Ovations, UnitedHealthcare, and any other UHG entities in which these
5 groups may have been located are “Related Entities” with their own legal obligations
6 relating to, among other things, the submission of valid risk adjustment data to the
7 Government and the deletion or withdrawal of invalid data.

8 33. Starting in 2007, the actual risk adjustment data submission work was performed
9 by the Risk Adjustment Group within Ingenix and then within Ingenix’s successor,
10 Optum. First Ingenix and then Optum operated a computer system called the Internal
11 Risk Adjustment Data System (“IRADS”) that electronically submitted risk adjustment
12 data (that is, diagnoses) to CMS’ Risk Adjustment Processing System (“RAPS”) in order
13 for the Defendant MA Organizations to claim and receive risk adjustment payments. In
14 addition, Ingenix and then Optum helped to manage the Chart Review, Claims
15 Verification, and RACCR Programs and performed the day-to-day activities necessary to
16 conduct these programs. Ingenix and then Optum performed activities relating to the
17 submission of risk adjustment data and operated the various risk adjustment-related
18 programs from offices in this District and elsewhere.

19 34. Similar to the other UHG Managing Defendants, Ingenix was and Optum is a
20 “Related Entity” because Ingenix was and Optum is related to the Defendant MA
21 Organizations by common ownership or control through Defendant UHG and performed
22 some or all of the management functions for the Defendant MA Organizations. As
23 previously explained, Optum is one of the “UHG Managing Defendants” because of the
24 role that it (and its predecessor, Ingenix) played in managing the Defendant MA
25 Organizations during the relevant time period. Any reference in this Amended
26 Complaint to the predecessors of the UHG Managing Defendants includes Ingenix.

27 35. Ingenix and then Optum also performed risk adjustment-related services for third-
28 parties which owned and operated their own MA Organizations and offered their own

1 Plans. The UHG Managing Defendants referred to these third-parties as Ingenix's and
2 then Optum's commercial clients. Ingenix and then Optum submitted risk adjustment
3 data to the Government on behalf of these commercial clients and conducted Chart
4 Review and other programs for them. Ingenix and then Optum performed this risk
5 adjustment-related work for commercial clients from offices in this District and
6 elsewhere.

7 36. UHG became the largest owner of MA Organizations in large part by acquiring
8 them. For example, in 2005, UHG (directly or through a subsidiary) acquired PacifiCare
9 Health Systems ("PacifiCare") and PacifiCare's and its affiliates' MA Organizations and
10 MA Plans, including the following MA Organization Defendants: PacifiCare of
11 Arizona, Inc., incorporated in Arizona; PacifiCare of California, incorporated in
12 California; PacifiCare of Colorado, Inc., incorporated in Colorado; PacifiCare of
13 Nevada, Inc., incorporated in Nevada; PacifiCare of Oklahoma, Inc., incorporated in
14 Oklahoma; PacifiCare of Oregon, Inc., incorporated in Oregon; PacifiCare of Texas, Inc.
15 incorporated in Texas; and PacifiCare of Washington, incorporated in Washington. Both
16 before and after the acquisition, PacifiCare of California and possibly other PacifiCare
17 MA Organizations and MA Plans referred to themselves or to their brand of MA Plans as
18 Secure Horizons. Since 2005, these PacifiCare MA Organizations have been indirect
19 subsidiaries of and controlled by UHG. Several years after the acquisition, these
20 PacifiCare plans were renamed or rebranded as UnitedHealthcare MA Organizations or
21 merged into other UHG MA Organizations. For instance, in 2011, PacifiCare of
22 California became Defendant UnitedHealthcare of California.

23 37. Defendant United HealthCare Services is the successor of PacifiCare Health
24 Systems and PacifiCare Health Plan Administrators, Inc., which were the direct or
25 indirect parents of the PacifiCare MA Organizations acquired by UHG in 2005. United
26 HealthCare Services became their successor sometime after the acquisition. For a short
27 period of time after the acquisition, PacifiCare Health Systems (and possibly also
28 PacifiCare Health Plan Administrators) was involved in the management of the

1 PacifiCare MA Organizations and perhaps other Defendant MA Organizations, including
2 the management of risk adjustment-related activities. All PacifiCare MA Organizations
3 and other entities and their successors were direct or indirect subsidiaries of Defendant
4 UHG. Any reference in this Amended Complaint to United HealthCare Services or the
5 UHG Managing Defendants includes PacifiCare Health Systems and PacifiCare Health
6 Plan Administrators.

7 38. Before UHG's acquisition of PacifiCare, the PacifiCare employees with
8 responsibilities relating to the submission of risk adjustment data to the Government and
9 responsibilities relating to other risk adjustment-related activities worked at a PacifiCare
10 office in Cypress, California, within this District. Sometime after the acquisition, this
11 office moved to Santa Ana, California, within this District, and continued to submit
12 claims and perform other risk adjustment-related activities. In 2007, the employees in
13 this Risk Adjustment Group in this District became employees of Ingenix and then they
14 became employees of Optum in 2011. A substantial part of the events or omissions
15 relevant to this litigation occurred at these and other locations within this District.

16 39. As an example of UHG's other acquisitions, UHG (directly or through a
17 subsidiary) acquired WellMed Medical Management, Inc. ("WMMI") in 2011. UHG's
18 acquisition of WMMI included its subsidiaries and affiliates, including, but not limited
19 to, WMMI's MA Organizations and MA Plans, Physician's Health Choice of Texas,
20 LLC and Citrus Health Care, Inc., which operated in Texas, Florida, New Mexico and
21 Arkansas. Citrus Health Care, Inc. was a Florida corporation and a subsidiary of PHC
22 Holdings of Florida, Inc. Sometime after the acquisition, UHG renamed or rebranded
23 these MA Organizations and MA Plans as UHG MA Organizations or MA Plans or
24 merged them with or into UHG's other MA Organizations or MA Plans in these states.

25 40. Over the last decade, UHG and its subsidiaries have also sought to vertically
26 integrate in the health care market by acquiring and/or operating large groups or
27 networks of direct providers of healthcare services and other entities that manage the
28 provision of such services to beneficiaries enrolled in the Defendant MA Organizations'

1 MA Plans. For example, UHG vertically integrated in several States when it acquired
2 WMMI in 2011. For many years, WMMI had subsidiaries and other affiliates that
3 directly managed the provision of or directly provided healthcare services. These
4 affiliates included WellMed Networks, Inc., WellMed Networks Inc. of Florida,
5 WellMed Medical Management of Florida Inc., and WellMed Medical Group, PA. After
6 the acquisition, WellMed became part of the group called OptumCare. After the
7 acquisition, WellMed also significantly expanded by acquiring more than 50 medical
8 practices in Texas and Florida. WellMed included more than 10,000 physicians that
9 provided healthcare to hundreds of thousands of Medicare beneficiaries in Texas and
10 Florida, including beneficiaries enrolled in Plans owned or operated by one or more
11 Defendant MA Organizations.

12 41. All references to “Defendants” in this Complaint include all of the Defendants
13 identified above.

14 **DEFENDANTS’ EXECUTIVES AND OTHER EMPLOYEES**

15 42. When the job titles of Defendants’ executives and other employees are provided in
16 this Amended Complaint, the United States, based on its best knowledge and belief, has
17 provided their titles at the time relating to the facts alleged. As a reference, the United
18 States also provides, based on its best knowledge and belief, the following list of the job
19 titles of Defendants’ executives and other employees who are referenced in this
20 Amended Complaint and the names of the specific business divisions or entities for
21 which they worked during the time period that they were involved in matters relevant to
22 this action (in alphabetical order by last name):

- 23 • Kyle Anderson – From 2009 to 2015, Anderson was the Director of Financial
24 Planning and Analysis at UnitedHealthcare.
- 25 • Jason Bainbridge – Bainbridge worked for UnitedHealthcare Community & State
26 in 2012.
- 27 • Paul Balthazor – From 2011 through 2015, Balthazor was the Chief Financial
28 Officer of UnitedHealthcare Community & State.

- 1 • Marc Beckmann – Beckmann worked for UnitedHealthcare Medicare &
2 Retirement in the Finance-Risk Adjustment Analysis Section.
- 3 • Paul Bihm – At PacifiCare, Bihm was a Vice President and Chief of Staff. After
4 the acquisition, he worked for Ingenix as Chief Financial Officer and Chief
5 Operating Officer from 2007 to 2010 and then for Optum’s Risk Adjustment
6 Group as a Senior Vice President of Client Management.
- 7 • Jon Bird – In 2008, Bird was hired to work for Ingenix’s Risk Adjustment Group.
8 In 2010, he became the Director of Revenue Projections for this group. In or
9 about 2011, when the Risk Adjustment Group was moved to Optum, Bird became
10 an employee of Optum. In or about 2013, Bird assumed significant responsibility
11 for the Chart Review and Claims Verification Programs. He was also a “decision
12 maker” for the Claims Verification and RACCR Programs and a member of
13 United’s Risk Adjustment Advisory Board/Council, which was chaired by
14 Defendant UHG’s Chief Executive Officer Steve Hemsley. By at least March
15 2014, Bird was the Senior Vice President of Risk and Quality Analytics at Optum.
- 16 • Gail Boudreaux – In 2008, Boudreaux became the Executive Vice President of
17 UnitedHealthcare. From 2011 to 2014, she was the Chief Executive Officer of
18 UnitedHealthcare. During Boudreaux’s time as Chief Executive Officer of
19 UnitedHealthcare, Steve Nelson, John Larsen, and Daniel Schumacher reported to
20 her. She reported to Steve Hemsley. According to a 2011 document, Boudreaux
21 was “significantly involved in the oversight and management of”
22 UnitedHealthcare’s “Medicare business.”
- 23 • Tracey Bradberry – From 2008 through 2012, Bradberry was an Operations
24 Manager at Ingenix. Since 2012, she has been an Associate Director of
25 Operations at Optum. In that role, she leads diagnosis coding teams for the Chart
26 Review Program.
- 27 • Patty Brennan – In 2008, Brennan was hired to work for Ingenix’s Risk
28 Adjustment Group. She was hired as Ingenix’s Compliance Manager for Risk

1 Adjustment Programs. In 2009, Brennan became the Ingenix Director of
2 Retrospective Services relating to risk adjustment. In or about 2011, when the
3 Risk Adjustment Group was moved to Optum, Brennan became an employee of
4 Optum. From 2009 to 2013, Brennan oversaw the Chart Review Program. In
5 2013, she became the Vice President of Retrospective Services. Brennan, along
6 with other individuals, was responsible for the development and execution of the
7 Internal Data Validation Program, the RACCR Program, and the Claims
8 Verification Program. She was also the Program Manager for the Claims
9 Verification Program for several years and had strategic oversight over the
10 RACCR Program from 2009 to 2013.

- 11 • Jonathon Bunker – In 2009, Bunker was the President of Sierra Health and Life
12 Insurance Company, Inc. and the President of Health Plan of Nevada, Inc. Upon
13 the close of the merger between UHG and Sierra Health Services, Bunker was the
14 Chief Executive Officer of the southwest region of UnitedHealthcare.
- 15 • Barbara Carlson – In 2011, Carlson was a Senior Regulatory Affairs Analyst at the
16 Regulatory Affairs Department at UnitedHealthcare Medicare & Retirement.
- 17 • Shelly Cranley – Cranley served as the Director of Regulatory Affairs for
18 UnitedHealthcare.
- 19 • Keith Dobbins – Since 2006, Dobbins has been UnitedHealthcare's Deputy
20 General Counsel.
- 21 • Juliet Domb – From 2012 to 2015, Domb was a Strategic Relationship Analyst at
22 Optum. She has also served as an administrative assistant to Larry Renfro.
- 23 • Jeffrey Dumcum – At PacifiCare, Dumcum was the Chief Financial Officer. After
24 the acquisition, he became a Vice President of Finance for Ovations. In 2007,
25 Dumcum became a Senior Vice President at Ingenix and oversaw the Risk
26 Adjustment Group at Ingenix and then Optum until approximately 2014.
- 27 • Karen Erickson – Since 2011, Erickson has been an Executive Vice President and
28 the Chief Quality Officer at Optum. In this role, Erickson has reported to the

1 Chief Executive Officer of Optum, Larry Renfro. Also in 2011, Erickson was the
2 Chief Administrative Officer of Optum, and prior to that she worked for Optum
3 for 12 years in various financial and administrative roles.

- 4 • Ronnie Grower – From 2008 to 2010 Grower was a Vice President of Market
5 Consultation and a Vice President of Account Management at Ingenix.
- 6 • Joseph Haferman – Haferman was the Chief Financial Officer of Ovations in 2005
7 and the Chief Financial Officer of Secure Horizons in 2007 and possibly for some
8 time thereafter. Relator Poehling reported to Haferman from early 2007 to late
9 2008.
- 10 • Kimberly Halva – In 2009, Halva was an attorney for UnitedHealthcare Medicare
11 & Retirement. From 2010 to 2013, Halva was the UnitedHealthcare Medicare &
12 Retirement’s Finance Compliance Officer. She also had the title Director of
13 Compliance. From 2010 to 2103, she reported to Jennifer O’Brien.
- 14 • Mary Hammond – From 2010 to 2013, Hammond was an Associate Director of
15 Strategy and Support who worked for the risk adjustment team at
16 UnitedHealthcare Medicare & Retirement. She reported to Relator Poehling until
17 he left at the end of 2012.
- 18 • Charles Hanson – From 2008 to 2013, Hanson was a Vice President of
19 Underwriting and Finance at UnitedHealthcare Medicare & Retirement.
- 20 • Steve Hemsley – Hemsley is currently the Executive Chairman of UHG’s Board
21 of Directors. He was the Chief Executive Officer of UHG from 2006 to 2017.
22 According to a 2011 document, Hemsley was “significantly involved in the
23 oversight and management of” UHG’s “Medicare business.”
- 24 • James Higgins – Higgins was the Finance Director at PacifiCare. After the
25 acquisition, Higgins became a Director for Revenue Analytics.
- 26 • William Hnath – Hnath was the financial controller for UnitedHealthcare
27 Medicare & Retirement.

- 1 • Pam Holt – Holt was a Project Manager for Network Management Operations at
2 PacifiCare. After the acquisition, she became a Manager of Provider Outreach for
3 the Risk Adjustment Program.
- 4 • Scott Hughes – Starting in mid-2012, Hughes was a Senior Project Manager at
5 Optum.
- 6 • Michael Jacobson – Jacobson was a Program Business Analyst/Project Manager at
7 Optum.
- 8 • Donald James – James was a Director of Program Strategy at Optum from 2012 to
9 2015.
- 10 • Thad Johnson – Johnson is an attorney for UnitedHealthcare and is the current
11 Chief Legal Officer for the company.
- 12 • Joseph Keen – Keen was a Vice President and Chief Compliance Audit Officer for
13 UnitedHealthcare Medicare & Retirement in 2011.
- 14 • Gerald (Jerry) Knutson – Knutson was the Chief Financial Officer of Ovations
15 from 2003 to 2009 and the Chief Financial Officer of OptumInsight from 2009 to
16 2012.
- 17 • John Larsen – Larsen was the Chief Financial Officer of UnitedHealthcare
18 Medicare & Retirement (previously called Ovations-PSMG) until 2010, when
19 Scott Theisen succeeded him in that position. Larsen reported to Larry Renfro
20 when Renfro was the Chief Executive Officer of Ovations-PSMG. Relator
21 Poehling reported to Larsen in 2010. In August 2012, Larsen became the Chief
22 Executive Officer of UnitedHealthcare Medicare & Retirement. In early 2014,
23 Steve Nelson took over that position.
- 24 • Pam Leal – Leal was the Executive Director of Provider Training and
25 Development at PacifiCare. After the acquisition, she became a Regional Vice
26 President for Market Consultation at Ingenix.
- 27 • Rebecca Martin – In 2010, Martin became the Director of Encounter Operations at
28 Ingenix. From 2011 to 2015, Martin was the Director of Data Remediation at

1 Optum. In 2015, she became the Director of Data Management Strategies at
2 Optum.

- 3 • Jay Matushak – From 2013 to 2015, Matushak was a Vice President of Financial
4 Planning and Analysis for UnitedHealthcare Medicare & Retirement. He reported
5 to Brian Thompson.
- 6 • Michael McCarthy – Starting in November 2011, McCarthy was the Executive
7 Director of UnitedHealthcare Medicare & Retirement. In 2013, he also served as
8 a Regional Vice President for Southern California for UnitedHealthcare Medicare
9 Solutions.
- 10 • Marybeth Meyer – Since 2013, Meyer has been a Vice President of Operations at
11 UnitedHealthcare Medicare & Retirement where she oversees risk adjustment
12 programs and activities. Meyer reported to Theisen and then to Brian Thompson.
- 13 • Bill Miller – Miller was the Chief Executive Officer of OptumInsight from 2012
14 to 2017.
- 15 • Eric Murphy – Murphy was the President of Payer Solutions at Optum.
- 16 • Randall Myers – Myers worked for PacifiCare and, after the acquisition, for
17 Ingenix and then Optum as a Director of Encounter Operations.
- 18 • Timothy Noel – Noel was the Vice President of Finance for Ovations and then
19 UnitedHealthcare Medicare & Retirement from 2007 to 2013 and reported to the
20 Chief Financial Officers of those groups. Poehling reported to Noel from the fall
21 of 2010 until his departure in December 2012.
- 22 • Steve Nelson – Since 2017, Nelson has been the Chief Executive Officer of
23 UnitedHealthcare. From 2014 to 2017, he was the Chief Executive Officer of
24 UnitedHealthcare Medicare & Retirement.
- 25 • Jennifer O’Brien – O’Brien was the Chief Medicare Compliance Officer of
26 Ovations and then UnitedHealthcare Medicare & Retirement. She reported to
27 David Orbuch. She was part of the UnitedHealthcare Medicare & Retirement
28 “Executive Leadership Team.”

- 1 • Karin O'Hara – O'Hara worked at UnitedHealthcare Community & State.
- 2 • David Orbuch – Orbuch was the Chief Compliance Office for PSMG and
- 3 UnitedHealthcare Medicare & Retirement.
- 4 • Thomas Paul – In the 2009 to mid-2010 time period, Paul was the Chief Executive
- 5 Officer and Chief Operating Office of Ovations and, in the mid-2010 to August
- 6 2012 time period, Paul was the Chief Executive Officer of UnitedHealthcare
- 7 Medicare & Retirement. He reported to Renfro and then to Gail Boudreaux. He
- 8 was part of the UnitedHealthcare Medicare & Retirement "Executive Leadership
- 9 Team."
- 10 • Karen Petroff – Petroff was the Senior Vice President of Business Development at
- 11 Optum.
- 12 • Cindy Polich – Polich was the President of Ovations and then UnitedHealthcare
- 13 Medicare & Retirement. She reported to Larry Renfro and Thomas Paul. She was
- 14 part of the UnitedHealthcare Medicare & Retirement "Executive Leadership
- 15 Team."
- 16 • Patricia Rasmussen – Rasmussen was Manager of Encounter Submissions at
- 17 Ingenix.
- 18 • Janice Redmond – Prior to 2012, Redmond was Senior Vice President of Provider
- 19 Outreach at Optum. Since 2012, Redmond has been a Vice President of Market
- 20 Consultation for Optum's Western Region.
- 21 • Anne Reis – In 2013, Reis was an Associate Director of Revenue for
- 22 UnitedHealthcare Medicare & Retirement.
- 23 • Larry Renfro – During the 2009 to 2011 time period, Renfro served in various
- 24 roles, including the Executive Vice President of Defendant UHG, the Chief
- 25 Executive Officer of Defendant Ovations, and the Chief Executive Officer of the
- 26 Public & Senior Markets Group. Since July 2011, Renfro has been the current
- 27 Chief Executive Officer of Defendant Optum. Since November 2014, he has also
- 28 been Vice Chairman of Defendant UHG.

- 1 • Sandy Rick – Rick was a Senior Regulatory Affairs Analyst at UnitedHealthcare
2 Medicare & Retirement.
- 3 • Kara Rios – Rios was the Chief Financial Officer of AmeriChoice, one of the
4 groups that managed some of the Defendant MA Organizations.
- 5 • Justin Roth – Roth was the Chief Financial Officer of Evercare, one of the groups
6 that managed some of the Defendant MA Organizations.
- 7 • Daniel Schumacher – Since 2017, Schumacher has been the President and Chief
8 Operating Officer of UnitedHealthcare. Prior to that, he was the Chief Financial
9 Officer of UnitedHealthcare.
- 10 • Melissa Sedor – Sedor worked in UnitedHealthcare’s controller’s office, in the
11 area of revenue accounting. Sedor was an accounting manager and reported to
12 Bill Hnath, the controller for UnitedHealthcare Medicare & Retirement.
- 13 • Matt Shors – Shors is UHG’s Senior Deputy General Counsel.
- 14 • Marianne Short – Short is UHG’s Executive Vice President and Chief Legal
15 Officer.
- 16 • Andy Slavitt – Slavitt was the Chief Executive Officer for OptumInsight and an
17 Executive Vice President for Optum.
- 18 • Scott Theisen – From 2010 to 2013, Theisen was the Chief Financial Officer of
19 UnitedHealthcare Medicare & Retirement. In 2011, he was part of the
20 UnitedHealthcare Medicare & Retirement “Executive Leadership Team” reporting
21 to Tom Paul. In 2014, Theisen moved to Optum, but, during that year, his
22 responsibilities continued to include the risk adjustment-related work that Optum
23 performed for UnitedHealthcare Medicare & Retirement.
- 24 • Brian Thompson – Since 2017, Brian Thompson has been the Chief Executive
25 Officer of UnitedHealthcare Medicare & Retirement. From 2013 to 2017, he was
26 the Chief Financial Officer of UnitedHealthcare Medicare & Retirement. He was
27 also previously the Chief Financial Officer of UnitedHealthcare Community &
28 State.

- 1 • Carol Thompson – Until 2009, Carol Thompson was a National Manager for Risk
2 Adjustment Programs at Ingenix. From 2009 to 2011, she was a Manager of the
3 ChartSync operations (part of the Chart Review Program) at Ingenix. From 2011
4 to 2014, she was a Manager and Analyst of Encounter Operations at Optum.
- 5 • Pam Thomsen – Thomsen worked for Optum in Data Validation Operations and
6 Clinical Performance & Compliance.
- 7 • Lee Valenta – At various times, Valenta was the Chief Financial Officer, the Chief
8 Operating Officer, the President of Life Sciences, and an Executive Vice President
9 at Ingenix and then OptumInsight.
- 10 • Emily Vue – From 2009 to 2014, Vue was a Senior Regulatory Analyst and later a
11 Manager of Regulatory Affairs at Ovations-PSMG and then UnitedHealthcare.
- 12 • Karen Wagor – Wagor was the Manager of the National Medical Coder Team and
13 the National Coding Trainer at Ingenix and then Optum. She previously worked
14 at PacifiCare.
- 15 • David Walsh – In 2011, Walsh was the Director for Regulatory Affairs for and, in
16 2012, became the Senior Director of Regulatory Affairs for UnitedHealthcare
17 Medicare & Retirement.
- 18 • John Way – Way was Chief Financial Officer of Secure Horizons. Relator
19 Poehling reported to Way from late 2008 to early 2010.
- 20 • Christopher Webb – Webb worked with Payer Operations at Optum in 2014.
- 21 • Timothy Wicks – Wicks served in a senior management position at Optum.
- 22 • Stephanie Will – Will had been a Principal Analyst at PacifiCare. After the
23 acquisition, she joined Ovations as the Program Manager for the national Chart
24 Review Program. In 2007, she became the Vice President of Risk Adjustment
25 Programs at Ingenix.
- 26
- 27
- 28

THE MEDICARE PROGRAM

I. The Medicare Statute

43. Medicare is a federally-operated health insurance program administered by CMS. Medicare benefits individuals age 65 and older and the disabled. 42 U.S.C. § 1395c *et seq.* Parts A and B of the Medicare Program are known as “traditional” Medicare.

Medicare Part A covers inpatient and institutional care. Medicare Part B covers physician, hospital outpatient, and ancillary services and durable medical equipment.

44. Under Medicare Parts A and B, CMS reimburses healthcare providers (*e.g.*, hospitals and physicians) using what is known as a “fee-for-service” (“FFS”) payment system. Under an FFS payment system, healthcare providers submit claims to CMS for reimbursement for each service actually rendered, such as a physician office visit or a hospital stay. CMS then pays the providers directly for each service based on payment rates pre-determined by the Government.

45. Under Medicare Part C, Medicare beneficiaries can opt out of the traditional Medicare Program (Parts A and B) and instead enroll in MA Plans and receive health care services managed by those MA Plans. MA Plans must provide Medicare beneficiaries all the services that they are entitled to receive from the traditional Medicare Program.

46. Under Medicare Part D, Medicare beneficiaries can elect to enroll in either a Prescription Drug plan (known as a PD Plan) or an MA Plan that provides prescription drug coverage in addition to the physician office visit and hospital outpatient and inpatient coverage provided under Part C (known as an MAPD Plan). For simplicity, in this Amended Complaint, the Government refers to Parts C and D collectively as the MA Program and refers collectively to MA, PD, and MAPD Plans as Plans.

47. MA Organizations are “risk-bearing” entities that must be licensed by the State in which they are located. 42 C.F.R. §§ 422.2 & 422.503(b)(2). Each MA Organization agrees to bear the risk that the amount that it pays providers for the health services for a

1 particular beneficiary in one of its Plans may exceed the amount that it was paid to
2 insure the beneficiary.

3 48. Medicare beneficiaries who enroll in an MA, PD or MAPD Plan are considered
4 members of and enrollees in that Plan. In this Amended Complaint, the terms
5 beneficiaries, members, enrollees, and patients are used interchangeably, but mean the
6 same thing, that is, individuals enrolled in Plans.

7 49. MA Organizations' obligations to the MA Program and the requirements for them
8 to participate in the Program are set forth in federal regulations and, each year, the MA
9 Organizations must agree in writing to comply with those regulations and to other terms
10 and conditions in order to participate in the MA Program. 42 C.F.R. §§ 422.504 &
11 422.505 (Part C); 42 C.F.R. §§ 423.504 & 423.505 (Part D). In addition, MA
12 Organizations must comply with requirements set forth in statutes, such as the FCA, and
13 guidance documents, such as the Medicare Managed Care Manual, the Medicare
14 Prescription Drug Benefit Manual, the Risk Adjustment Participant Guides, and
15 Medicare Advantage operating instructions.

16 50. Related Entities include those entities that are related to an MA Organization by
17 common ownership or control and perform at least some of the MA Organization's
18 management functions. 42 C.F.R. §§ 422.2 & 422.500. As previously explained, the
19 UHG Managing Defendants are or were Related Entities.

20 51. First Tier Entities include those providers or provider groups that enter into a
21 written arrangement with an MA Organization to provide healthcare services to the
22 beneficiaries in the organization's Plan(s). 42 C.F.R. §§ 422.2 & 422.500. The capitated
23 providers in the RACCR Program were First Tier Entities.

24 52. The obligations of Related Entities and First Tier Entities to the MA Program are
25 also set forth in the MA Program regulations. Related Entities and First Tier Entities
26 must, among other things, (i) perform their services in a manner that complies with the
27 MA Organization's contractual obligations to the Government, *id.* at 422.504(i)(3)(iii);
28 agree to "comply with all applicable Medicare laws, regulations, and CMS instructions,"

1 *id.* at 422.504(i)(4)(v); and receive effective compliance training and education relating
2 to preventing fraud, waste, and abuse. *Id.* at § 422.503(b)(4)(vi)(C)(1). Furthermore, if
3 a Related Entity or First Tier Entity generates data relating to an MA Organization’s
4 claims for payments from the MA Program, it (as well as the MA Organization) must
5 certify the accuracy and truthfulness of the data. *Id.* at § 422.504(l)(3).

6 53. An MA Organization, however, cannot evade its legal and contractual obligations
7 to the Government by using Related Entities to manage it or by contracting with First
8 Tier Entities to provide services to its beneficiaries. An MA Organization “maintains
9 ultimate responsibility for adhering to and otherwise fully complying with all terms and
10 conditions of its contract with CMS.” 42 C.F.R. § 422.504(i)(1). Thus, an MA
11 Organization cannot delegate away its ultimate responsibility for its obligations to the
12 Government.

13 **II. Medicare Parts C and D Risk Adjustment Payments**

14 54. Under Part C, the Government pays each MA Organization a predetermined base
15 monthly amount for each Medicare beneficiary in its MA Plans. This monthly payment
16 is known as a “per-member, per-month” payment. This predetermined base payment
17 varies for each MA Plan depending on various factors, including amounts set forth in the
18 MA Plan’s bid submitted to the Government, the scope of medical services covered by
19 the Plan’s benefit package (all packages must cover at least those services offered by
20 Parts A and B of the Medicare Program), and the amount of premiums, deductibles, and
21 co-pays for which an enrollee in the Plan is responsible (Plans have different premiums,
22 deductibles and co-pays such that Plans with higher deductibles and co-pays may have
23 lower premiums).

24 55. Since 2000, Congress has also required that the payments be risk adjusted for each
25 beneficiary based on “such risk factors as age, disability status, gender, institutional
26 status, and *such other factors as [the Secretary of the United States Department of*
27 *Health and Human Services] determines to be appropriate, including adjustment for*
28 *health status . . . to ensure actuarial equivalence.”* 42 U.S.C. § 1395w-23(a)(1)(C)

1 (emphasis added). By risk adjusting for health status, the Government pays MA
2 Organizations more for beneficiaries with certain serious chronic medical conditions
3 and, thus, higher risk scores than for beneficiaries who do not have those conditions and,
4 thus, have lower risk scores.

5 56. Pursuant to 42 U.S.C. § 1395w-23(a)(1)(C), the Secretary has the authority to
6 determine how to adjust for health status. For example, the Secretary has the authority to
7 decide to risk adjust only for serious chronic medical conditions and to risk adjust by
8 requiring the submission of diagnoses from medical encounters that occurred the year
9 preceding each payment year and projecting the possibility of additional costs for each
10 payment year. The Secretary also has authority to decide what historical cost and/or
11 utilization data it should consider in projecting how much more it may cost an MA
12 Organization to provide services to a beneficiary who has been assigned a diagnosis
13 relating to a serious chronic medical condition.

14 57. From 2000 to 2004, the Secretary employed a Principal Inpatient Diagnostic Cost
15 Group (“PIP-DCG”) model that took into account diagnoses from inpatient hospital
16 stays to determine the risk scores of beneficiaries in MA Plans. The PIP-DCG model
17 was prospective. Diagnoses for one year were used to determine each beneficiary’s risk
18 score for the following payment year. During the 2000 to 2004 time period, MA
19 Organizations (which were then called Medicare + Choice Organizations) had many of
20 the same obligations that they have had since 2004. For instance, they had the obligation
21 to design and implement effective systems to monitor and review the accuracy and
22 truthfulness of the diagnoses they submitted for risk adjustment payments in order to
23 certify the accuracy and truthfulness of that data. *See* Medicare Managed Care Manual,
24 Chapter 7, Section 110.2 (entitled “Certification of Data Accuracy, Completeness, and
25 Truthfulness”) (Rev. 2, 10-01-01).

26 58. Since 2004, the Secretary has employed the Hierarchical Conditions Category
27 (“HCC”) model, which takes into account both demographic factors (such as age and
28 gender) and health status to determine the risk scores for beneficiaries in MA Plans.

1 With respect to health status, the model takes into account diagnoses from physician
2 office visits and hospital outpatient encounters as well as hospital inpatient stays. Like
3 the PIP-DCG model, the HCC model is prospective, meaning that it relies on diagnoses
4 assigned to a beneficiary in one year (referred to by CMS as the “data collection” year
5 but also generally known as the “date of service” or “DOS” year) to determine the risk
6 score for the beneficiary for the following year (often referred to as the “payment year”
7 or “PY”). The medical conditions included in the model are grouped into HCCs, which
8 are categories of clinically-related medical diagnoses. *See* 42 C.F.R. § 422.2. The
9 diagnoses grouped into HCCs include major, severe, and/or chronic illnesses. Related
10 groups of diagnoses are ranked on the basis of disease severity and the cost associated
11 with their treatment. Between 2004 and 2013, the CMS-HCC model included 70 HCCs.
12 Starting in 2014, the CMS-HCC model included 79 HCCs.

13 59. Under Medicare Part D, payments to PD or MAPD Plans for prescription drug
14 benefits are also risk-adjusted based on health status. As with Part C, Part D employs a
15 health-based risk adjustment model known as the Rx Hierarchical Condition Categories
16 (“RxHCC”) model. Like HCCs, RxHCCs are also groups of clinically-related medical
17 diagnoses that are ranked by disease severity and the cost associated with the
18 pharmaceutical drugs used to treat them.

19 60. The Government assigns a relative numerical value (also known as a relative
20 factor, multiplier, or coefficient) to each HCC and RxHCC group that correlates to the
21 predicted incremental costs of care associated with treating the medical conditions in
22 each category. It currently determines the relative values based on an analysis of the
23 additional amounts that it paid on average for the treatment of these major, severe, and
24 chronic medical conditions under Parts A and B of the Medicare Program. Higher
25 relative values are assigned to HCCs and RxHCCs that include diagnoses with greater
26 disease severity and greater costs associated with their treatment.

27 61. As previously stated, the HCC and RxHCC risk adjustment models are
28 prospective and a beneficiary’s risk score for a particular payment year is determined by

his or her medical conditions during the previous year (*i.e.*, the date of service year). For risk adjustment payment purposes, these medical conditions must be documented by a qualified healthcare provider (*e.g.*, a doctor) in the beneficiary's medical record during the previous year. Accordingly, for risk adjustment payment purposes, the diagnosis codes that the healthcare provider, his or her administrative or billing support staff, or anyone else (such as the MA Organization or a Related Entity) assigns to a beneficiary must be supported by the beneficiary's medical record.

62. Each beneficiary's risk score is calculated anew for each payment year. For example, a beneficiary's risk score for payment year 2012 is determined by the diagnoses that his or her qualified healthcare providers documented in his or her medical records during medical encounters during date of service year 2011.

63. MA Organizations obtain diagnosis data from the healthcare providers that treat the beneficiaries in their plans (as well as through other means and sources such as the MA Organizations' own medical record reviews). Healthcare providers can transmit diagnosis codes to MA Organizations with claims for payment for services rendered, in encounter records reporting the services rendered, or by alternative means. In this Amended Complaint, the United States refers to diagnosis codes reported by providers through any means as "provider-reported diagnoses."

64. MA Organizations submit risk adjustment data, including diagnoses, to CMS using CMS' Risk Adjustment Processing System ("RAPS"). Each RAPS submission must include the following information: the Medicare beneficiary's identification number (called a "HIC number" or "HICN"); the date(s) of the medical encounter (the physician office visit, hospital outpatient visit, or hospital inpatient stay); the type of provider (physician or hospital); and the diagnosis code(s) reported by the provider for the encounter. Each RAPS submission is a claim for payment. If the data submitted is invalid, the claim is false.

65. RAPS also has a field that is called a "Delete Indicator" and allows MA Organizations and Related Entities to comply with their obligation to delete invalid

1 diagnoses that they previously submitted in order to withdraw or retract the invalid
2 diagnoses. That is, the RAPS system enables MA Organizations and Related Entities to
3 withdraw or retract their false claims for risk adjustment payments.

4 **DEFENDANTS' AGREEMENTS**

5 **I. The Annual Parts C and D Agreements**

6 66. As previously explained, in order to participate in the MA Program, the Defendant
7 MA Organizations were required to agree in writing to comply with the Part C and D
8 regulations and any other terms and conditions CMS deemed appropriate. 42 C.F.R.
9 §§ 422.504 & 422.505 (Part C); 42 C.F.R. §§ 423.504 & 423.505 (Part D). Each year
10 during the relevant time period, one or more executives of one or more of the UHG
11 Managing Defendants or their predecessors executed these written agreements or
12 renewals of these written agreements between the Defendant MA Organizations and
13 CMS.

14 67. The regulations specifying the terms and conditions of the contractual relationship
15 between MA Organizations and CMS have remained the same for many years.
16 Accordingly, from year to year, the terms and conditions of these written agreements
17 between the Defendant MA Organizations and CMS remained very similar, if not
18 identical.

19 68. The terms and conditions of the Part C agreements are exemplified by the attached
20 contract that Defendant UnitedHealthcare Plan of River Valley, Inc. entered into with
21 CMS relating to its participation in Medicare Part C in 2010. *See* Exhibit 1, attached
22 hereto. The terms and conditions of these Part C contracts include, among many other
23 things, that each of the MA Organizations agrees to (i) operate its Plans “in compliance
24 with the requirements of [the] contract and applicable Federal statutes, regulations, and
25 policies (e.g., policies as described in the Call Letter, Medicare Managed Care Manual,
26 etc.)” (Article II, Section A); (ii) “implement a compliance plan in accordance with the
27 requirements of § 422.503(b)(4)(vi)” (Article III, Section F); (iii) “[a]s a condition of
28 receiving a monthly payment under” the contract, “request payment under the contract

1 on the forms attached” to the contract, including “Attachment B (risk adjustment data)
2 which attest[s] to *(based on best knowledge, information and belief, as of the date*
3 *specified on the attestation form)* the accuracy, completeness, and truthfulness of the
4 data identified on” Attachment B (Article IV, Section C) (emphasis in the original); (iv)
5 ensure that related entities, contractors, and subcontractors that generated risk adjustment
6 data also attest to the accuracy and truthfulness of the data (Article IV, Section C.2); (v)
7 ensure that all agreements with related entities, contractors, and subcontractors specify
8 that the related entities, contractors, and subcontractors “must comply with all applicable
9 Medicare laws, regulations, and CMS instructions” (Article V, Section D(5)); and (vi)
10 comply with “Federal laws and regulations designed to prevent or ameliorate fraud,
11 waste, and abuse, including, but not limited to, applicable provisions of the Federal
12 criminal law [and] the False Claims Act (31 USC 3729 et seq.)” (Article IX, Section
13 A.1). In accordance with 42 C.F.R. § 422.510, the agreements also provided that CMS
14 may terminate the MA Organization’s participation in the MA Program if it determines
15 that the organization has submitted false data to it or “fail[ed] to provide CMS with valid
16 risk adjustment data.” Article VIII, Section B.1(a)(iv) & (vii).

17 69. The agreements for other years were very similar, if not identical. For example, in
18 September 2010, Tom Paul, the Chief Executive Office of UnitedHealthcare Medicare &
19 Retirement, executed a new agreement between Defendant UnitedHealthcare of
20 California (the successor to PacifiCare of California) and CMS relating to this MA
21 Organization’s participation in Medicare Part C in 2011. *See* Exhibit 2, attached hereto.
22 By executing this contract, UnitedHealthcare of California agreed to, among many other
23 things, (i) operate its Plans “in compliance with the requirements of [the] contract and
24 applicable Federal statutes, regulations, and policies (e.g., policies as described in the
25 Call Letter, Medicare Managed Care Manual, etc.)” (Article II, Section A); (ii)
26 “implement a compliance plan in accordance with the requirements of §
27 422.503(b)(4)(vi)” (Article III, Section F); (iii) “[a]s a condition of receiving a monthly
28 payment under” the contract, “request payment under the contract on the forms attached”

1 to the contract, including “Attachment B (risk adjustment data) which attest[s] to *(based*
2 *on best knowledge, information and belief, as of the date specified on the attestation*
3 *form)* the accuracy, completeness, and truthfulness of the data identified on” Attachment
4 B (Article IV, Section D); (iv) ensure that related entities, contractors, and
5 subcontractors that generated risk adjustment data also attest to the accuracy and
6 truthfulness of the data (Article IV, Section D.2); (v) ensure that all agreements with
7 related entities, contractors, and subcontractors specify that the related entities,
8 contractors, and subcontractors “must comply with all applicable Medicare laws,
9 regulations, and CMS instructions” (Article V, Section D.5); and (vi) comply with
10 “Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse,
11 including, but not limited to, applicable provisions of the Federal criminal law [and] the
12 False Claims Act (31 USC 3729 et seq.)” (Article IX, Section A.1). The agreement also
13 provided that CMS had the right to terminate the agreement with the MA Organization if
14 it determined that the organization had submitted false data to it or “fail[ed] to provide
15 CMS with valid risk adjustment data.” Article VIII, Section B.1(a)(iv) & (vii). In
16 September 2010, Paul also executed an agreement with CMS relating to
17 UnitedHealthcare of California’s offering of prescription drug benefits under Medicare
18 Part D. This Part D agreement was, in all respects relevant to this Amended Complaint,
19 very similar to the one described above for the offering of healthcare insurance benefit
20 packages under Part C. Furthermore, in September 2010, Tom Paul executed the same
21 Part C and D agreements on behalf of other of the Defendant MA Organizations. All
22 these agreements were very similar, if not identical, to the ones he executed for
23 UnitedHealthcare of California.

24 70. In September 2011, August 2012, and August 2013, Scott Theisen, the Chief
25 Financial Officer of UnitedHealthcare Medicare & Retirement, executed agreements for
26 many of the Defendant MA Organizations relating to their participation in Medicare
27 Parts C and D for 2012, 2013, and 2014, respectively. *See, e.g.*, Exhibits 3, 4, & 5,
28 attached hereto (Defendant UnitedHealthcare of California’s Parts C agreements for

1 these years). In August 2014 and 2015, Brian Thompson, the Chief Financial Officer of
2 UnitedHealthcare Medicare & Retirement, executed agreements for many of the
3 Defendant MA Organizations relating to their participation in Medicare Parts C and D
4 for 2015 and 2016. See, e.g., Exhibits 6 & 7, attached hereto (Defendant
5 UnitedHealthcare of California's Part C agreements for these years). These agreements
6 were, in all respects relevant to this Amended Complaint, very similar, if not identical, to
7 the agreements described in the preceding paragraphs relating to the agreements for 2010
8 and 2011 and imposed the same contractual obligations on the Defendant MA
9 Organizations as the earlier agreements.

10 71. The annual Attestations executed in order to renew existing contracts were also
11 very similar as shown by the following: In the fall of 2006, Jerry Knutson, the Chief
12 Financial Officer of Ovations and Jeff Putnam, the Chief Financial Officer of Secure
13 Horizons, executed Attestations renewing (for calendar year 2007) the existing contract
14 between PacifiCare of California (the predecessor of Defendant UnitedHealthcare of
15 California) and CMS. Knutson and Putnam attested that PacifiCare of California would
16 "comply with all applicable program guidance that CMS has issued to date and will issue
17 during the remainder of 2006 and 2007 pursuant to Medicare program authorizing
18 statutes and regulations, including but not limited to, . . . the CMS memoranda issued
19 through the Health Plan Management System (HPMS)." (HPMS is one of the web-
20 based systems used by CMS to provide program information to MA Organizations and is
21 used to communicate program requirements.) In September 2007, Joseph Haferman, the
22 Chief Financial Officer of Secure Horizons, executed another Attestation renewing the
23 existing contract for PacifiCare of California (this time for calendar year 2008).
24 Haferman thereby attested that PacifiCare of California would comply "with all
25 applicable program authorizing statutes and regulations and program guidance that CMS
26 has issued to date and will issue during the remainder of 2007 and 2008, including but
27 not limited to, . . . the Medicare Managed Care Manual, and CMS memoranda issued
28 through the Health Plan Management System (HPMS)." In September 2008, Kenneth

1 Burdick, the Chief Executive Officer of Secure Horizons at the time, executed another
2 Attestation renewing the existing contract for PacifiCare of California (this time for
3 calendar year 2009). Burdick thereby attested that PacifiCare of California would
4 comply “with all applicable Medicare program authorizing statutes and regulations and
5 program guidance that CMS has issued to date and will issue during the remainder of
6 2008 and 2009, including but not limited to, . . . the Medicare Managed Care Manual,
7 and the CMS memoranda issued through the Health Plan Management System
8 (HPMS).” In September 2009, both Tom Paul, the Chief Executive Officer of Ovations,
9 and John Way, the Chief Financial Officer of Secure Horizons, executed an Attestation
10 renewing the existing contract for PacifiCare of California (this time for calendar year
11 2010). They thereby attested that PacifiCare of California would comply “with all
12 applicable Medicare program authorizing statutes and regulations and program guidance
13 that CMS has issued to date or will issue during the remainder of 2009 and 2010,
14 including but not limited to, . . . the Medicare Managed Care Manual, and the CMS
15 memoranda issued through the Health Plan Management System (HPMS).”

16 72. The United States hereby incorporates by reference as if they were recited herein
17 and attached hereto all of the agreements that all of the Defendant MA Organizations
18 entered into with CMS relating to their participation in Medicare Parts C and D for 2007
19 to present date. All of these agreements were, in all respects relevant to this Amended
20 Complaint, very similar, if not identical, to the agreements described in the preceding
21 paragraphs.

22 **II. The Electronic Data Interchange Agreements**

23 73. In addition, since at least 2003, MA Organizations and entities that submit risk
24 adjustment data on their behalf have been required to execute Electronic Data
25 Interchange (“EDI”) agreements prior to submitting risk adjustment data. These EDI
26 agreements are considered contracts by which the MA Organizations attest to the
27 accuracy of the data submitted. Even if another entity submits the data, the MA
28 Organizations are still responsible for the content of the submissions. See 2003 Regional

1 Risk Adjustment Training for Medicare+Choice Organizations Participant Guide, §
2 6.1; 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations
3 Participant Guide, § 4.1; 2005 Risk Adjustment Data Basic Training for Medicare
4 Advantage Organizations Participant Guide § 4.1; 2006 Risk Adjustment Data Basic
5 Training for Medicare Advantage Organizations Participant Guide § 4.1; 2007 Risk
6 Adjustment Data Training for Medicare Advantage Organizations Participant Guide §
7 4.1; 2008 Risk Adjustment Technical Assistance for Medicare Advantage Organizations
8 Participant Guide § 4.1; Risk Adjustment 101 Participant Guide § 2.1 (2013). See also
9 Medicare Managed Care Manual, Chapter 7, § 111.6.1 (Rev. 57, 08-13-04); *id.* § 120.2.1
10 (Rev. 114, 06-07-13). By executing these EDI forms, the MA Organizations agree that
11 (i) they will be responsible for all risk adjustment data submitted to CMS by themselves,
12 their employees, and their agents; (ii) they will submit risk adjustment data that is
13 accurate, complete, and truthful based on best knowledge, information, and belief; (iii)
14 *they will research and correct risk adjustment data discrepancies*; and (iv) CMS has the
15 right to audit and confirm the risk adjustment data, including diagnoses, submitted by the
16 MA Organization and the right of access to the beneficiaries' medical records to conduct
17 such audits.

18 74. Each of the Defendant MA Organizations and Defendants Optum (and its
19 predecessor, Ingenix) and Ovations executed these EDI agreements and submitted them
20 to the MA Program in order to submit risk adjustment data to and receive risk adjustment
21 payments from the MA Program. Pursuant to the express terms of these EDI
22 agreements, these Defendants promised to submit valid risk adjustment data to the MA
23 Program and *to research and correct any data discrepancies*.

24 75. For instance, in 2005, Joseph Haferman, the Chief Financial Officer of Defendant
25 Ovations, executed and submitted to CMS an EDI agreement in order to obtain a
26 "submitter ID" permitting Ovations to submit risk adjustment data on behalf of various
27 of the Defendant MA Organizations. See Exhibit 8, attached hereto. By executing this
28 agreement and submitting it to CMS on behalf of the "eligible organization," which was

1 identified as “United Health Group – Ovations” on the form, Defendants UHG and
2 Ovations and the Defendant MA Organizations each agreed that they would (i) be
3 responsible for all risk adjustment data submitted to CMS by themselves, their
4 employees, or their agents; (ii) submit accurate and truthful risk adjustment data; and
5 (iii) *research and correct discrepancies with its risk adjustment data*. In addition, each
6 of them agreed that CMS could audit the data and have access to medical records to
7 conduct such audits.

8 76. Additional examples include the EDI agreements that James Higgins, the Finance
9 Director of PacifiCare Health Systems, executed on behalf of the following Defendant
10 MA Organizations or their predecessors: On September 14, 2006, Higgins signed EDI
11 agreements for UnitedHealthcare Insurance Company of New York (contract numbers
12 H5515 and R5342); UnitedHealthcare Insurance Company (the name for a number of
13 different MA Organizations with contract numbers R3175, R5287, H1717, H2803,
14 H2001, H2003, H2111, H2408, H0624, H0620, H1303, H1509, H3921, H0319, H5500,
15 H2406, H4106, H3812, H3209, H5918, H5697, H5754, H0315, H2228, H1108, H4522,
16 H5532, H5516, H5507, H5440, H5417, H5424, H5008, H5527, H2226 and H5518);
17 PacifiCare of Nevada, Inc. (contract number H2949); PacifiCare of Arizona, Inc.
18 (contract number H0303); UnitedHealthcare of Alabama, Inc. (contract number H0151);
19 UnitedHealthcare of the Midwest, Inc. (contract number H2654); Oxford Health Plans
20 (CT), Inc. (contract number H0752); Oxford Health Plans (NJ), Inc. (contract numbers
21 H3113 and H3107); UnitedHealthcare of Ohio, Inc. (contract numbers H3659 and
22 H5678); UHC of California, then known as PacifiCare of California (contract number
23 H0543); UnitedHealthcare of Florida, Inc. (contract number H1080 and H9011);
24 UnitedHealthcare Benefits of Texas, Inc. (contract number H4590); UnitedHealthcare of
25 Utah, Inc. (contract number H4604); UnitedHealthcare of Arizona, Inc. (contract number
26 H0316); UnitedHealthcare of Arkansas, Inc. (contract number H0401); UnitedHealthcare
27 of Georgia, Inc. (contract number H1111); UnitedHealthcare of Tennessee, Inc. (contract
28 number H4406); UnitedHealthcare of New England, Inc. (contract number H4102);

1 UnitedHealthcare of Oregon, Inc. (contract number H3805); UnitedHealthcare of
2 Oklahoma, Inc. (contract number H3749); UnitedHealthcare of New York, Inc. (contract
3 number H3379); Oxford Health Plans (NY), Inc. (contract number H3307);
4 UnitedHealthcare of the Midlands, Inc. (contract number H2802); UnitedHealthcare of
5 North Carolina, Inc. (contract number H3456); PacifiCare of Colorado, Inc. (contract
6 number H0609); Sierra Health and Life Insurance Company, Inc. (contract number
7 H5652); UnitedHealthcare of Washington, Inc. (contract number H5005);
8 UnitedHealthcare of Wisconsin, Inc. (contract number H5253); and UnitedHealthcare
9 Community Plan of Texas, L.L.C. (contract number H4514). On November 2, 2006,
10 Higgins signed EDI agreements for UnitedHealthcare of the Midwest, Inc. (contract
11 number H3887), UnitedHealthcare Insurance Company of New York (contract number
12 H4720), and UnitedHealthcare Insurance Company (contract numbers H9418, H8000,
13 and H4779). On December 13, 2006, Higgins signed EDI agreements for
14 UnitedHealthcare Insurance Company (the name for a number of MA Organizations
15 with contract numbers H0408, H1286, H3435, H7274, H7254, H0410, and H6717) and
16 UnitedHealthcare of Wisconsin, Inc. (contract number H7187). On January 1, 2007,
17 Higgins signed an EDI agreement for UnitedHealthcare Insurance Company (contract
18 number H5435). On January 14, 2008, Higgins signed an EDI agreement for
19 UnitedHealthcare Insurance Company (contract numbers H3912 and H0710). *See, e.g.,*
20 Exhibit 9, attached hereto (September 14, 2006 EDI for PacifiCare of California).
21 Pursuant to these EDI agreements, each of these MA Organizations agreed that it would
22 (i) be responsible for all risk adjustment data submitted to CMS by itself, its employees,
23 or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii) *research and*
24 *correct discrepancies with its risk adjustment data*. In addition, each of them agreed that
25 CMS could audit the data and have access to medical records to conduct such audits.
26 77. In addition, on January 14, 2008, Patricia Rasmussen, who worked as a manager
27 for Ingenix, signed EDI agreements for UnitedHealthcare Insurance Company (contract
28 numbers H4971, H0710, H3912, H7698, H4971, H0710, H6793, H5749, and H6228),

1 UnitedHealthcare of New England, Inc. (contract number H1944), and UnitedHealthcare
2 Insurance Company of New York (contract number H4720). On June 18, 2008,
3 Rasmussen signed an EDI agreement for PacifiCare of Nevada, Inc. (contract number
4 H7949). In January 2009, Rasmussen signed additional EDI agreements for
5 UnitedHealthcare Insurance Company (contract numbers H7444, H8748, H2182, and
6 H1949). Pursuant to these EDI agreements, each of these MA Organizations agreed that
7 it would (i) be responsible for all risk adjustment data submitted to CMS by itself, its
8 employees, or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii)
9 *research and correct discrepancies with its risk adjustment data*. In addition, each of
10 them agreed that CMS could audit the data and have access to medical records to
11 conduct such audits.

12 78. On December 15, 2010, Timothy Noel, who was Vice President of Finance for
13 UnitedHealthcare Medicare & Retirement, signed an EDI agreement for Oxford Health
14 Plans (CT), Inc. (contract number H0755). On September 22, 2011, Noel signed an EDI
15 agreement for UnitedHealthcare Insurance Company of New York (contract number
16 H1537). Pursuant to these EDI agreements, each of these MA Organizations agreed that
17 it would (i) be responsible for all risk adjustment data submitted to CMS by itself, its
18 employees, or its agents; (ii) submit accurate and truthful risk adjustment data; and (iii)
19 *research and correct discrepancies with its risk adjustment data*. In addition, each of
20 them agreed that CMS could audit the data and have access to medical records to
21 conduct such audits.

22 79. On April 27, 2011, Scott Theisen, the Chief Financial Officer of UnitedHealthcare
23 Medicare & Retirement, submitted an EDI agreement for PacifiCare of California, which
24 included all the same promises. On October 21, 2013, Theisen also signed EDI
25 agreements for Care Improvement Plus Wisconsin Insurance Company (contract number
26 H3794) and Care Improvement Plus South Central Insurance Co. (contract number
27 H5322). Accordingly, each of these Defendant MA Organizations also agreed that it
28 would (i) be responsible for all risk adjustment data (which includes encounter data)

1 submitted to CMS by itself, its employees, or its agents; (ii) submit accurate and truthful
2 risk adjustment data; and (iii) *research and correct discrepancies with its risk adjustment*
3 *data*. In addition, each of them agreed that CMS could audit the data and have access to
4 medical records to conduct such audits.

5 80. Patricia Rasmussen also executed and submitted an EDI agreement so that Ingenix
6 could submit risk adjustment data on behalf of the Defendant MA Organizations. *See*
7 Exhibit 10, attached hereto. By doing this, Ingenix also agreed that it would (i) be
8 responsible for all risk adjustment data submitted to CMS by itself, its employees, or its
9 agents; (ii) submit accurate and truthful risk adjustment data; and (iii) *research and*
10 *correct discrepancies with its risk adjustment data*. In addition, it agreed that CMS
11 could audit the data and have access to medical records to conduct such audits. When
12 Ingenix became OptumInsight, Rasmussen also notified CMS (that is, CMS' contractor
13 Palmetto, which helped operate RAPS) that its records should be updated to reflect that
14 OptumInsight was making the risk adjustment submissions for the Defendant MA
15 Organizations. Rasmussen identified OptumInsight as "part of Optum." *See* Exhibit 11,
16 attached hereto.

17 81. Jeffrey Dumcum, a Senior Vice President at Optum, also executed an EDI
18 agreement in May 2011 in order to submit risk adjustment data (also known as encounter
19 data) to the MA Program on behalf of many of the Defendant MA Organizations,
20 including those MA Organizations listed in a letter sent by Theisen to CMS' contractor
21 in April 2011. By doing this, Dumcum agreed that Optum would be responsible for the
22 data it submitted, submit valid data, and *research and correct data discrepancies*. *See*
23 Exhibit 12, attached hereto.

24 82. All EDI agreements executed by the UHG Managing Defendants on their own
25 behalf and on behalf of the Defendant MA Organizations are incorporated by reference
26 in this Amended Complaint as if they were recited in full and attached hereto.

III. The Ingenix/Optum Service Agreements

83. Depending on the time period, Ingenix or Optum entered into internal agreements with Ovation or UnitedHealthcare regarding the risk adjustment-related services that Ingenix or Optum would provide to the Defendant MA Organizations. These services included, among other things, the submission of risk adjustment data to CMS and the management of the Chart Review, Claims Verification, and RACCR Programs. These internal agreements further confirm the parties' joint and several obligations to the MA Program to submit accurate and truthful risk adjustment data and to investigate and correct any data discrepancies. These agreements also exemplify the UHG Managing Defendants' understanding of their joint and several obligations to the MA Program. All of these agreements are incorporated herein by reference.

84. By way of example, the Memorandum of Understanding ("MOU") entered into between Optum and UnitedHealthcare for risk adjustment-related services rendered by Optum in 2011 exemplifies the obligations undertaken by Optum not only to UnitedHealthcare but to the MA Program. That MOU was executed by Jerry Knutson, Chief Financial Officer of Optum, and Scott Theisen, Chief Financial Officer of UnitedHealthcare Medicare & Retirement. Paul Bihm at Optum, Relator Poehling at UnitedHealthcare Medicare & Retirement, and Jason Bainbridge at UnitedHealthcare Community & State were copied on the MOU. (The MOU referred to UnitedHealthcare Medicare & Retirement and UnitedHealthcare Community & State collectively as "UnitedHealth Group's Public and Senior Markets Group ("PSMG")." This is but one of many examples of the confusion that Defendants have created by the way they used names of groups and entities interchangeably.) Pursuant to the MOU, Optum was compensated for its services through an "intercompany allocation of fees paid pursuant to [a separate] Management Agreement."

85. Pursuant to this 2011 MOU, Optum provided many risk adjustment-related services to the Defendant MA Organizations, including, but not limited to the submission of risk adjustment data to CMS "pursuant to CMS risk adjustment rules and

requirements” and conducting the Chart Review, Claims Verification, and RACCR Programs. Importantly, Optum also agreed to (i) conduct “[p]rovider engagement and education regarding accurate and complete diagnostic coding and documentation”; (ii) “[c]ontribute (along with PSMG) to the level of accuracy and completeness of diagnostic coding for a respective population by identifying opportunities to improve documentation and coding for accuracy, facilitating improvement in accuracy by working directly with providers to improve documentation and coding practices, and executing the timely and accurate submission of claim coding information to CMS, thereby ensuring appropriate revenues are being paid by CMS for the underlying risk inherent within the member population;” (iii) “[m]onitor[] the appropriateness and accuracy of provider coding;” and (iv) conduct “[i]nternal validation testing of outlier providers, internal validation testing of other sample populations and support CMS validation requirements.”

86. The 2011 MOU also included a “Medicare Advantage Regulatory Requirements Appendix.” This Appendix included Optum’s agreement to (i) “comply with all applicable federal and Medicare laws, regulations, and CMS instructions, including but not limited to . . . federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including but not limited to, applicable provisions of federal criminal law [and] the False Claims Act (31 U.S.C. § 3729 et seq.);” (ii) “perform services and provide the products set forth in the MOU in a manner consistent with and in compliance with [the Defendant MA Organizations’] obligations under the CMS Contact[s]; “ and (iii) certify in writing that the risk adjustment data it submitted to CMS was “accurate, complete, and truthful, based on [its] best knowledge, information and belief.” The Appendix further specified that UnitedHealthcare and the Defendant MA Organizations were accountable to CMS for fulfilling their regulatory and contractual obligations under the MA Program, including those that they had delegated to Optum under the MOU and, thus, that they were responsible for overseeing and monitoring Optum’s performance under the MOU.

DEFENDANTS' DATA INTEGRITY OBLIGATIONS

I. Obligation to Submit Valid Diagnoses

87. MA Organizations are entitled to risk adjustment payments based on the diagnosis codes that they submit to CMS *only* if the codes are from face-to-face medical encounters between the Medicare beneficiary and provider, the encounter occurred during the relevant date of service year, the provider was of a type and specialty acceptable for risk adjustment purposes, and at the time of the encounter, the provider documented the medical conditions identified by the diagnosis codes in the medical record based on acceptable documentation. In addition, codes should be based on documented conditions that require or affect patient care treatment or management. *See* Medicare Managed Care Manual, Chapter 7, Exhibit 30 (August 13, 2004) (stating that diagnosis codes submitted for risk adjustment payments should be for documented conditions that “require or affect patient care treatment or management”). *See also* 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide (“2008 RA Participation Guide”) at § 6.4.1.

88. Risk adjustment claims are valid, and the resulting risk adjustment payments are therefore proper and justified, only to the extent that the diagnosis codes submitted by the MA Organizations are valid. The diagnoses must be coded according to the *International Classification of Diseases (ICD) Clinical Modification Guidelines for Coding and Reporting* (“ICD-9-CM” & “ICD-10-CM”) and documented with sufficient clinical specificity. *See* Medicare Managed Care Manual, Chapter 7, Exhibit 30 (August 13, 2004). In addition, codes cannot be submitted for diagnoses that are only probable or suspected, for diagnoses that are questionable, or for a condition that the provider is trying to rule out. *Id.*

89. Moreover, all diagnosis codes submitted by MA Organizations must be supported by medical record documentation. The 2004 Medicare Managed Care Manual stated that “M+C organizations [now known as MA Organizations] must submit risk adjustment data that are substantiated by the physician or provider’s full medical record.” Medicare

1 Managed Care Manual, Chapter 7, § 111.8 (August 13, 2004). A later version of the
2 Manual similarly states that MA Organizations “must . . . [e]nsure the accuracy and
3 integrity of risk adjustment data to CMS. All diagnosis codes submitted must be
4 documented in the medical record” Medicare Managed Care Manual, Chapter 7, §
5 40 (June 2013). Also similarly, the 2003 Participant Guide stated that MA
6 Organizations “must submit risk adjustment data that are substantiated by the patient’s
7 medical record.” 2003 Regional Risk Adjustment Training for Medicare+Choice
8 Organizations Participant Guide, § 4.1. This requirement was reiterated in the following
9 CMS training guides and materials since 2003: 2003 Regional Risk Adjustment
10 Training for Medicare+Choice Organizations Participant Guide, §§ 12.3, 12.6; 2004
11 Regional Risk Adjustment Training for Medicare+Choice Organizations Participant
12 Guide, §§ 5.1, 5.5, 6.1.3; 2005 Risk Adjustment Data Basic Training for Medicare
13 Advantage Organizations Participant Guide §§ 4.1, 5, 5.1, 5.5, 8.7.3, 9.1, 9.2; 2006 Risk
14 Adjustment Data Basic Training for Medicare Advantage Organizations Participant
15 Guide §§ 5.1, 5.4, 5.5, 7.7.3, 8.1, 8.2; 2007 Risk Adjustment Data Training for Medicare
16 Advantage Organizations Participant Guide §§ 6.1, 6.4, 7.1, 7.2, 8.7.3; 2008 Risk
17 Adjustment Technical Assistance for Medicare Advantage Organizations Participant
18 Guide §§ 5.6, 6, 6.1, 6.4, 6.5, 7.1, 7.2; 2012 Regional Technical Assistance Participant
19 Guide § 2.2; Risk Adjustment 101 Participant Guide §§ 3.2.4; 4.3 (2013); Risk
20 Adjustment Webinar at p. 48 (July 1, 2014). Furthermore, in a 2003 Regional Risk
21 Adjustment Training for Medicare+Choice Organizations presentation, organizations
22 were advised to “[t]ake steps to ensure that medical documentation supports submitted
23 diagnoses.” *Id.* at §8-19.

24 90. In connection with the requirement that the patient’s medical record support the
25 diagnosis(es) reported for him or her, the 2004 Medicare Managed Care Manual also
26 provided that “M+C organizations must maintain sufficient information to trace the
27 submitted diagnosis back to the hospital or physician that originally reported the
28 diagnosis. Since M+C organizations may submit summary level transactions without a

1 link to a specific encounter or claim, establishing an appropriate audit trail to the original
2 source of the data requires diligent information management on the part of the M+C.”
3 Medicare Managed Care Manual, Chapter 7, § 111.8 (August 13, 2004). Again, in the
4 2005 Risk Adjustment Data Basic Training for Medicare Advantage Organizations
5 Participant Guide § 8.7.3, CMS advised that “MA organizations should take steps to
6 ensure that they have, or have access to, the proper medical documentation to support
7 diagnoses being submitted for risk adjustment. MA organizations are responsible for the
8 accuracy of the data they submit to CMS. Where necessary, they should obtain the
9 proper documentation to support diagnoses and maintain an efficient system for tracking
10 diagnoses back to medical records.” This requirement was also reiterated in the
11 following CMS training guides: 2003 Regional Risk Adjustment Training for
12 Medicare+Choice Organizations Participant Guide, § 12.2; 2004 Regional Risk
13 Adjustment Training for Medicare+Choice Organizations Participant Guide, § 6.1.3;
14 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations Resource
15 Guide at p. 20; 2005 Risk Adjustment Data Basic Training for Medicare Advantage
16 Organizations Participant Guide §§ 5.1, 9.1.3; 2006 Risk Adjustment Data Basic
17 Training for Medicare Advantage Organizations Participant Guide §§ 5.1, 7.7.3, 8.7.3;
18 2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant
19 Guide §§ 6.1, 7.1.4, 8.7.3; 2008 Risk Adjustment Technical Assistance for Medicare
20 Advantage Organizations Participant Guide §§ 5.6.3, 6.1; 2012 Regional Technical
21 Assistance Participant Guide § 2.2.

22 91. Furthermore, the medical record relied on by an MA Organization to support
23 payment cannot be ambiguous. See 2008 RA Participation Guide at § 7.2.4.1 (stating
24 that risk adjustment claims and payments cannot be based on questionable diagnoses).

25 92. CMS recognizes that risk adjusting based on health status creates a strong
26 incentive for MA Organizations to report invalid diagnoses. Thus, CMS engages in a
27 variety of program integrity activities, including training MA Organizations about their
28 obligations to submit valid data and withdraw invalid data. For example, in a 2003

1 Regional Risk Adjustment Training for Medicare+Choice Organization Questions &
2 Answers document, CMS stated all information that is submitted must be correct. “If a
3 plan identifies incorrect or invalid information that has been submitted, it must delete
4 that information.” Likewise, in an August 9, 2005 Regional Training presentation made
5 jointly by CMS and its contractor, Aspen Systems Corporation, called “Risk Adjustment
6 Data Basic Training,” MA Organizations were told that they “must . . . Delete a
7 diagnosis cluster [that is, a RAPS submission] when any data in that cluster are in error.”

8 93. In addition, for many years, CMS has conducted audits of diagnoses submitted by
9 MA Organizations, known as Risk Adjustment Data Validation (“RADV”) audits. In
10 2001, when the old PIP-DCG model was in place, CMS alerted M+C organizations that
11 they were “required to submit medical records for validating encounter data” and that
12 “[m]edical record reviews of a sample of hospital encounters may be audited to ensure
13 the accuracy of diagnostic information.” Medicare Managed Care Manual, Chapter 7, §
14 110.3 (October 2001). In 2004, CMS revised the Manual to provide that “[a] sample of
15 risk adjustment data used for making payments may be validated against hospital
16 inpatient, hospital outpatient, and physician medical records to ensure the accuracy of
17 medical information. Risk adjustment data will be validated to the extent that the
18 diagnostic information justifies appropriate payment under the risk adjustment model.”
19 Medicare Managed Care Manual, Chapter 7, § 111.8 (August 13, 2004). The Manual
20 further explained that the MA Organizations must be prepared to locate and produce the
21 medical records to support the diagnoses codes that they submitted. *Id.* Federal
22 regulations also require MA Organizations and their providers to provide medical
23 records to CMS to validate the diagnoses they submitted for risk adjustment payments.
24 *See* 42 C.F.R. § 422.310(e).

25 94. When making risk adjustment payments, CMS relies on MA Organizations to
26 exercise due diligence to ensure that provider-reported diagnoses are supported by
27 beneficiaries’ medical records and are otherwise accurate and truthful. This is why
28 insurance companies that want to participate in the MA Program must agree, through

1 their Part C and D agreements and their EDI agreements, to provide valid diagnostic data
2 and investigate and delete invalid data. Moreover, this is why insurance companies that
3 want to participate in the MA Program must (i) establish and implement effective
4 compliance programs to ensure the integrity of their payment data, 42 CFR
5 § 422.503(b)(4)(vi) (Part C compliance program regulation); 42 C.F.R.
6 § 423.504(b)(4)(vi) (Part D compliance program regulation); (ii) annually attest to the
7 accuracy and truthfulness of the diagnosis data that they submit for risk adjustment
8 payments, 42 C.F.R. § 422.504(l) (Part C regulation); 42 C.F.R. § 423.505(k) (Part D
9 regulation); and (iii) “comply with . . . Federal laws and regulations designed to prevent
10 or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions
11 of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 et seq.).” 42
12 C.F.R. § 422 (Part C regulation); 42 C.F.R. § 423 (Part D regulation).

13 **II. Obligation to Implement an Effective Compliance Program**

14 95. The implementation of an effective compliance program is a prerequisite to an
15 MA Organization’s obtaining and retaining payments under both Parts C and D of the
16 Medicare Program. *Id.* §§ 422.503(a) (Part C) & 423.504(b)(4)(vi) (Part D). One
17 purpose of requiring a compliance program is to ensure that MA Organizations submit
18 accurate and truthful information to CMS. 65 Fed. Reg. 40170-01 at 40264 (June 29,
19 2000).

20 96. Specifically, each MA Organization must “[a]dopt and implement an effective
21 compliance program, which must include measures that prevent, detect, and correct non-
22 compliance with CMS’ program requirements as well as measures that prevent, detect,
23 and correct fraud, waste, and abuse.” 42 C.F.R. § 422.503(b)(4)(vi) (Part C); 42 C.F.R.
24 § 423.504(b)(4)(vi) (Part D). The compliance program “must, at a minimum, include
25 [certain] core requirements,” including (but not limited to):

26 (F) Establishment and implementation of an effective system for routine
27 monitoring and identification of compliance risks. The system
28 should include internal monitoring and audits and, as appropriate,

external audits, to evaluate the MA organization[’s], including first tier entities’, compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(G)(1) of this section.

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

97. A compliance program is not effective unless the MA Organization devotes adequate resources to the program.

III. Obligation to Attest to Validity of Risk Adjustment Data

98. After the final deadline for their submission of risk adjustment data but before their receipt of their final reconciliation payments for a given payment year, MA Organizations must attest to the validity of their risk adjustment data, including diagnoses, in a Risk Adjustment Attestation submitted to CMS. Specifically, the chief

1 executive officer, chief financial officer, or another individual with delegated authority
2 to sign on behalf of one of these officers, and who reports directly to such an officer,
3 must certify that the risk adjustment data that the MA Organization submitted to CMS
4 was accurate, complete, and truthful.

5 99. An MA Organization must request payment on a document that contains this
6 Attestation and the submission of this Attestation to CMS is a condition of receiving
7 Risk Adjustment payments.

8 100. The Part D regulations include a similar attestation for risk adjustment data,
9 including diagnoses, submitted for risk adjustment payments under the prescription drug
10 program. Under the applicable Part D regulation, these attestations are referred to as
11 certifications. 42 C.F.R. § 423.505(k).

12 101. Every year, each MA Organization agrees in writing that:

13 [a]s a condition for receiving a monthly payment under paragraph B of this
14 article, and 42 CFR Part 422 Subpart G, the MA Organization agrees that its
15 chief executive officer (CEO), chief financial officer (CFO), or an
16 individual delegated with the authority to sign on behalf of one of these
17 officers, and who reports directly to such officer, must request payment
18 under the contract on the form[] attached hereto as . . . Attachment B (risk
19 adjustment data) which attest to (based on best knowledge, information and
20 belief, as of the date specified on the attestation form) the accuracy,
21 completeness and truthfulness of the data identified on these attachments.

22 . . .

23 2. Attachment B requires the CEO, CFO, or an individual delegated with
24 the authority to sign on behalf of one of these officers, and who reports
25 directly to such officer, must attest to (based on best knowledge,
26 information and belief, as of the date specified on the attestation form) that
27 the risk adjustment data it submits to CMS under 42 CFR § 422.310 are
28 accurate, complete, and truthful. The MA Organization shall make annual

1 attestations to this effect for risk adjustment data on Attachment B and
2 according to a schedule to be published by CMS. If such risk adjustment
3 data are generated by a related entity, contractor, or subcontractor, then such
4 related entity, contractor, or subcontractor must also attest to (based on best
5 knowledge, information, and belief, as of the date specified on the
6 attestation form) the accuracy, completeness, and truthfulness of the data.
7 [422.504(l).]

8 102. MA Organizations have an obligation to acquire knowledge, information, and
9 belief about their risk adjustment data, including diagnoses, in order to both submit such
10 data and attest to the accuracy and truthfulness of the data. Nearly 17 years ago, CMS
11 put MA Organizations on notice that they were “responsible for making *good faith*
12 *efforts* to certify the accuracy, completeness, and truthfulness of the encounter [*i.e.*, risk
13 adjustment] data submitted” for payments from the Medicare Program. 65 Fed. Reg.
14 40,170, 40,268 (June 29, 2000) (emphasis added); *see also* Medicare Managed Care
15 Manual, Chapter 7, § 110.2 (October 2001) (stating, under section titled “Certification of
16 Data Accuracy, Completeness, and Truthfulness,” that “CMS expects M+C
17 organizations [now known as MA Organizations] to design and implement effective
18 systems to monitor the accuracy, completeness, and truthfulness of encounter data [that
19 is, diagnoses from hospital inpatient stays under the old PIP-DCG risk adjustment
20 model] and to exercise due diligence in reviewing the information provided to CMS”);
21 Medicare Managed Care Manual, Chapter 7, § 111.7 (August 2004) (stating, under
22 section titled “Certification of Data Accuracy, Completeness, and Truthfulness,” that
23 “CMS expects M+C organizations [now known as MA Organizations] to design and
24 implement effective systems to monitor the accuracy, completeness, and truthfulness of
25 risk adjustment data and to exercise due diligence in reviewing the information provided
26 to CMS”). When MA Organizations fail to act in good faith and deliberately ignore or
27 recklessly disregard information about their submission of inaccurate or untruthful data,
28 their Risk Adjustment Attestations are false.

IV. Obligation to Delete Invalid Diagnoses

103. MA Organizations are obligated to delete invalid diagnoses previously submitted by them to RAPS or to use other available means to return risk adjustment payments based on invalid diagnoses. Their deletion of invalid diagnoses is the principal mechanism by which CMS is able to recalculate beneficiaries' risk scores and ensure that the Government does not make improper risk adjustment payments to MA Organizations or that it recovers improper payments that were already made. In particular, the submission of diagnoses that are not supported by the beneficiaries' medical records and, thus, are invalid directly and necessarily causes CMS to make risk-adjustment payments that it would not have made but for the submission of that false data. Conversely, the "deletion" of previously-submitted diagnoses that are invalid because they are not supported by the beneficiaries' medical records directly and necessarily causes CMS either to avoid paying for previously-submitted false diagnoses or to recover payments it made for those false diagnoses. As a result, an MA Organization's failure to "DELETE" invalid diagnoses results in that MA Organization's retention of payments to which it was not entitled. Thus, both the submission of false diagnostic data and the failure to correct false diagnosis data influence CMS' payment, including the amount of the risk-adjustment payment, if any, that it makes for any given beneficiary based on his or her health status.

104. The obligation to delete invalid diagnoses previously submitted to RAPS or to otherwise return risk adjustment payments based on invalid diagnoses arises from the contractual relationship between MA Organizations and the Government, from regulation, and from the retention of an overpayment and, thus, constitutes an "obligation to pay . . . the Government" under the reverse false claims act provision of the FCA. 31 U.S.C. §§ 3729(a)(1)(G) & (b)(3). The obligation is imposed on MA Organizations by the following, among other things:

- The MA Organizations' execution of EDI agreements pursuant to which they agree to "research and correct risk adjustment data discrepancies." *See supra*

1 paragraphs 73-82 (describing these agreements). *See also* Exhibits 8-11, attached
2 hereto (examples of EDI agreements that the Defendant MA Organizations
3 executed).

- 4 • Regulations requiring MA Organizations to implement effective compliance
5 programs and to “detect and correct non-compliance with CMS’ program
6 requirements as well as . . . [to] prevent, detect, and correct fraud, waste, and
7 abuse.” *See supra* paragraphs 95-97 (describing these regulations). Plus, the MA
8 Organizations’ execution of agreements with CMS under Parts C and D pursuant
9 to which they agree to implement effective compliance programs. *See* 42 C.F.R.
10 § 422.504(a) (stating that the agreement between an MA Organization and CMS
11 must include a provision by which the MA Organizations agree to comply with
12 the Part C regulatory requirements and general instructions issued by CMS). *See*
13 *also supra* paragraphs 66-72 (describing the Part C and D agreements); Exhibits 1-
14 7, attached hereto (examples of Part C agreements between the Defendant MA
15 Organizations and CMS by which the Defendant MA Organizations agreed to
16 implement effective compliance programs).
- 17 • The regulations requiring the submission of the Risk Adjustment Attestations. *See*
18 *supra* paragraphs 98-102 (describing those regulations). Plus, the requirements set
19 forth in the Medicare Managed Care Manual and elsewhere that MA
20 Organizations exercise both good faith and due diligence in order to submit
21 truthful Risk Adjustment Attestations to the Government certifying that their risk
22 adjustment data is accurate and truthful. *See supra* paragraph 102. In addition,
23 the separate contractual requirement to submit Risk Adjustment Attestations and
24 to comply with the Medicare Managed Care Manual. *See, e.g.*, Exhibits 1-7,
25 attached hereto (examples of the Defendant MA Organizations’ Parts C
26 agreements with CMS by which they agree to submit such Attestations and to
27 comply with the Medicare Managed Care Manual).

- 1 • The requirement in the CMS' Participant Guides that MA Organizations delete
2 erroneous diagnosis data submitted to CMS. See 2003 Regional Risk Adjustment
3 Training for Medicare+Choice Organizations Participant Guide, § 6.1;
4 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations
5 Participant Guide, §§ 4.12 to 4.16; 2005 Risk Adjustment Data Basic Training for
6 Medicare Advantage Organizations Participant Guide §§ 4.12 to 4.16; 2006 Risk
7 Adjustment Data Basic Training for Medicare Advantage Organizations
8 Participant Guide §§ 4.12 to 4.16; 2007 Risk Adjustment Data Training for
9 Medicare Advantage Organizations Participant Guide §§ 4.12 to 4.16; 2008 Risk
10 Adjustment Technical Assistance for Medicare Advantage Organizations
11 Participant Guide §§ 4.12 to 4.16. This requirement is also included in 2014 and
12 2016 CMS training presentations. See *infra* paragraph 108. Plus, the regulatory
13 and contractual requirement that MA Organizations' comply with CMS'
14 instructions and policies. See 42 C.F.R. § 422.504(a) (stating that the agreement
15 between an MA Organization and CMS must include a provision by which the
16 MA Organizations agree to comply with the Part C regulatory requirements and
17 general instructions issued by CMS) (emphasis added). See also, e.g., Exhibits 1-
18 7 hereto (examples of the Defendant MA Organization's agreements to comply
19 with the CMS instructions and policies).
- 20 • The requirement in the Medicare Managed Care Manual that "[i]f upon
21 conducting an internal review of submitted diagnosis codes, the [MA
22 Organization] determines that any ICD-9-CM diagnosis codes that have been
23 submitted do not meet risk adjustment submission requirements [which includes
24 medical record support for all diagnoses], the [MA Organization] is responsible
25 for deleting the submitted ICD-9-CM diagnosis codes as soon as possible."
26 Medicare Managed Care Manual, Chapter 7, § 40 (June 2013). Plus, the
27 regulatory requirement that MA Organizations' comply with the Manual and MA
28 Organizations' contractual agreements to comply with the Manual. See 42 C.F.R.

§ 422.504(a) (stating that the agreement between an MA Organization and CMS must include a provision by which the MA Organizations agree to comply with the Part C regulatory requirements and general instructions issued by CMS). See also, e.g., Exhibits 1-7 hereto (examples of the Defendant MA Organization's agreements to comply with the Medicare Managed Care Manual).

105. Related Entities are also obligated to delete invalid diagnoses previously submitted by them to RAPS or to use other available means to return risk adjustment payments based on invalid diagnoses. Like the MA Organizations to which they are related, they are required to comply with the Part C and D regulations, the Medicare Managed Care Manual, the Participant Guides, and the other general instructions issued by CMS. In addition, when they submit risk adjustment data to the MA Program on behalf of their related MA Organizations, they are obligated to execute separate EDI agreements and Risk Adjustment Attestations, both of which impose an obligation to delete invalid diagnoses.

106. As previously explained, RAPS provides a means for MA Organizations and others submitting data on their behalf (such as Ingenix and then Optum) to withdraw or retract invalid diagnoses that they previously submitted to RAPS for risk adjustment payments. The process of withdrawing or retracting invalid diagnosis codes is often referred to as making "DELETES" because the field in RAPS that enables this to be accomplished is called a "Delete Indicator." The withdrawal or retraction of a diagnosis codes is also often referred to as a "DELETE."

107. CMS began instructing MA Organizations on the use of RAPS in the early 2000s in order to facilitate the phase in, during the 2004 to 2007 time period, of the use of diagnoses from physician office visits and hospital outpatient encounters to risk adjust for health status using the HCC model. It issued Risk Adjustment Training Participant Guides in order to provide instructions relating to, among other things, the use of RAPS to submit and delete data. The 2003 Risk Adjustment Training Participant Guide stated: "Now that the RAPS system is operational, effective October 1, 2002, the new system

1 allows for correction of risk adjustment data via the deletion process.” 2003 Regional
2 Risk Adjustment Training for Medicare+Choice Organizations Participant Guide, § 6.11
3 (titled “Modifying Risk Adjustment Data”). The 2003 Guide listed various reasons why
4 risk adjustment data may need to be deleted, including in order to withdraw an erroneous
5 diagnoses code. *Id.* at § 6.12.1. Finally, it stated that M+C organizations “must submit
6 delete records” to correct erroneous diagnosis data. *Id.* at § 6.12.3. The Guide made
7 very clear that deleting erroneous diagnoses was mandatory. Subsequent versions of the
8 Guide have included the same mandatory deletion requirement and instructions. *See*
9 2004 Regional Risk Adjustment Training for Medicare+Choice Organizations
10 Participant Guide, §§ 4.12 to 4.16; 2005 Risk Adjustment Data Basic Training for
11 Medicare Advantage Organizations Participant Guide §§ 4.12 to 4.16; 2006 Risk
12 Adjustment Data Basic Training for Medicare Advantage Organizations Participant
13 Guide §§ 4.12 to 4.16; 2007 Risk Adjustment Data Training for Medicare Advantage
14 Organizations Participant Guide §§ 4.12 to 4.16; 2008 Risk Adjustment Technical
15 Assistance for Medicare Advantage Organizations Participant Guide §§ 4.12 to 4.16.
16 108. The same mandatory requirement and instructions about deletions of invalid
17 diagnoses were also set forth in other CMS instructional materials used to train MA
18 Organizations. For instance, a 2003 presentation titled “Regional Risk Adjustment
19 Training for Medicare+Choice Organization Questions & Answers” instructed that “all
20 information that is submitted must be correct. If a plan identifies incorrect or invalid
21 information that has been submitted, it must delete that information.” These instructions
22 were also provided in CMS’ presentation slides for a July 1, 2014 Risk Adjustment
23 Webinar used to provide training to MA Organizations and others about how risk
24 adjustment operates. A training presentation that CMS made to MA Organizations and
25 others on June 23, 2016, also stated that it was the responsibility of each MA
26 Organization to “delete each instance of unsupported diagnoses from” RAPS. All of the
27 above-mentioned Participant Guides and other instructional materials also describe an
28 alternative method for deleting erroneous data using a Direct Data Entry system.

1 109. All of the above-mentioned Participant Guides and other instructional materials
2 have been and continue to be available to all MA Organizations and others on a website
3 hosted by a CMS contractor. *See* www.csscooperations.com. The 2003 to 2011 material
4 is in the Training subsection under Risk Adjustment Processing System in the Archives
5 and the 2012 to 2016 material is in the Training subsection under Risk Adjustment
6 Processing System on the Home page.

7 110. MA Organizations can delete invalid diagnoses both before and after the final
8 deadline for RAPS data submissions, which is sometime during the year following the
9 payment year at issue. The final deadline is only a submission deadline; it does not
10 pertain to deleting invalid diagnoses in order to withdraw them. *See* 42 C.F.R.
11 § 422.310(g)(2)(ii) (codifying pre-existing process permitting, after the final deadline,
12 only corrections to delete diagnoses from previously-submitted risk adjustment data).
13 Diagnoses deleted before the deadline for RAPS data submissions for a payment year are
14 known as “open-period deletes” and diagnoses deleted after the deadline for RAPS data
15 submissions for a payment year are known as “closed-period deletes.”

16 111. Because the final submission deadline is after the completion of the payment year,
17 monthly payments made during the payment year are interim payments. After the final
18 submission deadline, CMS determines if any adjustments to these interim monthly
19 payments are necessary based on all diagnoses submitted (and not deleted) for each
20 beneficiary up until the final submission deadline and re-calculates each beneficiary’s
21 risk score for the payment year to determine if it has changed and whether a plus or
22 minus adjustment to the payment for the beneficiary is necessary. If the beneficiary’s
23 risk score is higher because of the submission of additional diagnoses for that
24 beneficiary, CMS makes a final reconciliation payment of any additional payment owed
25 to the Plan for that beneficiary for that payment year. Conversely, if the beneficiary’s
26 risk score is lower because of the deletion of diagnoses for that beneficiary prior to the
27 final submission deadline, CMS recovers the payments associated with the deleted
28 diagnoses as part of this final reconciliation payment process.

1 112. Accordingly, if, prior to the final submission deadline, an MA Organization is in
2 possession of or has access to information about invalid diagnoses, it should delete
3 invalid diagnoses prior to that deadline to ensure that the final reconciliation payment
4 that it is claiming is correct. If, however, an MA Organization comes into possession or
5 otherwise gains access to information about invalid diagnoses after the final submission
6 deadline, it must still delete the invalid diagnoses, and CMS will still recover the risk
7 adjustment payments associated with the deleted diagnoses as part of additional risk
8 score rerun and reconciliation processes it has in place to recover overpayments.

9 113. The UHG Managing Defendants knew how to make deletes in RAPS. They also
10 knew the difference in making “open-period” and “closed-period” deletes. The
11 individuals who knew about the delete process and the difference between “open-period”
12 and “closed-period” deletes included, but were not limited to: Rebecca Martin, the
13 Director of Encounter Operations for Ingenix and then the Director of Data Remediation
14 for Optum; Jon Bird at Optum; and Scott Theisen and Brian Thompson at
15 UnitedHealthcare Medicare & Retirement.

16 114. However, Defendants violated the FCA by knowingly and improperly failing to
17 delete many invalid diagnoses and, thus, failing to repay risk adjustment payments to
18 which they were not entitled.

19 **THE FALSE CLAIMS ACT**

20 115. The FCA reflects Congress’s objective to “enhance the Government’s ability to
21 recover losses as a result of fraud against the Government.” S. Rep. No. 99-345, at 1
22 (1986), available at 1986 U.S.C.C.A.N. 5266. First, a defendant violates the FCA when
23 it “knowingly presents, or causes to be presented, a false or fraudulent claim for payment
24 or approval.” 31 U.S.C. § 3729(a)(1)(A). Under the FCA, a claim includes a request for
25 money. *Id.*, § 3729(b)(2). Further, a claim is “false or fraudulent” under the FCA if the
26 entity or person submitting the claim was not entitled to payment.

27 116. Second, after the 2009 amendments to the FCA by the Fraud Enforcement and
28 Recovery Act of 2009 (“FERA”), Pub.L. 111-21 (May 20, 2009), a defendant violates

1 the FCA when it “knowingly makes, uses, or causes to be made or used, a false record or
2 statement material to a false or fraudulent claim.” 31 U.S.C. § 3729(a)(1)(B). Prior to
3 FERA, a defendant violated this provision of the FCA when it “knowingly [made],
4 use[d], or cause[d] to be made or used, a false record or statement to get a false or
5 fraudulent claim paid or approved by the Government.”

6 117. Third, in May 2009, Congress amended the “reverse false claims act” provision of
7 the FCA to provide that a defendant violates the FCA when it “knowingly conceals *or*
8 knowingly and improperly avoids *or* decreases an obligation to pay or transmit money or
9 property to the Government.” 31 U.S.C. § 3729(a)(1)(G) (emphasis added). Prior to
10 FERA, this provision of the FCA provided that a defendant violates the FCA when it
11 “knowingly makes, uses, or causes to be made or used, a false record or statement to
12 conceal, avoid, or decrease an obligation to pay or transmit money or property to the
13 Government.” After FERA, a defendant violates this provision of the FCA when it
14 “knowingly makes, uses, or causes to be made or used, a false record or statement
15 material to an obligation to pay or transmit money or property to the Government, *or*
16 knowingly conceals *or* knowingly and improperly avoids *or* decreases an obligation to
17 pay or transmit money or property to the Government.” 31 U.S.C. § 3729(a)(1)(G)
18 (emphasis added).

19 118. Under the FCA, the terms “knowing” and “knowingly” mean that the defendant
20 had actual knowledge of or acted in deliberate ignorance or reckless disregard of
21 information relating to the truth or falsity of its claims for payment or its false records or
22 statements. *Id.* § 3729(b)(1)(A). Proof that the defendant had specific intent to defraud
23 the Government is not required. *Id.* § 3729(b)(1)(B). Congress included “deliberate
24 ignorance” in its definition of the terms “knowing” and “knowingly” to hold a defendant
25 accountable for failing to make the inquiry that a reasonable and prudent person or entity
26 would have made under the circumstances to be reasonably certain that he, she, or it was
27 entitled to the money that he, she, or it sought from the Government. S. Rep. No. 99-
28 345, at 21 (1986), as reprinted in 1986 U.S.C.A.N. 5266, 5286. The terms “knowing”

1 and “knowingly” used in this Amended Complaint have the meaning ascribed to them by
2 the FCA. Similarly, the terms “knowledge,” “knows” and “knew” are used in this
3 Amended Complaint to have the same meaning.

4 119. In 2009, Congress also amended the FCA to provide a definition of the term
5 “obligation” for the purpose of the new “reverse false claims act” provision of the
6 statute, section 3729(a)(1)(G). See FERA, Pub. L. 111-21, 123 Stat. 1617, 1621-25
7 (2009). It defined the term to mean “an established duty, *whether or not fixed*, arising
8 from an express or implied contractual ... relationship, from a fee-based or similar
9 relationship, from statute or regulation, or from the retention of any overpayment.” 31
10 U.S.C. § 3729(b)(3) (emphasis added). Congress promulgated this definition to reflect
11 its long-held view that an “obligation” under the FCA’s reverse FCA provision, 31
12 U.S.C. § 3729(a)(1)(G), encompasses non-fixed and contingent duties to pay or repay
13 monies to the Government. S. Rep. 111-10, 14, 2009 U.S.C.C.A.N. 430, 441.

14 120. Under the FCA, “material” means “having a natural tendency to influence, or
15 capable of influencing, the payment or receipt of money or property.” *Id.* § 3729(b)(4).

16 121. Under the FCA, the Government is entitled to recover three times the amount of
17 damages which it sustained because of a defendant’s violation of the statute and, for each
18 act by the defendant violating the statute, a civil penalty. For violations that occurred
19 before November 2, 2015, the FCA imposes a penalty for each violation of not less than
20 \$5,500 and not more than \$11,000. For violations occurring after November 2, 2015, all
21 civil statutory penalties, including the FCA, are subject to an annual adjustment for
22 inflation pursuant to Section 701 of the Bipartisan Budget Act of 2015, Public Law 114-
23 74 (No. 2, 2015) (“BBA”). At this time, by operation of the BBA, for violations that
24 occurred after November 2, 2015, the FCA imposes a penalty of not less than \$10,957
25 and not more than \$21,916 per violation, and these amounts are subject to annual
26 adjustment for inflation in future years. See 28 C.R.F. § 85.5 (identifying applicable
27 inflation adjustments on an annual basis).

THE FACTS

122. Since at least 2005, Defendants knew that diagnoses submitted to Medicare for risk adjustment payments had to satisfy various criteria and be supported and validated by the medical records of the beneficiaries in their MA Plans. Defendants also knew that many provider-reported diagnoses were not supported and validated by the beneficiaries' medical records and that they were obliged to undertake good faith efforts to identify and delete those unsupported and invalid diagnoses. Moreover, Defendants knew that they were obligated to "look both ways" at the results of their chart reviews and delete unsupported provider-reported diagnoses. Nonetheless, Defendants conducted millions of medical record reviews as part of their revenue-generating national Chart Review Program, turned a blind eye to the negative results of those reviews showing hundreds of thousands of unsupported diagnoses that the UHG Managing Defendants had previously submitted to Medicare on behalf of the Defendant MA Organizations, and knowingly and improperly avoided repaying Medicare for at least over a billion dollars in risk adjustment payments to which they were not entitled. Similarly, Defendants disregarded information from their RACCR Program about invalid coding practices by their incentivized capitated and gain-sharing providers and failed to repay Medicare for additional erroneous payments based on their invalid diagnoses.

I. Defendants Knew That Many Provider-Reported Diagnoses Were Invalid And That They Were Obligated To Undertake Good Faith Efforts To Identify And Delete Them

123. As part of its 2005 acquisition of PacifiCare, UHG retained the PacifiCare employees with knowledge about the requirements for the submission of valid diagnoses, the obligation to delete invalid diagnoses, and the various problems relating to the invalidity of provider-reported diagnoses. UHG retained these PacifiCare employees to continue performing work relating to risk adjustment.

124. For example, Jeffrey Dumcum, Stephanie Will, Pam Holt, and Pam Leal were all former PacifiCare employees knowledgeable about risk adjustment and were retained by

1 UHG to run its risk adjustment programs. Dumcum had been PacifiCare's Chief
2 Financial Officer and, after the acquisition, became Vice President of Finance for
3 Oventions. Will had been a Principal Analyst at PacifiCare who designed risk adjustment
4 programs and, after the acquisition, joined Oventions as the Program Manager for the
5 national Chart Review Program. Holt had been a Project Manager for Network
6 Management Operations at PacifiCare and, after the acquisition, became the Manager of
7 Provider Outreach for the Risk Adjustment Program. Leal had been an Executive
8 Director of Provider Training and Development for PacifiCare and, after the acquisition,
9 became a Regional Vice President for Market Consultation.

10 125. From 2005 to 2007, Dumcum, Will, Holt, and Leal worked at the PacifiCare
11 office in the Central District of California. Thereafter, Holt and Leal continued to work
12 for Ingenix at its office in the Central District of California.

13 126. The PacifiCare employees obtained their knowledge about risk adjustment from
14 various sources, including CMS. Will attended CMS training programs focused on the
15 Risk Adjustment Participant Guide and was also familiar with the content of this
16 document based on her reading of it. Prior to the acquisition, PacifiCare also conducted
17 various risk adjustment programs, including a chart review program, and provided
18 training to healthcare professionals concerning medical record documentation and
19 diagnosis coding.

20 127. In addition, PacifiCare had been a member of an industry association called the
21 Industry Collaboration Effort ("ICE") and ICE's Risk Adjustment Data Acquisition &
22 Reporting ("RADAR") team. ICE was an association of MA Organizations and provider
23 groups in California that served beneficiaries in MA Plans. ICE focused on risk
24 adjustment issues and other matters of particular importance to the managed care
25 industry. After PacifiCare became part of UHG, the PacifiCare employees continued to
26 participate in ICE and its RADAR team. During the 2006 and 2007 time period (perhaps
27 longer), Leal was the President and a member of the Board of Directors of ICE. Leal
28 continued in a leadership role at ICE until 2013. During that time period, she worked for

1 Ingenix and then Optum. At the ICE Annual Conferences in 2006 and 2007, Leal made
2 presentations about “[p]rovider coding [being] highly inaccurate and incomplete,” CMS
3 reviews showing that 30 percent of the provider-reported diagnoses were not supported
4 by medical records, and the use of chart reviews to generate larger risk adjustment
5 payments. Furthermore, throughout the time period relevant to this Amended
6 Complaint, one or more of the Defendants were members of ICE and, at various times,
7 employees of Ingenix, Optum, UnitedHealthcare of California, and UnitedHealthcare
8 participated in the activities of the RADAR team. As reflected in the meeting minutes of
9 the RADAR team, these Defendants included Ingenix (*e.g.*, August 2011),
10 UnitedHealthcare of California (*e.g.*, March 2014), Optum (*e.g.*, November 2014, June
11 2015, and March 2016), and UnitedHealthcare (*e.g.*, June 2015 and March 2016).

12 128. The former PacifiCare employees knew that a beneficiary’s medical record was
13 the “source of truth” for purposes of submitting valid diagnostic data to the MA Program
14 for risk adjustment payments. For example, in a March 2006 email, Will acknowledged
15 that diagnosis data had to be “fully supported by medical record documentation.” As
16 another example, in 2008, Ingenix sent notices to capitated provider groups in California
17 instructing them that they should only report to Ingenix “diagnosis codes that can be
18 supported by the documentation in the medical record.” Furthermore, according to
19 Randall Myers at Ingenix, these providers, when they submitted diagnoses through a
20 web portal referred to as the Alternate Submission Method, were required to attest that
21 their diagnostic data complied with CMS requirements for the submission of valid data.
22 Other employees of the UHG Managing Defendants also understood these requirements,
23 including Patty Brennan who, when she was Director of Retrospective Services
24 (including chart review services) at Ingenix and then Optum, acknowledged that CMS’
25 Risk Adjustment Participant Guide established that the medical record was the “one
26 source of truth” for MA Organizations to ensure that they were submitting accurate data
27 to CMS for risk adjustment payments. In addition, Kimberly Halva, the Compliance
28

Officer for UnitedHealthcare Medicare & Retirement from 2010 to 2013, was aware that “[a] medical record must substantiate all diagnostic information provided to CMS.”

129. In addition, those Defendants and their employees involved in ICE and its RADAR team knew or should have known that enrollees’ medical records are the “source of truth” based on guidance documents issued by the RADAR team about this fundamental payment requirement. In 2010, ICE’s RADAR team issued a guidance document highlighting that CMS requires complete and accurate documentation of medical conditions for the submission of diagnoses, that only diagnoses depicting documented medical conditions which required or affected patient care are valid, and that diagnosis codes cannot be submitted “until [the provider] is sure the patient has the condition.” The ICE RADAR Physician Education Work Group also issued a similar document called “Best Practices for Risk Adjustment,” which advised that “ICD-9-CM coding requires documentation of the diagnosis in the medical record as well as evaluation and management. Documentation should indicate how this diagnosis impacted this episode of care.” In 2012, ICE also issued a Medical Record Documentation Tips sheet, which once again warned MA Organizations and providers not to code diagnoses that are probable, suspected, questionable, or “working diagnoses,” and also not to code diagnoses when medical records use “other similar terms indicating uncertainty.” More recently, in 2013, ICE issued a “Documentation Newsletter” that repeated earlier advice and also cautioned that “[c]oding guidelines **prohibit coders from making assumptions**” regarding whether a diagnosis is or is not substantiated by a patient’s medical record. (Emphasis in the original.) That is, the medical record must “clearly reflect” the medical condition.

130. The former PacifiCare employees also were aware that provider-reported diagnoses often did not comply with CMS requirements and were often inconsistent with the information in their patients’ medical records. According to Dumcum, when he was the Chief Financial Officer of PacifiCare, he and others there knew “in Medicare Advantage that the claims did not always match the medical record documentation. So

1 ... we were concerned that it should be a place that we try to improve, that we try to
2 educate and try to identify things to make that better.” In addition, Will, Holt and other
3 former PacifiCare employees were aware of common diagnosis coding errors made by
4 providers. They learned of these problems from PacifiCare employees working in the
5 field with physicians, reports of physician-coding trends, and reports from PacifiCare-
6 employed certified coders. For example, a June 2003 PacifiCare PowerPoint
7 Presentation by Will, Holt, and other PacifiCare employees identified diabetes as a
8 medical condition that was often miscoded.

9 131. In 2005, the PacifiCare employees, including Dumcum, Will, Leal, and Holt, were
10 also aware of a data validation review conducted by the Government of diagnosis codes
11 previously submitted for medical encounters that occurred in 2003 (*i.e.*, encounters with
12 2003 dates of service). The PacifiCare employees were aware that the results of CMS’
13 medical record reviews showed that approximately 30 percent of the provider-reported
14 diagnoses were invalid and, after UHG acquired PacifiCare, Dumcum, Will, and Leal
15 shared this information with other individuals who worked for various UHG Managing
16 Defendants such as Jerry Knutson, Lee Valenta, Cynthia Polich, Relator Poehling, Paul
17 Bihm, Janice Redmond, and Carol Thompson. Furthermore, the results from this CMS
18 review also put the former PacifiCare employees on notice that providers were reporting
19 codes that were just plain wrong, were coded from laboratory reports, and did not reflect
20 current medical conditions – all of which was in breach of the fundamental rules that the
21 diagnosis codes submitted to Medicare must be accurate and truthful, based on face-to-
22 face visits (*e.g.*, not lab reports), reflect current conditions, and otherwise be valid.

23 132. Moreover, the former PacifiCare employees were aware that MA Organizations
24 are not entitled to risk adjustment payments based on diagnoses that are unsupported by
25 the beneficiaries’ medical records, and that CMS expected health plans to delete
26 incorrect diagnoses submitted for risk adjustment payments. They also knew, based on
27 their experiences at PacifiCare, that CMS could audit the diagnoses MA Organizations
28 submitted for risk adjustment payments.

1 133. In fact, in April 2005, Holt participated in a “CMS data validation call” in which
2 CMS explained that it expected MA Organizations to correct invalid diagnoses
3 submitted to Medicare for risk adjustment payments. Holt reported this to Will and
4 suggested creating a spreadsheet to give to providers for providers to use to inform
5 PacifiCare of invalid diagnoses and allow PacifiCare to delete them. As part of this
6 discussion, Leal explained to Will that, if provider groups “during their chart audits find
7 that physicians have documented rule-out or history-of but coded as if the member had
8 [the medical condition,] they want to be able to fix it so when we get audited again by
9 CMS it is fixed.” Leal further stated that “[o]bviously, as issues are identified there will
10 need to be education to physician[s] on changing their practice of coding incorrectly (as
11 you remember Dr. Norman mentioned habits doctors have, that we will need to break).”
12 Holt agreed that provider groups

- 13 • need something ‘standardized and formalized’ so they know what fields to report
14 if and when they find any obvious discrepancies. They are the type of thing that
15 Pam [Leal] stated in her email below, the code of the actual disease when the
16 documentation clearly only supports ‘history of’ or ‘suspected’ (and then it was
17 not confirmed), or an obvious miscode; the things that Melissa [Ferron] is finding
18 in the data validation. Provider groups will find this during their own chart audits.
- 19 • and CMS “was very firm that we need to be doing this, so I would expect [CMS]
20 will look for our process when they get around to more formally auditing our
21 oversight of this process.”

22 134. In addition, in August 2006, a year after the April 2005 CMS validation call, Will
23 and Holt knew that CMS had confirmed, in responses to questions about its RADV
24 audits, that it would invalidate diagnoses submitted to Medicare that were not supported
25 by the beneficiaries’ medical records.

26 135. After PacifiCare became part of UHG, the former PacifiCare employees began
27 educating others at the UHG Managing Defendants about risk adjustment. In particular,
28 Dumcum made a series of presentations to various employees, including senior

1 management employees of the UHG Managing Defendants such as Ovations' Jerry
2 Knutson, where he explained that "[p]rovider coding is highly inaccurate and
3 incomplete" and that "more than 30% of coded conditions are not supported by CMS
4 validation findings." Other senior executives or managers of the UHG Managing
5 Defendants that were recipients of the slide presentation with this information included
6 Cynthia Polich at Ovations (who was emailed a copy of the presentation in March 2007),
7 Lee Valenta at Ingenix (to whom Knutson emailed a copy of the presentation in May
8 2007), and Relator Poehling.

9 136. Furthermore, Defendants' own data revealed and confirmed problems with
10 provider-reported diagnoses. In September 2006, Will, Holt, Leal, and others generated
11 a list of providers that were outliers, which, at that time, they defined as providers with
12 significantly above average patient risk scores. This information made them "question
13 the validity" of these providers' codes. These provider groups included Healthcare
14 Partners Medical Group, Edinger Medical Group, WellMed, and other incentivized
15 provider groups which, based on subsequent reviews conducted as part of the RACCR
16 Program, submitted significant numbers of invalid diagnoses. After 2006, Ingenix and
17 then Optum continued to track risk scores of beneficiaries cared for by various provider
18 groups and saw risk scores they considered to be outliers. They also generated
19 prevalence reports that identified the provider groups with abnormally high average risk
20 scores. These prevalence reports also identified specific medical conditions (or
21 categories of medical conditions, that is, HCCs) that were reported by various provider
22 groups at rates significantly above average.

23 137. In 2007, Dumcum and other former PacifiCare employees were given the
24 responsibility for creating and then managing a risk adjustment service group within
25 Ingenix, the predecessor to Optum. This enabled UHG to move the risk adjustment
26 operations to Ingenix. Ovations and later UnitedHealthcare became Ingenix's internal
27 "client." This move also enabled Ingenix to offer its risk adjustment services to other
28 MA Organizations which it referred to as its "commercial clients." Dumcum became

1 Senior Vice President and Will became Vice President of Risk Adjustment Programs for
2 this new risk adjustment service group within Ingenix. After 2007, Ingenix hired
3 additional employees and increased the size of the Ingenix risk adjustment group,
4 including the size of the group in this District. The Ingenix risk adjustment group in this
5 District was responsible for, among other things, risk adjustment data/diagnosis codes
6 submissions, risk adjustment data remediation and the deletion of invalid diagnoses, risk
7 adjustment data analytics and finance (*e.g.*, tracking the results and financial impact of
8 the Chart Review and Claims Verification Programs), provider outreach and programs
9 relating to risk adjustment, and the Chart Review Program operations.

10 138. In January 2007, Dumcum made a presentation in which he stated that the
11 validation of provider-reported diagnosis codes had to improve. Dumcum knew that
12 providers were reporting unsupported diagnoses and that both fee-for-service and
13 capitated providers needed to improve their validation rates.

14 139. Prior to this, in 2006, Dumcum, Will, Holt and others had already participated in
15 discussions about conducting an Internal Data Validation (“IDV”) Program focused on
16 the validity of provider-reported diagnoses. The purpose of the IDV Program was to
17 determine whether the physicians’ medical records supported the diagnoses they
18 reported to the UHG Managing Defendants, who in turn submitted the diagnoses to
19 Medicare for risk adjustment payments.

20 140. In February 2007, Will, Holt, and Patricia Rasmussen, Manager of Encounter
21 Submissions at Ingenix, were informed of specific provider-reported codes that were
22 reported based on “faulty coding.” For example, Sharp Community Medical Group in
23 California submitted a diagnosis tracking to HCC 155 (Major Head Injury) but there was
24 “no documentation to support intracranial injury.” Likewise, Monarch/South Coast,
25 located in this District, submitted a diagnosis tracking to HCC 17 but there was “[n]o
26 documentation of diabetes or diabetic complication[.]” Will, Holt, and Rasmussen were
27 requested to remove, or delete, these codes before the final submission deadline but
28 Rasmussen replied that they did not have resources and could not do this.

1 141. In addition, UHG Managing Defendants knew that a significant percentage of
2 provider-reported diagnoses were invalid based on audits performed by CMS and similar
3 internal audits or reviews that they performed. For example, one such audit was
4 performed on diagnoses submitted for 2004 date of service medical encounters (*e.g.*
5 physician office visits) that mapped to 1,231 HCCs. The results were reported in a
6 September 2007 Risk Adjustment Programs presentation sent by Dumcum to Relator
7 Poehling. The presentation showed that no support was found in the beneficiaries'
8 medical records for 32 percent of the HCCs at issue. That is, the records did not confirm
9 the diagnoses mapping to 32 percent of the HCCs under review. The same presentation
10 showed the results of another audit of diagnoses submitted for 2005 date of service
11 medical encounters that mapped to 1,160 HCCs. It showed that, as of the date of the
12 presentation, 18 percent of the HCCs were "NOT supported" and another 8 percent were
13 most likely not supported.

14 142. In October 2007, Ingenix also emphasized the fact that more than 30 percent of
15 provider-reported diagnoses were unsupported by the beneficiaries' medical records as a
16 selling point for the risk adjustment services, including data validation services, that it
17 marketed to another MA Organization.

18 143. During the 2007 and 2008 time period, Ingenix implemented the IDV Program.
19 The program focused on physicians in California, Missouri, Texas, and Washington who
20 reported more than three times the number of diagnoses than the average. The program
21 was very small in scope, but the results confirmed that providers reported many invalid
22 diagnoses. In January 2008, the results for medical encounters in 2006 showed a 30
23 percent invalidation rate. That is, approximately 30 percent of provider-reported
24 diagnoses were invalid, which was consistent with what the PacifiCare employees had
25 known since at least 2005. In January 2008, these results were sent to Will, Holt, and
26 Rasmussen.

27 144. Accordingly, by at least 2005, the former PacifiCare employees Dumcum, Will,
28 Holt, and Leal knew that at least 30 percent of provider-reported diagnoses were not

1 supported by the beneficiaries' medical records; by at least 2007, Dumcum had imparted
2 this knowledge to others at the UHG Managing Defendants; and, by at least 2008, the
3 UHG Managing Defendants' own medical record reviews had confirmed that fact.

4 145. Additional evidence demonstrates that, by at least the 2007 and 2008 time period,
5 the invalidity of provider-reported diagnoses was an ongoing concern. For example, in
6 September 2008, one of United's own actuarial consulting subsidiaries, Reden &
7 Anders, made a presentation that identified unsupported diagnosis codes as a "Potential
8 Compliance Risk Area" and warned that "[t]here is no such thing as minimally
9 compliant." Ovation's President Cynthia Polich possessed a copy of this presentation.

10 146. In addition, by at least 2008, the former PacifiCare employees, then at Ingenix,
11 had also imparted their knowledge that the UHG Managing Defendants were obligated
12 to identify and delete invalid provider-reported diagnoses. For example, a January 2008
13 training guide entitled "CMS-HCC Risk Adjustment Training Module," created by
14 Ingenix personnel for provider outreach, recognized that it is the accuracy of medical
15 record documentation and coding that supports entitlement to risk adjusted payments
16 from the Medicare Program. The presentation recognized that accurate medical record
17 documentation is key to accurate risk adjustment payments and necessary to validate
18 payments. In addition, in June 2008 emails, Patty Brennan, the Compliance Manager for
19 Ingenix, and Karen Wagor, a Senior Coder and National Trainer for Ingenix, both of
20 whom worked at Ingenix's Santa Ana office, recognized that Defendant MA
21 Organizations were not entitled to payment based on diagnoses that were not validated
22 by beneficiaries' medical records and that those entities risked losing revenue based on
23 invalid diagnoses: "We could be at risk of losing \$\$ if there isn't another piece in the
24 documentation before or after this date of service for the HCC if it can't be verified with
25 the most accurate validation. **The medical record must support all diagnoses coded
26 for the date of service and must be able to stand alone for an audit on those reported
27 diagnosis codes.**" (Emphasis in the original.)
28

1 147. Moreover, the UHG Managing Defendants knew they were required to effectively
2 address compliance issues. For example, a presentation from November 2009 entitled
3 “UnitedHealth Group – Audit Management Overview,” made at a Medicare Compliance
4 Oversight Committee meeting, expressly acknowledged the legal obligation to
5 implement an effective compliance program and stated that “[i]n order to have an
6 effective Compliance Program, an organization must have a robust internal monitoring
7 and auditing process in place.” In 2009, Jenny O’Brien, the Chief Medicare Compliance
8 Officer, was a Co-Chair of the Medicare Compliance Oversight Committee, a position
9 she held until approximately 2015. During this time period, O’Brien worked for
10 Ovations and then UnitedHealthcare Medicare & Retirement. Her Co-Chair was the
11 Chief Executive Officer or another officer of Ovations and then UnitedHealthcare
12 Medicare & Retirement. In the 2010-2011 time frame, the Co-Chair was Tom Paul.
13 And, as another example, in approximately May 2010, Larry Renfro, who was then the
14 Chief Executive Officer of both the Public & Senior Market Group (PSMG) and
15 Defendant Ovations, and David Orbuch, who was then the Executive Vice President and
16 Chief Compliance Officer of PSMG, met with CMS regarding their Medicare
17 compliance program and represented to CMS that they would “meet and exceed” CMS’
18 expectations.

19 148. Kimberly Halva, UnitedHealth Medicare & Retirement’s Finance Compliance
20 Officer from 2010 to 2013, also was keenly aware that the validity of provider-reported
21 diagnoses needed to be addressed. Halva understood that MA Organizations had an
22 obligation to identify and delete diagnoses that were not supported by its beneficiaries’
23 medical records. (Halva was also familiar with the Risk Adjustment Participants Guide.)
24 In November 2010, she sent a memorandum to Relator Poehling with recommendations
25 for compliance problems focused on identifying and deleting invalid provider-reported
26 diagnoses. In January 2011, she sent Relator Poehling “a few suggestions for risk
27 mitigation type programs UnitedHealthcare Medicare and Retirement could take to more
28 equally distribute resources between programs dedicated to improper coding or billing

1 and those focused on identifying additional reimbursement opportunities through
2 improved coding/documentation.” One of Halva’s suggestions was for
3 UnitedHealthcare to perform “General Coding Accuracy Audits,” which were essentially
4 “look both ways” medical record reviews that would identify both incomplete coding
5 (which she referred to as “under-coding”) and inaccurate coding (which she referred to
6 as “over-coding”). Another of her suggestions was for UnitedHealthcare Medicare &
7 Retirement to “Specifically Identify Traditionally Over-Coded or Incorrectly Coded
8 Conditions,” “such as stroke or COPD,” and conduct medical record reviews to
9 determine if those traditionally over-coded or incorrectly coded conditions could be
10 validated. Halva and Scott Theisen, the Chief Financial Officer for UnitedHealthcare
11 Medicare & Retirement from 2010 to 2013, were Co-Chairs of the UnitedHealthcare
12 Medicare & Retirement Finance Compliance Oversight Committee, which was
13 responsible for risk adjustment compliance issues. Halva also reported to Theisen as
14 well as Jennifer O’Brien.

15 149. In or around early 2009, Deloitte & Touche, which served as the public
16 accounting firm for UHG (which filed a consolidated financial statement for all of its
17 businesses), sent a memo to Ovations regarding an audit it performed to investigate the
18 appropriateness of an accounting treatment used by Ovations. In the audit, Deloitte &
19 Touche “looked both ways” when reviewing MA Program beneficiaries’ medical records
20 because, according to Auditor Bill Nepple, that was the only way to achieve a full and
21 complete picture of a beneficiary’s health status. The results of this “look both ways”
22 audit were communicated to Relator Poehling in February 2009 and he was aware that
23 both ADDS and DELETES resulted from the audit.

24 150. In addition, as part of their compliance efforts, the UHG Managing Defendants
25 had, since at least 2008, required financially-incentivized capitated provider groups to
26 submit attestations to them that certified that the diagnoses that they reported to the UHG
27 Managing Defendants were valid and met CMS’s requirements. For example, in or
28 around 2008, Ingenix sent notices to these providers describing these “**CMS DATA**

1 **ACCEPTANCE GUIDELINES,”** and stating that “[a]ll diagnoses must be
2 **documented at the time of the patient encounter or after receipt and confirmation**
3 **of the diagnosis (i.e. Lab or Radiology report) and must be documented in the**
4 **medical record,”** and “[o]nly report diagnosis codes that can be supported by the
5 **documentation in the medical record,”** and “[a]ll diagnosis codes should be valid . . .
6 .” (Emphasis in the original.)

7 151. In 2010, Holt and Leal were a part of an email chain discussing California
8 provider groups and risk adjustment data validation. Based on Holt’s involvement with
9 ICE’s RADAR team (and possibly other sources), Holt noted that California provider
10 groups are “acutely aware of the importance of data validation” and that risk adjustment
11 data validation was “a subject discussed frequently at the ICE meetings.” In the same
12 email chain, Holt also assured Relator Poehling that provider groups in California would
13 understand the importance of CMS’s RADV audits.

14 152. In November 2009, the results of an IDV audit for one of Ingenix’s commercial
15 clients, another company that owned and operated MA Plans, further confirmed what the
16 UHG Managing Defendants already knew, that is, that providers were reporting invalid
17 diagnoses at an alarming rate. The results of the audit showed a 45 percent invalidation
18 rate. Providers in that commercial client’s plans were providers for beneficiaries in one
19 or more of the Defendant MA Organizations’ Plans.

20 153. In mid-2010, the results of IDV reviews once again confirmed an ongoing
21 problem with the validity of provider-reported diagnoses. The results showed an
22 invalidation rate of approximately 40 percent for California provider groups which cared
23 for beneficiaries enrolled in one of more UHG MA Plans. Higher than the 30 percent
24 invalidation rate reported in 2005, these results confirmed that a significant percentage of
25 provider-reported diagnoses were invalid. In mid-2010, these results were shared with
26 Relator Poehling, Keith Dobbins (an attorney for one of the UHG Managing
27 Defendants), Stephanie Will, Patty Brennan, Ronnie Grower, among other individuals
28 working for the UHG Managing Defendants.

1 154. Also, in June 2010, an Ingenix Health Reform Implementation (HRI) Report
2 prepared for UHG's then Chief Executive Officer, Steve Hemsley, and other members of
3 the "UHG executive team" identified compliance as an important issue of immediate
4 concern to UHG, particularly compliance with the FCA. This report was sent to
5 Dumcum, Knutson, Valenta, Andy Slavitt, Timothy Wicks, and other individuals
6 working for the UHG Managing Defendants at the time.

7 155. Furthermore, in 2010, additional Government audits confirmed the problem with
8 invalid provider-reported diagnoses. In March 2010, the HHS Office of Inspector
9 General ("OIG") sent Jack Larsen, the Chief Financial Officer of Ovations, a draft report
10 of an audit of the risk adjustment data that one of UHG's Texas MA Organizations, then
11 called PacifiCare of Texas, submitted for payment year 2007. In July 2010, OIG sent
12 Thomas Paul, the Chief Executive Officer of Ovations, a draft report of an audit of the
13 risk adjustment data that UHG's California MA Organization, then called PacifiCare of
14 California, submitted for payment year 2007. In the draft reports, the OIG concluded
15 that the diagnoses for half the beneficiaries in the California audit and 44 percent of the
16 beneficiaries in the Texas audit were invalid, and that both plans' practices were not
17 effective for ensuring that the diagnoses they submitted to CMS complied with CMS
18 requirements. These draft OIG reports were described as a "top issue" in the third
19 quarter 2010 Public & Senior Markets Group Medicare Compliance Program Overview
20 for which Jennifer O'Brien was the Compliance Program Lead and Tom Paul was the
21 Business Lead. In May 2010, Paul sent OIG a response about its draft report relating to
22 PacifiCare of Texas and, in October 2010, Paul (whose job title had then been changed
23 to Chief Executive Officer of UnitedHealthcare Medicare & Retirement) sent OIG a
24 response about its draft report relating to PacifiCare of California. After consideration of
25 Paul's responses to the draft audit reports, the OIG issued final reports concluding that
26 the health risk scores for 45 percent of the beneficiaries in the California audit and 43
27 percent of the beneficiaries in the Texas audit were invalid because the diagnoses were
28 not supported by the beneficiaries' medical records or were uncertain or unconfirmed

1 diagnoses. In both the draft and final reports, the OIG provided examples of
2 unsupported diagnoses. The OIG also concluded that the MA Organizations should
3 refund the overpayments due to these invalid diagnoses. In addition to Larsen and Paul,
4 other individuals who were aware of the OIG audit reports during the 2010 and 2011
5 time period included Scott Theisen, Jenny O'Brien, Kimberly Halva, Joseph Keen, and
6 Jeffrey Dumcum.

7 156. The results of RADV audits were also of concern to UnitedHealthcare. The third
8 quarter 2010 Public & Senior Markets Group Medicare Compliance Program Overview
9 (for which Jennifer O'Brien was the Compliance Program Lead and Tom Paul was the
10 Business Lead) also stated that CMS was conducting RADV audits of three of the
11 Defendant MA Organizations. Then, when CMS announced in February 2011 that it
12 planned to extrapolate the sample audit results, Charles Hanson, the then Vice President
13 of Finance and Underwriting at UnitedHealthcare Medicare & Retirement, left a
14 voicemail message for Relator Poehling stating: "I haven't been close to this for . . .
15 three or four years now probably, but back that far I know the results of our RADV
16 audits were concerning, to say the least. That we had significant . . . errors or
17 undocumented RAFs [*i.e.*, undocumented diagnoses] in our claim submissions." He
18 asked Poehling: "I'm sure we're careful about how we communicate these findings, but
19 can you give me a sense of kind of more recent RADV audits, what impact could this
20 have? So just generally, are we still sort of, I'll say as bad as we were a few years ago? .
21 . . So, what's the potential impact on revenue of extrapolating these RADV audit
22 findings . . . ?"

23 157. Because of the problem with provider-reported diagnoses, in 2010, the UHG
24 Managing Defendants started the RACCR Program, as described more fully at
25 paragraphs 239-292 below, and Claims Verification Program, as described more fully at
26 paragraphs 196-234 below. Mary Hammond, one of the UnitedHealthcare Medicare &
27 Retirement employees who oversaw the RACCR Program, described it as "an important
28 part of Medicare & Retirement's efforts to meet CMS requirements to submit accurate

1 risk adjustment data.” The Claims Verification Program was also supposed to satisfy
2 this basic payment rule.

3 158. However, the major effect of the Claims Verification and RACCR Programs was
4 that they highlighted that a significant amount of the risk adjustment payments claimed
5 by the UHG Managing Defendants on behalf of the Defendant MA Organizations and
6 paid to the Defendant MA Organizations by the Medicare Program were unsupported
7 and invalidated by beneficiaries’ medical records. For instance, as explained in more
8 detail in paragraph 206 below, in December 2010, the results of the first pilot phase
9 (Phase I) of the CV Program showed that provider-reported diagnoses were unsupported
10 for over 50 percent of the medical records reviewed. Over a year later, as explained in
11 more detail in paragraph 208 below, Optum had completed the second pilot phase (Phase
12 II) of the CV Program on 17,398 charts and the results were even more striking. Phase II
13 identified 4,786 invalid diagnoses to be deleted, which was greater than the number of
14 additional diagnoses (ADDS) identified based reviews of the same medical records. In
15 February 2012, Dumcum, who was responsible for the Claims Verification Program, met
16 with Relator Poehling and Theisen, who was the Chief Financial Officer of
17 UnitedHealthcare Medicare & Retirement at that time, and reported: “I’m deleting as
18 much as I’m adding at the end of the day. And I don’t know if—you know, what I want
19 to do.” He also stated: “we’re getting more and more red here,” and that Claims
20 Verification “eats in very substantially” to the revenue from ADDS from chart reviews.

21 159. In addition, as explained in more detail below, by February 2012, there were
22 “5,519 bad codes” that were “identified and deleted” as the result of RACCR reviews of
23 the medical records for only 13,451 beneficiaries. On a beneficiary basis, the results
24 showed more than a 40 percent invalidation rate.

25 160. Over time, the UHG Managing Defendants also obtained more information about
26 incorrect diagnosis coding by providers, some of which information confirmed what had
27 been known for years. For example, by at least 2013, Tracey Bradberry, an Ingenix and
28 then Optum employee who was a certified coder, was aware of various reasons for

1 invalid provider-reported diagnoses, including, for example, the “[c]linical findings
2 and/or treatment does not support the diagnosis” and “[n]ot a current condition.” In
3 addition, in March of 2014, Melissa Ferron, a coding consultant, sent Optum employee
4 Christopher Webb a list identifying various HCC codes and diagnosis codes that were
5 unlikely to validate based on medical record reviews because providers frequently used
6 the codes incorrectly. These included HCCs 17 (diabetes with acute complications), 96
7 (specified heart arrhythmias), 104 (monoplegia, other paralytic syndromes), and 111
8 (chronic obstructive pulmonary disease).

9 161. More recently, other employees of the UHG Managing Defendants also have
10 recognized the obligation to ensure the validity of diagnoses submitted for risk
11 adjustment payments. They also understood that the obligation to correct invalid data
12 provided to Medicare for risk adjustment payments. For example, in an April 2013
13 email, Marybeth Meyer, the Vice President of Operations for UnitedHealthcare
14 Medicare & Retirement who succeeded Relator Poehling in managing the risk
15 adjustment team for that group, stated that “as a Medicare Advantage Plan, if we become
16 aware of a coding issue that impacted the revenue received from CMS for risk
17 adjustment, we are obligated to investigate and correct the submissions to CMS.” In
18 response to Meyer’s email, Halva, then Compliance Officer for UnitedHealthcare
19 Medicare & Retirement, agreed. She also stated that “[w]e have an obligation to go back
20 to CMS and correct submissions that impact the revenue received for risk adjustment
21 purposes.” Halva did not think that anything was wrong with the requirement that
22 UnitedHealthcare Medicare & Retirement delete unsupported diagnoses. Moreover, she
23 believed that “arguably” this obligation existed for ten years because of the ten-year
24 statute of limitation for the Government to pursue FCA claims against entities that
25 knowingly fail to delete unsupported diagnoses.

26 162. As another example, in February 2014, Melissa Sedor who worked in
27 UnitedHealthcare Medicare & Retirement’s controller’s office, sent an email stating that
28 “it is our responsibility to submit accurate records to CMS. Even if the provider submits

1 bad data to us, the responsibility is on us to be submitting the correct data.” Sedor
2 further explained that this was the reason United implemented compliance programs like
3 RACCR and Claims Verification. Sedor’s email was sent to others at UnitedHealthcare,
4 including Marybeth Meyer and William Hnath.

5 163. Finally, other employees in addition to Halva were aware of the potential FCA
6 liability for submitting invalid diagnoses to CMS for risk adjustment payments or for
7 failing to delete them. For example, in 2010, Carol Thompson, then National Manager
8 for Ingenix’s Risk Adjustment Programs who worked at the Ingenix office in this
9 District, provided the following reason as justification for funding for a coding vendor
10 who was assisting the UHG Managing Defendants with a CMS RADV audit: “Politics
11 and Congressional scrutiny put an exclamation point on our need to demonstrate that the
12 data submitted to CMS for risk adjustment payment is valid. Data that drives payment
13 from the government can be reviewed to determine if the claims are ‘valid.’ Improper
14 claims submission can fall under the False Claims Act.” Also, as alleged more fully
15 below, Dumcum informed Relator Poehling that the FCA was a consideration in
16 deciding whether the UHG Managing Defendants should implement the Claims
17 Verification Program and “look both ways” at the results of their Chart Review Program.

18 **II. Chart Reviews and Claims Verification**

19 **A. United’s “Look One Way” Chart Review Program**

20 164. Over the last decade, Defendants have obtained billions of dollars of risk
21 adjustment payments from Medicare from its national Chart Review Program because
22 they only looked one way at the results of their coders’ chart reviews. As part of this
23 program, the coders were instructed to perform “blind” reviews of the beneficiaries’
24 medical records. That is, the coders did not know which, if any, diagnoses had been
25 reported by the providers who treated the beneficiaries and created the medical records.
26 Thus, rather than confirming diagnoses already reported by the providers or identifying
27 only additional diagnoses supported by the records, the coders were instructed to look
28 for all medical conditions purportedly documented in the records, record all diagnosis

1 codes identifying those conditions, and give all of those codes to the UHG Managing
2 Defendants. But, the UHG Managing Defendants selectively utilized results of these
3 chart reviews – that is, the coders’ list of diagnosis codes – for the sole purpose of
4 identifying diagnosis codes that the providers had not reported and submitting ADDS for
5 additional risk adjustment payments. They did not utilize the coders’ lists of diagnosis
6 codes to determine if the providers had reported codes that were not supported by their
7 own medical records. If the UHG Managing Defendants had looked both ways and
8 deleted these unsupported and, thus, invalid provider-reported codes, their national Chart
9 Review Program would have been far less lucrative.

10 165. The UHG Managing Defendants’ national Chart Review Program was their largest
11 risk adjustment revenue-generating program. This program was started in 2005 as an
12 outgrowth of the chart review program that PacifiCare was already conducting.
13 Dumcum, Will, and other former PacifiCare employees became key participants in
14 designing, implementing, and managing the United Managing Defendants’ revenue-
15 generating national Chart Review Program. Will was the Program Manager for the
16 program.

17 166. During the first few years of the program, hundreds of thousands of charts were
18 reviewed each year in order to mine them for additional diagnosis codes. In 2008, The
19 Coding Source (“TCS”), a chart review/diagnosis coding vendor retained by Ingenix,
20 reported to Carol Thompson at Ingenix that “[s]ince 2005, TCS has partnered with
21 PacifiCare-United and Ingenix to support your HHC initiatives. TCS has successfully
22 completed 460,000 chart reviews for multiple United regions.”

23 167. In 2009, the UHG Managing Defendants significantly expanded the size of the
24 national Chart Review Program by providing Ingenix with the funds to acquire a coding
25 vendor called AIM Healthcare Services, Inc. and integrating Ingenix’s operations in
26 Santa Ana, California, and the AIM coding operations in Tennessee, and by providing
27 Ingenix with the funds to develop an in-house chart review computer database system
28 called ChartSync so that Ingenix’s in-house coders and third-party coding vendors could

1 electronically review medical records and electronically record the coding results of their
2 reviews. At or about the same time, the UHG Managing Defendants also expanded the
3 size of the Chart Review Program by providing Ingenix with the funds to open offices in
4 foreign countries (the Philippines and India) where it could hire foreign workers to
5 review beneficiaries' medical records in order to try to find additional diagnosis codes.

6 168. Due to the increased resources devoted to the Chart Review Program, the number
7 of medical records reviewed in the hunt for additional codes significantly increased over
8 time. For the first few years of the Chart Review Program, between 500,000 and
9 600,000 charts were reviewed each year. According to a presentation by Dumcum,
10 600,000 charts were reviewed in 2006 and, as of September 21, 2007, 400,000 charts had
11 been reviewed so far that year with 200,000 charts remaining for review during the
12 fourth quarter of 2007.

13 169. By 2010, the number of chart reviews had increased substantially to
14 approximately 850,000 charts for that year. For 2011 to 2014, approximately 1.5 million
15 charts were reviewed each year. The Government believes that, after 2014, the national
16 Chart Review Program was most likely similar in size.

17 170. As part of this national Chart Review Program, the UHG Managing Defendants
18 focused primarily on the review of charts from providers paid on a fee-for-service basis.
19 Ingenix and then Optum or their vendors obtained medical records from thousands of
20 these providers throughout the United States. They or their vendors sent these medical
21 records to coders that they employed in Tennessee, India, and the Philippines. They also
22 hired coding vendors to review these medical records. Those vendors were located in
23 various locations within and outside of the United States.

24 171. Physician groups owned by one or more of the UHG Managing Defendants also
25 had chart review programs. WellMed had a group called DataRaps that conducted
26 reviews of its physicians' medical records for patients in one or more Defendant MA
27 Organizations' MA plans. Southwest Medical Associates conducted some of its own
28

1 reviews though it also relied on Ingenix's/Optum's coding operations in Tennessee and
2 coding vendors for its chart reviews.

3 172. In 2006, the Defendant MA Organizations obtained approximately \$270 million in
4 additional risk adjustment payments from the ADDS that were submitted on their behalf
5 by the UHG Managing Defendants based on the national Chart Review Program. The
6 return on investment was substantial (approximately \$250 million) as it cost only
7 approximately \$18 million to review the charts in 2006.

8 173. Not unexpectedly, as the number of medical records reviewed significantly
9 increased over the years, so did risk adjustment payments from ADDS based on the
10 national Chart Review Program. Defendant MA Organizations received approximately
11 \$426 million in additional risk adjustment payments from ADDs the UHG Managing
12 Defendants submitted to Medicare based on the medical record reviews conducted as
13 part of the Chart Review Program for the 2011 payment year, approximately \$455
14 million for the 2012 payment year, approximately \$758 million for the 2013 payment
15 year, and approximately \$882 million for the 2014 payment year.

16 174. For payment years 2010 to 2015 combined, Defendant MA Organizations
17 obtained over \$3 billion in additional risk adjustment payments from Medicare due to the
18 ADDs the UHG Managing Defendants submitted on their behalf based on medical
19 record reviews conducted as part of the national Chart Review Program.

20 175. United's Chart Review Program was conducted according to an annual cycle. For
21 example, in the spring of 2012, Optum started its collection and review of medical
22 records relating to medical encounters in 2011 (*i.e.*, with 2011 dates of service). These
23 efforts then intensified through the remainder of the year until the final deadline for
24 submitting diagnosis codes to Medicare for payment year 2012, which was February 15,
25 2013.

26 176. Prior to the start of each annual cycle, the UHG Managing Defendants' senior
27 executives set a revenue target for the program. After chart reviews started, these senior
28 executives then closely monitored the progress of the program and, if the forecast did not

1 look like the program would achieve the revenue target, they made changes to the
2 diagnostic coding being performed by the coders. For instance, when UnitedHealthcare
3 Medicare & Retirement and Optum were not achieving the return on investment
4 expected from chart reviews for the 2012 payment year, they “liberalized” coding
5 policies and engaged in a “Recode Project” consisting of re-reviewing 900,000 charts
6 that had already been mined once for additional diagnoses. They liberalized the coding
7 policies to enable the coders to identify more diagnosis codes purportedly supported by
8 the beneficiaries’ medical records. In this second-round review, the coders did identify
9 more codes purportedly supported by the records based on the liberalized coding
10 policies, and UnitedHealthcare Medicare & Retirement and Optum submitted those
11 codes to Medicare for additional risk adjustment payments. Scott Theisen at
12 UnitedHealthcare Medicare & Retirement and Karen Erickson and Jon Bird at Optum
13 were involved in this “Recode Project.”

14 177. Despite their aggressive coding to submit as many ADDS as possible to meet their
15 annual revenue targets for their Chart Review Program, officers of UnitedHealthcare
16 Medicare & Retirement attested to the validity of *all* of these ADDS in the annual Risk
17 Adjustment Attestations submitted to Medicare and various senior management
18 employees of both UnitedHealthcare Medicare & Retirement and Optum attested to the
19 validity of *all* of these ADDS in approving the annual Risk Adjustment Attestations
20 submitted to Medicare. *See infra* at paragraphs 296-308 (describing this internal
21 approval process). If the results of these chart reviews were so reliable that they could
22 attest to the validity of all of the ADDS, then the results were of equal reliability for
23 them to have deleted all previously-submitted diagnoses invalidated by the reviews. To
24 the extent that Defendants call into question the results of their own chart reviews in *not*
25 finding support for and *not* validating hundreds of thousands of diagnoses, they also call
26 into question the overall reliability of the chart reviews and validity of the ADDS.
27 Under those circumstances, Defendants acted with reckless disregard for the truth by
28 submitting the ADDS and attesting to their validity, knowing they were not entitled to

1 payments by Medicare based on such unreliable data and the United States is entitled to
2 recover those payments in this action.

3 **B. United Knew It Was Obligated To Look Both Ways At The**
4 **Results Of Its Chart Reviews And Make DELETES As**
5 **Well As ADDS**

6 178. By 2008, Relator Poehling and others began to question the practice of ignoring
7 the negative results of blind chart reviews invalidating many provider-reported
8 diagnoses. In May 2008, Relator Poehling participated in a meeting in which he
9 discussed this issue with Will. She explained to Relator Poehling that, as part of the
10 Chart Review Program, Ovations and Ingenix did not look at whether provider-reported
11 diagnoses were not substantiated by the results of the coders' blind chart reviews.
12 Poehling and Will discussed the idea of changing this process, comparing the results of
13 the blind chart reviews to the provider-reported diagnoses that Ovations and Ingenix had
14 submitted to CMS, and deleting the unsupported diagnoses.

15 179. Thereafter, the need to address problems with the diagnoses reported by providers
16 continued to be an issue. In March 2009, the question of how to address problems with
17 diagnoses reported by fee-for-service providers arose during a discussion among Ingenix
18 employees about the Internal Data Validation Program that Ingenix conducted for
19 Ovations and the Defendant MA Organizations. During that discussion, Ronnie Grower,
20 Vice President of Market Consultation for Ingenix, noted that the Internal Data
21 Validation Program excluded fee-for-service providers and questioned whether the UHG
22 Managing Defendants would have another program to address diagnoses reported by fee-
23 for-service providers given that "there are common coding errors that get reported across
24 all providers." In fact, other than its short-lived Claims Verification Program, the UHG
25 Managing Defendants never had a medical record review program like the IDV or
26 RACCR Programs to address the validity (or lack thereof) of diagnoses reported to it by
27 its fee-for-service providers.
28

180. In 2009, these internal discussions continued. In early April 2009, Relator Poehling, Dumcum, Will, Kimberly Halva, Janice Redmond (the Senior Vice President of Market Outreach for Ingenix's Risk Adjustment Group, who worked in Santa Ana, California) and others participated in a discussion about compliance risks, including provider over-coding (*i.e.*, invalid coding). One of the items on the agenda that they discussed included "[a]uditing under & over coded conditions" as part of the chart review process, that is, "looking both ways." A few weeks later, Relator Poehling again met with Will and others to discuss what to do when provider-reported diagnosis codes were inconsistent with the results of the coders' blind chart reviews of the providers' medical records. At this second meeting in April 2009, the participants began to design a methodology for "looking both ways." This led to subsequent discussions about creating a Claims Verification Program in order to look both ways at the coders' blind chart review results and make DELETES as well as ADDS.

181. A few months later, in August 2009, in an internal presentation, Redmond noted that chart reviews only looked for additional revenue and suggested that the process should also include a certain amount of charts that are reviewed to determine the validity of providers' codes. Redmond was concerned that providers paid on a fee-for-service basis were not being audited to validate their diagnoses. Her presentation stated: "Known problematic codes are not audited across plans/providers raising the risk of error."

182. In early 2010, Will sent Dumcum a presentation proposing the Claims Verification Program. The stated goal of the program was to improve the accuracy of the diagnosis data that the UHG Managing Defendants submitted to CMS. Will believed that Claims Verification would achieve this goal.

183. In May 2010, Relator Poehling discussed the potential creation of the Claims Verification Program with Dumcum. Dumcum referenced the Department of Justice's enforcement of the FCA as a consideration.

1 184. According to Halva, while she was the UnitedHealthcare Medicare & Retirement
2 Compliance Officer from 2010 to 2013, the “general consensus from the
3 [UnitedHealthcare Medicare & Retirement] point of view was . . . that any time we
4 opened a chart we should be looking both ways.”

5 185. In the fall of 2010, after two years of discussions, senior executives such as
6 Thomas Paul, Cynthia Polich, and Lee Valenta acknowledged that the UHG Managing
7 Defendants should “look both ways” at the results of their blind chart reviews. By at
8 least that time, however, these Defendants should and could have compared the results of
9 *all* chart reviews to the provider-reported diagnoses and deleted all of the invalid
10 provider-reported diagnoses that they previously had submitted to the Medicare
11 Program. They also should and could have done this contemporaneously with
12 submitting ADDS based on the same chart reviews. Instead, they embarked on a very
13 slow, phased development of their Claims Verification Program. The senior executives
14 authorized only a pilot test program to look at the negative results (*i.e.*, the results
15 showing that provider-reported diagnoses were invalid) from only a very small sample of
16 chart reviews. Moreover, the Claims Verification process was designed to “save” – that
17 is, avoid deleting – the provider-reported diagnoses invalidated by the blind chart
18 reviews conducted as a part of the Chart Review Program. The UHG Managing
19 Defendants attempted to and sometimes did save some of these invalid codes by re-
20 reviewing the beneficiaries’ medical records, sometimes multiple times, to try to glean
21 any support, even doubtful or ambiguous support, for the provider-reported diagnoses at
22 issue.

23 186. In August 2011, Relator Poehling made clear to Scott Theisen, then Chief
24 Financial Officer of UnitedHealthcare Medicare & Retirement, that Poehling did not
25 believe it was appropriate to conduct chart reviews unless and until Claims Verification
26 was fully implemented and they were “looking both ways.” Theisen was one of the
27 senior managers charged with making decisions regarding the implementation and
28 design of the Claims Verification Program. At that time, in an email to Paul Bihm at

1 Optum, Poehling wrote: “You (and Scott [Theisen]) know where I stand on chart
2 reviews without full CV in place ... I wouldn’t do them. Scott, though, is the decision
3 maker” At that time, Bihm was an Optum Senior Vice President of Client
4 Management and had responsibilities relating to the Chart Review Program.

5 187. In September 2011, Mary Hammond, Associate Director of Strategy and Support
6 for UnitedHealthcare Medicare & Retirement’s risk adjustment team, attended an
7 industry conference in Washington, D.C. on risk adjustment. She reported that it was
8 “great to get a perspective on what the activity in DC may mean for risk adjustment.
9 More audit protection (*looking both ways compliance programs*), . . . and less reliance
10 on chart review are the recommendations.” (Emphasis added.)

11 188. In approximately November 2011, a “factual and unbiased” presentation was
12 created for UHG’s Chief Executive Officer Steve Hemsley, to provide him information
13 about Optum’s and its competitors’ risk adjustment programs and other risk adjustment
14 services. The presentation described “Compliance” as “the True Value of Claims
15 Verification.” The presentation further noted that the medical record is the “source of
16 truth” and that looking at this “source of truth” had a negative revenue impact because
17 comparing provider-reported diagnoses with the information in the providers’ medical
18 records resulted in having to delete some of their diagnoses. In December 2011, a copy
19 of this presentation was sent by Karen Petroff, the Senior Vice President of Business
20 Development at Optum, to Dumcum and Eric Murphy at Optum. Murphy was the
21 President of Payer Solutions at Optum at the time.

22 189. In December 2012, Mike Jacobson, Program Business Analyst/Project
23 Management at Optum, sent Patty Brennan an updated version of Optum’s Business
24 Vision Document for the marketing of the Claims Verification Program to commercial
25 clients (*i.e.*, third-party MA Organizations). Under the section titled “Business Segment
26 Strategies and Tactics,” the document stated that “Optum has an industry compliance
27 duty and responsibility to ensure that each HCC code is accurate and can be
28 substantiated within the medical charts.” Under the section titled “Competitive Analysis

1 – Market Research,” the document stated: “The marketplace will soon recognize the
2 need and importance of performing due diligence on HCCs added during the chart
3 review process but also verifying HCCs submitted to CMS can be substantiated within
4 the medical chart according to CMS guidelines. For HCCs that cannot be substantiated
5 within the medical chart, clients will need to perform the appropriate deletes in order to
6 remain compliant with CMS guidelines.” At this time, Optum had already begun
7 marketing Claims Verification or “looking both ways” chart reviews to commercial
8 clients.

9 190. In September 2012, the Chief Executive Officer of OptumInsight, William Miller,
10 informed the Government that the UHG Managing Defendants were developing a
11 Claims Verification Program to ensure the accuracy of the diagnosis data they submitted
12 to CMS and look both ways at the results of the chart reviews conducted as part of the
13 Chart Review Program. Miller further stated that unsupported diagnoses would be
14 deleted. The UHG Managing Defendants knew that this information was important to
15 the Government. They led the Government to believe that they were not deliberately
16 ignoring or recklessly disregarding the negative results of their Chart Review Program
17 showing that numerous provider-reported diagnoses that they had submitted for payment
18 were invalid.

19 191. Until 2012, UnitedHealthcare Medicare and Retirement and Optum allowed
20 coders to review medical records at providers’ offices if the providers did not want to
21 provide copies of their records. However, in 2012, in accordance with their
22 acknowledgement of their obligation to “look both ways,” these Defendants changed this
23 policy and restricted on-site reviews because they needed copies of the charts in order to
24 conduct Claims Verification. Mary Hammond, in an April 2012 email, explained this
25 decision: “M&R has made a decision on the chart reviews where providers are requiring
26 onsite coding. We will ask the [United] Provider Advocates to talk to the groups to try
27 to talk them out of it. If they won’t budge, then we will allow onsite coding if
28 OptumInsight has a solution for doing claims verification on those charts.”

1 192. Similarly, at around the same time, a decision was also made that Optum's
2 commercial clients were required to retain Optum to perform Claims Verification (*i.e.*, to
3 "look both ways") if Optum performed chart reviews for them and submitted risk
4 adjustment data, including diagnoses, to CMS on their behalf. According to Dumcum,
5 Optum decided "that if we did chart review and submissions, that we then must do the
6 two-way look. It became our policy of how we executed business at the time. So if they
7 bought both, then we required that piece [*i.e.*, Claims Verification] be implemented."

8 193. UnitedHealthcare has also consistently demanded that CMS and HHS OIG, when
9 performing their audits, credit the Defendant MA Organizations for any additional
10 medical conditions that UnitedHealthcare believed were supported by the medical
11 records but that had not been reported by the providers. UnitedHealthcare took the firm
12 position with the Government that, in order to accurately reflect a patients' true health
13 status, it was necessary to review patients' medical records for both the under-reporting
14 (not reporting diagnoses supported by the beneficiaries' medical records) and over-
15 reporting (the reporting of codes unsubstantiated by the beneficiaries' medical records)
16 of medical conditions by providers. In fact, CMS RADV audits have historically
17 credited MA Organizations, including UnitedHealthcare, for additional diagnoses found
18 during such audits.

19 194. For example, in a February 2011 letter from Thomas Paul, the then Chief
20 Executive Officer of UnitedHealthcare Medicare & Retirement, to CMS concerning the
21 parties' dispute about the preliminary results of CMS' pilot RADV audit of one of the
22 Defendant MA Organizations, UnitedHealthcare argued that the dispute process
23 "incorrectly exclude[d] consideration of additional CMS-HCCs" supported by the
24 beneficiaries' medical records. The letter stated that UnitedHealthcare identified
25 additional HCCs (*i.e.*, additional diagnoses mapping to additional HCCs) in the medical
26 records and, if CMS refused to give it credit for them, it would challenge CMS legally.
27 In September 2012, in a letter from Theisen, the then Chief Financial Officer of
28 UnitedHealthcare Medicare & Retirement, to CMS about the same RADV audit,

1 UnitedHealthcare continued to complain that the audit incorrectly excluded
2 consideration of additional HCCs and argued that the Defendant MA Organization
3 should receive credit for the additional HCCs. The letter stated: “If [the MA
4 Organization] is not credited for these incremental HCCs, then any adjustments made by
5 CMS do not accurately reflect an enrollee’s comprehensive medical conditions. The
6 goal of RADV audits should be to determine the full extent of enrollees’ medical
7 conditions, and **make overpayment and underpayment adjustments so that [MA
8 Organizations] are paid commensurate with enrollees’ health status.**” (Emphasis
9 added.) Similarly, in a September 2012 letter from Thomas Paul to HHS OIG,
10 UnitedHealthcare stated that “the OIG should correct the invalid HCCs and credit [the
11 MA Organization] with the incidental HCCs documented in the submitted medical
12 records.”

13 195. ICE, the industry group to which several of the Defendants belonged and which
14 they financially supported, also opined that “looking both ways” was a “Best Practice.”
15 It issued a Best Practices document encouraging the industry to conduct chart reviews
16 that “looked both ways.” It described the advantages of such chart reviews as
17 “[p]romoting validation functions for diagnostic codes previously submitted by
18 providers” and “[p]roviding the ability to submit code corrections forward (additions and
19 deletions) to health plans upon the completion of review.”

20 **C. United’s Short-lived “Look Both Ways” Claims**
21 **Verification Program**

22 196. In September 2010, Lee Valenta, then Ingenix’s Chief Operating Officer, sent
23 Thomas Paul, then Chief Executive Officer of Ovations, a memorandum “summariz[ing]
24 Ingenix’s plans for implementing a claims verification program for charts reviewed by
25 Ingenix on behalf of Ovations Medicare Advantage Plans.” Valenta explained that the
26 “overarching aim” of the Claims Verification Program was “improving the quality of
27 member-level diagnosis information submitted to CMS.” He also explained that the
28 program’s purpose was to identify the provider-reported diagnoses that were not

1 validated by the blind medical record reviews conducted as part of the Chart Review
2 Program and for another coder to conduct a second non-blind review to determine if the
3 provider-reported diagnoses had been missed by the first blind coder.

4 197. Valenta's memorandum also set forth a three-phased approach for the
5 development of the Claims Verification Program. The first phase, Phase I, was supposed
6 to focus on a random sample of 850 beneficiaries in Ovations MA Plans whose medical
7 records for encounters (*i.e.*, provider office visits) in 2009 were included in the Chart
8 Review Program in 2010 and had already been subject to a blind review as part of that
9 Program. Phase I was supposed to start in October 2010 and be completed by January
10 31, 2011. The second phase, Phase II, was supposed to focus on a larger sample of
11 beneficiaries and, thus, a larger number of medical records for encounters in 2010. This
12 group was supposed to include all beneficiaries who had medical encounters with only
13 one provider during 2010. Phase II was supposed to start by May 2011. The final phase,
14 Phase III, was supposed to focus on all beneficiaries in Ovations' MA Plans whose
15 medical records for medical encounters in 2011 were included in the national Chart
16 Review Program in 2012 and had already been subject to a blind review as part of that
17 Program. Phase III was supposed to be implemented in 2012.

18 198. In October 2010, Cindy Polich, then President of Ovations, which was in the
19 Public and Senior Markets Group ("PSMG") that managed the Defendant MA
20 Organizations at the time, responded to Valenta's memorandum. Polich agreed to his
21 proposal. Polich also acknowledged the need to improve PSMG's risk adjustment
22 programs. She stated that "[w]hile Ingenix is implementing Phase II [of Claims
23 Verification], PSMG will conduct a comprehensive review of its current risk adjustment
24 strategies, including our chart review strategy. The purpose of this review is to
25 determine the future programs and approaches to be used to improve the accuracy of our
26 risk scores."

27 199. A Claims Verification project management document, prepared by Optum,
28 Ingenix's successor, described Claims Verification as "[a] risk adjustment chart audit

1 service designed to ensure that qualified patient diagnoses and conditions are identified
2 and supported in the physician medical record documentation. This audit service
3 identifies any discrepant coding patterns contained within the medical record
4 documentation and the associated claims and encounters. This service includes the
5 submission and delete process to CMS, financial reporting, and training/education for
6 providers. Claims Verification will further supplement our efforts to assess coding
7 accuracy and our ability to drive prospective improvements by engaging and educating
8 providers.”

9 200. At a meeting in September 2012, Theisen explained to Jason Bainbridge and
10 Karin O’Hara, both of whom worked for UnitedHealthcare Community & State, that
11 UHG decided to “look both ways” and implement Claims Verification in order to defend
12 the Chart Review Program in light of increased scrutiny on risk adjustment. According
13 to Relator Poehling’s notes, the meeting focused on the financial impact of Claims
14 Verification, and Theisen “said historically when we audited we only added codes.
15 UHG has decided from a defensibility standpt, & the increased scrutiny on risk
16 adjustment, that we would begin deleting unsupported codes as well. Scott [Theisen]
17 explained that [Optum] did a CV pilot on ~ 5k charts. Scott said we anticipated ~
18 \$100M in give backs related to CV, but the pilot is showing ~ \$225M/yr (extrapolating
19 results).” Other attendees at this meeting included, but were not limited to, Relator
20 Poehling, Jon Bird, William Hnath, and Melissa Sedor.

21 201. At some point in 2012, UnitedHealthcare Medicare & Retirement also started to
22 impose a “look both ways” requirement on providers with which it was sharing the cost
23 of chart reviews. Many, if not all, of these providers were incentivized capitated
24 providers. UnitedHealthcare Medicare & Retirement sent letters to these providers about
25 this requirement. Some of the letters expressly stated that UnitedHealthcare Medicare &
26 Retirement was agreeing to share in the cost of the chart reviews based on its
27 understanding that the provider would use the information gathered from the chart
28 reviews to verify the diagnosis data that it previously reported to UnitedHealthcare

1 Medicare & Retirement. In other of the letters, UnitedHealthcare Medicare &
2 Retirement requested that the provider ensure that it uses the information gathered
3 during the chart reviews to verify the diagnoses that it previously reported to
4 UnitedHealthcare Medicare & Retirement. All of the letters further instructed the
5 providers on how to submit to UnitedHealthcare Medicare & Retirement (via Optum) a
6 data file of diagnosis codes that should be deleted (as well as those that should be added)
7 as a result of the chart reviews. In addition, UnitedHealthcare Medicare & Retirement
8 required all of the providers to complete and return a certification. Pursuant to the
9 certification, the provider had to attest that it had compared diagnoses previously
10 reported to UnitedHealthcare Medicare & Retirement with the charts that it reviewed,
11 and that it had submitted to UnitedHealthcare Medicare & Retirement and Optum a data
12 file of diagnoses that it had determined should be added or deleted. Pursuant to the
13 certification, the provider also had to certify that the information in the data file was
14 accurate and truthful. There was an attachment to the letters that specified the fields for
15 the data file that the providers were required to use. One of the fields was for the
16 providers to identify diagnoses that needed to be deleted because they were not validated
17 by the chart reviews.

18 202. UnitedHealthcare Medicare & Retirement and Optum, however, took over three
19 years to develop the Claims Verification Program. Furthermore, the manner in which
20 they developed and then implemented the Program shows that they were never
21 committed to honoring their obligation to undertake good faith efforts to ensure the
22 validity of the risk adjustment data that they submitted to the Medicare Program. They
23 did not automatically delete the provider-reported diagnoses that were not supported by
24 the medical record reviews conducted as part of the Chart Review Program. Rather, they
25 considered these invalid diagnoses as mere “potential deletes” and instructed the coders
26 to re-review the medical records to try to avoid deleting them. Optum also trained the
27 Claims Verification coders that the goal of Claims Verification, above all else, was to
28 “validate” or “save” the potential deletes through finding any support for the diagnosis in

1 the beneficiary's chart. Additionally, Optum instructed its coders to "save" these invalid
2 diagnoses even if the information in the medical records was ambiguous.

3 203. When performing Claims Verification, Optum also did not consult providers even
4 when medical records were ambiguous concerning whether the beneficiaries actually had
5 the medical conditions corresponding to the diagnosis codes.

6 204. Optum also saved "potential deletes" by simply accepting the diagnoses reported
7 by providers even when the medical conditions were not unambiguously documented in
8 the beneficiaries' medical records. Optum characterized this practice as deferring to the
9 judgment of the provider or the provider's administrative staff who assigned the
10 diagnosis codes. For example, if a chart was unclear, illegible, or missing, and even
11 though Optum could not identify any medical records documenting the medical
12 conditions identified by the provider-reported codes, it just accepted the codes and did
13 not delete them. Optum did this with either deliberate ignorance or reckless disregard
14 for the truth in light of the mountain of knowledge it possessed about the significant
15 percentage of invalid provider-reported diagnoses.

16 205. However, despite all its flaws, the Claims Verification Program confirmed what
17 UnitedHealthcare Medicare & Retirement and Optum already knew about the significant
18 error rate associated with provider-reported diagnoses that they submitted to the
19 Medicare Program for risk adjustment payments.

20 206. At the end of 2010, Ingenix, Optum's predecessor, had conducted the first pilot
21 phase, Phase I, of its development of the Claims Verification Program. As specified in
22 Valenta's memorandum, Phase I included a very small sample of medical records that
23 Ingenix had reviewed as part of the Chart Review Program for encounters (*e.g.*, office
24 visits) that beneficiaries had with providers in 2009. A "CV Dashboard" summary from
25 December 2010 shows that out of the many hundreds of thousands of medical records
26 included in the Chart Review Program for 2009 encounters, only 843 records were
27 included in Phase I of the Claims Verification Program. By December 2010, the review
28 for 728 of those medical records had been completed. The results showed that 224 of the

728 medical records re-reviewed as part of Claims Verification (*i.e.*, reviewed once as part of the Chart Review Program and then again as part of Phase I of the Claims Verification Program) had both at least one ADD (a diagnosis code that the provider had not reported) and at least one DELETE (a diagnosis code that was reported by the provider but not validated by the medical record) and 167 of the 728 medical records re-reviewed as part of Claims Verification had at least one DELETE but no ADDS. Furthermore, of the HCCs and the RxHCCs for which Ingenix looked for validation in these 728 records that it had re-reviewed, 19 percent of the HCCs and 15 percent of the RxHCCs did not validate. At the time that the summary was prepared, Ingenix was conducting “follow-up” on 39 medical records. Of the HCCs and the RxHCCs for which Ingenix looked for validation in these 39 medical records that it had re-reviewed, 47 percent of the HCCs and approximately 45 percent of the RxHCCs did not validate.

207. As part of Phase I, but only as part of Phase I, Ingenix sometimes contacted the providers who gave it the medical records. It did this when the second non-blind review of the records in Claims Verification failed to validate the diagnoses that the first blinded review had failed to validate as part of the Chart Review Program. For some beneficiaries, the providers responded that they should not have submitted their claims (*i.e.*, the claims which included the diagnoses). Consequently, the diagnoses should not have been submitted to CMS. For some other beneficiaries, the providers did not have additional records or their additional records did not support the diagnoses in question.

208. In mid-2011, Ingenix/Optum began conducting the second pilot phase, Phase II, of the Claims Verification Program. Phase II began in the summer of 2011 and was completed in early 2012. Out of the many hundreds of thousands of medical records included in the Chart Review Program for 2010 medical encounters, only approximately 17,000 charts were included in Phase II. Coders tried to save as many “potential deletes” as possible when reviewing these medical records as part of Phase II. Nonetheless, the results of their Claims Verification reviews confirmed more invalid diagnoses

(DELETES) than the number of additional codes (ADDS) gleaned from the same records.

209. In mid-2012, Optum began conducting a preliminary test or pilot for Phase III of the Claims Verification Program. This pilot included approximately 5,000 medical records relating to encounters (*e.g.*, office visits) that beneficiaries had with providers during calendar year 2011. In September 2012, Theisen explained to others including Relator Poehling, that UnitedHealthcare Medicare & Retirement, relying on the results of this sample review, had increased its estimate of the financial impact of Claims Verification deletes. In October 2012, Theisen sent Daniel Schumacher, the then Chief Financial Officer of Defendant UnitedHealthcare, and others a “CV III analysis – based on 2011-2012 Chart review activity for 2011 DOS.” The document showed validation rates based on the review of HCCs because the coders were instructed to find support for any diagnosis that mapped to the HCC under review even if it was not the same diagnosis reported by the provider that originally mapped to that HCC. The document showed that the validation rate “[b]ased on results of CV3 pilot (5,000 chart sample)” was 66.4 percent. In other words, only 66.4 percent of the HCCs reviewed were supported by the beneficiaries’ medical records. That meant that 33.6 percent of the HCCs were unsupported by the beneficiaries’ medical records even after UnitedHealthcare Medicare & Retirement and Optum had them reviewed twice, once as part of the Chart Review Program and again as part of the pilot Claims Verification Phase III process. Based on these results, UnitedHealthcare Medicare & Retirement estimated that the negative financial impact of Claims Verification in 2012 would be \$231 million based on the number of estimated “potential deletes” that it could not save and would have to be made. It estimated that diagnoses mapping to 120,147 HCCs would have to be deleted and that, on average, each delete would result in a \$1,924 negative financial impact.

210. In or about October 2012, UnitedHealthcare Medicare & Retirement recorded in its financial records a \$208 million accrual for potential revenue reductions due to

1 deletes that would need to be made as part of the Claims Verification Program
2 (hereinafter referred to as a “CV liability accrual”) for payment year 2012. Relator
3 Poehling and Kyle Anderson were aware of this CV liability accrual. In late 2012, other
4 individuals at UnitedHealthcare Medicare & Retirement and Optum, including Timothy
5 Noel, Scott Theisen, and Jon Bird, were also aware of the CV liability accrual and/or the
6 estimated negative financial impact of the Claims Verification Program.

7 211. UnitedHealthcare Medicare & Retirement and Optum did not complete their pilot
8 tests and start to implement their Claims Verification Program for charts relating to 2011
9 medical encounters (*i.e.*, with 2011 dates of service) until late 2012. Even after that,
10 they never fully implemented the program. They also continually changed the program
11 in order to limit its scope and created arbitrary rules to avoid looking at the negative
12 results of many of the blind chart reviews conducted as part of the Chart Review
13 Program. In addition, when they learned that their second review of the medical records
14 in Claims Verification was not saving a significant number of diagnoses from deletion,
15 they created another level of review. That is, it created a re-re-review or third review of
16 the beneficiaries’ medical records in order to keep trying to save the diagnoses from
17 deletion. They also limited the scope of Claims Verification by excluding certain
18 providers, including providers that they or their affiliates owned and operated. In 2014,
19 Defendants UHG and UnitedHealthcare then terminated CV without completing the
20 program for charts relating to 2012 medical encounters (with 2012 dates of service).

21 212. UnitedHealthcare Medicare & Retirement and Optum imposed several arbitrary
22 exclusionary rules to improperly disqualify many medical records reviewed as part of
23 their Chart Review Program from their Claims Verification Program. For medical
24 records for encounters in 2011 and 2012, they arbitrarily and improperly excluded
25 numerous medical records from Claims Verification. For example, they excluded
26 numerous charts from Claims Verification because the image of the chart was
27 purportedly “unavailable.” Yet, when making ADDS in the Chart Review Program, the
28 image of the chart or chart itself must have been available. But, instead of locating the

1 images or obtaining the charts for Claims Verification, they decided not to re-review the
2 charts to save those diagnoses invalidated by the results of their Chart Review Program.
3 They also did not delete those invalid diagnoses.

4 213. The re-reviews conducted as part of the Claims Verification Program did not save
5 as many deletes as UnitedHealthcare Medicare & Retirement would have liked and, in
6 2013, Theisen and others at UnitedHealthcare Medicare & Retirement became
7 increasingly concerned about the financial impact of the deletes. UnitedHealthcare
8 Medicare & Retirement decided that its coders were not saving enough “potential
9 deletes.” Accordingly, sometime in 2013, UnitedHealthcare Medicare & Retirement
10 decided that a third review or a re-re-review of the medical records had to be conducted
11 to try to save more deletes.

12 214. Thus, if Optum’s internal coders were unable, despite their best efforts, to “save” a
13 diagnosis code, Optum sent that code to a coding consultant for re-re-review. Optum
14 knew, however, that the consultant engaged in a pattern of “saving” diagnoses without
15 supporting medical records in several circumstances, including when the chart was
16 scanned illegibly, when pages were missing from a chart and the diagnosis could not be
17 validated, and when the reported date of service did not appear in the chart. By
18 accepting validation of these diagnoses without supporting medical records, Optum
19 knowingly and improperly avoided its and UnitedHealthcare Medicare and Retirement’s
20 obligation to return monies wrongfully obtained from the Medicare Program.

21 215. In November 2013, Donald James, then Director of Program Strategy for Optum
22 in Santa Ana, California, reported to senior management that the Claims Verification
23 Program had not yet started for charts reviewed as part of the 2013 Chart Review
24 Program. In December 2013, Patty Brennan, then also in the Optum Santa Ana office,
25 reported to Dumcum that “[h]alf of the CV volume for 2012 DOS has been completed
26 but deletes are on hold.” She also informed him that UnitedHealthcare Medicare &
27 Retirement “[r]equested all CV deletes be held until further noticed so Ops is not going
28 to complete the second half of the volume at this time.”

1 216. When Steve Nelson became the Chief Executive Officer of UnitedHealthcare
2 Medicare & Retirement in early 2014, he spoke with Steve Hemsley, then Chief
3 Executive Officer of UHG, about whether UnitedHealthcare Medicare & Retirement
4 should continue the Claims Verification Program. Hemsley encouraged Nelson to look
5 into whether or not it should do so, formulate an opinion, and report back to him.

6 217. In February 2014, Marc Beckmann, then in the Finance – Risk Adjustment
7 Analysis Group at UnitedHealthcare Medicare & Retirement, sent information about CV
8 liability accruals to Daniel Schumacher, the Chief Financial Officer of Defendant
9 UnitedHealthcare, and Brian Thompson, the Chief Financial Officer for
10 UnitedHealthcare Medicare & Retirement. He estimated that the effect of Claims
11 Verification on UnitedHealthcare Medicare & Retirement’s revenue would be \$208
12 million for payment year 2012, \$125 million for payment year 2013, and either \$125
13 million or \$175 million (depending on the number of charts reviewed) for payment year
14 2014. This information was also provided to other individuals at UnitedHealthcare
15 Medicare & Retirement including, but not limited to, Jay Matushak, Marybeth Meyer,
16 and Kyle Anderson.

17 218. On March 3, 2014, Jon Bird, the Optum Senior Vice President of Risk and Quality
18 Analytics, participated in a meeting with Brian Thompson about the CV liability accrual
19 for 2013. Thompson wanted to “move toward the more conservative range of the
20 confidence interval (from 50% to 80%) resulting in [a] \$29M higher CV estimate” for
21 the liability accrual. By March 3, 2014, UnitedHealthcare Medicare & Retirement’s
22 estimate of its CV liability accrual for 2013 already had been increased by over \$50
23 million dollars from \$125 million to \$180 million.

24 219. Also, in February or March 2014, the financial managers at UnitedHealthcare
25 Medicare & Retirement, including Brian Thompson, performed a comparison of their
26 then-expected revenues for 2014 with the revenue estimated in UnitedHealthcare
27 Medicare & Retirement’s annual budget for 2014. They determined that there was going
28

1 to be a shortfall in their financial performance relative to that budget and they started to
2 think about ways to eliminate the shortfall.

3 220. In March 2014, Thompson sent Nelson “a current brain dump of ‘shut off/stop
4 doing’ that is not yet valued/included in the road back to plan.” Part of the “brain dump”
5 was to “shut off” or reduce compliance efforts. Thompson asked others at
6 UnitedHealthcare Medicare & Retirement for other “shut offs.”

7 221. Subsequently in March 2014, Marybeth Meyer, who ran the risk adjustment team
8 at UnitedHealthcare Medicare & Retirement, reported to Thompson that the “CV
9 estimate of \$125M may be light (estimate for 2012 DOS/2013 payment year of
10 \$167M).”

11 222. In late March or early April 2014, Nelson met with other Chief Executive Officers
12 at Defendant UnitedHealthcare to discuss UnitedHealthcare Medicare & Retirement’s
13 financial performance. A very detailed slide deck was created for that meeting. The
14 slide deck was sent by Schumacher to senior executives at UnitedHealthcare, including
15 Gail Boudreaux (who reported to Hemsley), Nelson, Brian Thompson, and Paul
16 Balthazor. The slide deck highlighted that UnitedHealthcare Medicare & Retirement
17 was projecting that its actual revenues for 2014 were going to miss the target set forth in
18 the annual budget by half of a billion dollars. It stated: “Best estimate of \$500 million
19 budget miss.” It also stated that, because of that projected miss, UnitedHealthcare
20 Medicare & Retirement’s management was making a commitment to the senior
21 executives to “find \$250 million to cut miss in half.” UnitedHealthcare Medicare &
22 Retirement referred to this “Management Commitment” as a \$250M “good guy.”

23 223. Nelson and others, including Boudreaux (who reported to Hemsley), knew that, if
24 UnitedHealthcare Medicare & Retirement terminated the Claims Verification Program, it
25 could reduce the \$500 million budget miss by not deleting the provider-reported
26 diagnoses invalidated by its chart reviews and reversing the CV liability accruals. This
27 was their “good guy.” But, it appears that UHG, UnitedHealthcare, and Optum were
28 concerned about the consequences of terminating the program and reverting to ignoring

1 the negative results of their chart reviews. They decided to ask CMS about the
2 retroactivity of a proposed regulation requiring MA Organizations to design all medical
3 record reviews to validate diagnoses submitted to CMS.

4 224. Under Hemsley's direction, Larry Renfro, the Chief Executive Officer of Optum,
5 contacted senior government employees at CMS, including the Administrator of CMS,
6 to ask whether the Defendants had a legal obligation to perform Claims Verification
7 before the effective date of the proposed rule. These employees were not government
8 attorneys and could not render the requested legal advice. Renfro, moreover, knew
9 nothing about the UHG Managing Defendants' Chart Review and Claims Verification
10 Programs and could not impart any meaningful information about these programs to the
11 government employees. Accordingly, Renfro could not and did not provide the senior
12 government employees with any description of the Claims Verification Program or its
13 purpose. Hemsley and his attorneys, however, continued to push Renfro to make further
14 contacts with these government employees when UHG, UnitedHealthcare, and Optum
15 did not obtain from these government employees the legal opinion they wanted.

16 225. On or before April 8, 2014, Renfro asked Karen Erickson, an Optum executive
17 who worked directly for him, for speaking points for a call with the Administrator of
18 CMS. On April 8, 2014, Erickson sent Renfro's assistant, Juliet Domb, "aspirational"
19 talking points, that is, things that they wanted Renfro to get the CMS employees to say,
20 including "CV is not currently required" and that Defendants were "allowed to stop any
21 CV activities (including delete submission) currently underway." (Emphasis in the
22 original.) In her email, Erickson told Domb: "I sent this to Marianne [Short] and Matt
23 Shors for editing – they will send final directly, and they know it has to be today." The
24 same day, Renfro spoke to Hemsley and Short to obtain direction about what he should
25 say to the Administrator of CMS on the call that he had scheduled with the
26 Administrator. Renfro then purportedly spoke with the CMS Administrator and
27 purportedly dictated notes of the call to Domb, who wrote the notes by hand on Renfro's
28

1 notepad and sent them to Short. According to Renfro, he dictated these notes from
2 memory and he does not usually take notes, but was asked to do so by Short.
3 226. On April 26, 2014, Short asked Renfro to again contact the Administrator of CMS.
4 According to Brian Thompson (the Chief Financial Officer of UnitedHealthcare
5 Medicare & Retirement in 2014), Renfro had not obtained the “clarity” they wanted
6 from the Administrator about whether they were obligated to perform Claims
7 Verification. Accordingly, on April 27, 2014, Renfro sent an email to the Administrator
8 asking the same questions he had purportedly asked her on April 8 and to which she
9 purportedly had responded on April 8. He also asked for a meeting with other
10 employees at CMS who were responsible for operating the MA Program. On April 27,
11 2017, Renfro reported to Hemsley and Short that CMS was arranging for the UHG
12 Managing Defendants to meet with these employees. On April 29, 2014, Hemsley sent
13 UnitedHealthcare’s attorney, Thad Johnson, to Washington, D.C. to speak with those
14 CMS employees responsible for the MA Program, including Cheri Rice, the Director of
15 the Medicare Plan Payment Group at CMS. Nelson, Schumacher, and an Optum
16 executive, Karen Erickson, also attended the meeting. At the meeting, when the UHG
17 Managing Defendants informed CMS about the possibility of terminating their Claims
18 Verification Program, CMS told them that they had a statutory obligation to report and
19 repay the Medicare Program for erroneous risk adjustment payments and that there were
20 FCA implications if they failed to do so. CMS also told the UHG Managing Defendants
21 that they could not ignore information in their possession showing that diagnoses may be
22 invalid and that they were obligated to delete invalid diagnoses. According to Erickson,
23 CMS told the UHG Managing Defendants that “if there was reason to have knowledge
24 that something had been begun and we were [*i.e.*, Defendants were] far enough along
25 that there was knowledge that something might not be supported that we needed to
26 continue the investigation into those numbers, or those codes.” Erickson further recalled
27 CMS stating that, if they had “knowledge of things that might not be supported we [*i.e.*,
28 the Defendants] needed to continue the investigation.” According to Schumacher, CMS

1 also told them that CMS did not have sufficient information about the Claims
2 Verification Program to provide further guidance.

3 227. On April 30, 2014, Nelson sent an email to Cheri Rice at CMS about the meeting
4 between the UHG Managing Defendants and CMS on April 29, 2014. He stated: “[A]s
5 we discussed yesterday, CMS recently issued a proposed rule that would, if finalized,
6 require MA plans to design any medical record reviews to determine the accuracy of risk
7 adjustment diagnoses associated with those records. During our conversation yesterday
8 and other recent conversations, CMS confirmed to us that these requirements do not
9 apply until the effective date of the rule, and that MA plans are thus not currently
10 required to design their medical record reviews to determine the accuracy of risk
11 adjustment diagnoses. We currently have a process through which we review certain
12 medical records to determine the accuracy of risk adjustment diagnoses and submit
13 appropriate deletes. This process already has resulted in the identification of and, in
14 some instances, the submission of deletes for 2012 dates of service. But based on the
15 proposed rule, including the preamble, and recent conversations with CMS, we
16 suspended that process for 2012 dates of service while we consider whether to make
17 changes. Pursuant to our discussion, however, we will soon submit for deletion those
18 diagnosis codes that have undergone a complete review and that we have therefore
19 identified as appropriate deletes. In the near future, we will determine whether to
20 continue our review process for the diagnosis codes which were still under review at the
21 time we suspended our process. In the meantime we will not delete these codes.”

22 228. On May 2, 2014, Cheri Rice replied to Nelson’s email: “[R]egardless of the
23 effective date of the proposed requirement related to medical record reviews, there are
24 other laws that do impose standards, requirements and responsibilities on MA plans in
25 connection with the federal payments they receive from CMS. We cannot provide
26 advice to United about the scope of those other laws. Nor can we provide advice on
27 whether United’s plan[ned] course of action and/or purported limits on the scope of its
28 [Risk Adjustment Attestation, submitted April 30, 2014] are compliant with such other

1 laws. Your statement concerning the data submissions that have already been made and
2 United's plans for future action will be included in our records and we will proceed with
3 our evaluation and use of the risk adjustment data consistent with 42 CFR § 422.308, §
4 422.310, and other applicable law."

5 229. According to Schumacher and Nelson, Rice's May 2, 2014 email did not say
6 anything that was inconsistent with what CMS said in the meeting on April 29, 2014.
7 After Rice sent her May 2 email, the Department of Justice sent a letter to Defendants'
8 counsel emphasizing that the FCA is one of the "other laws" that imposes standards,
9 requirements, and responsibilities on MA Organizations and Related Entities in
10 connection with the federal payments received from the Medicare Program.

11 230. On May 5, 2014, Jay Matushak informed Jeffrey Putman, UHG's Controller who
12 reported to Hemsley, and others (including Schumacher and Brian Thompson) that
13 "M&R CV delete, good guy, is ~\$250M for the year (note this is just the M&R piece and
14 there is an incremental component at C&S)." On the same date, Brian Thompson also
15 informed Putnam and others (including Matushak and Schumacher) that
16 UnitedHealthcare Medicare & Retirement had "not made a final determination to our CV
17 policy," "[o]ur RAF counsel will make that determination," and that "determination will
18 not occur until later in May most likely." According to Schumacher, the \$250 million
19 was the estimated amount of the deletes from Claims Verification for 2014 and prior
20 years and, thus, the CV liability accruals that had been recorded for 2014 and prior years.
21 The "good guy" was the hoped-for release or reversal of those accruals.

22 UnitedHealthcare Medicare & Retirement knew the accruals were likely underestimated
23 and the financial impact likely greater if it did not terminate the Claims Verification
24 Program.

25 231. Despite CMS' warnings in the April 29 meeting and Cheri Rice's May 2 email,
26 Nelson, Schumacher, and Brian Thompson decided to go forward with the idea of
27 terminating the Claims Verification Program. This decision was reported to Hemsley
28

1 and, according to Nelson, Hemsley could have reversed this decision but instead he
2 supported it.

3 232. Despite the warnings, UnitedHealthcare Medicare & Retirement also decided not
4 to delete or otherwise report to CMS at least 100,000 invalid diagnoses about which it
5 had *actual* knowledge based on more than one review of the patients' medical records
6 for encounters in 2011 and 2012 (*i.e.*, encounters with 2011 and 2012 dates of service).
7 The single damages to the Medicare Program arising from its submission of and failure
8 to delete just these invalid diagnoses is approximately \$190 million under Part C alone.

9 233. After they terminated the Claims Verification Program, UnitedHealthcare
10 (including UnitedHealthcare Medicare & Retirement and UnitedHealthcare Community
11 & State) and Optum reverted to "looking one way" at the results of their chart reviews,
12 making only ADDS, and knowingly and improperly failing to delete invalid provider-
13 reported diagnoses and repay the Medicare Program for them.

14 234. At the time they decided to terminate the Claims Verification Program, Steve
15 Nelson, Dan Schumacher, and Brian Thompson knew that their decision would enable
16 UnitedHealthcare Medicare & Retirement to reverse its CV liability accruals by more
17 than \$250 million dollars. Hemsley also was aware that terminating Claims Verification
18 would enable UnitedHealthcare Medicare & Retirement to achieve this financial benefit.
19 This was important to all of them because they wanted to represent to investors that
20 UnitedHealthcare Medicare & Retirement's actual revenues were on target. An internal
21 document relating to their second quarter 2014 "earnings release" issued in July 2014
22 states: "Q2 was on track and we are building momentum that will take us through the
23 year and into 2015. Internal: Important to note that 2014 benefits from the one-time
24 claims verification policy change which investors are unaware of." (Emphasis in the
25 original.) On July 11, 2014, this internal document was sent to Nelson and Thompson,
26 among others.

**D. United Failed to Delete Diagnoses Invalidated By Its Own
Chart Review Program**

235. The results of the UHG Managing Defendants' national Chart Review Program provided them information about a significant number of invalid provider-reported diagnoses that should not have been, but were, submitted by them on behalf of the Defendant MA Organizations to the Medicare Program for risk adjustment payments. For example, for the 2011 payment year (involving payments based on diagnoses with 2010 dates of service), UnitedHealthcare Medicare & Retirement and Optum submitted at least 197,000 diagnoses that were invalidated by the medical record reviews conducted as part of their Chart Review Program. But, for that year, they deleted only a very few (only about 1,800) of these invalid diagnoses based on the results of Phase II of the Claims Verification Program. For the 2012 payment year (involving payments based on diagnoses with 2011 dates of service), UnitedHealthcare Medicare & Retirement and Optum submitted at least 222,329 diagnoses that were invalidated by the medical record reviews conducted as part of their national Chart Review Program. Based on the results of the Claims Verification Program for charts with 2011 dates of service, they deleted approximately 120,000 of these invalid diagnoses despite their arbitrary exclusionary rules and attempts to save these deletes. For the 2013 payment year (involving payments based on diagnoses with 2012 dates of service), UnitedHealthcare Medicare & Retirement and Optum submitted at least 285,122 diagnoses that were invalidated by the medical record reviews conducted as part of their national Chart Review Program. Based on the results of the Claims Verification Program for charts with 2012 dates of service, they deleted approximately 27,000 of these invalid diagnoses despite their arbitrary exclusionary rules, multiple attempts to save these deletes, and failure to complete the program. For the 2014 payment year (involving payments based on diagnoses with 2013 dates of service), UnitedHealthcare Medicare & Retirement and Optum submitted at least 199,039 diagnoses that were invalidated by the medical record reviews conducted as part of their Chart Review Program. Because UHG,

1 UnitedHealthcare, and Optum terminated the Claims Verification Program, they did not
2 delete any of these invalid diagnoses. These numbers apply to invalid diagnoses relating
3 to risk adjustment payments under Part C only and not also Part D.

4 236. Accordingly, the UHG Managing Defendants knowingly and improperly failed to
5 delete or otherwise repay Medicare for most of the diagnoses invalidated by their
6 national Chart Review Program over the last decade.

7 237. For example: for the 2011 payment year, they failed to repay the Medicare
8 Program at least \$377,734,792 by failing to look both ways and delete diagnoses
9 invalidated by the Chart Review Program; for the 2012 payment year, they failed to
10 repay the Medicare Program at least \$213,978,134 by failing to look both ways and
11 delete diagnoses invalidated by the Chart Review Program; for the 2013 payment year,
12 they failed to repay the Medicare Program at least \$317,329,602 by failing to look both
13 ways and delete diagnoses invalidated by the Chart Review Program; and for the 2014
14 payment year, they failed to repay the Medicare Program at least \$234,159,775 by
15 failing to look both ways and delete diagnoses invalidated by the Chart Review Program.
16 These numbers apply to the failure to make repayments relating to risk adjustment
17 payments under Part C only and not also Part D.

18 238. Examples of beneficiaries with invalid diagnoses about which Defendants knew
19 but failed to delete based on its Chart Review Programs for payment years 2011 through
20 2014 are set forth in Exhibit 13 to this Complaint.

21 **III. The RACCR Program**

22 239. The UHG Managing Defendants (which, in this section, refers to Ingenix or
23 Optum, depending on the time period, and Ovations or UnitedHealthcare Medicare &
24 Retirement, depending on the time period) negotiated agreements with some of the
25 largest healthcare provider groups that tied the provider groups' compensation to their
26 beneficiaries' risk scores. The UHG Managing Defendants knew that this compensation
27 structure created a financial incentive for the provider groups to increase the number and
28 severity of diagnoses they reported and to report invalid diagnoses. Nonetheless, while

1 the UHG Managing Defendants were scouring millions of medical records through the
2 Chart Review Program to identify additional diagnoses and increase their revenue, their
3 effort to identify the invalid codes submitted by these incentivized providers was limited
4 to the RACCR Program. Moreover, the UHG Managing Defendants designed and
5 implemented the RACCR Program to limit its scope and to minimize the number of
6 invalid diagnoses for which the UHG Managing Defendants would have to return
7 overpayments to CMS. They failed to delete invalid diagnosis codes identified through
8 the RACCR Program, and eventually restructured the RACCR program to become just
9 another program to identify additional diagnoses and to increase revenue, rather than a
10 program to remedy the known problem of invalid coding by incentivized providers.

11 **A. Defendants Knew That Their Financially-Incentivized**
12 **Providers Were Reporting Invalid Codes**

13 240. As discussed above, the UHG Managing Defendants entered into financial
14 arrangements with capitated and gainsharing providers that were tied to the risk
15 adjustment payments that the Defendant MA Organizations received from the Medicare
16 Program. As a result, these providers benefited financially from any increase in risk
17 adjustment payments resulting from the diagnoses they reported to the UHG Managing
18 Defendants for beneficiaries enrolled in the Defendant MA Organizations' Plans.

19 241. The UHG Managing Defendants knew that these compensation arrangements
20 created a strong financial incentive for these providers to increase the number and
21 severity of diagnoses they reported for each beneficiary, and in some cases to report
22 invalid diagnosis codes.

23 242. Early on, Ingenix implemented the Internal Data Validation ("IDV") reviews
24 discussed earlier in this Amended Complaint. In or about 2010, Ovations (or its
25 successor, UnitedHealthcare Medicare & Retirement) and Ingenix expanded and
26 changed the name of that program to RACCR. Ingenix was responsible for conducting
27 the RACCR Program until Optum succeeded it in 2011, after which Optum was
28 responsible for conducting the program. Likewise, Ovations was responsible for

1 managing the RACCR Program until UnitedHealthcare Medicare & Retirement
2 succeeded it and assumed responsibility for the program in 2010.

3 243. Although the IDV and RACCR Programs were extremely limited in scope and
4 utility, they confirmed what the UHG Managing Defendants already knew: that there
5 were serious problems with the diagnoses being reported by a number of the financially-
6 incentivized providers, including WellMed (which UHG acquired in 2011).

7 **B. UnitedHealthcare Structured The RACCR Program To**
8 **Limit The Number Of Invalid Diagnosis Codes It Identified**

9 244. The UHG Managing Defendants knew they had an obligation to review diagnoses
10 reported by incentivized providers to determine their validity. In an April 23, 2012
11 email to many United Healthcare executives and managers (including Scott Theisen,
12 Keith Dobbins, Michael McCarthy, and Kimberly Halva), Mary Hammond, one of the
13 UnitedHealthcare employees who oversaw the RACCR program, described RACCR as
14 “an important part of Medicare & Retirement’s efforts to meet CMS requirements to
15 submit accurate risk adjustment data.” Later, in a June 22, 2012 agenda for a meeting
16 attended by Keith Dobbins, Kim Halva, Benjamin Poehling, and others, Mary Hammond
17 stated that the answer to “Why RACCRs?” was that “We have an obligation to submit
18 accurate Dx data to CMS.”

19 245. Despite the UHG Managing Defendants’ understanding that the RACCR Program
20 was part of UHG’s effort to comply with CMS’s accuracy requirements, they structured
21 the RACCR Program to limit its utility in identifying invalid diagnosis codes. There
22 were various fundamental limitations on the RACCR Program.

23 246. First, the UHG Managing Defendants excluded from their RACCR Program any
24 incentivized providers who cared for fewer than 500 beneficiaries in a Plan. This
25 resulted in the exclusion of approximately 40 percent of the financially-incentivized
26 providers from the RACCR Program for medical encounters in 2008, 2009, and 2010
27 (*i.e.*, with dates of service in those years).

247. Second, for the incentivized provider groups with 500 beneficiaries or more, the UHG Managing Defendants did not review the medical documentation for any diagnoses unless the provider group was an extreme outlier in reporting diagnoses that mapped to one or more HCCs. For medical encounters in 2008, 2009, and 2010 (*i.e.*, with dates of service in those years), the UHG Managing Defendants defined an outlier as a provider that reported diagnoses mapping to a particular HCC more than three times as often as the average national prevalence rate for that HCC for all beneficiaries in the Defendant MA Organizations' MA Plans. For example, if 15 percent of the beneficiaries in these MA Plans nationwide were reported by providers to have a diagnosis that mapped to HCC 52 (Drug/Alcohol Dependence), the UHG Managing Defendants did not consider the incentivized provider an outlier unless it reported diagnoses mapping to HCC 52 for more than 45 percent of its patients enrolled in a Defendant MA Organization's Plan. Combined with the exclusion of providers with less than 500 beneficiaries, this resulted in a total exclusion of over 80 percent of the financially-incentivized providers for medical encounters in 2008, 2009, and 2010.

248. For medical encounters in 2011 and 2012, the UHG Managing Defendants further limited which providers would qualify as outliers in order to reduce the number of providers and HCCs subject to review. Instead of using a national average prevalence rate for each HCC based on diagnoses reported by *all* of the providers in the Defendant MA Organizations' MA Plans, the UHG Managing Defendants used the average rate at which only financially-incentivized providers reported diagnoses mapping to each HCC. Thus, an incentivized provider was considered an outlier only if it reported diagnoses mapping to an HCC greater than two standard deviations above the rate that the HCC was coded by other incentivized providers, that is, providers who *also* had a financial incentive to invalidly code.

249. A large percentage of the outliers were located in the Central District of California. They are listed in Exhibit 14 to this Complaint.

250. Third, after limiting the program to only extreme outliers, the UHG Managing Defendants conducted an initial review of just a small sample of beneficiaries for whom the provider had reported diagnoses mapping to the outlier HCC or HCCs (as used herein, an “outlier HCC” is one that meets the criteria identified in Paragraphs 246 and 247 above for a particular provider and a particular encounter year). For medical encounters in 2008, 2009, and 2010, the initial sample size for even the largest provider groups was never more than 30 beneficiaries per outlier HCC, and was often as few as 10 beneficiaries per outlier HCC. The UHG Managing Defendants purposefully kept the sample size small to ensure the samples were not statistically significant, in the hope of preserving the ability to argue later that they were unable to extrapolate the results of their sample reviews to all of the diagnoses reported by the provider that mapped to the outlier HCC. For 2011 and 2012 medical encounters, the UHG Managing Defendants increased the initial sample size to 50 beneficiaries per provider for each outlier HCC.

251. Fourth, after reviewing the medical records for the beneficiaries in the sample to determine if the diagnoses were valid, the UHG Managing Defendants gave a provider a “passing” grade if anything less than 20 percent of the diagnoses were determined to be invalid. Accordingly, even if 19 percent of the diagnoses in the sample were invalid, the provider passed and no further review was conducted.

252. Fifth, if a provider failed the initial review for a particular outlier HCC, the UHG Managing Defendants often added only a few additional beneficiaries to the sample (*i.e.*, additional beneficiaries for whom the provider had reported diagnoses mapping to the outlier HCC). The UHG Managing Defendants called this slightly larger sample an “incremental sample.” If they were successful in decreasing the invalidation rate to below 20 percent based on increasing the sample size, the UHG Managing Defendants considered the provider group to have a passing grade for that HCC. Accordingly, if 19 percent of the diagnoses in the “incremental sample” were invalid, the provider passed and no further review was conducted.

253. Sixth, when the UHG Managing Defendants determined that a provider failed the incremental sample review for an outlier HCC, their RACCR policy specified that, with limited exceptions, *all* diagnoses reported by that provider mapping to the outlier HCC should be reviewed. In other words, once it was established that a provider reported diagnoses mapping to a particular HCC three times or more than the national average *and* that 20 percent or more of the diagnoses in a sample review were not supported by the beneficiaries' medical records *and* that increasing the sample size did not reduce the percentage of unsupported codes, even the UHG Managing Defendants recognized that, with limited exceptions, a complete review of the medical records for all beneficiaries for whom the provider had reported diagnoses mapping to the outlier HCC was essential. But in most cases, the UHG Managing Defendants did not conduct these 100 percent reviews themselves. Instead, as part of the RACCR Program, the UHG Managing Defendants purported to require the financially incentivized providers – the very providers who had over-reported the diagnoses at issue – to conduct these 100 percent reviews.

**C. Despite Its Limited Scope, The RACCR Program
Confirmed That Financially Incentivized Providers Were
Submitting Invalid Diagnosis Codes**

254. Despite the many flaws of the RACCR Program, the UHG Managing Defendants knew from the results of their small sample reviews and the 100 percent reviews that were actually conducted that significant problems existed with diagnoses reported by financially-incentivized providers.

255. By the end of March 2011, the UHG Managing Defendants were analyzing final results of RACCR sample analyses for encounters in 2008 and 2009, and had determined that a majority of the outlier HCCs analyzed in those years had validation rates below 80 percent, according to a March 29, 2011 email and spreadsheet that Benjamin Poehling sent to Paul Bihm.

1 256. By mid-February 2012, the UHG Managing Defendants reviewed samples for
2 encounters in 2010 and, again, found a substantial number of outlier HCCs that had
3 validation rates below 80 percent, according to a February 13, 2012 email and supporting
4 materials that Mary Hammond sent to Benjamin Poehling.

5 257. Overall, for the sample reviews for 2008, 2009, and 2010 encounters, nearly half
6 (49.61 percent) of the outlier HCCs reviewed failed the 80 percent validation test. Over
7 a third (37.01 percent) of all sampled diagnoses were not supported by the beneficiaries'
8 medical records. On April 23, 2012, Mary Hammond reported to numerous of the
9 employees of the UHG Managing Defendants (including Scott Theisen, Michael
10 McCarthy, Kimberly Halva, Keith Dobbins, and others) that Optum had calculated the
11 final results for samples from encounters in 2008, 2009, and 2010, and had identified the
12 providers who had failed the 80% validation test.

13 258. For the sample reviews for 2011 encounters, more than half (57.34 percent) of the
14 outlier HCCs reviewed failed the 80 percent validation test, and over 30 percent of all
15 sampled diagnoses reviewed for that year were not supported by the beneficiaries'
16 medical records, according to an August 8, 2013 email and supporting documentation
17 from Optum's Tracey Bradberry to Scott Hughes at Optum and Melissa Ferron, the
18 President of iCodify, a diagnosis coding consultant.

19 259. For the sample reviews for 2012 encounters, more than half of the outlier HCCs
20 failed the 80 percent validation test, and more than a third (38 percent) of all sampled
21 diagnoses were invalid, according to a July 2, 2014 presentation by Marybeth Meyer.

22 260. The problems with incentivized providers' invalid diagnoses were not isolated
23 incidents, but in many circumstances reflected a clear pattern of miscoding by provider
24 groups. Although the UHG Managing Defendants purposefully reviewed only a small
25 sample of medical records each year, they knew that certain provider groups were
26 consistently identified as extreme outliers on certain HCCs and failed the 80 percent
27 sample validation test year after year. For example:

1 • Every year from 2008 through 2011, Edinger Medical Group was an
2 extreme outlier for Spinal Cord Disorders/Injuries (HCC 69). Over those four years,
3 Optum (or its predecessor, Ingenix) reviewed medical records for a total of 126
4 beneficiaries that Edinger diagnosed with Spinal Cord Disorders/Injuries and determined
5 that the medical records of only *two* of those beneficiaries actually supported those
6 diagnoses. (Under the RACCR Program, Edinger or the UHG Managing Defendants
7 should have conducted 100 percent reviews of its diagnoses that mapped to this HCC for
8 the years 2008 through 2011, but they did not do so.)

9 • Every year from 2008 through 2012, HealthCarePartners was an extreme
10 outlier for Drug/Alcohol Psychosis (HCC 51). During those five years,
11 HealthCarePartners's highest sample validation rate for this HCC was 57.14 percent.
12 HealthCarePartners conducted 100 percent reviews for 2008, 2009, and 2011, and even
13 HealthCarePartners recognized that over a third of the diagnoses it reported were not
14 supported by its medical records. (Under the RACCR Program, HealthCarePartners or
15 the UHG Managing Defendants should have conducted 100 percent reviews for 2010
16 and 2012, but they did not do so.)

17 • Every year from 2008 through 2012, a provider named CAIPA was an
18 extreme outlier for Chronic Hepatitis (HCC 27). During those five years, CAIPA's
19 highest sample validation rate for this HCC was 76.92 percent. CAIPA conducted 100
20 percent reviews for 2008 and 2009 encounters, and its highest self-audit validation rate
21 was 56.73 percent. (Under the RACCR Program, CAIPA or the UHG Managing
22 Defendants should have conducted a 100 percent reviews for 2010 through 2012, but
23 they did not do so.)

24 • Every year from 2008 through 2012, Hemet Community Medical Group
25 was an extreme outlier for Spinal Cord Disorders/Injuries (HCC 69). During those five
26 years, Hemet's highest sample validation rate for this HCC was 50 percent. Hemet
27 conducted 100 percent reviews for 2008 through 2011, and its highest self-audit
28 validation rate also was 50 percent. (Under the RACCR Program, Hemet or the UHG

1 Managing Defendants should have conducted a 100 percent review for 2012, but they
2 did not do so.)

3 • Every year from 2008 through 2012, WellMed was an extreme outlier for
4 Disorders of Immunity (HCC 45). During those five years, WellMed's highest sample
5 validation rate for this HCC was 56.00 percent. WellMed conducted 100 percent
6 reviews for 2008, 2009 and 2011, and its highest self-audit validation rate was 63.64
7 percent. (Under the RACCR Program, WellMed or the UHG Managing Defendants
8 should have conducted a 100 percent review for 2010 and 2012 encounters, but they did
9 not do so.)

10 261. In those cases in which providers performed 100 percent reviews, the results
11 confirmed that the providers had initially submitted numerous invalid codes. Marybeth
12 Meyer and Scott Hughes's RACCR tracking spreadsheet indicated that more than 65
13 percent of the HCCs that providers reviewed in conducting 100 percent reviews had
14 validation rates below 80 percent. The RACCR "master tracking" documents that
15 Hughes updated regularly for Marybeth Meyer from 2013 through 2015 showed that
16 validation rates for problematic HCCs did not improve over time.

17 262. The UHG Managing Defendants' executives were routinely informed of RACCR
18 results. Beginning in 2011 and until at least 2014, the UHG Managing Defendants held
19 frequent meetings – usually weekly – concerning the status of the RACCR Program and
20 its results, with regular attendance by those responsible for the RACCR Program
21 (including, at various times, Kim Halva, Keith Dobbins, Marybeth Meyer, Benjamin
22 Poehling, Patty Brennan, Mary Hammond, Scott Hughes, and Pam Thomsen). During
23 these meetings, participants discussed the status and results of RACCR reviews, coding
24 results for individual practice groups, provider meetings to discuss results and 100
25 percent reviews, how 100 percent reviews would be handled in cases of provider
26 resistance, the financial impact of RACCR reviews, and changes to the RACCR
27 Program.

263. At least as early as February 14, 2012, Scott Theisen, Mary Hammond, and Benjamin Poehling met to discuss the deletion of codes resulting from the IDV and RACCR Programs for encounters in 2008, 2009, and 2010, and whether those deletions had been submitted. In March 2012, Theisen asked Hammond, Dumcum, Poehling, and Paul Bihm to pull together summary data concerning RACCR sample results for discussions with the incentivized providers. Theisen continued to be actively involved with some of the large incentivized providers that month, reviewing HealthCarePartners' results with Hammond and asking Hammond to identify the volume of codes that might be reviewed if WellMed were asked to do a 100 percent review so that he could provide a "worst case" scenario to John Way. In April 2012, Poehling updated Way regarding the status of WellMed's RACCR review, and Kimberly Fadden wrote to a number of employees of the UHG Managing Defendants, including Jeff Dumcum, Stephanie Will, and Jon Bird, noting that, among other things, there were then 40 to 42 provider groups in the 100 percent review process. The UHG Managing Defendants continued to provide periodic overviews or status updates concerning the RACCR Program to their executives and responsible employees. For example, in October 2013, Hammond sent Karen Erickson, Jon Bird, Scott Theisen, Jeff Dumcum, Patty Brennan, Marybeth Meyer, and others a "two-page detailed document that outlines the status, by provider group and year, of the 2008-2012 RACCR program."

264. The UHG Managing Defendants also kept their financial teams apprised of the status of the RACCR Program so that they could monitor, report, and account for its financial impact. For example, at some time before April 4, 2012, Jon Bird and Scott Theisen began discussing a rough estimate of the financial impact of the deletion of diagnosis codes as a result of RACCR. Theisen, Jon Bird, Bill Hnath, Melissa Sedor, and others also attended a December 3, 2012 meeting discussing, among other things, the financial effect of the IDV (*i.e.*, RACCR) Program, including the deletion of thousands of diagnosis codes as a result of that program. As set forth in more detail below, the UHG Managing Defendants' financial teams, including, at various times,

1 Theisen, Brian Thompson, Sedor and Hnath, also calculated liability accruals that
2 UnitedHealthcare Medicare & Retirement took in 2012 and 2013 to account for the
3 financial effect of the diagnosis codes that would have to be deleted as a result of the
4 RACCR Program.

5 **D. UnitedHealthcare Knew It Was Obligated To Delete**
6 **Invalid Diagnosis Codes Identified Through The RACCR**
7 **Reviews**

8 265. The Managing Defendants knew that they were required to submit accurate
9 diagnosis data to the Medicare Program. First, as described above, many of those
10 executives understood that RACCR was an important part of UnitedHealthcare Medicare
11 & Retirement's efforts to meet CMS's requirements regarding the submission of
12 accurate risk adjustment data, which necessarily implied the correction of inaccurate data
13 identified through the program.

14 266. Second, the UHG Managing Defendants' conduct demonstrated their knowledge
15 that they were required to delete invalid diagnosis codes identified through the RACCR
16 Program. From 2012 through 2015, the Managing Defendants deleted – albeit belatedly
17 – many invalid diagnosis codes submitted to CMS for encounters from 2008 through
18 2013, after determining, through the RACCR Program, that those codes were invalid.

19 267. Third, UnitedHealthcare Medicare & Retirement's practice of booking contra-
20 revenue accruals for the value of the deletions it had to submit as a result of the RACCR
21 Program demonstrated that the UHG Managing Defendants knew of their obligation to
22 return overpayments discovered through that program to the Government. Pursuant to
23 Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*, an
24 estimated loss from a loss contingency shall be accrued by a charge to income if both:
25 (a) a liability or impairment of an asset is "probable"; and (b) the amount of the loss can
26 be reasonably estimated. Thus, the accrual of loss contingencies relating to RACCR
27 reflected an acknowledgement that the return of an overpayment to the Government was
28

1 “probable,” and that UnitedHealthcare could reasonably estimate the amount of the
2 overpayment to be returned.

3 268. Beginning in 2012, UnitedHealthcare began taking liability accruals to account for
4 changes in its revenue that it expected to incur as a result of deletion of invalid codes
5 identified through the RACCR Program. By end of year 2012, it calculated that it would
6 have to reduce its revenue by \$79 million to account for its deletion of invalid codes
7 resulting from RACCR reviews (including expected 100 percent reviews) of medical
8 encounters in 2008, 2009, and 2010. That \$79 million was less than the total amount of
9 overpayment that it estimated it owed the United States, since it included both a
10 reduction in revenue resulting from the expected return of the overpayment and an offset
11 for the amount of money that it expected to recover from the incentivized providers,
12 which would have to share a portion of the burden of overpayment.

13 269. Accordingly, UnitedHealthcare took a liability accrual of \$79 million. It shared
14 this calculation with Deloitte and Touche in connection with that firm’s audit of UHG’s
15 financial statements, as part of UnitedHealthcare’s quarterly RAF Accounting Treatment
16 for Q4 2012 and Risk Adjustment Factor Revenue and Receivable Accounting for 2012.
17 Bill Hnath and Melissa Sedor told UHG’s Deloitte auditors that the \$79 million liability
18 accrual was “related to overpayments by CMS” that were identified through the RACCR
19 Program.

20 270. Scott Theisen was aware of the existence of a RACCR liability, and the
21 expectation that UnitedHealthcare would take an accrual for it, at least as early as
22 October 9, 2012, when Melissa Sedor sent him and Bill Hnath an August 2012 RAF
23 Financial Summary showing a \$97.5 million exposure (*i.e.*, amount of overpayment to
24 be returned) relating to the RACCR Program for encounters in 2008, 2009, and 2010.

25 271. In December 2013, Anne Reis, UnitedHealthcare Medicare & Retirement’s
26 Associate Director of Revenue, shared risk adjustment accruals with UnitedHealthcare
27 executives, including Scott Theisen, Brian Thompson, Bill Hnath, and Marybeth Meyer.
28 Those accruals included an additional liability accrual of \$34.5 million for RACCR

1 overpayments for the 2012 date of service year (2013 payment year), increasing the total
2 liability accrual for the RACCR Program to \$90.7 million for the 2008-2012 date of
3 service years (2009-2013 payment years). In taking a liability accrual for the 2012 date
4 of service year, UnitedHealthcare determined that it was probable that RACCR reviews
5 for the 2012 date of service year would result in the identification of deletes of diagnoses
6 reported by incentivized providers for medical encounters in 2012, as these reviews had
7 done in previous years.

8 272. The accuracy of the risk adjustment data that UnitedHealthcare and others
9 submitted to CMS on behalf of the Defendant MA Organizations was material to the
10 government's decision to pay and to the amount of risk adjustment payments. The
11 submission of inaccurate diagnosis data from incentivized providers directly resulted in
12 increases in risk adjustment payments that the Government made to the Defendant MA
13 Organizations.

14 273. Similarly, when the UHG Management Defendants deleted inaccurate diagnoses –
15 as they did when inaccurate diagnoses were identified in sample RACCR reviews or 100
16 percent reviews under the RACCR Program – the Government was able to offset its
17 subsequent payments to the Defendant MA Organizations by the value of those
18 deletions. UnitedHealthcare Medicare & Retirement's and Optum's failure to delete
19 unsupported codes because of their failure to conduct or complete 100 percent reviews
20 when their sample reviews identified Provider/HCC combinations with unacceptably
21 high error rates was material because if they had conducted the 100 percent reviews and
22 submitted deletes for the inaccurate diagnosis codes found in those reviews, those
23 deletions would have resulted in further offsets and, thus, reductions of payments to the
24 Defendant MA Organizations.

25 **E. Defendants Failed To Follow Their Own RACCR Protocol**
26 **Requiring 100 Percent Reviews**

27 274. As set forth above, the RACCR Program provided that if the sample review of an
28 outlier HCC showed that less than 80 percent of the diagnoses were supported by the

1 medical record, the provider would be required to perform a 100 percent review of all
2 instances of that outlier HCC coded by that provider for the date-of-service year at issue.
3 This requirement reflects a recognition by the UHG Managing Defendants that if a
4 provider codes a diagnosis three times as often as the national average rate *and* a sample
5 review shows that more than 1 in 5 diagnoses are not supported by the medical record,
6 then the provider's other uses of the same diagnosis code are highly likely to include
7 invalid diagnoses and must be reviewed for accuracy. Nonetheless, despite this
8 requirement of the RACCR Program, the UHG Managing Defendants frequently did not
9 require providers to perform 100 percent reviews of problematic HCCs for which sample
10 results showed unacceptably high error rates.

11 275. Not surprisingly, many providers were very resistant to performing 100 percent
12 reviews. Sometimes, the providers reviewed the records for only some, but not all,
13 additional beneficiaries for whom they had reported diagnoses mapping to the outlier
14 HCC. Sometimes, they did nothing.

15 276. For medical encounters in 2008 to 2010, at least 58 provider groups should have
16 performed 100 percent reviews because they failed the sample validation test for at least
17 one outlier HCC. Combined, these providers should have conducted 100 percent
18 reviews relating to 192 problematic HCCs. However, the providers only conducted
19 reviews of 143 of the 192 HCCs. Thus, a quarter of all outlier HCCs that failed the
20 sample validation test were not further reviewed by either the provider groups or
21 UnitedHealthcare. Similarly, for 2011 encounters, 100 percent reviews were conducted
22 for only 69 of 82 HCCs that failed Optum's sample validation test. Because the UHG
23 Managing Defendants did not require provider to perform 100 percent reviews of these
24 high-frequency but low-validating codes, they were able to avoid deleting the invalid
25 codes among them.

26 277. For example, for 2010 encounters, Edinger Medical Group coded Drug/Alcohol
27 Dependence (HCC 52) at a rate greater than three times the national rate. Optum (or its
28 predecessor, Ingenix) determined that only 70 percent of the diagnoses in its sample

1 were supported by medical record documentation. Because 30 percent of the sampled
2 diagnoses were invalid, the UHG Managing Defendants should have required Edinger to
3 review the additional 66 Edinger beneficiaries with a diagnosis mapping to HCC 52 that
4 were not included in the sample (or the UHG Managing Defendants should have
5 performed that review themselves). Nonetheless, the UHG Managing Defendants did
6 not require Edinger to do this review and they did nothing further to examine Edinger's
7 additional diagnoses mapping to HCC 52 that were not included in the sample.

8 278. Additional examples of provider groups that failed to conduct 100 percent reviews
9 for particular HCCs are shown in the chart attached as Exhibit 15 to this Complaint. The
10 UHG Managing Defendants also did not conduct the 100 percent reviews of these
11 problematic HCCs.

12 279. Moreover, even when a financially incentivized provider group conducted a 100
13 percent review, the UHG Managing Defendants knew they could not rely on the
14 accuracy of that review. For example, in a draft "WellMed RACCR Audit Status
15 Summary as of 2-9-12" that Mary Hammond circulated to Benjamin Poehling for
16 discussion with John Way in February 2012, Hammond reported that WellMed did a
17 self-audit for eight HCCs, but that the UHG Managing Defendants determined that "70%
18 of the codes [WellMed] indicated were properly documented actually were not supported
19 in the medical record." Hammond's summary also stated that, based on sample reviews
20 for medical encounters in 2008, 2009, and 2010, "WellMed failed to achieve an
21 acceptable validation rate for multiple HCCs ..., as defined by the RACCR audit
22 program policy and procedure."

23 **F. Even After Identifying Miscoding By Providers,**
24 **Defendants Failed To Delete Invalid Codes**

25 280. Even when the UHG Managing Defendants determined that diagnoses in a sample
26 review or 100 percent review were not supported by the medical records,
27 UnitedHealthcare Medicare & Retirement did not always delete them. For example:
28

1 • For 2008 medical encounters, the UHG Managing Defendants conducted a
2 sample review for Edinger Medical Group of diagnoses mapping to Drug/Alcohol
3 Dependence (HCC 52) and Major Complications of Medical Care & Trauma
4 (HCC 164). Optum's (or Ingenix's) coders determined that "[t]here was no
5 clinical documentation to support the diagnoses" mapping to HCC 52 for six
6 beneficiaries and that the diagnosis mapping to HCC 164 was the "wrong code"
7 for one beneficiary. (For all examples, further information to identify or aid in
8 identifying the beneficiaries will be separately provided to the Defendants.) On
9 January 23, 2013, Mary Hammond recommended to Keith Dobbins and Marybeth
10 Meyer that these results be put "on hold." The UHG Managing Defendants never
11 deleted these codes.

12 • For 2008 medical encounters, Optum (or its predecessor, Ingenix)
13 conducted a sample review for Family Practice Medical Group's diagnoses
14 mapping to Drug/Alcohol Dependence (HCC 52). For two beneficiaries, Optum's
15 (or Ingenix's) coder concluded there was "no clinical documentation to support
16 the diagnoses." In the Corrective Action Plan for the sample review, the reviewer
17 gave the provider "the benefit of the doubt" for the two diagnoses, despite noting
18 that "if these were submitted for a CMS or OIG audit, they may have been
19 rejected."

20 • In a sample review for Sharp-Rees Sealy for Vascular Disease (HCC 105)
21 for 2011, the UHG Managing Defendants failed to delete a diagnosis for
22 Beneficiary AA even though Optum's (or Ingenix's) coder, iCodify, determined it
23 was the "wrong code."

24 • In a sample review for HealthCarePartners for Protein-Calorie Malnutrition
25 (HCC 21) for 2011, the UHG Managing Defendants failed to delete a diagnosis for
26 Beneficiary BB even though Optum's (or Ingenix's) coder, iCodify, determined it
27 was the "wrong code."
28

1 • In a sample review for Mercy Physicians Medical Group for Protein-Calorie
2 Malnutrition (HCC 21) for 2011, the UHG Managing Defendants failed to delete a
3 diagnosis for Beneficiary CC even though Optum's (or Ingenix's) coders, under
4 the supervision of Tracey Bradberry, an Optum Operations Manager, determined
5 that it was the "wrong code."

6 • In a sample review for WellMed for Major Complications of Medical Care
7 and Trauma (HCC 164) for 2011, the UHG Managing Defendants did not delete a
8 diagnosis for Beneficiary DD even though Optum's (or Ingenix's) coder noted the
9 "dx [was] not documented" in the record.

10 • In a sample review for HealthCarePartners for Pneumococcal Pneumonia,
11 Emphysema, Lung Abscess (HCC 112) for 2012, the UHG Managing Defendants
12 did not delete a diagnosis code for Beneficiary EE even though Optum's (or
13 Ingenix's) coder determined the "dx [was] not documented."

14 • In a sample review for WellMed for Disorders of Immunity (HCC 45) for
15 2011, the UHG Managing Defendants did not delete a diagnosis code for
16 Beneficiary FF even though Optum's (or Ingenix's) coder determined the
17 diagnosis in the record was "not a current condition."

18 281. For some providers, the UHG Managing Defendants simply agreed not to delete
19 invalid codes. In January 2013, Keith Dobbins was informed that the UHG Managing
20 Defendants had not yet submitted deletes reflecting invalid codes found in RACCR
21 sample reviews of Edinger and WellMed diagnoses for encounters in 2008, 2009, and
22 2010. Optum kept those deletes "on hold," meaning that the UHG Managing Defendants
23 did not submit them, despite knowledge that the underlying codes had led to improper
24 payments from CMS.

**G. UnitedHealthcare Medicare & Retirement Discontinued
100 Percent Reviews And Converted The RACCR
Program Into A Revenue Generating Program**

282. By early 2014, UnitedHealthcare Medicare & Retirement knew, based on its observation of the results of the RACCR Program (as set forth above), that many of its large incentivized providers had reported unacceptably high rates of invalid diagnoses for numerous conditions. However, rather than redoubling its efforts to address invalid coding by incentivized providers, UnitedHealthcare Medicare & Retirement had Optum restructure the RACCR Program to turn it into just another chart review program focused on making ADDS. By July 2014, Optum made changes to the RACCR Program that effectively terminated the program as a tool for remedying the known problem of invalid coding by incentivized providers and refunding Medicare for risk adjustment payments based on those providers' invalid diagnoses.

283. First, UnitedHealthcare Medicare & Retirement stopped requiring any 100 percent reviews when the sample reviews failed the 80 percent sample validation test. At the time it made this decision, it was conducting RACCR sample reviews for 2012 DOS medical encounters. Accordingly, no 100 percent reviews were conducted for any outlier HCCs associated with 2012 medical encounters.

284. For 2012 DOS, there were 21 provider groups that had failed the 80 percent sample validation test for at least one outlier HCC. Optum had determined that the average invalidation rate was 34.73 percent for these 21 providers based on the sample reviews of their outlier HCCs. The UHG Managing Defendants knew from prior years that 100 percent reviews would result in the identification of more deletes. Nonetheless, they failed to require 100 percent reviews of the outlier HCCs or perform reviews themselves.

285. Second, for dates of service years after 2012, the UHG Managing Defendants stopped selecting sample beneficiaries for reviews based on whether the providers had submitted diagnoses for them mapping to outlier HCCs. Instead, they began selecting

1 beneficiaries and medical records based on what they believed would yield additional
2 codes and result in increased risk adjustment payments.

3 286. Third, starting with 2013 DOS medical encounters, UnitedHealthcare Medicare &
4 Retirement and Optum reviewed even fewer medical records than in previous years (less
5 than 100 total) for each incentivized provider group. Thus, they reviewed only several
6 thousand medical records as part of this new program.

7 287. By making these changes, the UHG Managing Defendants and Optum effectively
8 terminated the RACCR Program as an effort to correct the submission of invalid
9 diagnosis codes. Instead, they deliberately avoided identifying (and, thus, deleting)
10 invalid diagnoses reported by their financially-incentivized providers and repaying
11 Medicare for risk adjustment payments based on them.

12 288. Executives at Optum and UnitedHealthcare, including Scott Theisen, Jeff
13 Dumcum, Karen Erickson, Brian Thompson, and Keith Dobbins, were aware that the
14 changes to the RACCR Program for 2013 DOS and future years created a program that
15 no longer targeted outlier HCCs by provider, but instead selected beneficiaries and
16 medical records based on methods that Optum believed would yield additional codes and
17 result in increased risk adjustment payments. They knew that there was no replacement
18 program put into place to target the outlier HCCs and providers that had previously been
19 identified by the RACCR program. They knew that by stopping its program to look for
20 inaccurate codes, outlier providers who had failed the 80 percent validation tests would
21 continue to submit inaccurate codes to UnitedHealthcare, causing the submission of
22 inaccurate codes to CMS.

23 **H. RACCR-Related Falsehoods In UnitedHealthcare's And**
24 **Optum's Attestations**

25 289. As discussed in more detail below, Defendant UnitedHealthcare, on behalf of the
26 Defendant MA Organizations, submitted a Risk Adjustment Attestation to the Medicare
27 Program each year after the final risk adjustment submission deadline. *See infra*
28

1 paragraphs 309 to 327. Defendant Optum approved these Attestations in order for
2 UnitedHealthcare to submit them. *Id.*

3 290. In March 2012, Scott Theisen signed an Attestation on behalf of United's
4 Medicare & Retirement health plans certifying to the accuracy of UnitedHealthcare's
5 data for the 2010 date of service year (2011 payment year). By that date, the members of
6 UHG Management Defendants' RACCR team (including Michael McCarthy, Keith
7 Dobbins, Kim Halva, Benjamin Poehling, and Mary Hammond) knew that the RACCR
8 Program had identified thousands of invalid codes mapping to outlier HCCs from
9 encounters in 2010, that those codes had not yet been deleted, and that efforts were
10 underway to identify the providers that would be required to conduct 100 percent
11 reviews for encounters in 2010 because some of their diagnosis codes did not pass the 80
12 percent sample validation test.

13 291. In April 2013, Scott Theisen signed an Attestation on behalf of
14 UnitedHealthcare's Medicare & Retirement health plans certifying to the accuracy of
15 UnitedHealthcare's data for the 2011 date of service year (2012 payment year). By that
16 date, Theisen, along with the members of UHG Management Defendants' RACCR team
17 (including Marybeth Meyer, Keith Dobbins, Kim Halva, Patty Brennan, Benjamin
18 Poehling, and Scott Hughes) knew that the RACCR Program had identified thousands of
19 invalid codes mapping to HCCs from encounters in 2011, that those codes had not yet
20 been deleted, and that efforts were underway to identify the providers that would be
21 required to conduct 100 percent reviews for encounters in 2011 because some of their
22 diagnosis codes did not pass the 80 percent sample validation test.

23 292. In April 2014, Brian Thompson signed an Attestation on behalf of
24 UnitedHealthcare's Medicare & Retirement health plans certifying to the accuracy of
25 UnitedHealthcare's data for the 2012 date of service year (2013 payment year). By that
26 date, the members of UHG Management Defendants' RACCR team (including Marybeth
27 Meyer, Keith Dobbins, Kim Halva, Scott Theisen, Scott Hughes, and Tracey Bradberry)
28 knew that the RACCR Program had identified thousands of invalid codes mapping to

HCCs from encounters in 2012 through sample reviews, and that those codes had not yet been deleted. Additionally, Thompson was aware that there was a contra-revenue accrual in the amount of \$34.5 million for anticipated RACCR deletes for the 2012 date of service year alone.

IV. Defendants' False Risk Adjustment Attestations

293. The UHG Managing Defendants submitted or caused the submission, on behalf of the Defendant MA Organizations, of the annual Risk Adjustment Attestations to the Medicare Program after the final submission deadline but before the final reconciliation payment each year. Officers of Defendants Ovations and UnitedHealthcare reviewed and signed these Attestations. Defendant Optum and its predecessor Ingenix reviewed and approved these Attestations. These Defendants knew that the Defendant MA Organizations were required to submit truthful Risk Adjustment Attestations to the Medicare Program. Their officers and employees (*e.g.*, Jeffrey Dumcum, Stephanie Will, Jon Bird, Patty Brennan, Rebecca Martin, Scott Theisen, Relator Poehling, Mary Hammond) were aware of the obligations for deleting invalid diagnoses from RAPs or otherwise reporting and repaying risk adjustment overpayments by other means. Their officers and employees (*e.g.*, Jeffrey Dumcum, Stephanie Will, Jon Bird, Patty Brennan, Rebecca Martin, Scott Theisen, Relator Poehling, Mary Hammond) also knew that, if they deleted or withdrew invalid diagnoses from RAPS prior to the submission of an Attestation, Medicare would not pay for them or would recover any erroneous payments associated with them. However, Defendants failed to do this and knowingly submitted or caused the submission of false Attestations. They did this with actual knowledge that the Attestations were false or acted in deliberate ignorance or reckless disregard of the falsity of the Attestations.

294. Starting with the Attestation for payment year 2008 (if not for earlier Attestations) and continuing forward, attorneys for one or more of the UHG Managing Defendants added a footnote to the Attestations which stated that the Attestations were "based on facts reasonably available or made available to" the Defendant MA Organizations as of

1 the date of the Attestations. Optum and its predecessor Ingenix knew about this footnote
2 because its senior management, including Karen Erickson, Jeff Dumcum and Scott
3 Theisen, reviewed the Attestations and approved them prior to their submission to the
4 Medicare Program. The officers of Ovations and UnitedHealthcare who signed the
5 Attestations also knew about this footnote. Even without this footnote, the Attestations
6 themselves state that they must be made based on information available to the MA
7 Organizations: “Based on best knowledge, *information*, and belief as of the date
8 indicated below, all information submitted to CMS in such report [*i.e.*, the risk
9 adjustment data reported for the payment year at issue] and not subsequently deleted
10 prior to the date hereof is accurate, complete, and truthful.” (Emphasis added).

11 295. Information and facts reasonably available or made available to the Defendant
12 MA Organizations and the groups and entities that managed them at the time the
13 Attestations were submitted included the results of the medical record reviews conducted
14 as part of the Chart Review, Claims Verification, and RACCR Programs. In particular,
15 the results of the Chart Review Program were available before the final submission
16 deadline each year as the Chart Review Program ended when additional diagnoses could
17 no longer be submitted. Thus, the results of the Chart Review Program were
18 “information” and “facts reasonably available” before Ingenix and Optum approved the
19 Attestations and before Ovations and UnitedHealthcare executed and submitted the
20 Attestations to CMS on behalf of the Defendant MA Organizations. However, these
21 Defendants knowingly failed to delete numerous diagnoses that they had previously-
22 submitted that were unsupported and invalidated by their own chart reviews.

23 **A. Defendants’ Internal Attestation Approval Process**

24 296. Generally, the Chief Financial Officers of the groups with responsibility for
25 managing the Defendant MA Organizations owned by UHG were the officers designated
26 to sign and execute the annual Risk Adjustment Attestations on behalf of the Defendant
27 MA Organizations. Over the relevant time period, these groups included, but were not
28 limited to, Secure Horizons, the Public & Seniors Markets Group, Ovations,

1 UnitedHealthcare Medicare & Retirement, and UnitedHealthcare Community & States.
2 They were “responsible for establishing and maintaining adequate internal controls over
3 completion of attestations” submitted to the Medicare Program. They used a form to
4 “confirm that the appropriate legal, regulatory, and business owners” reviewed and
5 approved the attestations. *Id.* These legal, regulatory, and business owners were
6 required to sign Internal Approval Forms in order for the designated officials to sign the
7 Risk Adjustment Attestations.

8 297. Part C regulation, 42 C.F.R. § 422.504(1), and the agreements between the MA
9 Organizations and CMS required that this internal approval process include any related
10 entity, contractor or subcontractor of the Defendant MA Organizations that generated or
11 submitted risk adjustment data on their behalf. Furthermore, if a related entity generated
12 data relating to an MA Organization’s claims for payments from the Medicare Program,
13 the related entity (as well as the MA Organization) must certify the accuracy and
14 truthfulness of the data. *Id.* at § 422.504(l)(3). The contracts stated: “If such risk
15 adjustment data are generated by a related entity, contractor, or subcontractor of an MA
16 Organization, such entity, contractor, or subcontractor must also attest to (*based on best*
17 *knowledge, information, and belief, as of the date specified on the attestation form*) the
18 accuracy, completeness, and truthfulness of the data.” See Exhibits 1-7, attached hereto
19 (Article IV, Section D.2). Optum (and its predecessor, Ingenix), Ovation, and
20 UnitedHealthcare Medicare & Retirement understood this requirement as shown by the
21 previously-described MOU that obligated Optum to attest to the validity of the risk
22 adjustment data that it submitted to the Medicare Program on behalf of the Defendant
23 MA Organizations. See *supra* paragraphs 83-86.

24 298. During the time period relevant to this Complaint, the “business owners” that
25 signed off on the Internal Approval Forms were executives of Optum and Ingenix. One
26 of these business owners was Jeffrey Dumcum, who ran the Risk Adjustment Group at
27 Ingenix and then Optum. Dumcum’s internal attestations stated that he had reviewed the
28 content of the Risk Adjustment Attestations to be submitted by the managing entity (e.g.,

1 Oventions or UnitedHealthcare) to the Medicare Program and confirmed that the
2 Attestations were factually accurate. For example, on March 26, 2010, Dumcum sent an
3 email to Emily Vue, a Senior Regulatory Affairs Analyst for “Oventions – PSMG,
4 UnitedHealth Group, Inc.,” stating that he approved the Risk Adjustment Attestation for
5 John Larsen, the Chief Financial Officer of the Ovation Public & Senior Markets Group,
6 to submit to Medicare for payment year 2009. On March 24, 2011, Dumcum sent an
7 email to Barbara Carlson, a Senior Regulatory Affairs Analyst for UnitedHealthcare
8 Medicare & Retirement, stating that he approved the Risk Adjustment Attestation for
9 Scott Theisen, the Chief Financial Officer of UnitedHealthcare Medicare & Retirement,
10 to submit to Medicare for payment year 2010. On March 8, 2012, Dumcum sent an
11 email to Sandy Rick, a Senior Regulatory Affairs Analyst for UnitedHealthcare
12 Medicare & Retirement, stating that he approved the Risk Adjustment Attestation for
13 Mr. Theisen to submit to Medicare for payment year 2011.

14 299. Mr. Dumcum approved the Larsen and Theisen Risk Adjustment Attestations after
15 reviewing them and the footnotes added by the attorneys to them, including the footnote
16 stating that the Attestations were based on information available to the Defendant MA
17 Organizations about the accuracy and truthfulness of the diagnosis data that was
18 submitted on their behalf to the Medicare Program for risk adjustment payments.
19 However, Dumcum deliberately ignored or recklessly disregarded information available
20 to the Defendant MA Organizations and the entities that managed them (including
21 Oventions, UnitedHealthcare, Ingenix, and Optum, depending on the time period) about
22 invalid diagnoses, that is, he deliberately ignored and recklessly disregarded the negative
23 results of the medical record reviews conducted as part of the Chart Review, Claims
24 Verification, and RACCR Programs. Accordingly, Dumcum, as a senior executive of
25 Defendant Optum (and its predecessor, Ingenix), caused false Risk Adjustment
26 Attestations to be submitted to the Medicare Program.

27 300. For example, in March 2010, when Dumcum approved the Larsen Attestation for
28 payment year 2009, his Risk Adjustment Group at Ingenix possessed information about

1 the negative results of the Chart Review Program focused on the review of medical
2 records for medical encounters in date of service year 2008. Also, in March 2010,
3 Dumcum knew (or deliberately ignored or recklessly disregarded) that the managing
4 entities were not deleting or withdrawing the diagnoses unsubstantiated and invalidated
5 by those chart reviews. At that time, Dumcum also knew (or deliberately ignored or
6 recklessly disregarded) that these managing entities and the MA Organizations had an
7 obligation to delete or withdraw those invalid diagnoses. In fact, in 2009 prior to
8 Dumcum's approval of the Larsen Attestation, Dumcum knew that his Risk Adjustment
9 Group had already started discussing "looking both ways" at the results of chart reviews
10 and the methodology to do so in order to make DELETES as well as ADDS. *See supra*
11 paragraphs 180-182. Nonetheless, Dumcum signed the Internal Approval Form and
12 caused Larsen to submit a false Attestation to the Medicare Program.

13 301. As another example, in March 2011, when Dumcum approved the Theisen
14 Attestation for payment year 2010, his Risk Adjustment Group at Optum possessed
15 information about the negative results of the Chart Review Program focused on the
16 review of medical records for medical encounters in date of service year 2009. Also, in
17 March 2011, Dumcum knew (or deliberately ignored or recklessly disregarded) that
18 neither Optum nor UnitedHealthcare were deleting or withdrawing the diagnoses
19 invalidated by those chart reviews because they were not supported by the beneficiaries'
20 medical records. At that time, Dumcum also knew (or deliberately ignored or recklessly
21 disregarded) that both UnitedHealthcare and Optum had an obligation to delete or
22 withdraw those invalid diagnoses. In fact, in the fall of 2010 prior to Dumcum's
23 approval of the Theisen Attestation, Dumcum knew that senior executives of Ingenix and
24 Ovations had already acknowledged that they should be "looking both ways" at the
25 results of the chart reviews to make DELETES as well as ADDS. *See supra* paragraphs
26 185 and 196-198. In December 2010, the results of the first pilot phase (Phase I) of the
27 Claims Verification Program, which showed that provider-reported diagnoses were
28 unsupported for over 50 percent of the medical records reviewed, were also known by or

1 available to Dumcum. *See supra* paragraph 206. Nonetheless, Dumcum signed the
2 Internal Approval Form and caused Theisen to submit a false Attestation to the Medicare
3 Program.

4 302. In addition, in March 2012, when Dumcum approved the Theisen Attestation for
5 payment year 2011, his risk adjustment group at Optum possessed information about the
6 negative results of the Chart Review Program focused on the review of medical records
7 for medical encounters in date of service year 2010. Also, in March 2012, Dumcum
8 knew (or deliberately ignored or recklessly disregarded) that neither Optum nor
9 UnitedHealthcare were deleting or withdrawing the diagnoses invalidated by those chart
10 reviews, *i.e.*, those diagnoses not supported by the beneficiaries' medical records. At
11 that time, Dumcum also knew (or deliberately ignored or recklessly disregarded) that
12 both UnitedHealthcare and Optum had an obligation to delete or withdraw those invalid
13 diagnoses but were not doing so. In fact, by the time that Dumcum approved Theisen's
14 Attestation in March 2012, Optum had completed the second pilot phase (Phase II) of the
15 Claims Verification Program on 17,398 charts and the results were striking. Optum
16 identified 4,786 invalid diagnoses to be deleted, which was greater than the number of
17 additional diagnoses (ADDS) identified by the coders based on their review of the same
18 medical records. And, as previously stated, in February 2012, Dumcum, who was
19 responsible for the Claims Verification Program, met with Relator Poehling and Theisen
20 and reported: "I'm deleting as much as I'm adding at the end of the day. And I don't
21 know if—you know, what I want to do." He also stated: "we're getting more and more
22 red here," and that Claims Verification "eats in very substantially" to the revenue from
23 ADDS from chart reviews. Nonetheless, Dumcum signed the Internal Approval Form
24 and caused Theisen to submit a false Attestation.

25 303. Another "business owner" who executed the Internal Approval Form was Karen
26 Erickson, an Executive Vice President of Optum. On April 3, 2013, Erickson approved
27 Risk Adjustment Attestations for Scott Theisen, the Chief Financial Officer of
28 UnitedHealthcare Medicare & Retirement, and Paul Balthazor, the Chief Financial

1 Officer of UnitedHealthcare Community & State, to submit to Medicare for payment
2 year 2012. Erickson's internal attestation stated that she had reviewed the content of the
3 Theisen and Balthazor Risk Adjustment Attestations and confirmed that the Attestations
4 were factually accurate. Because she reviewed these Risk Adjustment Attestations she
5 knew about the footnotes that UnitedHealthcare included in the Attestations, stating that
6 the Attestations were based on information available to the Defendant MA
7 Organizations. In April 2013, Erickson knew (or deliberately ignored or recklessly
8 disregarded) that this information included the negative results of the Chart Reviews
9 focused on the review of medical records for medical encounters in date of service year
10 2011. Also, in April 2013, Erickson knew (or deliberately ignored or recklessly
11 disregarded) that neither Optum nor UnitedHealthcare were deleting or withdrawing all
12 of the diagnoses invalidated by those chart reviews because they were not supported by
13 the beneficiaries' medical records. At that time, Erickson also knew (or deliberately
14 ignored or recklessly disregarded) that both UnitedHealthcare and Optum had an
15 obligation to delete or withdraw all invalid diagnoses. In addition, prior to approving the
16 Attestations in 2013, Erickson, who was part of the team that developed the operational
17 plan for Claims Verification, knew and was concerned about the error rates based on
18 chart reviews conducted as part of the Claims Verification Program. Nonetheless,
19 Erickson signed the Internal Approval Forms and caused Theisen and Balthazor to
20 submit false Attestations.

21 304. In addition, on April 17 and 21, 2014, Erickson approved Risk Adjustment
22 Attestations for Brian Thompson, the Chief Financial Officer of UnitedHealthcare
23 Medicare & Retirement, and for Paul Balthazor, the Chief Financial Officer of
24 UnitedHealthcare Community & State, to submit to Medicare for payment year 2013.
25 Erickson's internal attestation stated that she reviewed the content of the Thompson and
26 Balthazor Risk Adjustment Attestations and confirmed that the Attestations were
27 factually accurate. Because she reviewed these Risk Adjustment Attestations she knew
28 about the footnotes that UnitedHealthcare included in the Attestations, stating that the

1 Attestations were based on information available to the Defendant MA Organizations.
2 In April 2014, Erickson knew (or deliberately ignored or recklessly disregarded) that this
3 information included the negative results of the Chart Reviews focused on the review of
4 medical records for medical encounters in date of service year 2012. Also, in April
5 2014, Erickson knew (or deliberately ignored or recklessly disregarded) that neither
6 Optum nor UnitedHealthcare were deleting or withdrawing all of the diagnoses
7 invalidated by those chart reviews because they were not supported by the beneficiaries'
8 medical records. At that time, Erickson also knew (or deliberately ignored or recklessly
9 disregarded) that both UnitedHealthcare and Optum had an obligation to delete or
10 withdraw all invalid diagnoses. Nonetheless, Erickson signed the Internal Approval
11 Forms and caused Thompson and Balthazor to submit false Attestations.

12 305. During the time period relevant to this Complaint, one of the "regulatory owners"
13 that executed the Internal Approval Form was David Walsh, the Senior Director of
14 Regulatory Affairs for UnitedHealthcare. He attested that he had reviewed the content
15 of the Risk Adjustment Attestation "to confirm that it complies with applicable
16 *regulatory* requirements and determined that it is appropriate for the designated
17 executive to proceed with signature." However, Walsh deliberately ignored or recklessly
18 disregarded the negative results of the Chart Review Program. He also ignored and
19 disregarded that Defendants had failed to comply with the requirements that diagnoses
20 must be supported by patients' medical records and those diagnoses that are not
21 supported by the patients' medical records must be deleted from RAPS or otherwise
22 reported to CMS and corrected to repay or avoid any overpayment.

23 306. During the time period relevant to this Complaint, one of the "legal owners" that
24 executed the Internal Approval Form was UnitedHealthcare's Senior General Counsel
25 Keith Dobbins. For example, on March 26, 2010, Dobbins approved the Risk
26 Adjustment Attestation for John Larsen to submit to the Medicare Program for payment
27 year 2009. Dobbins attested that he had reviewed the content of the Risk Adjustment
28 Attestation to confirm that it complied with "applicable *legal* requirements" and was

1 “appropriate” for Larsen to sign. (emphasis in the original). As another example, on
2 March 25, 2011, Dobbins approved the Risk Adjustment Attestation for Scott Theisen,
3 the Chief Financial Officer of UnitedHealthcare Medicare & Retirement, to submit to the
4 Medicare Program for payment year 2010. Again, Dobbins attested that he reviewed the
5 content of the Attestation to confirm that it complied with “applicable legal
6 requirements” and was “appropriate” for Theisen to submit to the Medicare Program for
7 payment year 2011. In addition, on March 9, 2012, Dobbins approved the Risk
8 Adjustment Attestation for Scott Theisen, the Chief Financial Officer of
9 UnitedHealthcare Medicare & Retirement, to submit to the Medicare Program for
10 payment year 2011. Again, Dobbins attested that he reviewed the content of the
11 Attestation to confirm that it complied with “applicable legal requirements” and was
12 “appropriate” for Theisen to submit to the Medicare Program for payment year 2011.
13 On April 30, 2014, Dobbins also approved the Risk Adjustment Attestation for Brian
14 Thompson, the Chief Financial Officer of UnitedHealthcare Medicare & Retirement, to
15 submit to Medicare for payment year 2013. Again, Dobbins attested that he reviewed
16 the content of the Attestation to confirm that it complied with “applicable legal
17 requirements” and was “appropriate” for Theisen to submit to the Medicare Program for
18 payment year 2011. On information and belief, Dobbins approved other Risk
19 Adjustment Attestations for other payment years and attested to their accuracy.
20 307. Each time Dobbins approved the Attestations, he knew (or deliberately ignored or
21 recklessly disregarded) that information available to the Defendant MA Organizations
22 included the negative results of the chart reviews for the date of service years at issue.
23 Also, he knew (or deliberately ignored or recklessly disregarded) that neither
24 Ingenix/Optum nor Ovations/UnitedHealthcare (depending on the time period) were
25 deleting or withdrawing all of the diagnoses invalidated by those chart reviews because
26 they were not supported by the beneficiaries’ medical records. At that time, he also
27 knew (or deliberately ignored or recklessly disregarded) that both Ingenix/Optum and
28 Ovations/UnitedHealthcare had an obligation to delete or withdraw all invalid diagnoses.

308. During the years relevant to his approvals, Dobbins was a member of UnitedHealthcare's Risk Adjustment Compliance Oversight Committee and Optum's Clinical Programs and Compliance Oversight Committee. During those years, Dobbins also attended various meetings involving the work that Ingenix and then Optum performed for Ovations and then UnitedHealthcare. As a member of these committees and a participant in these meetings, Dobbins was included in numerous discussions about the validity of the risk adjustment data submitted to the Medicare Program, the Chart Review Program, the development and results of the Claims Verification Program, and the RACCR Program. Dobbins was also one of the individuals who was responsible for reviewing quarterly compliance scorecards that included detailed information about the Chart Review, Claims Verification, and RACCR Programs. Despite these compliance responsibilities and this knowledge, Dobbins ignored and disregarded that Ovations, UnitedHealthcare, Optum, and Ingenix had failed to comply with the requirements that diagnoses must be supported by patients' medical records and that diagnoses unsupported by patients' medical records must be deleted from RAPS or otherwise reported to CMS and corrected to repay or avoid any overpayments.

B. The False Attestations Submitted To The Government

309. On March 19, 2009, John Way executed and submitted or caused to be submitted to the Medicare Program an "Attestation of Risk Adjustment Data Information Relating to CMS Payment to a Medicare Advantage Organization." He submitted this Attestation "[o]n behalf of the UnitedHealth Group entities listed in Attachment 1." This Attestation related to risk adjustment data, that is, diagnoses, which Ovations and/or UnitedHealthcare and Ingenix submitted on behalf of many of the Defendant MA Organizations for risk adjustment payments for payment year 2008. See Exhibit 16, attached hereto. The Risk Adjustment data, that is, the diagnoses, were related to medical encounters that occurred in date of service year 2007. Way signed the Attestation as "Chief Financial Officer, SecureHorizons." At this time, March 2009, SecureHorizons was an internal group within Ovations or UnitedHealthcare. Way added

1 a footnote to the Attestation which stated that the Attestation was “based on facts
2 reasonably available or made available to the MA Organization as of the date of” the
3 Attestation. The Attestation itself said it was made based on information available to the
4 MA Organizations. In March 2009, information and facts reasonably available to the
5 Defendant MA Organizations, Ovations and/or UnitedHealthcare, and Ingenix included
6 the negative results of the Chart Review Program for 2007 date of service medical
7 encounters.

8 310. In March 2009, when Way signed the Attestation, he deliberately ignored or
9 recklessly disregarded the negative results of the Chart Review Program relating to
10 medical encounters with 2007 dates of service. Way also ignored and disregarded that
11 Defendants had failed to comply with the requirements that diagnoses must be supported
12 by patients’ medical records and those diagnoses that are not supported by patients’
13 medical records are invalid and must be deleted from RAPS or otherwise reported to
14 CMS and corrected to repay or avoid any overpayment. In addition, at this time, Relator
15 Poehling was a direct report to Way, Relator Poehling and Way had numerous
16 conversations about risk adjustment programs, and Relator Poehling voiced his concerns
17 to Way about Ovations failure to “look both ways” at the results of medical record
18 reviews conducted as part of the Chart Review Program.

19 311. On March 18, 2009, Kara Rios executed and submitted or caused to be submitted
20 to the Medicare Program an “Attestation of Risk Adjustment Data Information Relating
21 to CMS Payment to a Medicare Advantage Organization.” She submitted this
22 Attestation “[o]n behalf of the UnitedHealth Group entities listed in Attachment 1.” This
23 Attestation related to Risk Adjustment data, that is, diagnoses, that Ovations (or the
24 group known as AmeriChoice, which, on information and belief, was located within
25 Ovations at this time) and Ingenix submitted on behalf of certain Defendant MA
26 Organizations for Risk Adjustment payments for payment year 2008. The Risk
27 Adjustment data, that is, the diagnoses, were related to medical encounters that occurred
28 in date of service year 2007. Rios signed the Attestation as “Chief Financial Officer,

1 AmeriChoice.” Rios added a footnote to the Attestation which stated that the Attestation
2 was “based on facts reasonably available or made available to the MA Organization as of
3 the date of” the Attestation. The Attestation itself said it was made based on information
4 available to the MA Organizations. In March 2009, information and facts reasonably
5 available to all Defendants included the negative results of the Chart Review Program.

6 312. On March 2, 2009, Jonathan Bunker executed and submitted or caused to be
7 submitted to the Medicare Program an “Attestation of Risk Adjustment Data Information
8 Relating to CMS Payment to a Medicare Advantage Organization.” He submitted this
9 Attestation “[o]n behalf of Sierra Health and Life Insurance Company, Inc.,” a
10 Defendant MA Organization. This Attestation was for payment year 2008. The Risk
11 Adjustment data, that is, the diagnoses, were related to medical encounters that occurred
12 in date of service year 2007. Bunker signed the Attestation as President of Sierra Health
13 and Life Insurance Company, Inc. At this time, March 2009, Sierra Health and Life
14 Insurance Company, Inc. was an MA Organization owned by UHG and managed by
15 UnitedHealthcare. The Attestation was submitted to the Medicare Program by Shelly
16 Cranley, the Director of Regulatory Affairs for UnitedHealthcare.

17 313. On March 2, 2009, Jonathan Bunker executed and submitted or caused to be
18 submitted to the Medicare Program another “Attestation of Risk Adjustment Data
19 Information Relating to CMS Payment to a Medicare Advantage Organization.” He
20 submitted this Attestation “[o]n behalf of Health Plan of Nevada, Inc.,” a Defendant MA
21 Organization, and its MA Plans. This Attestation was for payment year 2008. The Risk
22 Adjustment data, that is, the diagnoses, were related to medical encounters that occurred
23 in date of service year 2007. Bunker signed the Attestation as President of Health Plan
24 of Nevada, Inc. At this time, March 2009, Health Plan of Nevada, Inc. was an MA
25 Organization owned by UHG and managed by UnitedHealthcare. The Attestation was
26 submitted to the Medicare Program by Shelly Cranley, the Director of Regulatory
27 Affairs for UnitedHealthcare.

314. On March 19, 2009, Justin Roth executed and submitted or caused to be submitted to the Medicare Program another “Attestation of Risk Adjustment Data Information Relating to CMS Payment to a Medicare Advantage Organization.” This Attestation was for payment year 2008. The Risk Adjustment data, that is, the diagnoses, were related to medical encounters that occurred in date of service year 2007. Roth signed the Attestation as “Chief Financial Officer of Evercare” and stated that the Attestation was signed “[o]n behalf of the UnitedHealth Group entities listed in Attachment 1,” which included various Defendant MA Organizations, including many United Healthcare Insurance Company MA Organizations, Oxford Health Plans of New Jersey, Inc., and Evercare of Texas. At this time, March 2009, these MA Organizations were owned by UHG and managed by UnitedHealthcare. The Attestation stated that it was based on information and facts reasonably available or made available to the MA Organizations listed in Attachment 1 at the time the Attestation was submitted.

315. On March 26, 2010, John Larsen executed and submitted or caused to be submitted to CMS an “Attestation of Risk Adjustment Data Information Relating to CMS Payment to a Medicare Advantage Organization.” He submitted this Attestation “[o]n behalf of the UnitedHealth Group entities listed in Attachment 1.” These entities included numerous Defendant MA Organizations. This Attestation related to Risk Adjustment data, that is, diagnoses, that Optum (or its predecessors Ingenix) and Ovations and/or UnitedHealthcare submitted on behalf of these MA Organizations to Medicare for Risk Adjustment payments for payment year 2009. See Exhibit 17, attached hereto. The Risk Adjustment data, that is, the diagnoses, were related to medical encounters that occurred in date of service year 2008. Larsen signed the Attestation as “Chief Financial Officer, Public & Senior Markets Group.” At this time, the Public & Senior Markets Group included Ovations. Larsen added a footnote to his Risk Adjustment Attestation which stated that the Attestation was “based on facts reasonably available or made available to the MA Organization as of the date of” the Attestation. The Attestation itself stated that it was based on information available to the

1 MA Organizations. In March 2010, information and facts reasonably available to the
2 Defendant MA Organizations included the negative results of the Chart Review Program
3 relating to medical encounters that occurred in 2008.

4 316. When Larsen signed the Attestation, he deliberately ignored or recklessly
5 disregarded the negative results of the Chart Review Program. Larsen also ignored or
6 disregarded that Defendants had failed to comply with the requirements that diagnoses
7 must be supported by patients' medical records and that diagnoses that are not supported
8 by patients' medical records are invalid and must be deleted from RAPS or otherwise
9 reported to CMS and corrected to repay or avoid any overpayment. During the relevant
10 time period, Larsen was involved in meetings concerning the Chart Review Program and
11 knew that the Public & Senior Markets Group could have "looked both ways" at the
12 results of the chart reviews but was not doing so and, thus, that the Public & Senior
13 Markets Group was not reporting to CMS those provider-reported codes that were not
14 supported by the beneficiaries' medical records.

15 317. On March 25, 2011, Scott Theisen executed and submitted or caused to be
16 submitted to CMS an "Attestation of Risk Adjustment Data Information Relating to
17 CMS Payment to a Medicare Advantage Organization." He submitted this Attestation
18 "[o]n behalf of the UnitedHealth Group entities listed in Attachment 1." This Attestation
19 related to Risk Adjustment data, that is, diagnoses, that UnitedHealthcare and Optum (or
20 its predecessor Ingenix) submitted on behalf of numerous Defendant MA Organizations
21 to Medicare for risk adjustment payments for payment year 2010. See Exhibit 18,
22 attached hereto. The risk adjustment data, that is, the diagnoses, were related to medical
23 encounters that occurred in date of service year 2009. Theisen signed the Attestation as
24 "Chief Financial Officer, UnitedHealthcare Medicare & Retirement." Theisen added a
25 footnote to his Risk Adjustment Attestation which stated that the Attestation was "based
26 on facts reasonably available or made available to the MA Organization as of the date
27 of" the Attestation. The Attestation itself stated that it was made based on information
28 available to the Defendant MA Organizations. In March 2011, information and facts

1 reasonably available to the Defendant MA Organizations, UnitedHealthcare, and Optum
2 (or its predecessor, Ingenix) included the negative results of the Chart Review Program
3 relating to medical encounters in 2009.

4 318. On March 9, 2012, Scott Theisen executed and submitted or caused to be
5 submitted to CMS an “Attestation of Risk Adjustment Data Information Relating to
6 CMS Payment to a Medicare Advantage Organization.” He submitted this Attestation
7 “[o]n behalf of the UnitedHealth Group entities listed in Attachment 1.” This Attestation
8 related to Risk Adjustment data, that is, diagnoses, that UnitedHealth and Optum
9 submitted to on behalf of numerous MA Organizations to Medicare for risk adjustment
10 payments for payment year 2011. See Exhibit 19, attached hereto. The risk adjustment
11 data, that is, the diagnoses, were related to medical encounters that occurred in date of
12 service year 2010. Theisen signed the Attestation as “Chief Financial Officer,
13 UnitedHealthcare Medicare & Retirement. The Attestation stated that it was based on
14 information available to the MA Organizations. It also included a footnote that stated
15 the Attestation was “based on facts reasonably available or made available to the MA
16 Organization as of the date” of the Attestation. In March 2012, information and facts
17 reasonably available to all Defendants included the negative results of the medical record
18 reviews conducted as part of the Chart Review Program for payment year 2011 (date of
19 service year 2010).

20 319. On April 9, 2013, Scott Theisen executed and submitted or caused to be submitted
21 to CMS an “Attestation of Risk Adjustment Data Information Relating to CMS Payment
22 to a Medicare Advantage Organization.” He submitted this Attestation “[o]n behalf of
23 the UnitedHealth Group entities listed in Attachment A.” This Attestation related to
24 Risk Adjustment data, that is, diagnoses, that UnitedHealthcare and Optum submitted on
25 behalf of numerous MA Organizations to Medicare for risk adjustment payments for
26 payment year 2012. See Exhibit 20, attached hereto. The risk adjustment data, that is,
27 the diagnoses, were related to medical encounters that occurred in date of service year
28 2011. Theisen signed the Attestation as “Chief Financial Officer, UnitedHealthcare

1 Medicare & Retirement.” The Attestation stated that it was based on information
2 available to the MA Organizations and also included a footnote stating that the
3 Attestation was “based on facts reasonably available or made available to the MA
4 Organization as of the date of” the Attestation. In March 2013, information and facts
5 reasonably available to the MA Organizations, UnitedHealthcare, and Optum included
6 the negative results of the medical record reviews conducted as part of the Chart Review
7 Program for payment year 2012 (date of service year 2011).

8 320. Each time Theisen signed the Attestations, he deliberately ignored or recklessly
9 disregarded the negative results of the Chart Review Program for the 2010, 2011, and
10 2012 payment years and 2009, 2010, and 2011 date of service years at issue. Theisen
11 also ignored or disregarded that the Defendant MA Organizations, UnitedHealthcare,
12 and Optum (or its predecessor, Ingenix) had failed to comply with the requirements that
13 diagnoses must be supported by patients’ medical records and that those diagnoses that
14 are not supported by patients’ medical records are invalid and must be deleted from
15 RAPS or otherwise reported to CMS and corrected to repay or avoid any overpayments.

16 321. During the years in which he was Chief Financial Officer of UnitedHealthcare
17 Medicare & Retirement and approved the Attestations, Theisen was co-chair and
18 business lead of UnitedHealthcare Medicare & Retirement’s Financial Compliance
19 Oversight Committee. He also attended quarterly meetings with UnitedHealthcare
20 Medicare & Retirement’s Compliance Committee, comprised of UnitedHealthcare
21 Medicare & Retirement’s executive leadership team; Executive Steering Committee
22 meetings; and meetings to identify and evaluate corporate risks. As a member of these
23 committees, a participant in these meetings, and in fulfilling his duties as
24 UnitedHealthcare Medicare & Retirement’s Chief Financial Officer, Theisen was
25 involved in discussions about the Chart Review Program, the implementation and results
26 of the Claims Verification Program, and the RACCR Program. During this time period,
27 Theisen had authority to make decisions on behalf of UnitedHealthcare, including how
28 much to spend on the Chart Review Program, how many charts to include in the Chart

1 Review Program, and whether to submit DELETES based on information available to
2 UnitedHealthcare. He also had authority to make similar decisions about the RACCR
3 Program.

4 322. In addition, Theisen was aware of the significant number of invalid provider-
5 reported diagnoses based on the results of the Chart Review and Claims Verification
6 Programs. For example, when Theisen executed the Risk Adjustment Attestation in
7 March 2011, the results of the first pilot phase (Phase I) of the Claims Verification
8 Program were available. As previously explained, those results showed that provider-
9 reported diagnoses were unsupported for over 50 percent of the medical records
10 reviewed. *See supra* paragraph 206. As another example, in February 2012 prior to his
11 signing the March 2012 Attestation, Theisen (as well as Dumcum and Relator Poehling)
12 had actual knowledge of the strikingly negative results of the Claims Verification Phase
13 II pilot program showing that there were more DELETES than ADDS. *See supra*
14 paragraph 158. In addition, on April 3, 2013, when Theisen executed and submitted the
15 Risk Adjustment Attestations for payment year 2012, the information available to the
16 Defendants MA Organizations, UnitedHealthcare Medicare & Retirement (including
17 Theisen), and Optum included the results of the chart reviews for 2011 dates of service,
18 which showed that they had submitted at least 100,000 diagnoses that were invalid, but
19 had not been deleted (and never were deleted). *See supra* paragraph 235. Yet, Theisen
20 attested that these invalid diagnoses were accurate and truthful.

21 323. On March 25, 2011, Brian Thompson, the Chief Financial Officer of
22 UnitedHealthcare Community & State, executed and submitted or caused to be
23 submitted an “Attestation of Risk Adjustment Data Information Relating to CMS
24 Payment to a Medicare Advantage Organization.” He submitted this Attestation on
25 behalf of “the UnitedHealth Group entities listed in Attachment 1.” This Attestation
26 related to risk adjustment data, that is, diagnoses, that UnitedHealthcare and Optum (or
27 its predecessor, Ingenix) submitted on behalf of certain of the Defendant MA
28 Organizations to Medicare for payment year 2010. The data related to the 2009 date of

1 service year. The Attestation as based on information and facts reasonably available to
2 the MA Organizations, including the negative results of the Chart Review Program based
3 on medical record reviews for date of service year 2009. Information and facts available
4 to the MA Organizations, UnitedHealthcare, and Optum (or its predecessor, Ingenix)
5 included the results of the medical record reviews conducted as part of the Chart Review
6 Program for medical encounters during the 2009 date of service year. However,
7 Thompson and these Defendants deliberately ignored or recklessly disregarded the
8 negative results of these chart reviews. They also ignored or disregarded that the
9 Defendant MA Organizations, UnitedHealthcare, and Optum (or its predecessor,
10 Ingenix) had failed to comply with the requirements that diagnoses must be supported by
11 patients' medical records and that those diagnoses that are not supported by patients'
12 medical records are invalid and must be deleted from RAPS or otherwise reported to
13 CMS and corrected to repay or avoid any overpayments.

14 324. On March 29, 2012, Paul Balthazor, the Chief Financial Officer of
15 UnitedHealthcare Community & State, executed and submitted or caused to be
16 submitted an "Attestation of Risk Adjustment Data Information Relating to CMS
17 Payment to a Medicare Advantage Organization." He submitted this Attestation on
18 behalf of "the UnitedHealth Group entities listed in Attachment 1." This Attestation
19 related to risk adjustment data, that is, diagnoses, that UnitedHealthcare and Optum (or
20 its predecessor, Ingenix) submitted on behalf of certain of the Defendant MA
21 Organizations to Medicare for payment year 2011. The data related to 2010 date of
22 service year. The Attestation was based on information and facts reasonably available to
23 the MA Organizations, UnitedHealthcare, and Optum including the negative results of
24 the medical record reviews conducted as part of the Chart Review Program for the 2010
25 date of service year. However, Balthazor and these Defendants deliberately ignored or
26 recklessly disregarded the negative results of these chart reviews. They also ignored or
27 disregarded that the Defendant MA Organizations, UnitedHealthcare, and Optum had
28 failed to comply with the requirements that diagnoses must be supported by patients'

1 medical records and that those diagnoses that are not supported by patients' medical
2 records are invalid and must be deleted from RAPS or otherwise reported to CMS and
3 corrected to repay or avoid any overpayments. In April 2013, Balthazor also executed
4 the Risk Adjustment Attestation for the MA Organizations managed by
5 UnitedHealthcare Community & State for payment year 2012 (date of service year
6 2011). For this year too, Balthazor and the Defendant MA Organizations,
7 UnitedHealthcare, and Optum ignored the results of the chart reviews and their
8 obligations to delete invalid diagnoses.

9 325. On April 30, 2014, Brian Thompson executed and submitted or caused to be
10 submitted Risk Adjustment Attestations on behalf of all of the Defendant MA
11 Organizations managed by UnitedHealthcare Medicare & Retirement at that time. (On
12 the same date, Paul Balthazor executed and submitted or caused to be submitted Risk
13 Adjustment Attestations on behalf of all Defendant MA Organizations managed by
14 UnitedHealthcare Community & State at the time.) An example of one of Thompson's
15 Attestations includes the Attestation he submitted "[o]n behalf of the UnitedHealth of
16 California." See Exhibit 21, attached hereto. This Attestation related to risk adjustment
17 data, that is, diagnoses, which UnitedHealthcare and Optum submitted on behalf of
18 UnitedHealthcare of California to the Government for risk adjustment payments for
19 payment year 2013. The risk adjustment data, that is, the diagnoses, were related to
20 medical encounters that occurred in date of service year 2012. At the time Thompson
21 signed this Attestation he was the Chief Financial Officer of UnitedHealthcare Medicare
22 & Retirement. The Attestation was based on information available to the MA
23 Organizations. UnitedHealthcare could not add a footnote to the Attestation because it
24 was submitted electronically. However, Steve Nelson, the Chief Executive Officer of
25 UnitedHealthcare Medicare & Retirement, sent CMS an email on April 30, 2014, stating
26 that the Attestation was "based on facts reasonably available or made available to *us* as
27 of the date of" the Attestation. (Emphasis added). In April 2014, facts reasonably
28 available to all the Defendant MA Organizations, UnitedHealthcare, and Optum included

1 the negative results of the Chart Review and Claims Verification Programs relating to
2 medical encounters in 2012. Other information and facts that were available included,
3 for instance, millions of dollars of invalid diagnoses about which United had *actual*
4 knowledge but never deleted. *See supra* paragraph 232.

5 326. In April 2014, when Thompson signed the Attestation, he deliberately ignored or
6 recklessly disregarded the negative results of the Chart Review Program. Thompson
7 also ignored that Defendants had failed to comply with the requirements that diagnoses
8 must be supported by patients' medical records and that those diagnoses that are not
9 supported by patients' medical records must be deleted from RAPS or otherwise
10 reported to CMS and corrected to repay or avoid any overpayment. At the time that
11 Thompson submitted the Attestation on April 30, 2014, he knew about the actual or
12 estimated adverse financial impact of DELTES from the Chart Review and Claims
13 Verification Programs for payment year 2013 (date of service year 2012) and he knew
14 about CV liability accruals. *See supra* paragraphs 217-221. Furthermore, on April 30,
15 2014, the date the Attestations were submitted for the 2013 payment year, the
16 information available to the Defendant MA Organizations, UnitedHealthcare Medicare
17 & Retirement (including Thompson), and Optum included the results of the chart
18 reviews for the date of service year 2012, which showed that at least 250,000 diagnoses
19 were invalid. *See supra* paragraph 235. Yet, Thompson certified that this invalid data
20 was accurate and truthful even though the invalid diagnoses had not been deleted (and
21 never have been).

22 327. On June 26, 2015 and June 7, 2016, Thompson executed and submitted or caused
23 to be submitted Risk Adjustment Attestations on behalf of all of the Defendant MA
24 Organizations managed by UnitedHealthcare Medicare & Retirement on those dates.
25 (On the same dates, UnitedHealthcare Community & State also submitted Risk
26 Adjustment Attestations for the Defendant MA Organizations that it managed.) These
27 Attestations related to risk adjustment data, that is, diagnoses, which UnitedHealthcare
28 and Optum submitted on behalf of these MA Organizations to the Government for risk

1 adjustment payments for payment years 2014 and 2015. The risk adjustment data, that
2 is, the diagnoses, were related to medical encounters that occurred in date of service
3 years 2013 and 2014. At the time Thompson signed these Attestations he was the Chief
4 Financial Officer of UnitedHealthcare Medicare & Retirement. The Attestations were
5 the same as those for prior years (except that they did not have footnotes.) The
6 Attestations were based on information available to the MA Organizations, including
7 information about diagnoses unsupported and, thus, invalidated by the chart reviews for
8 the dates of service years at issue. On June 26, 2015, the date the Attestations were
9 submitted for the 2014 payment year, the information available to the Defendant MA
10 Organizations, UnitedHealthcare Medicare & Retirement (including Thompson), and
11 Optum were the results of the chart reviews for date of service year 2013, which showed
12 that at least 199, 039 diagnoses were invalid. *See supra* paragraph 235. Yet, Thompson
13 certified that this invalid data was accurate and truthful even though the invalid codes
14 had not been deleted (and never have been).

15 **V. Diagnoses Solely Determine Risk Adjustment Payments Based**
16 **On Health Status**

17 328. The diagnostic data submitted by an MA Organizations are not merely ancillary to
18 its claims for risk adjustment payments. Rather, the diagnoses are the sole determinant
19 in the calculation of any risk adjustment payment based on a beneficiary's health status.
20 The submissions of diagnoses are themselves claims for risk adjustment payments and
21 are inexorably material to any payment based on the beneficiary's health status. The
22 diagnoses are the *raison d'être* of RAPS submissions, *i.e.*, risk adjustment claims.

23 329. As emphasized throughout this Amended Complaint, the Government has never
24 agreed to make risk adjustment payments based on invalid diagnoses, and MA
25 Organizations are required by their contracts with CMS, federal regulations, and CMS
26 instructions (*e.g.*, the Managed Care Manual and Participant Guide) to delete invalid
27 diagnoses. Moreover, no statute or regulation entitles an MA Organization to risk
28 adjustment payments based on invalid diagnoses, including payments based on

1 diagnoses that are unsubstantiated by the beneficiaries' medical records. *See Swoben*,
2 848 F.3d at 1179 (rejecting arguments that MA Organizations are allowed to ignore
3 information about invalid diagnoses based on their own chart reviews and that they are
4 not obligated to delete such invalid diagnoses submitted by them for risk adjustment
5 payments).

6 330. When MA Organizations provide CMS with information identifying specific
7 invalid diagnoses that were submitted for payment (such as by deleting the invalid
8 diagnoses in the RAPS system) and, thus, CMS has *actual knowledge* about the specific
9 invalid diagnoses that were submitted for payment (such as because they were deleted in
10 the RAPS system), Medicare recovers the associated overpayments. *See United States*
11 *ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 906 (9th Cir. 2017) (holding that,
12 in assessing materiality, the court must examine what the agency does when it has *actual*
13 *knowledge* of the regulatory violation). There is no way that CMS can obtain this actual
14 knowledge about invalid diagnoses by looking at an Attestation. The falsity of the
15 Attestation is not apparent on the face of the document. Someone must inform CMS that
16 the MA Organization has information showing that its diagnoses are invalid and that it
17 failed to delete those invalid diagnoses.

18 331. The UHG Managing Defendants and the Defendant MA Organizations knew that
19 they were required to delete invalid diagnoses that they had submitted for payment and,
20 in fact, they did this by making deletes in the RAPS system. For example, as previously
21 explained, based on their short-lived Claims Verification Program, UnitedHealthcare
22 Medicare & Retirement and Optum deleted diagnoses from the RAPS system. They also
23 deleted some invalid diagnoses from the RAPS system based on their RACCR reviews.

24 332. In addition, in the past, when UnitedHealthcare has informed CMS that it is in
25 possession of information about invalid diagnoses that it had submitted and requested
26 some direction with respect to deleting the invalid diagnoses, CMS has worked with it to
27 recover the overpayments. In 2010 and 2011, CMS did this when Joseph Keen, the
28 Chief Compliance Audit Officer at UnitedHealthcare, informed it about risk adjustment

1 data that UnitedHealthcare had submitted that included invalid diagnoses. Importantly,
2 CMS also asked Keen a series of questions to obtain information about the invalid
3 diagnoses, an explanation why the deletes were being made after the final submission
4 deadline for the payment year (because, if made prior to the deadline, CMS would have
5 been able to offset the overpayment as a part of the final reconciliation payment
6 process), and for an explanation of the steps that UnitedHealthcare was taking to ensure
7 that deletes were made in a timely manner. Keen responded that UnitedHealthcare was
8 “continuing to conduct targeted chart validation reviews to determine if the member-
9 diagnoses reviewed are supported by a medical record. These reviews continue and we
10 may need to delete certain risk adjustment data in the future. We will promptly notify
11 CMS of any risk adjustment data determined through these reviews to have been
12 incorrectly submitted.”

13 333. If Defendants had complied with their obligation to delete invalid diagnoses from
14 RAPS, Medicare’s Risk Adjustment System (“RAS”) would have processed the
15 corrected data and recalculated the risk score for the beneficiaries for whom an invalid
16 diagnosis had been deleted. The degree of the change in the payment amount for that
17 beneficiary would have depended on the HCC to which the invalid diagnosis was
18 grouped. The risk adjustment reconciliation payment system would have made these
19 adjustments automatically if the DELETES were made in RAPS. The system would
20 have done this as part of the final reconciliation payment process or future
21 reconciliations conducted by CMS for the payment year at issue.

22 334. If an MA Organization does not comply with its express obligation to delete the
23 invalid diagnoses from RAPS prior to the final submission deadline, Medicare pays for
24 the invalid diagnoses as part of its final reconciliation payment to the MA Organization
25 or, if it already paid for the invalid diagnosis, does not recover the overpayment as part
26 of the final reconciliation payment process. If the MA Organization never deletes the
27 invalid diagnoses from RAPS, Medicare does not recover the overpayment when future
28 payment reconciliations are done for the payment year at issue. Accordingly, the

1 diagnostic information submitted by an MA Organization is not merely ancillary to its
2 claim for risk adjustment payments, it is the sole determinant in the calculation of the
3 amount (if any) of the risk adjustment payments made by Medicare based on the health
4 status of a beneficiary and, therefore, inexorably material to the amount (if any) paid.

5 335. A false Risk Adjustment Attestation, by its very nature, is also material as it
6 relates directly to the data element – diagnoses – that is the sole determinant of risk
7 adjustment payments based on health status. Submission of invalid diagnoses and
8 failing to delete them are not minor or insubstantial infractions of the MA Organization’s
9 obligations to Medicare with which they pledge to comply. Keen, the UnitedHealthcare
10 Chief Compliance Audit Officer, and others at UnitedHealthcare and Optum were aware
11 of these obligations.

12 336. The purpose of the Risk Adjustment Attestation is, first, to remind MA
13 Organizations that they may not ignore or disregard information about invalid diagnoses,
14 such as (but not limited to) the negative results of chart reviews showing that diagnoses
15 previously submitted for payment are unsupported by the charts; and, second, to enforce
16 the fundamental program requirement that MA Organizations delete invalid diagnoses.
17 *See* 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) (noting that “certifications would help
18 ensure accurate data submissions”). When MA Organizations do not comply with these
19 payment data integrity requirements of the MA Program (which are reiterated and
20 enforced by the Attestations), the result is the submission of and/or failure to delete false
21 diagnostic data and, thus, the submission of false Attestations that the data is accurate
22 and truthful. When MA Organizations do this by deliberately ignoring or recklessly
23 disregarding information about invalid diagnoses and, thus fail to delete invalid
24 diagnoses, as Defendants here have done, they are unable to represent that their data is
25 accurate, complete, and truthful, as the Attestations require. Moreover, in that situation,
26 their Attestations are “knowingly” false, as the term knowingly is defined in the FCA.

27 337. The Risk Adjustment Attestation itself includes language warning about the
28 serious legal implications of making false representations about diagnoses. It states that

1 “[t]he MA Organization acknowledges . . . that misrepresentations to CMS about the
2 accuracy of such [risk adjustment] information may result in Federal civil action and/or
3 criminal prosecution.” See Exhibits 15-21. Risk adjustment Attestations thus are
4 intended to serve as a powerful deterrent against an MA Organization’s “knowingly”
5 submitting false claims for payment. *United States ex rel. Swoben v. UnitedHealthcare*
6 *Insurance Co. et al.*, 848 F.3d 1161, 1168 (9th Cir. 2016) (characterizing certifications
7 “[a]s a further bulwark against fraud”).

8 338. Defendants’ knowledge of the importance of the Attestations is demonstrated by
9 the footnotes that UnitedHealthcare and other UHG Managing Defendants added to the
10 Attestations they submitted on behalf of the Defendant MA Organizations, such as the
11 footnotes that stated the Attestations should not be construed as representations that the
12 data may not require subsequent modification should additional information become
13 available. See Exhibits 15-20. According to Dumcum, UnitedHealthcare’s counsel
14 added these footnotes.

15 339. Defendants’ knowledge of the importance of the Attestations is also demonstrated
16 by the meeting they requested with CMS in April 2014. As previously explained, on
17 April 29, 2014, Steve Hemsley, Defendant UHG’s Chief Executive Officer, sent
18 UnitedHealthcare’s attorney Thad Johnson, UnitedHealthcare Medicare & Retirement’s
19 Chief Executive Officer Steve Nelson, UnitedHealthcare’s Chief Financial Officer
20 Daniel Schumacher, and Optum executive Karen Erickson, to meet with CMS
21 employees responsible for the MA Program, including Cheri Rice, the Director of the
22 Medicare Plan Payment Group at CMS. Defendant UHG and its subsidiaries,
23 UnitedHealthcare and Optum, asked for this meeting on very short (just a few days)
24 notice because the Chief Financial Officer of UnitedHealthcare Medicare & Retirement,
25 Brian Thompson, had to execute and submit the Risk Adjustment Attestations for the
26 Defendant MA Organizations on April 30, 2014. Defendants UHG, UnitedHealthcare
27 and Optum wanted to disclose to CMS, before the Attestations were submitted, that they
28 were in possession of information **from chart reviews** (the nature and mechanics of

1 which they did not describe in any detail) about invalid diagnoses (which were not
2 specifically identified to CMS) that they had submitted to the Government but had not
3 deleted. They apparently believed that this sort of very vague disclosure would
4 somehow render the Attestations truthful even if they did not delete the invalid diagnoses
5 from RAPS.

6 340. In addition, for many years, Jeffrey Dumcum, the senior executive overseeing all
7 risk adjustment programs and activities at Ingenix and then Optum, was also aware of
8 the FCA implications of ignoring information about invalid diagnoses. He told Poehling
9 that the Department of Justice's enforcement of the FCA was a consideration in deciding
10 to delete diagnoses when the results of blind chart reviews showed that they were
11 unsupported by the patients' medical records. In fact, Optum even decided that all of its
12 clients (its commercial clients as well as its internal client, UnitedHealthcare) had to look
13 both ways at the results of blind chart reviews and delete diagnosis codes invalidated by
14 the chart reviews if Optum was responsible for submitting risk adjustment data to CMS
15 on their behalf. This requirement was most likely imposed by Optum (at least for some
16 period of time) because Optum had to execute the internal attestations certifying the
17 accuracy and truthfulness of the diagnoses it submitted to Medicare on behalf of its
18 clients and, perhaps, it was also concerned about violating the FCA by causing its MA
19 Organization clients to submit false Attestations. Accordingly, like UHG and
20 UnitedHealthcare, Optum was aware that the Attestations required it to make deletes
21 based on information available to it about the negative results of chart reviews.

22 **FIRST CLAIM FOR RELIEF**

23 **False Claims Act: Reverse False Claims**

24 **31 U.S.C. § 3729(a)(1)(G) (formerly 31 U.S.C. § 3729(a)(7))**

25 341. The United States repeats and re-alleges the allegations contained in Paragraphs 1
26 to 340 above as though they are fully set forth herein.

27 342. Defendants violated the second part of 31 U.S.C. § 3729(a)(1)(G) as follows:
28 Defendants knowingly (as "knowingly" is defined by 31 U.S.C. § 3729(b)(1)) concealed

1 or knowingly and improperly avoided or decreased an obligation to pay or transmit
2 money or property to the Government. Specifically, Defendants knowingly concealed or
3 knowingly and improperly avoided or decreased an obligation to repay risk adjustment
4 payments to which they were not entitled from the Medicare Program. In particular,
5 Defendants knowingly and improperly failed to delete in the RAPS system the invalid
6 diagnoses that had been submitted to the Medicare Program for risk adjustment
7 payments which were made by the Medicare Program to them or knowingly and
8 improperly failed to otherwise return to the Medicare Program the overpayments based
9 on the invalid diagnoses.

10 343. By virtue of the said acts of concealment and/or improper avoidance, the United
11 States incurred damages and therefore is entitled to multiple damages under the False
12 Claims Act, plus a civil penalty for each violation of the Act.

13 **SECOND CLAIM FOR RELIEF**

14 **False Claims Act: Presentation of False or Fraudulent Claims**

15 **31 U.S.C. § 3729(a)(1)(A) (formerly 31 U.S.C. § 3729(a)(1))**

16 344. The United States repeats and re-alleges the allegations contained in Paragraphs 1
17 to 340 above as though they are fully set forth herein.

18 345. Defendants violated 31 U.S.C. § 3729(a)(1)(A) as follows: Defendants knowingly
19 (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) presented or caused to be
20 presented a false or fraudulent claim for payment or approval. Specifically, Defendants
21 knowingly presented or caused to be presented to the Medicare Program a false or
22 fraudulent Risk Adjustment Attestation claiming risk adjustment payments from the
23 Medicare Program.

24 346. Defendants violated former 31 U.S.C. § 3729(a)(1) as follows: Defendants
25 knowingly presented, or caused to be presented, to the Government a false or fraudulent
26 claim for payment or approval. Specifically, Defendants knowingly presented or caused
27 to be presented to the Medicare Program a false or fraudulent Risk Adjustment
28 Attestation claiming risk adjustment payments from the Medicare Program.

347. By virtue of the said false or fraudulent claim, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

THIRD CLAIM FOR RELIEF

False Claims Act: Making or Using False Records or Statements

31 U.S.C. § 3729(a)(1)(B) (formerly 31 U.S.C. § 3729(a)(2))

348. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

349. Defendants violated 31 U.S.C. § 3729(a)(1)(B) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation material to a false or fraudulent claim for risk adjustment payments from the Medicare Program.

350. Defendants violated former 31 U.S.C. § 3729(a)(2) as follows: Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation to get a false or fraudulent claim for risk adjustment payments paid or approved by the Medicare Program.

351. By virtue of the said false record or statement, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

FOURTH CLAIM FOR RELIEF

False Claims Act: Reverse False Claims

31 U.S.C. § 3729(a)(1)(G) (formerly 31 U.S.C. § 3729(a)(7))

352. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

353. Defendants violated the first part of 31 U.S.C. § 3729(a)(1)(G) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government. Specifically, Defendants knowingly made, used, or caused to be made or used a false Risk Adjustment Attestation material to an obligation to repay risk adjustment payments to which they were not entitled from the Medicare Program.

354. Defendants also violated former 31 U.S.C. § 3729(a)(7) as follows: Defendants knowingly (as “knowingly” is defined by 31 U.S.C. § 3729(b)(1)) made, used, or caused to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government. Specifically, Defendants knowingly made, used, or caused to be made or used, a false Risk Adjustment Attestation to conceal, avoid or decrease an obligation to repay risk adjustment payments to which they were not entitled from the Medicare Program.

355. By virtue of the said false record, statement, and other acts of concealment and improper avoidance, the United States incurred damages and therefore is entitled to multiple damages under the False Claims Act, plus a civil penalty for each violation of the Act.

FIFTH CLAIM FOR RELIEF

Unjust Enrichment

356. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

357. Defendants have received money from the United States to which Defendants were not entitled, which unjustly enriched Defendants, and for which Defendants must make restitution. Defendants received such money by claiming and retaining Medicare risk adjustment payments based on invalid risk adjustment data. In equity and good conscience, such money belongs to the United States and to the Medicare Program.

358. The United States is entitled to recover such money from Defendants in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF

Payment by Mistake

359. The United States repeats and re-alleges the allegations contained in Paragraphs 1 to 340 above as though they are fully set forth herein.

360. The United States paid money to Defendants as a result of a mistaken understanding. Specifically, the United States paid Defendants claims for risk adjustment payments under the mistaken understanding that such claims were based on valid risk adjustment data. Had the United States known the truth, it would not have paid such claims. Payment was therefore by mistake.

361. As a result of such mistaken payments, the United States has sustained damages for which Defendants are liable in the amount to be determined at trial.

PRAYER

WHEREFORE, the United States requests that judgment be entered in its favor and against Defendants as follows:

362. On Claims I, II, III, and IV (False Claims Act), against all Defendants jointly and severally, for the amount of the United States' damages, trebled as required by law, together with the maximum civil penalties allowed by law, costs, post-judgment interest, and such other and further relief as the Court may deem appropriate;

363. On Claim V (Unjust Enrichment), against all Defendants jointly and severally, for an amount equal to the monies that Defendants obtained from the United States without right and by which Defendants have been unjustly enriched, plus costs, pre- and post-judgment interest, and such other and further relief as the Court may deem appropriate; and

364. On Claim VI (Payment By Mistake), against Defendants for an amount equal to the United States' damages, plus costs, pre- and post-judgment interest, and such other and further relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States of America hereby demands a trial by jury.

Dated: November 17, 2017

Respectfully submitted,

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EXHIBIT P-48

ICD-10-CM Official Guidelines for Coding and Reporting

FY 2022 -- UPDATED April 1, 2022

(October 1, 2021 - September 30, 2022)

Narrative changes appear in bold text

Items underlined have been moved within the guidelines since the FY 2021 version
***Italics* are used to indicate revisions to heading changes**

The Centers for Medicare and Medicaid Services (CMS) and the National Center for Health Statistics (NCHS), two departments within the U.S. Federal Government's Department of Health and Human Services (DHHS) provide the following guidelines for coding and reporting using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). These guidelines should be used as a companion document to the official version of the ICD-10-CM as published on the NCHS website. The ICD-10-CM is a morbidity classification published by the United States for classifying diagnoses and reason for visits in all health care settings. The ICD-10-CM is based on the ICD-10, the statistical classification of disease published by the World Health Organization (WHO).

These guidelines have been approved by the four organizations that make up the Cooperating Parties for the ICD-10-CM: the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), CMS, and NCHS.

These guidelines are a set of rules that have been developed to accompany and complement the official conventions and instructions provided within the ICD-10-CM itself. The instructions and conventions of the classification take precedence over guidelines. These guidelines are based on the coding and sequencing instructions in the Tabular List and Alphabetic Index of ICD-10-CM, but provide additional instruction. Adherence to these guidelines when assigning ICD-10-CM diagnosis codes is required under the Health Insurance Portability and Accountability Act (HIPAA). The diagnosis codes (Tabular List and Alphabetic Index) have been adopted under HIPAA for all healthcare settings. A joint effort between the healthcare provider and the coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. These guidelines have been developed to assist both the healthcare provider and the coder in identifying those diagnoses that are to be reported. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved. The entire record should be reviewed to determine the specific reason for the encounter and the conditions treated.

The term encounter is used for all settings, including hospital admissions. In the context of these guidelines, the term provider is used throughout the guidelines to mean physician or any qualified health care practitioner who is legally accountable for establishing the patient's diagnosis. Only this set of guidelines, approved by the Cooperating Parties, is official.

The guidelines are organized into sections. Section I includes the structure and conventions of the classification and general guidelines that apply to the entire classification, and chapter-specific guidelines that correspond to the chapters as they are arranged in the classification. Section II includes guidelines for selection of principal diagnosis for non-outpatient settings. Section III includes guidelines for reporting additional diagnoses in non-outpatient settings. Section IV is for outpatient coding and reporting. It is necessary to review all sections of the guidelines to fully understand all of the rules and instructions needed to code properly.

EXHIBIT

15871

EXHIBIT P-49


[\(https://www.aapc.com/\)](https://www.aapc.com/)
[What's New \(https://www.aapc.com/about-us/whats-new/\)](https://www.aapc.com/about-us/whats-new/) |
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Coding Compass

Because so many factors weigh into the answer, it depends.

By Robert A. Pelaia, Esq., CPC, CPCO

Every year at AAPC's national conference, several members of AAPC's Legal Advisory Board present an open forum session to respond to a wide variety of questions from attendees. For the past few years, without fail, audience members have asked for guidance on medical record entry timeliness and reasonable record keeping. This is not an easy topic and there is no one answer that will apply to the many scenarios coders encounter.

In 2006, however, useful and practical guidance regarding medical record documentation was released by the medical director of First Coast Service Options, Inc. (FCSO). The current Medicare administrative contractor for Puerto Rico, the U.S. Virgin Islands, and Florida also has recently issued helpful information regarding this. In addition to several other issues, FCSO's medical director touched upon the overall timeliness of documentation, medical record addenda, legibility, and "cloning." Here are selected excerpts in regards to timeliness from the FCSO memo (http://medicare.fcso.com/Publications_B/2006/141067.pdf) (see pages 3-6), followed by practical compliance tips that apply to each issue raised.

Medicare Comment No. 1

"Medicare expects the documentation to be generated at the time of service or shortly thereafter. Delayed entries within a reasonable time frame (24 to 48 hours) are acceptable for purposes of clarification, error correction, the addition of information not initially available, and if certain unusual circumstances prevented the generation of the note at the time of service."

Compliance Tips: Medicare has clearly stated that “reasonable” means 24 to 48 hours. Understand that anything beyond 48 hours could be considered unreasonable. Providers should comply with this requirement and complete documentation in a timely manner. Those responsible for coding and/or entering charges need to be cognizant of the timeliness of medical record completion. It’s unreasonable to expect a provider to recall the specifics of a service two weeks after the service was rendered. Nor should an entry be made in advance.

Medicare Comment No. 2

"The medical record cannot be altered. Errors must be legibly corrected so that the reviewer can draw an inference as to their origin. These corrections or additions must be dated, preferably timed, and legibly signed or initialed."

Compliance Tips: To properly execute a medical record addendum, the provider must, at a minimum, write the following details in the medical record:



(<https://www.aapc.com/medical-coding-education/webinars/selection-of-principal-diagnosis-for->

inpatient-admission)

EXHIBIT
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- The date the record is being amended

(<https://cta-redirect.hubspot.com/cta/redirect/2072848/24bd00b5-f062-4000-b010-280000000000>)

The details of the amended information

- A statement that the entry is an addendum to the medical record (An addendum should not be added to the medical record without identifying it as such.)

(<https://www.aapc.com>)

What's New (<https://www.aapc.com/about-us/whats-new>) | About Us (<https://www.aapc.com/about-us/>) | Support (<https://www.aapc.com/support>)

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Sign In (<https://www.aapc.com/sso-landing/loginAzure.aspx?action=signin>)

Sign Up (<https://www.aapc.com/sso-landing/loginAzure.aspx?action=signup>)

- The signature of the provider writing the addendum

/seal

The medical record should be amended within a reasonable time that would allow the service provider to recall the specific details of the patient encounter. Medical record addenda should be an exception, rather than a routine or recurring part of medical record documentation. Medical record addenda must be properly identified and reference must be made to the original note being amended. Failure to properly amend the medical record may give the appearance of "falsifying documentation," which is considered fraudulent.

Medicare Comment No. 3

"Every note must stand alone, i.e., the performed services must be documented at the outset. Delayed written explanations will be considered. They serve for clarification only and cannot be used to add and authenticate services billed and not documented at the time of service or to retrospectively substantiate medical necessity. For that, the medical record must stand on its own with the original entry corroborating that the service was rendered and was medically necessary."

Compliance Tips: Again, addenda to the medical record should not be a normal practice—these should be the exception and not the rule. Coders responsible for reviewing documentation should be cognizant of providers who demonstrate patterns of insufficient documentation that necessitate addenda. It's also important to remember that medical record addenda need to be made to the original medical record, not just to the billing copy.

Medicare Comment No. 4

"All entries must be legible to another reader to a degree that a meaningful review may be conducted. All notes should be dated, preferably timed, and signed by the author."

Compliance Tips: Legibility of medical record documentation is not just a billing issue; it's a patient care issue. Illegible documentation may result in medication errors and incorrect diagnoses being assigned to the patient. The medical record must be legible to an individual who is not familiar with the provider's handwriting. Notes should be timed and dated appropriately, as well. The timing of a medical record note is especially important in inpatient charts, emergency department settings, trauma settings, and critical care units. It's especially critical for the service provider's identity to be legible. Signatures also should include the provider's credentials.

Medicare Comment No. 5

"Documentation is considered cloned when each entry in the medical record for a patient is worded exactly alike or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from patient to patient. It would not be expected that every patient had the exact same problem, symptoms, and required the exact same treatment."

"Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information. All documentation in the medical record must be specific to the patient and her/his situation at the time of the encounter. Cloning of documentation is considered a misrepresentation of the medical necessity requirement for coverage of services. Identification of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made."

Compliance Tips: Templates certainly are useful tools, but providers must use caution when applying “templated” language. Specifically, (although it may seem obvious) providers must ensure that what is being represented in the medical record actually took place and isn’t something the provider normally does, but may not have done for that particular patient.

Robert A. Pelaia, Esq., CPC, CPCO, is senior university counsel for health affairs at the University of Florida College of Medicine in Jacksonville, Fla. He is certified as a Health Care Law Specialist by the Florida Bar Board of Legal Specialization and Education, serves on AAPC's Legal Advisory Board, and was a 2011-2013 AAPC National Advisory Board member. Pelaia is a member of the Jacksonville River City, Fla., local chapter.

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No Responses to “Medical Record Entries: What Is Timely and Reasonable?”

Angie says:
January 7, 2015 at 11:12 pm (https://www.aapc.com/blog/25667-medical-record-entries-what-is-timely-and-reasonable/#comment-4981)

Thank you thank you THANK YOU for the straightforward and direct answer to this question that so many medical professionals are asking. There are many articles out there that touch on this, but this article is the first that is thorough and understandable, using direct Medicare standards and regulations. I appreciate the use of excerpts to verify and support each point. Thank you again!
Angie Cox- SLP

Denise Ladd says:
June 1, 2017 at 12:29 pm (https://www.aapc.com/blog/25667-medical-record-entries-what-is-timely-and-reasonable/#comment-4982)

The information I have spent most of the afternoon searching for I found on your site.
Thank you!

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EXHIBIT P-50

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.

BENJAMIN POEHLING,

Plaintiffs,

v.

UNITEDHEALTH GROUP, INC., et al.,

Defendants

EXPERT REPORT OF JEAN ACEVEDO

SEPTEMBER 29, 2023

Amended April 5, 2024

I. QUALIFICATIONS

1. I am a Certified Professional Coder (“CPC”) and Certified ENT Coder (“CENTC,” i.e., coding focused on ear, nose, and throat conditions), and have been so designated since 1999 and 2008, respectively, through the American Academy of Professional Coders (“AAPC”).¹ I achieved AAPC Fellow status in January 2017, which indicates that I have been recognized for my professional achievements in coding and continuous adherence to the ethical and professional standards of the AAPC.² I have also held the Certified in Healthcare Compliance (“CHC”) certification from the Health Care Compliance Association (“HCCA”) since 2002.³ Additionally, I have been a health care risk manager since 1989 (currently inactive).

2. I have experience in all areas of medical coding and reimbursement, particularly with Current Procedural Terminology (“CPT”), Healthcare Common Procedure Coding System (“HCPCS”), the International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM)⁴ diagnosis coding,⁵ and third-party payer billing and payment rules, including the Centers for Medicare and Medicaid Services (“CMS”) Medicare Advantage risk adjustment program.

3. From 2007 through 2022, I developed and taught the regulatory and compliance modules of the Certificate in Medical Business Management program at Florida Atlantic University’s School of Business.

4. For the past twenty-three years, I have maintained an active healthcare consulting practice as the founder and senior consultant of Acevedo Consulting Incorporated (“ACI”). ACI assists clients in the healthcare industry in all areas concerning reimbursement, including coding

¹ *Coding Certifications*, AAPC, <https://www.aapc.com/certifications?tag=coding> (last visited Sept. 29, 2023).

² *AAPC Fellow Application Process*, AAPC, <https://www.aapc.com/recognition/aapc-fellow.aspx> (last visited Sept. 29, 2023) (“Fellows are highly experienced in their position within the business of healthcare. This status indicates your professional achievement and continuous adherence to the ethical and professional standards of AAPC. Fellowship is earned through hard work, written demonstration of your professional expertise, and regular commitment to dedicated leadership in the healthcare community.”).

³ *Certified in Healthcare Compliance (CHC)*, HCCA, <https://www.hcca-info.org/certification/become-certified/chc> (last visited Sept. 29, 2023).

⁴ For purposes of this report, I use the term “ICD-9” to refer to “ICD-9-CM” and “ICD-10” to refer to “ICD-10-CM,” respectively. Furthermore, I use the term “ICD” to refer both to ICD-9 and ICD-10.

⁵ See *ICD-10, ICD-10-CM, & ICD-10-PCS*, University of Kansas Medical Center, <https://guides.library.kumc.edu/icd10> (last visited Sept. 29, 2023).

and medical records review. The firm's clients span the gamut of the United States' healthcare system, from large Medicare Advantage Organizations ("MAOs") to small private health insurers, small physician practices to large healthcare systems, and the federal government.

5. I have provided education on ICD coding rules to large and small physician organizations, Accountable Care Organizations ("ACOs"), and a national MAO. I have also advised physician practice groups on accuracy and compliance with the coding and Medicare Advantage risk adjustment rules on a proactive basis as well as assisting them through risk adjustment audits by any one of the Medicare contractors. I have had a longstanding contract with a large Program of All-Inclusive Care for the Elderly ("PACE") to provide documentation and education on ICD-10 coding, and to provide monthly quality reviews and feedback on the accuracy and completeness of the providers' documentation.

6. A copy of my Curriculum Vitae, including a list of all publications I have authored, is attached as **Appendix A**. A list of my prior testimony is attached as **Appendix B**.

II. COMPENSATION

7. My contract with the United States Department of Justice is on an hourly basis. For my work on this case, I am being compensated at my standard billing rate of \$325.00 per hour for guidance and development of my report. My rate for testifying at a deposition or appearing at any proceeding is \$468.75 per hour. My compensation is not contingent on the content of my opinions or the outcome of this matter.

III. SCOPE OF ASSIGNMENT

8. I have been engaged by the Plaintiffs to provide expert testimony in this matter. Specifically, I have been asked to provide background on medical record coding, including ICD-9 and ICD-10 diagnosis coding, and its relationship to the Hierarchical Condition Categories ("HCCs") used in the Medicare Advantage risk adjustment program. I have also been asked to provide expert testimony on the following topics: (1) the documentation standards required in risk adjustment coding; (2) the standards and guidelines governing medical record coding; and (3) industry best practices for achieving accurate and complete coding in the Medicare Advantage context. The relevant time period for my report covers dates of service in 2008 through 2016.

9. I reserve the right to supplement or revise my opinions should additional information become available.

IV. BASIS FOR OPINIONS

10. I have reviewed publicly-available materials for the relevant time period, including the ICD-9 official Coding Guidelines applicable during the 2008–2014 dates-of-service years and the ICD-10 official Coding Guidelines applicable during the 2015–2016 dates-of-service years; the CMS 2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide (“2008 Participant Guide”); the CMS Medicare Managed Care Manual, Chapter 7 – Risk Adjustment; and various publications regarding coding. I have also reviewed deposition transcripts from this case. A complete list of the materials that I have relied upon as a basis for my opinions rendered in this report is attached as **Appendix C**.

V. BACKGROUND

A. Introduction to Medical Record Coding

11. When an individual goes to a doctor’s office, an urgent care center, hospital, or other health care facility, the physician or other provider documents one or more of the following in the patient’s medical record: the patient’s complaint and related history, a physical examination, and the assessment/impression and plan. In determining whether to pay for a healthcare service, the patient’s insurance company or other payer generally requires information on what was done to the patient (i.e., the medical service provided), and why. There are industry-standard medical “codes” used to report “what was done” and “why” on claims made to insurance companies. These codes ensure that all healthcare providers are speaking the same language when submitting a claim for payment.

12. While the American Medical Association has created Current Procedural Terminology (“CPT”) codes to describe “what was done” (e.g., an office visit, an ultrasound, a blood draw, etc.), ICD diagnosis codes tell the insurer “why”—i.e., what health condition the medical service addresses. ICD diagnosis codes designate diseases, symptoms, abnormal findings, and other elements of the patient’s diagnosis. For example, when a physician sees a patient for a new patient office visit, the CPT code may be 99204, which represents the service provided. If the medical record appropriately documents that the patient exhibits symptoms of

diabetes and that blood tests confirm that the patient has diabetes mellitus, the proper ICD-10-CM code is E11.9, which represents the diagnosis.

13. When insurance payment is on a “fee-for-service” basis, the physician is paid based on the specific CPT code submitted for the office visit, and the payment amount is the same regardless of how sick the patient is. Continuing the example from paragraph 12, the physician would be paid based on CPT code 99204 (new patient office visit), regardless of the patient’s confirmed diabetes mellitus diagnosis (E11.9). The ICD code does not impact the payment.

14. By contrast, in the Medicare Advantage program discussed further below, the reported ICD codes are relevant because payment is on a “risk adjusted” basis. This means that CMS pays MAOs a monthly amount per beneficiary based on the risk profile of that beneficiary. Generally, the sicker a beneficiary is, the higher the payment. The risk adjustment system sets the monthly payment amount by estimating the healthcare expenditures a patient is likely to require in a given year, based in part on the health status of the patient, which in turn is based on the Hierarchical Condition Categories (“HCCs”) reported for that patient. As explained below, ICD codes underlie HCCs, and therefore, may impact payment in this system.

B. ICD-9 and ICD-10 Coding

15. The International Classification of Diseases is a medical classification system maintained by the World Health Organization (“WHO”) and used worldwide for health management and clinical purposes. WHO issues new revisions of the ICD periodically.

16. At the beginning of the relevant time period, ICD-9 was the operative classification system. There were approximately 14,000 ICD-9 diagnosis codes. When the United States Department of Health and Human Services switched to ICD-10 in 2015, that number rose to almost 70,000, because ICD-10 allows for greater specificity and more granularity in describing a patient’s condition, variants of that condition, or complications present with certain conditions.⁶

⁶ *International Classification of Diseases, (ICD-10-CM/PCS) Transition - Background*, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm (last visited Sept. 29, 2023).

17. Depending on the date-of-service year in the relevant time period, the authoritative source for diagnosis coding is the ICD-9 or ICD-10 Coding Guidelines published by the Centers for Disease Control and Prevention (CDC).⁷ There are a number of additional sources that explain coding rules and guidelines that must be followed for proper reporting of diagnoses. These additional sources include coding guidelines, manuals, and training published by CMS.⁸ Organizations such as hospitals and MAOs also subscribe to the American Hospital Association's "Coding Clinic," another recognized source for ICD-9 and ICD-10 guidance.

18. There are two recognized organizations that certify professional coders, the AAPC and American Health Information Management Association ("AHIMA"). The main credential provided by the AAPC is the CPC (Certified Professional Coder) and the main credential provided by AHIMA is the CCS (Clinical Coding Specialist).⁹

19. Coding certification from either the AAPC or AHIMA requires following the AAPC and AHIMA's guidelines for ethical coding.¹⁰

C. ICD Coding and Reporting Process

20. In the Medicare Advantage context, both ICD and CMS have set out rules on the provider documentation (and content of that documentation) needed to assign and report particular ICD codes on insurance claims. Historically, before this process became electronic, physicians handwrote notes in patient charts, the billing staff looked up the applicable diagnosis code(s) supported by notes in patient charts in an ICD code book, and then the staff would report the assigned ICD codes on a claim submitted for payment.

21. With the adoption of electronic medical records (EMRs) beginning in 2011, it has become increasingly common for physicians to select the ICD-9 or ICD-10 code(s) as they

⁷ *International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM)*, Centers for Disease Control and Prevention, <https://www.cdc.gov/nchs/icd/icd-10-cm.htm> (last visited Sept. 29, 2023); *ICD-9-CM Addenda, Conversion Table, and Guidelines*, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/icd/icd9cm_addenda_guidelines.htm (last visited Sept. 29, 2023).

⁸ See, e.g., *ICD-10 Resources*, Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-resources> (last visited Sept. 29, 2023).

⁹ See *Certified Professional Coder (CPC) Certification*, AAPC, <https://www.aapc.com/certifications/cpc> (last visited Sept. 29, 2023); *Certified Coding Specialist (CCS)*, AHIMA, <https://www.ahima.org/certification-careers/certification-exams/ccs/> (last visited Sept. 29, 2023).

¹⁰ See *Code of Ethics*, AAPC, <https://www.aapc.com/about-us/code-of-ethics> (last visited Sept. 29, 2023); *Ethics*, AHIMA, <https://www.ahima.org/who-we-are/governance/ethics/> (last visited Sept. 29, 2023).

complete their notes in the EMR system. This is especially true in an outpatient office or clinic setting. As a physician starts to type “diabetes” in the section of the note where diagnoses are listed, the EMR presents a list of possible ICD codes. For example, if the patient has Type 2 diabetes mellitus without complications, the physician should select E11.9 as the corresponding ICD-10 code. Billing staff may verify that the physician selected the correct code(s) and then include them on an insurance claim. In hospital settings, which tend to have more resources than the typical outpatient provider’s office, dedicated coders may look at the appropriate sections of medical charts and, following the applicable payer rules for the type of medical facility, report diagnosis codes on the insurance claim.

D. Medicare Advantage Program

22. The federal government’s Medicare program provides health insurance for people ages 65 or older as well as younger individuals with certain disabilities.¹¹ Medicare beneficiaries have the option to enroll in “Traditional Medicare” or “Medicare Advantage.” Medicare Advantage beneficiaries enroll in plans administered by private insurance companies known as “Medicare Advantage Organizations,” or “MAOs.”¹²

23. CMS enters into annual contracts with MAOs that participate in the Medicare Advantage program and imposes numerous requirements on the MAOs pursuant to statutes, regulations, guidance materials, and through the contracts.¹³

Risk Scores Under the CMS-HCC Risk Adjustment Model

24. In the Medicare Advantage program, CMS pays MAOs a monthly premium for each beneficiary enrolled in the MAOs’ plans.¹⁴ The amount of payment depends in part on the beneficiary’s “risk score,” which is calculated using the CMS Hierarchical Condition Category (“HCC”) Risk Adjustment Model.¹⁵

25. Each beneficiary’s risk score is newly calculated each payment year based on health conditions documented in the beneficiary’s medical records during the prior year (referred

¹¹ 42 U.S.C. § 426 *et seq.*; 42 C.F.R. § 406.5; 42 C.F.R. §§ 406.10–406.13.

¹² 42 U.S.C. § 1395w *et seq.*; 42 C.F.R. § 422 *et seq.*

¹³ 42 U.S.C. § 1395w *et seq.*; 42 C.F.R. § 422 *et seq.*

¹⁴ 42 U.S.C. § 1395w-23(a)(1)(A); 42 C.F.R. § 422 *et seq.*

¹⁵ 42 U.S.C. § 1395w-23(a)(1)(C); 42 C.F.R. §§ 422.300–422.308.

to as the “service year” or “date-of-service” (“DOS”) year). For example, a beneficiary’s risk score for payment year 2016 is based on conditions documented in that beneficiary’s medical records during encounters that took place in 2015, but that risk score would not reflect conditions documented in that beneficiary’s medical records during encounters in 2014 or in 2016.

26. The purpose of these individualized risk scores is to capture anticipated differences in the costs of coverage for beneficiaries given differences in their health status and demographic background.¹⁶ Thus, the risk score is calculated based on both the health status of the beneficiary and demographic factors (e.g., a patient’s gender and age, disability status, institutional status).¹⁷

Hierarchical Condition Categories (HCCs)

27. The health status component of the risk score is based on the HCCs or Hierarchical Condition Categories reported for the beneficiary. CMS groups ICD-9/ICD-10 diagnosis codes with other clinically similar diagnosis codes.¹⁸ These diagnosis code groupings are in turn grouped into “condition categories.”¹⁹ Similar “condition categories” are organized hierarchically based on severity of the condition and cost implications, such that the most severe and costly condition category is at the “top” of the hierarchy.²⁰ Once hierarchically organized, these condition categories become HCCs.

28. This hierarchical organization ensures a beneficiary’s risk score will incorporate only the HCC that represents the most severe and costly manifestation of a disease documented in a given year. For example, if claims data shows a patient has both diabetes without complications (ICD-10 code E11.9, HCC 19), and diabetes with acute complications (ICD-10 code E11.8, HCC 18), only HCC 18 is used in computing the patient’s risk score, as it is the more severe form of diabetes.

¹⁶ See Medicare Managed Care Manual, Ch. 7, § 20 (June 7, 2013) (“Risk adjustment allows CMS to pay plans for the risk of the beneficiaries they enroll, instead of an average amount for Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs Risk scores measure individual beneficiaries’ relative risk and risk scores are used to adjust payments for each beneficiary’s expected expenditures.”).

¹⁷ See *id.* § 70 (“Risk scores are used to adjust payments and bids based on the health status (diagnostic data) and demographic characteristics (such as age and gender) of an enrollee.”).

¹⁸ *Id.* § 70.1.

¹⁹ *Id.*

²⁰ *Id.*

29. Each year, CMS determines the groupings of diagnosis codes that “map” to a given HCC.²¹ If a beneficiary has a condition corresponding to a diagnosis code that maps to an HCC, that HCC will be incorporated into the calculation of the beneficiary’s risk score. For example, under the current CMS-HCC Risk Adjustment Model, of the approximately 70,000 total ICD-10 codes, over 9,700 of those codes map to one or more of the 86 HCCs in the model.²²

30. Multiple ICD codes can map to the same HCC. ICD-10 codes each contain up to 7 characters. Although slight variations in the last characters in the code string leads to distinct ICD-10 codes, these distinct ICD-10 codes may still map to the same HCC. For example:

- a. E11.10 (Type 2 diabetes mellitus with ketoacidosis without coma) and E11.11 (Type 2 diabetes mellitus with ketoacidosis with coma) both map to HCC 17 (diabetes with acute complications).
- b. M35.00 (Sjögren syndrome, unspecified) and M35.3 (Polymyalgia rheumatica) both map to HCC 40 (Rheumatoid arthritis and inflammatory connective tissue disease).

31. However, certain diagnosis codes indicating historical conditions or potential risk for future conditions may be documented in the patient’s medical record and assigned an ICD code, but they would not map to an HCC. For example:

- a. If an individual is diagnosed with thyroid cancer, it is appropriate to assign the ICD-10 code C73 (malignant neoplasm of the thyroid gland). After the thyroid is removed, if the patient is asymptomatic and no further treatment is being provided, then Z85.850 (personal history of malignant neoplasm of thyroid) is the proper ICD-10 code to report.
- b. If a patient’s blood sugar has been elevated on lab tests, but there is not enough information to diagnose the patient with diabetes mellitus, the proper code to report in this situation is a code for abnormal glucose (R73.09), rather than E11.9 (diabetes mellitus without complications).

²¹ Not all ICD-9/ICD-10 diagnosis codes map to an HCC included in the CMS-HCC Risk Adjustment Model, and therefore not all ICD-9/ICD-10 diagnosis codes affect risk adjustment payments.

²² Amerigroup, *CMS-HCC Risk Adjustment Model (V24), ICD-10-CM to CMS-HCC Crosswalk*, https://provider.amerigroup.com/dam/publicdocuments/ALL_CARE_CMSHCCRAModel_mrdcoding_tip_s.pdf (last visited Sept. 29, 2023).

32. Where a patient has several diseases corresponding to several HCCs, the risk adjustment model allows those multiple HCCs to be assigned and accounted for in the risk score. The number of HCCs reported and the severity of the HCCs tend to increase the risk score. Thus, a 72-year-old male with COPD, diabetes mellitus, and coronary artery disease would have a higher risk score than a 72-year-old male with diabetes mellitus only.

Medical Record Documentation to Support HCCs Under CMS Rules

33. During the relevant time period, CMS had specific rules governing the submission of diagnosis codes for inclusion in the HCC risk adjustment model. HCC coding requires clinical support in medical record documentation.

34. As explained in the 2008 Participant Guide, CMS requires that diagnosis codes submitted for risk adjustment result from a face-to-face encounter between a beneficiary and a provider of a qualifying physician specialty.²³ In addition, the medical record for a particular encounter used as the basis for submission of a diagnosis code must be signed and include the provider's credentials.²⁴

35. In addition, both the ICD guidelines and CMS specify that all conditions reported should be based on documentation showing that conditions exist at the time of the encounter/visit and "require or affect patient care, treatment or management."²⁵

36. Importantly, regulations and official CMS publications require all diagnosis codes submitted by MAOs to be documented in the medical record, and ICD Coding Guidelines must be followed for coding and reporting.²⁶ For example, the Medicare Managed Care Manual, Chapter 7 states that MAOs must:

²³ 2008 Participant Guide, § 7.2.4.2; *see also id.* Table 3H (setting forth acceptable physician specialties, which include physicians and other qualified healthcare providers, such as nurse practitioners and physician assistants).

²⁴ *Id.* § 7.2.4.2 ("For purposes of risk adjustment data submission and validation, the MA organizations must ensure that the provider of service for face-to-face encounters is appropriately identified on medical records via their signature and physician specialty credentials.").

²⁵ ICD-9, § IV.K (effective Oct. 1, 2011), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; *see also* 2008 Participant Guide, § 6.4.1.

²⁶ *See, e.g.*, 45 C.F.R. § 162.1002(a)(1)(i), (b)(1), (c)(2)(i) (establishing the ICD, including the ICD Guidelines, as the national standard for diagnosis coding); 42 C.F.R. § 422.310(d)(1) ("MA organizations

Ensure the accuracy and integrity of risk adjustment data submitted to CMS. ***All diagnosis codes submitted must be documented in the medical record*** and must be documented as a result of a face-to-face visit. The diagnosis must be coded according to International Classification of Diseases, (ICD) Clinical Modification Guidelines for Coding and Reporting.²⁷

In addition, the 2008 Participant Guide states:

Standard ICD-9-CM coding practices support the CMS-HCC model. ***In all cases, the documentation must support the code selected and substantiate that the proper coding guidelines were followed.***²⁸

OPINIONS

a. Diagnosis Codes Submitted for Risk Adjustment Must Be Supported By Documentation in the Medical Record Meeting CMS Requirements.

37. The principal requirement for assigning and reporting diagnosis codes in the Medicare Advantage risk adjustment model is that the codes are supported by appropriate medical record documentation.²⁹

38. As referenced above, the medical record cannot merely contain a list of the patient's conditions without supporting documentation showing that the conditions "require or affect patient care, treatment or management."³⁰ In the absence of such documentation, the coder cannot assign codes for listed conditions. In my experience, such documentation may include physician notes on disease progression or stabilization, patient response to the treatment, and whether test results were reviewed by the physician.

39. In sum, the diagnosis codes that MAOs submit to CMS for risk adjustment purposes must be (1) based on a face-to-face encounter; (2) by a qualified provider (either a physician or other qualified healthcare provider); (3) documented in the medical record; and (4) coded in compliance with the ICD Guidelines.³¹

must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.").

²⁷ Medicare Managed Care Manual, Ch. 7, § 40 (emphasis added).

²⁸ 2008 Participant Guide, § 6.4 (emphasis added).

²⁹ See Medicare Managed Care Manual, Ch. 7, § 40; 2008 Participant Guide, § 6.4.

³⁰ ICD-9, § IV.K (effective Oct. 1, 2011),

https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § IV.J (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>; see also 2008 Participant Guide, § 6.4.1.

³¹ 2008 Participant Guide, § 7.2.4.2.

b. Coding is Governed by Objective Standards and Guidelines.

40. It is my opinion that, if a coder is knowledgeable of the official ICD and CMS coding rules discussed above, he or she should be able to identify an objectively correct ICD code or set of ICD codes that can be reported based on a particular medical record and thus there should be little variance in code assignment among coders.

41. The coding rules are by design clear, consistent, and specific. They offer detailed instructions on what codes should be assigned based on features of a patient's condition and what is documented in the medical record. If qualified coders properly follow these rules, they are able to identify appropriate ICD codes and rule out inappropriate codes.

Coding is a Methodical Step-By-Step Process.

42. To begin, coders must follow a methodical step-by-step process in arriving at a code assignment under the ICD guidelines. The "Alphabetical Index" and "Tabular List" in both the ICD-9 and ICD-10 set out these directions.

43. The Alphabetical Index lists conditions and subvariants of conditions in alphabetical order. At the first step of coding, a coder looks up in the Alphabetical Index a condition he or she identifies that meets the medical record documentation requirements.

44. This Index supplies the initial ICD code string for that condition. For example, for Parkinson's disease with dementia a coder would look up "Parkinsonism," under which there are sub-listings of around twenty variations of "Parkinsonism," including with "dementia."³²

³²ICD-10-CM Index to Diseases and Injuries, *available at* https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/ (Table and Index zip.zip) (last visited April 5, 2024).

Parkinsonism (idiopathic) (primary) G20
 - with neurogenic orthostatic hypotension (symptomatic) G90.3
 - arteriosclerotic G21.4
 - dementia G31.83 [F02.80]
 - - with behavioral disturbance G31.83 [F02.81]
 - due to
 - - drugs NEC G21.19
 - - - neuroleptic G21.11
 - medication-induced NEC G21.19
 - neuroleptic induced G21.11
 - postencephalitic G21.3
 - secondary G21.9
 - - due to
 - - - arteriosclerosis G21.4
 - - - drugs NEC G21.19
 - - - - neuroleptic G21.11
 - - - encephalitis G21.3
 - - - external agents NEC G21.2
 - - - syphilis A52.19
 - - specified NEC G21.8
 - syphilitic A52.19
 - treatment-induced NEC G21.19
 - vascular G21.4

The index directs the coder that “Parkinson’s with Dementia without behavioral disturbance” may be coded with the ICD code strings “G20” (Parkinsonism) and “F02.80.”

Next, the coder must consult the “Tabular List” for further step-by-step instructions on the requirements to assign a code.³³ In this case, the Tabular List entry for “G20” (Parkinson’s disease) instructs the coder to: Use additional code to identify: dementia with behavioral disturbance (F02.81) dementia without behavioral disturbance (F02.80). Therefore, the proper codes for Parkinson’s with dementia without behavioral disturbance are G20 and F02.80.

³³ ICD-10-CM Tabular List of Diseases and Injuries, *available at* https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/ (Table and Index zip.zip) (last visited April 5, 2024).

G20 Parkinson's disease

Hemiparkinsonism
Idiopathic Parkinsonism or Parkinson's disease
Paralysis agitans
Parkinsonism or Parkinson's disease NOS
Primary Parkinsonism or Parkinson's disease

Use additional code to identify:

dementia with behavioral disturbance (F02.81)
dementia without behavioral disturbance (F02.80)

Excludes1: dementia with Parkinsonism (G31.83)

45. As shown above, the coding rules provide clear instructions on (1) the specific items the medical record documentation must contain to support a condition, *supra* ¶¶ 37–39, (2) how to look up a particular condition or variants of a condition in the Alphabetical Index to identify the ICD code and further requirements for assigning the code, and (3) the step-by-step process of applying those requirements to arrive at code assignment.

46. In addition, there are rules about how a coder should use these resources. For example, it is well established a coder must use the Alphabetical Index and Tabular List sequentially and follow the instructional notations in both.³⁴ Coders may never select a final code based just on what the Alphabetical Index provides. As long as the coder follows this order of operations, the instructions in the Alphabetical Index and Tabular List are consistent and will lead the coder to the proper code assignment.

Coding Rules Are Highly Specific and Particularized to Features of Patients' Conditions.

47. The ICD guidelines provide specific rules for assigning ICD codes regarding how particular features of a patient's condition should be coded. This specificity makes clear to coders under what circumstances a particular ICD code should be assigned.

48. For example, ICD-10 specifies the codes to assign when a condition occurs on the left or right side of the body, and in some cases provides a code indicating that a condition occurs on both sides of the body (bilaterally). If the medical record does not specify which side the condition occurs, the rules generally require the coder to assign the code denoting the side is

³⁴ ICD-9, § I.B.1–2 (effective Oct. 1, 2015), https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf; ICD-10, § I.A.1, § I.B.1 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

unspecified.³⁵ If, however, the condition occurs bilaterally, but there is no specific ICD code designating that the condition occurs bilaterally, the guidelines require the coder to report the ICD codes for both the right and left sides of the body separately.³⁶

49. For example, ICD-10 provides codes based on where the condition staphylococcal arthritis manifests: M00.011 (Staphylococcal arthritis, right shoulder), M00.012 (Staphylococcal arthritis, left shoulder), and M00.019 (Staphylococcal arthritis, unspecified shoulder). There is no code designating this condition as bilateral. If the medical record indicates that the patient has staphylococcal arthritis in both shoulders, the coder should report *both* M00.011 (right shoulder) and M00.012 (left shoulder) as there is no specific ICD code designating this condition as bilateral.

Difficult Coding Scenarios Do Not Indicate that Coding is a Subjective or Ambiguous Process.

50. The existence of difficult coding scenarios does not mean coding itself is a subjective process with no right answers as to whether a code is properly assigned or not. Nor do these difficult scenarios show that the coding guidelines themselves are ambiguous or fail to provide objective rules for a coder to follow.

51. Rather, difficult scenarios generally are caused by and reflect (1) the varying degrees of skill level and experience among coders; (2) errors in how those coders apply the guidelines and rules; and (3) problems extrinsic to the guidelines and the required coding process, such as problems with the medical record documentation itself. All of these issues, however, are far less likely to be present in sophisticated coding programs that use certified, well-trained coders and implement sufficient quality assurance processes to check coders' work.

52. Below, I address some potentially difficult coding scenarios, and explain why they do not demonstrate the coding process and guidelines are fundamentally subjective or ambiguous:

- a. **Updated coding guidelines:** One potential source of error during the relevant time period was coders' relative levels of experience with and training on operative coding

³⁵ ICD-10, § I.B.13 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf>.

³⁶ *Id.*

guidelines. The CDC transitioned from ICD-9 to ICD-10 in 2015. While some less-experienced coders may have erred in applying the new ICD-10 guidelines, this does not indicate that the guidelines themselves were unclear or ambiguous.

For example, as the table below shows, under ICD-10, coders are required to assign a single combination code (E11.331) where a patient has both diabetes mellitus with diabetic retinopathy. ICD-9, however, provided a different rule where these conditions were required to be coded separately (250.52, 362.05). Under the new rule, the objectively correct code is the single combination code. In my experience, coders who were unfamiliar with the operative ICD-10 rules might attempt to search for two separate codes or simply miss the combination code and apply a different diabetes code. This example does not illustrate that ICD-10 is itself ambiguous or allows for varying or inconsistent results (i.e., different diabetes code assignments) among coders. Rather, it indicates that lack of experience with the operative rules may lead to error.

ICD-9 Coding	ICD-10 Coding
250.52 – Diabetes with ophthalmic manifestations, type II or unspecified type, controlled	E11.331 – Type II diabetes mellitus with moderate non-proliferative diabetic retinopathy with macular edema
362.05 – Moderate non-proliferative diabetic retinopathy	

Notably, the coding industry attempts to provide training and other resources to address varying levels of experience on the part of coders. For example, during the transition to ICD-10, there were numerous continuing education classes that focused on educating coders on the new rules. The AAPC also required its certified members to pass a proficiency assessment on ICD-10 “format and structure, groupings and

categories of codes, ICD-10-CM official guidelines, and coding concepts.”³⁷ A major focus on my work during this time was providing trainings on ICD-10 rules, including trainings customized for specific practice groups.

- b. **Problems extrinsic to coding rules, guidelines, and resources:** Some difficult coding scenarios are due to problems extrinsic to the coding rules, for example, issues in the medical record documentation itself or its legibility. These issues do not indicate that the coding rules or process themselves are subjective, and experienced coders are trained to handle these circumstances properly.

For example, a provider might use the abbreviation “PE” in a medical record, which typically stands for “pulmonary embolism,” but may also mean “pulmonary edema” or “physical exam.” Under this circumstance, unless the coder is able to verify the meaning of the ambiguous or illegible term (e.g., via a physician query), the coder should not assume the meaning of the term and base a coding assignment on it.³⁸ Rather, a code assignment is only appropriate if based on clear and consistent medical record documentation.³⁹

53. I also reviewed the deposition transcripts of some United witnesses that discuss difficult coding scenarios. For example, United coding supervisor, Tammy Dickey, testified: “if

³⁷ See *ICD-10 Proficiency Assessment*, AAPC (Mar. 26, 2013), <https://www.aapc.com/blog/24145-icd-10-proficiency-assessment/#:~:text=The%20assessment%20will%20measure%20your,for%20other%20exams%20or%20Oassessments>.

³⁸ ICD-10 at 1 (updated Apr. 1, 2022), <https://www.cms.gov/files/document/fy-2022-icd-10-cm-coding-guidelines-updated-02012022.pdf> (stating that “The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved.”). The AHIMA Standards of Ethical Coding also provide that coders should “[a]ssign and report . . . only the codes and data that are clearly and consistently supported by health record documentation in accordance with applicable code set and abstraction conventions” and should “[q]uery and/or consult as needed with the provider for clarification and additional documentation prior to final code assignment in accordance with acceptable healthcare industry practices.” *American Health Information Management Association Standards of Ethical Coding (2016 Version)*, AHIMA (revised and approved Dec. 12, 2016), https://bok.ahima.org/doc?oid=302237#.X0-0BRNKg_U.

³⁹ *Id.*

you gave the same record to ten coders, you would probably be get [sic] five sets of answers.”⁴⁰ To the extent this example illustrates that coding is subjective and the rules lack clarity, I disagree. In my opinion, what Ms. Dickey describes does not reflect a phenomenon in ICD coding. ICD coding is highly specific and governed by a set of particularized rules. In my opinion and experience, there is not substantial variance in ICD coding among qualified coders, nor have I experienced this level of variance in my own practice.

c. There Are Well-Established Industry Best Practices For Achieving Complete and Accurate Coding.

54. In the Medicare Advantage context, there are industry best practices for achieving accurate and complete coding. In my opinion, these best practices include: (1) requiring coders to be certified; (2) providing extensive and ongoing training to the coders, including training in Medicare Advantage risk adjustment; (3) requiring coders to meet high quality standards in order to graduate from training; (4) requiring coders to maintain high quality standards after training; (5) providing coders with resources to address coding questions; (6) providing remedial training to coders who fall below the organization’s standards; (7) terminating coders who fail to perform up to the organization’s standards despite remedial training; and finally, (8) maintaining robust quality assurance processes to check the coders’ work on an ongoing basis. Issues with coding accuracy and completeness are more likely to be avoided when an organization’s policies and procedures encompass these elements.

55. Although coders approach their work with varying types of experience, the impact of these variances is limited when they are certified and provided with training that augments their prior work experience. For example, coders who have only worked on electronic medical records should be trained on coding from handwritten records and vice versa. In addition, coders should be exposed to different medical specialties during training if they had previously only worked in one specialty.

56. As discussed throughout this report, using certified coders is key in ensuring accurate and complete coding. Coders certified by the AAPC or AHIMA have had their knowledge tested by an independent body and must obtain a number of Continuing Education Credits (“CEUs”) to retain their certification. In addition, organizations participating in the

⁴⁰ Dickey Dep. 195:8–12, 220:17–23, May 24, 2022.

Medicare Advantage risk adjustment program should ensure that their coders are trained in risk adjustment coding.

Signed on April 5, 2024.

A handwritten signature in dark ink, appearing to read "Jean Acevedo". The signature is written in a cursive, flowing style.

Jean Acevedo

EXHIBIT P-51

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL ***

VIDEOCONFERENCE VIDEOTAPED DEPOSITION OF
JANET FRY

(Taken virtually)

9:02 a.m. Eastern

Thursday, June 2, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 discipline that is based on multiple --
2 multiple documentation by multiple people in
3 the medical record. So one coder may have
4 seen something in a particular note that he
5 or she felt was important to pick up whereas
6 another coder might either just decided that
7 wasn't appropriate to code at that point or
8 maybe was a historical condition that the
9 person doesn't have anymore.

10 So there's these types of decisions
11 that are made every time you open up a
12 medical record to determine whether to
13 include the condition or not.

14 BY MS. MADDUX:

15 Q. So this situation is describing a
16 scenario where the senior coder may disagree about
17 whether a medical record documentation supported a
18 diagnosis code or HCC?

19 A. Yes.

20 Q. And in addition to the reasons you just
21 gave, are there any other reasons two certified
22 coders may disagree about whether a medical record
23 documentation supports a diagnosis or HCC?

24 MS. ZUPAC: Object to form.

25 THE WITNESS: Just in general. I don't

1 have any specific examples to give you, but
2 that's just a known fact. That's why we do
3 audits, because people disagree with the
4 information that's in the medical record.

5 BY MS. MADDUX:

6 Q. In your experience working with trained
7 coders, do you think it was not uncommon for two
8 certified coders to disagree on whether or not a
9 particular diagnosis code is supported in the
10 medical record?

11 MS. ZUPAC: Object to form.

12 THE WITNESS: I can't really put a
13 percentage whether to say it's common or not
14 common. I believe I mentioned before that
15 we only saw a -- we didn't see the whole --
16 100 percent of the records did not come
17 through as discrepant. So, therefore, some
18 did, but I don't have numbers as far as
19 which ones -- what the numbers were to give
20 you.

21 BY MS. MADDUX:

22 Q. While you were the ICC, do you recall
23 senior coders raising situations with you where the
24 senior coder disagreed with a primary coder or
25 senior coder?

1 A. Yes.

2 Q. Do you know how often this occurred?

3 MS. ZUPAC: Object to form.

4 THE WITNESS: Same response. I don't
5 have a percentage or a number for you.

6 BY MS. MADDUX:

7 Q. How would you resolve the disagreement?

8 A. The case would be discussed with the
9 es- -- the -- how do I say it?

10 The -- I would review the medical
11 record and look at what both -- the notes that both
12 coders gave to say what the problem was, where were
13 they having issues, you know, why did they
14 disagree, that sort of thing. And then, again,
15 since I was kind of the -- at the top as far as the
16 buck stops here, I would -- we would make a
17 decision on the guidance that we have. I'd either
18 agree with the primary or agree with the senior.
19 We may have to bring in a physician if we wanted to
20 look at it a little further, if it was a clinical
21 issue that they were disagreeing on. But primarily
22 between discussion of the -- myself plus other
23 professional coders that were on the QA panel, we
24 could typically come up with a good decision as far
25 as what the medical record documented.

1 A. Again, if it's potentially they -- and
2 I don't even know if there were productivity
3 standards at the MRRCs. But, again, if the coder
4 felt stressed to work faster, they might forget or
5 miss a particular diagnosis, which is why we have
6 the various levels so that the next person could
7 pick it up.

8 Q. And looking at this list today, are
9 there any other factors that you can think of that
10 may contribute to coder disagreement?

11 A. No. I think it's pretty -- you know,
12 can pretty much generalize because of documentation
13 and signatures and guidance. That's pretty much
14 what the -- subjectively, what we think causes
15 differences in coding.

16 MS. MADDUX: So I think if we can go
17 off the record.

18 THE VIDEOGRAPHER: We are going off the
19 record. The time is 12:09 p.m.

20 (Recess taken from 12:09 p.m. until 12:40 p.m.)

21 THE VIDEOGRAPHER: We are back on the
22 record. The time is 12:40 p.m.

23 (Exhibit 1215 marked for
24 identification.)

25 BY MS. MADDUX:

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 6th day of June, 2022.



Christine A. Taylor, RPR
CCR-4736

EXHIBIT P-52

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 2
DEPOSITION OF CHRISTOPHER BRESETTE
As 30(b)(6) Designee 5 of
The United States

(Via Zoom Videoconference)
August 9, 2023

Reported by: John L. Harmonson, RPR
Job No. 1001591

1 was not validated but OIG ultimately determined
2 that it in fact was validated?

3 A. I'm not going to say that it did or did
4 not happen. It very well may have happened. I did
5 not study the results of the first senior coder and
6 the second senior coder.

7 Q. We can go back to that and look at some
8 specific examples to refresh your recollection.

9 A. Absolutely.

10 Q. So if the second senior coder determines
11 that the HCC that the first senior coder -- let me
12 restart that.

13 If the second senior coder determines
14 that a particular HCC is validated despite the
15 first senior coder determining that it was not
16 supported, then it escalated to a physician to
17 independently review the medical record and make a
18 final determination. Is that right?

19 A. It's mostly correct. There were
20 oftentimes where the senior coders -- I shouldn't
21 say often. There was the opportunity and there
22 were times that existed that either the first

1 senior coder or the second senior coder asked for
2 assistance with that physician reviewer to make the
3 determination.

4 There were, as you say, instances in
5 which the physician reviewer would review that. I
6 believe independently, but I don't want to say that
7 it was exclusively independently. A lot of times I
8 believe it was in consultation with the senior
9 coder to make that determination.

10 Q. So are you saying that the example that
11 I gave, that's not the only time a physician would
12 weigh in?

13 A. Correct.

14 Q. But you're not -- you're agreeing that
15 if the second senior coder found support in that
16 example, then a physician would independently
17 review the medical record to make the final
18 determination?

19 A. I would agree with that.

20 Q. Was the physician review blind as well?

21 A. No, it was not. And independently is
22 correct. So my apologies. I see "independently"

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that CHRISTOPHER BRESETTE, the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

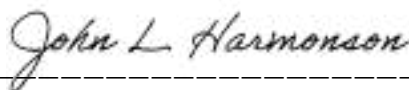
10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 11th day of August, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

EXHIBIT P-53

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	No. CV 16-08697 FMO
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et	)	
al.,	)	
	)	
Defendants.	)	
_____	)	

*** CONFIDENTIAL TRANSCRIPT WITH REDACTED ATTORNEYS' EYES
ONLY PORTIONS. REFER TO SEPARATE TRANSCRIPT ***

VIDEOTAPED VIDEOCONFERENCE ZOOM DEPOSITION OF

THOMAS KORNFIELD

March 10, 2022
10:14 a.m.
Rockville, Maryland

Magna Legal Services
(866) 624-6221
www.MagnaLS.com

Prepared by:
Marcella Daughtry, RPR, RMR
CA CSR 14315
GA No. 6595-1471-3597-5424

1 of sort of the overall level, and I don't know that I
2 fully understand all of the ways in which it would -- it
3 would work, to be honest with you. I mean, I know --
4 well, I know the way it's being discussed, which is that
5 it's, you know, an overall adjustment to the -- based on
6 the extrapolation amount.

7 But I'm sorry. I lost -- I think I'm -- I'm
8 not really answering your question. Or can you repeat
9 the question? Because I think I have --

10 Q BY MS. SCHEFFLER DO: Yeah.

11 A I have lost track of it.

12 Q Sure. No problem.

13 So my question was: Outside of RADV, do you
14 believe there is a need for an adjuster if MA Plans are
15 coding in a way that systematically differs from how
16 fee-for-service providers are coding under traditional
17 Medicare?

18 A No. I think it's only needed in a -- in a RADV
19 or overpayment context.

20 Q Okay. Can you explain --

21 A When you are extrapolating.

22 Q Can you explain to me why you think that it's
23 only necessary in the context of RADV when you are
24 extrapolating?

25 A I guess it's just a policy piece of it. I

1 mean, I think I have just had a hard time with the
2 argument that if a diagnosis code is not valid and, you
3 know, there is -- there is -- it's known that it's not
4 valid, that there shouldn't just be something taken --
5 you know, money taken back with that. And maybe some of
6 it is level of effort involved in, you know, getting to
7 a -- getting to an adjustment and applying a
8 fee-for-service adjuster outside of a -- outside of a
9 case where, you know, if you -- if you've audited -- I
10 guess, if you've audited 200 records or something --
11 something to that effect and you are taking back money
12 with those 200 records, I -- I guess I just don't know
13 that it's worth the government's time to -- and I don't
14 know that it really means a whole lot from a payment
15 perspective just in terms of dollars to -- to adjust each
16 one of those coefficients and to get to the right -- you
17 know, what the right level of payment should be with a
18 fee-for-service adjuster if we are not doing
19 extrapolation, but I don't know.

20 But with extrapolation it just feels like a
21 different argument to me, and it -- it just seemed much
22 larger in scale. From that perspective, it seems like
23 something that shouldn't be ignored. But when it's
24 not -- when it's not done in an extrapolation, it's
25 just -- and maybe this is just my own personal feeling

1 about it, about sort of thinking about, okay, and -- in
2 fairness and -- you know, and I guess impact.

3 Q So I believe you were sort of referring to
4 whether specific codes found in RADV, whether you have to
5 apply some sort of adjuster before deleting those as
6 opposed to, you know, when RADV, they -- they determined
7 that they were going to extrapolate that error rate.
8 What I was curious about is sort of just outside of RADV
9 altogether. Why would this principle of the
10 fee-for-service adjuster only be limited to the context
11 of RADV?

12 A Because I think when you're estimating a model,
13 paying on that model and not doing any adjustment, and
14 you are sort of assuming, making the same -- I don't
15 know. It's just sort of how people have talked about it,
16 I guess, that -- that when you are estimating the model,
17 it's built into the model that there are errors. There
18 may be some errors that are, you know, in the MA data in
19 some way, and you haven't corrected for that in a
20 systematic way, that you don't have to then adjust the
21 payments.

22 But if you -- the way -- the way -- the way I
23 have heard it explained is, you know, if you have a, you
24 know, audited -- a model that's on audited data and you
25 pay on audited data, that's completely on audited data,

1 but that's not exactly what's happening right now.

2 Q So I think you said a little bit ago that in an
3 ideal world you would have data -- fee-for-service data
4 that was validated, and you would base the coefficients
5 based out of that.

6 A Yeah, I mean, I should say --

7 MS. KRIEG: Object to form. Misstates prior
8 testimony.

9 THE WITNESS: Yeah, I mean, I would say if you
10 were doing an -- an adjustment, that's -- that's how it
11 would be done on the fee-for-service data.

12 Q BY MS. SCHEFFLER D0: That's not how it -- so
13 that's the ideal world, but that's not how it's being
14 done, because CMS does not audit that fee-for-service
15 data before setting the risk --

16 A Well --

17 MS. KRIEG: Object to form, compound.

18 THE WITNESS: No, I mean, I think I was just
19 thinking about how the fee-for-service adjuster should be
20 calculated, or I would think it should be calculated,
21 which is to reestimate the data, reestimate the model and
22 all the coefficients associated with the model on audited
23 data.

24 Q BY MS. SCHEFFLER D0: So going back to the clip
25 that we just watched, what did you mean by diagnosis

1 STATE OF GEORGIA)
)
2 COUNTY OF DEKALB) ss:
3

4 I HEREBY CERTIFY that the foregoing deposition
5 was taken before me; that I was then and there a
6 Registered Professional Reporter and Registered Merit
7 Reporter, License No. 6595-1471-3597-5424 for the State
8 of Georgia, and License No. 14315 in the State of
9 California; that the witness before testifying was duly
10 sworn by me to testify to the whole truth; that the
11 questions propounded by counsel and the answers of the
12 witness thereto were taken down by me in shorthand and
13 thereafter transcribed under my direction; and that the
14 foregoing pages contain a full, true, and accurate
15 transcript of all deposition testimony and proceedings
16 had, all done to the best of my skill and ability.

17 Signature requested.

18 I FURTHER CERTIFY that I am in no way related
19 to, nor employed by any of the parties hereto, nor am I
20 in any way interested in the outcome.

21 DATED at Dunwoody, Georgia, this 21st day of
22 March, 2022.

23
24
25


MARCELLA L. DAUGHTRY, RPR, RMR
GA License No. 6595-1471-3597-5424
CA CSR 14315

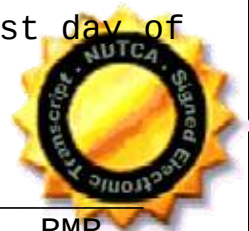


EXHIBIT P-54

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	CV 16-8697 FMO (SSx)	Date	September 10, 2021
Title	United States of America, <u>ex rel.</u> Benjamin Poehling v. United Health Group, Inc., <u>et al.</u>		

Present: The Honorable Fernando M. Olguin, United States District Judge		
Gabriela Garcia	None	None
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorney Present for Plaintiff(s):	Attorney Present for Defendant(s):	
None Present	None Present	

Proceedings: (In Chambers) Order Re: Objections to Special Master's Order

The court has reviewed and considered all the briefing filed with respect to plaintiff United States's Motion for Review of Special Master's Order Denying Without Prejudice Motion to Compel Discovery (Dkt. 422, "Motion"). The Special Master did not err in the Order of May 28, 2021 (Dkt. 419), by denying plaintiff's motion to compel discovery responses at this stage and providing plaintiff the opportunity to renew the motion at a later time. See Fed. R. Civ. Proc. 53(f). Accordingly, plaintiff's Motion (**Document No. 422**) is **denied**.

Initials of Preparer 00 : 00
gga

EXHIBIT P-55

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel. BENJAMIN POEHLING NO. CV 16-08697 FMO

VS.

UNITEDHEALTH GROUP,
INC., et al.

* * * * *

Remote Videotaped Deposition of
PAT RASMUSSEN
July 22, 2022
9:10 a.m. Eastern

Reported by Rita A. DeRouen, RPR, CRR

MAGNA LEGAL SERVICES
(866) 624-6221
www.MagnaLS.com

1 A. I think the way I could answer that is
2 that we would ensure what was submitted to us was
3 sent on to CMS. I couldn't ensure that whoever
4 put that code on the form we were looking at did a
5 correct job.

6 BY MS. GLOVER:

7 Q. Understood.

8 So you submitted data received by Optum
9 from providers and submitted that data to CMS,
10 correct?

11 A. Correct.

12 Q. And earlier we spoke about error
13 corrections.

14 Do you recall that?

15 A. Yes.

16 Q. And if you saw errors in the data that you
17 received from providers, you -- you researched and
18 corrected those errors; is that correct?

19 MS. RAMAKRISHNAN:

20 Objection; misstates prior testimony.

21 A. I -- I'm really struggling to even
22 remember what IRAD looked like. But there were
23 instances where a code might have been truncated
24 or there was a line, a box, that a number was in
25 the middle of and the system couldn't read it.

1 When I say we corrected errors, it's like
2 we might stop at something like that that was
3 thrown out by the system to reach out to the
4 provider's office to have them pull the records or
5 whatever and give us the correct code to enter.

6 BY MS. GLOVER:

7 Q. Understood.

8 And so when you would research -- when you
9 would research data errors, you would reach out to
10 the provider and ask them for the correct code; is
11 that -- am I understanding you correctly?

12 MS. RAMAKRISHNAN:

13 Objection.

14 A. That is correct.

15 THE COURT REPORTER:

16 I'm sorry, didn't heard the objection.

17 MS. RAMAKRISHNAN:

18 Objection; misstates prior testimony.

19 BY MS. GLOVER:

20 Q. And, Ms. Rasmussen, I realize you've said
21 that your role was to submit data received by
22 providers to CMS.

23 Did you also have an understanding that
24 CMS required that all diagnosis codes must be
25 documented in a medical record?

1 REPORTER'S CERTIFICATE

2 This certification is valid only for a
3 transcript accompanied by my original signature
4 and original required seal on this page.

5 I, Rita DeRouen, Certified Court Reporter in and
6 for the State of Louisiana, (CCR #2014018),
7 Registered Professional Reporter (RPR #006908), as
8 the officer before this testimony was taken
9 remotely via videoconferencing, do hereby certify
10 that PAT RASMUSSEN, having been duly sworn by me
11 upon authority of R.S. 37:2554, did testify on
12 July 22, 2022, as hereinbefore set forth in the
13 foregoing 207 pages; that this testimony was
14 reported by me in stenographic shorthand, prepared
15 and transcribed by me or under my personal
16 direction and supervision, and is a true and
17 correct transcript to the best of my ability and
18 understanding; that the transcript has been
19 prepared in compliance with transcript format
20 guidelines required by statute and rules of the
21 Board; that I am informed about the complete
22 arrangement, financial or otherwise, with the
23 person or entity making arrangements for
24 deposition services; that I have acted in
25 compliance with the prohibition on contractual

1 relationships, as defined by Louisiana Code of
2 Civil Procedure Article 1434 and in Rules and
3 Advisory Opinions of the Board; that I have no
4 actual knowledge of any prohibited employment or
5 contractual relationship, direct or indirect,
6 between a court reporting firm and any party
7 litigant in this matter, nor is there any such
8 relationship between myself and a party litigant
9 in this matter; that I am not related to counsel
10 or to any of the parties hereto, I am in no manner
11 associated with counsel for any of the interested
12 parties to this litigation, and I am in no way
13 concerned with the outcome thereof.

14 SIGNED THIS 27TH DAY OF JULY, 2022,
15 BATON ROUGE, LOUISIANA.

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21 RITA DEROUEN, CCR, RPR
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EXHIBIT P-56

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

DEPOSITION OF CAROLYN KAPUSTIJ
As 30(b)(6) Designee 6 of
The United States

Baltimore, Maryland
August 25, 2023

Reported by: John L. Harmonson, RPR
Job No. 1011736

1 Q. And why did CMS develop a methodology
2 for selecting Medicare Advantage plans for its RADV
3 audits based on an increase in -- a plan's increase
4 in coding from year to year?

5 A. I believe there was a hypothesis that an
6 increase in coding might be indicative of larger
7 probability for an error.

8 Q. So in selecting Medicare Advantage plans
9 for the 2011 to 2013 RADV audits, was it CMS's goal
10 to identify plans that were more likely to have
11 payment errors?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: I'm not sure, and none of
14 the documentation confirmed that.

15 BY MR. MARTINEZ:

16 Q. Do you have an understanding as to what
17 CMS's purpose was in designing the MA selection
18 process for the RADV audits 2011 to 2013?

19 MS. OBEREMBT: Objection; vague.

20 THE WITNESS: The objective was to get a
21 selection of contracts to audit.

22 BY MR. MARTINEZ:

23 Q. Okay. Well, you testified earlier to a
24 hypothesis that an increase in coding might be
25 indicative of a larger probability for a payment

1 error; correct?

2 A. Correct.

3 Q. So is it your understanding that CMS --
4 the reason why they were selecting plans using this
5 methodology was to try and identify plans that were
6 more likely to have higher rates of payment errors?

7 A. That was the hypothesis and that was the
8 research question. But plans were selected from
9 all three groups, high, medium and low.

10 Q. And of the 30 plans selected for each --
11 let's start with payment year 2011. How many were
12 from the high increase group?

13 A. I am going to have to look at that. I
14 do not recall offhand. I'm trying to...

15 Q. Are you searching for Tab 18 by chance?

16 A. 18 and perhaps 19. I'll start with 19.
17 And so for 2011, it was 20 from the high group,
18 five from medium, and five from low.

19 Q. So two-thirds of the plans selected for
20 payment year 2011 came from the high coding
21 increase group; is that right?

22 A. Correct.

23 Q. What about for payment year 2012? And I
24 think to help you answer that question, I've marked
25 what's in your binder as Tab 18 as Exhibit 1498.

1 prior rule had been that MA plans could submit only
2 one supporting record per HCC per enrollee. Is
3 that correct?

4 MS. OBEREMBT: Objection; outside the
5 scope.

6 THE WITNESS: To the best of my
7 recollection.

8 BY MR. MARTINEZ:

9 Q. Okay. And then CMS changed that policy
10 and, for example, payment year 2011 allowed plans
11 to submit up to five medical records to support a
12 particular HCC for a particular sampled enrollee.
13 Is that right?

14 A. Yes.

15 Q. And CMS made that change because it
16 understood that even if a particular HCC is not
17 supported by one medical record, it might be
18 supported by another; correct?

19 A. Correct.

20 Q. I want to talk now about the medical
21 record review process in some more detail.

22 So we had kind of a brief exchange
23 earlier about initial validation contractors and
24 secondary validation contractors, and I think you
25 said at one point that that wasn't really the

1 particular sampled beneficiary; correct?

2 A. No. The way it worked was they -- there
3 was a system, and the coder would receive one
4 medical record and code that record. They would
5 not receive -- I do not believe they received all
6 of an enrollee's records.

7 Q. Okay. But in the focused review
8 process, was the -- was the mandate to -- for the
9 coders involved in that process to review all of
10 the medical records that an MA plan had submitted
11 in support of HCCs for sampled enrollees?

12 A. Yeah, the focused review process
13 resulted in a review of all the medical records
14 submitted.

15 Q. And the focused review was a blind
16 review; right?

17 MS. OBEREMBT: Objection; vague.

18 THE WITNESS: Define what you mean by
19 blind.

20 BY MR. MARTINEZ:

21 Q. Well, have you seen the term "blind
22 review" in preparing for your testimony today?

23 A. I have.

24 Q. What do you understand that term to
25 mean?

1 A. It's used different ways. The way I've
2 seen it used in preparing was that the medical
3 record review contractors were blind to one
4 another's findings.

5 Q. And isn't it also true that the
6 individuals doing the focused review were blind as
7 to which HCCs the MA plan had submitted for payment
8 for a given sampled enrollee?

9 A. Based on my conversations, it was my
10 understanding that the coders did have knowledge to
11 see what is called the cover sheet which indicated
12 what HCCs were submitted for payment.

13 Q. And is it your understanding that all of
14 the coders who were doing this first-level review
15 knew which HCCs were being audited?

16 A. I believe that that was the procedure
17 that was eventually adopted.

18 Q. And in preparing to testify today, you
19 didn't review any documents that referred to the
20 blind review method as meaning the coders don't
21 know which HCCs or diagnoses are being audited?

22 A. I am not sure.

23 Q. You're not sure whether you reviewed any
24 materials that defined blind review in the way that
25 I did?

1 plan in support of the sampled enrollee?

2 A. So that record will then go forward to
3 the second coder no matter what, and the second
4 coder will have a set of findings also. So at the
5 end of the review process you have a set of
6 findings from one coder and a set of findings from
7 another coder.

8 Q. And CMS understands that sometimes one
9 of those coders might miss the HCC in the medical
10 records and yet the second coder would find it to
11 be supported; correct?

12 MS. OBEREMBT: Objection; vague.

13 THE WITNESS: I would not necessarily
14 say that the coder misses it. Working with coders,
15 there are some gray areas and some things are open
16 to interpretation. But there are circumstances
17 where one coder would find evidence for it and the
18 other coder would feel no, that that was not
19 sufficient.

20 BY MR. MARTINEZ:

21 Q. Right. Medical record review coding
22 involves gray areas; right?

23 A. Yes.

24 Q. And lots of things in medical record
25 reviews are subject to interpretation; right?

1 MS. OBEREMBT: Objection; vague.

2 THE WITNESS: Yes.

3 BY MR. MARTINEZ:

4 Q. So I want to drill down on this a little
5 bit. Did CMS understand, then, that sometimes an
6 initial coder, as part of the RADV process, would
7 not abstract an HCC that a different coder perhaps
8 later in the process would abstract?

9 MS. OBEREMBT: Objection; vague.

10 THE WITNESS: That's why there were
11 two -- always two reviews.

12 BY MR. MARTINEZ:

13 Q. Right. And it was important to CMS to
14 have those multiple layers of review; right?

15 A. Correct.

16 Q. To make sure that they were getting the
17 most accurate results that they could in terms of
18 reviewing the medical records for supportable HCCs;
19 right?

20 A. Yes.

21 Q. Because obviously CMS would not want to
22 come out with even a preliminary finding that an
23 HCC is not supported by a medical record if it
24 hadn't done its best to make sure that that's
25 actually the case; right?

1 A. Correct.

2 Q. And so kind of in the same vein, CMS
3 understood when it was conducting its audits, RADV
4 audits for payment years 2011 through 2015, that
5 sometimes the coders that CMS oversaw would
6 disagree about whether or not an HCC was supported
7 by medical records; right?

8 A. Yes.

9 Q. And in fact, CMS I believe instructed
10 the medical record review contractors to develop
11 protocols for handling those very situations in
12 which one coder might disagree with the judgment of
13 another coder. Is that right?

14 A. I'm not sure what you're referring to.

15 Q. Have you heard of the concept of quality
16 assurance protocols in the context of the RADV
17 audits that CMS oversaw?

18 A. Medical record review contractors, it
19 was contingent on them to monitor the quality of
20 their coders.

21 Q. And that was a requirement that CMS
22 imposed on the medical record review contractors;
23 right?

24 A. Yes.

25 Q. And as one of those quality control

1 mechanisms that the medical record review
2 contractors had to have in place was a process for
3 resolving disagreements between coders about
4 whether an HCC was in fact supported by the medical
5 records?

6 A. I believe something like that did exist.
7 When I talked to Michelle Atkins to kind of
8 understand how they implemented this, when you have
9 focused review and discrepant confirmation, when
10 you have one MRRC coding it and then it goes to
11 another coder rather than a primary and senior at
12 each organization looking at it, she said that her
13 process was to -- for those HCCs that were not in
14 agreement, they would internally have someone look
15 at it and see if the coder needed additional
16 training.

17 Q. So in that instance that Michelle Atkins
18 was talking to you about, there would be a third
19 layer of review to kind of assess --

20 A. No.

21 Q. -- or remediate the disagreement?
22 No?

23 A. No, it was an internal practice by the
24 medical record review contractors. There were two
25 layers of review, and the HCC was considered

1 validated if either of the coders abstracted it.

2 Q. And was that the process for payment
3 year 2012 and 2013 as well?

4 A. I believe so, yes.

5 Q. And is that the process CMS intends to
6 employ for payment years 2014 and 2015?

7 A. I believe so.

8 Q. And what's your source for your
9 understanding with respect to payment years '14 and
10 '15?

11 A. That was discussions with Michelle
12 Atkins.

13 Q. Okay. Has that process, the medical
14 record review process for payment year 2014, has
15 that started yet?

16 A. I believe it has just based on when --
17 the date of the sampling evaluation report, and
18 then I also have some CON14 training in Tab 9. So
19 it appears those samples have started.

20 Q. Do you know whether they started before
21 or after July 2021?

22 A. I don't know. I believe CON14 did, but
23 I can't say with 100 percent certainty. What
24 started, the coding or --

25 Q. The coding. Sorry.

1 collection, CMS went with a very conservative
2 approach and offset those overpayments by what it's
3 calling underpayments for additional diagnoses.

4 BY MR. MARTINEZ:

5 Q. And that's CMS's own terminology; right?

6 A. I believe so, yes.

7 Q. And I think you said that whenever a
8 diagnosis code cannot be validated by the medical
9 records, that is an overpayment. But isn't it true
10 that not all diagnosis codes or HCCs actually
11 impact payment?

12 A. I believe all HCCs by definition impact
13 payment. All diagnosis codes do not. You can have
14 two HCCs.

15 Q. And you understand that multiple
16 diagnosis codes could support the same HCC; right?

17 A. Yes.

18 Q. And so I guess what I'm wondering is,
19 then, just because the CMS medical record review
20 contractors find that there is a certain percentage
21 of unsupported HCCs in an MA plan's submitted data
22 for a particular payment year, that does not mean
23 that the MA plan has been net overpaid as CMS
24 defines it for that payment year; correct?

25 MS. OBEREMBT: Objection; vague.

1 THE WITNESS: It's not in the terms of
2 the RADV payment recovery context.

3 BY MR. MARTINEZ:

4 Q. Is there a different context that you're
5 thinking your answer might be different?

6 A. Yes. In the payment context, plans have
7 a firm deadline for the date by which they must
8 submit diagnoses for payment.

9 Q. And so how does that deadline inform
10 your answer to my question?

11 A. Plans would not be allowed -- diagnoses
12 would not be considered that were not submitted
13 within the data submission period.

14 Q. So it's possible that a plan might just
15 submit a code or an HCC too late to be paid in a
16 certain payment year; right?

17 A. It's possible, yes.

18 Q. Is that what you're referring to?

19 A. Yeah, that's one example.

20 Q. Okay. Are there other examples?

21 A. No. Just RADV is not kind of considered
22 a forum to introduce new diagnoses into the
23 payment.

24 Q. Okay. And I want to understand that a
25 little bit. Just because in performing the medical

1 record reviews as part of the RADV program, as we
2 established, the medical record review contractors
3 also report additional HCCs that were not submitted
4 by the plans for payment; correct?

5 A. That is correct.

6 Q. And because of those additional HCCs
7 that are found by CMS's own coders, that's why you
8 get sometimes net underpayments to MA plans for a
9 particular year?

10 MS. OBEREMBT: Objection; misstates
11 prior testimony.

12 THE WITNESS: You get an enrollee net
13 underpayment.

14 BY MR. MARTINEZ:

15 Q. And then when you extrapolate to the
16 entire contract as a whole taking account of any
17 additional HCCs, that also leads to net
18 underpayments for the plan as a whole in the RADV
19 context; right?

20 A. Well, in the RADV methodology, the
21 payment recovery amount is constrained to zero. So
22 it's not a forum for plans to receive additional
23 payment.

24 Q. Right. And so what that means, it's
25 constrained to zero -- well, it means a couple of

1 things, but one thing it means is that if a
2 particular plan has a net underpayment that CMS has
3 calculated for a given payment year, there is no
4 payment recovery for CMS for that particular plan;
5 correct?

6 A. Correct. That was the methodology.

7 Q. Using the extrapolated methodology;
8 right?

9 A. Correct.

10 MS. OBEREMBT: Counsel, we've been going
11 an hour now. Can we take a break, please? We
12 started at 1:15.

13 MR. MARTINEZ: Would you like a break?

14 THE WITNESS: Uh-huh.

15 MR. MARTINEZ: Sure. We can go off the
16 record.

17 THE VIDEOGRAPHER: We are off the record
18 at 14:23.

19 (Recess taken.)

20 THE VIDEOGRAPHER: We are back on the
21 record at 14:35.

22 BY MR. MARTINEZ:

23 Q. Ms. Kapustij, I would like to dig a
24 little deeper now into the extrapolation
25 methodology that CMS published in February of 2012.

1 So I think as we talked about
2 previously, Step 1 is CMS will calculate an
3 enrollee-level payment error for each sampled
4 enrollee. Is that right?

5 A. Correct.

6 Q. And then CMS will, through a specific
7 methodology, apply sampling weights to those
8 enrollees; right?

9 A. Correct.

10 Q. And then CMS adds together the weighted
11 enrollee payment errors of all the enrollees in the
12 sample for that MA plan; correct?

13 A. Correct.

14 Q. And that's how they generate what CMS
15 calls a point estimate. Is that right?

16 A. Correct.

17 Q. And then CMS calculates a 99 percent
18 confidence interval around that point estimate. Is
19 that right?

20 A. That is correct.

21 Q. And then from that confidence interval
22 is how CMS determines what the extrapolated payment
23 recovery amount is; correct?

24 A. Correct.

25 Q. And if the lower bound of that

1 99 percent confidence interval is negative or
2 crosses zero, then there is no payment recovery for
3 CMS; correct?

4 A. Correct.

5 Q. And the reason why it could be negative
6 is because of the additional HCCs that CMS's coders
7 are reporting in the medical record review process;
8 right?

9 A. Correct. I also believe the confidence
10 interval calculation may play into that.

11 Q. Is it your understanding that either the
12 confidence interval calculation or the presence of
13 additional HCCs, one of those two variables is more
14 responsible for negative results?

15 A. I couldn't opine on that.

16 Q. And conversely, if the confidence -- if
17 the lower bound of the 99 percent confidence
18 interval is positive, then there is a payment
19 recovery; correct?

20 A. Correct.

21 Q. And it's calculated at that -- whatever
22 that lower bound for the 99 percent confidence
23 interval is. Is that right?

24 A. Correct.

25 Q. Okay. And that was the final

1 methodology that CMS published in February of 2012;
2 right?

3 A. Correct.

4 Q. And I should say that was the final
5 extrapolation methodology that CMS published in
6 February of 2012; correct?

7 A. Yes. It was called the "Notice of Final
8 Payment Error Calculation Methodology for Part C
9 Medicare Advantage Risk Adjustment Data Validation
10 and Contract-Level Audits."

11 Q. And you're reading the title of Tab 10
12 in your binder?

13 A. Yes.

14 Q. And then on page 4 of that document, CMS
15 then said it will apply a fee-for-service adjuster
16 as an offset to the extrapolated recovery amount to
17 determine what CMS referred to as a final recovery
18 amount. Is that right?

19 A. That is what the paper states.

20 Q. Were you involved in writing that paper?

21 MS. OBEREMBT: Objection; vague.

22 MR. MARTINEZ: I'll rephrase it.

23 BY MR. MARTINEZ:

24 Q. Were you involved in preparing the
25 February 2012 final notice of RADV methodology?

1 A. It's through July -- I can speak to
2 July 2021. I don't think it's happened to date.

3 Q. So as I understand, the way it's
4 supposed to work is an MA plan will submit medical
5 records to support HCCs for a sampled enrollee;
6 right? Just starting at the beginning.

7 A. Correct.

8 Q. And then there's two layers of review by
9 well-trained, well-qualified RADV coders that
10 happens next. Right?

11 MS. OBEREMBT: Objection; vague.

12 THE WITNESS: There are two levels of
13 review by RADV coders.

14 BY MR. MARTINEZ:

15 Q. Okay. And then sometimes the RADV
16 coders, both of them agree that an HCC that was
17 submitted by an MA plan is not supported by the
18 medical records that have been submitted; right?

19 A. Correct.

20 Q. And then CMS presumably alerts the MA
21 plan through that preliminary audit report of that
22 finding; right?

23 A. The plan would be alerted through that
24 preliminary audit report. However, that has not
25 been issued.

1 Q. That report has not been issued for
2 payment year 2011 even?

3 A. Correct.

4 Q. So let's assume it has -- let's assume
5 that CMS alerts a plan about the HCCs that CMS
6 claims are unsupported by the medical records. Now
7 we move to the reconsideration process. And in
8 that process, an MA plan can say: No, wait a
9 minute. Take a look at this one record and that's
10 where we think it is in fact supported. Is that
11 right?

12 MS. OBEREMBT: Objection; calls for
13 speculation.

14 THE WITNESS: It would have to be a
15 record that was already submitted.

16 BY MR. MARTINEZ:

17 Q. So it's a record that's already
18 submitted; right?

19 A. Correct.

20 Q. And the plan can only point to one
21 record in the reconsideration context, not the
22 five, or up to five; right?

23 A. I believe it's one per each HCC.

24 Q. And so once the plan identifies that one
25 medical record for that one HCC, then there is a

1 third layer of review by a third coder who then
2 makes an assessment as to whether or not that
3 record supports the HCC that has been submitted for
4 payment; correct?

5 A. That was the process as designed.
6 Again, these results have not been issued, so I'm
7 being kind of speculative.

8 Q. Well, you're not being speculative, but
9 you're just explaining how the process is supposed
10 to work; right?

11 A. Based on my knowledge, yes.

12 Q. And based on your having been designated
13 as the government's representative to testify on
14 Topic 5.

15 And so if CMS's findings were in fact
16 overturned with respect to a particular HCC, that
17 would mean that this third coder would have found
18 support in the medical record submitted for that
19 HCC that two previous well-trained, well-qualified
20 coders did not report; correct?

21 MS. OBEREMBT: Objection; vague. And
22 calls for speculation.

23 THE WITNESS: That is one option.
24 Another reason a lot of records were found not to
25 support the HCC was not because of a disagreement

1 not designed to determine fraud. CMS can't make
2 that determination whether or not it has committed
3 fraud.

4 BY MR. MARTINEZ:

5 Q. But you understand that CMS has said in
6 the RADV context that neither payment errors nor
7 coding differences are fraud; right?

8 A. Correct. In and of themselves, no.

9 Q. Right. So in and of themselves, the
10 plans on here, not the UHG plans but the other
11 plans that have contract-level overpayments, that
12 fact alone does not mean that CMS believes they
13 have all committed fraud; right?

14 MS. OBEREMBT: Objection; calls for
15 speculation. Asked and answered.

16 THE WITNESS: Correct. But CMS is not
17 conducting this exercise to determine if there is
18 fraud.

19 BY MR. MARTINEZ:

20 Q. So staying on page 5 of Exhibit 1187-1,
21 all three -- excuse me, all four of the UHG plans
22 that were audited, CMS determined that they had no
23 recovery amounts at any of the three confidence
24 intervals listed in this chart. Is that right?

25 A. That is correct.

1 C E R T I F I C A T E

2

3 STATE OF MARYLAND

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the State of Maryland, do hereby
6 certify that CAROLYN KAPUSTIJ, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 28th day of August, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 08/16/25

22

23

24

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EXHIBIT P-57

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

---o0o---

UNITED STATES OF AMERICA, ex)
rel., BENJAMIN POEHLING,)

Plaintiff,)

vs.)

UNITEDHEALTH GROUP, INC., et)
al.,)

Defendants.)

Case No.

16-08697 FMO

---o0o---

TUESDAY, MARCH 12, 2024

VIDEOTAPED DEPOSITION OF PHILIP STARK, PH.D.

CONFIDENTIAL TRANSCRIPT

---o0o---

REPORTER: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

1 Q. Okay. I am going to try to use the same
2 term today, "member-HCC-year," so that we're
3 consistent.

4 A. Thank you.

5 Q. All right. Now, in your -- I am going to 10:28:41
6 call this Opinion II on Page 7 because it's got the
7 Roman II. Your Opinion II found support in RADV
8 for diagnosis instances with no payment impact was
9 higher than those with payment impact, correct?

10 A. I'm sorry. I didn't hear the last part of 10:29:07
11 the question.

12 Q. That you -- in your Opinion II, you found
13 that the RADV validation rate of diagnosis
14 instances with no payment impact was higher than
15 those with payment impact, correct? 10:29:24

16 A. No, sir. I didn't independently examine
17 whether any diagnosis instance had financial
18 impact. I'm relying on Mr. Renjilian's Opinions 2
19 and 3 for that determination. I'm doing
20 calculations based on his labeling of diagnosis 10:29:40
21 instances as potentially having financial impact or
22 not.

23 Q. Fair enough. Let's go into what you did
24 here. Let's look at your Paragraph 24.

25 In Paragraph 24 you write "To evaluate the 10:29:59

1 rates at which RADV audits found support for
2 member-HCC-years that Mr. Renjilian identified as
3 having financial impact if deleted, I replicated
4 and extended portions of Mr. Renjilian's analysis,"
5 right?

10:30:17

6 A. Yes, sir.

7 Q. So you did not verify Mr. Renjilian's work
8 on whether a diagnosis instance had payment impact
9 or not; you just accepted his Opinions 2 and 3,
10 correct?

10:30:32

11 A. I used his determination. I -- "accepted"
12 is a little stronger. I used his determination.

13 Q. Fair enough. You used his determination.
14 And you did the work identified in your Paragraphs
15 25 through 29, correct?

10:30:47

16 A. Yes, sir.

17 Q. All right. After doing that work -- well,
18 I should say in Paragraph 24 you say "I replicated
19 and extended portions of Mr. Renjilian's analysis."
20 And you did that by doing the work in Paragraphs 25
21 through 29, correct?

10:31:28

22 A. Yes, sir.

23 Q. And in Paragraph 30 --

24 A. Some of the extension is not just

25 described there. That's -- Paragraphs 25 through

10:31:41

1 29 are for preparing the database for -- creating a
2 database that I used then for subsequent
3 calculations that are described later in the
4 report.

5 Q. Okay. 10:31:55

6 A. That's not the full extent of the work.

7 Q. Fair enough. You feel confident in the
8 methods you used, correct?

9 A. Yes, yes.

10 Q. And you feel confident in the results you 10:32:07
11 achieved, right?

12 A. Yes.

13 Q. All right. In Paragraph 30 you state the
14 following: "My results match the 2011-2013 counts
15 in the left panel of Figure 15 of the Renjilian 10:32:20
16 report." Do you see that?

17 A. Yes, sir.

18 Q. Is that accurate?

19 A. That's to the best of my recollection,
20 yes. 10:32:32

21 Q. So the independent analysis that you
22 performed matched the same results as Mr. Renjilian
23 on Figure 15 of his report, right?

24 A. The left panel?

25 Q. Yes. 10:32:45

1 A. For 2013 -- from 2011 through 2013, yes,
2 sir.

3 Q. And let's go ahead and look at that left
4 panel in Mr. Renjilian's report. And that's on
5 Page 87 of his report. 10:33:01

6 You're referring, Dr. Stark, to the panel
7 that says at the top "Member-HCCs, 2011-2013"?

8 A. I think it says CON13 -- "CON11-13."

9 Q. Yeah, I think you have a different
10 pagination than I do. So go to Page 86. 10:33:38
11 Member-HCC-years -- member-HCCs 2011-2015. Do you
12 see that?

13 A. I see something that says "CON11-13." Is
14 that --

15 Q. CON11-13? 10:33:57

16 A. Not 2011 through '15. Yes, sir.

17 Q. Great. Okay. And Dr. Stark, you
18 replicated and reached the same result as in that
19 upper left panel, right?

20 A. Our arithmetic agrees, yes. 10:34:12

21 Q. Your arithmetic agrees.

22 A. Yes.

23 Q. All right. So you found, Dr. Stark, that

24 -- I want to go through these numbers in some more

25 detail. You found that for 2011 through 2013, your 10:34:24

1 arithmetic found that there was 1,119

2 member-HCC-years with a diagnosis instance that was

3 on the first interrogatory response, right?

4 A. As I sit here, I can't remember whether

5 this is counting diagnosis instances or HCCs rolled 10:35:05

6 up to the member-year level.

7 Q. Well, you stated in your report you

8 replicated and found the same results, correct?

9 A. Yes.

10 Q. And Mr. Renjilian writes "Member-HCCs" at 10:35:25

11 the top of that chart, correct?

12 A. Yes, sir.

13 Q. So that would suggest these are

14 member-HCC-years, correct?

15 A. It would, although Mr. Renjilian's 10:35:36

16 terminology isn't -- I think he sometimes uses the

17 same phrase to talk about diagnosis instances and

18 sometimes to talk about HCC-years.

19 Q. Okay. Well, assuming this is

20 member-HCC-years for now, and if you discover later 10:35:54

21 it was diagnosis instance, you'll let us know.

22 A. Yes.

23 Q. Okay. So to state it plainly, there were

24 1,119 instances where a provider submitted a code

25 after an encounter, a United chart review coder 10:36:09

1 reviewed the chart and did not identify that
2 submitted code, and then the member-HCC-year was
3 reviewed in RADV, correct?

4 A. That's my understanding, yes.

5 Q. And out of those 1,119 instances, the RADV 10:36:31
6 auditors found 980 of them to be supported, right?

7 A. Not of the diagnosis instances, but of the
8 resulting HCC for that beneficiary for that year.

9 Q. Thank you for correcting that.

10 So in -- let me restate. So in 980 of 10:36:50
11 those instances, the RADV auditors validated the
12 member-HCC-year associated with that diagnosis
13 instance, right?

14 A. That's my understanding. My understanding
15 is that RADV does not look at the diagnosis 10:37:06
16 instances to see whether the diagnosis instances
17 are supported. RADV looks at members and the HCCs
18 that those members were assigned for the year and
19 asks United or whoever the MAO is to provide
20 documentation to support that HCC for that 10:37:29
21 beneficiary for that year.

22 Q. All right. Let me just establish some
23 foundation about RADV. What do you understand RADV
24 to be?

25 A. I understand it to be a review that's done 10:37:40

1 by CMS of some contracts and some years, that it
2 involves sampling beneficiaries and then looking
3 for -- or asking the MAO for support for the HCCs
4 that were assigned to that beneficiary that year,
5 that the MAO is allowed to provide up to five
6 pieces of information -- I think their chart
7 specifically, but five pieces of information to
8 support each HCC, and that support might or might
9 not be from the diagnosis instance that was
10 originally submitted.

10:38:06

10:38:26

11 Q. And you understand that the CMS auditors
12 will then review the charts to determine if the
13 member-HCC-year is supported, correct?

14 A. That's my understanding, yes, sir.

15 Q. All right.

10:38:45

16 A. I have a little bit more detail in the
17 understanding of RADV. I understand that at least
18 in some years the sample -- first of all, I
19 understand that the samples are drawn from contract
20 years.

10:38:59

21 Second, I understand that at least in some
22 years, the sample was a stratified random sample,
23 that it was stratified by a tercile of payment for
24 the beneficiary in question.

25 I have also seen language somewhere that

10:39:14

1 said it was somehow risk -- risk aware, that
2 somehow it was attempting to focus on things that
3 were perceived to have more risk, but I don't
4 understand the detail of that.

5 Q. Okay. Thank you for clarifying that. 10:39:29

6 We are going to assume today, Dr. Stark,
7 that the RADV auditors always get it right.

8 A. I don't know whether the RADV auditors
9 always get it right.

10 Q. Do you have any doubts whether they always 10:39:41
11 get it right?

12 A. I mean, any process involving humans
13 reading printed materials, some error rate. I just
14 don't know -- I haven't seen attempts to quantify
15 it. I don't have an independent basis for knowing 10:39:59
16 what the accuracy would be.

17 Q. Fair enough. Well, let's assume for the
18 purposes of today, I'll give you an assumption,
19 that the RADV auditors are always correct.

20 A. Okay. 10:40:16

21 Q. And I'll -- I'll restate that assumption
22 when I ask you various questions.

23 A. Okay.

24 Q. But if you have any doubts, you can say,
25 "Are you assuming RADV is correct?" 10:40:25

1 A. I'll do my best here.

2 Q. Okay. Great. All right. Going back to

3 Mr. Renjilian's chart that you verified the

4 arithmetic, you agree that there were 980 instances

5 where a provider submitted a code after an 10:40:42

6 encounter, United chart review coders reviewed the

7 chart and failed to find the diagnosis code

8 submitted by the provider, and RADV auditors

9 reviewed the member-HCC-year associated with that

10 diagnosis instance and found it to be supported, 10:41:06

11 right?

12 A. My understanding is that one of -- at

13 least one of the up to five pieces of information

14 provided by United, possibly from different

15 diagnosis instances or even diagnosis instances 10:41:20

16 that were not submitted, provided support for that

17 HCC, or possibly something in the -- higher in the

18 hierarchy for that beneficiary for that year.

19 Q. Okay. Thank you for those caveats. But

20 in summary, in those 980 instances, ultimately the 10:41:41

21 RADV auditors found the member-HCC-year to be

22 supported, correct?

23 A. They found the member-HCC-year to be

24 supported, yes, sir.

25 Q. All right. And then the next line in 10:41:54

1 So somewhere in some chart that was
2 presented by United to RADV, there was support for
3 that HCC for that member for that year.

4 Q. I understand that caveat, and you've
5 mentioned it a few times. In understanding that 11:22:24
6 caveat, which I am going to cover in a minute, I
7 just want to restate the hypothesis and make sure I
8 understand your opinion.

9 The hypothesis is every time a United
10 chart review coder fails to find a diagnosis code 11:22:37
11 submitted by a provider, the member-HCC-year
12 associated with that diagnosis code is not
13 supported, that hypothesis is false, correct?

14 A. I agree.

15 Q. Okay. And you agree that that's false to 11:22:56
16 a certainty, right?

17 A. Yes, sir. Well, yes, my -- if by
18 "supported," we mean RADV found support, yes.

19 Q. Fair enough. We talked about that
20 assumption earlier, but you had said that human 11:23:12
21 beings are fallible and so RADV auditors may be
22 fallible, right?

23 A. Yes, I am just worried about the
24 definition of "supported," but yes, I -- yes, RADV
25 finds support for some nonzero fraction of 11:23:27

1 member-HCC-years for which corresponding to some of
2 the diagnoses that were originally submitted but
3 not found in chart review.

4 Q. All right. Fair enough.

5 I want to cover this caveat that you've 11:23:48
6 raised a number of times about a member-HCC-year
7 potentially being supported from another chart.

8 And so if I understand what you're saying,
9 Dr. Stark, is that a diagnosis instance in the
10 first interrogatory response would have involved a 11:24:14
11 provider meeting with a patient in an encounter,
12 having an encounter with a patient, submitting a
13 diagnosis and that mapping to a member-HCC-year;
14 but then another provider, meaning -- or having an
15 encounter with a patient and also submitting a 11:24:35
16 diagnosis.

17 And you're saying that the member-HCC-year
18 in RADV could have been supported by that second
19 encounter, not the first encounter on the first
20 interrogatory response; is that correct? 11:24:50

21 A. That's my understanding, or it could have
22 been a different encounter with the same provider,
23 or it could have been an encounter with the same
24 provider or a different provider with a different
25 diagnosis that mapped to either the same HCC or an 11:25:02

1 HCC higher in the hierarchy.

2 Q. That's correct. So just to put it in

3 plain terms, a provider may meet with a patient and

4 diagnosis a patient as having diabetes and that may

5 not be found in chart review, the diabetes

11:25:19

6 diagnosis; but then a different provider may meet

7 with the same patient, diagnosis diabetes, and then

8 that would be the chart that the RADV auditors

9 would find as supporting the member-HCC-year,

10 right?

11:25:37

11 A. I think it's a little more complicated

12 than that, in that my understanding is that RADV

13 doesn't do its own selection of materials to

14 review, that it's the MAO that provides RADV with

15 materials that they purport support the HCC for

11:25:53

16 that member for that year.

17 So my understanding is that the materials

18 presented to RADV in support of a particular

19 HCC-member-year could be one of the diagnosis codes

20 that chart review -- diagnosis instances that chart

11:26:15

21 review did not find.

22 It could be based on an encounter with the

23 same or a different provider, a different

24 encounter, and it could be support for, for

25 example, a more severe form of diabetes than the

11:26:35

1 particular HCC corresponding to the diagnosis event
2 that was originally submitted but not found in
3 chart review.

4 Q. Fair enough. Okay. Dr. Stark, I want to
5 change the hypothesis a little bit and focus just 11:26:53
6 on payment impact codes.

7 So the -- I want to present to you this
8 hypothesis. Every time a United chart review coder
9 fails to find a diagnosis code with payment impact
10 that had been submitted by a provider, the 11:27:13
11 member-HCC-year associated with that diagnosis
12 instance was unsupported.

13 You agree, based on the work you
14 performed, that that hypothesis is false, right?

15 A. Not quite. I have made no independent 11:27:31
16 determination of whether a diagnosis instance has
17 financial impact. My analysis relies either on --
18 in some cases on Mr. Renjilian's determination of
19 whether it has financial impact, and in some case
20 on Mr. Garthwaite -- Dr. Garthwaite's determination 11:27:51
21 on whether that diagnosis instance has financial
22 impact.

23 But I agree with what I think the gist is
24 of your assertion, which is that there are examples
25 of HCCs that were identified by one or the other or 11:28:04

1 both of Mr. Renjilian and Dr. Garthwaite as having
2 financial impact where RADV found support for that
3 HCC for that member for that year.

4 That determination might or might not have
5 been based on a review of the chart corresponding 11:28:25
6 to that, to the diagnosis event that was explicitly
7 stated.

8 Q. Okay. Dr. Stark, thank you for that
9 clarification. I will make my hypothesis even more
10 precise. 11:28:42

11 A. Okay.

12 Q. Because I am not trying to play gotcha,
13 and I'm glad you're being careful about the
14 wording.

15 So let me present you this hypothesis: 11:28:49
16 Every time a United chart review coder fails to
17 find a diagnosis code that either Mr. Renjilian or
18 Dr. Garthwaite identified as having payment impact
19 that have been submitted by a provider, the
20 member-HCC-year associated with that diagnosis 11:29:10
21 instance was unsupported?

22 A. Again, the word "supported" bothers me.
23 RADV found support for some of them.

24 Q. That RADV found support?

25 A. Yeah. So if you change that to "RADV 11:29:22

1 determined that it was unsupported," then -- then I
2 would agree.

3 Q. Okay. And the reason you have trouble
4 with "found support" is it requires an assumption
5 that the RADV auditors were correct, right?

11:29:41

6 A. Well, I -- RADV reviews -- my
7 understanding is that RADV reviews up to five
8 pieces of information provided by United. There
9 might be other charts that were not presented to
10 RADV -- even though I understand those to be
11 United's best attempt to demonstrate support for
12 that member-HCC-year combination. It's possible
13 that there would be support somewhere else. It's
14 possible that -- it's possible that RADV made a
15 mistake. There's a lot of things that are
16 possible.

11:30:11

11:30:28

17 And I just want to be clear that we are
18 talking about whether RADV found support rather
19 than some more abstract notion --

20 (Clarification by the reporter.)

11:30:46

21 THE WITNESS: Abstract notion of
22 supported. And I want to be also clear about the
23 distinction between whether a particular diagnosis
24 instance is supported by the chart corresponding to
25 that diagnosis instance or the HCC that that

11:31:03

1 diagnosis instance maps to has support somewhere in
2 some chart for that subscriber for that year.

3 Q. BY MR. ABASCAL: Thank you.

4 A. Or something higher in the hierarchy.

5 Q. But assuming the RADV auditors were 11:31:22
6 correct, you would agree that that hypothesis is
7 false, right?

8 A. I have now -- I am no longer holding your
9 statement in memory. Let me try to say it myself.
10 I agree that the hypothesis that when RADV reviewed 11:31:42
11 a member-HCC-year instance that -- for which a
12 diagnosis code had been submitted but not found by
13 the chart reviewers, and that -- and that diagnosis
14 instance had been identified by either
15 Mr. Renjilian and/or Mr. Garthwaite as having 11:32:29
16 financial impact, some fraction of the time that
17 they never found -- with a hypothesis that they
18 never -- that RADV never found support for that
19 HCC. And I agree that that hypothesis is false.

20 Q. All right. Let me try to state this in a 11:32:53
21 little plain terms, which is pretty dangerous.

22 So just because a United chart review
23 coder did not find a provider-submitted code, that
24 does not mean that the associated member-HCC-year
25 is unsupported, assuming RADV is correct? You 11:33:27

1 agree with that, right?

2 A. Yes, the -- just because chart review did
3 not find support for a diagnosis code submitted for
4 a particular diagnosis instance, there might be
5 somewhere -- there still might be somewhere support
6 for the HCC that that diagnosis code maps to or an
7 HCC higher in the hierarchy, possibly in the chart
8 that was reviewed by the United chart reviewers and
9 possibly in some other chart for that member for
10 that year.

11:33:56

11:34:17

11 Q. And you verified that through your own
12 analysis as reflected in Table 2?

13 A. I couldn't hear the last part of your
14 sentence. My analysis of?

15 Q. As reflected in your Table 2?

11:34:32

16 A. Yes, sir.

17 Q. All right. Dr. Stark, you understand that
18 payment to United is based on a member-HCC-year,
19 correct?

20 A. That's my understanding, yes, sir.

11:34:46

21 Q. All right.

22 A. And other characteristics of the members,
23 including demographic information.

24 Q. Fair enough. And you understand that if
25 the RADV auditors find support for the

11:34:58

1 member-HCC-year, then the payment is appropriate,
2 right, that portion of the --

3 MS. GLOVER: Objection; calls for legal
4 conclusion.

5 THE WITNESS: Yeah, I don't know what 11:35:14
6 "appropriate" means in this context. I don't know
7 the terms of the contract between the MAOs and CMS.

8 I understand that as a matter of practice
9 that RADV does not ask to be reimbursed when they
10 find -- if support is found for that HCC, but I 11:35:33
11 don't know the connection between the common
12 practice and RADV and the legal terms of the
13 contract between the MAO and the government.

14 Q. BY MR. ABASCAL: That's fair, Dr. Stark.

15 Do you understand that if a 11:35:54
16 member-HCC-year is unsupported, that would be
17 considered an overpayment?

18 MS. GLOVER: Objection; calls for a legal
19 conclusion.

20 THE WITNESS: I don't know -- I don't know 11:36:08
21 how that word is used in this context. I mean, in
22 lay terms, my understanding is that the practice of
23 RADV is to count that payment against -- against
24 the MAO, but I don't know -- again, I don't know
25 how the term is used. I don't know whether it is a 11:36:30

1 legal term of art. I don't know whether it is a
2 term that appears in the contract.

3 Q. BY MR. ABASCAL: That's fair. I am not
4 trying to play gotcha or suggest a term or trick
5 you with a term of art. So let me rephrase it. 11:36:42

6 Do you understand that if a
7 member-HCC-year is unsupported, then the payment
8 would be inappropriate?

9 A. Again, I don't really know what
10 "inappropriate" means here. And "unsupported," I 11:37:10
11 think you mean if RADV determines that none of the
12 pieces of information provided by the MAO support
13 that HCC for that member for that year. I
14 understand that that's considered some kind of
15 error and that there's some kind of accounting. 11:37:27
16 But I don't know -- I don't know details.

17 I understand informally that RADV allows
18 offsets as well, but, again, this is -- I don't
19 know the rules under which RADV operates. And I
20 don't understand in detail how a RADV audit results 11:37:48
21 in any kind of reconciliation of money between the
22 MAO and the government.

23 Q. I understand you're not an expert in RADV,
24 and I am not trying to suggest that anything you
25 say would bind the government on its interpretation 11:38:04

1 of RADV.

2 I am trying to find the word that would
3 make you more comfortable. And you said the word
4 "improper," so let me try that.

5 A. I'm sorry. I need to answer verbally 11:38:20
6 here. I don't -- I mean, I understand that there's
7 some kind of accounting for HCCs that RADV
8 determines were unsupported, HCC-member-year
9 combinations that RADV determines were unsupported,
10 but I don't know the details of that. 11:38:40

11 Q. Fair enough. Do you understand that
12 payment would be improper to United if the
13 member-HCC-year were unsupported?

14 A. Again, I'm a little hung up on the word
15 "improper." I think that I -- I think that -- 11:38:55
16 yeah, I don't know what to say.

17 Q. That's fair enough. If you're
18 uncomfortable, I don't want to make you
19 uncomfortable.

20 You do not know whether payment would be 11:39:07
21 proper or improper if a United member-HCC were
22 unsupported, correct?

23 A. Again, I don't know the sense of the word
24 "improper." I understand that -- I understand
25 informally that the MAOs don't submit HCCs. They 11:39:35

1 submit diagnosis instances to a government system.

2 And I understand that payments are based on the
3 member demographics and the HCCs that the diagnoses
4 for that member map to for the year that only a
5 single instance of each HCC matters. Multiple

11:40:05

6 instances don't change anything. And that there
7 are hierarchies for some HCCs and only, in some
8 sense, the riskiest of HCC in that hierarchy
9 matters if more than one has been assigned to a

10 given subscriber for the year.

11:40:25

11 I understand that there is some obligation
12 to submit only genuine diagnosis instances and some
13 obligation to correct errors that the MAO is aware
14 of or should be aware of. But beyond that, I don't
15 really know.

11:40:50

16 Q. All right. Fair enough. Well, Dr. Stark,
17 let's move on to a different part of your report.
18 I am going to focus on Section III of your report,
19 and this is where you analyze the member-HCC-year
20 combinations associated with the Garthwaite final
21 delete list, right?

11:41:16

22 I am going to draw your attention to
23 Paragraph 39, Dr. Stark. In Paragraph 39 you state
24 "For the V12 model, overall, RADV found support for
25 41,681 of 49,978 audited member-HCC-year

11:41:45

1 A. There's a very long list of reasons. One
2 of them is that in sampling and extrapolation, we
3 draw -- meaning statistics draws a distinction
4 between the sampling frame and the population.

5 The sampling frame is the collection of 02:56:27
6 units from which the sample is drawn, and that
7 might or might not be identical to the population
8 to which one would like to extrapolate.

9 My understanding is that the sampling
10 frame for RADV was a particular collection of 02:56:43
11 contract years that did not comprise every contract
12 year that's relevant to the present matter.

13 So there's a mismatch between the sampling
14 frame and the population that already makes
15 extrapolation impossible without bias of unknown 02:57:09
16 magnitude.

17 Second issue is within each contract year
18 that RADV did examine, the way the sample was drawn
19 was not a simple random sample of HCCs, which is
20 what would be required for -- in order to 02:57:39

21 extrapolate from a sample of HCCs to the contract
22 year from which those HCCs were selected, those
23 member-HCC-years were selected, for the raw rate to
24 be an unbiased estimate, that sample needs to have
25 been drawn in such a way that every HCC-member-year 02:58:06

1 in that contract was equally likely to be selected.

2 That is not how the sample was drawn. The

3 sample was drawn -- I understand the way that RADV

4 works in general -- although I understand there's

5 been some variation from year to year. But I 02:58:25

6 understand in general the way RADV works is by

7 sampling members, not sampling HCCs. Because it is

8 sampling members and then looking at all of the

9 HCCs that go with a given member. Instead of being

10 an equal probability sample, it is a cluster 02:58:40

11 sample. It doesn't sample all the subsets with

12 equal probability.

13 And secondly, even the members are not

14 drawn with equal probabilities -- sorry. The

15 design of the sample, even at the member level -- 02:58:56

16 at the level of members is a stratified sample, I

17 understand that it involves first dividing payments

18 -- dividing members into three groups based on the

19 amount that was paid for that member in that year.

20 So terciles of payment. 02:59:20

21 So all of those differences need to be

22 taken into account in extrapolating the sample rate

23 for the RADV sample from a single contract year to

24 that entire contract year. But then the number of

25 the sampling rates, meaning the fraction of the 02:59:52

1 population that each sample represents, I
2 understand may vary from contract to contract that
3 RADV audits. So weights need to be used to adjust
4 for those differences in sampling rates.

5 And beyond that, there's no statistical 03:00:13
6 justification for extrapolating beyond the
7 particular contract years that RADV looked at.

8 So there are a large list of reasons that
9 the raw rate of support has unknown bias in
10 addition to statistical variability if it's being 03:00:38
11 used as an estimate of the overall rate of support
12 for HCCs corresponding to diagnosis instances
13 identified on the Garthwaite final deletes list.

14 Q. Have you completed your answer, Doctor?

15 A. Yes, I think so. 03:01:02

16 Q. All right. Great. I may have to ask you
17 to repeat it again because I am going to change --
18 I am going to change -- it's torture, isn't it --
19 the question slightly.

20 You said in Paragraph 54 "the raw RADV 03:01:17
21 support rate should not be extrapolated to the
22 Garthwaite Final Deletes List."

23 Now I want to be a little bit more
24 specific. In Paragraph 39 you concluded, or you
25 found -- you counted, you counted that RADV found 03:01:33

1 one to estimate what fraction of the diagnosis --
2 sorry. What fraction of the diagnosis events in
3 the final deletes list map to an HCC-member-year
4 that RADV would have found support for had it
5 examined every member-HCC-year that intersects
6 Garthwaite's final deletes list.

03:55:05

7 Q. I am going to try to restate that.

8 A. You want me to say it again?

9 Q. No, I am going to try to restate it.

10 A. Okay.

03:55:46

11 Q. Based on the data that you have available
12 and that you have reviewed in your work on this
13 case, there is not a way to reliably estimate the
14 fraction of diagnosis instances in the final
15 deletes -- the Garthwaite final deletes list that
16 map to an HCC-member-year that would be supported
17 by RADV auditors, right?

03:56:03

18 A. I agree with that.

19 Q. And similarly, there's not a way to
20 estimate the fraction that would not be supported,
21 correct?

03:56:32

22 A. I agree with that, too.

23 Q. All right.

24 A. If there were, there would be a way to do
25 it the first time.

03:56:44

1 DEPOSITION OFFICER'S CERTIFICATE

2 (Civ. Proc. § 2025.520(e))

3 STATE OF CALIFORNIA)

4) Ss

5 COUNTY OF SAN FRANCISCO)

6 I, BALINDA DUNLAP, CSR #10710, hereby
7 certify:

8 I am a duly qualified Certified Shorthand
9 Reporter, in the State of California, holder of
10 Certificate Number CSR 10710 issued by the Court
11 Reporters Board of California and which is in full
12 force and effect. (Bus. & Prof. § 8016)

13 I am not financially interested in this
14 action and am not a relative or employee of any
15 attorney of the parties, or of any of the parties.
16 (Civ. Proc. § 2025.320(a))

17 I am authorized to administer oaths or
18 affirmations pursuant to California Code of Civil
19 Procedure, Section 2093(b) and prior to being
20 examined, the deponent was first placed under oath
21 or affirmation by me. (Civ. Proc. §§ 2025.320,
22 2025.540(a))

23 I am the deposition officer that
24 stenographically recorded the testimony in the
25 foregoing deposition and the foregoing transcript

1 is a true record of the testimony given. (Civ.
2 Proc. § 2025.540(a))

3 I have not, and shall not, offer or
4 provide any services or products to any party's
5 attorney or third party who is financing all or
6 part of the action without first offering same to
7 all parties or their attorneys attending the
8 deposition and making same available at the same
9 time to all parties or their attorneys. (Civ.
10 Proc. § 2025.320(b))

11 I shall not provide any service or product
12 consisting of the deposition officer's notations or
13 comments regarding the demeanor of any witness,
14 attorney, or party present at the deposition to any
15 party or any party's attorney or third party who is
16 financing all or part of the action, nor shall I
17 collect any personal identifying information about
18 the witness as a service or product to be provided
19 to any party or third party who is financing all or
20 part of the action. (Civ. Proc. § 2025.320(c))

21

22 Dated: _____

23

Balinda Dunlap

24

25

EXHIBIT P-58

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	No. 16-08697 FMO
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et	)	
al.,	)	
	)	
Defendants.	)	
_____	)	

VIDEOTAPED VIDEOCONFERENCE ZOOM DEPOSITION OF
LISA LARA

March 18, 2022
10:01 a.m. Eastern Standard Time

(ATTORNEYS' EYES ONLY PORTION BOUND IN
SEPARATE TRANSCRIPT)

Magna Legal Services
(866) 624-6221
www.MagnaLS.com

Prepared by:
Marcella Daughtry, RPR, RMR
CA CSR 14315
GA No. 6595-1471-3597-5424

1 PDF, question 4 at the very bottom of page 5 --

2 A Okay.

3 Q -- Bates number ending 4716. Okay. So there
4 is a question about obtaining copies of the P&P that were
5 in effect during calendar year 2006. Do you see that?

6 A I do.

7 Q And is that a request for policies and
8 procedures?

9 A It is.

10 Q Okay. Is that part of your standard auditing
11 practice, to ask the companies -- or MA Plans for
12 policies and procedures?

13 A Yes, it is.

14 Q So if you sort of scroll down and look at the
15 response there, I want to direct your attention to the
16 first full paragraph on page 6 in particular. And there
17 is a description there of chart validations and chart
18 reviews. Do you see that paragraph --

19 A I do.

20 Q -- that I am referring to?

21 And it states, "A chart validation involved the
22 review of a provider's patient charts to determine
23 whether they supported certain codes that the provider
24 had reported."

25 Do you see that?

1 A I do.

2 Q "We selected a provider for chart validation
3 based principally on whether the provider's coding was
4 unusually high compared to a national benchmark
5 established by our risk adjustment system."

6 Do you see that?

7 A I do.

8 Q "The chart validation tested the provider's
9 deviation from that benchmark. Codes found to be
10 inaccurate or incomplete through chart validations were
11 deleted."

12 Do you see all of that?

13 A I do.

14 Q Do you recall representatives from the
15 PacifiCare of Texas explaining what their chart
16 validation process was --

17 MS. GLOVER: Objection.

18 Q BY MS. SCHEFFLER D0: -- as part of this?

19 MS. GLOVER: Form.

20 Sorry. Objection. Form.

21 THE WITNESS: I do not recall.

22 Q BY MS. SCHEFFLER D0: Is that just because it
23 was a long time ago; you are not sure whether --

24 A Yes.

25 Q -- you did or not?

1 STATE OF GEORGIA)
)
2 COUNTY OF DEKALB) ss:
3

4 I HEREBY CERTIFY that the foregoing deposition
5 was taken before me; that I was then and there a
6 Registered Professional Reporter and Registered Merit
7 Reporter, License No. 6595-1471-3597-5424 for the State
8 of Georgia, and License No. 14315 in the State of
9 California; that the witness before testifying was duly
10 sworn by me to testify to the whole truth; that the
11 questions propounded by counsel and the answers of the
12 witness thereto were taken down by me in shorthand and
13 thereafter transcribed under my direction; and that the
14 foregoing pages contain a full, true, and accurate
15 transcript of all deposition testimony and proceedings
16 had, all done to the best of my skill and ability.

17 Signature requested.

18 I FURTHER CERTIFY that I am in no way related
19 to, nor employed by any of the parties hereto, nor am I
20 in any way interested in the outcome.

21 DATED at Dunwoody, Georgia, this 30th day of
22 March, 2022.

23
24
25


MARCELLA L. DAUGHTRY, RPR, RMR
GA License No. 6595-1471-3597-5424
CA CSR 14315

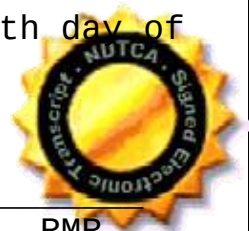


EXHIBIT P-59

From: Brennar, Patty [patty.brennar@optum.com]
Sent: 10/6/2014 1:57:14 PM
To: Bragg, Esperanza [essy.bragg@optum.com]
Subject: FW: CMS Guidance for Chart Records
Attachments: 2012 Encounter Data Participant Guide U85112.pdf

in the attached document, section 2.4.3 references chart review - this is the MA guidance.

2.4.3 Chart Reviews Chart reviews may be performed by MAOs and other entities for the purpose of diagnosis code validation. Because diagnoses drive risk adjustment, all chart review encounters must be supported by the medical record. MAOs and other entities may submit chart reviews that are linked to an original encounter stored in FDS (linked ICD chart reviews) or chart reviews that are not linked to an original encounter stored in FDS (unlinked ICD chart reviews). All chart review encounters should be flagged by MAOs and other entities.

From: Kral, Michael J
Sent: Wednesday, October 08, 2014 10:19 AM
To: Lessor, Carl S; Brennan, Patty
Subject: CMS Guidance for Chart Records

Carl.

Here are the CMS links for chart reviews.

The 2012 guidance originally defining Chart Programs.

<http://www.sagepub.com/usandcanetextbooks/for/Quinn/CSSC/CSSC-2009quinn-us-canetextbooks/2009information-PK/MG/2008openingsmen-us-canetextbooks/cssc-2009/>

Current Companion Guide

[illegible]

Let me know if you need anything else

Michael

EXHIBIT P-59A



2012 Regional Technical Assistance Participant Guide



**Monday, August 6 –
Tuesday, August 7, 2012**

Encounter Data





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- Module 3 (Professional Submission) and Module 4 (Institutional Submission) provide detailed guidance on proxy data submission requirements.
- If MAOs and other entities have any questions about submission of proxy claim information, with regard to any situation outlined in the Participant Guide, contact CMS at eds@ardx.net.

2.4.3 Chart Reviews

Chart reviews may be performed by MAOs and other entities for the purpose of diagnosis code validation. Because diagnoses drive risk adjustment, all chart review encounters must be supported by the medical record. MAOs and other entities may submit chart reviews that are linked to an original encounter stored in EDS (linked ICD chart reviews) or chart reviews that are not linked to an original encounter stored in Encounter Operational Data Store (EODS) (unlinked ICD chart reviews). All chart review encounters should be flagged by MAOs and other entities.

- Module 3 (Professional Submission) and Module 4 (Institutional Submission) provide detailed guidance on chart review submission.

2.4.4 Bundled Claims

Bundled claims refer to the bundling of claim lines meeting the definition of the National Correct Coding Initiative (NCCI) or the bundling of claim lines in adjudication to match the benefit structure of the MAO or other entity. The NCCI was developed to promote correct coding methodologies and to control improper coding. The purpose of the NCCI edit is to prevent improper payment when incorrect code combinations are reported. Only claims bundled using the NCCI will be accepted for encounter data submission. The Coding Policy Manual found on the CMS website can be utilized by MAOs and other entities as a general reference tool.

2.4.5 Minimum Data Elements

Minimum data elements are required to properly process and price encounters. MAOs and other entities must include at least the minimum data elements when submitting encounter data, including paper, DU10, and foreign provider generated encounters, as well as typical provider submissions. The EDS Minimum Data Elements and EDS Completion Guides provide details on the required elements.

 www.cms.gov/edsturn

2.4.6 Home Health Submission

EDS is not currently accepting Home Health encounter submissions from MAOs and other entities. CMS will provide further guidance on the submission of this data in the near future.



the minimum frequency standards established by the tiered scale, but are encouraged to submit encounter data more often. More frequent submission will keep the EDS maintain its systematic capabilities to process encounter data. Table 2G provides the minimum frequency standards for encounter data submission based on the number of Medicare beneficiaries enrolled per contract.

TABLE 2G — TIERED DATA SUBMISSION FREQUENCY

Number of Medicare Enrollees	Minimum Submission Frequency
Greater than 100,000	Weekly
50,000 – 100,000	Bi-weekly
Less than 50,000	Monthly

Table 2G identifies minimum frequency standards for submission. MAOs and other entities may submit data as often as daily and should not delay the submission of data for any reason.

2.5.2 Quantity of Submission

EDS specifications require that the volume of encounters submitted to the system align with the number of enrollees per contract ID. Specific metrics include, but are not limited to, submission rates, proportions of claims in particular service categories, and overall volume of submission. It is MAOs and other entities' responsibility to ensure the volume of encounters submitted is appropriate in relation to the frequency standards established. CMS will confirm the anticipated volume annually and will run submission quantity analyses on a quarterly basis. CMS will also perform analyses on the quantity of encounters submitted to EDS against the volume of RAPS submissions for each Contract ID.

- MAOs and other entities are strongly encouraged to evenly distribute the volume of encounters submitted according to the required frequency requirements.

2.5.3 Quality of Submission

Quality standards allow CMS to analyze encounter data submission to ensure that EDS collects accurate and complete data. Adherence to quality standards requires that MAOs and other entities collect and submit all encounter data in the appropriate ANSI X12 V5010 format. The quality of encounter data submitted is partially evidenced by the number of errors returned to the submitter and the number of duplicates submitted per Contract ID. CMS will develop error frequency benchmarks and will monitor resubmission and duplicate rates on a quarterly basis.

2.5.4 Accuracy of Submission

MAOs and other entities are responsible for the accuracy of all encounter data submitted and must ensure that every submission can be supported by an original source document (i.e., a medical record). MAOs and other entities must also attest that the data submitted is based on best knowledge, information, and belief and be accurate and truthful.

EXHIBIT P-60

This content is from the eCFR and is authoritative but unofficial.

Title 42 — Public Health

Chapter IV — Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B — Medicare Program

Part 422 — Medicare Advantage Program

Subpart G — Payments to Medicare Advantage Organizations

Source: 70 FR 4729, Jan. 28, 2005, unless otherwise noted.

Authority: 42 U.S.C. 1302, 1306, 1395w-21 through 1395w-28, and 1395hh.

Source: 63 FR 18134, Apr. 14, 1998, unless otherwise noted.

Editorial Note: Nomenclature changes to part 422 appear at 70 FR 4741, Jan. 28, 2005.

§ 422.310 Risk adjustment data.

- (a) **Definition of risk adjustment data.** Risk adjustment data are all data that are used in the development and application of a risk adjustment payment model.
- (b) **Data collection: Basic rule.** Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.
- (c) **Sources and extent of data.**
 - (1) To the extent required by CMS, risk adjustment data must account for the following:
 - (i) Items and services covered under the original Medicare program.
 - (ii) Medicare covered items and services for which Medicare is not the primary payer.
 - (iii) Other additional or supplemental benefits that the MA organization may provide.
 - (2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.
- (d) **Other data requirements.**
 - (1) MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards. CMS may specify abbreviated formats for data submission required of MA organizations.
 - (2) The data must be submitted electronically to the appropriate CMS contractor.
 - (3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service.

- (4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.
- (5) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.
- (e) **Validation of risk adjustment data.** MA organizations and their providers and practitioners are required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS. For RADV audits, CMS may extrapolate RADV Contract-Level audit findings for payment year 2018 and subsequent payment years.
- (f) **Use and release of data –**
 - (1) **CMS use of data.** CMS may use the data described in paragraphs (a) through (d) of this section for the following purposes:
 - (i) To determine the risk adjustment factors used to adjust payments, as required under §§ 422.304(a) and (c);
 - (ii) To update risk adjustment models;
 - (iii) To calculate Medicare DSH percentages;
 - (iv) To conduct quality review and improvement activities;
 - (v) For Medicare coverage purposes;
 - (vi) To conduct evaluations and other analysis to support the Medicare and Medicaid programs (including demonstrations) and to support public health initiatives and other health care-related research;
 - (vii) For activities to support the administration of the Medicare and Medicaid programs;
 - (viii) For activities conducted to support program integrity; and
 - (ix) For purposes authorized by other applicable laws.
 - (2) **CMS release of data.** Regarding data described in paragraphs (a) through (d) of this section, CMS may release the minimum data it determines is necessary for one or more of the purposes listed in paragraph (f)(1) of this section to other HHS agencies, other Federal executive branch agencies, States, and external entities in accordance with the following:
 - (i) Applicable Federal laws;
 - (ii) CMS data sharing procedures;
 - (iii) Subject to the protection of beneficiary identifier elements and beneficiary confidentiality, including—
 - (A) A prohibition against public disclosure of beneficiary identifying information;
 - (B) Release of beneficiary identifying information to other HHS agencies, other Federal executive branch agencies, and States only when such information is needed; and

- (C) Release of beneficiary identifying information to external entities only to the extent needed to link datasets.
- (iv) Subject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.
- (v) Risk adjustment data other than data described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section will be released without the redaction or aggregation described in paragraphs (f)(2)(iii) and (f)(2)(iv) of this section, respectively.
- (3) Risk adjustment data will not become available for release under this paragraph (f) unless—
 - (i) The risk adjustment reconciliation for the applicable payment year has been completed;
 - (ii) CMS determines that data release is necessary under paragraph (f)(1)(vi) of this section for emergency preparedness purposes before reconciliation; or
 - (iii) CMS determines that extraordinary circumstances exist to release the data before reconciliation.
 - (iv) CMS determines that releasing aggregated data before reconciliation is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.
 - (v) CMS determines that releasing data to State Medicaid agencies before reconciliation for the purpose of coordinating care for dually eligible individuals is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.
- (g) **Deadlines for submission of risk adjustment data.** Risk adjustment factors for each payment year are based on risk adjustment data submitted for items and services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate. CMS may adjust these deadlines, as appropriate.
 - (1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting items and services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.
 - (2) After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary.
 - (i) Prior to calculation of final risk factors for a payment year, CMS allows a reconciliation process to account for risk adjustment data submitted after the March deadline until the final risk adjustment data submission deadline in the year following the payment year.
 - (ii) After the final risk adjustment data submission deadline, which is a date announced by CMS that is no earlier than January 31 of the year following the payment year, an MA organization can submit data to correct overpayments but cannot submit diagnoses for additional payment.
 - (3) Submission of corrected risk adjustment data in accordance with overpayments after the final risk adjustment data submission deadline, as described in paragraph (g)(2) of this section, must be made as provided in § 422.326.

[73 FR 48757, Aug. 19, 2008, as amended at 79 FR 29956, May 23, 2014; 79 FR 50358, Aug. 22, 2014; 80 FR 7960, Feb. 12, 2015;
83 FR 16733, Apr. 16, 2018; 88 FR 6665, Feb. 1, 2023; 88 FR 79539, Nov. 16, 2023; 89 FR 30822, Apr. 23, 2024]

EXHIBIT P-61

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

Videotaped Deposition of
JEFFERY S. DUMCUM
Given Remotely
Wednesday, July 28, 2021
9:12 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. And the second bullet there says:
2 Goal to launch claims verification process; do you
3 see that?

4 A. I see it. I -- I see that.

5 Q. Is -- is the timing of this consistent
6 with your -- this is a 2010 presentation. Does
7 that line up with when you were -- you had a goal
8 to launch the claims verification process?

9 MR. ABASCAL: Object to the
10 characterization as "you."

11 THE WITNESS: It aligns to the
12 approximate time that there was a goal to
13 launch claims verification.

14 BY MR. MASON:

15 Q. Okay. And the second bullet there
16 says: Compare to codes from claim.

17 And, again, this is in a presentation
18 about chart review. And it says: Compare to
19 codes from claim.

20 I'm interested in what that means. Do
21 you have any understanding of what that means,
22 compare to codes from claim?

23 A. I don't recall this specific
24 presentation. I do recall in the claims
25 verification process, that was eventually

1 incorporated.

2 Q. Does -- does that mean -- when it says
3 "Compare to codes from claims," does that mean
4 comparing the codes submitted by a provider --
5 that's what claims is -- to the codes identified
6 by a chart review of -- of that encounter?

7 MR. ABASCAL: Asked and answered.

8 THE WITNESS: Yes.

9 BY MR. MASON:

10 Q. You understood that that was a
11 comparison that -- that UnitedHealth could run?

12 A. Yes.

13 Q. That UnitedHealth could identify if
14 there were codes that a provider recorded that a
15 chart review of that same provider encounter did
16 not identify?

17 A. United could compare data from claims
18 with data from chart review. So they could
19 identify for a member what codes were submitted in
20 claims and what codes were captured from chart
21 review. They could not -- it took work to
22 identify if all the information was captured in
23 chart review. The data comparison was able to be
24 compared. The completeness of the chart review
25 information had limitations.

1 Q. Okay. It -- it took work, but that
2 was something that could be done?

3 A. There was research that could be done.
4 The delta between what was in claims and what was
5 in charts would lack certainty. So there was
6 research that could be done. But because of lack
7 of -- their interpretation in the coding process,
8 as one coder viewed something as legible versus
9 another does not, if people code in a medical
10 group setting and you get a chart for one doctor,
11 do you know if you have it for all the doctors,
12 even though it may be from a similar date of
13 service, that they see multiple providers.

14 So the data comparison was easy
15 enough, and we could do research. But there were
16 always still areas of uncertainty in the
17 completeness of the chart data.

18 Q. Okay. And when there was a code that
19 was submitted by a provider that a chart review
20 did not identify, was that sometimes referred to
21 as a discrepant code?

22 A. I -- I don't recall.

23 Q. That's not a term you're familiar
24 with, discrepant code?

25 A. I've heard it. I'm unsure of the

1 CERTIFICATE OF REPORTER

2

3 I, Cindy A. Hayden, Registered Merit
4 Reporter and Notary Public for the State of North
5 Carolina at Large, do hereby certify that the
6 foregoing transcript is a true, accurate, and
7 complete record.

8 I further certify that I am neither
9 related to nor counsel for any party to the cause
10 pending or interested in the events thereof.

11 Witness my hand, I have hereunto
12 affixed my official seal this 5th day of August,
13 2021 at Charlotte, Cabarrus County, North Carolina.

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Cindy A. Hayden, RMR, CRR
My Commission expires
April 7, 2022

22

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EXHIBIT P-62

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
 Plaintiff,)
)
 v.)Case No. 16-08697 FMO
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
 Defendants.)
-----)

VIDEOTAPED DEPOSITION OF JOHN N. MARTINEZ, taken on
behalf of Relator BEN POEHLING, at 650 Town Center Drive,
20th Floor, Costa Mesa, California 92626, beginning at
9:48 a.m., and ending at 3:55 p.m., on Tuesday,
August 30, 2022, before Marceline F. Noble, RPR, CRR,
Certified Shorthand Reporter No. 3024.

Magna Legal Services
866-624-6221
www.MagnaLS.com

Reported by:
Marceline F. Noble
CSR No. 3024
Job No. 835287

1 Q. Okay. Why was CV limited to members with
2 exclusive HCCs?

3 A. I don't know.

4 Q. Okay.

5 A. I didn't -- I didn't build that rule.

6 Q. Do you know who did build that rule?

7 A. I don't know. It was a rule that was
8 already there.

9 Q. Okay. Did you ever question that rule?

10 A. Not to my recollection.

11 Q. Okay. Why not?

12 A. It wasn't my role.

13 Q. Okay. Whose role would it have been?

14 MR. RYDBERG: Objection. Calls for
15 speculation.

16 THE WITNESS: Yeah. I would assume my
17 manager's.

18 BY MR. VOLDMAN:

19 Q. Okay. The third step is called "system
20 matching."

21 What does that mean?

22 A. So the system matching is now at the point
23 in claims verification, where a chart is deemed to be
24 eligible because it contains a date of service for
25 the year we're evaluating. It has one or more

1 exclusive HCCs in the claims.

2 And the system matching is the process of
3 taking HCCs from claim and comparing them to the HCCs
4 that were found during the first step -- the chart
5 review process.

6 Q. Okay. What were the points of comparison?

7 A. To the best of my recollection, the points
8 of comparison were -- we did everything at the HCC
9 level. And the date of service was important. So
10 we -- we tried to ensure that we wouldn't identify
11 HCCs that could not be validated in the chart.

12 So dates of service were a driver of what
13 was deemed to be CV eligible or continue within the
14 process of CV eligibility.

15 Q. Okay. So the date of service had to match
16 between whatever came out of chart review and
17 whatever is in the claims or encounter system?

18 A. Yes.

19 Q. Okay. What would happen if it didn't match,
20 but a member had an exclusive HCC?

21 A. At a high level, that -- that chart would
22 either not be eligible, or if there were other dates,
23 the HCC would be dispositioned appropriately,
24 depending on what -- where it was found -- or when it
25 was found or when it was incurred.

1 Q. Okay. Do you know who made the rules for
2 what counts as a match and what doesn't?

3 MR. RYDBERG: Objection. Calls for
4 speculation.

5 THE WITNESS: I don't recall.

6 BY MR. VOLDMAN:

7 Q. Okay. Do you know who did the actual coding
8 to match these things together?

9 A. A technical team. Developers.

10 Q. Do you remember any of them by name?

11 A. No.

12 Q. Okay.

13 A. No.

14 Q. Fair enough.

15 A. Sorry.

16 Q. What's the fourth step, CVA coding?

17 A. Fourth step is now at the point in the
18 evaluation of the -- of that chart. And where we
19 find -- or we have deemed that a HCC is found in the
20 claim stream. And, of course, all eligibility rules
21 are -- are -- are applicable.

22 But where we find an HCC that is found in
23 claims, but we did not find that HCC in the coding
24 results, that -- that is part of step 1.

25 Q. Okay. And -- and is that determination made

1 at the system matching step?

2 A. I consider it separate. System matching is
3 simply comparing an HCC from one data stream to the
4 other.

5 CVA coding was now queuing the H- -- that
6 bar code to a coder for review.

7 Q. Okay. So only -- only instances without a
8 perfect match, went to CVA coding; is that correct?

9 MR. RYDBERG: Objection. Vague.

10 THE WITNESS: There are other reasons why
11 HCCs would go to coding.

12 But at a high level, if it matched, it would
13 not go to coding.

14 BY MR. VOLDMAN:

15 Q. Okay. What were the other reasons you just
16 referenced?

17 A. Well, HCCs have a hierarchy. So if the
18 hierarchy -- and I'm going to try to go really slow
19 here, 'cause this is very confusing.

20 But if the hierarchy was higher in claim,
21 but it was lower in chart, we would still route it
22 for a coder to review.

23 Q. Okay. Why is that?

24 A. We wanted to be accurate in ensuring that
25 the member truly had the condition, according to the

1 BY MR. VOLDMAN:

2 Q. Okay. Is HCC 96 something that was not
3 found by a CV analyst but submitted by a provider,
4 based on your understanding of how CV worked?

5 MR. RYDBERG: Object to form.
6 Mischaracterizes the document.

7 THE WITNESS: So in this slide, this is
8 referring to the system matching process.

9 BY MR. VOLDMAN:

10 Q. Okay.

11 A. And so it depends on where you are in the
12 process.

13 But this slide HCC 96 would be marked --
14 marked as a discrepancy.

15 Q. Okay. And is "potential delete" just
16 another word for discrepancy?

17 MR. RYDBERG: Objection. Calls for
18 speculation.

19 THE WITNESS: I believe so.

20 BY MR. VOLDMAN:

21 Q. Okay. And do you know what converts
22 potential deletes into deletes?

23 MR. RYDBERG: Objection. Vague.

24 THE WITNESS: Yeah, I think I do.

25 ///

1 BY MR. VOLDMAN:

2 Q. What is it?

3 A. The following processes of claims
4 verification. They're sent -- they're sent to a
5 coder for review.

6 Q. Okay. Got it.

7 And if the coder doesn't find support, and
8 then the next coder doesn't find support, it gets
9 sent to the delete team; is that right?

10 A. It's dispositioned as a delete.

11 Q. Okay. Thanks.

12 Did you use the phrase "risk mitigation"
13 when working in CV?

14 A. I don't recall.

15 Q. Got it.

16 Did you ever talk about risks of not doing
17 CV?

18 MR. RYDBERG: Object to form.

19 THE WITNESS: Not to my recollection.

20 BY MR. VOLDMAN:

21 Q. Okay. Did CV generally cost clients that
22 were using it, money?

23 MR. RYDBERG: Object to form. Lacks
24 foundation.

25 THE WITNESS: We offered it as a service

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REPORTER'S CERTIFICATION

I, Marceline F. Noble, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 5th day of September, 2022.

-----*Marceline F. Noble*

Marceline F. Noble, CSR No. 3024

EXHIBIT P-63

Optum Medicare Risk Adjustment Operations

Policy Name: Chart Review Services for Medicare Advantage Plan Clients

Issue Date:
6/30/2014

Pages: 5

Approvals

Approved By:

Dave Thomas Optum Legal 5/26/2015

Name	Title	Date
Dave Thomas	Optum Legal	5/26/2015

Status

Approved

Effective

Retired

Date:

6/9/2015

6/9/2015

NA

Approved By:

Sean Heath Dir Compliance 5/26/2015

Name	Title	Date
Sean Heath	Dir Compliance	5/26/2015

Applicable To:

☒ Chart Review Services

Approved By:

Tim Trujillo VP Risk Adjustment 6/9/2015

Name	Title	Date
Tim Trujillo	VP Risk Adjustment	6/9/2015

PURPOSE

Optum Medicare Advantage Risk Adjustment Operations provides Chart Review services to Medicare Advantage Organizations (MAO) Clients that support risk adjustment submissions in accordance with CMS risk adjustment regulations, the Medicare Managed Care Manual and the CMS Risk Adjustment Participant Guide. This policy addresses standards for the review of medical record documentation that supports the diagnoses submitted to CMS for Medicare program risk adjustment.

SCOPE

This policy addresses Optum Medicare Advantage Risk Adjustment Operations Chart Review services.

DEFINITIONS

TERM	DESCRIPTION
Hierarchical Condition Category (HCC)	HCC is a disease group broadly organized into body systems. The HCC assigned to a disease group is determined by the ICD-CM diagnosis code.
MAO Client	Medicare Advantage Organization that holds a Medicare Advantage contract.
PCP	Primary Care Physician

POLICY

Where Optum Medicare Advantage Risk Adjustment Operations performs Chart Review services on behalf of its MAO Clients, it will do so in accordance with CMS standards. Optum Medicare Advantage Risk Adjustment Operations will abide by instructions in the applicable Medicare regulations, CMS Risk Adjustment Participant Guides and Medicare Managed Care Manual, CH. 7 addressing medical record documentation sources and content, coding review, coding standards and quality activities.

CHART REVIEW SERVICES

Chart Review services, which will be conducted if and as specified in the contract with the Client, include a number of programs that are designed to collect, assess and evaluate documentation that supports health plan risk adjustment submissions. Chart Review services are designed to review individual medical records to identify and capture risk adjusted member diagnoses and chronic conditions based on review of the member's medical record. Chart Review services include:

A. Standard Chart Review :

The standard chart review includes retrieval, review, coding and confirming signature and credential requirements of the medical record to capture the risk adjusted diagnosis information from the member's medical record documentation for a specific date of service or timeframe.

B. Attestations:

An optional Medicare risk adjustment chart review service a client may select to retrieve attestations from providers. Attestations capture a providers signature or credentials when absent from the chart documentation. The provider states in writing that the pre-existing medical record accurately reflects the care of a member in a given encounter.

Optum Medicare Advantage Risk Adjustment Chart Review Operations Team will follow Optum coding guidelines for Risk Adjustment submissions when reviewing medical record documentation as outlined in the Retrospective Services Standards section of this policy.

1. Standards for Reviewing Medical Records for Chart Review Services:

Optum Medicare Advantage Risk Adjustment Operations has developed standards for reviewing medical records based on CMS risk adjustment instructions. These standards include:

- A.** The diagnosis must be coded in accordance with the ICD-CM Coding Guidelines as mandated by CMS and Optum coding guidelines;

B. The medical record documentation meets the CMS medical records guidelines and includes the following risk adjustment information:

- The service was provided by an acceptable risk adjustment provider and physician type.
- Dates of service are within the data collection period.
- Diagnoses are supported by medical record documentation.
- A provider signature and credentials are documented for each note.
 - Client may exercise discretion, consistent with CMS guidance on attestation, as to how to address records that have not yet been fully authenticated by the treating practitioner at the time of chart review.
- Coding level specificity – 3-5 digit codes

2. Coding Review Requirements:

To meet this standard, Optum Medicare Advantage Risk Adjustment Operations has developed requirements for coding reviews based on the Medicare Advantage regulations, the Medicare Managed Care Manual and CMS Risk Adjustment Participant Guide. These requirements include:

- A. Optum Medicare Advantage Risk Adjustment Operations will utilize certified medical coders.
- B. The certified coders will use ICD-CM Diagnosis Codes Guidelines as mandated by CMS, Optum coding guidelines, and Coding Clinics published by American Hospital Association (AHA), and comply with Optum Medicare Advantage Diagnostic Coding Standards and any other applicable Optum Coding Compliance Policies when evaluating assigned medical charts.
- C. Certified coders will review medical records to identify risk adjusting conditions supported in the medical record documentation. When performing chart reviews, the certified coders will apply CMS standards for Medicare Risk Adjustment submissions as detailed above.
- D. Optum Medicare Advantage Risk Adjustment Operations will document and implement a procedure for receipt, research and response to coding questions from internal coders or its vendors.
- E. Optum Medicare Advantage Risk Adjustment Operations will provide training to its internal coding staff that specifically addresses the above standards. This training will be conducted for all new coding staff before they begin coding charts and on-going thereafter for all coding staff.
- F. Optum Medicare Advantage Risk Adjustment Operations will conduct coding accuracy reviews of its internal coding staff to validate that data is coded correctly and meets CMS standards

3. Chart Review Vendor Engagement and Oversight

Optum Medicare Advantage Risk Adjustment Operations will conduct reasonable due diligence on potential vendors that conduct chart reviews and may engage vendors to conduct chart reviews pursuant to a written agreement that meets business, legal and regulatory requirements. Optum Medicare Advantage Risk Adjustment Operations will follow appropriate procurement processes when engaging chart review vendors. When Optum Medicare Advantage Risk Adjustment Operations engages a vendor to conduct chart reviews, Optum Medicare Advantage Risk Adjustment Operations will follow the following standards:

A. Contract Standards:

The terms of a vendor agreement with Optum Medicare Advantage Risk Adjustment Operations will include: the specific retrospective program activities, measurement or performance standards, if applicable, auditing and monitoring rights and payment terms. The vendor agreement will also include a Business Associate Agreement (BAA) or other appropriate terms that describe the permitted and required uses of protected health information.

B. Coding Standards:

See coding standards guidelines from Section 1 Standards for Reviewing Medical Records.

4. Vendor Oversight:

Optum Medicare Advantage Risk Adjustment Operations will design and execute appropriate coding reviews for its external vendors as part of its overall quality review program. Optum Medicare Advantage Risk Adjustment Operations will establish performance measurements, corrective action and disciplinary action guidelines for vendors that do not meet the quality review standards.

5. Provider Communications Standards

Optum Medicare Advantage Risk Adjustment Operations will obtain prior review as required by Optum Legal and Compliance and prior approval from the Client for all provider correspondence related to the chart review process.

6. Privacy Standards

Optum Medicare Advantage Risk Adjustment Operations will only receive, use and disclose Protected Health Information pursuant to the Optum privacy and security standards, including the use of secure transmission methods.

7. Standards Management

The Director of Chart Review Programs is responsible for collaborating with Optum Compliance to identify changes to the standards for all risk adjustment data collection and submission and ensuring implementation of any new requirements.

- The policy will be reviewed for updates periodically or when changes are indicated by CMS.
- All policy changes will be approved by the policy owner, Compliance and Legal.

Version control will apply to all policies.

CHANGE CONTROL LOG

Date	Brief Description of Change	Author	Approver(s)
6/30/2014	Create new document	Baker	Thomas, Pettersen-Scott, Trujillo and Fabrizio
5/20/2015	2015 review and updates.	Baker	Thomas, Heath, Trujillo

EXHIBIT P-64

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
STEPHANIE DAWN GARDNER
Given Remotely
Wednesday, June 30, 2021
9:04 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 deletes being discussed earlier in the e-mail chain?

2 A. I don't recall, but I have no reason to
3 doubt that.

4 Q. Okay. Your full sentence reads: "I would
5 advise continuing with them because if we know data
6 was incorrectly submitted, we have an obligation to
7 notify CMS and they have the right to retro adjust
8 pay." Did you believe this when you wrote it?

9 A. I don't recall.

10 Q. Okay. Do you have any reason to doubt
11 that you believed this when you wrote it?

12 A. I -- I don't recall. I have -- I have no
13 reason to doubt what I wrote.

14 Q. Okay. Did you believe, during the period
15 that you worked at United, that if data was
16 incorrectly submitted, you had an obligation to
17 notify CMS?

18 A. My understanding was that if we were aware
19 that a -- a condition was not -- incorrectly
20 submitted, as in not supported by the medical record
21 documentation, then that we should proceed with
22 deleting it.

23 Q. What was this belief based on?

24 A. I don't recall specifically.

25 Q. Was this belief based on discussions you

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 STEPHANIE GARDNER was duly remotely sworn by me to
7 testify to the truth, the whole truth and nothing but
8 the truth.

9 I DO FURTHER CERTIFY that the foregoing is a
10 verbatim transcript of the testimony as taken
11 stenographically by me at the time, place and on the
12 date hereinbefore set forth, to the best of my
13 ability.

14 I DO FURTHER CERTIFY that I am neither a
15 relative nor employee nor attorney nor counsel of any
16 of the parties to this action, and that I am neither
17 a relative nor employee of such attorney or counsel,
18 and that I am not financially interested in this
19 action.

20

21

22 Karen K. Kidwell
23 Registered Merit Reporter
24 Certified Realtime Reporter
25 Notary Public
Dated: July 13, 2021

25

EXHIBIT P-65

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex

rel. BENJAMIN POEHLING,

Plaintiffs,

vs.

No. CV 16-08697 FMO

UNITEDHEALTH GROUP, INC., et al,

Defendants.

_____ /

REMOTE VIDEOCONFERENCE DEPOSITION OF

KIMBERLY HALVA

February 24, 2022

Reported by:

Anne E. Vosburgh, CSR-6804, RPR, CRR

Job No. 792083

1 K. Halva

2 A. I don't understand the "but" -- "but
3 did not find" --

4 I'm just not clear on what I'm
5 trying to answer. Could you rephrase it?

6 BY MS. LIKOFF:

7 Q. Sure. Give me just one minute.

8 All right. If M&R opened a given
9 medical record to look for all diagnosis codes
10 that were supported by documentation in that
11 record, but did not find documentation to
12 support a diagnosis that had been previously
13 submitted --

14 A. Okay.

15 Q. -- do you believe that M&R had an
16 obligation to delete that code?

17 MR. SCHINDLER: Same objection.

18 Vague and ambiguous as framed. Calls for
19 a legal conclusion as well.

20 A. My general thought is if the
21 circumstances were correct, yes. I mean, as
22 we discussed before, there's potentially some
23 one-offs that wouldn't require the deletion of
24 that code. But, in general, yes, I believe it
25 should be deleted.

1 K. Halva

2 C E R T I F I C A T E

3

4 I, ANNE E. VOSBURGH, Certified Shorthand
5 Reporter, Registered Professional Reporter,
6 Certified Realtime Reporter, and Closed
7 Captioner, hereby certify:

8 That KIMBERLY HALVA, via remote
9 videoconference, solemnly affirmed and agreed to
10 testify to the truth, the whole truth and
11 nothing but the truth; that all counsel
12 stipulated to this process, notwithstanding the
13 location of reporter or witness at time of
14 deposition; and that this transcript is a true
15 and correct record of testimony given.

16 I further certify that I am not related
17 to any of the parties to this action and that I
18 am in no way interested in the outcome of this
19 matter.

20

21



22

ANNE E. VOSBURGH

23

Certified Shorthand Reporter No. 6804

24

Registered Professional Reporter

25

Certified Realtime Reporter

EXHIBIT P-66

Message

From: Cavanaugh, Sean (CMS/CM) [/O=HHS EES/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=SEAN.CAVANAUGH.CMS]
Sent: 6/26/2015 5:18:53 PM
To: Rice, Cheri M. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=cheri.rice.cms59728027]; Tudor, Cynthia G. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=cynthia.tudor.cms06246732]; Harlow, Jennifer A. (CMS/CM) [/O=HHS EES/OU=First Administrative Group/cn=Recipients/cn=jennifer.harlow.cms20728073]
Subject: Re: 2013 CMS RAF Attestation

I disagree that we stated the last part of this sentence beginning "...and that MA plans..."

"During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses."

From: Rice, Cheri M. (CMS/CM)
Sent: Friday, June 26, 2015 12:49 PM
To: Tudor, Cynthia G. (CMS/CM); Cavanaugh, Sean (CMS/CM); Harlow, Jennifer A. (CMS/CM)
Subject: Fw: 2013 CMS RAF Attestation

Sent from my BlackBerry Wireless Device

From: Nelson, Steve H [mailto:steve_nelson@uhc.com]
Sent: Friday, June 26, 2015 12:41 PM
To: Rice, Cheri M. (CMS/CM)
Subject: 2013 CMS RAF Attestation

Cheri,

Similar to last year, we are reaching out to you, to reiterate our approach to the electronic annual risk adjustment certifications. As you know, annual risk adjustment data certifications before 2014 were submitted on paper, enabling companies to add notes explaining their understanding of these certifications (including any remediation efforts). As we discussed with you last year, because the certifications are now electronic, companies are unable to include explanatory notes. As such, we informed you in writing our understanding of these certifications.

Because the certifications remain electronic with no ability to add explanatory notes, we feel it would again be helpful, and appropriate, to capture our discussion and understanding regarding the certifications.

- As with our past certifications, the 2013 certifications are based on facts reasonably available or made available to us as of the date of the certifications. As we receive additional information, we may be required to modify the data to which the certifications relate
- The certifications use the phrase "best knowledge, information, and belief," which is based on our ordinary business practices.

- The certifications only cover risk adjustment data for 2013 dates of service that were submitted to CMS and not subsequently deleted prior to the date of the certifications.
- As we have mentioned to you previously, we are engaged in an ongoing review of our risk adjustment processes and submission system. This review has identified areas for improvement and, as a result, we will be deleting all risk adjustment data for 2013 dates of service that we ultimately determine should be deleted consistent with this email.
- CMS issued a proposed rule last year that would have required MA plans to design any medical record reviews to determine the accuracy of risk adjustment diagnoses associated with those records. In May 2014, CMS withdrew the proposed rule. During our conversations last year before the proposed rule was withdrawn, CMS confirmed to us that the proposed requirements would not apply until the effective date of the rule, and that MA plans were thus not required to design their medical record reviews to determine the accuracy of risk adjustment diagnoses. As we discussed last year, we previously had a process through which we reviewed certain medical records to determine the accuracy of risk adjustment diagnoses and submitted appropriate deletes. Based on our conversations with CMS last year, CMS's withdrawal of the proposed rule, and CMS's ongoing consideration of a FFS Adjuster to address diagnoses not supported by a medical record in the context of RADV, we ended this process and informed you of that decision. That decision remains operative for 2013 dates of service. In particular, we did not use our previous process to determine whether diagnosis codes submitted through claims are unsupported in the medical record. We do have a quality assurance process that deletes codes initially identified during chart review and that are later determined to be unsupported.

The certifications we submit this year are made subject to these clarifications. Please let me know if you have any questions. As always, we appreciate your time and attention on this matter.

Steve Nelson
Chief Executive Officer
UnitedHealthcare Medicare & Retirement

This e-mail, including attachments, may include confidential and/or proprietary information, and may be used only by the person or entity to which it is addressed. If the reader of this e-mail is not the intended recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this e-mail in error, please notify the sender by replying to this message and delete this e-mail immediately.

EXHIBIT P-67

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,)
ex rel., BENJAMIN POEHLING,)
)
Plaintiffs,)
) Civil Action No.
vs.)
) 16-08697 FMO
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

* * * * *

HIGHLY CONFIDENTIAL

* * OUTSIDE COUNSELS' EYES ONLY * *
* * * * *

VIDEOTAPED DEPOSITION OF
JULIA M. LAMBERT, FSS, MAAA
Friday, April 5, 2024; 9:11 a.m. CDT

Reported by: Cindy L. Sebo, RMR, CRR, CLR, RPR,
CCR, CSR, RSA, CA CSR 14409, NJ Certified CR
30XI0024460, NJ Certified RT 30XR00019500, NM CSR
589, NY Realtime Court Reporter, NY Association
Certified Reporter, OR CSR 230105, TN CSR 998, TX
CSR 12778, WA CSR 23005926, Notary Public
Job No. 1101160

1 other reason, the average of the relative values
2 go up.

3 I don't know what "definitionally"
4 means, but in general, that is the result when
5 you take out markers.

6 Q. Okay. Fair enough.

7 I think "definitionally," I
8 mean categorically, that it doesn't matter
9 whether the error rate is 1 percent or
10 99 percent, the average relative factor
11 increases if you take out markers from this
12 calibration?

13 A. Yes, that is what the proof shows.

14 Q. Okay. So then if you recalibrated
15 the model using both unsupported codes and
16 unsubmitted codes, doesn't that connection
17 between -- can I call it "directionality"?

18 It doesn't definitely go up
19 anymore; is that -- is that right?

20 A. That would be something different,
21 not addressed by my proof, for sure.

22 Q. Sure. But if you take out markers
23 and add in markers, it's no longer necessarily
24 true that the relative factors would increase;

1 is that --

2 A. That's correct.

3 Q. -- correct?

4 Yeah. Because they would net
5 out and there's a chance that more markers end
6 up, or different, higher value markers; is that
7 correct?

8 A. I didn't perform that study, but
9 adding markers has the opposite effect as
10 removing markers --

11 Q. And --

12 A. -- at that --

13 Q. Sorry.

14 Are you finished?

15 A. Yes.

16 Q. And recalibrating with both adding
17 and removing markers, it -- the average can go
18 up, the average can go down, or the average can
19 stay the same; is that correct?

20 A. As a matter of math, yes. It
21 depends on how many markers you add and how many
22 markers you take out.

23 Q. Yep. Totally agree with you there.

24 Okay. So that being said, is

1 I, Cindy L. Sebo, Nationally Certified Court
2 Reporter herein, do hereby certify that the
3 foregoing deposition of JULIA M. LAMBERT, FSS, MAAA
4 was taken before me pursuant to notice at the time
5 and place indicated; that said witness duly swore to
6 tell the truth, the whole truth, and nothing but the
7 truth under penalties of perjury; that said
8 testimony of witness was correctly recorded to the
9 best of my abilities in machine shorthand,
10 thereafter transcribed under my supervision with
11 computer-aided transcription; that deposition is a
12 true and accurate record of the testimony given by
13 the witness; that I am neither counsel, nor kin to
14 any party in said action, nor interested in the
15 outcome; and that a copy of this transcript obtained
16 from a source other than the court reporting firm,
17 including an adversary or co-counsel in the matter,
18 is uncertified and may not be used at trial.

19 Cindy L. Sebo
CINDY L. SEBO, RMR, CRR, CLR, RPR, CCR, CSR, RSA,
20 CA CSR 14409, NJ Certified CR 30XI0024460,
NJ Certified RT 30XR00019500, NM CSR 589,
21 NY Realtime Court Reporter, NY Association Certified
Reporter, OR CSR 230105, TN CSR 998,
22 TX CSR 12778, WA CSR 23005926, Notary Public
23
24

EXHIBIT P-68

Transforming

Collaborating

Communicating



Medicare Advantage & Prescription Drug Plan

FALL CONFERENCE & WEBCAST

CONFERENCE GUIDE



September 7, 2017 • 9:30 am – 4:30 pm EDT
CMS Grand Auditorium

Speaker Bios, cont.

appeals operations for the FFS, MA, and Part D Qualified Independent Contractors, the appeals units of the Medicare administrative contractors, and CMS' Beneficiary Notice Initiative, which includes provider-issued notices such as the Important Message from Medicare, the Advance Beneficiary Notices of Noncoverage, and the Medicare Outpatient Observation Notice.

Mike previously worked on program integrity issues, including overseeing the implementation of several new program safeguard contractors. He began his federal career in budget formulation, where his main area of concentration was the Medicare managed care program. Mike has been at CMS for 20 years and holds a BS.

Judy Geisler

BA, BS, Deputy Director, Medicare Parts C and D Oversight and Enforcement Group, Center for Medicare, CMS

Judy is currently the Deputy Director of the Medicare Parts C and D Oversight and Enforcement Group (MOEG). Prior to joining MOEG she served briefly as the Acting Deputy Director of the Medicare Enrollment and Appeals Group and the Medicare Drug Benefit and C & D Data Group and spent 10 years as the Director

of the Division of Formulary and Benefit Operations in the Medicare Drug Benefit and C & D Data Group.

Staci Paige

MA, Social Science Research Analyst, Division of Appeals Policy, Medicare Enrollment and Appeals Group, Center for Medicare, CMS

Staci Paige is a Social Science Research Analyst in the Division of Appeals Policy (DAP), Medicare Enrollment and Appeals Group (MEAG). As a Medicare Advantage appeals and grievances subject matter expert, Staci works on regulations, beneficiary notices and manual guidance. She also works closely with the Medicare-Medicaid Coordination Office on appeals and grievance issues related to Medicare-Medicaid Plans (MMPs). Prior to working at CMS, Staci directed admissions at a skilled nursing facility and also has a background in community case management and care coordination.

Rebecca Paul

MPH, MA, Director, Division of Payment Policy, Medicare Plan Payment Group, Center for Medicare, CMS

Rebecca Paul currently serves as the Director of the Division of Payment Policy (DPP) in the Medicare Plan Payment Group (MPPG) in the Center for Medicare (CM). Since joining CMS in 2005, Rebecca has worked on a variety of Medicare payment issues and policies.

Christine Reinhard

BA, MBA, JD, Technical Advisor, Medicare Drug and Health Plan Contract Administration Group, Center for Medicare, CMS

Christine has been with CMS since 1995, working in managed care since 1998. Her previous work has focused on many aspects of the Part C and Part D programs including bid submissions, plan benefits, auditing, enforcement actions,

and financial analysis of contractors. She is currently a Technical Advisor for the Division of Surveillance, Compliance, and Marketing.

John Scott

JD, Senior Advisor, Medicare Drug Benefit and C and D Data Group, Center for Medicare, CMS

John Scott has been employed by CMS since 2003, and has worked extensively on the Medicare Part C and Part D Programs since coming to CMS. John has been on detail in the Medicare Drug Benefit and C and D Data Group since January 2017. John previously worked in the Medicare Parts C and D Oversight and Enforcement Group (MOEG) as the Director of the Division of Compliance Enforcement. Prior to joining MOEG in April 2016, John worked in the Medicare Plan Payment Group (MPPG) as the Director of the Division of Payment Systems, Director of the Division of Payment Operations, and Special Assistant to the Director of MPPG. John's first position at CMS was in the Medicare Enrollment and Appeals Group's Division of Appeals Policy. John holds a BA from Ripon College and a JD from North Carolina Central University.

Scott Sturiale

Deputy Director, Medicare Drug and Health Plan Contract Administration Group, Center for Medicare, CMS

Scott is the Deputy Director for the Medicare Drug and Health Plan Contract Administration Group (MCAG) in the Center for Medicare, providing leadership and he is director over the development of new policies to reflect changes in program objectives, the health care delivery system, beneficiary health care needs, and new plan types to support an appropriate range of choices for beneficiaries.



EXHIBIT P-69

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	
ex rel. BENJAMIN POEHLING,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. CV 16-08697 FMO
	)	
UNITEDHEALTH GROUP, INC.,	)	
et al.,	)	
Defendants.	)	
_____	)	

VIDEOTAPED DEPOSITION OF JIMMY ARTHUR HIGGINS, taken on behalf of Plaintiff, UNITED STATES OF AMERICA, at 650 Town Center Drive, Costa Mesa, California 92626, beginning at 9:16 a.m., and ending at 5:42 p.m., on Tuesday, May 3, 2022, before Marceline F. Noble, RPR, CRR, Certified Shorthand Reporter No. 3024.

Magna Legal Services
866-624-6221
www.MagnaLS.com

Reported by:
Marceline F. Noble
CSR No. 3024
Job No. 821137

1 of what the word "accurate" means --

2 MS. DO: Object --

3 BY MS. GLOVER:

4 Q. -- in -- in that attestation?

5 MS. DO: Objection. Calls for a legal
6 conclusion.

7 THE WITNESS: My idea of "accurate," you
8 know -- it represents things that really happened.

9 BY MS. GLOVER:

10 Q. Understood.

11 So if a -- if -- if a provider is submitting
12 a diagnosis code, your understanding of accurate is
13 that that diagnose code is, in fact, supported by
14 medical record documentation that the provider has;
15 is that correct?

16 MS. DO: Objection. Hypothetical. And
17 mischaracterizes prior testimony.

18 THE WITNESS: Yeah. Our basic mantra was,
19 if it wasn't in the medical record, it didn't happen.

20 BY MS. GLOVER:

21 Q. Understood. Understood.

22 And -- and was that a mantra that was
23 repeated to providers in provider education sessions,
24 that you and Ms. -- Ms. Leal and Ms. Holt held with
25 certain providers?

1 MS. DO: Okay. Preferably, just keep
2 looking at the camera so Madam Court Reporter can
3 hear you.

4 THE WITNESS: Okay.

5 MS. DO: That's kind of awkward. Do you
6 mind if I switch with you?

7 MS. GLOVER: I -- I do not.

8 Why don't we go off the record.

9 THE VIDEOGRAPHER: We're now off record.
10 The time is 5:16 p.m.

11 (Off record.)

12 THE VIDEOGRAPHER: Stand by, please.

13 We are now on the record.

14 The time is 5:19 p.m.

15

16 EXAMINATION

17 BY MS. DO:

18 Q. All right, Mr. Higgins. I just have a few
19 questions, and then hopefully we'll get out of here.

20 Can you remind me, when did you leave
21 United?

22 A. The end of August 2007.

23 Q. And after your departure from United, did
24 you ever return --

25 A. No.

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REPORTER'S CERTIFICATION

I, MARCELINE F. NOBLE, a Certified Shorthand Reporter in and for the State of California, do hereby certify:

That the foregoing witness was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and later transcribed into typewriting under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 12th day of May, 2022.

Marceline F. Noble

MARCELINE F. NOBLE, CSR No. 3024

EXHIBIT P-70

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

CONFIDENTIAL
CONTAINS ATTORNEYS' EYES ONLY PORTIONS
(See Note on Index Page)

Videotaped Deposition of
REBECCA PAUL
Given Remotely
Wednesday, April 13, 2022
9:02 a.m. Eastern Time

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 this piece fit with that, with seeing this went
2 to RADV, so it also went to CPI.

3 BY MR. QURESHI:

4 Q. Ms. Paul, you -- you referenced
5 discussions with CPI about taking on the role of
6 conducting RADV audits. Who had those discussions?

7 MR. MASON: Objection to form.

8 THE WITNESS: I don't know. I don't know
9 if Cheri was involved in them or if it was
10 people above her.

11 BY MR. QURESHI:

12 Q. Who told you --

13 A. It was not me. I was not involved with
14 them.

15 Q. Who told you that CPI would be taking over
16 the project that you described as modeling changes in
17 the risk adjustment model?

18 MR. MASON: Objection. Misstates prior
19 testimony.

20 THE WITNESS: I don't remember. Probably
21 Cheri. I -- it wasn't -- I don't remember.

22 BY MR. QURESHI:

23 Q. And do you recall why CPI was taking it
24 over, according to Ms. Rice?

25 MR. MASON: Objection. Asked and

1 answered.

2 THE WITNESS: I'm assuming it's Cheri
3 because I don't know who else would have told
4 me, but I don't know. I mean, it came up in
5 conversation or -- you know, someone would have
6 told me -- not conversational. It would have
7 been updates.

8 I -- I don't know why. I mean, like I
9 said, the context was that this was part of
10 RADV, and CPI already had RADV, so that, you
11 know, would be seen as linking it. But I
12 don't -- I don't know that it was a big formal
13 announcement.

14 BY MR. QURESHI:

15 Q. Do you recall who at CPI would take over
16 responsibility for the task Ms. Rice previously asked
17 you to perform?

18 MR. MASON: Objection. Misstates
19 testimony.

20 THE WITNESS: I mean, I know who worked on
21 it. I don't think that was part of the -- I
22 don't remember how we discussed it. I -- I
23 can't recall the conversation or -- or how the
24 conversation went. But I only know who ended up
25 working on it. I don't know if that was part of

1 identified, and understand them.

2 BY MR. QURESHI:

3 Q. Ms. Paul, did you ever ask Ms. Cheri Rice
4 why CPI was given responsibility to calculate the
5 methodology for the fee-for-service adjuster?

6 MR. MASON: Objection to form. Confusing.
7 Misstates prior testimony.

8 THE WITNESS: I don't know if I asked her
9 or not. I mean, the impression I have today is
10 that it was a RADV side issue that went with it.

11 BY MR. QURESHI:

12 Q. What is that impression based on?

13 A. Well, it was a RADV-related effort, and
14 that RADV had gone to CPI. I don't recall discussing
15 with her.

16 Q. But while the division --

17 A. (Simultaneous speaking.)

18 Q. I'm sorry. Were you finished?

19 A. Yeah, I just meant, the negotiations and
20 discussions about what went over there, I -- I was
21 not involved with them.

22 Q. And while you were in the Division of
23 Payment Policy, you weren't working on RADV, were
24 you?

25 A. I did not work on RADV.

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

19

20

Karen K. Kidwell

21

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

22

23

24

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EXHIBIT P-71

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
-----	)	

Videotaped Deposition of
JON HARVEY BIRD
Given Remotely
Wednesday, August 10, 2022

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 A. Typically we would target certain medical
2 records for retrieval. You know, once those medical
3 records are retrieved, they would be reviewed by
4 certified coders. There would be QA processes in
5 place to ensure the -- the codes are appropriately
6 supported in the medical record. And then those
7 codes would be submitted.

8 Q. You talked about certified coders who
9 abstracted medical records. What was the entire
10 universe of information provided to the certified
11 coders who abstract the medical records?

12 A. Yeah, those reviews would have been --
13 yeah, so the information that would have been
14 provided to the -- the coders at the time would be an
15 image of the -- the medical record, so it is what we
16 would refer to as a blind interview, you know, where
17 we're not getting any additional information related
18 to codes that were previously submitted; just a blind
19 abstraction, looking at the documentation provided in
20 the record, and assigning the appropriate ICD
21 diagnosis codes to that documentation.

22 Q. In this chart review process that you've
23 described, what attempt was made to compare diagnoses
24 codes abstracted by certified coders with diagnoses
25 codes that might have been identified by a coder

1 working for a hospital or a provider?

2 A. That -- that comparison would not have
3 been completed at, you know, through the chart review
4 program, but, you know, as we, you know, as I
5 testified earlier, there was a claims verification
6 process, you know, where there was an attempt to
7 match the diagnosis submitted by providers; they're
8 also part of the chart review program.

9 You know, I call it an attempt because it
10 a very complex process; it has, you know, several
11 challenges, you know, in particular related to the
12 quality of data around the provider IDs across
13 various systems. And also, you know, the
14 completeness of the medical records that would have
15 been reviewed as part of the chart review process.

16 Q. You talked a little bit about the
17 complexity of the process. What additional
18 information would be required in order to undertake a
19 comparison between diagnoses codes identified by
20 United's certified coders with codes that might have
21 been identified by coders working for a hospital or a
22 provider?

23 MR. MASON: Objection to form.

24 Foundation.

25 THE WITNESS: So, you know, the first

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

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Karen K. Kidwell
Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-72

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel. BENJAMIN POEHLING,

Plaintiff,

No. CV 16-08697 FMO

VS.

UNITEDHEALTH GROUP, INC.,
et al.,

Defendants.

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 2

DEPOSITION OF BIGGS T. CANNON, III

As 30(b)(6) Designee 6 of UHC of California, Inc.,
OptumInsight, Inc.
UnitedHealthcare, Inc.

Washington, DC
June 7, 2023

Reported by: John L. Harmonson, RPR

Job No. 983691

1 if it passes the other checks -- there is a check
2 in there, we may have referenced it yesterday,
3 called an X19. I think if that had been identified
4 in the same six-month window -- and I think we
5 talked about this. It's not a rolling six months.
6 It's January 1st to June 30th, July 1st to
7 December 31st.

8 I believe if that came in and a claim
9 had already been submitted for that same
10 member/diagnosis combination, I believe IRADS would
11 have assigned it an X19, kind of indicating it had
12 been submitted before. And I think we talked about
13 the definition yesterday. It will stop it from
14 submission at that time.

15 BY MS. GLOVER:

16 Q. Okay. So in this process, you were able
17 to assess whether a diagnosis code identified in
18 chart review had already been identified and
19 submitted by a provider previously; is that
20 correct?

21 MS. DO: Objection; misstates prior
22 testimony. Outside the scope. Lacks foundation.

23 THE WITNESS: I don't think the X19
24 process, as I recall, takes into consideration who
25 the provider was. In the RAPS system, I don't know

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C E R T I F I C A T E

DISTRICT OF COLUMBIA

I, JOHN L. HARMONSON, a Notary Public within and for the District of Columbia, do hereby certify that BIGGS T. CANNON, III, the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

That before completion of the proceedings, review and signature of the transcript was reserved.

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 9th day of June, 2023.


JOHN L. HARMONSON, RPR
My commission expires: 04/14/26

EXHIBIT P-73

Risk Adjustment Chart Review

Stephanie Wil

EXHIBIT

00167-1
4913

Nevada Chart Review

Targeted 2500 members/2747 charts

2398 members/1991 charts reviewed

2003 and 2004 DOS

PCP charts only

\$117,000 or \$43 per chart

\$28.50 per chart base rate –mileage –copying

Membership Targeting

Membership divided into four tiers using
PHS reports:

Tier 1 - HIGH likelihood

at least 3 HCC qualifying dx in previous year with none in
current year

Tier 2 - MEDIUM to LOW likelihood

between 1-3 HCC qualifying dx in previous year

Tier 3 - HCC history

HCC in claims history but not appearing on PHS reports

Tier 4

No HCC's in member history

Findings

2004

350 members had positive RAF improvement

Average RAF increase of .44

2005 payment (50% blend) impact of \$656K

2003

251 members had positive RAF improvement

Average RAF increase of .43

2004 payment (30% blend) impact of \$260 K

Combined ROI (after costs) of \$800K

Most Commonly Found HCC's

HCC	Description	Count	RAF
168	COPD	127	.376
19	Diabetes	57	.2
105	Vascular Disease	36	.357
71	Rheumatoid Arthritis	23	.268
80	CHF	22	.417
83	Old MI, Angina	17	.235
92	Atrial fibrillation	12	.266
10	Cancer	10	.233

Potential Unconfirmed Diagnoses

- Compared chart review findings with reported qualifying diagnoses

- Isolated qualifying diagnosis codes not found in chart review

- Reviewed member history to identify if HCC was reported from other source or diagnosis

- Identified 131 members with average potential negative RAF impact .4

- Possible negative impact of \$223K for 2004

Most Common Unconfirmed HCC's

HCC	Description	Count	RAF
19	Diabetes	34	.2
105	Vascular Disease	18	.357
80	CHF	18	.417
108	COPD	17	.376
16	Diabetes (neuro)	13	.552
18	Diabetes (ophth)	7	.343
92	Atrial fibrillation	7	.266

Arizona Chart Review

- Same targeted approach using PHS reports

- Include Tucson PCP capitated group

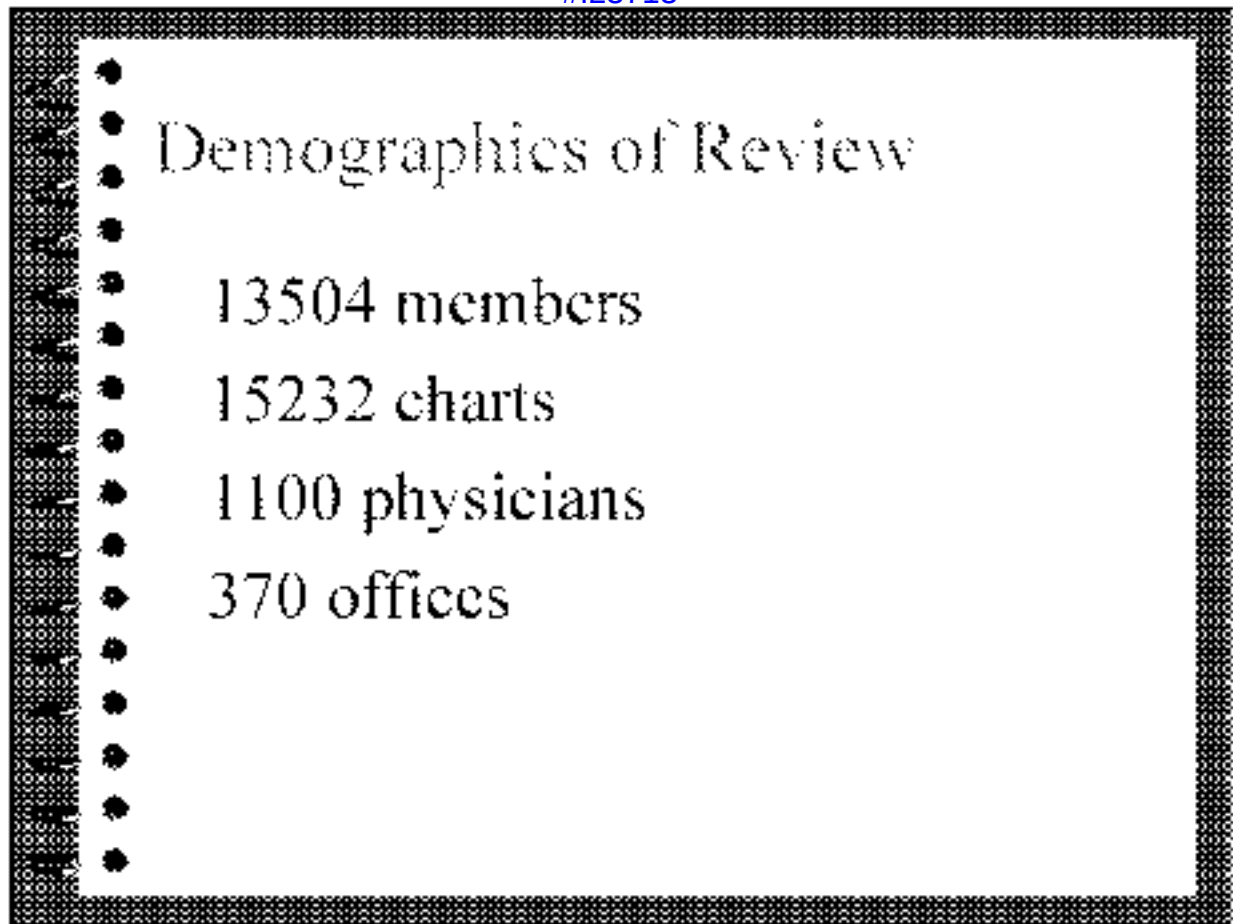
- Group identified as having poor coding quality,
low RAF score and poor diagnosis submission

- 9746 members in Tiers 1-2

- 100% of AZ membership in these tiers

- 3758 members in Tier 3

- limited to Tucson PCP capped group



Summary of Costs and Potential ROI

ARIZONA MEDICAL RECORD REVIEW SUMMARY OF TARGETED MEMBERSHIP COSTS AND ROI							
2004	# of members	# of charts	2004 conversion rate	Eligible conversions 2004	Return	Costs	ROI
Doc 1	1880	2738	17.0%	332	\$563,750.72	\$41,148.00	\$542,111.22
Doc 2a	2144	2519	13.1%	281	\$480,582.40	\$45,342.00	\$481,645.20
Doc 2b	5842	8998	12.0%	677	\$1,280,264.64	\$111,330.00	\$1,168,141.62
ACIP Physician group - Total	3756	3758	11.6%	511	\$845,634.40	\$87,844.00	\$841,000.40
TOTAL	13564	15232		1802	\$3,270,681.20	\$285,464.00	\$3,006,227.20

2003	# of members	# of charts	2003 conversion rate	Eligible conversions 2003	Return	Costs	ROI
Doc 1	1880	2738	13.5%	214	\$224,480.20	\$4,672.00	\$218,811.20
Doc 2a	2144	2519	9.2%	236	\$235,981.20	\$5,038.00	\$230,953.20
Doc 2b	5842	8998	7.6%	442	\$482,205.97	\$12,330.00	\$448,087.97
ACIP Physician group - Total	3758	3758	14.7%	552	\$580,205.99	\$57,510.00	\$572,689.05
TOTAL	13564	15232		1410	\$1,475,788.11	\$80,464.00	\$1,445,322.11

2003 and 2004					Return	Costs	ROI
TOTALS					\$4,746,471.31	\$285,928.00	\$4,420,849.31

Current Status

- Test data to consultant for validating format
- Files in final stages of preparation for submission to vendor
- Contract being finalized
- Start reviewing week of 1/31
- Completion date of early March in time for March submission to CMS

Next Phases of Chart Review

Specialist Charts

Target high volume specialists

Cardiology

Pulmonology

Rheumatology

Endocrinology

Oncology

Larger scale AZ review of Tier 3 members
among high volume PCP's

AZ specialists

Potential need for CMS validation

PCP's and specialists in other DCN/flat cap
markets

EXHIBIT P-74

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

---000---

UNITED STATES OF AMERICA, ex)
rel., BENJAMIN POEHLING,)

Plaintiff,)

vs.)

UNITEDHEALTH GROUP, INC., et)
al.,)

Defendants.)

Case No.
16-08697 FMO

---000---

TUESDAY, APRIL 2, 2024

VIDEOTAPED DEPOSITION OF CRAIG GARTHWAITE, PH.D.

CONFIDENTIAL TRANSCRIPT

---000---

REPORTER: BALINDA DUNLAP, CSR 10710, RPR, CRR, RMR

1 Q. BY MR. GALLAGHER: At various points in
2 your report you refer to something called a list of
3 potential deletes. Are you familiar with that?

4 A. I am familiar with the writing of that.
5 There was no actual list of potential deletes, but 09:22:56
6 it's a way we describe it in the report
7 conceptually.

8 Q. Well, you have not seen a list of
9 potential deletes, but that doesn't mean that
10 Analysis Group could not have created one, right? 09:23:09

11 MR. MASON: Objection to form.

12 THE WITNESS: I should be very clear on
13 what I'm saying here, that there's no list of
14 potential deletes, that the process by which the
15 code operates does not create a list of potential 09:23:21
16 deletes as described in the report.

17 Q. BY MR. GALLAGHER: Correct. But the way
18 the databases work, if you wanted to create a
19 report that was an actual list of the potential
20 deletes that were -- that would have been created 09:23:35
21 under the logic described in your report, you and
22 the Analysis Group certainly have the technological
23 capability to do that, do you not?

24 A. There could have been an entirely
25 different structure of the code that did that in 09:23:48

1 the logic in the report, but that is not the way
2 that we approached the problem, nor is it the way
3 the code currently operates.

4 Q. Let me ask you, in your Appendix D at
5 Paragraph 49 --

09:24:04

6 A. Did you say paragraph or page? I
7 apologize.

8 Q. Paragraph 49.

9 A. Oh, thank you.

10 Q. So you have "Identification of Potential
11 Deletes" as the heading VI, and then you talk about
12 how you identified potential deletes?

09:24:26

13 A. Yes, I do see that.

14 Q. And you give examples here in Paragraph 50
15 of something that would not be on the list of
16 potential deletes. Do you see that?

09:24:45

17 A. If you give me a second to read 49 and 50
18 just to make sure we are on the same page. I see
19 the part you're talking about, yes.

20 Q. How do you know whether an example is on
21 the list of potential deletes or not on the list of
22 potential deletes?

09:25:35

23 A. I am going to, again, refer back to what I
24 said earlier. There is no actual list of potential
25 deletes. I understand that the report is written

09:25:51

1 that way to provide a way to, in English language,
2 describe a set of steps that are happening
3 concurrently.

4 So it is not a question of some list of
5 potential deletes and something that's on it. It's 09:26:05
6 something that's happening sort of in realtime in
7 the code.

8 Q. So how do you -- if you need to confirm
9 that something is on -- would be on the list of
10 potential deletes or not on the potential list of 09:26:16
11 deletes, how do you do that?

12 MR. MASON: Objection to form.

13 THE WITNESS: Again, there is no list of
14 potential deletes that I have to confirm that
15 something is on. 09:26:30

16 Q. BY MR. GALLAGHER: You said earlier that
17 the way the code is currently -- the way the code
18 currently operates, there's no, you know,
19 preparation of a potential deletes list. Was there
20 ever a draft of the code that created a potential 09:26:44
21 deletes list?

22 A. If I did say they word "currently
23 operates," I did not mean to say "currently
24 operates." There's not been under my direction a
25 time where a list of potential deletes was created 09:26:59

1 and that we changed the code. This is the way we
2 have always approached the problem in this report.

3 Q. There was, however, a time where the code
4 was operated by Analysis Group to create a list of
5 potential deletes, was there not? 09:27:13

6 A. I am unaware of that.

7 Q. If that was something that they were
8 directed to do by the DOJ lawyers, that's something
9 you're not familiar with, don't know about?

10 A. I was not involved in any process of 09:27:25
11 creating a list of codes outside of what's in my
12 report.

13 Q. Have you read the first interrogatory
14 response that you referenced earlier today?

15 A. I don't know if I referenced it. I think 09:27:36
16 you might have referenced it. I have since writing
17 the report become aware of the first interrogatory,
18 but it is not something I was involved in creating
19 or crafting or discussed with Analysis Group in any
20 way. 09:27:51

21 Q. That is something that you understand
22 Analysis Group created the list that is -- that was
23 submitted in the first interrogatory response?

24 MR. MASON: Objection to form; foundation.

25 THE WITNESS: It's come to my attention 09:28:05

1 that they were involved in it. Whether they solely
2 created it or there was other people that counsel
3 had involved with that, I don't know.

4 Q. BY MR. GALLAGHER: You would, in fact, be
5 able to write code or instruct Analysis Group to 09:28:25
6 write code that would produce the potential deletes
7 list that you referenced throughout your report,
8 right?

9 MR. MASON: Objection; asked and answered.

10 THE WITNESS: As a matter of sort of 09:28:38
11 technological capability, yes, but it would be an
12 entirely different approach to writing the code to
13 answer the question in the report.

14 Q. BY MR. GALLAGHER: How would it be
15 different? 09:28:49

16 A. At no point is the code intended to create
17 a list of potential deletes.

18 Q. Right. But if you intended it to create a
19 list of potential deletes, you could, right?

20 MR. MASON: Objection; asked and answered. 09:29:00

21 THE WITNESS: Again, that's why it would
22 be different. Because it would be a different
23 intention, so...

24 Q. BY MR. GALLAGHER: Right. So my question
25 is if you wanted to create a list of potential 09:29:08

1 deletes, you could, right?

2 MR. MASON: Objection; asked and answered.

3 THE WITNESS: As a matter of course, we
4 could do it, yes.

5 Q. BY MR. GALLAGHER: And what would it 09:29:23
6 entail if you wanted to do that? What would you
7 have to do?

8 A. Well, we would -- I can't find a complete
9 answer to that. We would sit down and think about
10 the goal being creating a list of potential deletes 09:29:36
11 as opposed to what was the goal as I state in the
12 report, which is developing an analysis of what are
13 the codes that lack support in United's data. And
14 more specifically, what we are trying to understand
15 is how would the flow of funds change between the 09:29:55
16 United States government and United Healthcare as a
17 result of the removal of the codes that lack
18 support in the data.

19 Q. So you were not asked to produce or to
20 identify a list of diagnosis codes that would meet 09:30:11
21 your definition of potential deletes? That wasn't
22 -- that was not your assignment?

23 A. That would meet the list of potential
24 deletes?

25 Q. Correct. 09:30:25

1 A. No. I was asked to come up with an
2 estimate of how the flow of funds would change
3 between the United States government and United as
4 a result of the removal of unsupported codes in the
5 chart review and risk adjustment data.

09:30:38

6 There was no specific interim step that I
7 was asked to create.

8 Q. So specifically your assignment was to
9 determine how the flow of funds would change if you
10 removed what you call unsupported codes in the
11 chart review, right?

09:30:57

12 MR. MASON: Objection; mis --

13 Q. BY MR. GALLAGHER: That was your
14 assignment?

15 MR. MASON: Objection; misstates
16 testimony.

09:31:10

17 THE WITNESS: I think if you kept reading
18 there's an "and" after "chart review."

19 Q. BY MR. GALLAGHER: I will do that. Your
20 assignment was to determine how the flow of funds
21 would change as a result of the removal of
22 unsupported codes in the chart review and risk
23 adjustment data, right?

09:31:18

24 A. That is a summary of what we're trying to
25 do here, yes.

09:31:34

1 Q. And when you say unsupported codes in the
2 chart review, you're referring to the list of
3 potential deletes, right?

4 MR. MASON: Objection; misstates
5 testimony.

09:31:44

6 THE WITNESS: No, I'm referring to the
7 codes that we have in our final deletes list that
8 were unsupported in the chart review and risk
9 adjustment data.

10 I am not sure why you keep stopping at
11 chart review. Because I am referring to the chart
12 review and risk adjustment data together.

09:31:54

13 Q. BY MR. GALLAGHER: So the concept of
14 whether a code is supported or not, to know that
15 you have to look at not just the chart review but
16 also risk adjustment data?

09:32:05

17 MR. MASON: Objection to form.

18 THE WITNESS: Yes.

19 Q. BY MR. GALLAGHER: Okay. And what risk
20 adjustment data do you have to look at to determine
21 whether a code is or is not supported?

09:32:15

22 A. So if you look in the report, what we are
23 -- there are a few places where we talk about sort
24 of things where we -- where we develop our final
25 deletes list.

09:32:31

1 the opinion you're offering about the flow of funds
2 is not an opinion about what would happen if you
3 took a list that corresponds to what you describe
4 as the potential deletes and were to delete that?

5 A. By definition, we remove things -- we 10:09:48
6 don't -- there are some things that initially lack
7 support from chart review that we are giving United
8 credit for. We are not saying that they have
9 support. We are saying there's enough evidence
10 there in United's data that could have been relied 10:10:01
11 upon for support that we don't feel comfortable
12 saying that those are unsupported codes in United's
13 chart review and risk adjustment data.

14 Q. I think my question is simpler. You are
15 not offering an opinion about what -- how the flow 10:10:12
16 of funds would change if you took a list of codes
17 that corresponds to what you call potential deletes
18 in your report and deleted them? That's not the
19 analysis you're offering?

20 MR. MASON: Objection; asked and answered. 10:10:26

21 Q. BY MR. GALLAGHER: Right?

22 A. It is -- it's -- everything on --
23 everything that we do delete is identified in that
24 unsupported data. So it would be sort of a related
25 but not identical exercise. 10:10:37

1 Q. It's not the exercise you undertook?

2 A. No. We gave credit to United for codes

3 that they had evidence for that they also, I would

4 note, could have identified in their data or could

5 have said the reason why we're not going to delete 10:10:52

6 that code is that there's other evidence.

7 So it is not a question of them changing

8 their behavior, but a question about sort of the

9 knowledge they had at the time.

10 Q. And you also are not offering an opinion 10:11:03

11 on what would traditionally be called but-for

12 damages, right?

13 MR. MASON: Objection to form.

14 THE WITNESS: Or answering the question as

15 of what would have happened as of 2019 -- I 10:11:14

16 shouldn't say 2019. The time period I am sort of

17 looking at this question, which is given the sort

18 of COVID and the length of this from '19 to '23,

19 pick a date in there, what would happen if the

20 codes were removed. 10:11:29

21 Q. BY MR. GALLAGHER: That's not a -- you are

22 not offer -- sorry. Let me clarify.

23 You are offering an opinion about what

24 would happen if after the fact, in like 2019 or

25 2020, you removed the codes, what the flow of funds 10:11:40

1 would look like in that -- that scenario?

2 A. If it is a question about as of 2019 what
3 would happen if we removed the codes then, yes.

4 Q. You are not offering an opinion about what
5 would happen if United had done something different 10:11:58
6 in 2008 or 2009 or 2010 or 2011 at the time?

7 A. Yeah, I'm not offering an opinion about
8 how contemporaneously they would have changed their
9 other behavior.

10 Q. And you are not offering an opinion about 10:12:15
11 what would happen in a but-for world where United
12 had done the analysis you did in 2008, 2009, 2010
13 and had changed its submission of codes accordingly
14 in those years at the time?

15 MR. MASON: Objection to form. 10:12:31

16 THE WITNESS: No, I think we are very
17 clear in the report that the question we are trying
18 to answer is how would the flow of funds have
19 changed if as of the time period we're asking the
20 question, the code that lacks support in United's 10:12:41
21 chart review and risk adjustment data were removed
22 from the system.

23 Q. BY MR. GALLAGHER: Effectively giving away
24 the payments on contract years, you're effectively
25 offering an opinion about what would happen if you 10:12:54

1 A. It would seem like it's possible that
2 given that there's no provider encounter data from
3 Connor for February 1st, that this would be an
4 encounter that we matched in No. 2 which was sort
5 of -- would not be a reviewed encounter.

02:37:45

6 I wouldn't say -- we spent a lot of time
7 in doing this and doing these kind of validation
8 checks to figure out if systematically this was
9 showing up.

10 There are millions of diagnosis codes, 1.9
11 million diagnosis codes on Attachment 1. It is
12 possible that there is a single one that you are
13 identifying here.

02:38:00

14 Q. Well, I'm just identifying -- I'm just
15 trying to first identify that this is an example of
16 something that you would have, and, in fact, in
17 this case did, identify as a reviewed encounter
18 under your match method No. 2, okay.

02:38:14

19 So assuming the data is as follows: There
20 is a February 1, 2011, encounter from which a
21 provider-reported code 1742 was submitted to CMS.
22 There is no record in the chart review database
23 identified as being from Allen on that date. There
24 is no other provider-reported code from February 1,
25 2011, and the only chart reviewed in chart review

02:38:39

02:39:04

1 DEPOSITION OFFICER'S CERTIFICATE

2 (Civ. Proc. § 2025.520(e))

3 STATE OF CALIFORNIA)

4) Ss

5 COUNTY OF SAN FRANCISCO)

6 I, BALINDA DUNLAP, CSR #10710, hereby
7 certify:

8 I am a duly qualified Certified Shorthand
9 Reporter, in the State of California, holder of
10 Certificate Number CSR 10710 issued by the Court
11 Reporters Board of California and which is in full
12 force and effect. (Bus. & Prof. § 8016)

13 I am not financially interested in this
14 action and am not a relative or employee of any
15 attorney of the parties, or of any of the parties.
16 (Civ. Proc. § 2025.320(a))

17 I am authorized to administer oaths or
18 affirmations pursuant to California Code of Civil
19 Procedure, Section 2093(b) and prior to being
20 examined, the deponent was first placed under oath
21 or affirmation by me. (Civ. Proc. §§ 2025.320,
22 2025.540(a))

23 I am the deposition officer that
24 stenographically recorded the testimony in the
25 foregoing deposition and the foregoing transcript

1 is a true record of the testimony given. (Civ.
2 Proc. § 2025.540(a))

3 I have not, and shall not, offer or
4 provide any services or products to any party's
5 attorney or third party who is financing all or
6 part of the action without first offering same to
7 all parties or their attorneys attending the
8 deposition and making same available at the same
9 time to all parties or their attorneys. (Civ.
10 Proc. § 2025.320(b))

11 I shall not provide any service or product
12 consisting of the deposition officer's notations or
13 comments regarding the demeanor of any witness,
14 attorney, or party present at the deposition to any
15 party or any party's attorney or third party who is
16 financing all or part of the action, nor shall I
17 collect any personal identifying information about
18 the witness as a service or product to be provided
19 to any party or third party who is financing all or
20 part of the action. (Civ. Proc. § 2025.320(c))

21

22 Dated: _____

23 _____ *Balinda Dunlap* _____

24

25

EXHIBIT P-75



U.S. Department of Justice

Civil Division

Washington, DC 20530

October 22, 2014

Roger S. Goldman
Latham & Watkins LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, D.C. 20004

Re: UnitedHealth Group Investigation

Dear Mr. Goldman,

We sincerely appreciate the two presentations that Mr. Meron and you provided to us on October 9th in Buffalo. The presentations were very informative and helpful. One of the purposes of this letter is to follow-up on our requests for additional information about the issues raised by your presentations. These requests are set forth in the attachment to this letter. Please let us know if you have any questions about these requests or would like to discuss them further before responding to them. We are available to discuss at your convenience.

In addition, we would like to follow-up on our request for a presentation about UnitedHealth Group's Chart Review program and for a demonstration of UnitedHealth Group's ChartSync system. We are also very interested in learning more about the Ingenix Risk Adjustment Data System (IRADS), including the systems which interface with it. We are available December 2 in Washington or December 9, 10, 11, 15 or 17 in Buffalo. Please let us know if you are agreeable to meeting with us on any of these dates.

Furthermore, we would like to schedule a telephone call with you very soon to discuss UnitedHealth Group's privilege assertion with respect to documents and information that the government is seeking from one of UnitedHealth Group's vendors, iCodify. Please let us know when you are available this week or next week for this telephone call.

Finally, in response to the arguments that you made as part of your presentation about UnitedHealth Group's termination of its Claims Verification Program and UnitedHealth Group's annual attestation about the truthfulness and accuracy of its risk adjustment submissions, we wish to remind you of Cheri Rice's May 2, 2014 response to Mr. Nelson's April 30, 2014 email quoted at page 20 of your presentation. In particular, we note that she stated that there are "laws that do impose standards, requirements and responsibilities on [Medicare Advantage] plans in connection with the federal payments they receive from [the Centers for Medicare & Medicaid Services]" Ms. Rice also stated that CMS could not provide advice about whether UnitedHealth

EXHIBIT

00328

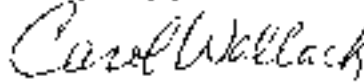
1942

- 2 -

Group's plan of action and purported limits on the scope of its attestation are compliant with these laws. Thus, CMS did not agree that UnitedHealth Group's planned actions and its purported limited attestation are compliant with the laws that apply to Medicare Advantage plans. As you know, such laws include the federal False Claims Act.

Please do not hesitate to call Gretchen Wylegala or me if you wish to discuss this matter. Again, we sincerely appreciate the two presentations that you made on October 9th and we look forward to UnitedHealth Group's and your continued cooperation in this matter.

Very truly yours,



Carol Lynn Wallack

Chief Attorney

Commercial Litigation Branch

Civil Division

cc: Daniel Meron
Abid R. Qureshi
Gretchen Wylegala

- 3 -

Attachment

Requests relating to the "UnitedHealthcare of California, Inc. (plan #E10543) Closed-Period Deletes for 2010 and 2011 DOS" presentation:

- Page 6, sub-bullet point 2, refers to deletes that CMS refused to process for 2010 DOS. Please identify the risk adjustment (RA) submissions that UHC sought to delete. Similarly, page 9, states that CMS has not processed an additional approximate \$4.8 million in 2010 DOS deletes submitted by UHC after May 31, 2013. Please also identify the RA submissions associated with these deletes.
- Page 12 describes the Ingenix Risk Adjustment Data System (IRADS). Please describe the data system(s) that feed into IRADS with respect to the UHC of California plan and, if this has changed over time, please specify. Please describe the data system(s) that feed into IRADS with respect to UHC's other plans and how this changed over time. Also, if there is an integrated system, please identify and describe it. We are also interested in knowing what system UHC used prior to IRADS to make its RA submissions. (You may wish address these questions as part of a larger presentation about IRADS.)
- Page 13 refers to approximately \$11.9M in deletes due to IRADS improvements. Please breakdown the monetary amounts of the deletes for each type of improvement.
- Page 20 refers to Provider Specialty Code 70 deletes and page 21 refers to Unknown Physician Specialty ("99") deletes. We have additional inquiries about these deletes and will provide them to you soon.
- Page 25 of the presentation discusses the Risk Adjustment Data Reconciliation (RADR) team. When was this team created? What are the team's responsibilities, and what policies and procedures govern its decisions. Also, please identify the UHC employees who have been part of this team since its inception to present. Additionally, identify what role (and title) each individual had and whether the individual is a current or former employee. If a former employee, please provide their home address and contact information.
- Page 26 states that "the largest single provider" initiated proposed deletes totaling \$2.6 million for 2010 DOS. You identified this provider as Sharp. Is this Sharp Community Medical Group in San Diego or another entity? What deletes did it propose? What deletes were actually made (all of the proposed deletes)? Please provide a list of all of these deletes and the dates on which they were made and state the amount of the monetary impact, if any. Additionally, provide all correspondence (in any format) between UHC and Sharp, and identify the UHC and Sharp employees who were part of this process. Also, please explain whether UHC of California, Sharp or both have any monetary impact associated with those deletes?

- 4 -

- Please identify all provider groups with which UHC of California has contracted from 2006 to present and, for each year, the number of Medicare Part C plan members in each group.
- Page 27 refers to RA Coding Compliance Reviews. What were the parameters for selecting providers or provider groups for these reviews? Please explain what rules or guidelines UHG used in conducting these reviews and, if those rules and guidelines changed over time, please explain how so. Please identify (1) all provider groups for which UHG has performed RACCR reviews, (2) any provider groups with which UHG has discontinued its relationship based on any RACCR reviews, and (3) if any provider groups were required to return money to UHG. Also, identify what information UHG provided to the providers or provider groups about the results of those reviews. In addition, we would like to know whether UHG is continuing to perform RACCR reviews.
- Page 32 refers to RACCR Look-backs. What were the criteria used to determine that a significant number of sampled codes failed to validate? Was 80% validation required? If a significant number of sampled codes failed to validate, was the 100% look-back only for the DOS or payment year for which the sampled was pulled? Or did UHG look back to prior years and, if so, how far back?
- Please provide background information relating to UHG's RACCR 150 patient review of WellMed, including, but not limited to, a list identifying the patients' name and HIC numbers, when the review was conducted, how it was conducted and by whom, and the results of the review.

Requests relating to the "Claims Verification Program" presentation:

- Page 18 refers to a discussion between UHG and CMS on April 29, 2014, page 20 refers to a communication with Sean Cavanaugh at CMS on June 10, 2014, and page 24 and 25 refer to other conversations and communications with CMS. Please provide all documents relating to these communications, including, but not limited to, emails, letters, memos, notes and bid documents. For each communication, please identify the participants/attendees.
- The first section of the presentation refers to Chart Reviews conducted by UHG to find additional diagnoses that are not made by and/or reported to it by providers. Please provide a list of all chart reviewers and companies hired by UHG since it started conducting chart reviews. Please specify the time period(s) for which UHG used each reviewer and company. Please specify who currently performs chart reviews for UHG.
- Page 20 refers to 2012 DOS deletes. For 2012 DOS, please identify the RA submissions that UHG identified for Claims Verification (CV) review but for which

- 5 -

UHG did not perform the CV review or for which it performed the review but did not make the delete even if the diagnosis was not confirmed.

- Page 23 refers to the 2015 contract bid process. Please specify whether any monetary amount(s) were included in UHG's 2015 proposed bid that UHG believed may be associated with deletes for payment years 2015 if it continued the CV program and, if so, please specify those amount(s). Please provide this information for each of UHG's MA plans. Also, please provide this information for bids prior to 2015 if monetary amounts for projected deletes were included in those bids.
- Also, during the meeting, you stated that UHG has represented to CMS that the cost of completing CV reviews (which reviews UHG stopped conducting in or about May 2014) would not be taken as profit by UHG but would be used to provide additional benefits to Medicare beneficiaries in 2015. Please provide that part of UHG's 2014 bid proposal (or contract with CMS) that sets forth the monies that UHG stated that it would expend to perform CV work in 2014. In addition, please identify the monies that UHG received from CMS after May 2014, i.e. after it stopped CV reviews, to perform these reviews and how UHG used these funds. Furthermore, please identify the total costs of additional benefits that UHG intends to provide to Medicare beneficiaries in 2015 that are specifically attributed to not performing or completing CV work and identify the specific additional benefits. As an example, please provide the breakdown of these calculations from the bid proposals/contracts for UHG of California (013543). Also, please provide a copy of the contracts between UHG and CMS for this plan for 2014 and 2015.
- Did UHG conduct audits or reviews of any fee for service providers? If so, how were the providers chosen for the audits or reviews and how were the reviews conducted?
- What is the current status of the UHG of California RADV audit?

EXHIBIT P-76

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
REBECCA MARTIN
Given Remotely
Friday, August 5, 2022
9:03 a.m.

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 diagnosis clusters that map to a specific HCC and
2 looking to see if there are other records that we may
3 have on file for that member that otherwise risk
4 adjust but had not been submitted to CMS due to some
5 of their submission limitations. And when we had
6 that condition of a record that otherwise risk
7 adjusts, that map to the same HCC, we would use that
8 record to basically save the HCC from being deleted.

9 Q. Understood. And are you familiar with
10 something called an "X19" as the term was used at
11 Optum within IRADS?

12 A. Yes.

13 Q. What's an X19?

14 A. It is a specific status that is assigned
15 to otherwise risk adjusting transactions that could
16 not be submitted to CMS due to submission
17 limitations.

18 Q. And what submission limitations are you
19 referring to?

20 A. For example, CMS would not allow the
21 submission of multiple records for the same member,
22 the same date of service, the same diagnosis code,
23 even if they were for different providers. You could
24 only submit one.

25 Q. Understood. And in the delete netting

1 CERTIFICATE

2

3 I, KAREN K. KIDWELL, Registered Merit Reporter,
4 and Certified Realtime Reporter, do hereby certify
5 that prior to the commencement of the examination,
6 the deponent was remotely sworn to testify to the
7 truth, the whole truth under penalty of perjury.

8 I DO FURTHER CERTIFY that the foregoing is a
9 verbatim transcript of the testimony as taken
10 stenographically by me at the time, place and on the
11 date hereinbefore set forth, to the best of my
12 ability.

13 I DO FURTHER CERTIFY that I am neither a
14 relative nor employee nor attorney nor counsel of any
15 of the parties to this action, and that I am neither
16 a relative nor employee of such attorney or counsel,
17 and that I am not financially interested in this
18 action.

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Karen Kidwell
Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-77

This content is from the eCFR and is authoritative but unofficial.

Title 45 — Public Welfare

Subtitle A — Department of Health and Human Services

Subchapter C — Administrative Data Standards and Related Requirements

Part 162 — Administrative Requirements

Subpart J — Code Sets

Authority: 42 U.S.C. 1320d–1320d-9 and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

Source: 65 FR 50367, Aug. 17, 2000, unless otherwise noted.

§ 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

- (a) For the period from October 16, 2002 through October 15, 2003:
 - (1) *International Classification of Diseases, 9th Edition, Clinical Modification, (ICD-9-CM), Volumes 1 and 2* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:
 - (i) Diseases.
 - (ii) Injuries.
 - (iii) Impairments.
 - (iv) Other health problems and their manifestations.
 - (v) Causes of injury, disease, impairment, or other health problems.
 - (2) *International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures* (including The Official ICD-9-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:
 - (i) Prevention.
 - (ii) Diagnosis.
 - (iii) Treatment.
 - (iv) Management.
 - (3) *National Drug Codes* (NDC), as maintained and distributed by HHS, in collaboration with drug manufacturers, for the following:
 - (i) Drugs
 - (ii) Biologics.
 - (4) *Code on Dental Procedures and Nomenclature*, as maintained and distributed by the American Dental Association, for dental services.

(5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT-4)*, as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

- (i) Physician services.
- (ii) Physical and occupational therapy services.
- (iii) Radiologic procedures.
- (iv) Clinical laboratory tests.
- (v) Other medical diagnostic procedures.
- (vi) Hearing and vision services.
- (vii) Transportation services including ambulance.

(6) The *Health Care Financing Administration Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services. These items include, but are not limited to, the following:

- (i) Medical supplies.
- (ii) Orthotic and prosthetic devices.
- (iii) Durable medical equipment.

(b) For the period on and after October 16, 2003 through September 30, 2015:

(1) The code sets specified in paragraphs (a)(1), (a)(2), (a)(4), and (a)(5) of this section.

(2) **National Drug Codes (NDC)**, as maintained and distributed by HHS, for reporting the following by retail pharmacies:

- (i) Drugs.
- (ii) Biologics.

(3) **The Healthcare Common Procedure Coding System (HCPCS)**, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:

- (i) Medical supplies.
- (ii) Orthotic and prosthetic devices.
- (iii) Durable medical equipment.

(c) For the period on and after October 1, 2015:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) (including The Official ICD-10-CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

- (i) Diseases.

- (ii) Injuries.
 - (iii) Impairments.
 - (iv) Other health problems and their manifestations.
 - (v) Causes of injury, disease, impairment, or other health problems.
- (3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) (including The Official ICD-10-PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:
- (i) Prevention.
 - (ii) Diagnosis.
 - (iii) Treatment.
 - (iv) Management.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8397, Feb. 20, 2003; 74 FR 3362, Jan. 16, 2009; 77 FR 54720, Sept. 5, 2012; 79 FR 45134, Aug. 4, 2014]

EXHIBIT P-78

FILED
CLERK, U.S. DISTRICT COURT

MAY 28 2021

CENTRAL DISTRICT OF CALIFORNIA

BY: ydr DEPUTY

Suzanne H. Segal (Ret.)
United States Magistrate Judge
SIGNATURE RESOLUTION, LLC
633 W. 5th Street, Suite 1000
Los Angeles, CA 90071
judgesegal@signatureresolution.com

WESTERN DIVISION

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA ex rel.
BENJAMIN POEHLING,

Plaintiffs,

vs.

UNITED HEALTH GROUP, INC., et. al.

Defendants.

Case No. CV 16-8697 FMO (SSx)

ORDER DENYING WITHOUT PREJUDICE
PLAINTIFF'S MOTION TO COMPEL RE
INTERROGATORY NO. 14 AND REQUEST
FOR PRODUCTION NO. 147

On April 16, 2021, Plaintiff United States (the "government") filed a motion to compel (the "Motion" or "MTC") seeking an order regarding Defendant United Health Group, Inc. and related entities ("UnitedHealth" or "UHG") to provide a supplemental response to Interrogatory No. 14 ("Interrogatory 14") and Request for Production No. 147 ("RFP 147" or "Request 147"). The parties submitted a Joint Stipulation in connection with the Motion. Each party also filed a Supplemental Memorandum. On May 20, 2021, the Special Master held a Zoom hearing on the

1 Motion. For the reasons discussed below, the Motion is DENIED without prejudice
2 to renewing the motion at a later stage in the litigation.
3

4 5 I. FACTUAL AND PROCEDURAL BACKGROUND 6

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8 The government contends that UnitedHealth has refused to reasonably
9 respond to two discovery requests that address whether UnitedHealth improperly
10 failed to delete diagnosis codes from its Medicare Part C risk adjustment submission.
11 According to the government, UnitedHealth systematically ignored medical record
12 reviews when it indicated that diagnosis codes UnitedHealth previously submitted
13 to CMS were not supported by beneficiaries' medical records.
14
15

16 The government contends that it has identified every diagnosis code that
17 UnitedHealth submitted to CMS to increase its risk adjustment payments and then
18 improperly failed to delete when UnitedHealth's own review found no support for
19 the diagnosis code in the medical records. The government asserts that Interrogatory
20 14 and Request 147 are intended to discover UnitedHealth's contentions about the
21 very same diagnosis codes. The government seeks to discover whether
22 UnitedHealth contends that any of the diagnosis codes on the government's list were
23 supported by medical records, despite not being found during any of UnitedHealth's
24 reviews of the associated medical records.
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1 Interrogatory 14 asked UnitedHealth to, with respect to every diagnosis code
2 on the government's list, (a) identify which code is supported by a medical record
3 and (b) identify every medical record review that UnitedHealth conducted. (MTC
4 at 5-7). Request 147 requests all medical records associated with the diagnosis codes
5 on the government's list. (Id. at 7).

6
7
8 In response to Interrogatory 14, UnitedHealth objected on the grounds that
9 "this Interrogatory is an improper contention interrogatory that impermissibly seeks
10 to shift the burden of proving an essential element of the government's False Claims
11 Act case on to UnitedHealth and seeks expert opinion." (Id. at 8). In response to
12 Request 147, UnitedHealth stated: "Based upon its General and Specific Objections,
13 UnitedHealth does not intend to produce documents responsive to this Request."
14

15
16 At the meet and confer on this issue, UnitedHealth indicated that it would
17 produce the responsive medical records in its possession. This production, however,
18 would require a production of approximately 21 million charts and take 8 months to
19 produce. This proposal did not resolve the discovery dispute.
20

21
22 The government asserts that, as it was required to provide a list of 28 million
23 diagnosis codes to comply with its obligation to identify the diagnosis codes it
24 contends UnitedHealth knew were invalid, UnitedHealth should now explain
25 whether medical records do or do not support these codes. (Id. at 9).
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1 According to UnitedHealth, Interrogatory 14A requires it to identify the over
2 20 million medical records corresponding to each of the 28 million codes on the
3 government's list and then to hire experts to review those charts to determine
4 whether each code on the government's list is or is not supported by the medical
5 chart. Subpart 14B requests that UnitedHealth "[i]dentify each Medical record
6 Review(s) of the chart(s) corresponding to that Diagnosis, etc." According to UHG,
7 this request would also require it to engage in a massive and complex matching
8 analysis. RFP 147 seeks the documents that relate to the answer required in
9 Interrogatory 14.
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15 II. INTERROGATORY 14 REQUIRES EXPERT ANALYSIS TO
16 RESPOND
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19 Although the government argues that Interrogatory 14 is "only seeking facts,"
20 it would be impossible for anyone other than an expert to provide a reliable answer.
21 Only an expert -- or someone with specialized knowledge -- could do a fair
22 comparison of the medical records and the diagnosis codes to determine if the
23 medical record supported the code. It is also undeniable that the interrogatory would
24 impose a tremendous burden on the responding party to prepare an answer that does
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1 not currently exist. For these reasons, Interrogatory 14 is an improper interrogatory
2 at this stage of the proceedings.

3
4 Contention interrogatories may be improper “[when] they ask the respondent
5 to provide an expert opinion.” Amgen Inc. v. Sandoz Inc., 2017 WL 1352052, at *2
6 (C.D. Cal. April 13, 2017); Montgomery v. Wal-Mart Stores, Inc., 2015 WL
7 11233384, at *6 (S.D. Cal. July 17, 2015). In addition, a court has discretion to
8 delay an answer to a contention interrogatory until designated discovery is complete
9 or at some other time. See Capacchione v. Charlotte-Mecklenburg Sch., 182 F.R.D.
10 486, 489 (W.D.N.C.1998) (stating that “[d]ue to the nature of contention
11 interrogatories, they are more appropriately used after a substantial amount of
12 discovery has been conducted - typically, at the end of the discovery period”). In
13 general, courts prefer to defer answers to contention interrogatories that are
14 propounded prematurely. See e.g., Everett v. USAir Group, Inc., 165 F.R.D. 1, 3
15 (D.D.C. 1995) (denying without prejudice motion to compel response to contention
16 interrogatory on grounds that interrogatory served too early in discovery process);
17 B. Braun Medical, Inc. v Abbott Lab., 155 F.R.D. 525, 527 (E.D. Pa. 1994) (“[T]here
18 is considerable support to defer answering contention interrogatories until the end of
19 the discovery period.”).

20
21 In the present action, the request seeks the application of expert knowledge to
22 facts, i.e., the medical records. This interrogatory cannot be answered until after
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1 expert discovery is completed and only if UnitedHealth intends to assert a defense
2 based upon this information. Indeed, parties generally provide this type of
3 information through expert testimony. See United States ex rel. Desrosiers v. Thaller,
4 2016 WL 6441548, at *4-6 (S.D. Fla. Nov. 1, 2016) (whether medical codes
5 submitted for reimbursement were proper was subject of expert testimony); Counts
6 v. Pollock, 2020 WL 5534444, at *2 (M.D. Fla. August 21, 2020) (providing expert
7 testimony on whether plaintiff's medical bills were properly coded); United States
8 ex rel Armfield v. Gills, 2012 WL 12918274, at * 2 (M.D. Fla. 2012) (qualifying
9 expert for testimony regarding improperly coded claims). Accordingly, this
10 interrogatory is improper at this stage of the proceedings because it would require
11 expert analysis to respond.

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15
16 It is also undeniable that preparation of the response to the request would be
17 extremely burdensome and costly. It would require UnitedHealth to pay for and
18 create an analysis for 20 million documents. Ordinarily, a respondent is not required
19 to undertake investigation and analysis to prepare a response to an interrogatory.
20
21 See Behrazfar v. Unisys Corp., 2009 WL 10673197, at *4 (C.D. Cal. June 3, 2009)
22 (party need not respond to an interrogatory that would require extensive analysis and
23 cost). While this analysis and cost may be necessary at some point in the litigation,
24 the Special Master concludes that it is premature to order UHG to undertake this
25 analysis now.
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1 UnitedHealth has stated that if it discloses during the expert discovery phase
2 that it has retained an expert to testify at trial that the 28 million codes on the
3 government's list are supported by medical records, that information will be
4 produced in a manner that provides the government sufficient time to prepare a
5 rebuttal. (MTC at 42). Nothing more is required during this phase of the litigation.
6 Because Request 14 is a contention interrogatory and requires expert analysis,
7 UnitedHealth is not required to prepare a response at this time.
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12 III. REQUEST 147 IS DEPENDENT UPON A RESPONSE TO
13 INTERROGATORY 14 AND THEREFORE IS
14 DENIED WITHOUT PREJUDICE
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18 Request 147 seeks: "All Chart(s) corresponding to, associated with, or related
19 to each Beneficiary, from each DOS Year(s) in which that Beneficiary is listed in
20 the United States Response to Defendants' Interrogatory No. 1 (Including the United
21 States' First Supplemental Response served on August 17, 2020, the United States
22 Amended First Supplemental Response served on October 13, 2020, the United
23 States' Second Supplemental Response served on October 30, 2020, and any other
24 subsequent responses)." (Mason Decl., Ex. B). The government agreed to limit this
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1 request to production of only those medical records UHG contends supports a
2 diagnosis code on the government's list. (MTC at 7-8).

3
4 During the meet and confer process, UnitedHealth offered to produce the
5 responsive medical records in its possession which would amount to an estimated
6 21 million charts and take 8 months to collect and produce. This would allow the
7 government to review the medical records that UnitedHealth reviewed as part of its
8 chart review program and the government could then determine which of the codes
9 on its list are or are not supported. (MTC at 17). At the hearing on the MTC,
10 counsel for the government argued that at a minimum the medical records should be
11 produced to allow the government to review the medical evidence underlying
12 UnitedHealth's codes. Production of these records would allow the government to
13 determine for itself which of the codes on its list are supported or are not supported.
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18 However, in the Motion itself, the government asserted the following: "After
19 the United States identified its list of all diagnosis codes it contends are at issue, it
20 served Interrogatory 14 and Request 147 to discover UnitedHealth's contentions
21 about the very same diagnosis codes. In particular, the United States seeks to
22 discovery whether UnitedHealth contends that any of the diagnosis codes on the
23 United States' list were supported by medical records, despite not being found
24 during any of UnitedHealth's reviews of the associated medical records. The United
25 States further seeks to discover factual information related to UnitedHealth's
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1 medical record reviews.” (MTC at 2, ll. 18-24). The United States also noted:
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3 “Request 147, as written, relatedly requests all medical records associated with the
4 diagnosis codes on the United States’ list. (citation omitted). Importantly, as a result
5 of the meet and confer process . . . the United States agreed to limit its request for
6 medical records to only those records associated with the diagnosis codes that
7 UnitedHealth contends were supported (i.e., the medical records UnitedHealth
8 identifies in response to Part A of Interrogatory 14).” (MTC at 3, ll. 5-11) . . .
9
10 “Subsequently, UnitedHealth agreed to produce some (but not all) of the underlying
11 medical records, but that offer is hollow without identifying which codes
12 UnitedHealth contends are supported by medical records (i.e., responding to
13 Interrogatory 14). Simply producing millions of medical records alone does nothing
14 to illuminate UnitedHealth’s contentions.” (MTC at 3, ll. 17-21).

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18 As UHG observed, “RFP 147 is . . . dependent entirely on whether United is
19 required to Interrogatory 14A; if the Court agrees that United is not required to hire
20 experts to engage in the coding reviews that responding to Interrogatory 14A would
21 require, then there would be no medical records responsive to RFP 147 as now
22 recrafted by the government.” (MTC at 16, ll. 2-6). UHG, as part of the meet and
23 confer efforts, offered to produce to the government every medical record in
24 United’s possession that United reviewed as part of its chart review program, to
25 allow the government to determine for itself which of the codes on its list are or are
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28

1 not supported. (MTC at 16, ll. 25-28; 17, ll. 1-2). The government rejected this
2 offer. UHG contends that the government's position regarding Request 147 has
3 "vacillated dramatically over time." (MTC at 17, ll. 12-13). At the hearing on the
4 MTC, the government did take a position that contradicted the government's prior
5 arguments in the MTC, i.e., the government argued that a response to Request 147
6 would be meaningful even without a response to Interrogatory 14.

7
8
9 The Special Master finds that the inconsistency in the government's
10 arguments undermines their persuasiveness. The Special Master concludes that if
11 the two discovery requests are related and linked as the government originally
12 argued, then the Order should be consistent regarding both requests. Accordingly,
13 the MTC is DENIED without prejudice as it pertains to Request 147. The
14 government may renew Request 147 if the requested documents are relevant to
15 UHG's defenses asserted at a later phase of the action.
16
17
18
19
20

21 IT IS SO ORDERED.

22
23
24 **DATE: May 28, 2021**

DocuSigned by:
Hon. Suzanne Segal (Ret.)
202105280901:496
Hon. Suzanne H. Segal (Ret.)

PROOF OF SERVICE

RE: United States ex rel. Poehling v. United Health Group, Inc., et al.
Case ID: KEERX

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES:

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and am not a party to the within action. My business address is 633 West 5th Street, Suite 1000 Los Angeles, CA 90071

On June 1 2021 I served the **ORDER DENYING WITHOUT PREJUDICE PLAINTIFF'S MOTION TO COMPEL RE INTERROGATORY NO. 14 AND REQUEST FOR PRODUCTION NO. 147** on the following parties. Placing a true copy to all parties as follows:

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- ☐ BY U.S. MAIL: I caused such envelope(s), with postage fully prepaid, to be placed in the U.S. Mail at Los Angeles, California.
- ☐ BY FACSIMILE: I caused such document to be sent via facsimile to each person.
- ☒ BY ELECTRONIC MAIL: I caused such document to be sent via electronic mail to each person.
- ☐ BY PERSONAL SERVICE: I caused such envelope to be delivered by hand to the office of the addressee.
- ☒ STATE: I declare under penalty of perjury under the laws of the State of California that the above is true and correct.
- ☐ FEDERAL: I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Executed on June 1, 2021 at Los Angeles, California.

Alisa Martinez
Alisa Martinez
Signature Resolution

EXHIBIT P-79

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA,)
ex rel., BENJAMIN POEHLING,)
)
 Plaintiffs,)
) Civil Action No.
vs.)
) 16-08697 FMO
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
-----)

* * * * *

HIGHLY CONFIDENTIAL

* * OUTSIDE COUNSEL'S EYES ONLY * *

* * * * *

VIDEOTAPED DEPOSITION OF PAUL IRA SPITALNIC
Wednesday, March 20, 2024; 9:07 a.m. EDT

Reported by: Cindy L. Sebo, RMR, CRR, CLR, RPR, CCR,
CSR, RSA, CA CSR 14409, NJ Certified CR 30XI0024460,
NJ Certified RT 30XR00019500, NM CSR 589, NY Realtime
Court Reporter, NY Association Certified Reporter, OR
CSR 230105, TN CSR 998, TX CSR 12778, WA CSR
23005926, Notary Public
Job No. 1097542

1 records if the plan has any information that is --
2 might not be supported, right?

3 A. I cannot provide such reference.

4 Q. Can you provide me a specific law,
5 regulation, piece of subregulatory guidance or
6 contractual provision that obligates MA plans to
7 design their chart reviews to identify and delete
8 diagnosis codes that are not supported by medical
9 records?

10 A. I cannot.

11 Q. Do -- by the way, do you know what
12 "chart reviews" are?

13 A. I'm familiar with the term.

14 Q. You understand that United had a
15 chart review program in place during the period
16 relevant to this case?

17 A. I understand United takes a number of
18 actions with respect to supporting or developing or
19 -- related to the diagnoses they submit for plan
20 payment.

21 Q. And would those actions include a

1 chart review program?

2 A. That is my understanding.

3 Q. When did you first become aware that
4 United had a chart review program?

5 A. I don't think I was ever aware that
6 there was a specific program. I know that United
7 and other MAOs, Medicare Advantage organizations,
8 do various -- have various initiatives in support
9 of their diagnosis submission.

10 Q. So you have no specific information
11 about how United may have conducted its chart
12 review program during the period relevant to this
13 case?

14 A. I do not have any specific
15 information.

16 Q. I want to go back to Page 3 of your
17 report, Mr. Spitalnic. We read the first half of
18 this sentence in Paragraph Number 2. I -- I want
19 to focus now on the second half of the sentence,
20 but I'll -- I'll read the whole sentence so we've
21 got the full context.

1 you agree with me that it's important for CMS to
2 review bid submissions by MA plans?

3 A. Yes.

4 Q. You're not suggesting here that CMS
5 should ignore portions of MA plan bid submissions,
6 right?

7 A. I'm suggesting that there may not
8 have been a reliance on certain statements that are
9 included in some aspects of the bid submission.

10 Q. Do you think it's reasonable for
11 MA plans like United to presume that CMS is
12 reviewing the bid submissions that the plans submit
13 to the Agency?

14 ATTORNEY ZUPAC: Object to form.

15 Go ahead.

16 THE WITNESS: I'm sorry. Could you
17 repeat the question?

18 BY ATTORNEY MARTINEZ:

19 Q. Do you think it's reasonable for
20 MA plans like United to presume that CMS is
21 reviewing the bid submissions that the plans submit

1 to the Agency?

2 A. I -- I certainly believe that it's
3 reasonable for a plan to expect that CMS is going
4 to do a thorough review of their bid submission.
5 And I think many of the actuaries that go through
6 the bid review procedure would agree that there is
7 a thorough review of the bid submission -- of their
8 bid submissions.

9 I would also expect that actuaries
10 would not be surprised that every word of their
11 submission is not reviewed or necessarily relied
12 upon in drawing ultimate conclusions and that, as I
13 included in this sentence before you started
14 reading, that there is a specific reliance on the
15 actuary to -- that that's -- that CMS places on the
16 actuary to ensure that there is compliance with the
17 laws, regulations and instructions and the various
18 Actuarial Standards of Practice.

19 Q. CMS does a thorough review of bid
20 submissions from MA plans, right?

21 A. Speaking on behalf of the -- on

1 behalf of the Office of the Actuary, we do as
2 thorough and comprehensive a job in reviewing those
3 bids that have been submitted as possible, given
4 the various time and other constraints placed upon
5 us.

6 Q. And you believe it's reasonable for
7 MA plans to presume that CMS is doing that thorough
8 review that you just spoke about, right?

9 A. Plans are familiar with our review
10 process.

11 Q. And how thorough it is, right?

12 A. Yes.

13 Q. Mr. Spitalnic, on the top of
14 Page 8 -- we're still in -- in Paragraph 8,
15 you -- you also wrote -- and this is in response to
16 a couple of bulleted statements -- quoting from
17 United's bid submissions. You wrote, An actuary
18 cannot disclaim that they are knowingly violating
19 the rules of the program.

20 Do you see that?

21 A. I do.

1 Q. Are you aware of any instance in
2 which CMS responded to the bulleted statements you
3 include in Paragraph 8 by saying that United's
4 decision to cease its prior process of identifying
5 and deleting certain diagnosis codes violated
6 United's obligations?

7 ATTORNEY ZUPAC: Object to form.

8 THE WITNESS: I am not aware of
9 discussions that were related to the subject
10 of those quotations.

11 BY ATTORNEY MARTINEZ:

12 Q. So let -- let's -- let's drill down
13 on one of them. Let's look at the second bullet --
14 sorry to keep flipping back.

15 We're on the bottom of Page 7 --
16 starting with the BPT submissions in 2015. And --
17 and what does "BPT" stand for?

18 A. "BPT" stands for bid pricing tool.

19 Q. All right.

20 -- starting with the bid pricing
21 tool submissions in 2015, quote, We also adjusted

1 projected risk scores to account for changes in our
2 medical record review processes. Specifically,
3 based on multiple conversations with CMS and CMS'
4 treatment of medical record review in its recent
5 rulemaking process, the health plan has decided to
6 cease one of its prior processes that identified
7 and deleted certain diagnoses codes through the
8 medical record review process.

9 Do you see that?

10 A. I do see that.

11 Q. Are you aware of any instance in
12 which CMS responded to that statement by saying
13 that United's decision to cease its prior process
14 of identifying and deleting certain diagnosis codes
15 violated United's obligations under the MA program?

16 A. I am not aware of any such
17 statements.

18 Q. Were you aware of these statements
19 from United in its BPT submissions at the time they
20 were made?

21 A. I do not believe I have -- I -- I do

1 not believe I was aware of these statements at that
2 time.

3 Q. Was anyone else in your office aware
4 of them?

5 A. I do not know of anyone in my office
6 being specifically aware of this specific
7 statement.

8 Q. And after writing your report or
9 during the process of writing your report, did you
10 ask anyone at the Office of the Actuary or at CMS
11 whether they were aware of these statements from
12 United?

13 A. I did not specifically ask anybody
14 about anything going back to 2015.

15 Q. So going -- going back to the top
16 of -- of Page 8, Mr. Spitalnic, where you wrote An
17 actuary cannot disclaim that they are knowingly
18 violating the rules of the program.

19 Are you aware of United ever
20 asserting in this case that it could knowingly
21 violate the rules of the MA program by issuing a

1 disclaimer in its bid submissions to CMS?

2 A. I took the potential qualification
3 that I referenced in those two preceding bullets
4 that there was some acknowledgment by United in
5 this case -- I took the suggestion that they were
6 trying to disclaim that they knew of unsupported
7 doc- -- documentation -- unsupported diagnoses
8 being used for payment and if the contention was --
9 and if the reason for the inclusion in the
10 actuarial support materials was to reference that
11 they were aware of additional codes that were
12 unsupported as being included in their basis for
13 payment -- if that was the intention, then that's
14 how I would potentially read those -- that
15 particular statement.

16 And so that was what got me to say --
17 and in complete fairness or disclosure, if I were
18 to have read this statement in 2015 without knowing
19 the history of exactly what all the -- you know,
20 some of the background that I'm now more familiar
21 with, you know, given some of the either facts of

1 this case or implications that I've made in reading
2 Ms. Lambert's report, without that additional
3 detail, I would not be exactly sure what this was
4 referencing or what this was getting into.

5 And so with that additional
6 background, if the intent of this -- these
7 paragraph -- or this paragraph or two was to say
8 that United was aware that they had unsupported
9 diagnoses and they're going to continue to include
10 them in their bid development, I would think that
11 to be inappropriate.

12 Q. That is your -- an assumption that
13 you're making, right?

14 A. Absolutely.

15 Q. Just so we're clear.

16 You have no information of United
17 in this case ever asserting, arguing, claiming that
18 it can knowingly violate the rules of the
19 MA program by issuing a disclaimer in its bid
20 submissions to CMS, right?

21 A. I would say United, nor anyone else,

1 I, Cindy L. Sebo, Nationally Certified Court
2 Reporter herein, do hereby certify that the foregoing
3 deposition of PAUL IRA SPITALNIC was taken before me
4 pursuant to notice at the time and place indicated;
5 that said witness duly swore to tell the truth, the
6 whole truth, and nothing but the truth under
7 penalties of perjury; that said testimony of witness
8 was correctly recorded to the best of my abilities in
9 machine shorthand, thereafter transcribed under my
10 supervision with computer-aided transcription; that
11 deposition is a true and accurate record of the
12 testimony given by the witness; that I am neither
13 counsel, nor kin to any party in said action, nor
14 interested in the outcome; and that a copy of this
15 transcript obtained from a source other than the
16 court reporting firm, including an adversary or
17 co-counsel in the matter, is uncertified and may not
18 be used at trial. 

19 CINDY L. SEBO, RMR, CRR, CLR, RPR, CCR, CSR, RSA, CA
CSR 14409, NJ Certified CR 30XI0024460, NJ Certified
20 RT 30XR00019500, NM CSR 589, NY Realtime Court
Reporter, NY Association Certified Reporter, OR CSR
21 230105, TN CSR 998, TX CSR 12778, WA CSR 23005926,

EXHIBIT P-80

April 2, 2012

NOTE TO: All Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties

SUBJECT: Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

In accordance with section 1853(b)(1) of the Social Security Act (the Act), we are notifying you of the annual Medicare Advantage (MA) capitation rate for each MA payment area for CY 2013 and the risk and other factors to be used in adjusting such rates. The capitation rate tables for 2013 are posted on the Centers for Medicare & Medicaid Services (CMS) web site at <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/index.html> under Ratebooks and Supporting Data. The statutory component of the regional benchmarks, transitional phase-in periods for the Affordable Care Act rates, qualifying counties, and each county's applicable percentage are also posted at this website.

Attachment I shows the final estimates of the increases in the National Per Capita MA Growth Percentages for 2013 and the national Medicare fee-for-service growth percentage. These growth rates will be used to update the 2013 rates. As discussed in Attachment I, the final estimate of the increase in the National Per Capita MA Growth Percentage for combined aged and disabled beneficiaries is 2.80 percent. Attachment II provides a set of tables that summarizes many of the key Medicare assumptions used in the calculation of the National Per Capita MA Growth Percentages.

Section 1853(b)(4) of the Act requires CMS to release county-specific per capita fee-for-service (FFS) expenditure information on an annual basis, beginning with March 1, 2001. In accordance with this requirement, FFS data for CY 2010 are being posted on the above website.

Information on deductibles for MSA plans is included below.

Attachment III presents responses to comments on the Advance Notice of Methodological Changes for CY 2013 MA Capitation Rates and Parts C and Part D Payment Policies (Advance Notice). Attachment VII presents the final Call Letter. We received 114 submissions in response to CMS' request for comments on the Advance Notice/Call Letter, published on February 17, 2012. Eight of the comments were from advocacy groups, 22 were from associations, 5 were from members of the public, 1 was from a State, 1 was from a Congressman, 1 was from a Congressional Advisory Committee, 68 were from health plans and 8 were from consultants.

Disease Coefficients	Description Label	Community Factors	Institutional Factors
HCC83	Angina Pectoris/Old Myocardial Infarction	0.170	0.331
HCC92	Specified Heart Arrhythmias	0.289	0.245
HCC95	Cerebral Hemorrhage	0.359	0.151
HCC96	Ischemic or Unspecified Stroke	0.265	0.151
HCC100	Hemiplegia/Hemiparesis	0.534	0.069
HCC101	Cerebral Palsy and Other Paralytic Syndromes ³	0.131	-
HCC104	Vascular Disease with Complications	0.594	0.470
HCC105	Vascular Disease	0.302	0.138
HCC107	Cystic Fibrosis	0.385	0.378
HCC108	Chronic Obstructive Pulmonary Disease	0.340	0.378
HCC111	Aspiration and Specified Bacterial Pneumonias	0.734	0.605
HCC112	Pneumococcal Pneumonia, Emphysema, Lung Abscess	0.206	0.197
HCC119	Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	0.236	0.440
HCC130	Dialysis Status	1.348	2.228
HCC131	Renal Failure	0.297	0.353
HCC132	Nephritis	0.116	0.353
HCC148	Decubitus Ulcer of Skin	1.165	0.517
HCC149	Chronic Ulcer of Skin, Except Decubitus	0.476	0.291
HCC150	Extensive Third-Degree Burns ³	1.246	-
HCC154	Severe Head Injury	0.580	0.060
HCC155	Major Head Injury ³	0.171	-
HCC157	Vertebral Fractures without Spinal Cord Injury	0.467	0.154
HCC158	Hip Fracture/Dislocation ³	0.435	-
HCC161	Traumatic Amputation	0.793	0.266
HCC164	Major Complications of Medical Care and Trauma	0.311	0.325
HCC174	Major Organ Transplant Status	1.084	0.925
HCC176	Artificial Openings for Feeding or Elimination	0.659	0.861
HCC177	Amputation Status, Lower Limb / Amputation Complications	0.793	0.266
Disabled/Disease Interactions			
D_HCC5	Disabled_Opportunistic Infections ³	0.597	-
D_HCC44	Disabled_Severe Hematological Disorders	1.340	0.633
D_HCC51	Disabled_Drug/Alcohol Psychosis	0.383	0.284
D_HCC52	Disabled_Drug/Alcohol Dependence	0.105	0.284
D_HCC107	Disabled_Cystic Fibrosis ³	2.556	-
Disease Interactions			
INT1	DM_CHF ²	0.150	0.111
INT2	DM_CVD	0.150	0.051
INT3	CHF_COPD	0.278	0.248
INT4	COPD_CVD_CAD	0.233	0.118
INT5	RF_CHF ^{2,3}	0.262	-
INT6	RF_CHF_DM ²	0.600	0.373

NOTES:

¹ Includes Type I or Type II Diabetes Mellitus.

² Beneficiaries with the three-way interaction RF*CHF*DM are excluded from the two-way interactions DM*CHF and RF*CHF. Thus, the three-way interaction term RF*CHF*DM is not additive to the two-way interaction terms

EXHIBIT P-81

Medicare & Retirement

2015 Business Plan

August [XX], 2015

DRAFT

EXHIBIT

00309



Financial Summary

Key Takeaways



2014 Financial Summary

- Best estimate of (\$500M) miss, M&R management commitment to find \$250M
- Submitted 2014 2+10 forecast \$250M down from budget
- Excluding insurer's fee 22% earnings growth at the 2+10 forecast
- Recent development on CV (under review), and additional Optum contributions may result in an additional \$350M in IOI versus the 2+10 forecast

2015 Estimate

- CMS rate pressure driving unprecedented member premiums \$520M and benefit reductions \$255M
- The expiration of the demonstration period drives 280 bps of pressure (\$535M in IOI)
- Insurer's Fee increase of 44bps drives (\$163M) of IOI pressure
- Pulling all levers to minimize plan closures
- Aggressive 100K growth assumption

2016 – 2017 Long Term Outlook

- Assuming 38% of members in a 4.0+ in 2016 and 50% in 2017
- Volume capture is key
- Net core trend of 3% throughout
- Net operating cost takeout of \$120M in 2016 and \$100M in 2017
- Consistent IOI contribution from HouseCalls
- Incremental Insurer's Fee headwind in 2017 (\$203M) as tax increases nearly 35 bps and 2016 revenues rebound from 2015
- MAPD plan liability increasing as coverage gap fills; \$280M in 2016 and \$270M in 2017

	2014 Budget	2014 Outlook	2015 Estimate	2016 Estimate	2017 Estimate
Gross IOI	\$2,254	\$2,354	\$2,000	\$2,250	\$2,677
Growth:					
MA	(65)	(5)	100	200	200
Part D	300	300	300	100	0
Med Supp	235	270	229	208	191
Metrics:					
MA BCR %	84.3%	84.3%	84.6%	85.0%	84.5%
M&R OCR %	11.4%	11.3%	12.1%	11.5%	11.3%
M&R IOI %	5.1%	5.2%	4.1%	4.2%	4.6%
Benefits	\$455	\$435	\$255	\$90	\$90
Premiums	\$20	\$20	\$520	\$190	\$180



Performance Architecture

MA Growth

Enrollment

Gross Margin

Benefits / Mix

Rates & RAF

Trend Outlook

Affordability

Network

Other

Operating Costs

Stars

Other

What Has Changed

2015 – 100K growth versus (300K)
2017 – 200K growth versus 100K

2015 – \$175M increase in benefit reductions/
member premiums; \$775M total
2016/2017 – incremental benefit cuts/member
premiums of \$280M and \$270M, respectively

2015 – \$220M incremental earnings from
HouseCalls versus \$0M

2015 – \$25M versus \$0M

2015 – \$60M net productivity versus \$0M

2015 – 37% in 4.0+ versus 24%
2016 – 38% in 4.0+ versus 35%
2017 – 50% in 4.0+ versus 45%

2015 – removal of (\$300M) IOI from one-
time prior year CV/QA deletes

What Hasn't Changed

2016 – 100K growth

2016/2017 – Trend neutral RAF programs

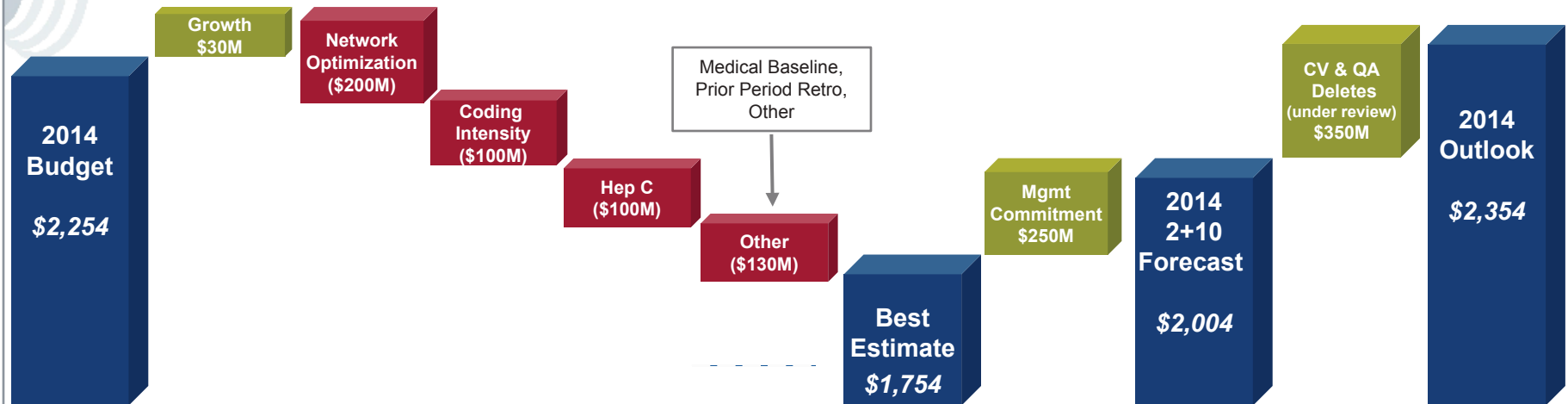
2015 - 2017 – ~3% net core trend

2015 - 2017 – Trend neutral impact

2016 – \$120M net productivity
2017 – \$100M net productivity



2014 Budget to 2014 Outlook Bridge



	2014 Budget	2014 Best Est.	2014 2+10	2014 Outlook
Growth	470	565	565	565
MA	(65)	(5)	(5)	(5)
Part D	300	300	300	300
MedSupp	235	270	270	270
Revenue	\$44,293	\$45,085	\$45,085	\$45,470
MA	31,249	31,930	31,930	32,315
Part D	5,016	4,978	4,978	4,978
MedSupp	8,028	8,177	8,177	8,177
KEY METRICS				
Reported BCR				
MA	84.3%	85.8%	85.2%	84.3%
Part D	74.9%	75.1%	75.1%	75.1%
MedSupp	85.7%	85.9%	85.9%	85.9%
Total M&R OCR	11.4%	11.5%	11.3%	11.3%
Total M&R OCR (excl. F)	10.2%	10.3%	10.1%	10.1%
IOI Margin %				
MA	5.5%	3.8%	4.6%	5.6%
Part D	6.4%	5.9%	5.9%	5.9%
MedSupp	2.8%	3.0%	3.0%	3.0%

- 2014 Outlook **revenue and earnings better than budget** by \$1,177 million and \$100 million respectively
- Best Estimate IOI gap of (\$500M) versus budget comprised of (\$200M) in network optimization, (\$100M) in lower coding intensity (net of HouseCalls upside), (\$100M) of Hep C, and (\$100M) of other medical baseline and prior period retro.
- Will cut gap in half with \$250M in M&R management commitment. Earnings recouped through network contracting and new ideation, additional clinical based affordability, further operating cost reductions, and contributions from Optum and other UHC partners.
- CV & QA deletes opportunity driving \$350M in IOI
- 2014 Outlook IOI MA margin of 5.6% is slight improvement versus budget margin of 5.5%

EXHIBIT P-82

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.	)	No. 16-08697 FMO
BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
UNITEDHEALTH GROUP, INC., et al.,	)	
	)	
Defendants.	)	
_____	)	

Videotaped Deposition of
MELISSA FERRON
Given Remotely
Wednesday, July 27, 2022
11:13 a.m. Eastern

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 should be looking at?

2 Q. It is page 3 of Exhibit 348.

3 A. Oh, page 3. Okay.

4 Q. Yeah, I think I misspoke and told you
5 page 4 earlier.

6 A. Okay. Yes.

7 Q. All right. So Mr. Webb wrote to you,
8 "There was also a key takeaway that you were going to
9 work on:

10 "Identifying the HCC's (or hcc/dx code
11 combinations) that could be used to further filter
12 the CV populations due to the inability to validate."

13 Do you see that?

14 A. Yes.

15 Q. So what Mr. Webb is asking you to do is
16 identifying a set of HCCs that you have determined
17 often do not validate in your second-level review.
18 Is that right?

19 MS. SOBEL: Objection to form. Document
20 speaks for itself.

21 THE WITNESS: Yes.

22 BY MS. CHEN:

23 Q. And the purpose of identifying these HCCs
24 was to allow United to get a second-level review for
25 those HCCs. Is that right?

1 MS. SOBEL: Objection to form. Calls for
2 speculation.

3 THE WITNESS: Yes. That would -- my
4 understanding was that there are certain HCCs
5 and diagnosis that are likely to be miscoded
6 from a physician office. And if the first-level
7 reviewer deemed it as not valid, that the second
8 level wouldn't need to be done.

9 BY MS. CHEN:

10 Q. In other words, one level of review was
11 sufficient to determine that these codes should be
12 deleted?

13 MS. SOBEL: Objection. Form.

14 THE WITNESS: Yes, that's a good
15 interpretation.

16 I might -- can I just offer just an
17 observation, also, that in the first amended
18 complaint, there's some misquoting of what these
19 HCCs are. So my e-mail has a numerical label
20 for the HCCs; and in the first amended
21 complaint, the diagnosis narrative was put in,
22 which does not coincide with the HCC numbers.

23 BY MS. CHEN:

24 Q. Okay. So -- okay. So -- so, Ms. Ferron,
25 I think what you're saying is that there was a

1 documentation that's capable of being understood in
2 two or more possible ways?

3 A. Yes.

4 Q. Conflicting documentation includes
5 documentation that is opposing, or that does -- is
6 not internally consistent?

7 A. Yes.

8 Q. And incomplete documentation, similar to
9 what we've been discussing for a while now, is
10 documentation that's lacking certain information?

11 A. Yes.

12 Q. And you would agree that there are certain
13 circumstances where it would be appropriate to use
14 queries, correct?

15 A. Yes.

16 Q. One of those circumstances is when a
17 documented diagnosis lacks specificity for which
18 clarification will yield the assignment of the
19 accurate specific code?

20 MR. McNAMARA: Are you just going to read
21 the slide and run through the slide? We can all
22 see what's on the slide.

23 THE WITNESS: Yes.

24 BY MS. CHEN:

25 Q. Another circumstance when it would be

1 appropriate to use a physician query is when the
2 medical record indicates that the patient is
3 receiving treatment for a diagnosis that is not
4 clearly documented. Is that right?

5 A. Yes. Yes.

6 Q. Another circumstance where it would be
7 appropriate to use a physician query is when the
8 physician has used a symbol or abbreviation, and a
9 clarification is needed to assign the appropriate
10 code, correct?

11 A. Yes.

12 Q. A fourth circumstance where it would be
13 appropriate to use a physician query are when there
14 are multiple possible interpretations to what is
15 documented, and clarification is needed to assign the
16 appropriate code?

17 A. Yes.

18 Q. Another circumstance where a physician
19 query might be appropriate is when clarification is
20 needed as to whether a listed diagnosis still exists
21 or if it has resolved? Is that correct?

22 A. Yes.

23 Q. Another circumstance where it would be
24 appropriate to use a physician query is when
25 clarification of the cause or etiology of a diagnosis

1 or condition is needed to assign the appropriate
2 code? Is that correct?

3 MR. McNAMARA: Can you indicate which --
4 which slide you're reading from, Counsel?

5 MS. CHEN: I'm asking Ms. Ferron the
6 question.

7 MR. McNAMARA: Okay. But you appear to be
8 reading from something. Are you reading from
9 Slide 23?

10 MS. CHEN: I am reading from Slide 23, but
11 the question to Ms. Ferron concerns -- the
12 question to Ms. Ferron was simply another
13 circumstance where it would be appropriate to
14 use a physician query is when clarification for
15 the cause or etiology of a diagnosis or
16 condition is needed to assign the appropriate
17 code.

18 BY MS. CHEN:

19 Q. Correct?

20 A. Correct.

21 Q. And can you explain what etiology of a
22 diagnosis or condition is?

23 A. Yes.

24 Q. And what is it?

25 A. Okay. Sorry.

1 Q. Sorry.

2 A. It would be -- there's certain code
3 assignments that could differ, based on the etiology
4 of the condition. So the etiology is the underlying
5 cause.

6 So typically -- I'll give you an example.
7 So peripheral neuropathy can be caused by diabetes.
8 It can be caused by chemotherapy. It can be caused
9 by spinal disorders. So knowing the etiology of a
10 condition could change the code assignment.

11 Q. Thank you.

12 Another circumstance where physician query
13 would be appropriate would be to clarify the
14 cause-and-effect relationship between two conditions
15 needed to assign the appropriate code; is that right?

16 A. Yes.

17 Q. Another circumstance where it would be
18 appropriate to use a physician query is when clinical
19 indications are noted in the medical record that
20 raise the possibility that a condition may be
21 present, but is not stated as a diagnosis. Correct?

22 A. Yes, correct.

23 Q. And then there's one final circumstance
24 for using a physician query, which is present on
25 admission. But I'm going to have to ask you to

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

Karen Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-83

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA) No. 16-08697 FMO
ex rel. BENJAMIN POEHLING,)
)
 Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
 Defendants.)
-----)

*** CONFIDENTIAL ***

CONTAINS ATTORNEYS' EYES ONLY PORTIONS
Videoconference Videotaped Deposition OF
CAROLYN KAPUSTIJ
(Taken virtually)
9:03 a.m. Eastern
Thursday, August 25, 2022

REPORTED BY: Christine A. Taylor, RPR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Inspector General, you were with CMS?

2 A. Correct.

3 Q. And you were with CMS for about
4 12 years from 2009 through 2021?

5 A. Yes. Yes. 12 years.

6 Q. Okay. And during the period when you
7 were at CMS, you worked on a research matter
8 looking into a potential fee-for-service adjuster
9 in the context of RADV?

10 A. I was involved in that during
11 different time periods at CMS.

12 Q. And can you tell us a little bit about
13 that? What is a fee-for-service adjuster?

14 MS. YEVTUKHOVA: Objection. Form.

15 THE WITNESS: So the fee-for-service
16 adjuster was a concept that was put forward
17 by the MA industry and taken up by CMS as a
18 means to offset recoveries for risk
19 adjustment data validation audits.

20 BY MR. QURESHI:

21 Q. And when you say it was taken up by
22 CMS, what do you mean by that?

23 A. I mean the industry contacted Tom
24 Hutchinson about it and then he kind of directed
25 his staff to calculate it.

CERTIFICATE OF REPORTER

I, Christine A. Taylor, Certified Court Reporter within and for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before me on the date and at the time and location stated on Page 1 of this transcript; that the deponent was duly sworn to testify to the truth, the whole truth and nothing but the truth; that the testimony of the deponent and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed; that the foregoing deposition as typed is a true, accurate and complete record of the testimony of the deponent and of all objections made at the time of the examination to the best of my ability.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof. Witness my hand, this 29th day of August, 2022.

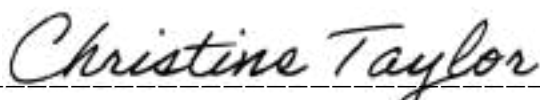

Christine A. Taylor, RPR
CCR-4736

EXHIBIT P-84

CLAIMS VERIFICATION

Business Requirements

Sep 15, 2010

Claims Verification Manual Specs [Page]

EXHIBIT

712-4

5003

PARA161485

Process to Review Chart for Discrepancies Continued



EXHIBIT P-85

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.,)
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
vs.) Civil Action No.
) 16-08697 FMO
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----/

VIDEOTAPED DEPOSITION OF PATRICIA BRENNAN
(Taken Virtually by Plaintiff)
Tuesday, September 12th, 2023
11:34 a.m. EDT

Reported Stenographically by

1 Q. Do you recall any sort of ballpark
2 estimate or range?

3 A. No.

4 Q. Was there at any point in time a
5 discussion about -- a discussion not involving
6 lawyers about expanding CV to include members with
7 nonexclusive HCCs?

8 A. I don't recall that.

9 Q. Okay. And so what happened with the
10 charts once they went through the chart eligibility
11 step in this workflow?

12 A. So then they went through -- obviously,
13 if you look at the written part about we would
14 import the claims data that was related to those
15 charts, so we would pull in the member claim data,
16 and then match it against the coding results to
17 determine if the exclusive HCC that was in claim
18 matched to what was coded. If it did, the process
19 ended because there was a match. The coder coded
20 the condition that was in claim, so the medical
21 records supported it. If it did not match, it went
22 to coding, and a coder -- claims verification
23 analyst coder would perform a review to see if that
24 code was supported in the medical record.

25 Q. And the system-matching logic phase,

1 placed on hold at some point, yes.

2 Q. And do you have an understanding of why
3 the deletes were placed on hold?

4 A. No.

5 Q. Do you have an understanding of what
6 time period during which the deletes were placed on
7 hold?

8 A. No.

9 Q. Do you have an understanding of who at
10 M&R would have made the decision to place CV
11 deletes on hold?

12 A. No.

13 Q. Do you recall anything about the volume
14 of deletes that were placed on hold?

15 A. No.

16 Q. Did you ever become aware of the volume
17 of deletes that were placed on hold after the date
18 of this e-mail?

19 A. Not that I recall.

20 Q. Do you have any understanding of the
21 outcome of the assessment that's referenced here by
22 M&R of the CV program?

23 A. No.

24 Q. Do you have any understanding of what
25 happened with those CV deletes that were placed on

1 hold?

2 A. No.

3 Q. So you don't know whether deletes were
4 actually ever submitted to CMS for those -- for
5 those deletes that had been placed on hold; is that
6 correct?

7 A. Correct.

8 Q. Did you become aware at some point in
9 2014 that Optum had suspended the claims
10 verification program for M&R?

11 A. Yes.

12 Q. And when did you become aware of that?

13 A. I don't know the exact timing, but I
14 got an e-mail that informed me of that.

15 Q. And do you recall who that e-mail was
16 from?

17 A. I believe it was from Jeff Dumcum.

18 Q. Jeff Dumcum.

19 And do you recall what that e-mail
20 said?

21 A. Just that the CV program -- I don't
22 recall the specifics of the e-mail, but I know that
23 that's when we found out the CV program was going
24 to be stopped.

25 Q. Okay. And do you have any sense of --

1 do you recall receiving that e-mail sometime during
2 2014?

3 A. I don't remember the timing, like I
4 mentioned, but I do recall receiving it. I just
5 don't know the timing.

6 Q. Okay. And the e-mail that you're
7 thinking of, did that inform you that the CV
8 program was being terminated entirely?

9 A. Yes.

10 Q. Okay. Prior to that, did you become
11 aware at any point that M&R had suspended the CV
12 program for a period of time?

13 A. I really don't recall the suspension or
14 the holds. I mean, I recall hearing about it, but
15 I don't recall being involved in the specifics
16 around it.

17 Q. Do you recall whether during this time
18 frame, so I guess starting in 2013 with the e-mail
19 that we just looked at, going into 2014, do you
20 recall whether you were engaged in any operations
21 activities for the CV program?

22 A. I don't recall.

23 Q. And do you recall -- I think you said
24 that you remembered hearing something about CV
25 being suspended. Do you recall hearing anything

1 CERTIFICATE OF NOTARY PUBLIC

2

3 I, Amy A. Brauser, RPR RMR CRR, the officer
4 before whom the foregoing deposition was taken, do
5 hereby certify that the witness was duly sworn by me
6 prior to the taking of the foregoing deposition; that
7 the testimony of said witness was taken by me to the
8 best of my ability and thereafter reduced to
9 typewriting under my direction; that I am neither
10 counsel for, related to, nor employed by any of the
11 parties to the action in which this deposition was
12 taken, and further that I am not a relative or
13 employee of any attorney or counsel employed by the
14 parties thereto, nor financially or otherwise interest
15 in the outcome of the action.

16

17 This is the 15th day of September, 2023.

18

19 Amy A Brauser

20

Amy A. Brauser, RPR RMR CRR

Notary Public

21

for the Commonwealth of Virginia

22

23 Notary Registration No.: 7675529

24 My Commission Expires: January 31, 2024

25

EXHIBIT P-86

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Madrid	Washington, D.C.

LATHAM & WATKINS LLP

May 27, 2016

VIA EMAIL AND FEDEX

Carol Wallack
Jessica Krieg
Civil Division, Fraud Section
U.S. Department of Justice
601 D. Street, NW, Room 9128
Washington, D.C. 20004

Re: Response to Follow Up Questions on March 18, 2016 Letter re: 2012 DOS Encounters Identified for CV Review

Dear Carol and Jessica:

I am writing in response to your April 4, 2016 follow up questions regarding UnitedHealth Group's ("UHG's") March 18, 2016 letter re: 2012 DOS Encounters Identified for CV Review (the "March 18 Letter").

As explained in the March 18 Letter, UHG was still in the process of confirming whether or not MARA1298042 (produced on May 12, 2015) included all 2012 DOS CV encounters with financial impact for which the multi-stage CV process was begun but not completed at the time M&R discontinued CV ("In Process CV Encounters") and anticipated supplementing its response upon completion of that review. That review is now complete. Rather than producing another supplemental spreadsheet, the enclosed spreadsheet, MARA2160501, includes a complete list of all identified 2012 DOS In Process CV Encounters or CV Cancelled Deletes with Part C financial impact to UHG, including, but not limited to, the relevant encounters identified in your April 4, 2016 email. Please note that the Plan Number(s) listed are Contracts in the corresponding Payment Year 2013.

In your April 4, 2016 email, you request an explanation for "why the deletes were never made." As you know, based on discussions and correspondence with CMS in March – June 2014, M&R undertook to delete only those diagnosis codes that had undergone a complete CV review and been identified as appropriate deletes at the time M&R discontinued CV. The encounters in the enclosed spreadsheet were not deleted because they had not completed the

EXHIBIT

726⁵⁰¹³

May 27, 2016
Page 2

LATHAM & WATKINS LLP

multi-stage CV process in place at the time M&R discontinued CV. In particular, none of the encounters in the enclosed spreadsheet completed the expert coding review stage of the CV process, and approximately 800 encounters were not reviewed by any coder as part of the CV process. UHG has flagged the 800 encounters that were not reviewed by any coder as part of the CV process with a "0" under Column J of the enclosed spreadsheet ("Initial_CV_Review").

In response to your request that we identify each encounter with "a project number or some other identifier," please note that the great majority of the encounters in the enclosed spreadsheet were not far enough along in the CV process to be assigned such an identifier at the encounter level. UHG has included the ProjectID number in the enclosed spreadsheet, where available.

Please also note that the enclosed spreadsheet and facts described above are based on the information we have been able to gather to date. UHG reserves the right to modify, supplement, correct, or otherwise amend these responses as it gathers additional information in the course of its review.

As with the prior productions and responses, these documents and responses contain highly proprietary and competitively sensitive commercial information, and UHG requests confidential treatment of these documents and responses and exemption from disclosure under the Freedom of Information Act. These documents and responses may also contain patient health information protected by the Health Insurance Portability and Accountability Act of 1996, as amended and implemented. Per our discussions, UHG is producing these documents and response pursuant to 45 C.F.R. § 164.512 and/or 45 C.F.R. § 164.502(a)(3), and pursuant to its understanding that the government has a standard business associate agreement in place with Relator's counsel.

* * * *

Please do not hesitate to contact me with any questions.

Very truly yours,



Abid R. Qureshi
of LATHAM & WATKINS LLP

cc: Roger S. Goldman
Daniel Meron

May 27, 2016
Page 3

LATHAM & WATKINS LLP

Anne Robinson
Kirstin Scheffler Do
Peggy B. Glynn
Martha Glover
Gretchen Wylegala

EXHIBIT P-87

**REDACTED VERSION OF
DOCUMENT PROPOSED TO BE
FILED UNDER SEAL**

	A	B	C	D	E	F	G	H	I	J
1	ProjectID			FromDate	ThroughDate	DiagnosisCode	Contract1	Contract2	Contract3	Initial CV_Review
2	000012215			2012-03-29 00:00:00.000	2012-03-29 00:00:00.000	436	H5005			1
3	000012215			2012-06-01 00:00:00.000	2012-06-01 00:00:00.000	25000	H5005			1
4	000012215			2012-02-25 00:00:00.000	2012-02-25 00:00:00.000	4476	H5005			1
5	000012215			2012-09-29 00:00:00.000	2012-09-29 00:00:00.000	4476	H5005			1
6	000012215			2012-01-30 00:00:00.000	2012-01-30 00:00:00.000	25040	H5005			1
7	000012215			2012-08-29 00:00:00.000	2012-08-29 00:00:00.000	70714	H4514			0
8	000012215			2012-09-05 00:00:00.000	2012-09-05 00:00:00.000	70714	H4514			0
9	000012215			2012-09-05 00:00:00.000	2012-09-05 00:00:00.000	7079	H4514			0
10	000012215			2012-09-12 00:00:00.000	2012-09-12 00:00:00.000	70714	H4514			0
11	000012215			2012-09-19 00:00:00.000	2012-09-19 00:00:00.000	70714	H4514			0
12	000012215			2012-09-26 00:00:00.000	2012-09-26 00:00:00.000	70714	H4514			0
13	000012215			2012-09-26 00:00:00.000	2012-09-26 00:00:00.000	7079	H4514			0
14	000012215			2012-10-03 00:00:00.000	2012-10-03 00:00:00.000	70712	H4514			0
15	000012215			2012-10-03 00:00:00.000	2012-10-03 00:00:00.000	70714	H4514			0
16	000012215			2012-10-10 00:00:00.000	2012-10-10 00:00:00.000	70712	H4514			0
17	000012215			2012-10-10 00:00:00.000	2012-10-10 00:00:00.000	70714	H4514			0
18	000012215			2012-10-17 00:00:00.000	2012-10-17 00:00:00.000	70714	H4514			0
19	000012215			2012-10-17 00:00:00.000	2012-10-17 00:00:00.000	7079	H4514			0
20	000012215			2012-10-24 00:00:00.000	2012-10-24 00:00:00.000	70714	H4514			0
21	000012215			2012-10-24 00:00:00.000	2012-10-24 00:00:00.000	7079	H4514			0
22	000012215			2012-10-31 00:00:00.000	2012-10-31 00:00:00.000	70714	H4514			0
23	000012215			2012-10-31 00:00:00.000	2012-10-31 00:00:00.000	7079	H4514			0
24	000012215			2012-11-07 00:00:00.000	2012-11-07 00:00:00.000	70714	H4514			0
25	000012215			2012-11-07 00:00:00.000	2012-11-07 00:00:00.000	7079	H4514			0
26	000012215			2012-11-21 00:00:00.000	2012-11-21 00:00:00.000	70714	H4514			0
27	000012215			2012-11-21 00:00:00.000	2012-11-21 00:00:00.000	7079	H4514			0
28	000012215			2012-11-28 00:00:00.000	2012-11-28 00:00:00.000	70714	H4514			0
29	000012215			2012-12-11 00:00:00.000	2012-12-11 00:00:00.000	70714	H4514			0
30	000012215			2012-12-18 00:00:00.000	2012-12-18 00:00:00.000	70714	H4514			0
31	000012215			2012-04-16 00:00:00.000	2012-04-16 00:00:00.000	25062	H5005			1
32	000012215			2012-09-11 00:00:00.000	2012-09-11 00:00:00.000	42781	H0303			0
33	000012215			2012-08-09 00:00:00.000	2012-08-09 00:00:00.000	1889	H0303			0
34	000012215			2012-05-21 00:00:00.000	2012-05-21 00:00:00.000	3572	H0303			1
35	000012215			2012-06-12 00:00:00.000	2012-06-12 00:00:00.000	48230	R5287			0
36	000012215			2012-07-30 00:00:00.000	2012-07-30 00:00:00.000	48230	R5287			0
37	000012215			2012-11-13 00:00:00.000	2012-11-13 00:00:00.000	48230	R5287			0
38	000012215			2012-01-10 00:00:00.000	2012-01-10 00:00:00.000	436	H0303			1
39	000012215			2012-02-13 00:00:00.000	2012-02-13 00:00:00.000	1718	H4514			1
40	000012215			2012-01-19 00:00:00.000	2012-01-19 00:00:00.000	4280	H0543			1
41	000012215			2012-02-20 00:00:00.000	2012-02-20 00:00:00.000	4280	H0543			1
42	000012215			2012-08-09 00:00:00.000	2012-08-09 00:00:00.000	4280	H0543			1
43	000012215			2012-01-09 00:00:00.000	2012-01-09 00:00:00.000	1729	H0609			1
44	000012215			2012-01-19 00:00:00.000	2012-01-19 00:00:00.000	25092	H3107			0
45	000012215			2012-07-12 00:00:00.000	2012-07-12 00:00:00.000	25092	H3107			0
46	000012215			2012-10-18 00:00:00.000	2012-10-18 00:00:00.000	25092	H3107			0
47	000012215			2012-08-02 00:00:00.000	2012-08-02 00:00:00.000	25000	H0609			1
48	000012215			2012-08-21 00:00:00.000	2012-08-21 00:00:00.000	2252	H0609			1
49	000012215			2012-01-18 00:00:00.000	2012-01-18 00:00:00.000	42781	H0316			1
50	000012215			2012-01-27 00:00:00.000	2012-01-27 00:00:00.000	42781	H0316			1
51	000012215			2012-03-06 00:00:00.000	2012-03-06 00:00:00.000	40493	H0755	H0303		1
52	000012215			2012-04-10 00:00:00.000	2012-04-10 00:00:00.000	40493	H0755	H0303		1
53	000012215			2012-09-12 00:00:00.000	2012-09-12 00:00:00.000	8970	H5424			0
54	000012215			2012-05-23 00:00:00.000	2012-05-23 00:00:00.000	4139	R5287			1
55	000012215			2012-10-26 00:00:00.000	2012-10-26 00:00:00.000	40211	H3749			1
56	000012215			2012-10-25 00:00:00.000	2012-10-25 00:00:00.000	4470	H2931			0
57	000012215			2012-08-08 00:00:00.000	2012-08-08 00:00:00.000	436	R5287			0
58	000012215			2012-02-23 00:00:00.000	2012-02-23 00:00:00.000	5853	H0303			1
59	000012215			2012-05-17 00:00:00.000	2012-05-17 00:00:00.000	70715	H5005			1
60	000012215			2012-10-11 00:00:00.000	2012-10-11 00:00:00.000	25010	R5342			1
61	000012215			2012-10-11 00:00:00.000	2012-10-11 00:00:00.000	40291	R5342			1
62	000012215			2012-11-28 00:00:00.000	2012-11-28 00:00:00.000	40291	R5342			1
63	000012215			2012-11-30 00:00:00.000	2012-11-30 00:00:00.000	29620	H1509			0
64	000012215			2012-10-26 00:00:00.000	2012-10-26 00:00:00.000	29620	H1509			0
65	000012215			2012-10-26 00:00:00.000	2012-10-26 00:00:00.000	41519	H1509			0
66	000012215			2012-11-19 00:00:00.000	2012-11-19 00:00:00.000	25060	H5005			1
67	000012215			2012-05-22 00:00:00.000	2012-05-22 00:00:00.000	5839	R3175			1
68	000012215			2012-06-08 00:00:00.000	2012-06-08 00:00:00.000	25020	H5424			1
69	000012215			2012-07-10 00:00:00.000	2012-07-10 00:00:00.000	25020	H5424			1
70	000012215			2012-09-17 00:00:00.000	2012-09-17 00:00:00.000	25020	H5424			1
71	000012215			2012-01-24 00:00:00.000	2012-01-24 00:00:00.000	41071	R3175			0
72	000012215			2012-01-05 00:00:00.000	2012-01-05 00:00:00.000	42781	H5424			1
73	000012215			2012-05-22 00:00:00.000	2012-05-22 00:00:00.000	42781	H5424			1
74	000012215			2012-11-26 00:00:00.000	2012-11-26 00:00:00.000	42781	H5424			1
75	000012215			2012-02-15 00:00:00.000	2012-02-15 00:00:00.000	25020	H5424			1
76	000012215			2012-08-14 00:00:00.000	2012-08-14 00:00:00.000	25020	H5424			1
77	000012215			2012-08-21 00:00:00.000	2012-08-21 00:00:00.000	25020	H5424			1
78	000012215			2012-09-25 00:00:00.000	2012-09-25 00:00:00.000	25020	H5424			1
79	000012215			2012-02-17 00:00:00.000	2012-02-17 00:00:00.000	436	H5424			1
80	000012215			2012-03-13 00:00:00.000	2012-03-13 00:00:00.000	436	H5424			1
81	000012215			2012-05-25 00:00:00.000	2012-05-25 00:00:00.000	436	H5424			1
82	000012215			2012-07-27 00:00:00.000	2012-07-27 00:00:00.000	436	H5424			1
83	000012215			2012-10-16 00:00:00.000	2012-10-16 00:00:00.000	436	H5424			1
84	000012215			2012-02-28 00:00:00.000	2012-02-28 00:00:00.000	25002	H5424			1
85	000012215			2012-04-28 00:00:00.000	2012-04-28 00:00:00.000	25002	H5424			1
86	000012215			2012-08-18 00:00:00.000	2012-08-18 00:00:00.000	25002	H5424			1
87	000012215			2012-01-19 00:00:00.000	2012-01-19 00:00:00.000	25090	R3175			1
88	000012215			2012-06-06 00:00:00.000	2012-06-06 00:00:00.000	25090	R3175			1
89	000012215			2012-11-16 00:00:00.000	2012-11-16 00:00:00.000	20410	H1509			1
90	000012215			2012-07-31 00:00:00.000	2012-07-31 00:00:00.000	4260	H7187			0
91	000012215			2012-10-31 00:00:00.000	2012-10-31 00:00:00.000	5569	H1509			1
92	000012215			2012-04-30 00:00:00.000	2012-04-30 00:00:00.000	436	H1080			1
93	000012215			2012-05-29 00:00:00.000	2012-05-29 00:00:00.000	4439	H3920			1
94	000012215			2012-01-19 00:00:00.000	2012-01-19 00:00:00.000	1532	R5287			1
95	000012215			2012-04-19 00:00:00.000	2012-04-19 00:00:00.000	1532	R5287			1
96	000012215			2012-07-18 00:00:00.000	2012-07-18 00:00:00.000	1532	R5287			1
97	000012215			2012-09-24 00:00:00.000	2012-09-24 00:00:00.000	5829	H3920			1
98	000012215			2012-02-03 00:00:00.000	2012-02-03 00:00:00.000	4439	H3887			1
99	000012215			2012-05-18 00:00:00.000	2012-05-18 00:00:00.000	4439	H3887			1
100	000012215			2012-08-17 00:00:00.000	2012-08-17 00:00:00.000	4439	H3887			1
101	000012215			2012-04-10 00:00:00.000	2012-04-10 00:00:00.000	496	H0251			

	A	B	C	D	E	F	G	H	I	J
1	ProjectID			FromDate	ThroughDate	DiagnosisCode	Contract1	Contract2	Contract3	Initial CV_Review
1514	N/A			2012-11-29 00:00:00.000	2012-11-29 00:00:00.000	496	R5342			1
1515	N/A			2012-05-11 00:00:00.000	2012-05-11 00:00:00.000	185	R5287			1
1516	N/A			2012-05-24 00:00:00.000	2012-05-24 00:00:00.000	1744	H1509			1
1517	N/A			2012-06-20 00:00:00.000	2012-06-20 00:00:00.000	586	R5287			1
1518	N/A			2012-02-13 00:00:00.000	2012-02-13 00:00:00.000	586	R5287			1
1519	N/A			2012-03-27 00:00:00.000	2012-03-27 00:00:00.000	586	R5287			1
1520	N/A			2012-06-18 00:00:00.000	2012-06-18 00:00:00.000	586	R5287			1
1521	N/A			2012-10-18 00:00:00.000	2012-10-18 00:00:00.000	586	R5287			1
1522	N/A			2012-05-09 00:00:00.000	2012-05-09 00:00:00.000	29620	H1080			1
1523	N/A			2012-11-29 00:00:00.000	2012-11-29 00:00:00.000	1723	H5435			1
1524	N/A			2012-02-10 00:00:00.000	2012-02-10 00:00:00.000	25000	H1111			1
1525	N/A			2012-05-04 00:00:00.000	2012-05-04 00:00:00.000	25000	H1111			1
1526	N/A			2012-08-03 00:00:00.000	2012-08-03 00:00:00.000	25000	H1111			1
1527	N/A			2012-08-17 00:00:00.000	2012-08-17 00:00:00.000	25000	H1111			1
1528	N/A			2012-11-02 00:00:00.000	2012-11-02 00:00:00.000	25000	H1111			1
1529	N/A			2012-05-25 00:00:00.000	2012-05-25 00:00:00.000	185	H5435			1
1530	N/A			2012-05-08 00:00:00.000	2012-05-08 00:00:00.000	42781	H0755			1
1531	N/A			2012-07-02 00:00:00.000	2012-07-02 00:00:00.000	25080	H1509			1
1532	N/A			2012-07-09 00:00:00.000	2012-07-09 00:00:00.000	25080	H1509			1
1533	N/A			2012-07-16 00:00:00.000	2012-07-16 00:00:00.000	25080	H1509			1
1534	N/A			2012-07-23 00:00:00.000	2012-07-23 00:00:00.000	25080	H1509			1
1535	N/A			2012-01-27 00:00:00.000	2012-01-27 00:00:00.000	185	H0609			1
1536	N/A			2012-05-21 00:00:00.000	2012-05-21 00:00:00.000	4111	H4102			1
1537	N/A			2012-07-11 00:00:00.000	2012-07-11 00:00:00.000	42781	H4102			1
1538	N/A			2012-06-29 00:00:00.000	2012-06-29 00:00:00.000	5853	H4102			1
1539	N/A			2012-09-26 00:00:00.000	2012-09-26 00:00:00.000	42731	H1509			1
1540	N/A			2012-01-17 00:00:00.000	2012-01-17 00:00:00.000	25070	H4102			1
1541	N/A			2012-05-15 00:00:00.000	2012-05-15 00:00:00.000	25070	H4102			1
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1544	N/A			2012-03-12 00:00:00.000	2012-03-12 00:00:00.000	4254	H4102			1
1545	N/A			2012-03-12 00:00:00.000	2012-03-12 00:00:00.000	4280	H4102			1
1546	N/A			2012-04-30 00:00:00.000	2012-04-30 00:00:00.000	4111	H4102			1
1547	N/A			2012-07-27 00:00:00.000	2012-07-27 00:00:00.000	4928	H4102			1
1548	N/A			2012-02-13 00:00:00.000	2012-02-13 00:00:00.000	1749	H4102			1
1549	N/A			2012-05-02 00:00:00.000	2012-05-02 00:00:00.000	3560	H4102			1
1550	N/A			2012-02-16 00:00:00.000	2012-02-16 00:00:00.000	436	H4102			1
1551	N/A			2012-03-09 00:00:00.000	2012-03-09 00:00:00.000	436	H4102			1
1552	N/A			2012-05-14 00:00:00.000	2012-05-14 00:00:00.000	436	H4102			1
1553	N/A			2012-06-18 00:00:00.000	2012-06-18 00:00:00.000	436	H4102			1
1554	N/A			2012-08-06 00:00:00.000	2012-08-06 00:00:00.000	436	H4102			1
1555	N/A			2012-08-16 00:00:00.000	2012-08-16 00:00:00.000	436	H4102			1
1556	N/A			2012-09-11 00:00:00.000	2012-09-11 00:00:00.000	436	H4102			1
1557	N/A			2012-09-27 00:00:00.000	2012-09-27 00:00:00.000	436	H4102			1
1558	N/A			2012-10-09 00:00:00.000	2012-10-09 00:00:00.000	436	H4102			1
1559	N/A			2012-12-27 00:00:00.000	2012-12-27 00:00:00.000	436	H4102			1
1560	N/A			2012-05-24 00:00:00.000	2012-05-24 00:00:00.000	1749	H4102			1
1561	N/A			2012-01-19 00:00:00.000	2012-01-19 00:00:00.000	1749	H4102			1
1562	N/A			2012-01-24 00:00:00.000	2012-01-24 00:00:00.000	41519	H4102			1
1563	N/A			2012-05-29 00:00:00.000	2012-05-29 00:00:00.000	1748	H4102			1
1564	N/A			2012-02-07 00:00:00.000	2012-02-07 00:00:00.000	73313	H4102			1
1565	N/A			2012-12-19 00:00:00.000	2012-12-19 00:00:00.000	4270	H4102			1
1566	N/A			2012-09-24 00:00:00.000	2012-09-24 00:00:00.000	4160	H4102			1
1567	N/A			2012-05-01 00:00:00.000	2012-05-01 00:00:00.000	7202	H4102			1
1568	N/A			2012-07-24 00:00:00.000	2012-07-24 00:00:00.000	42823	H1509			1
1569	N/A			2012-06-19 00:00:00.000	2012-06-19 00:00:00.000	44422	H4102			1
1570	N/A			2012-03-05 00:00:00.000	2012-03-05 00:00:00.000	25000	H4102			1
1571	N/A			2012-04-09 00:00:00.000	2012-04-09 00:00:00.000	25001	H4102			1
1572	N/A			2012-05-11 00:00:00.000	2012-05-11 00:00:00.000	25000	H4102			1
1573	N/A			2012-05-11 00:00:00.000	2012-05-11 00:00:00.000	44020	H4102			1
1574	N/A			2012-12-14 00:00:00.000	2012-12-14 00:00:00.000	1749	H4102			1
1575	N/A			2012-09-26 00:00:00.000	2012-09-26 00:00:00.000	1889	H4102			1
1576	N/A			2012-04-10 00:00:00.000	2012-04-10 00:00:00.000	586	H4102			1
1577	N/A			2012-01-27 00:00:00.000	2012-01-27 00:00:00.000	436	H4102			1
1578	N/A			2012-07-23 00:00:00.000	2012-07-23 00:00:00.000	436	H4102			1
1579	N/A			2012-10-23 00:00:00.000	2012-10-23 00:00:00.000	436	H4102			1
1580	N/A			2012-03-30 00:00:00.000	2012-03-30 00:00:00.000	25060	H4102			1
1581	N/A			2012-03-30 00:00:00.000	2012-03-30 00:00:00.000	3369	H4102			1
1582	N/A			2012-09-20 00:00:00.000	2012-09-20 00:00:00.000	41181	H4102			1
1583	N/A			2012-06-20 00:00:00.000	2012-06-20 00:00:00.000	4928	H1080			1
1584	N/A			2012-06-05 00:00:00.000	2012-06-05 00:00:00.000	29630	H4102			1
1585	N/A			2012-06-27 00:00:00.000	2012-06-27 00:00:00.000	29621	H4102			1
1586	N/A			2012-07-11 00:00:00.000	2012-07-11 00:00:00.000	29621	H4102			1
1587	N/A			2012-08-08 00:00:00.000	2012-08-08 00:00:00.000	29621	H4102			1
1588	N/A			2012-08-03 00:00:00.000	2012-08-03 00:00:00.000	436	H4102			1
1589	N/A			2012-07-30 00:00:00.000	2012-07-30 00:00:00.000	1749	H4102			1
1590	N/A			2012-06-27 00:00:00.000	2012-06-27 00:00:00.000	43491	H0303			1
1591	N/A			2012-06-22 00:00:00.000	2012-06-22 00:00:00.000	1749	H4102			1
1592	N/A			2012-03-13 00:00:00.000	2012-03-13 00:00:00.000	45341	H4102			1
1593	N/A			2012-09-14 00:00:00.000	2012-09-14 00:00:00.000	45341	H4102			1
1594	N/A			2012-10-23 00:00:00.000	2012-10-23 00:00:00.000	4254	H4102			1
1595	N/A			2012-06-13 00:00:00.000	2012-06-13 00:00:00.000	44020	R5287			1
1596	N/A			2012-10-23 00:00:00.000	2012-10-23 00:00:00.000	40291	H4102			1
1597	N/A			2012-02-16 00:00:00.000	2012-02-16 00:00:00.000	4260	H4102			1
1598	N/A			2012-05-04 00:00:00.000	2012-05-04 00:00:00.000	586	H4102			1
1599	N/A			2012-07-18 00:00:00.000	2012-07-18 00:00:00.000	42731	H4102			1
1600	N/A			2012-07-18 00:00:00.000	2012-07-18 00:00:00.000	4280	H4102			1
1601	N/A			2012-06-04 00:00:00.000	2012-06-04 00:00:00.000	25000	H4102			1
1602	N/A			2012-11-07 00:00:00.000	2012-11-07 00:00:00.000	1749	H4102			1
1603	N/A			2012-05-07 00:00:00.000	2012-05-07 00:00:00.000	1536	H4102			1
1604	N/A			2012-04-12 00:00:00.000	2012-04-12 00:00:00.000	42731	H4102			1
1605	N/A			2012-10-15 00:00:00.000	2012-10-15 00:00:00.000	4820	H4102			1
1606	N/A			2012-07-20 00:00:00.000	2012-07-20 00:00:00.000	7079	H4102			1
1607	N/A			2012-10-12 00:00:00.000	2012-10-12 00:00:00.000	3349	H4102			1
1608	N/A			2012-03-29 00:00:00.000	2012-03-29 00:00:00.000	5852	H4102			1
1609	N/A			2012-06-12 00:00:00.000	2012-06-12 00:00:00.000	7424	H4102			1
1610	N/A			2012-06-21 00:00:00.000	2012-06-21 00:00:00.000	1548	H4102			1
1611	N/A			2012-03-21 00:00:00.000	2012-03-21 00:00:00.000	28800	H0609			1
1612	N/A			2012-05-02 00:00:00.000	2012-05-02 00:00:00.000	43491	H4102			1
1613	N/A			2012-05-08 00:00:00.000	2012-05-08 00:00:00.000	49120	H4102			1
1614	N/A			2012-04-02 00:00:00.000	2012-04-02 00:00:00.000	7140	H1509			1
1615	N/A			2012-05-10 00:00:00.000	2012-05-10 00:00:00.000	7140	H1509			1
1616	N/A			2012-05-11 00:00:00.000	2012-05-11 00:00:00.000	7140	H1509			1
1617	N/A			2012-05-21 00:00:00.000	2012-05-21 00:00:00.000	7140	H1509			1
1618	N/A			2012-06-06 00:00:00.000	2012-06-06 00:00:00.000	7140	H1509			1
1619	N/A			2012-08-07 00:00:0						

EXHIBIT P-88

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex	)	
rel. BENJAMIN POEHLING,	)	
	)	
Plaintiffs,	)	
vs.	)	CASE NO.
	)	CV 16-08697 FMO
UNITEDHEALTH GROUP, INC. et	)	
al.,	)	
	)	
Defendants.	)	

VIDEOTAPED DEPOSITION of KATHLEEN BAKER
taken by Plaintiffs, held at Riley, Warnock &
Jacobson, 1906 West End Avenue, Nashville,
Tennessee, commencing at 8:19 A.M., on July 12,
2022, before Gary Schneider, RPR, CRR, RMR, TLCR
and Notary Public within and for the State of
Tennessee.

1 Q. What was your involvement in
2 making decisions about whether to submit deletes
3 from Optum's CV program?

4 A. I made no decisions regarding
5 that.

6 Q. What was your involvement in
7 decisions regarding whether a claims verification
8 program should be implemented?

9 A. I was not involved in those
10 conversations or decisions.

11 Q. Earlier today do you recall that
12 you testified that you used chart retrieval
13 vendors to retrieve charts for Optum's
14 retrospective chart review program?

15 A. Yes.

16 Q. In your experience, did these
17 chart retrieval vendors retrieve all charts for a
18 member for a given date of service year?

19 A. No, that's not possible.

20 Q. When you say it's not possible,
21 what do you mean?

22 A. Meaning there's just so many
23 charts for members. So, like, you know, if we go
24 back to, like, my -- well, actually, where we're
25 positioned right now, like, my cancer diagnosis is

1 that, you know, a member can have multiple charts
2 across different locations, across different
3 providers. So, like, here we sit in -- you know,
4 I had services done at Saint Thomas Ascension that
5 also has a private ambulatory surgery center that
6 also houses a medical -- a medical building that
7 housed my breast surgeon and my plastic surgeon,
8 and then also Vanderbilt where I had some
9 procedures done.

10 You know, even if I just go back
11 to the date where I had, you know, surgery done at
12 the ASC, I would have, you know, four different
13 visits from separate doctors regarding my date of
14 service that day, but they're all different charts
15 or, you know, Vanderbilt's in their charts. If I
16 would go to one location to grab a chart, it
17 doesn't mean I would have grabbed all charts for
18 that member because it would've only been what was
19 available that day. But even if I -- you know,
20 for instance, for Vanderbilt or maybe personal
21 experience, we've all been to doctors, where
22 Monday -- well, here, I mean, I'll say Vanderbilt,
23 like, Monday and Wednesdays they're here downtown
24 or Midtown here at Vanderbilt. But then on, you
25 know, Tuesdays and Thursdays, they're out in

1 Franklin office location. And so depending upon
2 how their medical charts are, those could be
3 different locations for charts for that member.
4 And so, you know, it's just charts -- a chart for
5 a member doesn't contain every single encounter
6 that that member has had, nor is it possible to
7 say whether or not it's always a complete chart
8 because it's based upon what was available at that
9 time or if the provider sent it and what the
10 provider sent to us.

11 Q. Did Optum review all of the
12 charts for a member in a particular date of
13 service year in its retrospective chart review
14 program?

15 A. Did we review all? No, it's
16 not -- I mean, we didn't have all of the data. We
17 didn't have all of the medical charts for them.

18 Q. Earlier today do you recall
19 testifying about blind -- blind chart reviews?

20 A. Yes.

21 Q. Do you know what a blind chart
22 review is?

23 A. Yes.

24 Q. What is it?

25 A. It's when the coders are not

1 STATE OF TENNESSEE)
2 COUNTY OF DAVIDSON) SS:

3 I, Gary Schneider, TLCR No. 676, in and
4 for the State of Tennessee, do hereby certify:

5 That, prior to being examined, the
6 witness named in the foregoing deposition was by
7 me duly sworn to testify the truth, the whole
8 truth and nothing but the truth;

9 That said deposition was taken down by
10 me stenographically at the time and place therein
11 named, and thereafter transcribed via
12 computer-aided transcription under my direction,
13 and the same is a true, correct and complete
14 transcript of said proceedings;

15 Before completion of the deposition,
16 review of the transcript was not requested. If
17 requested, any changes made by the deponent (and
18 provided to the reporter) during the period
19 allowed are appended hereto.

20 I further certify that I am not
21 interested in the outcome of the action.

22 Witness my hand this July 15, 2022.

23
24 
GARY SCHNEIDER, TLCR No. 676

25 Certified Shorthand Reporter
State of Tennessee
State of Tennessee

EXHIBIT P-89

Message

From: Melissa Ferron [mferron@MelissaFerron.com]
Sent: 3/6/2014 2:57:58 AM
To: Webb, Christopher R [chris.webb@optum.com]
Subject: Re: hccs dx likely to not validate in our CV

2012 HCCs:

HCC	# of rows	# of Y validations
2	6	0
5	17	1
17	33	0
37	55	2
75	6	1
78	0	
81	18	1
95	50	0
96	895	1
104	246	5
111	96	1
112	89	1
154	2	0
158	88	1
161	13	0

Dx codes:

25090-25093	94	1 (3 to a higher HCC)
3369	9	1
74239	8	0
80600-8069	4	0
95200-9529	1	0
9583	17	2
80000-80099	0	
80410-80449	0	
80460-80499	0	

On 3/5/2014 10:06 AM, Webb, Christopher R wrote:

Thanks. I will look for it later

Also, I cancelled our call today as I'm in offsite meetings this week but any chance I can get the new dashboard report sooner this morning?"

Thanks.

Chris

EXHIBIT

00348

5026

ICODIFY-0170934

-- Original Message --

From: mferron@MelissaFerron.com

Sent: Wednesday, March 05, 2014 11:41 AM Central Standard Time

To: Webb, Christopher R

Subject: Re: hccs dx likely to not validate in our CV

Ashley and I can work on it later

On 3/5/2014 8:33 AM, Webb, Christopher R wrote:

Are you able to send me stats for these based on the CV that you have already completed? Can we see, even at a total level and not detail, the number of records for all of these and the number that do NOT validate?

No, yes

Chris Webb

christopher@optum.com | 612.462.9700 ext. 110

12000 E. 15th Ave., Suite 1000

Denver, CO 80202

1.785.333.1100

1.785.333.1100

chris.webb@optum.com

Finally a new Outlook for Windows! Outlook is the only modern email client that

 OPTUM

From: mferron@MelissaFerron.com

Sent: Tuesday, March 04, 2014 11:25 AM

To: Webb, Christopher R

Subject: hccs dx likely to not validate in our CV

Here is the list of HCC's and dx codes that are unlikely to validate in our second level CV (from office medical records)

2017 HCCs:

2

6

17

37

75

78

81

95

96

104

111
112
154
158
161

Dx codes:
25090-25093
3369
74259
80600-8069
95700-95729
9584
80000-80099
80410-80449
80460-80499

On 3/4/2014 10:06 AM, Webb, Christopher R wrote:

There was also a key takeaway that you were going to work on

Identifying the HCC's (or hcc/dx code combinations) that could be used to further filter the CV populations due to the inability to validate, both for the work you currently have as well as the upcoming work

We started with the HCC 9596 items but you were going to expand in that in writing. When do you think that can be accomplished?

Thanks,

Chris

-----Original Message-----

From: mferrom@Melissahermon.com

Sent: Tuesday, March 04, 2014 10:45 AM Central Standard Time

To: Webb, Christopher R

Subject: Re: FW: Preliminary 2015 Payment Year ICD-10 to HCC Mappings

so funny - I was just about to ask for this

On 3/4/2014 8:33 AM, Webb, Christopher R wrote

Attached is the ICD-10 comparison document we talked about yesterday.

Thanks,

Melissa Hermon

Attachments: 2 - Preliminary 2015
ICD-10 to HCC mappings
1 - CMS ICD-10 to HCC

Chris Webb
Senior Analyst
chris.webb@optum.com

I have attached Optum's preliminary ICD-10 to HCC mappings to the relevant spreadsheet.

 OPTUM

From: Kedzierski, Janice L

Sent: Wednesday, February 26, 2014 8:49 AM

To: Bird, Jon H; Trujillo, Tim J; Smed, Mike; Bellile, Susan K; Howell, Scott C; Huie, Frederick J; Spaeth, Tim A; Santos, Karen S; James, Donald W; Larson, Mary J; Webb, Christopher R; Green, Amber S; Redmond, Janice L; Myers, Randall L; Rasmussen, Patricia R

Subject: Preliminary 2015 Payment Year ICD-10 to HCC Mappings

I formatted the preliminary ICD-10 to HCC mappings. CMS will continue to blend the V12 and V22 models for 2015 payment, but did not publish a V12 ICD-10 to HCC mapping yet. They provided mappings for the V22 part C model, the PACE/ESRD model for part C, and the new V04 Rx HCC model for Part D.

The attached file contains 5 tabs:

1. All_ICD10_Prelim
 - a. Contains all ICD-10 codes, with a column to indicate which HCC the code maps to in each model
 - b. Includes non-risk-adjusting codes
 - b. A blank indicates the code does not map in that model
 - c. Note that incomplete codes do not (and should not) map to HCCs
2. MAPart_C_Prelim - Contains the Part C mapping for the V22 model
3. Rx_Prelim - Contains the Part D mapping for the new V04 model
4. PACE_ESRD_Part_C_Prelim - Contains the Part C mapping for the PACE/ESRD model
5. MultHCCs_Prelim
 - a. Lists ICD-10s that map to more than 1 HCC in any model
 - b. 5 Diabetes codes map to 3 HCCs (these are the only codes that map to 3 HCCs)
 - c. The maximum number of HCCs per ICD-10 is 3
 - d. There are 366 codes that map to more than 1 HCC in at least 1 model (158 for the V22 Part C model)

The original files from CMS can be found here:

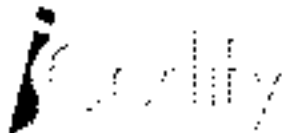
https://www.cms.gov/Medicare/Health_Plans/MedicareAdvgtSpecRateStats/Risk_Adjusters_Items/fisk2015.html?D1:Page=1&D1:sort=0&D1:SortDir=descending

Feel free to forward this internally.

Janice Kedzierski
Owner
31001 124 Center Drive | Suite 100 | CA 92104
Tel: 760 825 6011
Janice.Kedzierski@Optum.com

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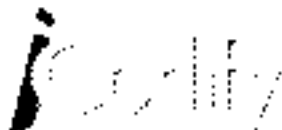
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Melissa Ferron



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Healthcare Consulting

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Melissa Ferron



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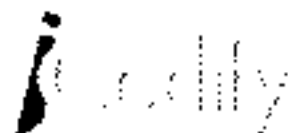
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EXHIBIT P-90

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA, ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
_____)

Videotaped Deposition of
MARYBETH MEYER
Given Remotely
Tuesday, June 7, 2022

Reported by: Karen K. Kidwell, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 earlier that towards the end of 2013, Scott
2 Theisen, who was my boss, asked me to review the
3 proposed CV deletes.

4 BY MR. LEE:

5 Q. And in accordance with that instruction
6 from Scott Theisen, you would review deletes and
7 instruct Optum to submit them after you reviewed
8 them?

9 A. We reviewed the -- the CV deletes. Yes.

10 Q. And was that for the purpose of
11 instructing Optum to delete them when appropriate?

12 A. We were asked to review the CV deletes
13 because we were receiving complaints from providers
14 that transactions were being deleted inappropriately.
15 We received those complaints through the RACCR
16 program specifically.

17 So when Scott asked me to start reviewing
18 and approving CV deletes, we were finding the same --
19 we were finding similar logic errors in Optum's
20 proposed deletes. So I don't recall how many deletes
21 were approved for Optum to process.

22 MR. LEE: Okay. Let me ask my colleague
23 to put up Tab 14, which will be Exhibit 198.

24 (Exhibit 198 was marked for identification.)

25

CERTIFICATE

I, KAREN K. KIDWELL, Registered Merit Reporter, and Certified Realtime Reporter, do hereby certify that prior to the commencement of the examination, the deponent was remotely sworn to testify to the truth, the whole truth under penalty of perjury.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in this action.

Karen K. Kidwell

Karen K. Kidwell
Registered Merit Reporter
Certified Realtime Reporter
Notary Public

EXHIBIT P-91

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 3
DEPOSITION OF ANNE HORNSBY
As 30(b)(6) Designee 1 of
The United States

Washington, DC
November 21, 2023

Reported by: John L. Harmonson, RPR

1 typical result of the audit process. For each
2 contract audited, there would be a payment error
3 amount.

4 And in addition, as I had been talking
5 about, CMS was aware that parent organizations were
6 deleting records that they had been paid on because
7 they found errors in the diagnosis codes.

8 BY MR. BAAK:

9 Q. You mentioned -- Dr. Hornsby, you
10 mentioned an error where a plan submits a diagnosis
11 code and then subsequently determines for some
12 reason that that code ought to be deleted. That
13 was an example you gave me a little bit earlier.

14 A. That was one example I gave, yes, that
15 CMS has seen.

16 Q. CMS is also aware that there are errors
17 where in fact a provider does document a diagnosis
18 code on a medical record but fails to submit it;
19 right? CMS knows that from the RADV process?

20 MS. LIKOFF: Objection to form. Vague.
21 Beyond the scope.

22 THE WITNESS: CMS did not have evidence
23 of that. You know, around the time of the 2014
24 rule, CMS had anecdotal evidence that MAOs were
25 conducting medical record reviews to find what

1 everybody calls additional to find diagnoses that
2 had not been submitted before that appear to be
3 supported by the medical record. CMS was not aware
4 of that as a fact, as clear knowledge. It was all
5 through professional networks and, you know, that
6 level of knowledge.

7 BY MR. BAAK:

8 Q. Just to make sure I understand,
9 Dr. Hornsby, you're testifying that over time CMS
10 became aware through professional discussions,
11 industry conferences and the like that Medicare
12 Advantage organizations were conducting medical
13 record reviews to add diagnosis codes that the
14 provider had failed to submit. Is that what you
15 just testified to?

16 A. Yes. Over time CMS became aware, around
17 2014 as a tipping point.

18 Q. It had knowledge that CMS obtained about
19 what plans were doing. That obviously predated the
20 proposed medical record review, right, since that
21 was targeted at Medicare Advantage organization's
22 chart review activities?

23 MS. LIKOFF: Object to form. Vague.
24 Misstates the witness's testimony.

25 THE WITNESS: CMS did not propose a

1 medical records provision because of plans seeking
2 additional. CMS had heard anecdotally that many
3 MAOs were failing to submit their deletes.
4 Therefore, CMS wanted to put in a reg an
5 application of the long-standing broader
6 requirement that diagnoses must be supported in the
7 medical record to be accurate. And that's what the
8 provision said.

9 MR. BAAK: I'm going to move to strike
10 that as nonresponsive.

11 BY MR. BAAK:

12 Q. My question, Dr. Hornsby, was about when
13 CMS obtained the knowledge that MA plans were
14 conducting medical record review to add diagnosis
15 codes but not to delete them. And my question is
16 simple.

17 Did CMS have that knowledge at the time
18 it proposed the medical record review rule in early
19 2014?

20 MS. LIKOFF: Objection to form.

21 THE WITNESS: CMS does not consider it
22 knowledge. CMS considers it informal network
23 information but nothing that would rise to the
24 level of knowledge because CMS cannot see what's
25 inside an MAO in terms of its data and its due

1 diligence activities.

2 BY MR. BAAK:

3 Q. I want to come back just to the basic
4 concept of an error in the diagnosis codes that go
5 provider to MA and from MA to CMS. Okay? So there
6 can be two types of errors, Dr. Hornsby; right?
7 You've mentioned one. I want to make sure we're
8 clear there are two types.

9 There can be an error when a provider
10 submits a diagnosis code to an MA plan that then
11 gets sent to CMS where that diagnosis code is not
12 reflected on a medical record. That's one example;
13 right?

14 MS. LIKOFF: Objection to form.

15 THE WITNESS: CMS does not agree with
16 that. Let's go to the contract. I can read you
17 Article 5. The MAO is responsible. CMS does not
18 have a concept of error that lands just on the
19 provider. It is the MAO's responsibility.

20 BY MR. BAAK:

21 Q. Dr. Hornsby, I don't think maybe you
22 understood my question. I'm just talking about the
23 true state of the universe. Did the provider
24 submit to the MA plan an accurate diagnosis code?
25 I want to figure out why that can go wrong. Are

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that ANNE HORNSBY, the witness whose
7 deposition is hereinbefore set forth, was duly
8 sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 27th day of November, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

23

24

25

EXHIBIT P-92

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 424

[CMS-4159-F]

RIN 0938-AR37

Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: The final rule will revise the Medicare Advantage (MA) program (Part C) regulations and prescription drug

benefit program (Part D) regulations to implement statutory requirements; improve program efficiencies; and clarify program requirements. The final rule also includes several provisions designed to improve payment accuracy.

DATES: *Effective Dates:* These regulations are effective on July 22, 2014 except for the amendment in instruction 27 to § 423.100, the amendment in instruction 30 to § 423.501, and the amendment in instruction 34 to § 423.505, which are effective on January 1, 2016.

Applicability Dates: In the **SUPPLEMENTARY INFORMATION** section of this final rule, we provide a table (Table 1) which lists key changes in this final rule that have an applicability date other than the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT:

Christopher McClintick, (410) 786-4682, Part C issues.

Marie Manteuffel, (410) 786-3447, Part D issues.

Kristy Nishimoto, (206) 615-2367, Part C and D enrollment and appeals issues.

Whitney Johnson, (410) 786-0490, Part C and D payment issues.

Joscelyn Lissone, (410) 786-5116, Part C and D compliance issues.

Frank Whelan, (410) 786 1302, Part D improper prescribing issues.

SUPPLEMENTARY INFORMATION: Table 1 lists key changes that have an applicability date other than 60 days after the date of publication of this final rule. The applicability dates are discussed in the preamble for each of these items.

TABLE 1—APPLICABILITY DATE OF KEY PROVISIONS OTHER THAN 60 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE

Preamble section	Section title	Applicability date
III.A.4	Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C)).	01/01/2016
III.A.7	Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)	01/01/2015
III.A.20	Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(6))	06/01/2015
III.A.24	Eligibility of Enrollment for Incarcerated Individuals (§§ 417.1, 417.460(b)(2)(i), 417.460(f)(1)(i)(A) through (C), 422.74(d)(4)(i)(A), 422.74(d)(4)(v), 423.44(d)(5)(iii) and (iv)).	01/01/2015

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detailed in forthcoming operational guidance.

We received the following comments on general rules for overpayments and our responses follow.

Comment: Several commenters requested that CMS clarify when the 60-day period begins. Specifically, does the period begin once the MA organization or Part D sponsor has identified that there is an overpayment or once the organization has determined the exact amount of the overpayment? A commenter expressed concern that the proposed rule does not appear to acknowledge that the amount of an overpayment must be quantified before it is “identified.” Another commenter requested that CMS address the situation where an MA organization or Part D sponsor becomes aware of an issue or error that may have resulted in one or more overpayments, but could not determine, with reasonable certainty, the amount of the overpayment(s) within a 60-day period.

Response: It is important to understand the distinctions among identifying, reporting, and returning an overpayment in this rulemaking for the purposes of the MA and Part D programs. Once an organization has identified that it has received an overpayment, the 60-day period for reporting and returning the overpayment begins. Because of the nature of the Part C and Part D programs, we did not propose that “identified” includes completion of the act of quantification of an overpayment amount. Rather, we proposed that identification of an overpayment means knowing that the MA organization or Part D sponsor has submitted erroneous data to CMS that caused CMS to overpay the organization.

An organization can identify or assess that there is a problem with data submitted to CMS, and determine that it is incorrect data, prior to actually calculating what the payment impact is of that erroneous data. For the MA and Part D programs, the relevant factor is identifying that the data is incorrect and will result in an overpayment. For example, a risk adjustment diagnosis that has been submitted for payment but is found to be invalid because it does not have supporting medical record documentation would result in an overpayment. Under this provision, the day after the date on which the organization has confirmed an identified overpayment—because the organization knows that the diagnosis is not supported by documentation—is the first day of the 60-day period for reporting and returning the overpayment. As another example, an

MA organization may find that data used to calculate Healthcare Effectiveness Data and Information Set (HEDIS) measures that the organization submitted to CMS are found to be invalid; when the organization has confirmed that it has identified invalid data leading to an overpayment, this is the first day of the 60-day period for reporting and returning the overpayment.

Then, during the 2-month period for reporting and returning the overpayment, the organization must determine what data should be submitted to CMS to correct the identified overpayment, and then must engage in the reporting and returning process that we will describe in forthcoming guidance. This reporting and returning process will involve: (1) Notifying CMS that an overpayment exists, including notification of the reason and estimated amount for that overpayment; and (2) submitting the corrected data to CMS.

In other words, we believe that the MA organization and Part D sponsor will discover through appropriate payment evaluation procedures when a 60-day period would begin under the requirements of this provision, because “day one” of the 60-day period is the day after the date on which organization has determined that it has identified the existence of an overpayment. Once the organization “starts the clock,” it has 60 days to submit to CMS the corrected data that is the basis of the overpayment. It is the act of submitting the corrected data to CMS, along with a reason and an amount of the overpayment (which may be an estimate), that constitutes fulfillment of the requirement to report and return the overpayment.

As we stated in the January 10, 2014 proposed rule preamble (79 FR 1997), “It also is important to note that the MA organization and Part D sponsor are deemed to have returned the overpayment when they have taken the actions that we will specify, in forthcoming operational guidance, to submit the corrected data that is the source of the overpayment”. We will recover the returned overpayment through routine CMS payment processes. That is, payments will continue to be recovered through the established payment adjustment processes and schedules. As a result the payment recovery may not occur within the 60-day window triggered by identifying an overpayment. Rerunning payment reconciliations and conducting payment recovery within CMS payment systems each time an entity identifies an

overpayment that triggers its 60-day clock is simply not feasible for CMS.

We will release operational guidance on the process an organization will use for informing CMS that it has identified a Part C and/or Part D overpayment. This guidance will also address how an organization will be required to provide a reason for and the amount of the overpayment (which may be estimated). We seek to reduce burden and implement an efficient process for administering the reporting and return of overpayments, so we are considering making use of existing procedures for organizations to communicate payment data issues to CMS. For example, MA organizations and Part D sponsors have used the Remedy system for a number of years to inform CMS of payment issues and provide relevant information on that issue.

In the forthcoming operational guidance, we will address the question of how to report the overpayment amount, including estimation of the overpayment amount and updates under certain scenarios.

Comment: A commenter contended that, applying the principles adopted by CMS in the RADV audit context, an overpayment cannot exist for a particular MA contract unless CMS’ payments as a whole to the MA organization pursuant to the contract are inaccurate in light of an appropriate FFS Adjuster applied to the entire contract. Potential overpayments can be determined, therefore, based only on processes such as CMS’ RADV audits, which are designed to measure whether contract-level payments to an MA organization are accurate when compared to an appropriate FFS Adjuster. The commenter further contended that to the extent an MA organization develops processes intended to measure payment accuracy at the contract-level, the MA organization would be required to report and repay inaccuracies calculated after applying CMS’s FFS Adjuster, and consistent with prior CMS guidance, this is the sole instance in which an “overpayment” can be determined for purposes of proposed § 422.326.

Response: We disagree with the commenter. Our RADV methodology does not change our existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must

be supported by medical record documentation.

However, we are clarifying the link between the § 422.326 overpayment provisions and RADV audits under § 422.311 by adding a condition to the requirement at § 422.326(d), as follows: an MA organization must report and return any overpayment it received no later than 60 days after the date on which it identified it received an overpayment. We are adding to paragraph (d) the provision “unless otherwise directed by CMS for the purpose of § 422.311.” Thus, when an MA organization has a contract selected for a RADV audit, during the audit the MA organization will not be allowed to report and return an overpayment under § 422.326 that is due to errors in the data used to risk-adjust payments for the audited contract for the payment year that is the subject of the RADV audit. We will notify the MA organization about the timeline for reporting and returning any overpayments for a contract under a RADV audit. This new provision protects the integrity of the RADV audit process, including the sampling frame of beneficiaries in a selected MA plan, whose diagnoses will be audited.

Comment: A commenter stated that there will be many circumstances and situations where entities receiving an overpayment will not have the ability to repay funds within the 60-day period without undue hardship.

Response: MA organizations and Part D sponsors have an obligation to pay an overpayment owed under Section 1128J(d). As noted previously, our recovery of overpayments will occur through routine payment processing cycles and schedules. In most circumstances, MA organizations and Part D sponsors will be submitting corrected data, which will be re-run by CMS and then CMS will recover the overpayment.

Comment: A commenter noted that 60 days is not a sufficient timeframe, as identifying and quantifying overpayments can be a very involved process. Another commenter stated that most overpayments are identified through analyses and studies, such as internal RADV studies; the commenter requested that the 60-day time period begin at the conclusion of the internal study, so that overpayments can be referred to CMS after all issues have been identified and confirmed.

Response: We provide that the 60-day period is the time period for reporting and returning an identified overpayment, after the organization has conducted the activities needed to identify that it has received an

overpayment. As explained previously, for the purposes of the MA and Part D programs, the MA organization or Part D sponsor must report and return the identified overpayment, which is due to incorrect data it has submitted to CMS, no later than 60 days after the date on which the organization identified it received the overpayment. Subsequently and within the 60-day period the MA organization or Part D sponsor is required to report and return the overpayment. Reporting the overpayment involves notifying CMS of the reason for and the amount of the overpayment. Returning the overpayment is deemed to have occurred through the act of correcting the erroneous data submitted to CMS, for example, by deleting incorrect PDEs or risk adjustment data. Note that if an organization identifies one set of erroneous data that has caused an overpayment, the organization must begin the 60-day clock on that date, and if subsequent overpayments are identified, the organization must begin subsequent 60-day reporting and returning periods.

Comment: A commenter questioned whether CMS will be identifying criteria for organizations to use to determine an overpayment.

Response: We have specified in this final rule the specific types of “funds” that are subject to the provisions under this section through the definition of “funds”. Funds are payments an organization has received that are based on data that the organization submitted to CMS for payment purposes. We will not provide additional criteria or a checklist.

Comment: A commenter stated that logically, an MA organization or Part D sponsor cannot return an overpayment until it has calculated the exact amount that it must return. It might take a considerable amount of time for the MA organization or Part D sponsor to audit its records to determine the amount, whether there is an issue in previous years, and whether extrapolation, or case by case analysis, is appropriate. The commenter was concerned that while a plan sponsor might be able to report to CMS that it has identified an issue within 60 days, a plan sponsor may not have enough information after identification to be able to report the exact amount. Therefore, the commenter requested that CMS clarify that the 60 days begins once the organization has identified the exact amount of the overpayment. The commenter suggested, as an alternative, that if the MA organization or Part D sponsor has notified CMS that it believes there is an overpayment, but it will take more than

60 days to determine the exact amount, CMS consider allowing a “tolling” of the 60 days so that the organization may determine the amount it must return to CMS. Under this “tolling” process, the organization would be required to notify CMS within 60 days of identifying that an overpayment likely exists, but would be provided additional time by CMS to determine the exact amount.

Response: We have not used the phrase “exact amount” in this rule-making. For the MA and Part D programs, we define overpayment in the regulation as “funds” the organization has received to which it is not entitled, and then defines “funds” as any payment based on data submitted by an MA or Part D organization. Because of the nature of the Part C and Part D programs, the key focus in implementing these statutory provisions for the MA and Part D programs is thus correcting the incorrect data that the organization submitted to CMS that resulted in an overpayment. We will then run reconciliation on its routine operational schedule to recover overpayment amounts based on the corrected data. The purpose of the 60 days is to provide the MA or Part D organization with sufficient time to correct the incorrect data submitted to CMS using established data correction processes. MA organizations and Part D sponsors are deemed to have returned the overpayment when they have taken the actions to submit the corrected data that is the source of the identified overpayment. Within the 60 days the MA organization and Part D sponsor must also report the overpayment amount (or estimated amount). If an estimated overpayment amount is reported, it may be higher or lower than the actual overpayment amount recovered because additional payment data submitted into the CMS payment system from other sources may be incorporated into the payment calculations.

Comment: A commenter stated that it is unclear what may occur post-reconciliation if both parties have been overpaid. For example, if CMS owes the Part D sponsor \$10 million due to activity post-reconciliation and a \$2 million overpayment is discovered, the commenter questioned whether we will still require that the \$2 million be refunded within 60 days or whether the sponsor will be allowed to offset amounts owed by CMS. The commenter recommended that if an overpayment would be reduced or fully covered by a reopening, that CMS allow sponsors to request a reopening and offset the reopening amount due from the

submitted by every provider, while others thought this implied a restriction on the ability of plans to identify what medical records to review. Other commenters believed the proposed amendment limited plans' ability to review medical records for operational purposes other than risk-adjusted payment, such as focusing on only a portion of a medical record for a subset of beneficiaries in order to enhance HEDIS scores, conduct contract compliance reviews, and validate claims processing and billing.

Finally, a few commenters argued that CMS should offset the payment impact of diagnoses an MA organization submitted to CMS that were later found through medical record reviews to not be supported by medical record documentation by adjusting the amount of CMS' overpayment to the MA organization for the level of error in equivalent diagnoses in FFS claims data. Specifically, the commenters argued that CMS should give MA organizations a credit for erroneous diagnoses they submitted from their providers' claims up to the rate identified by CMS as the applicable FFS Adjustor in the RADV program. The commenters also argued that there is no reason to require that both MA and FFS diagnosis data be scrutinized for error rates when determining retroactive payment adjustments, while not engaging in a similar adjustment process when paying plans prospectively.

Response: We thank the commenters for their input. We are not finalizing the proposed amendment to § 410.322(e).

However, we emphasize that our decision to not finalize this regulatory proposal does not change CMS' existing contractual requirement that MA organizations must certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the risk adjustment data they submit to CMS. Further, this decision does not change the long-standing risk adjustment data requirement that a diagnosis submitted to CMS by an MA organization for payment purposes must be supported by medical record documentation.

Comment: A few commenters supported CMS' proposal to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually, with the proviso that CMS' timing of this annual deadline always allows sufficient opportunity for organizations to make final data submissions. Several other commenters stated their concern about this proposed change in deadline, including a concern

that CMS might announce a deadline earlier than January 31 in some years. These commenters requested that CMS clarify that the annual deadline would never be before January 31, and a few commenters suggested that the regulation state that the deadline is January 31 but may be extended. Finally, a few commenters requested that CMS not change the January 31 date to a floating date, in order to allow operational stability.

Response: We are not finalizing this proposal at this time.

Comment: Many commenters disagreed with CMS' proposal under § 410.322(g)(2) that, after the final risk adjustment data submission deadline, CMS would permit submission of data to correct overpayments but not permit late submission of diagnosis data that would result in additional payment, asserting that this asymmetrical approach does not promote CMS' stated goal of improving payment accuracy. The commenters maintained that an MA organization should be allowed to submit additional diagnoses after the final risk adjustment data submission deadline to correct not only an overpayment to the MA organization, but also an underpayment. A commenter recommended that, after the final deadline, MA organizations should be able to submit paired deletions-additions of diagnoses as long as the result is not an increased payment to the organization but a smaller reduction in payment than would otherwise occur if only the deletion were submitted; for example, an MA organization may want to delete the diagnosis code for diabetes with acute complications and replace it with the code for diabetes without complications so that it loses only some of the payment. Finally, a commenter requested that CMS allow exceptions to the general rule that no new diagnoses may be submitted after the final risk adjustment data submission deadline for special circumstances such as system failures, file formatting issues, and other technical problems.

Response: For a given payment year (which is a calendar year), CMS applies diagnoses from the previous year (the data collection year) to calculate beneficiary risk scores used to risk-adjust payments to MA organizations in the payment year. MA organizations must finalize any corrections and new submissions of diagnosis data for a data collection year by January 31 of the year after the payment year. That is, we allow 13 months after the end of the diagnosis year for MA organizations to identify errors in data they have submitted (that is, deleting diagnoses from CMS' systems) and to identify and

submit additional diagnoses that were not submitted during the diagnosis year. We believe that is a very reasonable period of time to finalize risk adjustment data for a diagnosis year.

These risk adjustment processes have been in place for many years, and we believe it is the responsibility of MA organizations to have internal audit processes in place allowing them to finalize their risk adjustment data for a payment year by the conclusion of this 13-month period. Therefore, we are finalizing, as proposed, the provision codified at § 422.310(g)(2)(ii) that, after the final deadline, an MA organization may submit risk adjustment data to correct overpayments but not to add payments.

Comment: A commenter supported CMS' proposal to limit post-deadline modifications to deletions of incorrect diagnoses but requested that CMS offer one additional opportunity to eliminate unsupported diagnosis codes in advance of a RADV audit.

Response: When we are preparing to initiate a RADV audit cycle, all MA organizations are notified that they should eliminate unsupported diagnoses from CMS' systems by a date specified in the notice. Subsequently, we inform the contracts that have been selected for RADV.

In summary, after consideration of the public comments received, we are not finalizing the proposed amendment to § 410.322(e). Also, we are not finalizing at this time our proposal at § 422.310(g)(2)(ii) to remove the current date of January 31 as the annual final risk adjustment data submission deadline and replace it with the provision that CMS will announce the deadline annually. We are finalizing as proposed the restructuring of §§ 422.310(g)(2) and the 422.310(g)(2)(ii) provision to prohibit submission of diagnoses for additional payment after the final risk adjustment data submission deadline. We did not receive any comments on subparagraph (g)(3) and are finalizing it as proposed.

3. RADV Appeals

a. Background

We published final Risk Adjustment Data Validation (RADV) appeals regulations in the April 15 2010 **Federal Register** (75 FR 19677). These rules were proposed and finalized under our authority to establish Medicare Advantage (MA) program standards at section 1856(b)(1) of the Act and are found at § 422.311 et seq. Since finalizing these rules in 2010, we conducted additional RADV audits and determined that some of the appeals

EXHIBIT P-93

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA ex rel.) No. 16-08697 FMO
BENJAMIN POEHLING,)
)
Plaintiffs,)
)
v.)
)
UNITEDHEALTH GROUP, INC., et al.,)
)
Defendants.)
-----)

Videotaped Deposition of
CYNTHIA G. TUDOR, Ph.D.
Given Remotely
Tuesday, August 23, 2022
9:59 a.m. Eastern Time

Reported by: Cindy A. Hayden, RMR, CRR

Magna Legal Services
866-624-6221
www.MagnaLS.com

1 Q. You can answer, Dr. Tudor.

2 A. The answer is: Probably.

3 Q. Can you --

4 A. In general -- in general, I would say
5 that you have to design medical record review to
6 look for both adds and deletes.

7 Q. Dr. Tudor, sitting here today, can you
8 identify any Medicare Advantage plan that you
9 advised that they had to design their chart-review
10 programs to look to delete diagnosis codes in
11 addition to add?

12 A. I don't remember which specific
13 plans --

14 MS. CHEN: Object to form.

15 BY MR. BAAK:

16 Q. The answer to my question, Dr. Tudor,
17 is: Sitting here today, you can't identify any
18 Medicare Advantage plan that you recall telling
19 that they needed to design their chart review to
20 look to delete diagnosis codes in addition to add,
21 correct?

22 A. That's correct.

23 Q. I want to back up in time. When did
24 you first join CMS?

25 A. 1992.

CERTIFICATE OF REPORTER

I, Cindy A. Hayden, Registered Merit Reporter and Notary Public for the State of Maryland at Large, do hereby certify that the foregoing transcript is a true, accurate, and complete record.

I further certify that I am neither related to nor counsel for any party to the cause pending or interested in the events thereof.

Witness my hand, I have hereunto affixed my official seal this 26th day of August, 2022.

Cindy A. Hayden

Cindy A. Hayden, RMR, CRR

My Commission expires

April 26, 2025

EXHIBIT P-94

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA)
ex rel. BENJAMIN POEHLING,)
)
Plaintiff,) No. CV 16-08697 FMO
)
vs.)
)
UNITEDHEALTH GROUP, INC.,)
et al.,)
)
Defendants.)
-----)

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Volume 2
DEPOSITION OF CHRISTOPHER BRESETTE
As 30(b)(6) Designee 5 of
The United States

(Via Zoom Videoconference)
August 9, 2023

Reported by: John L. Harmonson, RPR
Job No. 1001591

1 coder to take another look to determine whether
2 they agreed with the first senior coder who
3 identified a new HCC that had not been submitted by
4 the MAO; correct?

5 A. Correct.

6 Q. Why was the second senior coder -- why
7 wasn't that reviewed blind as well?

8 A. This was a process that we believed was
9 reasonable to accomplish our audit objective.

10 Q. Would you agree that coders can
11 sometimes miss diagnosis codes on a blind review?

12 MS. OBEREMBT: Objection; calls for
13 speculation.

14 THE WITNESS: I would have to speculate
15 on that. We've asked the senior coders to
16 determine whether they believe something is -- if a
17 diagnosis is supported or not.

18 BY MS. SCHEFFLER DO:

19 Q. In your preparation for today and
20 reviewing all of these audits, you're not aware of
21 any instances where the first senior coder
22 conducting a blind review determined that an HCC

1 was not validated but OIG ultimately determined
2 that it in fact was validated?

3 A. I'm not going to say that it did or did
4 not happen. It very well may have happened. I did
5 not study the results of the first senior coder and
6 the second senior coder.

7 Q. We can go back to that and look at some
8 specific examples to refresh your recollection.

9 A. Absolutely.

10 Q. So if the second senior coder determines
11 that the HCC that the first senior coder -- let me
12 restart that.

13 If the second senior coder determines
14 that a particular HCC is validated despite the
15 first senior coder determining that it was not
16 supported, then it escalated to a physician to
17 independently review the medical record and make a
18 final determination. Is that right?

19 A. It's mostly correct. There were
20 oftentimes where the senior coders -- I shouldn't
21 say often. There was the opportunity and there
22 were times that existed that either the first

1 senior coder or the second senior coder asked for
2 assistance with that physician reviewer to make the
3 determination.

4 There were, as you say, instances in
5 which the physician reviewer would review that. I
6 believe independently, but I don't want to say that
7 it was exclusively independently. A lot of times I
8 believe it was in consultation with the senior
9 coder to make that determination.

10 Q. So are you saying that the example that
11 I gave, that's not the only time a physician would
12 weigh in?

13 A. Correct.

14 Q. But you're not -- you're agreeing that
15 if the second senior coder found support in that
16 example, then a physician would independently
17 review the medical record to make the final
18 determination?

19 A. I would agree with that.

20 Q. Was the physician review blind as well?

21 A. No, it was not. And independently is
22 correct. So my apologies. I see "independently"

1 C E R T I F I C A T E

2

3 DISTRICT OF COLUMBIA

4 I, JOHN L. HARMONSON, a Notary Public
5 within and for the District of Columbia, do hereby
6 certify that CHRISTOPHER BRESETTE, the witness
7 whose deposition is hereinbefore set forth, was
8 duly sworn by me and that such deposition is a true
9 record of the testimony given by such witness.

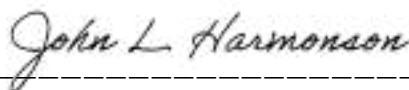
10 That before completion of the
11 proceedings, review and signature of the transcript
12 was reserved.

13 I further certify that I am not related
14 to any of the parties to this action by blood or
15 marriage; and that I am in no way interested in the
16 outcome of this matter.

17 IN WITNESS WHEREOF, I have hereunto set
18 my hand this 11th day of August, 2023.

19

20



21

JOHN L. HARMONSON, RPR

My commission expires: 04/14/26

22

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,
Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

JOINT EVIDENTIARY APPENDIX

**VOLUME 14 OF 14
DECLARATIONS IN SUPPORT
OF JOINT EVIDENTIARY
APPENDIX
PAGES 5058 THROUGH 5085**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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DECLARATION DA-1

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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,

Plaintiff,

v.

UNITEDHEALTH GROUP, INC. *et al.*,

Defendants.

CASE NO. 2:16-cv-08697-FMO-PVCx

**DECLARATION OF DAVID J.
SCHINDLER IN SUPPORT OF
UNITED'S MOTION FOR
SUMMARY JUDGMENT**

Hon. Fernando M. Olguin

Hearing Date: September 5, 2024

Hearing Time: 10:00 a.m.

Courtroom: 6D

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14 *Attorneys for United Defendants*

DECLARATION OF DAVID J. SCHINDLER

I, David J. Schindler, hereby declare as follows:

I am an attorney at Latham & Watkins LLP, the law firm which represents Defendant UnitedHealth Group Incorporated and its affiliated entities named as Defendants in this action (collectively, "United"). I submit this Declaration in support of the Joint Brief regarding the Cross Motions for Summary Judgment, and in particular, United's Motion for Summary Judgment and United's Opposition to Plaintiff United States' Motion for Partial Summary Judgment. I have personal knowledge, information, or belief of the facts stated herein and, if called as a witness, I could and would testify competently thereto.

1. Attached as **Exhibit D-1** is a true and correct copy of excerpts from the Amended Complaint dated November 17, 2017 (ECF 171).

2. Attached as **Exhibit D-2** is a true and correct copy of United's Answer to Amended Complaint dated March 23, 2018 (ECF 223).

3. Attached as **Exhibit D-3** is a true and correct copy of the Statement of Genuine Disputes of Material Fact dated July 23, 2018 (ECF 250-1).

4. Attached as **Exhibit D-4** is a true and correct copy of the Amended Joint Rule 26(f) Report dated April 2, 2018.

5. Attached as **Exhibit D-5** is a true and correct copy of the Joint Stipulation re United States' Motion to Compel Discovery dated April 16, 2021.

6. Attached as **Exhibit D-6** is a true and correct copy of the Order Denying Motion to Compel re Rog 14 and RFP 147 dated May 28, 2021.

7. Attached as **Exhibit D-7** is a true and correct copy of Defendant UHC Of California's First Interrogatory to the Government dated January 3, 2020.

8. Attached as **Exhibit D-8** is a true and correct copy of United States' Responses and Objections to Defendant UHC Of California's Second Set of Interrogatories, No. 5 dated April 21, 2021.

1 9. Attached as **Exhibit D-9** is a true and correct copy of United States'
2 Responses and Objections to Defendant UHC Of California's Request for
3 Admission Nos. 26, 36, 48, 79, 81, 90 dated November, 4, 2019.

4 10. Attached as **Exhibit D-10** is a true and correct copy of United States'
5 Responses and Objections to Defendant UHC Of California's Request for
6 Admission No. 117, 147 dated February 12, 2020.

7 11. Attached as **Exhibit D-11A** is a true and correct copy of United States'
8 Responses and Objections to Defendant UHC of California's First Interrogatory
9 dated February 3, 2020.

10 12. Attached as **Exhibit D-11B** is a true and correct copy of United States'
11 First Supplemental Responses and Objections to Defendant UHC Of California's
12 First Set of Interrogatories dated August 17, 2020.

13 13. Attached as **Exhibit D-12** is a true and correct copy of United States'
14 Responses and Objections to Defendant UHC of California's Interrogatory No. 12
15 dated June 23, 2022.

16 14. Attached as **Exhibit D-14** is a true and correct copy of excerpts from
17 73 Fed. Reg. 48434 (Aug. 19, 2008).

18 15. Attached as **Exhibit D-15** is a true and correct copy of excerpts from
19 75 Fed. Reg. 19678 (Apr. 15, 2010).

20 16. Attached as **Exhibit D-16** is a true and correct copy of excerpts from
21 79 Fed. Reg. 1918 (Jan. 10, 2014).

22 17. Attached as **Exhibit D-17** is a true and correct copy of excerpts from
23 79 Fed. Reg. 29844 (May 23, 2014).

24 18. Attached as **Exhibit D-18** is a true and correct copy of excerpts from
25 88 Fed. Reg. 6643 (Feb. 1, 2023).

26 19. Attached as **Exhibit D-21** is a true and correct copy of the document
27 bates numbered MARA2152278.

20. Attached as **Exhibit D-22** is a true and correct copy of the document bates numbered MARA2157039.

21. Attached as **Exhibit D-23** is a true and correct copy of the document bates numbered USBP000498420.

22. Attached as **Exhibit D-24** is a true and correct copy of the document bates numbered USBP000548071.

23. Attached as **Exhibit D-25** is a true and correct copy of document bates numbered USBP000674257.

24. Attached as **Exhibit D-26** is a true and correct copy of the document bates numbered USBP001354107.

25. Attached as **Exhibit D-27** is a true and correct copy of the document bates numbered USBP001354165.

26. Attached as **Exhibit D-28** is a true and correct copy of the document bates numbered USBP008083511.

27. Attached as **Exhibit D-29** is a true and correct copy of the document bates numbered USBP009417442.

28. Attached as **Exhibit D-30** is a true and correct copy of the document bates numbered USBP009417526.

29. Attached as **Exhibit D-31** is a true and correct copy of the document bates numbered USBP009417534.

30. Attached as **Exhibit D-32** is a true and correct copy of the document bates numbered USBP009417619.

31. Attached as **Exhibit D-33** is a true and correct copy of the document bates numbered USBP058101090.

32. Attached as **Exhibit D-34** is a true and correct copy of the document bates numbered USBP062135635.

33. Attached as **Exhibit D-35** is a true and correct copy of the document bates numbered USBP066819447.

5063

34. Attached as **Exhibit D-36** is a true and correct copy of the 2007 Risk Adjustment Data Training for Medicare Advantage Organizations Participant Guide.

35. Attached as **Exhibit D-38** is a true and correct copy of Excerpts from 71 DOJ J. FED. L. & PRAC. 4 (Dec. 2023).

36. Attached as **Exhibit D-39** is a true and correct copy of the Advance Notice of Methodological Changes for Calendar Year (CY) 2009 dated February 22, 2008.

37. Attached as **Exhibit D-40** is a true and correct copy of a Claim Form 1500 (available at: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf>).

38. Attached as **Exhibit D-41** is a true and correct copy of CMS, Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits dated February 24, 2012.

39. Attached as **Exhibit D-42** is a true and correct copy of Gregory C. Pope et al., Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model, Health Care Financing Review (Summer 2004).

40. Attached as **Exhibit D-43** is a true and correct copy of Kimberly O'Malley et al., Measuring Diagnoses: ICD Code Accuracy, 40 Health Services Research 1620 dated October 2005.

41. Attached as **Exhibit D-44** is a true and correct copy of Medicare Payment Advisory Commission, Issues for Risk Adjustment in Medicare Advantage, in Report to Congress: Medicare and Health Care Delivery System (Chapter 4), Washington, DC dated June 2012.

42. Attached as **Exhibit D-45** is a true and correct copy of an OIG Toolkit dated December 2023.

43. Attached as **Exhibit D-46** is a true and correct copy of OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Cigna-HealthSpring

Insurance Life & Health Insurance Contract first Health Plan, Inc., (Contract H4513) dated March 2023.

44. Attached as **Exhibit D-47** is a true and correct copy of OIG, Medicare Advantage Compliance Audit of Specific Diagnosis Codes that Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS in January 2022.

45. Attached as **Exhibit D-48** is a true and correct copy of Richard Kronick & W. Pete Welch, Measuring Coding Intensity in the Medicare Advantage Program, Medicare & Medicaid Research Review (2014).

46. Attached as **Exhibit D-52** is a true and correct copy of the Amended Expert Report of Jean Acevedo dated April 5, 2024.

47. Attached as **Exhibit D-53** is a true and correct copy of the Expert Rebuttal Report of Jean Acevedo dated January 29, 2024.

48. Attached as **Exhibit D-54** is a true and correct copy of the Expert Report of Barbara Blair dated September 29, 2023.

49. Attached as **Exhibit D-56** is a true and correct copy of the Expert Report of Mark Duggan, PhD dated September 29, 2023.

50. Attached as **Exhibit D-57** is a true and correct copy of the Expert Report of Craig Garthwaite dated September 29, 2023.

51. Attached as **Exhibit D-59** is a true and correct copy of the Errata to Expert Report of Craig Garthwaite dated March 11, 2024.

52. Attached as **Exhibit D-60** is a true and correct copy of the Expert Report of Melvin J. Ingber, PhD dated January 29, 2024.

53. Attached as **Exhibit D-61** is a true and correct copy of the Expert Report of Daniel Kessler, PhD dated September 29, 2023.

54. Attached as **Exhibit D-62** is a true and correct copy of the Expert Report of Julia Lambert dated September 29, 2023.

55. Attached as **Exhibit D-63** is a true and correct copy of the Updated Expert Report of Philip B. Stark dated March 28, 2024.

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56. Attached as **Exhibit D-64** is a true and correct copy of the Updated Expert Report of M. Timothy Renjilian dated December 3, 2024.

57. Attached as **Exhibit D-65** is a true and correct copy of the Updated Rebuttal Report of M. Timothy Renjilian dated March 18, 2024.

58. Attached as **Exhibit D-66** is a true and correct copy of Exhibit 164 to the May 3, 2022 deposition of Jimmy Higgins.

59. Attached as **Exhibit D-67** is a true and correct copy of Exhibit 1582 to the March 22, 2024 deposition of Jean Acevedo.

60. Attached as **Exhibit D-68** is a true and correct copy of Exhibit 324 to the July 26, 2022 deposition of Steven Nelson.

61. Attached as **Exhibit D-69** is a true and correct copy of Exhibit 608 to the May 30, 2023 deposition of 30(b)(6) Designee 3 Katie Baker.

62. Attached as **Exhibit D-70** is a true and correct copy of Exhibit 1062 to the February 17, 2022 deposition of Sean Cavanaugh.

63. Attached as **Exhibit D-71** is a true and correct copy of Exhibit 1063 to the February 17, 2022 deposition of Sean Cavanaugh.

64. Attached as **Exhibit D-72** is a true and correct copy of Exhibit 1067 to the February 17, 2022 deposition of Sean Cavanaugh.

65. Attached as **Exhibit D-73** is a true and correct copy of Exhibit 1133-2 to the April 22, 2022 deposition of Lisa Lara.

66. Attached as **Exhibit D-74** is a true and correct copy of Exhibit 1143-1 to the March 21, 2022 deposition of Maricruz Bonfante.

67. Attached as **Exhibit D-75** is a true and correct copy of Exhibit 1187-1 to the April 13, 2022 deposition of Rebecca Paul.

68. Attached as **Exhibit D-76** is a true and correct copy of Exhibit 1253 to the August 5, 2022 deposition of Jennifer Harlow.

69. Attached as **Exhibit D-77** is a true and correct copy of Exhibit 1306 to the August 25, 2022 deposition of Carolyn Kapustij.

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70. Attached as **Exhibit D-79** is a true and correct copy of Exhibit 1460 to the May 25, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby.

71. Attached as **Exhibit D-80** is a true and correct copy of Exhibit 1497-10 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij.

72. Attached as **Exhibit D-81** is a true and correct copy of Exhibit 1497-18 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij.

73. Attached as **Exhibit D-82** is a true and correct copy of Exhibit 1498 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij .

74. Attached as **Exhibit D-83** is a true and correct copy of Exhibit 1501 to the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij.

75. Attached as **Exhibit D-84** is a true and correct copy of Exhibit 1521 to the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Exhibit is Excel native file, lodged separately).

76. Attached as **Exhibit D-85** is a true and correct copy of Exhibit 1522 to the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Exhibit is Excel native file, lodged separately).

77. Attached as **Exhibit D-86** is a true and correct copy of Exhibit 1535 to the March 5, 2024 deposition of Richard Kronick.

78. Attached as **Exhibit D-87** is a true and correct copy of excerpts from the March 22, 2024 deposition of Jean Acevedo.

79. Attached as **Exhibit D-88** is a true and correct copy of excerpts from the July 12, 2022 deposition of Katie Baker.

80. Attached as **Exhibit D-89** is a true and correct copy of excerpts from the May 30, 2023 deposition of 30(b)(6) Designee 3 Katie Baker.

81. Attached as **Exhibit D-90** is a true and correct copy of excerpts from the May 31, 2023 deposition of 30(b)(6) Designee 3 Katie Baker.

82. Attached as **Exhibit D-91** is a true and correct copy of excerpts from the June 22, 2023 deposition of 30(b)(6) Designee 2 Jon Bird.

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83. Attached as **Exhibit D-92** is a true and correct copy of excerpts from the August 10, 2022 deposition of Jon Bird.

84. Attached as **Exhibit D-93** is a true and correct copy of excerpts from the April 3, 2024 deposition of Barbara Blair.

85. Attached as **Exhibit D-94** is a true and correct copy of excerpts from the May 13, 2022 deposition of Mary Bonner.

86. Attached as **Exhibit D-95** is a true and correct copy of excerpts from the September 12, 2023 deposition of Patricia Brennan.

87. Attached as **Exhibit D-96** is a true and correct copy of excerpts from the May 31, 2023 deposition of 30(b)(6) Designee 5 Christopher Bresette.

88. Attached as **Exhibit D-96-A** is a true and correct copy of excerpts from the August 9, 2023 deposition of 30(b)(6) Designee 5 Christopher Bresette.

89. Attached as **Exhibit D-97** is a true and correct copy of excerpts from the February 17, 2022 deposition of Sean Cavanaugh.

90. Attached as **Exhibit D-98** is a true and correct copy of excerpts from the August 10, 2022 deposition of Ilina Chaudhuri.

91. Attached as **Exhibit D-99** is a true and correct copy of excerpts from the March 23, 2022 deposition of Sean Creighton.

92. Attached as **Exhibit D-100** is a true and correct copy of excerpts from the Oct. 4, 2022 deposition of Sean Creighton.

93. Attached as **Exhibit D-101** is a true and correct copy of excerpts from the September 8, 2022 deposition of Joanne Davis.

94. Attached as **Exhibit D-102** is a true and correct copy of excerpts from the May 24, 2022 deposition of Tammy Dickey.

95. Attached as **Exhibit D-103** is a true and correct copy of excerpts from the March 29, 2024 deposition of Mark Duggan.

96. Attached as **Exhibit D-104** is a true and correct copy of excerpts from the August 2, 2022 deposition of Karen Erickson.

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1 97. Attached as **Exhibit D-105** is a true and correct copy of excerpts from
2 the March 18, 2022 deposition of Daniel Farmer.

3 98. Attached as **Exhibit D-106** is a true and correct copy of excerpts from
4 the July 27, 2022 deposition of Melissa Ferron.

5 99. Attached as **Exhibit D-107** is a true and correct copy of excerpts from
6 the March 31, 2022 deposition of Richard Foster.

7 100. Attached as **Exhibit D-108** is a true and correct copy of excerpts from
8 the June 2, 2022 deposition of Janet Fry.

9 101. Attached as **Exhibit D-109** is a true and correct copy of excerpts from
10 the June 30, 2021 deposition of Stephanie Gardner.

11 102. Attached as **Exhibit D-110** is a true and correct copy of excerpts from
12 the April 2, 2024 deposition of Craig Garthwaite.

13 103. Attached as **Exhibit D-111** is a true and correct copy of excerpts from
14 the March 10, 2022 deposition of Ronnie Grower.

15 104. Attached as **Exhibit D-112** is a true and correct copy of excerpts from
16 the March 30, 2022 deposition of Mary Guy.

17 105. Attached as **Exhibit D-113** is a true and correct copy of excerpts from
18 the May 3, 2022 deposition of Jimmy Higgins.

19 106. Attached as **Exhibit D-114** is a true and correct copy of excerpts from
20 the May 18, 2022 deposition of Anne Hornsby.

21 107. Attached as **Exhibit D-115** is a true and correct copy of excerpts from
22 the May 19, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby.

23 108. Attached as **Exhibit D-116** is a true and correct copy of excerpts from
24 the May 25, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby (Attorneys Eyes
25 Only).

26 109. Attached as **Exhibit D-117** is a true and correct copy of excerpts from
27 the November 21, 2023 deposition of 30(b)(6) Designee 1 Anne Hornsby.
28

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1 110. Attached as **Exhibit D-118** is a true and correct copy of excerpts from
2 the February 4, 2022 deposition of Lateefah Hughes.

3 111. Attached as **Exhibit D-119** is a true and correct copy of excerpts from
4 the January 26, 2022 deposition of Thomas Hutchinson.

5 112. Attached as **Exhibit D-120** is a true and correct copy of excerpts from
6 the June 14, 2022 deposition of Melvin Ingber.

7 113. Attached as **Exhibit D-121** is a true and correct copy of excerpts from
8 the March 14, 2024 deposition of deposition of Melvin Ingber.

9 114. Attached as **Exhibit D-122** is a true and correct copy of excerpts from
10 the August 25, 2022 deposition of Carolyn Kapustij.

11 115. Attached as **Exhibit D-122A** is a true and correct copy of excerpts from
12 the August 25, 2023 deposition of 30(b)(6) Designee 6 Carolyn Kapustij.

13 116. Attached as **Exhibit D-123** is a true and correct copy of excerpts from
14 the March 25, 2024 deposition of Daniel Kessler.

15 117. Attached as **Exhibit D-124** is a true and correct copy of excerpts from
16 the March 10, 2022 deposition of Thomas Kornfield.

17 118. Attached as **Exhibit D-125** is a true and correct copy of excerpts from
18 the April 5, 2024 deposition of Julia Lambert.

19 119. Attached as **Exhibit D-126** is a true and correct copy of excerpts from
20 the May 26, 2023 deposition of 30(b)(6) Designee 4 Connie Leonard.

21 120. Attached as **Exhibit D-127** is a true and correct copy of excerpts from
22 the June 21, 2023 deposition of 30(b)(6) Designee 2 Kirk Limmer.

23 121. Attached as **Exhibit D-128** is a true and correct copy of excerpts from
24 the August 30, 2022 deposition of John Martinez.

25 122. Attached as **Exhibit D-129** is a true and correct copy of excerpts from
26 the September 7, 2023 deposition of 30(b)(6) Designee 3 George Mills.

27 123. Attached as **Exhibit D-130** is a true and correct copy of excerpts from
28 the August 17, 2022 deposition of Jonathan Morse.

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1 124. Attached as **Exhibit D-131** is a true and correct copy of excerpts from
2 the July 26, 2022 deposition of Steven Nelson.

3 125. Attached as **Exhibit D-132** is a true and correct copy of excerpts from
4 the April 13, 2022 deposition of Rebecca Paul.

5 126. Attached as **Exhibit D-133** is a true and correct copy of excerpts from
6 the October 18, 2022 deposition of Benjamin Poehling.

7 127. Attached as **Exhibit D-134** is a true and correct copy of excerpts from
8 the September 28, 2022 deposition of Cynthia Polich.

9 128. Attached as **Exhibit D-135** is a true and correct copy of excerpts from
10 the March 21, 2024 deposition of M. Timothy Renjilian.

11 129. Attached as **Exhibit D-136** is a true and correct copy of excerpts from
12 the August 24, 2022 deposition of Jeff Renshaw.

13 130. Attached as **Exhibit D-137** is a true and correct copy of excerpts from
14 the August 3, 2022 deposition of Cheri Rice.

15 131. Attached as **Exhibit D-138** is a true and correct copy of excerpts from
16 the September 20, 2022 deposition of Daniel Schumacher.

17 132. Attached as **Exhibit D-139** is a true and correct copy of excerpts from
18 the June 29, 2023 deposition of 30(b)(6) Designee 1 Melissa Sedor.

19 133. Attached as **Exhibit D-140** is a true and correct copy of excerpts from
20 the March 20, 2024 deposition of Paul Spitalnic.

21 134. Attached as **Exhibit D-141** is a true and correct copy of excerpts from
22 the March 12, 2024 deposition of Philip Stark.

23 135. Attached as **Exhibit D-142** is a true and correct copy of excerpts from
24 the February 28, 2018 deposition of Marilyn Tavenner.

25 136. Attached as **Exhibit D-143** is a true and correct copy of excerpts from
26 the November 30, 2022 deposition of Gift Tee.

27 137. Attached as **Exhibit D-144** is a true and correct copy of excerpts from
28 the June 6, 2023 deposition of 30(b)(6) Designee 4 Scott Theisen.

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1 138. Attached as **Exhibit D-145** is a true and correct copy of excerpts from
2 the August 23, 2022 deposition of Cynthia Tudor.

3 139. Attached as **Exhibit D-146** is a true and correct copy of excerpts from
4 the June 29, 2022 deposition of Julie Uebersax.

5 140. Attached as **Exhibit D-147** is a true and correct copy of excerpts from
6 the June 7, 2022 deposition of Marybeth Meyer.

7 141. Attached as **Exhibit D-148** is a true and correct copy of the Brief for
8 United States, *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023).

9 142. Attached as **Exhibit D-149** is a true and correct copy of the Advance
10 Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice
11 (M+C) Payment Rules dated March 28, 2003.

12 143. Attached as **Exhibit D-150** is a true and correct copy of the document
13 bates numbered MAPL006426592.

14 144. Attached as **Exhibit D-151** is a true and correct copy of Exhibit 1124-
15 2 to the March 18, 2022 deposition of Lisa Lara.

16 145. Attached as **Exhibit D-152** is a true and correct copy of AAPC, Risk
17 Adjustment—Predictive Modeling, Documentation & Capture of Diagnosis Code at
18 19-20 (2014).

19 146. Attached as **Exhibit D-153** is a true and correct copy of excerpts from
20 83 Fed. Reg. 54982 (Nov. 1, 2018).

21 147. Attached as **Exhibit D-154** is a true and correct copy of excerpts from
22 the March 1, 2022 deposition of Brian Thompson.

23 148. Attached as **Exhibit D-155** is a true and correct copy of excerpts from
24 the March 4, 2022 deposition of Jonathan Blum.

25 149. Attached as **Exhibit D-156** is a true and correct copy of excerpts from
26 the August 5, 2022 deposition of Jennifer Harlow.

27 150. Attached as **Exhibit D-157** is a true and correct copy of excerpts from
28 the March 21, 2022 deposition of Maricruz Bonfante.

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1 151. Attached as **Exhibit D-158** is a true and correct copy of excerpts from
2 2010 Call Letter dated March 30, 2009.

3 152. Attached as **Exhibit D-159** is a true and correct copy of the document
4 bates numbered USBP060624234.

5 153. Attached as **Exhibit D-160** is a true and correct copy of the Joint
6 Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations
7 and Related Entities.

8
9 I declare under penalty of perjury under the laws of the United States that
10 the foregoing is true and correct.

11
12 Executed: August 6, 2024, at Los Angeles, California.

13
14 By: /s/ David J. Schindler
15 David J. Schindler
16 Attorney for United Defendants
17
18
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20
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25
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27
28

DECLARATION PA-1

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19

20 UNITED STATES DISTRICT COURT
21 FOR THE CENTRAL DISTRICT OF CALIFORNIA
22 WESTERN DIVISION

23 UNITED STATES OF AMERICA *ex rel.*
BENJAMIN POEHLING,
24
25 Plaintiffs,
26 v.
27 UNITEDHEALTH GROUP, INC., *et al.*,
28 Defendants.

No. CV 16-08697 FMO-PVCx

DECLARATION OF MARTHA N.
GLOVER

1 I, MARTHA N. GLOVER, hereby declare and state as follows:

2 1. I am a trial attorney at the Department of Justice, Civil Division,
3 Commercial Litigation Branch, Fraud Section. I represent the United States in the above-
4 captioned matter. I submit this Declaration in support of the United States' opposition to
5 United's Motion for Summary Judgment. I have personal knowledge of the matters set
6 forth herein and, if called to testify, could and would testify competently thereto.

7 2. Attached as Exhibit P-1 is a true and correct copy of the parties' Joint
8 Stipulation Re EDI Agreements, MA Contracts, MA-PD Addenda, and Attestations and
9 Related Entities dated May 28, 2024.

10 3. Attached as Exhibit P-1A is a true and correct copy of USBP009418488, an
11 exemplar of a 2017 Payment Year (PY) Contract between CMS and an MAO Defendant,
12 which is cited to in Exhibit P-1.

13 4. Attached as Exhibit P-1B is a true and correct copy of MAPL007637301, an
14 exemplar of an EDI Agreement signed by Optum, Inc., which is cited to in Exhibit P-1.

15 5. Attached as Exhibit P-1C is a true and correct copy of MAPL008081457, an
16 exemplar of an EDI Agreement signed by an MAO Defendants, which is cited to in
17 Exhibit P-1.

18 6. Attached as Exhibit P-1D is a true and correct copy of USBP001354165,
19 which is cited to in Exhibit P-1.

20 7. Attached as Exhibit P-1E is a true and correct copy of USBP001354107,
21 which is cited to in Exhibit P-1.

22 8. Attached as Exhibit P-1F is a true and correct copy of USBP009866579,
23 which is cited to in Exhibit P-1.

24 9. Attached as Exhibit P-1G is a true and correct copy of USBP009417433, an
25 exemplar of a 2017 PY Attestation signed by a Defendant MAO, which is cited to in
26 Exhibit P-1.

27 10. Attached as Exhibit P-2 is a true and correct copy of relevant excerpts of the
28 transcript of the June 6, 2023 deposition of Biggs Cannon taken pursuant to Federal Rule

1 of Civil Procedure (FRCP) 30(b)(6).

2 11. Attached as Exhibit P-3 is a true and correct copy of relevant excerpts of
3 2008 Risk Adjustment Data Technical Assistance For Medicare Advantage
4 Organizations Participant Guide, Deposition Exhibit 30B and Bates-stamped
5 MARA1576299.

6 12. Attached as Exhibit P-4 is a true and correct copy of relevant excerpts of the
7 transcript of the May 24, 2022 deposition of Tammy Dickey.

8 13. Attached as Exhibit P-5 is a true and correct copy of relevant excerpts of the
9 transcript of the June 29, 2023 deposition of Melissa Sedor taken pursuant to FRCP
10 30(b)(6).

11 14. Attached as Exhibit P-6 is a true and correct copy of relevant excerpts of the
12 transcript of the March 21, 2024 deposition of Timothy Renjilian, an expert retained by
13 United.

14 15. Attached as Exhibit P-7 is a true and correct copy of relevant excerpts of the
15 transcript of the May 30, 2023 deposition of Kathleen Baker taken pursuant to FRCP
16 30(b)(6).

17 16. Attached as Exhibit P-8 is a true and correct copy of relevant excerpts of
18 Chapter 7 of the Medicare Managed Care Manual (Rev. 118, September 19, 2014).

19 17. Attached as Exhibit P-9 is a true and correct copy of relevant excerpts of
20 Chapter 7 of the Medicare Managed Care Manual (August 13, 2004).

21 18. Attached as Exhibit P-10 is a true and correct copy of relevant excerpts of
22 the transcript of the August 3, 2022 deposition of Cheri Rice.

23 19. Attached as Exhibit P-11 is a true and correct copy of relevant excerpts of
24 Deposition Exhibit 381, containing United's Responses and Objections to the United
25 States' Sixth Set of Interrogatories, dated July 19, 2022.

26 20. Attached as Exhibit P-12 is a true and correct copy of Deposition Exhibit
27 265-1, which is a document Bates-Stamped MAPL000814082.

28 21. Attached as Exhibit P-13 is a true and correct copy of relevant excerpts of

Deposition Exhibit 33B, which is a document Bates-Stamped MARA1262848.

22. Attached as Exhibit P-14 is a true and correct copy of relevant excerpts of Deposition Exhibit 34B, which is a document Bates-Stamped MARA1546907.

23. Attached as Exhibit P-15 is a true and correct copy of relevant excerpts of the transcript of the May 31, 2023 deposition of Kathleen Baker taken pursuant to FRCP 30(b)(6).

24. Attached as Exhibit P-16 is a true and correct copy of relevant excerpts of the transcript of the June 22, 2023 deposition of Jon Bird taken pursuant to FRCP 30(b)(6).

25. Attached as Exhibit P-17 is a true and correct copy of relevant excerpts of Deposition Exhibit 508A, which is a document Bates-Stamped MAPL005123236.

26. Attached as Exhibit P-18 is a true and correct copy of relevant excerpts of Deposition Exhibit 201, which is a document Bates-Stamped MARA2036153.

27. Attached as Exhibit P-19 is a true and correct copy of relevant excerpts of the transcript of the May 25, 2023 deposition of Anne Hornsby taken pursuant to FRCP 30(b)(6).

28. Attached as Exhibit P-20 is a true and correct copy of relevant excerpts of the transcript of the February 17, 2022 deposition of Sean Cavanaugh.

29. Attached as Exhibit P-21 is a true and correct copy of relevant excerpts of the transcript of the November 21, 2023 deposition of Anne Hornsby taken pursuant to FRCP 30(b)(6).

30. Attached as Exhibit P-22 is a true and correct copy of relevant excerpts of the transcript of the May 18, 2022 deposition of Anne Hornsby.

31. Attached as Exhibit P-23 is a true and correct copy of relevant excerpts of the transcript of the March 4, 2022 deposition of Jon Blum.

32. Attached as Exhibit P-24 is a true and correct copy of Deposition Exhibit 324, which is Bates-Stamped as MAPL000497870.

33. Attached as Exhibit P-25 is a true and correct copy of relevant excerpts of

1 the transcript of the July 26, 2022 deposition of Steve Nelson.

2 34. Attached as Exhibit P-26 is a true and correct copy of relevant excerpts of
3 the transcript of the May 19, 2023 deposition of Anne Hornsby taken pursuant to FRCP
4 30(b)(6).

5 35. Attached as Exhibit P-27 is a true and correct copy of relevant excerpts of
6 the transcript of the August 23, 2022 deposition of Cynthia Tudor.

7 36. Attached as Exhibit P-28 is a true and correct copy of Deposition Exhibit
8 317, a document Bates-stamped MARA2156615.

9 37. Attached as Exhibit P-29 is a true and correct copy of relevant excerpts of
10 the transcript of the November 17, 2022 deposition of Thad Johnson.

11 38. Attached as Exhibit P-30 is a true and correct copy of relevant excerpts of
12 the transcript of the March 22, 2024 deposition of Jean Acevedo, an expert retained by
13 the United States.

14 39. Attached as Exhibit P-31 is a true and correct copy of relevant excerpts of
15 the transcript of the April 3, 2024 deposition of Barbara Blair, an expert retained by
16 United.

17 40. Attached as Exhibit P-32 is a true and correct copy of the Declaration of
18 Steven Ferraina, signed July 12, 2024.

19 41. Attached as Exhibit P-33 is a true and correct copy of relevant excerpts of
20 the transcript of the June 6, 2023 deposition of Scott Theisen taken pursuant to FRCP
21 30(b)(6).

22 42. Attached as Exhibit P-34 is a true and correct copy of relevant excerpts of
23 the transcript of the August 2, 2022 deposition of Karen Erickson.

24 43. Attached as Exhibit P-35 is a true and correct copy of relevant excerpts of
25 the transcript of the September 20, 2022 deposition of Daniel Schumacher.

26 44. Attached as Exhibit P-36 is a true and correct copy of Deposition Exhibit
27 331, a document Bates-stamped USBP000619443.

28 45. Attached as Exhibit P-37 is a true and correct copy of the Rebuttal Report

1 of Paul Spitalnic (signed January 25, 2024), an expert for the United States.

2 46. Attached as Exhibit P-38 is a true and correct copy of relevant excerpts of
3 the transcript of the June 21, 2023 deposition of Kirk Limmer taken pursuant to FRCP
4 30(b)(6).

5 47. Attached as Exhibit P-39 is a true and correct copy of a printout of “About
6 CMS,” available at: <https://www.cms.gov/about-cms> (last visited July 15, 2024).

7 48. Attached as Exhibit P-40 is a true and correct copy of Deposition Exhibit
8 327, a Letter from counsel at Latham & Watkins to counsel at the Department of Justice,
9 dated July 1, 2014.

10 49. Attached as Exhibit P-41 is a true and correct copy of 42 U.S. Code §
11 1395d.

12 50. Attached as Exhibit P-42 is a true and correct copy of relevant excerpts of
13 42 U.S. Code § 1395x.

14 51. Attached as Exhibit P-43 is a true and correct copy of P-43, a PDF copy of
15 an Excel titled “Risk Model Diagnoses for FY 2012,” available at:
16 [https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/risk-adjustors-](https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/risk-adjustors-items/risk2012)
17 [items/risk2012](https://www.cms.gov/medicare/health-plans/medicareadvtspeccratestats/risk-adjustors-items/risk2012) (last visited July 2, 2024).

18 52. Attached as Exhibit P-44 is a true and correct copy of relevant excerpts of
19 the transcript of the May 26, 2023 deposition of Connie Leonard taken pursuant to FRCP
20 30(b)(6).

21 53. Attached as Exhibit P-45 is a true and correct copy of relevant excerpts of
22 the transcript of the July 29, 2022 deposition of Janice Redmond.

23 54. Attached as Exhibit P-46 is a true and correct copy of relevant excerpts of
24 the transcript of the March 14, 2024 deposition of Melvin Ingber, an expert retained by
25 the United States.

26 55. Attached as Exhibit P-47 is a true and correct copy of the United States’
27 Amended Complaint in this matter (Dkt. 171).

28 56. Attached as Exhibit P-48 is a true and correct copy of relevant excerpts of

Deposition Exhibit 1581, ICD-10-CM Official Guidelines for Coding and Reporting.

57. Attached as Exhibit P-49 is a true and correct copy of Deposition Exhibit 815, an AAPC Article entitled “Medical Record Entries What Is Timely and Reasonable.”

58. Attached as Exhibit P-50 is a true and correct copy of the Amended Report of Jean Acevedo (signed April 5, 2024), an expert retained by the United States.

59. Attached as Exhibit P-51 is a true and correct copy of relevant excerpts of the transcript of the June 2, 2022 deposition of Janet Fry.

60. Attached as Exhibit P-52 is a true and correct copy of relevant excerpts of the transcript of the August 9, 2023 deposition of Chris Bresette taken pursuant to FRCP 30(b)(6).

61. Attached as Exhibit P-53 is a true and correct copy of relevant excerpts of the transcript of the March 10, 2022 deposition of Thomas Kornfield.

62. Attached as Exhibit P-54 is a true and correct copy of the Court’s Order re Objections to Special Master’s Order (Dkt. 437), dated September 10, 2021.

63. Attached as Exhibit P-55 is a true and correct copy of relevant excerpts of the transcript of the July 22, 2022 deposition of Pat Rasmussen.

64. Attached as Exhibit P-56 is a true and correct copy of relevant excerpts of the transcript of the August 25, 2023 deposition of Carolyn Kapustij taken pursuant to FRCP 30(b)(6).

65. Attached as Exhibit P-57 is a true and correct copy of relevant excerpts of the transcript of the March 12, 2024 deposition of Philip Stark, an expert retained by the United States.

66. Attached as Exhibit P-58 is a true and correct copy of relevant excerpts of the transcript of the March 18, 2022 deposition of Lisa Lara.

67. Attached as Exhibit P-59 is a true and correct copy of a document Bates-stamped MAPL001126483.

68. Attached as Exhibit P-59A is a true and correct copy of excerpts of the

1 2012 Encounter Data Participant Guide, an attachment to
2 MAPL001126483 Bates-stamped MAPL001126484 .

3 69. Attached as Exhibit P-60 is a true and correct copy of 42 C.F.R. 422.310.

4 70. Attached as Exhibit P-61 is a true and correct copy of relevant excerpts of
5 the transcript of the July 28, 2021 deposition of Jeff Dumcum.

6 71. Attached as Exhibit P-62 is a true and correct copy of relevant excerpts of
7 the transcript of the August 30, 2022 deposition of John Martinez.

8 72. Attached as Exhibit P-63 is a true and correct copy of a document Bates-
9 stamped MAPL000814082.

10 73. Attached as Exhibit P-64 is a true and correct copy of relevant excerpts of
11 the June 30, 2021 deposition of Stephanie Gardner.

12 74. Attached as Exhibit P-65 is a true and correct copy of relevant excerpts of
13 the February 24, 2022 deposition of Kimberly Halva.

14 75. Attached as Exhibit P-66 is a true and correct copy of a document Bates-
15 stamped USBP0061943.

16 76. Attached as Exhibit P-67 is a true and correct copy of relevant excerpts of
17 the transcript of the April 5, 2024 deposition of Julia Lambert, an expert retained by
18 United.

19 77. Attached as Exhibit P-68 is a true and correct copy of relevant excerpts of
20 the Medicare Advantage & Prescription Drug Plan Fall Conference & Webcast,
21 Conference Guide (Sept. 7, 2017), available at: [https://www.cms.gov/outreach-and-education/training/cteo/downloads/2017-fall-conference/cms-ma-](https://www.cms.gov/outreach-and-education/training/cteo/downloads/2017-fall-conference/cms-ma-pdpconffall2017guidefinalpdf.pdf)
22 [pdpconffall2017guidefinalpdf.pdf](https://www.cms.gov/outreach-and-education/training/cteo/downloads/2017-fall-conference/cms-ma-pdpconffall2017guidefinalpdf.pdf) (last visited July 9, 2024).

24 78. Attached as Exhibit P-69 is a true and correct copy of relevant excerpts of
25 the transcript of the May 3, 2022 deposition of Jimmy Higgins.

26 79. Attached as Exhibit P-70 is a true and correct copy of relevant excerpts of
27 the transcript of the April 13, 2022 deposition of Rebecca Paul.

28 80. Attached as Exhibit P-71 is a true and correct copy of relevant excerpts of

1 the transcript of the August 10, 2022 deposition of Jon Bird.

2 81. Attached as Exhibit P-72 is a true and correct copy of relevant excerpts of
3 the transcript of the June 7, 2023 deposition of Biggs Cannon taken pursuant to FRCP
4 30(b)(6).

5 82. Attached as Exhibit 73 is a true and correct copy of Deposition Exhibit 167-
6 1, Bates-stamped MAPL008247236.

7 83. Attached as Exhibit P-74 is a true and correct copy of relevant excerpts of
8 the transcript of the April 2, 2024 deposition of Craig Garthwaite, an expert retained by
9 the United States.

10 84. Attached as Exhibit P-75 is a true and correct copy of Deposition Exhibit
11 328, an October 22, 2014 Letter from counsel from the Department of Justice to counsel
12 from Latham & Watkins.

13 85. Attached as Exhibit P-76 is a true and correct copy of relevant excerpts of
14 the transcript of the August 5, 2022 deposition of Rebecca Martin.

15 86. Attached as Exhibit P-77 is a true and correct copy of 45 C.F.R. 162.1002.

16 87. Attached as Exhibit P-78 is a true and correct copy of an Order Denying
17 Without Prejudice Plaintiff's Motion to Compel Re Interrogatory 14 and Request For
18 Production 147 (Dkt. 419), dated May 28, 2021.

19 88. Attached as Exhibit P-79 is a true and correct copy of relevant excerpts of
20 the transcript of the March 20, 2024 deposition of Paul Spitalnic, an expert for the
21 United States.

22 89. Attached as Exhibit P-80 is a true and correct copy of relevant excerpts of
23 the 2013 Call Letter, available at: [https://www.cms.gov/medicare/health-](https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/2013-call-letter.pdf)
24 [plans/healthplansgeninfo/downloads/2013-call-letter.pdf](https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/2013-call-letter.pdf) (last visited July 25, 2024).

25 90. Attached as Exhibit P-81 is a true and correct copy of relevant excerpts of
26 Deposition Exhibit 309, Bates-stamped MAPL009701356.

27 91. Attached as Exhibit P-82 is a true and correct copy of relevant excerpts of
28 the transcript of the July 27, 2022 deposition of Melissa Ferron.

1 92. Attached as Exhibit P-83 is a true and correct copy of relevant excerpts of
2 the transcript of the August 25, 2022 deposition of Carolyn Kapustij.

3 93. Attached as Exhibit P-84 is a true and correct copy of relevant excerpts of
4 Deposition Exhibit 712-4, Bates-stamped MARA161485.

5 94. Attached as Exhibit P-85 is a true and correct copy of relevant excerpts of
6 the September 12, 2023 deposition of Patricia Brennan.

7 95. Attached as Exhibit P-86 is a true and correct copy of Deposition Exhibit
8 726, a March 27, 2016 Letter from counsel from Latham & Watkins to counsel from the
9 Department of Justice.

10 96. Attached as Exhibit P-87 is a true and correct copy of relevant excerpts of
11 Deposition Exhibit 727, Bates-stamped MARA2160501.

12 97. Attached as Exhibit P-88 is a true and correct copy of relevant excerpts of
13 the July 12, 2022 deposition of Kathleen Baker.

14 98. Attached as Exhibit P-89 is a true and correct copy of Deposition Exhibit
15 348, Bates-stamped ICODIFY-0170934.

16 99. Attached as Exhibit P-90 is a true and correct copy of relevant excerpts of
17 the transcript of the June 7, 2022 deposition of MaryBeth Meyer.

18 100. Attached as Exhibit P-91 is a true and correct copy of relevant excerpts of
19 the transcript of the November 21, 2023 deposition of Anne Hornsby taken pursuant to
20 FRCP 30(b)(6).

21 101. Attached as Exhibit P-92 is a true and correct copy of relevant excerpts of
22 Contract Year 2015 Policy and Technical Changes to the Medicare Advantage
23 Program, 79 Fed. Reg. 29,844 (May 23, 2014) (to be codified at 42 C.F.R. pts. 417,
24 422-24).

25 102. Attached as Exhibit P-93 is a true and correct copy of relevant excerpts of
26 the transcript of the August 23, 2022 deposition of Cynthia Tudor.

27 103. Attached as Exhibit P-94 is a true and correct copy of relevant excerpts of
28 the transcript of the August 9, 2023 deposition of Chris Bresette taken pursuant to

1 FRCP 30(b)(6).

2
3 I declare under penalty of perjury that the foregoing is true and correct.

4 Executed this 31st day of July, 2024

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8 Martha N. Glover

9 Attorney for the United States
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